Reference: FOI.ICB-2526/315

Subject: ADHD Service Provision, Demand and Contracts

I can confirm that the ICB does hold some of the information requested; please see responses below:

QUESTION	RESPONSE
1. Current Waiting Lists and Demand a. Current number of people waiting for ADHD assessment (broken down by adults/children) b. Average waiting time from referral to assessment (current data) c. Longest current wait time for ADHD assessment d. Number of referrals received monthly for ADHD assessment (last 12 months data) e. Number of assessments completed monthly (last 12 months data)	BNSSG ICB does not hold this information, and the requestor is advised to contact ADHD assessment providers directly. For CYP (Children and Young People) please contact Sirona care & health: Sirona.hello@nhs.net For adults please contact Avon and Wiltshire Mental Health Partnership (AWP) NHS Trust: https://www.awp.nhs.uk/contact-us/freedom-information
2. Service Providers and Contracts a. List of all NHS providers delivering ADHD assessment services in your area b. List of all Right to Choose providers currently accepting referrals from your ICB	a. The NHS providers delivering ADHD assessment services in BNSSG are: • AWP for adult assessments • Sirona care and health for Children and Young People (CYP) assessments (0-18 years)

c. Contract values and duration for each ADHD service provider d. Service specifications for ADHD assessment and treatment contracts e. Key Performance Indicators (KPIs) for each contract	b. We are aware of the following Independent Sector providers who are eligible to deliver ADHD assessments under Right to Choose in our area: **Children and Young People (up to 18 years, lower age limit varies between providers):** • ADHD 360 – 7-18 years • Clinical Partners – 5-18 years • Evolve Psychology – 5-18 years (up to 25 years of age for SEND) • Healios – 6-18 years • Held Health – 7-18 years • Help for Psychology Services – 6-18 years • Oakdale Therapies – 6-18 years (up to 25 years of age for SEND) • The Owl Centre – 6-18 years • Psicon – 6-18 years **Adults (all 18)+:** • ADHD 360 • Atrom Mindcare Ltd • Clinical Partners • The Centre for ADHD Research & Excellence (CARE ADHD) • Dr J & Colleagues • Harrow Health CIC • Healios • HealthHarmonie Minds

	• Oakdale Therapies • The Owl Centre • ProblemShared • Psicon • Psychiatry UK • RTN Medical • Sinclair Strong Consultants • Skylight Psychiatry c. AWP deliver ADHD assessments (and medication where required) to adults in BNSSG. The contract started on 1 April 2025 and expires on 31 March 2027. The contract is funded on a block payment basis and therefore a service value for the delivery of ADHD assessments is not available. Sirona Care and Health CiC deliver ADHD assessments (and medication where required) to children and young people in BNSSG through the Children's Community Health Partnership contract. The contract started on 1 April 2017 and expires on 31 March 2028. The contract is on a block payments and therefore a service value for the delivery of ADHD assessments is not available. BNSSG ICB currently holds a contract with Clinical Partners for Children, Young People and Adult ADHD and Autism Assessment and Treatment services. The contract started on 1st December 2024 and expires on 31st March 2026. This is a

	zero value contract and is paid on the basis of activity undertaken. We do not currently hold any other RTC provider contracts d. Please see service specifications enclosed for Children's and Adult services. These cover contracts held by BNSSG ICB for both the independent sector and NHS providers. We are unable to provide information on contracts held between other ICB's and providers. Please note the Children's Community Service Specification, which relates to ADHD Service Provision is part of the wider Community Paediatric Service Spec. There is not a stand-alone service spec for ADHD. This service spec is currently under review. e. Contracted providers are expected to provide regular reporting to the ICB around factors such as activity, flow, patient experience and outcomes. Providers are subject to national targets and KPIs such as Referral To Treatment (RTT).
3. Capacity and Workforce a. Current funded capacity for ADHD assessments per month b. Number of clinical staff (WTE) providing ADHD assessments	a, b & d: BNSSG ICB does not hold this information, and the requestor is advised to contact ADHD assessment providers directly. c. Please see the response to question 2 setting out the age ranges for each provider. Under the NHS Choice framework, a provider can operate as Right to Choose if they hold an NHS standard contract with an ICB in England or NHS

c. Details of any service restrictions (e.g., age limits, geographical restrictions) d. Plans for expanding capacity in 2025/26	England for the service being provided. This applies across NHS and Independent Sector providers. This framework covers England only and rules are different in other parts of the United Kingdom (Wales, Scotland and Northern Ireland). There are some instances where a patient does not have a right to choose, these are set out at this link https://www.nhs.uk/mental-health/social-care-and-your-rights/how-to-access-mental-health-services/#choice and below: You do not have a legal right to choose if: • you need urgent or emergency treatment • you already receive care and treatment for the condition • the organisation or clinical team you've chosen does not provide the right care for your condition • you're a prisoner or on temporary release from prison • you're detained in prescribed accommodation, such as a court, secure children's home, secure training centre, immigration removal centre or young offender institution • you're detained in a secure hospital setting • you're a serving member of the armed forces • you're detained under the Mental Health Act 1983 Some providers also have additional eligibility requirements and the requestor is advised to contact them directly for this information.
4. Clinical Pathways	Please find enclosed our BNSSG shared care protocols for adults and children's ADHD medications.

a. Current clinical pathways for ADHD assessment (adults and children) b. Shared care agreements/protocols with primary care c. Post-diagnostic support services available d. Medication initiation and monitoring arrangements	Further details about clinical pathways, post-diagnostic support services and medication can be found at the following website links: ADHD (adult) (Remedy BNSSG ICB) ADHD Care Pathway for school age children (Remedy BNSSG ICB) There is a specialist medicines monitoring local enhanced service to support the monitoring of ADHD medication and an ADHD annual review LES

The information provided in this response is accurate as of 14 January 2025 and has been approved for release by David Jarrett, Chief Delivery Officer and Dr Geeta Iyer, Deputy Chief Medical Officer for NHS Bristol, North Somerset and South Gloucestershire ICB.

SCHEDULE 2 – THE SERVICES

A. Service Specification

Service Specification No.	**2A6**
Service	**Attention Deficit Hyperactivity Disorder (ADHD) – Adults (18+ years)**
Commissioner Lead	**BNSSG Integrated Care Board (ICB)**
Provider Lead	**Avon and Wiltshire Mental Health Partnership NHS Trust (AWP)**
Period	**1st April 2024 – 31st March 2025**
Date Last Reviewed	**January 2024**
Date of Next Review	**Quarter 4 2025**

1. Purpose

This service specification outlines BNSSG ICB objectives, scope, pathway and principles of the Adult Attention Deficit Hyperactivity Disorder Service (ADHD).

1.1 Aims and objectives

1. To improve ADHD related outcomes for each service user:
   - ADHD related functional impairment as measured by the WEISS FI scale.
   - ADHD related quality of life as measured by the AAQoL.
   - Mental wellbeing measured by Warwick and Edinburgh Mental Wellbeing scale.
   - ADHD symptomology as measured by Barkley ADHD rating scales.
   - PROMS are measured at assessment, end of titration and at annual review.
2. To provide a quality service that ensures there is optimal patient safety, clinical effectiveness and a person-centred approach to care taken.
3. Provide accessible assessments and diagnosis either face to face or virtually with clear reasoning behind decision reached.
4. To offer advice specific to the individual to other services and agencies, to include primary mental health care, third sector provision, secondary and tertiary services; regarding the management of ADHD with an interagency and multidisciplinary approach.
5. Treatment plans will be devised collaboratively with reference to the service user's goals to meet psychological, behavioural and occupational needs. Environmental modifications will be considered and progress to pharmacological interventions considered only if ongoing impairment in one domain subsequent to this is present (NICE, 2018).

The adult ADHD service provided will be informed by the following guidance and good practice guidelines:

1. ADHD: diagnosis and management NICE guideline NG87, published 14 March 2018, last updated 13 Sep 2019. https://www.nice.org.uk/guidance/ng87#:~:text=In%20September%202019%2C%20we%20amended,that%20poses%20an%20increased%20cardiovascular
2. Royal College of Psychiatrists – ADHD in adults: good practice guidelines.

https://www.rcpsych.ac.uk/docs/default-source/members/divisions/scotland/adhd_in_adultsfinal_guidelines_june2017.pdf

3. British Journal of General Practice guidance – Assessments for adult ADHD: what makes them good enough? https://bjgp.org/content/73/735/473
4. British Association of Psychopharmacology's guidelines (Bolea-Alamañac et al, 2014) https://www.bap.org.uk/pdfs/BAP_Guidelines-AdultADHD.pdf and the European Consensus Statement (Kooij et al, 2010) https://pubmed.ncbi.nlm.nih.gov/30453134/
5. General Medical Council guidance 2021 on shared care and prescribing. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
6. https://osf.io/preprints/osf/dksqw

The Provider will work under the following values:

1. Personalised care and sharing decision-making ('No decision about me without me') should be a governing principle in service design and delivery.
2. It is important that all clinicians working with adults with ADHD are able to adopt a 'trauma-informed' approach as is appropriate since there is evidence that people with ADHD are more likely than their peers to have experienced adverse childhood events (ACEs) (Brown et al, 2017).
3. Equal and timely access to appropriate services and evidence-based interventions.
4. Proactive, assertive engagement, particularly with service users at higher risk (e.g. young people at risk of offending/offenders or older people who are homeless).
5. ADHD interventions planned around outcomes agreed by the user of the service, tailored to their individual needs, choices and preferences, with a holistic focus on building individual strengths and improving quality of life.
6. Culturally appropriate integrated approaches and interventions for neurodevelopmental disorders, co-existing mental health problems and co-existing alcohol and illicit drug use.
7. Early access to evidence-based interventions, right from the start of the patient journey in primary care with seamless interface/joint working between primary and secondary services and agreed criteria what is within the remit of the primary and secondary services.
8. In agreement with the service user, involvement of family, friends, partners and support networks and good, clear information to inform people's choices and decision-making.
9. Medication used in the treatment pathway must meet with commissioning organisation (BNSSG) requirements for an evidence based and cost-effective formulary, with clear governance arrangements for the use of unlicensed medicines.

1.2 National and local context and evidence base

Clear guidance on clinical practice to support healthcare in ADHD is spelled out in national clinical guidelines. NICE guidance is linked to each ICBs responsibility and legal duty to regard NICE quality standards and recommendations, secure high-quality services and ensure continual improvement in the quality of local NHS services (in addition to their legal duty to reduce health inequalities) as set out in the NHS Constitution and The National Health Service Act (2006), as amended by The Health and Social Care Act (2012).

Furthermore, it appears that courts are increasingly willing to acknowledge that national guidance may be relevant (in conjunction with clinical judgement) in setting standards of care because they are evidence based and reflect reasonable medical practice. This means ICBs and clinicians are potentially at risk of being challenged if they do not adopt and follow NICE Guidance and they should only not adopt if they have something better to offer and there is agreement from Commissioners.

The rights of people with ADHD in the UK are protected under the Human Rights Act 1998 (article 14: right to non-discrimination), and further under the UK Equality Act 2010, which protects people with a

disability (including ADHD). People with ADHD also have rights under the Public Sector Equality Duty in England, Scotland and Wales, which places an obligation on public authorities to positively promote equality, not merely to avoid discrimination.

1.2.1 Right to Choose

Since 2014, in England under the NHS, patients have a legal right to choose their mental healthcare provider and their choice of mental healthcare team. If a patient decides the waiting time for their ADHD assessment is too long, then they can choose alternative providers. The provider must be commissioned for the service by an ICB in order to offer Right to Choose.
https://www.england.nhs.uk/long-read/patient-choice-guidance/

NHS Choice Framework - what choices are available to you in your NHS care
https://www.gov.uk/government/publications/the-nhs-choice-framework/the-nhs-choice-framework-what-choices-are-available-to-me-in-the-nhs

Patients have the Right to Choose when the following conditions are met:

- The NHS practice is in England (different rules apply for Scotland, Wales and Northern Ireland).
- The General Practitioner (GP) has agreed to make a clinically appropriate referral.

Certain restrictions apply and patients cannot exercise their Right to Choose if they are:

- Already receiving mental health care following an elective referral for the same condition.
- Referred to a service that is commissioned by a local authority, for example a drug and alcohol service (unless commissioned under a Section 75 agreement).
- Accessing urgent or emergency (crisis) care.
- Already have a diagnosis of ADHD and are receiving treatment through a primary care contract.
- In high secure psychiatric services.
- Detained under the Mental Health Act 1983.
- Detained in a secure setting. This includes people in or on temporary release from prisons, courts, secure children's homes, certain secure training centres, immigration removal centres or young offender institutions.
- Serving as a member of the armed forces (family members in England have the same rights as other residents of England).

There are restrictions on who the patient can direct their care to. Patients cannot refer to just any provider. The provider must:

- Have a commissioning contract with any ICB in England or NHS England for the required service.

Furthermore, a diagnosis of ADHD should only be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD, as per the NICE Guidelines.

1.2.2 Strategic context

1. Under the NHS Long Term plan, https://www.longtermplan.nhs.uk/publication/nhs-mental-health-implementation-plan-2019-20-2023-24 the formation of Primary Care Networks (PCNs) in combination with the establishment of NHS Integrated Care Systems (ICSs), represents an opportunity to establish new and effective working practices to enable consistent and accessible healthcare for all people with ADHD. The NHS Community Mental Health Framework, https://www.england.nhs.uk/mental-health/adults/cmhs also sets out a vision for

how community services should modernise to offer joined-up-care for those with mental health needs, within ICSs.

2. Recent guidance, stemming from professionals across primary, secondary, and tertiary care in the UK, has recommended the development of an ADHD specialism within primary care as part of a roadmap for improving access to treatment https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-022-04290-7
   The evidence base outlined above, and current guidelines, highlight the key role primary care services have to play in the provision of healthcare for people with ADHD, and the potential for supporting an expansion of this role. Not only are primary care practitioners, such as GPs, often the gatekeepers through the referral system to secondary care services, such as adult mental health and specialist ADHD services, but NICE guidelines recommend that they also provide healthcare support such as routine monitoring and prescribing of medication under shared care agreements with secondary care services. Furthermore, primary care services have an increasing role to play in terms of providing mental health and well-being support to people with ADHD, with additional roles such as mental health workers and social prescribing link workers funded through PCNs.

Such joined up care is supported locally as follows: BNSSG's mission is *"Healthier together by working together."*

"People enjoying healthy and productive lives, supported by a fully integrated health and care system - providing personalised support close to home for everyone who needs it."

1.2.3 BNSSG ICS aims

BNSSG's Strategy and Joint Forward Plan have been developed to align with, and support, the four aims of Integrated Care Systems:

1. Improve outcomes in population health and health care.
2. Tackle inequalities in outcomes, experience and access.
3. Enhance productivity and value for money.
4. Help the NHS support broader social and economic development.

BNSSG's Joint Forward Plan https://bnssghealthiertogether.org.uk/library/joint-forward-plan/ (published June 2023) sets out how BNSSG ICB will deliver on the national vision of high-quality healthcare for all, through equitable access, excellent experience, and optimal outcomes over the next five years.

It aims to:

1. Improve the health and wellbeing of the population.
2. Provide high-quality services that are fair and accessible to everyone.

In 2024, BNSSG published a Mental Health Strategy. The strategy has six ambitions.

1. Holistic Care
2. Prevention and early help
3. Quality treatment
4. Sustainable System
5. Advancing equalities
6. Great place to work

https://bnssghealthiertogether.org.uk/health-wellbeing/mental-health-strategy/

The core reference for Adult ADHD provision:

National Institute for Health and Clinical Excellence (NICE) 2018: Attention Deficit Hyperactivity Disorder: diagnosis and management https://www.nice.org.uk/guidance/ng87

In BNSSG, as in many other parts of the country, we have seen unprecedented demand for diagnosis and treatment of ADHD over the last few years. Demand exceeds locally commissioned services resulting in long waiting times and significant growth.

2. Service Scope

2.1 Attention Deficit Hyperactivity Disorder summary

ADHD is a common condition in adulthood with estimated prevalence rates of 3-4% (NICE 2018, 2023). Attention Deficit Hyperactivity Disorder (ADHD) is a neurodevelopmental disorder consisting of the core symptoms: inattention, hyperactivity and impulsivity.

There are three subtypes of ADHD accounting for variations in the symptom profile:

- Combined presentation (50-75%),
- Predominately inattentive (20% to 30%) and
- Predominately hyperactive/impulsive presentation (15%). (NICE 2018, 2023)

In childhood, ADHD is more commonly diagnosed in boys than in girls. In adults the prevalence of ADHD in men and women is more equal. ADHD is a highly heritable condition. Approximately 2/3 of young people with a childhood diagnosis continue to suffer disabling ADHD symptoms in adulthood. ADHD is frequently associated with other developmental disorders (Autism Spectrum Disorders, Dyspraxia, Dyslexia, Dyscalculia, Tics, specific learning disorders, sensory integration problems etc), psychiatric disorders, alcohol & substance use, oppositional and unlawful conduct and other difficulties.

The suicide risk is increased in people with ADHD but this is largely down to co-morbid psychiatric disorders. In addition, physical health problems such as obesity, sleep disorders, migraine, epilepsy, asthma and accidents are more common in people with ADHD. Many of the associated conditions do not respond to treatment well until ADHD is diagnosed and managed. Untreated ADHD can affect all aspects of a person's life and wellbeing, impact on families and communities, and result in increased health, societal and economic costs. Treatment for ADHD is effective, improves health outcomes, reduces risks, improves quality of life and benefits the (health) economy.

2.2 Service description

Function of the Adult ADHD Service

The Provider will provide specialist assessment, management and prescribing (where clinically appropriate) for Adults over the age of 18 years with Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder.

All assessment, treatment, monitoring and review will be undertaken by the provider and reviewed within shared care protocols where applicable. The Provider must ensure that a diagnosis of ADHD is only made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD.

2.3 Population covered

BNSSG ICB is commissioning this service on behalf of patients registered with a GP for which the ICB is responsible. Under Patient Choice rules, patients from outside of BNSSG may choose to select the

provider and in these circumstances an invoice for payment should be directed to the appropriate responsible ICB.

2.4 Care pathway

The Provider will provide an ADHD assessment, diagnosis, prescribing and titration service with post diagnostic follow up reviews through a multi-disciplinary diagnostic and intervention service to service users registered with a BNSSG GP practice.

The pathway for shared prescribing is outlined in this document in Section 2.12. GP Practices may choose not to enter into shared care with a provider.

BNSSG general practices also have the option to sign up to a local enhanced service where the practice will undertake the prescribing and annual review of the patient. This sign up is voluntary. Please see appendix 1 for specification details.

The service will support the self-management of Service Users.

2.5 Referral Criteria and sources

Once an individual has selected their chosen provider, they will be referred directly to the provider by their GP or by secondary mental health services for assessment, diagnosis and treatment (if applicable).

2.6 Referral processes and Waiting List

The Provider must triage the referral within 5 working days of receipt of the referral where possible. It is recommended that the Provider undertake waiting list review to ensure service users' clinical needs have not changed. Prioritisation for assessment is not normally given, but certain patients may be prioritised depending on their circumstances

AWP's Priority (to include rational) – as at September 2024
- Expectant mothers – primary care giver 1st year after birth
- Prison leavers – 3 months (trying to stop reoffending)
- Criminal justice system involvement – last 6 months
- Armed service veterans
- Open child protection plan
- Safeguarding involvement
- MARAC involvement
- Currently or recent history of input from drug and alcohol treatment services

2.7 Any exclusion criteria

Individuals currently with co-existing mental health conditions receiving ADHD treatment as part of their secondary mental health services treatments and interventions.

The Provider will treat all service users in a safe and appropriate environment. The Provider is entitled to exclude certain groups of patients for reasons of clinical safety or complexity of support healthcare facilities normally required, which are not available. Any changes to the provider's exclusion and acceptance criteria must have previously been shared and agreed with the relevant commissioner(s).

The Provider shall reject any referred NHS patient for the following reasons;

Where it is felt the exclusion criteria should be applied, the Provider should make all reasonable attempts to discuss this with the service user and where appropriate, the service user's GP to ensure that the decision is informed and evidence based.

The Provider should ensure that when the exclusion criteria is applied, the service user is informed by a member of staff with an understanding of the criteria and the evidence used to inform the decision. The service user should receive a full explanation of the reasons for exclusion and where requested, the evidence used to inform the decision and signposted to other support services.

2.7.1 Referral accepted and assessment delayed

Alcohol and substance use that impacts on the current presentation in a way which renders the assessment invalid.

2.7.2 Do Not Attends (DNAs)

If a service user DNAs two appointments the service user will be discharged back to GP/referrer.

2.8 Assessment standards

As detailed in and derived from the documentation referenced under section 1.1 Aims and objectives, the locally agreed assessment standards are referenced on REMEDY https://remedy.bnssg.icb.nhs.uk/adults/mental-health/adhd-adult/ and the Provider will comply as follows:

- A comprehensive clinical and psychiatric history, to include mental state and risk assessment.
- A detailed developmental history.
- An up-to-date physical health history (primary care summary can be informative).
- Verbal and/or written collateral history, including school/educational reports, references etc.
- A diagnostic framework (currently ICD-11, DSM-5) should be referred to.
- Evidence of a diagnostic interview, either by using an established diagnostic instrument such as the DIVA, ACE + etc. or detailing systematic exploration of current and childhood symptoms.
- Reference to pervasiveness of symptoms across at least two important settings.
- Impact of ADHD symptoms on psychological, social, educational/occupational aspects of the person's life (The use of a questionnaire such as the WEISS functional impairment scale can be useful).
- Consideration of co-morbidities and their impact on ADHD symptomatology and overall impairment.
- Reference to limitations with the assessment due to inaccessible information, restrictive environments etc.

The assessment must be written into a comprehensive report and in addition to the above, should include:

- Information about the professional(s) who undertook the assessment, their role title, professional registration, and that the person/people undertaking the assessment are consistent with adopting NICE guidance on the composition of assessment teams. A diagnosis of ADHD can be made by a single clinician with appropriate training and experience in ADHD assessment (e.g., Psychiatrist, Psychologist or another appropriate qualified professional).
- In those circumstances where (ADHD) medication has been initiated following an assessment, it is important that the rationale for the treatment be stated by the professional who initiated the treatment. Reference to the guidelines and clinical practice to be included.

2.9 Assessment outcomes

All assessments must have a recorded outcome. Possible outcomes are:

- Diagnosis of ADHD.
- Confirmation of a previous or childhood diagnosis of ADHD.
- Non-diagnosis of ADHD.
- Identification of other needs/conditions and signposting.
- Liaison with other services, if required.
- Acceptance into the service for necessary treatment and interventions.
- Shared care agreement with GP with appropriate advice and support.

Service users will not need to have a care plan; however, their agreement will be sought in reaching and documenting a full written record of their assessment and care, including all relevant aspects of their assessment and treatment from the Provider.

2.10 Communication of outcome https://bjgp.org/content/73/735/473

The Provider will provide:

- Detailed feedback, explanation, and psychoeducation about ADHD, in easily accessible language.
- A discussion about psychosocial issues, including education or occupation and driving.
- Time for the service user to reflect on the diagnosis and ask questions and have the option available to go back to the assessment provider to ask further questions.
- A written summary of the discussion. This will be shared with the service user and other relevant parties, e.g. the referring professional and the GP.

2.11 Treatment https://bjgp.org/content/73/735/473
https://www.nice.org.uk/guidance/ng87#:~:text=In%20September%202019%2C%20we%20amended,that%20poses%20an%20increased%20cardiovascular

- A discussion to allow shared decision making about available treatment options, consideration of contraindications, and reasons for preferring one treatment to others.
- Consideration of measurable treatment goals before starting treatment.
- Treatment options are provided alongside or as an alternative to medication pathways to educate the patient on their condition and the alternatives available to them.
- Physical monitoring for medication (clinical examination, blood pressure, pulse, and weight) at baseline and during treatment to be undertaken by the provider. Some physical monitoring by patients themselves.
- Liaison with the GP to ascertain whether the GP is willing to take over future prescribing, while recognising there may be different patterns of 'shared' care.
- Provider to inform themselves on what NHS treatment provision is available locally in order to understand limits in provision and not raise patient expectations unreasonably.

2.12 Transfer to Shared care arrangement with Primary Care

Providers must be aware that some GPs in BNSSG are not undertaking shared care or Local Enhanced Services, so communication with the service user's GP is essential. If a GP does not agree to undertake prescribing and monitoring under a formal "Shared Care" agreement, they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist Provider.

The service will provide initiation of treatment, follow up appointments (including prescribing and associated physical monitoring) until treatment is stabilised as detailed in BNSSG approved shared care protocols https://remedy.bnssg.icb.nhs.uk/formulary-adult/scps/scps/ and https://remedy.bnssg.icb.nhs.uk/adults/mental-health/adhd-adult/

Shared care between the Provider and the patient's GP may be established according to the following principles:

- Shared care is with agreement of all parties i.e. specialist, GP and service user.
- The shared care protocol has been shared and agreed with the GP before the transfer of clinical and prescribing responsibility to the GP.
- The service user has undergone appropriate stabilisation period for a medicine, is on a stable dose and side effects treated before prescribing is handed over; duration determined by the shared care protocol e.g. 3 months.
- Discharge letters to be sent (either electronically or by post) to services users and copied to GPs/referrers within 10 days of appointment.
- At the point of the implementation of a shared prescribing protocol for Adult ADHD, the service user will be informed of the transition and shared ongoing care with the GP.
- There is a structure in place by the Provider for the GP to access on-going clinical advice and support, detailed in the shared care arrangement e.g. adverse effects, abnormal monitoring, advice during a medication shortage etc.

All prescribing and monitoring responsibilities remain with the Provider until the service user is stable and GP agrees to share care.

A prescriber can choose not to accept clinical responsibility because of lack of familiarity or competence in the use of a medicine or if it is used outside agreed guidance. Prescribers may not refuse clinical responsibility solely on grounds of cost. Distance is not a reason for requiring transfer of care.

2.13 Prescribing

Environmental Modifications

Environmental modifications and changes to the physical environment to minimise the impact of ADHD on day-to-day life should be discussed prior to medication treatment.

Non-pharmacological treatments consisting of structured supportive psychological interventions focused on ADHD, for example Cognitive Behavioural Therapy (CBT) and psycho education regarding ADHD should be discussed as treatment options and if offered be in line with NICE (2019) recommendations.

All prescribing should be within the agreed patient care pathway, and compliant with BNSSG Joint Formulary, with clear governance arrangements for the use of medicines, including any use of unlicensed medicines.

2.13.1 Medication

Medication titration as per NICE (2018) guidance and compliant with BNSSG Joint Formulary, with clear governance arrangements for the use of medicines, including any use of unlicensed medicines.

All prescribing for ADHD must be initiated by a healthcare professional with high quality training and expertise in diagnosing and managing ADHD and is expected to be in line with:

- Local BNSSG formulary https://remedy.bnssg.icb.nhs.uk/formulary-adult/chapters/4-central-nervous-system/42-mental-health-disorders/ and
- BNSSG shared care protocols https://remedy.bnssg.icb.nhs.uk/formulary-adult/scps/scps/ and
- NICE guidance NG87 Overview | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE

Any prescribing that is not in line with all of the above will not be considered suitable for shared care with GPs. Where the formulary specifies a first line brand of a medication, the expectation is that the

provider will also choose this first line unless there is a justifiable clinical reason why this is not suitable.

First line treatments

- Methylphenidate modified-release and immediate-release.
- Lisdexamfetamine.

Second line treatments

- Atomoxetine (recommended only if methylphenidate and lisdexamfetamine have been trialled and are unsuitable).
- Dexamfetamine (recommended only for adults whose ADHD symptoms are responding to Lisdexamfetamine but who cannot tolerate the longer effect profile).

If medication is agreed to be appropriate via shared decision making between the clinician and the service user, the following steps should be followed:

- All physical health monitoring should be undertaken as per the BNSSG shared care protocol to prepare for medication initiation.
- Treatment should be initiated and titrated until stable.
- Shared care with GP can be sought if all principles listed in 2.12 are met.

2.13.2 Treatments not suitable for shared care

- Dual treatment of stimulants or stimulants with atomoxetine is non-formulary in BNSSG and therefore is not suitable for shared care.
- NICE NG87 advises not to offer guanfacine for adults without advice from a tertiary ADHD service. Therefore GPs will be advised not to accept shared care of Guanfacine from providers.

2.14 Annual Reviews

- Annual reviews to be carried out with NICE Guideline NG87 and BNSSG ICB Shared Care protocols for medicines for ADHD in Adults. They may be undertaken by the Provider or the GP, depending on local commissioning arrangements. The Provider will need to confirm with the GP they wish to share care with, whether they are signed up to the BNSSG ADHD Local Enhanced Service (LES).
- Annual reviews can be undertaken by GP practice if signed up to BNSSG ADHD LES.
- Annual review to be undertaken by the Provider, if the patient is registered at a practice that is not signed up to the LES.
- In consultation with the patient, consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If the decision is made to continue medication, the reasons for this should be documented.

2.15 Days/ hours of operation

- The service will operate minimum Monday to Friday 5 days a week.
- The service does not operate an emergency service.

2.16 Response times

- Service will be monitored through monthly reports from the provider to the Commissioner.

2.17 Interdependencies with other services/providers

The Provider has a responsibility for the interface and development of appropriate pathways with other services; ensuring services are communicated to potential referrers. The provider will be required to work in co-operation with (and not limited to);

- ICB Commissioners and Exceptional Funding Request service.
- GPs, and any other ICB approved referrers.
- Commissioning Support Unit.
- Local mental health trust (AWP).
- Local primary and community teams and other interface services.
- Social services.
- Independent and third sector providers (voluntary sector).

2.18 Relevant networks and screening programmes

The service will work within the local area agreed referral pathway.

2.19 Training/ education/ research activities

It is expected that the staffing levels will be sufficiently resourced and have the appropriate skill mix to meet the defined needs of the service users and to provide the interventions. The service should ensure that they have the expertise to provide cultural awareness services.

2.19.1 Staff Training and Development

Staff will be expected to work locally with GPs offering advice and information.

It is the responsibility of the Provider to recruit/provide suitable personnel and as such the Provider will determine the exact person specification. However, the following guidelines will apply to all staff groups including temporary staff e.g. agency:

- All staff will be required to satisfy appropriate DBS checks.
- Staff will have the appropriate clinical and managerial qualifications for their role.
- All staff shall be appropriately trained/qualified and registered to undertake their roles and responsibilities.
- Professional accountability must be formulated within an agreed governance structure.
- Appropriate supervision arrangements for all levels of staff will be in place, including induction and clinical supervision.
- Staff will participate in regular personal performance reviews including the development of a personal development plan.
- All staff will be required to attend relevant mandatory training.
- Staff will be expected to work locally with GPs offering advice and information.

As set out by the Care Quality Commission (CQC), registration documentation will be held on record by the Provider for all medical staff and will be available for inspection. A certificate of registration will be prominently displayed by the Provider in all sites (if applicable) that the service is provided from.

2.19.2 Clinical or Managerial Supervision Arrangements

Supervision is regular protected time within work to reflect on and discuss a range of issues which together contribute to maintaining standards and ensure that the service delivers the highest quality of care to service users and carers.

2.20 Equality of Access

The Provider shall ensure the premises (if applicable), from which the service is to be provided, as well as any virtual provision shall be fully compliant with the Disability Discrimination Act (2005), the

Equality Act (2010) and any other statute or common law relevant to the provision of the service and relating to Equality and Discrimination.

The Provider will treat all service users in a safe and appropriate environment depending upon age and any existing medical conditions. The provider must ensure that services deliver consistent outcomes for patients regardless of:

- Gender
- Race
- Age
- Ethnicity
- Income
- Education
- Disability
- Sexual Orientation.

The Provider shall provide appropriate assistance and make reasonable adjustments for patients and carers who do not speak, read or write English or who have communication difficulties, in order to:

- Minimise clinical risk arising from inaccurate communication.
- Support equitable access to healthcare for people for whom English is not a first language.
- Support effectiveness of service in reducing health inequalities.

2.21 Subcontracting

The Provider shall ensure that no part of the services outlined in this specification may be subcontracted to any other party than the approved Provider without the prior agreement and approval of the Commissioner.

2.22 Notifying and agreeing changes to services

Providers must ensure that they seek Commissioners' consent to planned service changes as proposed Variations under NHS Standard Contract condition GC13. If changes are made without Commissioner agreement, the Commissioner may be entitled under the Contract to refuse to meet any increased costs which ensue.

3. Applicable Service Standards

3.1 Applicable national standards (eg NICE)

The Provider will have robust processes for reviewing, assessing, implementing and monitoring NICE technology appraisals and guidance.

Any and all treatments undertaken by providers as part of the service must be robust, evidence based, clinically effective treatments and the Provider must be qualified and registered to provide these treatments.

3.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

The Provider must deliver services in accordance with current best practice in healthcare and the range of policy and clinical/operational practice guidance relating to these services, complying in all respects with the standards and recommendations.

4. Location of Provider's premises

AWP Adult ADHD Service
Petherton Resource Centre
Petherton Road
Hengrove Bristol
BS14 9BP

Service Specification No.	**2A1**
Service	**Attention Deficit Hyperactivity Disorder (ADHD) – Adults (18+ years)**
Commissioner Lead	**BNSSG Integrated Care Board (ICB)**
Provider Lead	
Period	**1st December 2024 – 31st March 2026**
Date of Last Review	**January 2024**
Date of Next Review	**Quarter 4 2026**

1. Purpose

This service specification outlines BNSSG ICB objectives, scope, pathway and principles of the Adult Attention Deficit Hyperactivity Disorder Service (ADHD).

Aims and objectives

1. To improve ADHD related outcomes for each service user. A range of screening tools, tests and scales are available including (list not exhaustive):

    - Adult ADHD Self-Report Scale (ASRS-18)
    - WEISS FI scale
    - Adult ADHD Quality of Life Questionnaire (AAQoL)
    - Mental Health Quality of Life questionnaire MHQoL
    - Warwick and Edinburgh Mental Wellbeing scale
    - Barkley ADHD rating scale
    - Hospital Anxiety and Depression Scale (HADS)
    - Diagnostic Interview for ADHD in adults (DIVA)
    - Conners' Adult ADHD Rating Scales (CAARS)
    - Wender Utah Rating Scale
    - Autism Spectrum Quotient (AQ-10)

    The provider should be adopting a range of screening tools to provide a comprehensive assessment.

    - PROMS are measured at assessment, end of titration and at annual review.

2. To provide a quality service that ensures there is optimal patient safety, clinical effectiveness and a person-centred approach to care taken.
3. Provide accessible assessments and diagnosis either face to face or virtually with clear reasoning behind decision reached (see section 4 of this specification, location of the provider's premises).
4. To offer advice specific to the individual to other services and agencies, to include primary mental health care, third sector provision, secondary and tertiary services; regarding the management of ADHD with an interagency and multidisciplinary approach.
5. Treatment plans will be devised collaboratively with reference to the service user's goals to meet psychological, behavioural and occupational needs. Environmental modifications will be considered and progress to pharmacological interventions considered only if ongoing impairment in one domain subsequent to this is present (NICE, 2018).

The adult ADHD service provided will be informed by the following guidance and good practice guidelines:

1. ADHD: diagnosis and management NICE guideline NG87, published 14 March 2018, last updated 13 Sep 2019.

https://www.nice.org.uk/guidance/ng87#:~:text=In%20September%202019%2C%20we%20amended,that%20poses%20an%20increased%20cardiovascular
2. Royal College of Psychiatrists – ADHD in adults: good practice guidelines. https://www.rcpsych.ac.uk/docs/default-source/members/divisions/scotland/adhd_in_adultsfinal_guidelines_june2017.pdf
3. British Journal of General Practice guidance – Assessments for adult ADHD: what makes them good enough? https://bjgp.org/content/73/735/473
4. British Association of Psychopharmacology's guidelines (Bolea-Alamañac et al, 2014) https://www.bap.org.uk/pdfs/BAP_Guidelines-AdultADHD.pdf and the European Consensus Statement (Kooij et al, 2010) https://pubmed.ncbi.nlm.nih.gov/30453134/
5. General Medical Council guidance 2021 on shared care and prescribing. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care

The Provider will work under the following values:

1. Personalised care and sharing decision-making ('No decision about me without me') should be a governing principle in service design and delivery.
2. It is important that all clinicians working with adults with ADHD are able to adopt a 'trauma-informed' approach as is appropriate since there is evidence that people with ADHD are more likely than their peers to have experienced adverse childhood events (ACEs) (Brown et al, 2017).
3. Equal and timely access to appropriate services and evidence-based interventions.
4. Proactive, assertive engagement, particularly with service users at higher risk (e.g. young people at risk of offending/offenders or older people who are homeless).
5. Co-ordinated interventions planned around outcomes agreed by the user of the service, tailored to their individual needs, choices and preferences, with a holistic focus on building individual strengths and improving quality of life.
6. Culturally appropriate integrated approaches and interventions for neurodevelopmental disorders, co-existing mental health problems and co-existing alcohol and illicit drug use.
7. Early access to evidence-based interventions, right from the start of the patient journey in primary care with seamless interface/joint working between primary and secondary services and agreed criteria what is within the remit of the primary and secondary services.
8. In agreement with the service user, involvement of family, friends, partners and support networks and good, clear information to inform people's choices and decision-making.
9. Medication used in the treatment pathway must meet with commissioning organisation (BNSSG) requirements for an evidence based and cost-effective formulary, with clear governance arrangements for the use of unlicensed medicines.

1.1 National evidence base

Clear guidance on clinical practice to support healthcare in ADHD is spelled out in national clinical guidelines. NICE guidance is linked to each ICBs responsibility and legal duty to regard NICE quality standards and recommendations, secure high-quality services and ensure continual improvement in the quality of local NHS services (in addition to their legal duty to reduce health inequalities) as set out in the NHS Constitution and The National Health Service Act (2006), as amended by The Health and Social Care Act (2012).

Furthermore, it appears that courts are increasingly willing to acknowledge that national guidance may be relevant (in conjunction with clinical judgement) in setting standards of care because they are evidence based and reflect reasonable medical practice. This means ICBs and clinicians are potentially at risk of being challenged if they do not adopt and follow NICE Guidance and they should only not adopt if they have something better to offer and there is agreement from Commissioners.

The rights of people with ADHD in the UK are protected under the Human Rights Act 1998 (article 14: right to non-discrimination), and further under the UK Equality Act 2010, which protects people with a disability (including ADHD). People with ADHD also have rights under the Public Sector Equality Duty in England, Scotland and Wales, which places an obligation on public authorities to positively promote equality, not merely to avoid discrimination.

1.2 Right to Choose

Since 2014, in England under the NHS, patients have a legal right to choose their mental healthcare provider and their choice of mental healthcare team. If a patient decides the waiting time for their ADHD assessment is too long, then they can choose alternative providers. The provider must be commissioned for the service by an ICB in order to offer Right to Choose. https://www.england.nhs.uk/long-read/patient-choice-guidance/

NHS Choice Framework - what choices are available to you in your NHS care: https://www.gov.uk/government/publications/the-nhs-choice-framework/the-nhs-choice-framework-what-choices-are-available-to-me-in-the-nhs

Patients have the Right to Choose when the following conditions are met:

- The NHS practice is in England (different rules apply for Scotland, Wales and Northern Ireland).
- The General Practitioner (GP) has agreed to make a clinically appropriate referral.

Certain restrictions apply and patients cannot exercise their Right to Choose if they are:

- Already receiving mental health care following an elective referral for the same condition.
- Referred to a service that is commissioned by a local authority, for example a drug and alcohol service (unless commissioned under a Section 75 agreement).
- Accessing urgent or emergency (crisis) care.
- Already have a diagnosis of ADHD and are receiving treatment through a primary care contract.
- In high secure psychiatric services.
- Detained under the Mental Health Act 1983.
- Detained in a secure setting. This includes people in or on temporary release from prisons, courts, secure children's homes, certain secure training centres, immigration removal centres or young offender institutions.
- Serving as a member of the armed forces (family members in England have the same rights as other residents of England).

There are restrictions on who the patient can direct their care to. Patients cannot refer to just any provider. The provider must:

- Have a commissioning contract with any ICB in England or NHS England for the required service.

Furthermore, a diagnosis of ADHD should only be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD, as per the NICE Guidelines.

1.3 Local Context

BNSSG ICS aims:

BNSSG's Strategy and Joint Forward Plan have been developed to align with, and support, the four aims of Integrated Care Systems:

1. Improve outcomes in population health and health care.
2. Tackle inequalities in outcomes, experience and access.
3. Enhance productivity and value for money.
4. Help the NHS support broader social and economic development.

BNSSG's Joint Forward Plan https://bnssghealthiertogether.org.uk/library/joint-forward-plan/ (published June 2023) sets out how BNSSG ICB will deliver on the national vision of high-quality healthcare for all, through equitable access, excellent experience, and optimal outcomes over the next five years.

It aims to:

1. Improve the health and wellbeing of the population.
2. Provide high-quality services that are fair and accessible to everyone.

In 2024, BNSSG published a Mental Health Strategy. The strategy has six ambitions:

1. Holistic Care
2. Prevention and early help
3. Quality treatment
4. Sustainable System
5. Advancing equalities
6. Great place to work

https://bnssghealthiertogether.org.uk/health-wellbeing/mental-health-strategy/

The core reference for Adult ADHD provision:

National Institute for Health and Clinical Excellence (NICE) 2018: Attention Deficit Hyperactivity Disorder: diagnosis and management https://www.nice.org.uk/guidance/ng87

In BNSSG we have seen unprecedented demand for diagnosis and treatment of ADHD over the last few years. Demand exceeds locally commissioned services resulting in long waiting times and significant growth.

1.3.1 Strategic context

1. Under the NHS Long Term plan, https://www.longtermplan.nhs.uk/publication/nhs-mental-health-implementation-plan-2019-20-2023-24 the formation of Primary Care Networks (PCNs) in combination with the establishment of NHS Integrated Care Systems (ICSs), represents an opportunity to establish new and effective working practices to enable consistent and accessible healthcare for all people with ADHD. The NHS Community Mental Health Framework, https://www.england.nhs.uk/mental-health/adults/cmhs also sets out a vision for how community services should modernise to offer joined-up-care for those with mental health needs, within ICSs.
2. Recent guidance, stemming from professionals across primary, secondary, and tertiary care in the UK, has recommended the development of an ADHD specialism within primary care as part of a roadmap for improving access to treatment: https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-022-04290-7
   The evidence base outlined above, and current guidelines, highlight the key role primary care services have to play in the provision of healthcare for people with ADHD, and the potential for supporting an expansion of this role. Not only are primary care practitioners, such as GPs, often the gatekeepers through the referral system to secondary care services, such as adult mental health and specialist ADHD services, but NICE guidelines recommend that they also provide healthcare support such as routine monitoring and prescribing of medication under shared care agreements with secondary care services. Furthermore, primary care services have an increasing role to play in terms of providing mental health and well-being support to people with ADHD, with additional roles such as mental health workers and social prescribing link workers funded through PCNs.

Such joined up care is supported locally as follows: BNSSG's mission is *"Healthier together by working together."*

"People enjoying healthy and productive lives, supported by a fully integrated health and care system - providing personalised support close to home for everyone who needs it."

2. Service Scope

2.1 Attention Deficit Hyperactivity Disorder summary

ADHD is a common condition in adulthood with estimated prevalence rates of 3-4% (NICE 2018, 2023). Attention Deficit Hyperactivity Disorder (ADHD) is a neurodevelopmental disorder consisting of the core symptoms: inattention, hyperactivity and impulsivity.

There are three subtypes of ADHD accounting for variations in the symptom profile:

- Combined presentation (50-75%),
- Predominately inattentive (20% to 30%) and
- Predominately hyperactive/impulsive presentation (15%). (NICE 2018, 2023)

In childhood, ADHD is more commonly diagnosed in boys than in girls. In adults the prevalence of ADHD in men and women is more equal. ADHD is a highly heritable condition. Approximately 2/3 of young people with a childhood diagnosis continue to suffer disabling ADHD symptoms in adulthood. ADHD is frequently associated with other developmental disorders (Autism Spectrum Disorders, Dyspraxia, Dyslexia, Dyscalculia, Tics, specific learning disorders, sensory integration problems etc), psychiatric disorders, alcohol & substance use, oppositional and unlawful conduct and other difficulties.

The suicide risk is increased in people with ADHD but this is largely down to co-morbid psychiatric disorders. In addition, physical health problems such as obesity, sleep disorders, migraine, epilepsy, asthma and accidents are more common in people with ADHD. Many of the associated conditions do not respond to treatment well until ADHD is diagnosed and managed. Untreated ADHD can affect all aspects of a person's life and wellbeing, impact on families and communities, and result in increased health, societal and economic costs. Treatment for ADHD is effective, improves health outcomes, reduces risks, improves quality of life and benefits the (health) economy.

2.1.1 Service description

Function of the Adult ADHD Service

The Provider shall only be accredited via BNSSG ICB's accreditation process to provide those services for which they have been qualified.

The Provider will provide specialist assessment and prescribing for Adults over the age of 18 years with Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder.

All assessment, treatment, monitoring and review will be undertaken by the provider and reviewed within shared care protocols where applicable. The Provider must ensure that a diagnosis of ADHD is only made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD.

2.1.2 Care pathway

The Provider will provide an ADHD assessment, diagnosis, prescribing and titration service with post diagnostic follow up reviews through a multi-disciplinary diagnostic and intervention service to service users registered with a BNSSG GP practice.

The pathway for shared prescribing is outlined in this document in Section 2.7.5. GP Practices may choose not to enter into shared care with a provider.

BNSSG general practices also have the option to sign up to a local enhanced service where the practice will undertake the prescribing and annual review of the patient. This sign up is voluntary.

The service will support the self-management of Service Users.

2.2 Population covered

BNSSG ICB is commissioning this service on behalf of patients registered with a GP for which the ICB is responsible. Under Patient Choice rules, patients from outside of BNSSG may choose to select the provider and in these circumstances an invoice for payment should be directed to the appropriate responsible ICB.

2.3 Referral Criteria and sources

Once an individual has selected their chosen provider, they will be referred directly to the provider by their GP or by secondary mental health services for assessment, diagnosis and treatment (if applicable) when a service user has been assessed and found not to have a co-existing secondary mental health service need.

2.4 Referral processes and Waiting List

The Provider must aim to triage BNSSG referrals within 5 working days of receipt (where possible). The Provider is expected to undertake waiting list reviews on a quarterly basis to ensure service user's clinical needs have not changed.

Prioritisation for assessment is not normally given, but certain patients may be prioritised depending on their circumstances at the discretion of the clinician. A referral may be prioritised in cases where there is a significant risk of a delay in assessment causing:

1. A marked deterioration in the individual's mental health.
2. A significant increase in the individual's level of risk to self and/or others.
3. An increased likelihood of an individual losing their job and/or their accommodation leading to either of the above.

2.5 Any exclusion criteria

Individuals currently with co-existing mental health conditions receiving ADHD treatment as part of their secondary mental health services treatments and interventions.

The Provider will treat all service users in a safe and appropriate environment. The Provider is entitled to exclude certain groups of patients for reasons of clinical safety or complexity of support healthcare facilities normally required, which are not available. Any changes to the provider's exclusion and acceptance criteria must have previously been shared and agreed with the relevant commissioner(s).

The Provider shall reject any referred NHS patient for the following reasons;

- The patient meets any of the nationally defined exceptions listed under "you do not have a legal right to choose if:" at https://www.nhs.uk/mental-health/social-care-and-your-rights/how-to-access-mental-health-services/#choice
- The patient meets any of the Provider's own exclusion criteria as set down in their policy at Appendix 2A1_2A3.

Where it is felt the exclusion criteria should be applied, the Provider should make all reasonable attempts to discuss this with the service user and where appropriate, the service user's GP to ensure that the decision is informed and evidence based.

The Provider should ensure that when the exclusion criteria is applied, the service user is informed by a member of staff with an understanding of the criteria and the evidence used to inform the decision. The service user should receive a full explanation of the reasons for exclusion and where requested, the evidence used to inform the decision and signposted to other support services.

Referral accepted and assessment delayed
Alcohol and substance use that impacts on the current presentation in a way which renders the assessment invalid.

2.6 Did Not Attends (DNAs)

Any patient who does not attend their agreed appointment (new or follow up) may be discharged back to the care of their GP. Both the patient and GP will be notified in writing to ensure the referring GP is aware and can action further management of the patient if necessary. Exceptions to this are:

- When a clinical decision is taken that discharging the patient is contrary to the patient's clinical interests
- Children of 18 years and under or vulnerable adults.
- When one of the following can be confirmed:
  - If the patient did not receive the letter/ digital notification of the appointment including the appointment being sent to incorrect patient address / contact number
  - The appointment was not offered with reasonable notice.
  - If reasonable adjustments or patients' needs have not been supported – for example, accessible communications, translation, transport needs.

Outside of these exceptions, it will be at the providers' discretion as to whether a patient will be entitled to rebook an appointment after a first DNA without being discharged from the service. If a patient is offered another appointment and DNA after a second appointment is offered it is expected that the patient will be discharged back to the referrer.

The Provider will make every effort to rebook appointments where cancellations are received within 24 hours of appointment time. Where a patient DNAs the appointment without prior notice, the Provider will charge BNSSG ICB in line with the agreed DNA fee in the BNSSG Pricing Framework and the Payment schedule (schedule 3C – Local Prices) of this contract.

2.7 Assessment Outcomes

3 elements of service:
- Assessment
- Treatment (if applicable)
- Post diagnosis support
  - Support and liaison to local primary care, mental health and learning disability teams, in addition to social care and voluntary sector providers.

2.7.1 Assessment standards

As detailed in and derived from the documentation referenced under section 1 Aims and objectives, the locally agreed assessment standards are referenced on REMEDY https://remedy.bnssg.icb.nhs.uk/adults/mental-health/adhd-adult/ and the Provider will comply as follows:

- A comprehensive clinical and psychiatric history, to include mental state and risk assessment.
- A detailed developmental history.
- An up-to-date physical health history (primary care summary can be informative).
- Verbal and/or written collateral history, including school/educational reports, references etc.
- A diagnostic framework (currently ICD-11, DSM-5) should be referred to.
- Evidence of a diagnostic interview, either by using an established diagnostic instrument such as the DIVA, ACE + etc. or detailing systematic exploration of current and childhood symptoms.
- Reference to pervasiveness of symptoms across at least two important settings.
- Impact of ADHD symptoms on psychological, social, educational/occupational aspects of the person's life (The use of a questionnaire such as the WEISS functional impairment scale can be useful).
- Consideration of co-morbidities and their impact on ADHD symptomatology and overall impairment.
- Reference to limitations with the assessment due to inaccessible information, restrictive environments etc.

The assessment must be written into a comprehensive report and in addition to the above, should include:

- Information about the professional(s) who undertook the assessment, their role title, professional registration, and that the person/people undertaking the assessment are consistent with adopting NICE guidance on the composition of assessment teams. A diagnosis of ADHD can be made by a single clinician with appropriate training and experience in ADHD assessment (e.g., Psychiatrist, Psychologist or another appropriate qualified professional).

- In those circumstances where (ADHD) medication has been initiated following an assessment, it is important that the rationale for the treatment be stated by the professional who initiated the treatment. Reference to the guidelines and clinical practice to be included.

With the above standards in place, assessments can be accepted at face value between ADHD services, including from the independent sector. Where these standards have **not** been met, service users wishing to transfer into the NHS Bristol Adult ADHD Clinic (Avon and Wiltshire Partnership NHS Trust) will require a referral to the Clinic for a more comprehensive assessment, with a longer waiting time.

2.7.2 Diagnostic outcomes

All assessments must have a recorded outcome. Possible outcomes are:

- Diagnosis of ADHD.
- Confirmation of a previous or childhood diagnosis of ADHD.
- Non-diagnosis of ADHD.
- Identification of other needs/conditions and signposting.
- Liaison with other services, if required.
- Acceptance into the service for necessary treatment and interventions.
- Shared care agreement with GP with appropriate advice and support.

Service users will not need to have a care plan; however, their agreement will be sought in reaching and documenting a full written record of their assessment and care, including all relevant aspects of their assessment and treatment from the Provider.

2.7.3 Communication of outcome https://bjgp.org/content/73/735/473

The Provider will provide:

- Detailed feedback, explanation, and psychoeducation about ADHD, in easily accessible language.
- A discussion about psychosocial issues, including education or occupation and driving.
- Time for the service user to reflect on the diagnosis and ask questions and have the option available to go back to the assessment provider to ask further questions.
- A written summary of the discussion. This will be shared with the service user and other relevant parties, e.g. the referring professional and the GP.

2.7.4 Treatment https://bjgp.org/content/73/735/473
https://www.nice.org.uk/guidance/ng87#:~:text=In%20September%202019%2C%20we%20amended,that%20poses%20an%20increased%20cardiovascular

- A discussion to allow shared decision making about available treatment options, consideration of contraindications, and reasons for preferring one treatment to others.
- Consideration of measurable treatment goals before starting treatment.
- Treatment options are provided alongside or as an alternative to medication pathways to educate the patient on their condition and the alternatives available to them.
- Physical monitoring for medication (clinical examination, blood pressure, pulse, and weight) at baseline and during treatment to be undertaken by the provider. For services that have been commissioned to be delivered virtually, the patient will be responsible for measuring and providing physical health monitoring information to the Provider.
- Liaison with the GP to ascertain whether the GP is willing to take over future prescribing, while recognising there may be different patterns of 'shared' care.
- Right to Choose providers to inform themselves on what NHS treatment provision is available locally in order to understand limits in provision and not raise patient expectations unreasonably.

2.7.5 Transfer to Shared care arrangement with Primary Care

Providers must be aware that some GPs in BNSSG are not undertaking shared care or Local Enhanced

Services, so communication with the service user's GP is essential. If a GP does not agree to undertake prescribing and monitoring under a formal "Shared Care" agreement, they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist Provider.

The service will provide initiation of treatment, follow up appointments (including prescribing and associated physical monitoring) until treatment is stabilised as detailed in BNSSG approved shared care protocols https://remedy.bnssg.icb.nhs.uk/formulary-adult/scps/scps/ and https://remedy.bnssg.icb.nhs.uk/adults/mental-health/adhd-adult/

Shared care between the Provider and the patient's GP may be established according to the following principles:

- Shared care is with agreement of all parties i.e. specialist, GP and service user.
- The shared care protocol has been shared and agreed with the GP before the transfer of clinical and prescribing responsibility to the GP.
- The service user has undergone appropriate stabilisation period for a medicine, is on a stable dose and side effects managed before prescribing is handed over; duration determined by the shared care protocol e.g. 3 months.
- Discharge letters to be sent (either electronically or by post) to services users and copied to GPs/referrers within 10 working days of appointment.
- At the point of the implementation of a shared prescribing protocol for Adult ADHD, the service user will be informed of the transition and shared ongoing care with the GP.
- There is a structure in place by the Provider for the GP to access on-going clinical advice and support, detailed in the shared care arrangement e.g. adverse effects, abnormal monitoring, advice during a medication shortage etc.

All prescribing and monitoring responsibilities remain with the Provider until the service user is stable and GP agrees to shared-care.

A prescriber can choose not to accept clinical responsibility because of lack of familiarity or competence in the use of a medicine or if it is used outside agreed guidance. Prescribers may not refuse clinical responsibility solely on grounds of cost. Distance is not a reason for requiring transfer of care.

2.7.6 Discharge processes

The service is primarily diagnostic with treatment if required. Hence service users with on-going needs will need to be referred to the appropriate service following assessment.

Service users will be discharged from the service in accordance with the Providers Discharge Policy and take into consideration:

- Discussion with the service user and
- GPs can contact the Provider if concerns arise post discharge.

See Other Local Arrangements, Policies and Procedures (schedule 2G4) for provider's discharge policy/procedure.

2.8 Prescribing

Environmental Modifications
Environmental modifications and changes to the physical environment to minimise the impact of ADHD on day-to-day life should be discussed prior to medication treatment.

Non-pharmacological treatments consisting of structured supportive psychological interventions focused on ADHD, for example Cognitive Behavioural Therapy (CBT) and psycho education regarding ADHD should be discussed as treatment options and if offered be in line with NICE (2019) recommendations.

All prescribing should be within the agreed patient care pathway, and compliant with BNSSG Joint Formulary, with clear governance arrangements for the use of medicines, including any use of unlicensed medicines.

NHS Prescription Issuance for Patients in Regions with NHS Cost Centre Setup
For patients within the Bristol, North Somerset, South Gloucestershire (BNSSG) area or other regions where the Provider has been allocated an NHS cost centre and NHS FP10 prescription pads by the Integrated Care Board (ICB), the Provider shall issue NHS prescriptions. These prescriptions will be sent to the patient's nominated pharmacy, in accordance with local formularies and in compliance with applicable NHS guidelines and regulations.

For patients in regions where the Provider has not been set up with an NHS cost centre and is therefore unable to issue NHS prescriptions, the Provider shall issue private prescriptions. These prescriptions will be processed through an online pharmacy, which will contact the patient to arrange delivery at a suitable time and location convenient to the patient. The online pharmacy will invoice the Provider directly for the cost of the medication, which in turn will be recharged to the referring ICB.

2.8.1 Medication

Medication titration should be as per NICE guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management and for BNSSG patients, compliant with BNSSG Joint Formulary, with clear governance arrangements for the use of medicines, including any use of unlicensed medicines. All prescribing for ADHD must be initiated by a healthcare professional with high quality training and expertise in diagnosing and managing ADHD and is expected to be in line with:

- For BNSSG patients, local BNSSG formulary https://remedy.bnssg.icb.nhs.uk/formulary-adult/chapters/4-central-nervous-system/42-mental-health-disorders/ and
- BNSSG shared care protocols https://remedy.bnssg.icb.nhs.uk/formulary-adult/scps/scps/ and
- NICE guidance NG87 Overview | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE

Any prescribing that is not in line with all of the above will not be considered suitable for shared care with GPs. Where the formulary specifies a first line brand of a medication, the expectation is that the provider will also choose this first line unless there is a justifiable clinical reason why this is not suitable.

First line treatments
- Methylphenidate modified-release and immediate-release. Please refer to the BNSSG Joint formulary and shared care protocols for BNSSG first line product. Please prescribe the first line brand of Methylphenidate product, unless there is a clinical reason not to.
- Lisdexamfetamine.

Second line treatments
- Atomoxetine (recommended only if methylphenidate and lisdexamfetamine have been trialled and are unsuitable).
- Dexamfetamine (recommended only for adults whose ADHD symptoms are responding to Lisdexamfetamine but who cannot tolerate the longer effect profile).

If medication is agreed to be appropriate via shared decision making between the clinician and the service user, the following steps should be followed:

- All physical health monitoring should be undertaken as per the BNSSG shared care protocol to prepare for medication initiation.
- Treatment should be initiated and titrated until stable.
- Shared care with GP can be sought if all principles listed in 2.7.5 are met.

2.8.2 Treatments not suitable for shared care

- Dual treatment of stimulants or stimulants with atomoxetine is non-formulary in BNSSG and therefore is not suitable for shared care.

- NICE NG87 advises not to offer Guanfacine for adults without advice from a tertiary ADHD service. Therefore, GPs will be advised not to accept shared care of Guanfacine from providers.

2.8.3 Annual Reviews

- Annual reviews to be carried out with NICE Guideline NG87 and BNSSG ICB Shared Care protocols for medicines for ADHD in Adults. They may be undertaken by the Provider or the GP, depending on local commissioning arrangements. The Provider will need to confirm with the GP they wish to share care with, whether they are signed up to the BNSSG ADHD Local Enhanced Service (LES) and have capacity to undertake the annual review.
- Annual reviews can be undertaken by GP practice if signed up to BNSSG ADHD LES.
- Annual review to be undertaken by the Provider, if the patient is registered at a practice that is not signed up to the LES.
- In consultation with the patient, consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If the decision is made to continue medication, the reasons for this should be documented.

2.9 Reporting

As part of the Provider internal data completeness, cleansing and quality processes the ICB expect the information provided by operational team(s) to be scrutinised and understood by performance management staff and the senior management teams before submission to commissioners. The senior management team will take full responsibility for the accuracy of data insofar as the current level of completeness, coverage and accuracy of data has been established, taking into account any reported overall or service-specific improvements during the contract year(s).

A reporting schedule will be included in the NHS Standard Contract issued to the Provider. This will not be exhaustive.

Reporting should be submitted to the Commissioner quarterly. The Commissioner may make ad hoc requests for performance and quality data if required.

Service access will be monitored through reports from the provider and through regular contract review meetings with BNSSG ICB. Reporting frequency to be in line with the Contract Management, Reporting and Information (schedule 6A) requirements.

2.10 Days/hours of operation

- The service will operate minimum Monday to Friday 5 days a week.
- The service does not operate an emergency service.

2.11 Interdependencies with other services/providers

The Provider has a responsibility for the interface and development of appropriate pathways with other services; ensuring services are communicated to potential referrers.

The provider will be required to support the local BNSSG Integrated Care System and at times will be requested by the co-ordinating commissioner to work in co-operation with (and not limited to);

- ICB Commissioners and Exceptional Funding Request service.
- GPs, and any other ICB approved referrers.
- Commissioning Support Unit.
- Local mental health trust (AWP).
- Local primary and community teams and other interface services.
- Social services.
- Independent and third sector providers (voluntary sector).

2.12 Relevant networks and screening programmes

The service will work within the local area agreed referral pathway.

2.13 Training/ education/ research activities

It is expected that the staffing levels will be sufficiently resourced and have the appropriate skill mix to meet the defined needs of the service users and to provide the interventions. The service should ensure that they have the expertise to provide cultural awareness services.

2.13.1 Staff Training and Development

Staff will be expected to work locally with GPs offering advice and information.
It is the responsibility of the Provider to recruit/provide suitable personnel and as such the Provider will determine the exact person specification. However, the following guidelines will apply to all staff groups including temporary staff e.g. agency:

- All staff will be required to satisfy appropriate DBS checks.
- Staff will have the appropriate clinical and managerial qualifications for their role.
- All staff shall be appropriately trained/qualified and registered to undertake their roles and responsibilities.
- Professional accountability must be formulated within an agreed governance structure.
- Appropriate supervision arrangements for all levels of staff will be in place, including induction and clinical supervision.
- Staff will participate in regular personal performance reviews including the development of a personal development plan.
- All staff will be required to attend relevant mandatory training.
- Staff will be expected to work locally with GPs offering advice and information.

As set out by the Care Quality Commission (CQC), registration documentation will be held on record by the Provider for all medical staff and will be available for inspection. A certificate of registration will be prominently displayed by the Provider in all sites (if applicable) that the service is provided from.

2.13.2 Clinical or Managerial Supervision Arrangements

Supervision is regular protected time within work to reflect on and discuss a range of issues which together contribute to maintaining standards and ensure that the service delivers the highest quality of care to service users and carers.

2.14 Equality of Access

The Provider shall ensure the premises (if applicable), from which the service is to be provided, as well as any virtual provision shall be fully compliant with the Disability Discrimination Act (2005), the Equality Act (2010) and any other statute or common law relevant to the provision of the service and relating to Equality and Discrimination.

The Provider will treat all service users in a safe and appropriate environment (in accordance with the Providers process for determining suitable remote/digital environment) depending upon age and any existing medical conditions. The provider must ensure that services deliver consistent outcomes for patients regardless of:

- Gender
- Race
- Age
- Ethnicity
- Income
- Education
- Disability
- Sexual Orientation

The Provider shall provide appropriate assistance and make reasonable adjustments for patients and carers who do not speak, read or write English or who have communication difficulties including cognitive impairment, lack of capacity, hearing, oral or a learning disability in order to:

- Minimise clinical risk arising from inaccurate communication.
- Support equitable access to healthcare for people for whom English is not a first language.
- Support effectiveness of service in reducing health inequalities.

2.15 Information Governance

All organisations that have access to NHS patient data must provide assurances that they are practising good information governance and use the Data Security and Protection Toolkit to evidence this.
The Data Security and Protection Toolkit is a Department of Health Policy delivery vehicle that the Health and Social Care Information Centre (HSCIC) is commissioned to develop and maintain. It draws together the legal rules and central guidance and presents them in a single standard as a set of information governance and data security assertions. The Provider is required to carry out self-assessments of their compliance against these assertions.

The Provider will identify an Information Governance lead.

The Provider must complete and provide evidence that they have achieved a satisfactory position for their organisation's Data Security and Protection Toolkit through meeting all the mandatory requirements: https://www.dsptoolkit.nhs.uk/

Final publication assessment scores reported by organisations are used by the Care Quality Commission when identifying how well organisations are meeting the Fundamental Standards of quality and safety - the standards below which care must never fall.

The Provider shall comply with all relevant national information governance and best practice standards including NHS Security Management – NHS Code of Practice, NHS Confidentiality – NHS Code of Practice and the National Data Security Standards. The Provider will participate in additional Information Governance audits agreed with the Commissioner.

2.16 Subcontracting

The Provider shall ensure that no part of the services outlined in this specification may be subcontracted to any other party than the approved Provider without the prior agreement and approval of the Commissioner.

The commissioner acknowledges that where a proportion of a Provider's workforce is comprised of subcontracted clinicians, these are exempt from the Governance schedule (schedule 5).

2.17 Notifying and agreeing changes to services

Providers must ensure that they seek Commissioners' consent to planned service changes as proposed Variations under NHS Standard Contract condition GC13. If changes are made without Commissioner agreement, the Commissioner may be entitled under the Contract to refuse to meet any increased costs which ensue.

3. Applicable Service Standard

3.1 Applicable national standards (eg NICE)

The Provider will have robust processes for reviewing, assessing, implementing and monitoring NICE technology appraisals and guidance.

Any and all treatments undertaken by providers as part of the service must be robust, evidence based, clinically effective treatments and the Provider must be qualified and registered to provide these treatments.

3.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

The Provider must deliver services in accordance with current best practice in healthcare and the range of policy and clinical/operational practice guidance relating to these services, complying in all respects with the standards and recommendations.

4. Location of Provider's premises

The Provider will provide the service virtually.

Face to face assessments will only be available following an incomplete/failed remote assessment where there is no other option and where the provider and BNSSG ICB agree that this is a reasonable adjustment. This will be discussed on a case by case basis and face to face assessments will take place at one of the providers existing clinics. Where the provider clinic is located outside of BNSSG, the patient must indicate their willingness to travel the distance before final approval can be granted.

Service Specification No.	**2A2**
Service	**BNSSG Attention Deficit Hyperactivity Disorder (ADHD) Service (Children and young people (<18 years)**
Commissioner Lead	**BNSSG ICB**
Provider Lead	
Period	**1st December 2024 – 31st March 2026**
Date of Last Review	**Quarter 4 2024**
Date of Next Review	**Quarter 4 2026**

1. Purpose

This service specification outlines BNSSG ICB's objectives, scope, pathway and principles of the Children's and Young People Attention Deficit Hyperactivity Disorder (ADHD) Service. Throughout this document, the term 'Service User' will refer to the child/young person and/or the parent/carer of the child or young person who is being assessed.

The Provider is commissioned to provide evidence-based ADHD diagnostic assessment and post diagnostic support for children and young people, led and undertaken by appropriately skilled health professionals. The service offer will be based on NICE guidelines and best practice associated with ADHD diagnosis.

1.1 National evidence base

NICE Attention Deficit Hyperactivity Disorder Definition | Background information | Attention deficit hyperactivity disorder | CKS | NICE outlines the existing principles for the identification, assessment, treatment and management of ADHD.

There are three subtypes of ADHD:

- The inattentive subtype accounts for 20% to 30% of cases
- The hyperactive-impulsive subtype accounts for around 15% of cases
- The combined subtype accounts for 50% to 75% of cases

The global prevalence of ADHD in children is estimated to be around 5%, although studies based on US populations (where rates of diagnosis and treatment tend to be highest) estimate the rate at between 8% and 10%. Prevalence | Background information | Attention deficit hyperactivity disorder | CKS | NICE

1.2 Right to Choose

Since 2014, in England under the NHS patients have a legal right to choose their healthcare provider and healthcare team. If a patient decides the waiting time for their ADHD assessment is too long, then they can choose alternative providers. The provider must be commissioned for the service by an ICB in order to offer Right to Choose.

NHS Choice Framework - what choices are available to you in your NHS care
NHS Choice Framework - what choices are available to you in your NHS care - GOV.UK (www.gov.uk)

Patients have the Right to Choose when the following conditions are met:

- The NHS provider is in England (different rules apply for Scotland, Wales and Northern Ireland).
- The General Practitioner has agreed to make clinically appropriate referral.

Certain restrictions apply and patients cannot exercise their Right to Choose if they are:

- Already receiving mental health care following an elective referral for the same condition.
- Referred to a service that is commissioned by a local authority, for example a drug and alcohol service (unless commissioned under a Section 75 agreement).
- Accessing urgent or emergency (crisis) care.
- Already have a diagnosis of ADHD and are receiving treatment through a primary care contract.
- In high secure psychiatric services.
- Detained under the Mental Health Act 1983.
- Detained in a secure setting. This includes people in or on temporary release from prisons. courts, secure children's homes, certain secure training centres, immigration removal centres or young offender institutions.
- Serving as a member of the armed forces (family members in England have the same rights as other residents of England.

There are restrictions on who the patient can direct their care to. Patients cannot refer to just any provider. The provider must:

- Have a commissioning contract with any ICB or NHS England for the required service.
- Have a multi-disciplinary team including a paediatrician and/or child and adolescent psychiatrist.

1.3 Local Context

BNSSG ICS aims

BNSSG's Strategy and Joint Forward Plan have been developed to align with, and support, the four aims of Integrated Care Systems:

1. Improve outcomes in population health and health care
2. Tackle inequalities in outcomes, experience and access
3. Enhance productivity and value for money
4. Help the NHS support broader social and economic development.

BNSSG Joint Forward Plan Joint Forward Plan - BNSSG Healthier Together (published June 2023) sets out how BNSSG ICB will deliver on the national vision of high-quality healthcare for all, through equitable access, excellent experience, and optimal outcomes over the next five years.

It aims to:

1. Improve the health and wellbeing of the population.
2. Provide high-quality services that are fair and accessible to everyone.

In 2024, BNSSG published a Mental Health Strategy. The strategy has six ambitions:

1. Holistic Care
2. Prevention and early help
3. Quality treatment
4. Sustainable System
5. Advancing equalities
6. Great place to work

https://bnssghealthiertogether.org.uk/health-wellbeing/mental-health-strategy/

2. Service Scope

2.1 Aims

To provide an accessible, high quality and timely Children's and Young Person's ADHD diagnostic service, including post-diagnostic support as indicated by NICE guidelines and in line with

commissioning requirements. The Provider is required to develop an effective and efficient service model that incorporates national and local ICS wide requirements. In collaboration with a range of statutory and voluntary sector agencies, providers should offer Children and Young People with ADHD with a sufficient level of support to enable their continued independence and well-being.

2.1.1 Objectives

- To provide accurate diagnostic assessment, treatment including medication (if required) and a range of post diagnostic support.
- To provide a person-centred and flexible approach.
- To ensure that children, young people and their parents/carers are treated with compassion, respect and dignity, without stigma or judgment.
- To ensure that children and young people who access the service are seen in a timely manner.
- To ensure that the impact of trauma, abuse or neglect in the lives of children and young people is properly considered when identifying need and making diagnostic decisions and formulations.
- To ensure that any additional vulnerability or inequality suffered by children and young people (e.g. learning disability, victim of child sexual exploitation, homelessness) is properly considered when identifying need and making diagnostic decisions and formulations.
- To agree the aim and goal of assessment with the child/young person or parent/carer.
- To deliver a service informed by NICE guidance and NICE quality 8 statements.
- To promote active and full engagement of service users in their own homes.
- To provide a clinically effective and cost-effective service.
- To help service users make informed choices about their care and identified support needs, in partnership with their health and social care professionals.
- Improved quality of life, as identified by the service user and appropriate evidence-based measurement tools. This could include the Patient Satisfaction Questionnaire (PSQ) and the Friends and Family Test (FFT).

2.1.2 Service summary

The service is expected to conform to all relevant currently published and future NICE guidance.

The Provider is expected to ensure that they provide:

- Appropriate and accessible information to individuals about their service
- Appropriate and accessible information about timescales for assessment.
- Clear information to individuals about what will and may happen post diagnosis. Information about local signposting will be supplied to the provider by the lead Commissioner.
- Additional support if the individual is unable to consent to assessment and/or interventions. It may be appropriate for the referrer and provider to consider the Mental Capacity Act, and the use of an advocacy service if necessary.

2.2 Population covered

BNSSG ICB is commissioning this service on behalf of patients registered with a GP for which the ICB is responsible. Under Patient Choice rules, patients from outside of BNSSG ICB may choose to select the provider and in these circumstances an invoice for payment should be directed to the appropriate responsible ICB.

2.3 Referral Criteria

Children who are aged between 5 years and 17 years and 9 months and registered with a GP Practice within BNSSG.

Assessments of ADHD are restricted until children are over the age of 5.

If a young person is 17 years 9 months or older at the point of referral, or will reach this age while waiting for an assessment to be conducted, the Provider should either decline the referral or, if the Provider holds an NHS Standard Contract for Adult ADHD Assessment, the Provider may offer to transfer the

patient to their adult ADHD Assessment service (the date of the original referral to children and young people ADHD services will be honoured). Transfer to an adult service should only be done with consent from the patient, in line with referral criteria for adult services; and in the case of young people who have already received a diagnosis of ADHD from children and young people ADHD services, if they are stable on medication.

2.4 Referral process and Waiting List

Referral to be made through patient's GP.

The Provider must aim to triage BNSSG referrals within 5 working days of receipt (where possible). The Provider is expected to undertake waiting list reviews on a quarterly basis to ensure service user's clinical needs have not changed.

Prioritisation for assessment is not normally given, but certain patients may be prioritised depending on their circumstances at the discretion of the clinician e.g., those who are already diagnosed and/or clearly at risk from not being treated. A referral may be prioritised in cases where there is a significant risk of a delay in assessment causing:

1. A marked deterioration in the individual's mental health.
2. A significant increase in the individual's level of risk to self and/or others.
3. An increased likelihood of an individual losing their job and/or their accommodation leading to either of the above.

2.5 Any exclusion criteria

Individuals currently with co-existing mental health conditions receiving ADHD treatment as part of their secondary mental health services treatments and interventions.

The Provider will treat all service users in a safe and appropriate environment. The Provider is entitled to exclude certain groups of patients for reasons of clinical safety or complexity of support healthcare facilities normally required, which are not available. Any changes to the provider's exclusion and acceptance criteria must have previously been shared and agreed with the relevant commissioner(s).

The Provider shall reject any referred NHS patient for the following reasons;

- The patient meets any of the nationally defined exceptions listed under "you do not have a legal right to choose if:" at https://www.nhs.uk/mental-health/social-care-and-your-rights/how-to-access-mental-health-services/#choice
- The patient meets any of the Provider's own exclusion criteria as set down in their policy at Appendix 2A2_2A4.

Where it is felt the exclusion criteria should be applied, the Provider should make all reasonable attempts to discuss this with the service user and where appropriate, the service user's GP to ensure that the decision is informed and evidence based.

The Provider should ensure that when the exclusion criteria is applied, the service user is informed by a member of staff with an understanding of the criteria and the evidence used to inform the decision. The service user should receive a full explanation of the reasons for exclusion and where requested, the evidence used to inform the decision and signposted to other support services.

2.6 Was Not Brought (Did Not Attend)

Any patient who does not attend their agreed appointment (new or follow up) may be discharged back to the care of their GP. Both the patient and GP will be notified in writing to ensure the referring GP is aware and can action further management of the patient if necessary. Exceptions to this are:

- When a clinical decision is taken that discharging the patient is contrary to the patient's clinical interests.
- Children of 18 years and under or vulnerable adults.

- When one of the following can be confirmed:
  - If the patient did not receive the letter/ digital notification of the appointment including the appointment being sent to incorrect patient address / contact number
  - The appointment was not offered with reasonable notice.
  - If reasonable adjustments or patients' needs have not been supported – for example, accessible communications, translation, transport needs.

Outside of these exceptions, it will be at the providers discretion as to whether a patient will be entitled to rebook an appointment after a first DNA without being discharged from the service. If a patient is offered another appointment and DNA after a second appointment is offered it is expected that the patient will be discharged back to the referrer.

When a service user is not brought to an appointment, a risk assessment should be made and acted upon. A service should not close a case without informing the referrer that the service user has not attended. The service should make explicit re-engagement policies available to referrers, children / young people and parents / carers.

In the event of a paediatric patient making multiple (more than one) cancellations, multiple changes or if they DNA on multiple occasions - in addition to the clinical review process and active engagement with the patient, the provider will write to the patient's GP following the second DNA to establish if there are any particular circumstances, including safeguarding concerns, why the patient might not be attending. It is not acceptable to refer patients back to their GP simply because they wish to delay their appointment or treatment. However, there are situations when referring a patient back to their GP is in their best clinical interests. Such decisions should be made by the treating clinician on a case-by-case basis and following discussion and agreement with the patient.

The Provider will make every effort to rebook appointments where cancellations are received within 24 hours of appointment time. Where a patient DNAs the appointment without prior notice, the Provider will charge BNSSG ICB in line with the agreed DNA fee in the BNSSG Pricing Framework and Payment schedule (schedule 3C – Local Prices) of this contract.

The Provider should follow a robust Access Policy which supports the safeguarding of children, as described in clause 3.2.1.

2.7 Assessment Outcomes

3 elements of service:

- Assessment
- Treatment (if applicable)
- Post diagnosis support
  - Support and liaison to local primary care, mental health and learning disability teams, in addition to social care and voluntary sector providers

2.7.1 Assessment

The assessment may be conducted over a number of appointments, tailored to the need of the service user. In accordance with NICE guidance, a diagnosis of ADHD should only be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD, on the basis of:

- A full clinical and psychosocial assessment of the person; this should include discussion about behaviour and symptoms in the different domains and settings of the person's everyday life **and**
- A full developmental psychiatric history **and**
- Observer reports and assessment of the person's mental state.

The Children's and Young People's ADHD Diagnostic Service will offer:

- Initial triage based on a balance of waiting time and clinical assessment of need (see section 2.4 of this specification).

- Diagnostic assessment including gathering of developmental history, observations from home and education settings using agreed tools and process.
- Post-diagnostic signposting to appropriate services local to BNSSG.
- Post diagnostic initiation of medication trial if recommended with appropriate monitoring and follow up.
- The service will be person centred, based on the needs of the service users and involvement of their carer / families (if appropriate).

2.7.2 Diagnostic Outcomes

Assessment may result in three possible outcomes:

1. An ADHD diagnosis is confirmed as present.
2. The diagnosis is confirmed as not present. In this instance, the service user's GP, and (with the appropriate agreement and consent) any relevant services/carers/families should be notified accordingly. The service user would be referred on to other services, depending upon needs and presentation.
3. A diagnosis of ADHD is uncertain or inconclusive. A recommendation may be made to access a second opinion or to complete a re-assessment following a period of time (at which point it may be possible to arrive at a conclusive finding).

Service users will not need to have a care plan; however, their agreement will be sought in reaching and documenting a full written record of their assessment, including all relevant aspects of their assessment and treatment from the Provider. This will be communicated in written form to the service user and other relevant parties, e.g., the referring professional and/or the GP.

The Provider will ensure that, as part of their service offer and discharge processes, service users are well-informed about what to expect from the service. They should be given information and signposting to other community, voluntary and other services, including those local to BNSSG.

All service users should be made aware of the Provider's statutory duty to share any relevant information with other agencies when there is a safeguarding concern, or it is thought crime or disorder has possibly taken place. When there is a safeguarding concern the voice of the possible child at risk should be part of all stages of the process.

The service should be providing information to support the care of patients and signposting to other organisations including the voluntary sector.

Whilst providing care, support and treatment to patients, staff need to be able to support families with the role of carer and signpost them to support services that can provide information and undertake a carer's assessment if appropriate.

2.7.3 Feedback

Service users will be provided with detailed feedback where the results of the assessment and the implications of this are discussed with them. If they have not been given a diagnosis, the feedback session would be an opportunity to better explain their presenting difficulties. There, strengths and needs will be identified. Service users will also be signposted and/or referred to appropriate services, as required.

2.7.4 Treatment

- A discussion with the patient and/or parent/carer must take place to allow shared decision making about available treatment options, consideration of contraindications, and reasons for preferring one treatment to others.
- Consideration of measurable treatment goals before starting treatment.
- Treatment options are provided alongside or as an alternative to medication pathways to educate the patient on their condition and the alternatives available to them.

- Physical monitoring for medication (clinical examination, blood pressure, pulse, and weight) at baseline and during treatment to be undertaken by the provider. For services that have been commissioned to be delivered virtually, the patient will be responsible for measuring and providing physical health monitoring information to the Provider. This should be conducted in line with NICE guidance Recommendations | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE which provides recommendations for the frequency of review for children prescribed ADHD medication.
- Liaison with the GP to ascertain whether the GP is willing to take over future prescribing, while recognizing there may be different patterns of 'shared' care.
- Right to Choose providers to inform themselves on what NHS treatment provision is available locally in order to understand limits in provision and not raise patient expectations unreasonably.

2.7.5 Shared care arrangements

Providers must be aware that shared care for Children and Young People's ADHD in BNSSG covers medication prescribing only and willingness to engage in shared care may vary between GPs. In all cases, responsibility for physical health monitoring and annual reviews will remain with the provider and the service will also be required to retain prescribing where this isn't available in primary care. Early communication with the service user's GP is essential to determine whether they are able to take prescribing once the patient is stable on medication and if a GP does not agree to undertake prescribing under a shared care agreement, they are under no obligation to do so.

The service will provide initiation of treatment, follow up appointments (including prescribing and associated physical monitoring) until treatment is stabilised as detailed in BNSSG approved shared care protocols.

Shared care between the Provider and the patient's GP may be established according to the following principles:

- Shared care is with agreement of all parties i.e. specialist, GP and service user.
- The shared care protocol has been shared and agreed with the GP before the transfer of prescribing responsibility to the GP.
- The service user has undergone appropriate stabilisation period for a medicine, is on a stable dose and side effects treated before prescribing is handed over; duration determined by the shared care protocol e.g. 3 months.
- The provider understands that they will retain total clinical responsibility for the ongoing physical health checks and reviews (at the intervals recommended by NICE depending on the age of the child or young person).
- Discharge letters to be sent (either electronically or by post) to services users and copied to GPs/referrers within 10 working days of appointment.
- At the point of the implementation of a shared prescribing protocol, the service user (and/or their parent or carer) will be informed of the transition and shared ongoing care with the GP.
- There is a structure in place by the Provider for the GP to access on-going clinical advice and support, detailed in the shared care arrangement e.g. adverse effects, abnormal monitoring, advice during a medication shortage etc.

All prescribing responsibilities remain with the Provider until the service user is stable and GP agrees to shared-care.

A prescriber can choose not to accept responsibility because of lack of familiarity or competence in the use of a medicine or if it is used outside agreed guidance. Prescribers may not refuse responsibility solely on grounds of cost. Distance is not a reason for requiring transfer of care.

Recommendations | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE

2.7.6 Advice and Information

Following diagnosis the individual (and their parent/carer) should be provided with one follow up support session to provide feedback, signposting and advice regarding medication options if recommended.

The session would be used as follows:

- To provide the service user with more time to discuss their individual diagnosis and what it means to them.
- In discussion with the individual, referrals to other agencies may be made including to Social Care for an assessment of need under the Care Act 2014.
- To provide signposting to support and advice services local to BNSSG to support individuals (and those who support them) to develop coping mechanisms in order to improve their mental, physical and emotional health and wellbeing.
- It is important at this stage that written confirmation by the Provider is sent to the GP / referrer to provide information regarding the outcome of the assessment and also the future plan for the individual.

2.7.7 Discharge processes

The service is primarily diagnostic with treatment if required. Hence service users with on-going needs will need to be referred to the appropriate service following assessment.

Service users will be discharged from the service in accordance with the Providers Discharge Policy and take into consideration:

- Discussion with the service user and
- GPs can contact the Provider if concerns arise post discharge.

See Other Local Arrangements, Policies and Procedures (schedule 2G4) for provider's discharge policy/procedure.

2.8 Prescribing

NHS Prescription Issuance for Patients in Regions with NHS Cost Centre Setup
For patients within the Bristol, North Somerset, South Gloucestershire (BNSSG) area or other regions where the Provider has been allocated an NHS cost centre and NHS FP10 prescription pads by the Integrated Care Board (ICB), the Provider shall issue NHS prescriptions. These prescriptions will be sent to the patient's nominated pharmacy, in accordance with local formularies and in compliance with applicable NHS guidelines and regulations.

For patients in regions where the Provider has not been set up with an NHS cost centre and is therefore unable to issue NHS prescriptions, the Provider shall issue private prescriptions. These prescriptions will be processed through an online pharmacy, which will contact the patient to arrange delivery at a suitable time and location convenient to the patient. The online pharmacy will invoice the Provider directly for the cost of the medication, which in turn will be recharged to the referring ICB.

2.8.1 Medication

Medication titration as per NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management and, for BNSSG patients, compliant with BNSSG Paediatric Joint Formulary, with clear governance arrangements for the use of medicines, including any use of unlicensed medicines.

All prescribing for ADHD must be initiated by a healthcare professional with high quality training and expertise in diagnosing and managing ADHD and is expected to be in line with:

- For BNSSG patients, local BNSSG formulary Mental health disorders (Remedy BNSSG ICB) and
- NICE guidance NG87 Overview | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE

Please refer to the BNSSG Paediatric Joint formulary and shared care protocols for BNSSG first line product. Please prescribe the first line brand of Methylphenidate product, unless there is a clinical reason not to.

2.8.2 Annual Reviews

- Annual reviews to be carried out in line with NICE Guideline NG87 Recommendations | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE
- Annual review to be undertaken by the Provider.

2.9 Reporting

As part of the Provider internal data completeness, cleansing and quality processes the ICB expect the information provided by operational team(s) to be scrutinised and understood by performance management staff and the senior management teams before submission to commissioners. The senior management team will take full responsibility for the accuracy of data insofar as the current level of completeness, coverage and accuracy of data has been established, taking into account any reported overall or service-specific improvements during the contract year(s).

A reporting schedule will be included in the NHS Standard Contract issued to the Provider. This will not be exhaustive.

Reporting should be submitted to the Commissioner quarterly. The Commissioner may make ad hoc requests for performance and quality data if required.

2.10 Days/Hours of Operation

The service will operate Monday to Friday. The service does not operate an emergency service.

2.11 Interdependencies with other services/providers

The Provider has a responsibility for the interface and development of appropriate pathways with other services; ensuring services are communicated to potential referrers. The provider will be required to work in co-operation with (and not limited to):

- ICB Commissioners and Exceptional Funding Request service
- GPs, and any other ICB approved referrers
- Commissioning Support Unit
- Local mental health trust (AWP)
- Local primary and community teams and other interface services
- Social services
- Independent and third sector providers (voluntary sector)

2.12 Relevant networks and screening programmes

The service will work within the local area agreed referral pathway.

2.13 Training/ education/ research activities

It is expected that the staffing levels will be sufficiently resourced and have the appropriate skills mix to meet the defined needs of the service users and to provide the interventions. The service should ensure that they have the expertise to provide cultural awareness services.

2.13.1 Staff Training and Development:

It is the responsibility of the Provider to recruit/provide suitable personnel and as such the Provider will determine the exact person specification. However, the following guidelines will apply to all staff groups including temporary staff e.g. agency:

- All staff will be required to satisfy appropriate DBS checks.
- Staff will have the appropriate clinical and managerial qualifications for their role.
- All staff shall be appropriately trained / qualified and registered to undertake their roles and responsibilities.
- Professional accountability must be formulated within an agreed governance structure.
- Appropriate supervision arrangements for all levels of staff will be in place, including induction and clinical supervision.
- Staff will participate in regular personal performance reviews including the development of a personal development plan.
- All staff will be required to attend relevant mandatory training.
- All staff must have the relevant safeguarding training according to role as set out in the Intercollegiate Document 2019 and Intercollegiate Document for Looked after Children 2020.

As set out by the Care Quality Commission (CQC), registration documentation will be held on record by the Provider for all medical staff and will be available for inspection. A certificate of registration will be prominently displayed by the Provider in all sites (if applicable) from which the service is provided.

2.13.2 Clinical or Managerial Supervision Arrangements:

Supervision is regular protected time within work to reflect on and discuss a range of issues which together contribute to maintaining standards and ensure that the service delivers the highest quality of care to service users and carers.

2.14 Equality of Access

The Provider shall ensure the premises (if applicable) from which the service is to be provided shall be fully compliant with the Disability Discrimination Act (2005), the Equality Act (2010) and any other statute or common law relevant to the provision of the service and relating to Equality and Discrimination.

The Provider will treat all service users in a safe and appropriate environment (in accordance with the Providers process for determining suitable remote/digital environment) depending upon age and any existing medical conditions. The provider must ensure that services deliver consistent outcomes for patients regardless of:

- Gender
- Race
- Age
- Ethnicity
- Income
- Education
- Disability
- Sexual Orientation

The Provider shall provide appropriate assistance and make reasonable adjustments for patients and carers who do not speak, read or write English or who have communication difficulties including cognitive impairment, lack of capacity, hearing, oral or a learning disability in order to:

- Minimise clinical risk arising from inaccurate communication
- Support equitable access to healthcare for people whom English is not a first language
- Support effectiveness of service in reducing health inequalities

An interpreter, advocate or Independent Mental Capacity Advocate or contact with PALS should be provided if necessary. Translation and Interpreting services must meet the relevant standards.

2.15 Information Governance

All organisations that have access to NHS patient data must provide assurances that they are practising good information governance and use the Data Security and Protection Toolkit to evidence this.

The Data Security and Protection Toolkit is a Department of Health Policy delivery vehicle that the Health and Social Care Information Centre (HSCIC) is commissioned to develop and maintain. It draws together the legal rules and central guidance and presents them in a single standard as a set of information governance and data security assertions. The Provider is required to carry out self-assessments of their compliance against these assertions.

The Provider will identify an Information Governance lead.

The Provider must complete and provide evidence that they have achieved a satisfactory position for their organisation's Data Security and Protection Toolkit through meeting all the mandatory requirements, https://www.dsptoolkit.nhs.uk/

Final publication assessment scores reported by organisations are used by the Care Quality Commission when identifying how well organisations are meeting the Fundamental Standards of quality and safety - the standards below which care must never fall.

The Provider shall comply with all relevant national information governance and best practice standards including NHS Security Management – NHS Code of Practice, NHS Confidentiality – NHS Code of Practice and the National Data Security Standards. The Provider will participate in additional Information Governance audits agreed with the Commissioner.

2.16 Subcontracting

The Provider shall ensure that no part of the services outlined in this specification may be subcontracted to any other party than the approved Provider without the prior agreement and approval of the Commissioner.

The commissioner acknowledges that where a proportion of a Provider's workforce is comprised of subcontracted clinicians, these are exempt from the Governance schedule (schedule 5).

2.17 Notifying and agreeing changes to services

Providers must ensure that they seek Commissioners' consent to planned service changes as proposed Variations under GC13. If changes are made without Commissioner agreement, the Commissioner may be entitled under the Contract to refuse to meet any increased costs which ensue.

3. Applicable Service Standards

3.1 Applicable national standards

- Attention deficit hyperactivity disorder: diagnosis and management (2019) Overview | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE
- Attention Deficit Hyperactivity Disorder Quality standard [QS39] Overview | Attention deficit hyperactivity disorder | Quality standards | NICE
- Attention Deficit Hyperactivity Disorder Attention deficit hyperactivity disorder | Health topics A to Z | CKS | NICE
- Working together Working Together to Safeguard Children 2023 A guide to multi-agency working to help, protect and promote the welfare of children
- Safeguarding Looked after Children. Intercollegiate Role Framework: Looked after children: knowledge, skills and competences for health care staff (2020)
- Safeguarding children and young people. Intercollegiate Document: Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff (2019)

- Protecting Children and Young People -The responsibilities of doctors, GMC Protecting children and young people (May 2018)
- Safeguarding Children and Young People: Roles and Competencies for Health Care Staff, Intercollegiate document (March 2019).

3.2 Applicable standards set out in Guidance and/or issued by a competent body

3.2.1 As part of this specification, a safeguarding children policy or all age safeguarding policy is required which links to the local standards and protocols below.

BASIC PRINCIPLES OF SAFEGUARDING CHILDREN

- This specification seeks to emphasise the following principles:
- The welfare of the child is paramount.
- It is the responsibility of all staff to safeguard and promote the welfare of unborn babies, children, young people, adults and their families as defined in Section 2.6 above.

All staff should adopt a child-centred approach which is fundamental to safeguarding and promoting the welfare of every child. A child centred approach means keeping the child in focus when making decisions about their lives and working in partnership with them and their families.

All staff, both clinical and non-clinical, should:

- Be aware of the signs and symptoms of potential and actual abuse.
- Understand how to respond to actual or suspected abuse of a child.
- Know who to contact for advice and support in relation to safeguarding and promoting the wellbeing of unborn babies, children and young people.
- Understand the need to share appropriate information in a timely way and in accordance with current legislation and guidance, including responding to information requests to safeguard a child.
- All staff should actively contribute to multi-agency working in safeguarding children from abuse, neglect or exploitation regardless of protected characteristics.
- Children and their families must be able to share concerns and complaints and there are mechanisms in place to ensure these are heard and acted upon. For further information see below:

Local Authority Safeguarding Reporting processes:
- Bristol: Welcome to the Keeping Bristol Safe Partnership website. (bristolsafeguarding.org)
- North Somerset: Threshold Document - Continuum of Help and Support (proceduresonline.com)
- South Gloucestershire: Category: Children | SafeguardingSouth Gloucestershire Safeguarding (southglos.gov.uk)

Reporting forms can be accessed via the relevant Local Authority website, above, or via remedy Referrals & Procedures (Remedy BNSSG ICB)

3.2.2 Care Quality Commission

The Provider must be registered with the Care Quality Commission.

3.3 Applicable Local Standards

The Provider will maintain compliance for staff training on Safeguarding and Equality and Diversity at a minimum of 85%.

3.4 Applicable Quality Requirements

A quality schedule will be included in the NHS Standard Contract issued to the Provider. The Provider must comply will all quality requirements. Please see clause 2.9 Reporting for details on data submissions.

4. Location of Provider Premises

The provider will provide the service virtually.

Face to face assessments will only be available following an incomplete/failed remote assessment where there is no other option and where the provider and BNSSG ICB agree that this is a reasonable adjustment. This will be discussed on a case by case basis and face to face assessments will take place at one of the providers existing clinics. Where the provider clinic is located outside of BNSSG, the patient must indicate their willingness to travel the distance before final approval can be granted.

Service Specification: BNSSG Paediatrics in the Community March 2017

This specification must be read along with the overarching specification which applies to all services

1. Population Needs

1.1 Aims

To provide a consultant led, locality based paediatric service for children and young people who are vulnerable due to illness, disability and / or disadvantage.

To access traditionally 'hard to reach' groups of children and young people to ensure that they are able to receive the health input required.

To improve outcomes for children and young people as identified in national and local strategies.

To work towards an integrated approach to children's health and social care.

1.2 Policy Guidance

- National Service Framework for Children, Young People and Maternity Services (October 2004)
- Aiming High for Disabled Children (May 2007)
- Healthy Lives, Brighter Futures (Feb 2009)
- Joint Health and Wellbeing Strategies – Bristol and South Gloucestershire
- Children and Young People Plan/Partnership Strategies/Anti-poverty Strategies – Bristol and South Gloucestershire
- Working Together to Safeguard Children: A guide to Inter-agency working to safeguard and promote the welfare of children' HM Government 2015. http://www.workingtogetheronline.co.uk/index.html
- South West Safeguarding and Child Protection Procedures 2013 http://www.online-procedures.co.uk/swcpp/
- British Association of Community and Child Health guidelines. http://www.bacch.org.uk/policy/publishedguidelines.htm

1.3 General Overview

The Paediatrics in the Community service is to have two aspects:

- Delivery of a set of core community paediatric pathways for neurodevelopmental and neurodisabilities and associated conditions.
- Safeguarding, including child protection medical and clinical assessments for abuse and neglect and medical assessments of historical sexual abuse or potential current sexual abuse not requiring specialist forensic

assessments e.g. sexual assault. Assessing the health needs of looked after children and children undergoing the adoption process. Fulfilling the statutory responsibility for responding to unexpected child deaths.

Service Benefits

- Clinical leadership encompassing the most vulnerable groups with the objective of reducing health inequalities.
- Broad range of specialisms provided within the Service to ensure that complex health needs can be met.
- Strong, positive multi agency and multi-disciplinary planning and working relationships that ensure effective delivery of health services to vulnerable and disadvantaged children and young people.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	✓
Domain 2	**Enhancing quality of life for people with long-term conditions**	✓
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	✓
Domain 4	**Ensuring people have a positive experience of care**	✓
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	✓

2.3 Expected Outcomes

- The Service will aim to meet the relevant overarching outcomes identified locally in relevant strategies described above.
- Children and young people who are thought to be harmed by abuse or neglect receive a consultant led child protection medical or clinical assessment in a timely fashion by medical staff or nurse consultants with the appropriate competencies
- Early diagnosis and intervention is optimised therefore reducing late/more intense treatment of conditions.
- The emotional needs of children are assessed and supported.
- Co-ordination and dissemination of information relating to specific

children is facilitated by appropriate attendance at multidisciplinary and multi-agency team meetings.

- Providing the CCG designated doctors for safeguarding children, Looked after Children and designated clinical officer for SEND on behalf of Bristol and South Gloucestershire CCGs.
- Services work in an integrated way to provide a holistic care approach to vulnerable children. This is facilitated by appropriate engagement or attendance at strategy and planning meetings.
- Health inequalities are reduced.
- Access to services by the most vulnerable families is improved.
- All training delivered is evaluated and of high quality.

The Service will also meet the relevant outcomes identified in the national strategy for children and young people's health 'Healthy lives, brighter futures' (February 2009).

3. Scope

3.1 Objectives of service

- To keep children safe from abuse, neglect, exploitation and accident.
- To promote access to education for all children.
- To promote child health and prevent disease.
- To provide early recognition and effective support to disabled children.
- To ensure the emotional and physical health and medical needs of Looked after children, and those being adopted, are met.
- To work in partnership with other agencies and disciplines in achieving the above.
- To research child health in a manner that supports the objectives of the service.
- To teach medical undergraduates and post graduates, as well as professionals from other agencies, to allow the objectives to be met.
- To work as part of a broad children's services network to provide high quality specialist child centred care.
- To improve equity and accessibility of service to the most vulnerable and hard to reach children.
- Provide appropriate support to increase the knowledge and skills of staff in other services who are responsible for providing health, social care and education to vulnerable children.
- To provide expert clinical paediatric leadership across the health system

and in partnership with the local authority and the Police for child protection, Child death reviews, Children in Care and Special Educational Needs and Disability, including Designated roles.

- To work with Commissioners to ensure high quality, effective and value for money services are delivered.
- To provide palliative and end of life care for children

3.2 Service Description

The Service will provide:

- General community paediatric clinical assessment and diagnosis of children identified as in need of the service.
- Assessment, diagnosis and follow up of children in need of protection, in the care of the local authority, or with special educational needs.
- 24 hr urgent medical assessments and clinical assessments for children who may have been abused or neglected by the on call child protection team
- Contribution to multi-agency assessment of neglect and emotional abuse for children referred with developmental or health issues.
- Medical examinations for allegations of historical sexual abuse, ongoing medical care and examination for current or suspected child sexual abuse (cases that do not require a forensic medical assessment)
- Providing reports for and attendance at Case Conferences for families known to the Community Paediatric service. 95% production of reports, contribution and 95% attendance when currently in receipt of services from the Paediatrics in the Community team .
- Provision of witness of fact medical reports and attendance at Court as a professional witness.
- Initial and review health assessments of children taken into the care of the local authority (see LAC service specification).
- To contribute to Education Health and Care Planning following local SEND procedures.
- Medical and clinical advice on care pathways and planning processes and assessment and management of children with emotional and behavioural difficulties.
- Detailed assessment reports to other agencies, including family and criminal justice processes. as professional witnesses for children under our care
- Advice on health concerns related to safeguarding, adoption and fostering (LA permanency panels), childhood accident prevention and other health promotion initiatives.
- Leadership and co-ordination of the team around the child. NHS services

supporting children and young people with complex Special Educational Needs in the community.

- A Named Doctor and Named Nurse for safeguarding children to lead on child protection within the organisation (see separate SLA for the detailed requirements of this role).
- CCG Designated Professionals as strategic health system wide leaders including a Designated Doctor for safeguarding children and Looked After Children and designated medical / clinical officer for SEND on behalf of Bristol and South Gloucestershire CCGs.
- Medical Advisor role for Adoption Panels.
- Medical and clinical advice to planning processes and provision of clinics for vulnerable adolescents.
- Evaluated and high quality training for other professionals/agencies as appropriate.
- Clinical advice to parents following the death of a child (including Sudden Infant Death) where appropriate.
- Joint examinations with the Forensic Medical Examiner (FME) for children below the age of 16 years who have been subjected to an acute sexual assault. 14 - 17 year olds there will be discussion re need for paediatrician to attend depending on the vulnerability of the child – see the Sexual Assault Referral Service below for detailed specification.

Out of area cover

The following service requirements are not included in the contract value and have separate funding mechanisms in place.

- A Designated Paediatrician to support the West of England Child Death Overview Panel and 24hr 365 day input for the Rapid Response process for unexpected death in children by the on call child protection team (Bristol, North Somerset and South Gloucestershire only). Costs of this activity will be reimbursed by the managing organisation for CDOP.
- Maintain a reciprocal arrangement with the Community Paediatrics Service in North Somerset for maintenance of an out of hours rota
- Undertake physical examinations for cases of suspected sexual abuse in North Somerset on a case by case basis as agreed and funded by the North Somerset service

3.3 Accessibility / acceptability

The Service will make provision to address any issues that are within its power to resolve to ensure that it is accessible to all families, children and young people for appropriate targeted support.

The Service will be provided according to agreed priorities. The service will work to agreed waiting time standards, which will be agreed with commissioners and available to the public. Such waiting times will not exceed the 18 week Referral to Treatment pathway as specified in the NHS

Constitution.

For appointment based services, the provider will need to ensure that systems are in place to effectively take bookings whilst offering choice to patients. Target and maximum waiting times to be agreed with the provider

Where possible the service will offer a second opinion to families who have concerns about the diagnosis given to their child. Where possible the service will offer a change of lead professional where relationships between the lead professional and a family have irrevocably broken down. A second opinion may also be offered where a school or setting disagrees with the service's formulation of a child's needs.

The service is expected to conform to all relevant currently published and future NICE guidance.

The service will provide clear and accessible information to families and referrers on its role and eligibility criteria. The service will engage in the Local Offer for SEND, and in signposting of families to appropriate services, both within the service and outside.

3.4 Whole System relationships

- Commissioner/provider contract management processes.
- Local Safeguarding Children's Boards in Bristol and South Gloucestershire.
- Health and Wellbeing Boards in Bristol and South Gloucestershire.
- Children's Trust Boards in Bristol and South Gloucestershire.
- Public Health in Bristol and South Gloucestershire
- Avon and Somerset Constabulary

3.5 Safeguarding

Please also refer to the overarching specification.

- The Service must ensure that policies and procedures relating to safeguarding are adhered to and that it seeks advice from the Named Professionals within the organisation and the CCG Designated Professionals as strategic health system wide leaders.
- All Staff must have undertaken training and possess the competencies at a level consummate to their role as set out in in the Safeguarding Children and Young People: Roles and Competences for Health Care Staff (RCPCH 2014) http://www.rcpch.ac.uk/sites/default/files/page/Safeguarding%20Children%20-%20Roles%20and%20Competences%20for%20Healthcare%20Staff%20

%2002%200%20%20%20%20(3)_0.pdf

- All staff must have the appropriate level of Disclosure and Barring Service (DBS) criminal record checks, community paediatrics in the community clinical staff are expected to have enhanced checks including children's and adults' barred list check(s).
- The Service should adhere to the safeguarding quality schedule and its references in the main body of the contract.
- In addition to the general requirements described above, and given the crucial role for the paediatrics in the community workforce in local child protection processes, the service will be a key partner in inter-agency planning processes for ensuring the safety and wellbeing of all children and young people.
- Monday to Friday daytime rota covering Bristol and South Gloucestershire. This will be appropriately staffed with medical and nurse specialists or nurse consultants working under full Consultant supervision. It provides clinical safeguarding expertise input into strategy discussions / meetings , clinical safeguarding expertise to the Multi Agency Safeguarding Hub (MASH) or equivalent and medical or clinical examinations when there are concerns about abuse or neglect.
- Out of hours rota supervision. Covering Bristol and South Gloucestershire.
- Consultant delivered medical consultation and clinical medical input for complex Child Protection cases admitted to Bristol Children's Hospital.
- Provide clinical safeguarding expertise and advice to Multi Agency Safeguarding Hubs (MASH) or equivalent, participating in strategy discussions / meetings as appropriate to ensure a multi-agency decision is made.

3.5 Interdependence with other services / providers

Please also refer to the overarching specification

The service will work alongside services in the Local Authorities, schools, Police, Multi Agency Safeguarding Hub (MASH) or equivalent, third sector providers and others in supporting individual children, young people and families. The service will maintain clear channels of communication and collaboration with other agencies. In particular the service will work to locally agreed protocols for the inter - agency management of safeguarding concerns, Education Health and Care Plan assessment, planning and review, and Single Assessment Framework Early Help - SAF(eh). In some areas the service may be co-located with Local Authority services, e.g. 0 - 25 Disability Service, other social care or preventative services

Relevant networks

The service will be involved in a wide range of multidisciplinary and multi -

agency networks based around its key network planning groups and professional leadership areas:

- Safeguarding and Child Protection
- Looked After Children
- Special Educational Needs and Disabilities Vulnerable adolescents
- Neurodevelopmental and neuro-disabilities and associated conditions
- Children with additional needs
- Undergraduate medical training
- Postgraduate medical training
- Continuing professional development

3.6 Service Model

The Service will be delivered generically by consultant led area and locality teams of paediatricians, nurse consultants and nurse specialists based in the community.

They will be expected to work closely with community therapists, community nurses and others to deliver an integrated clinically safe service.

Specialist consultant clinical leadership will be provided for each of the network planning areas identified

The service will specifically target vulnerable and disadvantaged children with complex health needs and will work closely with public health colleagues to plan appropriate services.

A consultant will take a lead role for ensuring that overall professional standards are set and maintained, that a cost effective in-service training programme is provided and that the service collects robust and effective activity information.

There will be adequate support from an administration service to assist the specialist functions.

3.7 Care Pathways

Clinical care pathways that are likely to be followed in this Service are for:

- Attention deficit hyperactivity disorder (ADHD)
- Impaired communication, including autistic spectrum disorders (ASD)
- Child protection

- Continence
- Complex neurodevelopmental disorders, developmental delay, complex congenital disorders, cerebral palsy, developmental coordination disorder, high risk neonates.
- Sensory impairment pathways
- Child deaths, including rapid response
- Health assessments of Looked After Children
- Epilepsy
- Down's syndrome

3.8 Service Ethos

- Assessments and care plans will incorporate and evidence the voice of the child or young person.
- Assessments and care plans will incorporate and evidence the views of parents and carers.
- Children, young people, parents and carers will be actively involved in service development and monitoring.
- The service will support parents/carers in developing their capacity to reduce the health consequences of long term vulnerability in their children. This will include the appropriate provision of written materials and signposting to other support services.
- Early diagnosis and intervention is optimised thereby reducing late/more intense treatment requirements.
- The service supports the emotional and behavioural needs of children and young people, working alongside other services.
- The service considers the emotional wellbeing needs of children and young people with physical or sensory impairment, and makes appropriate linkages with other service to ensure these needs are met.

3.9 Referral Access and Acceptance Criteria

Geographic coverage/boundaries

The Service will be available to all families, children and young people who are registered with a GP in Bristol and South Gloucestershire.

Where cover is to be provided for North Somerset or any other area this will be set out and funded outside of the agreed contract value.

Location(s) of Service Delivery

The Service is locality and community focussed and therefore should be

delivered from appropriate locations and within suitable settings, including schools, early years settings and the service user's home/place of residence when necessary in order to ensure an effective service to assessed children and young people. Young people should be offered choice to be seen in clinic or in another setting.

Teams will be co-located with Preventative Services / Social Care colleagues in community children's hubs in South Gloucestershire or other co-location bases within Bristol and South Gloucestershire.

In addition to appointment - based service delivery, multi-disciplinary meetings etc., the service will develop mechanisms for families, referrers and other professionals to seek community paediatric advice by means of telephone advice, email, online chats on specific topics etc.

Days / Hours of operation

The Service will operate flexibly within normal working hours for the majority of its services. However the Service will also provide some twilight clinics within each CCG area in order to facilitate access.

Rapid response services for sudden child deaths, urgent child protection medical advice and urgent assessment of children who may have been sexually abused will be covered by an on-call consultant led service 24 hours a day and 365 days per year.

Referral criteria & sources

The Service is available to children and young people where there are concerns about a child's health, development or educational progress.

The following general categories describe the children and young people who can be referred for specialist assessment and treatment:

- Impaired communication (including where Autistic Spectrum Disorder is suspected)
- Impaired motor function (e.g. Cerebral Palsy)
- Sensory impairment
- Impaired feeding
- Impaired sleep
- Impaired continence
- Impaired/restricted attention
- Developmental impairments or at significant risk of developmental impairment (e.g. high risk neonates)
- Learning difficulties restricting access to learning activities or participation in school

- Prolonged absence from school on health grounds (> 6 weeks)
- Epilepsy / possible seizures
- Chronic unexplained symptoms (e.g. pain, fatigue)
- Palliative care in life limiting conditions
- Children experiencing or at risk of abuse or neglect

Referral route

Referrals will be made by:

- GPs
- Health Visitors
- School Health Nurses
- Acute and community paediatric health services
- Schools and early years settings
- Children's Social Care and Preventative Services
- Police

Each Local Authority has a Single Point of Access for Local Authority children's services.

The Provider will work with each Local Authority to develop systems and protocols for access to community health services through these Single Point of Access (SPAs). Referrals will be initially be triaged by the community paediatric team. After triage it may be there is a need for further information which the team will lead on acquiring. Whilst awaiting assessment, First Point / First Response will consider access for parents to parenting support and/or education. For safeguarding through the Multi Agency Safeguarding Hub (MASH) or equivalent

Acceptance criteria

The service will see children from birth up to their eighteenth birthday. For children in certain categories (e.g. those in special schools) care will be provided until their nineteenth birthday.

Response time & detail and prioritisation

The Service will meet the following response times:

- Urgent child protection referral requiring medical assessment and immediate response to unexpected child death within 4 hrs
- Non urgent requests from Children's Social Care, Police or an Multi Agency Safeguarding Hub within 24hrs –
- Children in Care initial assessments – within 28 days from becoming

looked after by the local authority

- Assessment for SEN Education, Health and Care Plan – to be agreed with provider.
- Other referrals – within 8 weeks.
- Referral to treatment – within 18 weeks.

3.12 Equality and Diversity

Please refer to the overarching specification.

3.13 Sexual Abuse Referral Service Detailed Specification

The service will maintain and develop the existing child and family centred approach which is recognised as an area of good practice. The service will be supported by appropriately trained paediatricians, forensic medical examiners and support staff. The service will be seamless despite different criteria being applied to a variety of case presentations, so that the most appropriate professionals provide care for a variety of presentations in different settings. This will be ensured by development of a clear care pathway for children presenting with allegations of sexual abuse.

Current data indicates that approximately 24 children over 14 and under the age of 16 years, and a further xx 16 aged 17 - 18 years, received a forensic medical examination during 2014. However this number is very likely to be an underestimate and with increasing awareness of various aspects of sexual assault in the press and improved pathways this number is likely to increase significantly.

Scope of the service

The service will see all children under the age of 18 where appropriate (specific age related criteria will apply), working in partnership with other professionals and agencies to link into the wider holistic care pathways of sexual abuse services.

- **Acute victims** will be seen within the required forensic timescales, working alongside the Forensic Medical Service to provide appropriately skilled paediatric input to age appropriate examination, in order to support the health needs of the child and any criminal justice proceedings that might take place. The service will provide an appropriate extended hours service for 365 days a year.
- **Historical victims** –clinics for victims of historical abuse (outside the forensic window) or current victims not requiring a forensic examination will be provided at appropriate times. The service will support the emotional and physical health needs of the victim, signpost to other appropriate services and support any subsequent criminal justice proceedings.

Location of Service delivery

Examinations for both acute and historic cases will usually take place at the SARC or Bristol Royal Hospital for Children and must be in the most appropriate place for the victim's needs with adequate clinical support.

Examinations will be undertaken in forensically clean rooms using appropriate equipment e.g. video colposcopy. The appropriate storage of samples, images etc. will follow National Guidance (including Forensic Regulator Standards)

Workforce

The staff will be skilled to appropriate national standards. Opportunities to maintain skills should be explored through a developing network of peer review (linking into the wider South West peer review network) and through joint training sessions.

Interagency working

The service will maintain appropriate links with partner agencies particularly in respect of Children Safeguarding Procedures (Local/Regional/National) including sexual health services, Police, social services, mental health etc. to enhance the onward care and support for victims.

Data and reporting

The provider will work with the commissioner/co-commissioner to develop data and service reporting to the SARC Commissioning Board

Future service development

Future service developments will be made in collaboration with the commissioner/co-commissioner as part of the ongoing performance and monitoring process.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

4.3 Applicable local standards

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4 Parts [A-D])

5.2 Applicable CQUIN goals (See Schedule 4 Part [E])

National shared care protocol:

Atomoxetine for patients within adult services

1 January 2025, Version 1

TLS- Amber 3 months

Review date – January 2028

The content of this shared care protocol was correct as of January 2022. As well as these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribing is normally for at least 12 weeks until the patient is stable and dose optimised.
- Counsel patient to contact their clinician if any new or worsening psychiatric symptoms occur at any point during treatment.

- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results, and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.
- Prescribing when a woman becomes or wishes to become pregnant can be managed in primary care with advice/input from the specialist.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist as soon as practicable if they are **unable** to support shared care (in writing or via secure email). It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5, taking into any account potential drug interactions in section 7.
- Adjust the dose of atomoxetine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with atomoxetine when starting new medicines (see section 7)
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop atomoxetine and make an urgent referral for appropriate care when contra-indications are suspected.
- Seek advice/input from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Patient and/or carer responsibilities

- Take atomoxetine as prescribed and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber and consider recording adverse effects by using checklist. Seek immediate medical attention if they develop any symptoms as detailed in section 11. Any new or worsening psychiatric symptoms should be highlighted to your clinician as soon as they occur.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of atomoxetine with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if atomoxetine affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 11).
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Atomoxetine is a sympathomimetic drug indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It is an alternative treatment option in patients who cannot tolerate lisdexamfetamine or methylphenidate, or whose symptoms have not responded to separate 6-week trials of lisdexamfetamine or methylphenidate see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management. NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Atomoxetine is licensed for use in adults with ADHD of at least moderate severity. Adults should have ADHD symptoms pre-existing from childhood, which should ideally be confirmed by a third party.

Atomoxetine should be used as part of a comprehensive treatment programme, typically including psychological, educational, and social measures.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if a need for ongoing treatment is anticipated.

Long-term usefulness of atomoxetine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate.

2. Indications

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Licensed indication: attention deficit hyperactivity disorder (ADHD)

3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)

N/A

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to the active substance or to any of the excipients
- During treatment with monoamine oxidase inhibitors (MAOI), or within 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Glaucoma
- Severe cardiovascular or cerebrovascular disorders, including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, cerebral aneurysm, or stroke
- Phaeochromocytoma

For patients with the following contraindications, atomoxetine can be prescribed under certain circumstances after a risk benefit consideration by the specialist has been taken into account:

- Psychiatric and neuropsychiatric symptoms or disorders, including psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, and mania
- Known serious structural cardiac abnormalities; consultation with a cardiac specialist required before treatment
- Underlying medical conditions which could be worsened by increases in blood pressure and heart rate, including hypertension, tachycardia, or cardiovascular or cerebrovascular disease

Cautions:

- Prolonged QT interval (congenital or acquired, e.g. drug-induced) or family history of QT prolongation
- Any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate or blood pressure changes (risk of orthostatic hypotension)
- Concomitant medications that elevate blood pressure: assess for neurological signs and symptoms at every monitoring visit
- Other conditions that may precipitate or otherwise induce cerebrovascular conditions: assess for neurological signs and symptoms at every monitoring visit
- Hepatic insufficiency; dose adjustments required, see section 5.
- History of seizures
- Susceptibility to angle-closure glaucoma
- Age over 65 years; safety and efficacy has not been systematically evaluated
- Known CYP2D6 poor metaboliser genotype. Dose reduction required, see section 5.
- Pregnancy or breast-feeding (see section 12)
- Potential for abuse, misuse, or diversion.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after the patient has been on treatment for at least 12 weeks, is stable and the dose optimised with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- Dose or formulation adjustments can be managed in primary care with advice/input from the specialist.
- Termination of treatment can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.

Initial stabilisation:

- Adults weighing 70 kg or above: 40 mg daily for at least 7 days,
- Adults weighing up to 70 kg: 500 micrograms/kilogram daily for at least 7 days

Then titrated according to clinical response and tolerability. Total daily dose may be given as a single dose in the morning or in two equally divided doses, with the last dose no later than the early evening.

The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

- Adults weighing 70 kg or above: 80 mg to 100 mg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 100 mg. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist.
- Adults weighing up to 70 kg: up to 1.2 mg/kg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 1.8 mg/kg daily. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Hepatic insufficiency:

- moderate hepatic insufficiency (Child-Pugh Class B) reduce starting and target doses to 50% of usual (reduce dose by half, i.e. starting dose should be 20mg daily, and total daily dose should not exceed 50mg daily)

- severe hepatic insufficiency (Child-Pugh Class C) reduce starting and target doses to 25% of usual (reduce dose by three quarters, i.e. starting dose should be 10mg daily, and total daily dose should not exceed 25mg daily)

Renal insufficiency:
No adjustment is necessary, but be aware that atomoxetine may exacerbate hypertension in patients with end stage renal disease.

Known CYP2D6 poor metaboliser genotype:

- Due to several-fold increase in atomoxetine exposure, consider a lower starting dose and slower up-titration.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Atomoxetine hydrochloride hard capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg Atomoxetine hydrochloride 4 mg/mL oral solution
Administration details:	Atomoxetine can be taken with or without food. Capsules should not be opened for administration: risk of irritation. Oral solution should not be mixed with food or water; it can prevent the full dose being administered and can negatively affect the taste. If a dose is missed then take it as soon as possible, but no later than the early evening. Do not take more than the usual total daily dose in any 24 hour period. A double dose should not be taken to make up for a missed dose.
Other important information:	The initiating specialist will decide the formulation on an individual basis as this will depend on the needs and preferences of the patient. **In times of medicine shortages, local guidance is available to support clinicians to manage supply disruptions. Management of Stock Shortages (Remedy BNSSG ICB)**

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- **MAOIs**: avoid atomoxetine use whilst using MAOIs and for a minimum of 14 days after stopping MAOIs. Increased risk of adverse effects.
- **CYP2D6 inhibitors**: increased atomoxetine exposure. E.g. selective serotonin reuptake inhibitors (SSRIs), quinidine, terbinafine, bupropion, cinacalcet, dacomitinib, and panobinostat. Slower dose titration and lower final dose may be necessary. Clinical response and tolerability should be re-evaluated if a CYP2D6 inhibitor is started or stopped.
- **Potent inhibitors of other cytochrome P450 isoforms** in patients who are poor CYP2D6 metabolisers. It is not clear whether there is a clinically significant increase in atomoxetine exposure in this patient group.
- **Beta-2 agonists, including salbutamol**: high dose beta-2 agonists, such as salbutamol, may potentiate cardiovascular effects.
- **Drugs which prolong the QT interval**: risk of QT interval prolongation. E.g. antipsychotics, class IA and III anti arrhythmics, some antibiotics such as ciprofloxacin or erythromycin, methadone, mefloquine, tricyclic, antidepressants, lithium, and some selective serotonin reuptake inhibitors (SSRIs) such as citalopram.
- **Drugs which cause electrolyte imbalance:** risk of QT interval prolongation. E.g. thiazide diuretics.
- **Drugs which lower the seizure threshold:** risk of seizures. E.g. tricyclic antidepressants, SSRIs, antipsychotics, phenothiazines, mefloquine, chloroquine, bupropion, and tramadol. Use caution when stopping medications that may induce seizures on withdrawal, such as benzodiazepines.
- **Anti-hypertensive drugs:** effectiveness of anti-hypertensives may be decreased, monitoring is required.
- **Drugs that increase blood pressure:** possible additive effects, monitoring is required.
- **Drugs that affect noradrenaline:** possible additive or synergistic pharmacological effects. E.g. dexamfetamine, lisdexamfetamine, imipramine, venlafaxine, mirtazapine, pseudoephedrine, phenylephrine.

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- Risk assessment for substance misuse and drug diversion
- Height, weight, and body mass index (BMI)
- Appetite
- Blood pressure (BP) and heart rate
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:
    - history of congenital heart disease or previous cardiac surgery
    - sudden death in a first-degree relative under 40 years suggesting a cardiac disease
    - shortness of breath on exertion compared with peers
    - fainting on exertion or in response to fright or noise
    - palpitations
    - chest pain suggestive of cardiac origin
    - signs of heart failure, heart murmur or hypertension
    - current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- After every change of dose: assess heart rate, blood pressure, changes in weight, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Development or worsening of tic and movement disorders
- Assessment of symptom improvement. Discontinue if no improvement is observed after 4-8 weeks.

Ongoing monitoring:

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient

preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

In BNSSG the annual review is done in primary care for patients registered at GP practices signed up to the ADHD locally enhanced service (LES) and by the specialist team where the GP practice is not signed up to the LES.

Patients should be encouraged to consider stopping the medication every 1 to 5 years, with the guidance of the specialist clinic if desired. If desired and clinically appropriate, atomoxetine can be restarted by the GP, referral back into the ADHD service is not necessary.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• Blood pressure and heart rate • Weight and appetite •	Every 6 months, and after any change of dose recommended by specialist team.
• Assessment of adherence, and for any indication of atomoxetine abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD • Review to include assessment for any new or worsening psychiatric symptoms and sleep problems.	Annually (by primary or secondary care depending on ADHD Annual Review LES uptake)

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular	Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP
Hypertension	Manage as per local pathways, taking into account risk of clinically significant interactions with several types of antihypertensive medication (see section 7). If blood pressure is significantly raised (see guidance box immediately above), reduce dose of atomoxetine by half and discuss with specialist for further advice.
Gastrointestinal disorders Including abdominal pain, vomiting, nausea, constipation, dyspepsia	Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in the late afternoon or early evening). Generally resolves.

Weight or BMI outside healthy range, including anorexia or weight loss	Recommend small, frequent meals and/or snacks, and high calorie foods of good nutritional value. Recommend taking atomoxetine with or after meals, and not before. Obtain dietary advice if required. Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medicine may be required.
Psychiatric disorders New or worsening psychiatric symptoms, e.g. suicide related behaviour, psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, or depression	Contact specialist team and refer for psychiatric assessment if appropriate. Refer for urgent psychiatric assessment if suicide related behaviour or ideation occurs. Discuss ongoing benefit of treatment with specialist team.
Hepatic effects Signs or symptoms of liver injury, e.g. abdominal pain, unexplained nausea, malaise, jaundice, or darkening of urine	Perform liver function tests (LFTs), including serum bilirubin, and discuss with specialist team. Discontinue atomoxetine permanently in patients who develop jaundice or for whom there is laboratory evidence of liver injury (if unclear if injury or transient derangement, discuss urgently with specialist).
Nervous system disorders Somnolence or sedation	Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in late afternoon or early evening). Generally resolves.
New onset of seizures, or increased seizure frequency	Discuss with specialist team. Discontinuation of atomoxetine should be considered.

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Abnormally sustained or frequent and painful erections. **If an erection persists for more than 2 hours go to A&E**; this is an emergency.
- Sudden acute, painful eye(s), impaired vision, red eye(s), and/or semi-dilated and fixed pupil; risk of **angle closure glaucoma**, seek immediate medical attention, ideally from an eye casualty unit or A&E.
- Symptoms suggestive of cardiac disease (e.g. palpitations, exertional chest pain, unexplained syncope, or dyspnoea).
- New or worsening psychiatric symptoms (e.g. psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, or mania).
- Report **suicidal thoughts or behaviour**, and development or worsening of irritability, agitation, and depression.
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, seizures, or impairment of coordination, vision, speech, language, or memory).
- Risk of **hepatic injury**: report unexplained nausea, malaise, jaundice, or darkening of urine, and new onset severe or persistent abdominal pain.
- Symptoms of allergic or anaphylactic reactions (e.g. rash, angioedema, or urticaria).
- If they suspect they may be pregnant or are planning a pregnancy.

The patient should be advised:

- Not to drive or operate machines if atomoxetine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or fatigue, and to inform the DVLA if their ability to drive safely is affected. See https://www.gov.uk/adhd-and-driving.
- Not to stop taking atomoxetine without talking to their doctor and not to share their medicines with anyone else.

Patient information:

- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults

- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=atomoxetine

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Atomoxetine is not recommended for use during pregnancy unless a clinical decision is made that the potential benefit outweighs the risk to the fetus.

Evidence on exposure to atomoxetine during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks, and additional monitoring should be considered on a case-by-case basis.

Patients who become pregnant while taking atomoxetine, or who plan a pregnancy, should be referred to the specialist team for review. Ongoing prescribing in pregnancy may be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Breastfeeding:

There is no published evidence on the safety of atomoxetine in breastfeeding. Decisions to use atomoxetine while breastfeeding should be made on a case-by-case basis, taking into account the risks to the infant and the benefits of therapy. Long half-life in slow metabolisers increases risk of accumulation in some breastfed infants. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite or slow weight gain, sleep disturbances, gastrointestinal symptoms), although these may be difficult to detect.

Information for healthcare professionals: https://www.sps.nhs.uk/home/about-sps/get-in-touch/medicines-information-services-contact-details/breastfeeding-medicines-advice-service/

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified. Further information for patients: https://www.medicinesinpregnancy.org/leaflets-a-z/atomoxetine/

13. Specialist contact information

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Name: *Dr Dietmar Hank*
Role and specialty: Consultant Psychiatrist and Clinical Lead Adult ADHD service, AWP
Daytime telephone number: 01275 796262 M-F 9-5
Email address: *Awp.specialisedadhdservices@nhs.net*
Alternative contact:
Out of hours contact details:

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- eBNF. Atomoxetine. Accessed via https://bnf.nice.org.uk/drug/atomoxetine.html on 16/01/2025
- Atomoxetine hydrochloride 10 mg hard capsulesAccessed via Atomoxetine 10 mg hard capsules - Summary of Product Characteristics (SmPC) - (emc) on 16/01/2025
- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 16/01/2025
- NICE NG43: Transition from children's to adults' services for young people using health or social care services. Last updated February 2016. Accessed via https://www.nice.org.uk/guidance/ng43/ on 16/01/2025
- UKTIS. Use of atomoxetine in pregnancy. Accessed via https://uktis.org/monographs/use-of-atomoxetine-in-pregnancy/ on 16/01/2025
- For information on Breastfeeding https://www.sps.nhs.uk/home/about-sps/get-in-touch/medicines-information-services-contact-details/breastfeeding-medicines-advice-service/ Accessed 16/01/2025
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Atomoxetine. Last updated December 2024. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/atomoxetine/ on 16/01/2025
- MHRA. Drug Safety Update: Atomoxetine (Strattera▼): increases in blood pressure and heart rate. January 2021. Accessed via https://www.gov.uk/drug-safety-update/atomoxetine-strattera-increases-in-blood-pressure-and-heart-rate on 16/01/2025

16. Other relevant national guidance

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- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Contact specialist for advice if:

- The patient finds the medication intolerable for any given reason
- If there is concern about observed mental or physical side effects (e.g. depression or hypertension)
- The side effects mentioned above, do not appear to be of a temporary and short lived nature.

Contact named responsible clinician in writing or via secure email detailed in clinic letter.

Also see BNSSG Remedy 'Adult ADHD' page ADHD (adult) (Remedy BNSSG ICB) for information for GP practices signed up to the ADHD LES.

Approved by BNSSG JFG: May 2025
Review date: January 2028
Version 1.3

BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	**Atomoxetine**
Amber ***three months***	
Indication	As part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children and adolescents of 5* years of age and over, where: • Treatment with methylphenidate or lisdexamfetamine has been considered to be: ○ Inadequate (Their symptoms have not responded to separate 6-week trials of each medicine.) ○ Not tolerated ○ Contraindicated ○ Inappropriate (eg concerns about misappropriation of stimulants). *'Atomoxetine is licensed from 6 years, off-label' use for 5 year old patients, but supported by NICE Guideline (NG87; 1.5.13)

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Atomoxetine is a non-stimulant selective noradrenaline reuptake inhibitor. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or ADHD specialist non-medial prescriber. Dose in children and young people 5 years and above: Up to 70kg body weight: 0.5 mg / kg daily, increased after 7 days according to response to approximately 1.2 mg / kg daily ; maximum 1.8 mg / kg daily or 120 mg daily* Over 70kg body weight: 40 mg daily, increased after 7 days according to response to 80 mg daily Usual maximum dose (BNF): Children – 1.2 mg / kg daily or 120 mg daily* * *Doses above 100mg/day are off label* N.B. total daily dose may be given either as a single dose in the morning or in two divided doses with last dose no later than early evening.

	The initial maintenance dose must be prescribed by the initiating specialist.
Route and formulation	Oral. 10mg,18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules 4mg/ml oral solution Atomoxetine can be administered with or without food.
Duration of treatment	Continued for as long as it is effective. Discontinue if there is no response after 1 month of maximum tolerated dose.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Monitoring at baseline and during initiation is the responsibility of the specialist; once the patient is optimised on the chosen medicine, with no anticipated changes expected in the immediate future, prescribing will be transferred to the GP. Monitoring will remain the with the specialist clinician in secondary care, unless specific arrangements are made with the GP. Patients will be reviewed by a specialist clinician annually as a minimum.

Baseline investigations include:

- Cardiovascular status, including blood pressure, heart rate, height and weight on growth chart (see table below)
- Comprehensive history of concomitant medicines (past and present), co-morbid physical and psychiatric disorders or symptoms, and family history of sudden cardiac/unexplained death

Blood tests, ECG and other parameters are not required unless specifically indicated for individual patients.

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	**Frequency**	**Who by**	**Action/management** **For paediatric patients the use of a centile chart is recommended**
Blood pressure (BP), pulse, weight, height	Prior to medication initiation	Initiating clinician (CAMHS* or Community Paediatrics department)	To prepare for medication titration
BP	After each dose increase, every 6 months and at annual review	CAMHS or Community Paediatrics	Compare with normal range for age, if there is a clinically significant increase in blood pressure or systolic

		department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care).	blood pressure is greater than 95th percentile (measured on 2 occasions), refer to paediatric hypertension specialist; consider dose adjustment or alternative ADHD treatment.
Pulse			Compare with normal range for age. NICE guidance suggest to investigate a resting tachycardia of > 120pbm; we suggest to monitor and possibly investigate a sustained resting tachycardia >100bpm; consider ECG; discuss with paediatric physical health colleagues as needed.
Height	Every 6 months		Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Weight	**Children 10 years and under:** 3 monthly **Children over 10 years and young people:** 3 and 6 months following initiation and 6 monthly thereafter *More often if concerns arise.*		If there is evidence of significant weight loss or nil weight gain where expected, measure BMI and discuss with patient and family/ carer as appropriate. Strategies to manage weight loss include: -Taking medication with or after food -Additional meals/snacks early morning or late evening when stimulant effects have worn off -Choosing high calorie foods of good nutritional value -Taking a planned break from treatment or changing medication. Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Assessment of adherence and monitoring for effectiveness and adverse effects including suicidal ideation or behaviour, tics, sexual dysfunction, seizures and sleep.	After each dose adjustments, at annual review and as required based on the patient's needs and individual circumstances.	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care)	This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document rationale. Seek secondary care advice. With stimulant medication, this should include review of potential misuse and diversion.

*Children and Adolescent Mental Health Service

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency	Action/management
GI effects: abdominal pain, nausea and vomiting, decreased appetite, constipation, dyspepsia.	Very common/ common	Often transient. Take medication after breakfast/food; Maximise food intake at times of least appetite suppression, inc. liquid calories (smoothies etc.) Consult specialist clinic if this persists.
Headache, somnolence	Very common	Split dose to BD regime; take medication at night; reduce dose.
Dry Mouth	Very common	Sugar free sweets and water to counteract dry mouth.
Urinary retention/ hesitancy	Common	Split dose; reduce dose. Seek expert advice.
Sleep disturbances: Early wakening	Common	Split dose; change timing of medication.
Decreased libido/Erectile disorder	Common	Reduce dose; seek expert advice.
Menstrual irregularities	Common	Reduce dose; seek expert advice.
Hot flushes	Common	Split dose; reduce dose.
Rash	Common	Stop medication; seek expert advice
Cardiac effects: pulse and BP increase	Common	Monitor the BP, pulse, and if necessary perform an ECG. If the resting pulse is consistently >100bpm, contact the specialist team (consideration must be given to child/young person's age and what is expected for age)
Suicidal ideation	Uncommon	Stop medication and seek medical review/input (see section 5).
Development of new or worsening of tics	Rare	Reduce dose, or switch to alternative drug

Referral back to specialist

Contact specialist for advice if:

- There is a query regarding medication efficacy
- Patient finds the medication intolerable for any given reason
- If there is concern about observed mental/psychological or physical side effects (e.g. depression, hepatic impairment or hypertension)
- If medication side effects persist despite intervention
- If patient is pregnant or breastfeeding

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues

Significant drug interactions of atomoxetine

MAOIs	Contraindicated due to risk of hypertensive crisis.
Caution is advised due to potential for additive pharmacological effects in co-administration of the following:	
Beta-2 agonists	e.g. high dose nebulised or systemically administered salbutamol.
Pressor agents	e.g. the decongestants pseudoephedrine or phenylephrine.
Noradrenaline antagonists	e.g. antidepressants such as imipramine, venlafaxine and mirtazapine.
CYP2D6 inhibitors	e.g. fluoxetine and paroxetine – slower titration and a lower final dosage may be necessary.

Potential drug interactions of atomoxetine

QT prolonging drugs	e.g. neuroleptics, tricyclic antidepressants, lithium, erythromycin, drugs that cause electrolyte imbalance (such as thiazide diuretics) and drugs that inhibit CYP2D6.
Seizure threshold lowering drugs	e.g. tricyclic antidepressants or SSRIs, neuroleptics, phenothiazines or butyrophenone, mefloquine, chloroquine, buproprion or tramadol. In addition, caution is advised when stopping concomitant treatment with benzodiazepines due to potential withdrawal seizures.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Atomoxetine use in combination with monoamine oxidase inhibitors (MAOIs). Atomoxetine should not be used within a minimum of 2 weeks after discontinuing therapy with a MAOI. Treatment with a MAOI should not be initiated within 2 weeks after discontinuing atomoxetine.
- Atomoxetine should not be used in patients with:
  - narrow-angle glaucoma (associated with an increased incidence of mydriasis in trials).
  - severe cardiovascular or cerebrovascular disorders (including cerebral aneurysm or stroke).
  - phaeochromocytoma or a history of phaeochromocytoma.

Cautions

- Suicide attempts and suicidal ideation have been reported - carefully monitor for the appearance or worsening of suicide related behaviour.
- Use with caution in patients with known serious structural cardiac abnormalities and in consultation with a cardiac specialist.
- A modest increase in BP and pulse is common - monitor as above. Refer for a prompt specialist cardiac evaluation if appropriate. Use with caution in patients with, or a family history of, QT prolongation.
- Incidents of psychotic or manic symptoms: e.g. hallucinations, delusional thinking, mania or agitation in patients – consider discontinuation.

	• Behavioural changes: Hostility (predominantly aggression, oppositional behaviour and anger) - patients should closely monitor for worsening of aggressive behaviour or emotional lability. • Seizures- Introduce with caution in patients with a history of seizure, and consider discontinuation if new onset or worsening of seizures where no other cause is identified. • Breastfeeding – Avoid atomoxetine during breastfeeding. • Pregnancy - Avoid unless the potential benefit justifies the potential risk to the foetus. **Dose reduction and discontinuation** If the symptoms of ADHD do not improve after appropriate dosage adjustment, or serious adverse event occurs, then atomoxetine treatment must be stopped by the clinic. If paradoxical aggravation of symptoms occurs, the dosage should be reduced or discontinued.
Reminder to ask patient about specific problems	Ask about emergence of any possible side effects/compliance to treatment issues. Ask about suicidal ideation.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient:

The patient and/or family/carer should be advised:

1. Not to drink alcohol, use recreational substances or consume excessive amounts of caffeine whilst taking Atomoxetine.
2. The patient should immediately report abdominal pain, unexplained nausea, malaise, darkening of the urine, jaundice, or suicidal thinking and/or self-harm to the AWP team or GP.
3. Failure to attend annual reviews could result in the medication being stopped.
4. They can choose to try stopping the medication. Annual reviews are an ideal opportunity to discuss this but a desire to stop medication can be expressed and discussed at any time.
5. Where they can find information on the medicine prescribed, including a patient information leaflet (PIL). Information on mental health conditions, treatments and medication can be found here:

Choice and Medication
NHS – Attention Deficit Hyperactivity Disorder
Medicines for Children leaflet: Atomoxetine for ADHD
Atomoxetine Patient Information Leaflet

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Communicate changes of medication form, strength or dose to the GP before the next repeat prescription is due (i.e. within 28 days). Note that a change of dose does not itself imply instability, and is usually done as a response to patient growth. If the secondary care clinician feels the medication is not at a stable dose, the GP will be informed that the secondary care provider will supply medication until this is again stable
5. Refer patients to GP and provide information of further action where appropriate e.g. if blood

test is due.
6. To provide advice to primary care when appropriate including queries about medication efficacy and side effects.
7. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
8. Stopping treatment where appropriate or providing advice on when to stop.
9. Reporting adverse events to the MHRA.
10. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Initiating Clinician	AWP/Sirona	As provided on correspondence	As provided on correspondence
Sarah Steel Highly Specialised Clinical Pharmacist	AWP	01249 474542	Sarah.steel6@nhs.net

Section 10: Document Details

Date prepared	28th April 2023
Prepared by	Sarah Steel
Date approved by JFG	October 2023 (Minor update March 2025 updating clinical review frequency)
Date of review	October 2026
Document Identification: Version	V3

Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Sarah Steel highly specialised clinical pharmacist AWP
2. Samantha Hayer CAMHS consultant AWP
3. Alfred Perrera CAMHS consultant AWP
4. Richard Williams consultant paediatrician Sirona care & health
5. Richard Lee-Kelland, consultant community paediatrician Sirona care & health – from June 2023

Section 12: References

Please list references

1. NICE Guideline [NG87]. Attention Deficit Hyperactivity Disorder: diagnosis and management. Updated 13.09.2019. Accessed Feb 2023.
2. SPC Atomoxetine. Updated 08.12.2020. https://www.medicines.org.uk/emc/product/10507/smpc. Accessed Feb 2023.
3. BNF Online. Atomoxetine. Updated September 2022. Accessed Feb 2023.
4. Cortese S, *et al.* Pharmacological and non-pharmacological interventions for adults with ADHD: protocol for a systematic review and network meta-analysis *BMJ Open*. Accessed May 2023.

National shared care protocol:

Dexamfetamine for patients within adult services

1 January 2025, Version 1

TLS Amber – 3 months

Review date – January 2028

The content of this shared care protocol was correct as of January 2022. As well as these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

BNSSG Adult ADHD referral and treatment pathway – GP Practices signed up to ADHD LES

Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribing is normally for at least 12 weeks until the patient is stable and dose optimised.
- Counsel patient to contact their clinician if any new or worsening psychiatric symptoms occur at any point during treatment.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.
- Prescribing when a woman becomes or wishes to become pregnant can be managed in primary care with advice/input from the specialist.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist as soon as practicable if they are **unable** to support shared care (in writing or via secure email). It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into account any potential drug interactions in section 7.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Adjust the dose of dexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with dexamfetamine when starting new medicines (see section 7)
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop dexamfetamine and make an urgent referral for appropriate care when contra-indications are suspected.
- Seek advice/input from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Patient and/or carer responsibilities

- Take dexamfetamine as prescribed and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11. Any new or worsening psychiatric symptoms should be highlighted to your clinician as soon as they occur.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of dexamfetamine with their pharmacist before purchasing any OTC medicines.
- Be aware that dexamfetamine can affect cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving (see section 11).
- Avoid alcohol while during treatment, as it may make some side effects worse. Avoid recreational drugs.

- Dexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions and should store dexamfetamine safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Dexamfetamine sulfate is a sympathomimetic amine with central stimulant and anorectic activity indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It may be offered as an alternative treatment in patients who have been appropriately diagnosed and whose symptoms are responding to lisdexamfetamine but are unable to tolerate the drug's longer effect profile (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Dexamfetamine is not licensed for all the indications listed in section 2. However, its use for the indications below are established and supported by various sources and bodies including the BNF and NICE.

Dexamfetamine is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated.

Long-term usefulness of dexamfetamine for extended periods (over 12 months) should be periodically re-evaluated by a healthcare professional with expertise in ADHD for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is recommended a trial discontinuation at least once yearly to assess the patient's condition. Improvement may be sustained when the medicinal product is either temporarily or permanently discontinued.

2. Indications

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- Attention deficit hyperactivity disorder (ADHD) in adults ‡

‡ Off-label indication. (Please note licensed indications vary by manufacturer. See SPCs for full details).

3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)

N/A

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines. Note: some dexamfetamine brands may contain isomalt which is unsuitable for people with fructose intolerance.
- Glaucoma
- Phaeochromocytoma or porphyria
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment
- Hyperthyroidism or thyrotoxicosis.

For patients with the following contraindications, dexamfetamine can be prescribed under certain circumstances after a risk benefit consideration by the specialist has been taken into account:

- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include; structural cardiac abnormalities and/or moderate hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels)
- Severe depression, anorexia nervosa/anorexic disorders, suicidal ideation, hyperexcitability, psychotic symptoms, severe and episodic (Type I) Bipolar (affective)

Disorder (that is not well-controlled), schizophrenia, psychopathic/borderline personality disorder

- Cerebrovascular disorders (cerebral aneurysm, vascular abnormalities including vasculitis or stroke)
- Gilles de la Tourette syndrome or similar dystonias
- History of drug abuse or alcohol abuse

Cautions:

- History of epilepsy (discontinue if seizures occur)
- Mild hypertension, history of cardiovascular disease, or concomitant medications that elevate blood pressure
- susceptibility to angle-closure glaucoma
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, tics, anxiety/agitation, or bipolar disorder
- Depressive symptoms; patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Renal and hepatic insufficiency (due to lack of data).
- Family history of sudden cardiac or unexplained death or malignant arrhythmia
- Pregnancy or breast-feeding (see section 12)
- Potential for abuse, misuse, or diversion.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after the patient has been on treatment for at least 12 weeks, is stable and the dose optimised with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- Dose or formulation adjustments can be managed in primary care with advice/input from the specialist.
- Termination of treatment can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.

Initial stabilisation:

ADHD: Initially 5 mg twice daily, dose should be increased according to response at intervals no shorter than 1 week.

Dexamfetamine must be prescribed by the initiating specialist during initiation and dose stabilisation.

Maintenance dose (following initial stabilisation):

ADHD: maximum 60 mg per day to be given in 2–4 divided doses;

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. This should be undertaken and supervised by the specialist who will advise the patient and primary care prescriber of the outcome. Alternatively, this can be managed in primary care within the competence of the prescriber (section 8).

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Dexamfetamine sulfate 5mg, 10mg and 20mg immediate release tablets (Amfexa®) Dexamfetamine sulfate 5mg immediate release tablets Dexamfetamine sulfate 5mg/5mL sugar-free oral solution▼ Please note licensed indications vary by manufacturer. See SPCs for full details
Administration details:	Tablets can be halved Dexamfetamine should not be taken too late after lunch time to avoid disturbances of sleep • If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose.
Other important information:	Dexamfetamine is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of dexamfetamine. Dexamfetamine is subject to additional monitoring by the Medicines and Healthcare products

	Regulatory Agency (MHRA) and healthcare professionals are encouraged to report any suspected adverse reactions Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations **In times of medicine shortages, local guidance is available to support clinicians to manage supply disruptions. Management of Stock Shortages (Remedy BNSSG ICB)**

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

The following medicines must not be prescribed without consultation with the specialist:

- **Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics** (e.g. rasagiline, selegiline, safinamide) – additive hypertensive effect
- **Clonidine** – increased duration of action of dexamfetamine, reduced antihypertensive action of clonidine

Other clinically significant interactions

- **Coumarin anticoagulants, anticonvulsants, selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs)**: metabolism may be inhibited by dexamfetamine. Dose adjustment may be required when starting or stopping dexamfetamine.
- **SSRIs (e.g. fluoxetine, paroxetine)**: may increase exposure to dexamfetamine. Risk of serotonin syndrome.
- **Serotonergic drugs, bupropion, tapentadol, tramadol:** Risk of serotonin syndrome
- **TCAs and nabilone**: may increase risk of cardiovascular adverse events.
- **Anticonvulsants (e.g. phenobarbital, phenytoin, primidone)**: Metabolism may be inhibited and absorption may be delayed by dexamfetamine. Dose adjustment may be required when stopping or starting dexamfetamine.
- **Antacids** (e.g. sodium bicarbonate) **and urinary alkalinizing agents** (e.g. acetazolamide, some thiazides): may increase exposure to dexamfetamine
- **Gastrointestinal acidifying agents** (e.g. ascorbic acid, fruit juices) and **urinary acidifying agents** (e.g. ammonium chloride, sodium acid phosphate): may reduce exposure to dexamfetamine

- **Antihistamines:** sedative effect may be counteracted
- **Antihypertensives, including guanethidine**: effects may be reduced by dexamfetamine
- **Beta-blockers (e.g. propranolol)**: risk of severe hypertonia. May reduce effects of dexamfetamine
- **Lithium, phenothiazines, haloperidol**: may reduce the effects of dexamfetamine
- **Disulfiram**: may inhibit metabolism and excretion of dexamfetamine
- **Opioids**: analgesic effects may be increased and the depressant effects (e.g. respiratory depression) may be decreased by dexamfetamine
- **Halogenated anaesthetics:** risk of sudden blood pressure increase during surgery. Avoid dexamfetamine on the day of planned surgery.
- **Cytochrome P450 (CYP450) substrates, inducers or inhibitors**: use with caution; role of CYP450 in dexamfetamine metabolism is not known
- **Alcohol:** may exacerbate adverse CNS effects of dexamfetamine
- **Apraclonidine:** effects decreased by dexamfetamine
- **Ritonavir, tipranavir:** may increase exposure to dexamfetamine

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- A risk assessment for substance misuse and drug diversion
- Blood pressure (BP) and heart rate
- Height, weight and body mass index (BMI)
- Appetite
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:
  - History of congenital heart disease or previous cardiac surgery
  - Sudden death in a first-degree relative under 40 years suggesting a cardiac disease
  - Shortness of breath on exertion compared with peers
  - Fainting on exertion or in response to fright or noise

- Palpitations
- Chest pain suggestive of cardiac origin
- Signs of heart failure, heart murmur or hypertension
- Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- After every change of dose: assess heart rate and blood pressure, changes in weight, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Assessment of symptom improvement. Discontinue if no improvement is observed after reaching normal therapeutic doses.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

In BNSSG the annual review is done in primary care for patients registered at GP practices signed up to the ADHD locally enhanced service (LES) and by the specialist team where the GP practice is not signed up to the LES.

Patients should be encouraged to consider stopping the medication every 1 to 5 years, with the guidance of the specialist clinic if desired. If desired and clinically appropriate, dexamfetamine can be restarted by the GP, referral back into the ADHD service is not necessary.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• Blood pressure and heart rate • Weight and appetite •	Every 6 months, and after any change of dose recommended by specialist team.
• Assessment of adherence, and for any indication of dexamfetamine abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD • Review to include assessment for any new or worsening psychiatric symptoms and sleep problems.	Annually (by primary or secondary care depending on ADHD Annual Review LES uptake)

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	

Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP	• In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management • In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.
New or worsening seizures	Stop dexamfetamine and discuss with specialist. Discontinuation may be indicated.
Anorexia or weight loss, weight or BMI outside healthy range	Exclude other reasons for weight loss. Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before • additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction	Review timing of doses and continue treatment unless severe, Give advice on sleep hygiene. Discuss with specialist if required
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required
New or worsening psychiatric or neuropsychiatric symptoms, e.g. mania, depression, paranoia, anxiety and agitation. NB: psychosis may occur following consumption of very high doses.	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia,	Discontinue dexamfetamine as soon as possible. Management depends on severity;

hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether dexamfetamine can be re-started.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient/carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Any mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania, and suicidal ideation
- Palpitations, chest pain or syncope
- Cerebrovascular symptoms, such as severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language, or memory
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

The patient/carer should be advised:

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Dexamfetamine can affect impair cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving. For information on 2015 legislation regarding driving whilst taking certain controlled drugs,

including amfetamines, see drugs and driving: the law. People who drive must inform the DVLA if their ADHD, or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving

- Avoid alcohol while taking dexamfetamine, as it may make some side effects worse. Avoid recreational drugs. Due to the risks of severe depression, over-activity, extreme fatigue as well as changes in the EEG during sleep, abrupt withdrawal after a prolonged period of intake of high doses of dexamfetamine should be avoided. Patients wishing to reduce their dose or stop dexamfetamine treatment should discuss with their specialist before doing so.

- Dexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store dexamfetamine safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences.

Patient information:

- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults

- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Dexamfetamine is not recommended for use during pregnancy The limited data available shows a risk of premature birth and reduced birth weight. Infants may also develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion.

If a patient becomes pregnant or is planning a pregnancy during treatment they should discuss treatment options with their specialist. Ongoing prescribing in pregnancy may be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Healthcare professional information available from: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AMFETAMINES-IN-PREGNANCY/

Breastfeeding:

Dexamfetamine is excreted in human milk, therefore a risk to infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from dexamfetamine, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. High doses may interfere with lactation, although this is not confirmed in practice. If breastfeeding does take place, infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite/weight gain, sleep disturbances, irritability), although these may be difficult to detect.

Healthcare professional information available from: Breastfeeding Medicines Advice service – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified. Further information for patients: https://www.medicinesinpregnancy.org/leaflets-a-z/dexamfetamine/

13. Specialist contact information

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Name: *Dr Dietmar Hank*

Role and specialty: Consultant Psychiatrist and Clinical Lead Adult ADHD service, AWP

Daytime telephone number: 01275 796262 M-F 9-5

Email address: *Awp.specialisedadhdservices@nhs.net*

Alternative contact: *[insert contact information, e.g. for clinic or specialist nurse]*

Out of hours contact details: *[insert contact information, e.g. for duty doctor]*

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 16/01/2025
- eBNF. Dexamfetamine. Accessed via https://bnf.nice.org.uk/ on 16/01/2025
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- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Amfetamines. Last revised December 2024. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/ on 16/01/2025
- Gov.uk. Drugs and driving: the law. Accessed via https://www.gov.uk/drug-driving-law on 16/01/2025

16. Other relevant national guidance

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- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Contact specialist for advice if:

- The patient finds the medication intolerable for any given reason
- If there is concern about observed mental or physical side effects (e.g. depression or hypertension)
- The side effects mentioned above, do not appear to be of a temporary and short lived nature Contact named responsible clinician in writing or via secure email detailed in clinic

Contact named responsible clinician in writing or via secure email detailed in clinic letter.

Also see BNSSG Remedy 'Adult ADHD' page ADHD (adult) (Remedy BNSSG ICB) for information for GP practices signed up to the ADHD LES.

Approved by BNSSG JFG: May 2025
Review date: September 2027
Version 1.1

National shared care protocol:

Guanfacine for patients within adult services

1 July 2025, Version 1

TLS Amber – 3 Months

Review date – July 2028

This shared care protocol is based on content originally published by RMOC/NHS England in January 2022. As well as these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Prior to prescribing guanfacine, obtain advice from a tertiary service on the suitability for the patient.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribing is normally for at least 12 weeks until the patient is stable and dose optimised.
- Counsel patient to contact their clinician if any new or worsening psychiatric symptoms occur at any point during treatment.

- Once treatment is optimised, complete the shared care documentation and send to patient's GP detailing the diagnosis, current and ongoing dose, any relevant test results, and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.
- Prescribing when a woman becomes or wishes to become pregnant can be managed in primary care with advice/input from the specialist. Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist as soon as practicable if they are **unable** to support shared care (in writing or via secure email). It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5, taking into any account potential drug interactions in section 7.
- Adjust the dose of guanfacine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with guanfacine when starting new medicines (see section 7).
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Make an urgent referral for appropriate care if suicidal behaviour or ideation, syncope, or other signs or symptoms of cardiovascular adverse effects occur.
- Seek advice/input from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Patient and/or carer responsibilities

- Take guanfacine as prescribed and avoid abrupt withdrawal unless advised by their prescriber. Stopping guanfacine suddenly increases the risk of withdrawal effects, namely rebound hypertension, so it is important to gradually reduce the dose under medical supervision.
- Attend all monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11. Any new or worsening psychiatric symptoms should be highlighted to your clinician as soon as they occur.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of guanfacine with their pharmacist before purchasing any OTC medicines.
- Avoid alcohol and grapefruit juice while taking guanfacine, and drink plenty of other fluids.
- Not to drive, cycle, or operate heavy machinery if guanfacine affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 11).
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Guanfacine is a centrally-acting adrenergic medicine indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents. Use in adults is off-label, and should only be considered on the advice of a tertiary ADHD service. It may be recommended for people who have not responded to one or more stimulants, and one non-stimulant (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Guanfacine should be used as part of a comprehensive treatment programme, typically including psychological, educational and social measures.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) or Community Paediatric service but is approaching their 18th birthday, it is expected that CAMHS/Community Paediatric service will refer to the appropriate adult service if need for

ongoing treatment is anticipated. NICE Guidance NG43 Transition from children's to adults' services for young people using health or social care services should be followed.

Long-term usefulness of guanfacine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate.

2. Indications

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- Attention-deficit hyperactivity disorder ‡

‡ Off-label indications – not licensed in adults. See section 1 for circumstances where NICE recommend use in adults.

3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)

N/A

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to guanfacine or to any of the excipients
- Hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

Cautions:

- Risk factors for torsades de pointes: bradycardia, heart block, hypokalaemia, history of QT interval prolongation, concomitant use of other medicines which may prolong the QT interval.
- History of cardiovascular disease, hypotension, orthostatic hypotension, or syncope.
- Family history of cardiac or unexplained death.
- Dehydration (may increase risk of syncope).
- Alcohol consumption (not recommended during treatment).

- Concomitant treatment with centrally acting depressants or antihypertensives (see section 7).
- Suicidal ideation or behaviour.
- Prescribing in the elderly is potentially inappropriate. See BNF information on prescribing in the elderly.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- Dose or formulation adjustments can be managed in primary care with advice/input from the specialist.
- To minimise the risk of an increase in blood pressure upon discontinuation, the manufacturer advises that the total daily dose should be tapered in decrements of no more than 1 mg every 3 to 7 days. Blood pressure and pulse should be monitored when reducing the dose or discontinuing treatment. Termination of treatment can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Initial stabilisation:

1 mg once daily, adjusted in increments of not more than 1 mg every week, if necessary and tolerated.

The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

0.05-0.12 mg/kg/day. Maximum dose 7 mg daily.

The initial maintenance dose must be prescribed by the initiating specialist.

Adults who have shown clear benefit from guanfacine in childhood or adolescence may continue treatment into adulthood at the same daily dose.

Conditions requiring dose adjustment:

Hepatic or renal insufficiency:

Dose reduction may be required in patients with hepatic impairment, severe renal impairment (GFR 29-15 mL/min), end stage renal disease (GFR <15 mL/min) or in patients requiring dialysis.

Patients taking CYP3A inhibitors or inducers:

A 50% reduction in guanfacine dose is recommended with concurrent use of moderate and potent inhibitors of CYP3A4. Dose titration may be required with concurrent use of potent inducers of CYP3A4.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Guanfacine hydrochloride (Intuniv®▼) • Prolonged-release tablets: 1 mg, 2 mg, 3 mg, 4 mg
Administration details:	Guanfacine can be taken with or without food, but should not be given with high fat meals due to increased exposure. Tablets should be swallowed whole and not split, crushed or chewed. Guanfacine should be taken once daily in the morning or evening. If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. If two or more consecutive doses are missed, re-titration is recommended, a lower starting dose may be required based on the patient's tolerance to guanfacine. Discuss with the specialist team or HCP with expertise in ADHD who conducts the annual review for advice on re-titrating guanfacine.
Other important information:	Grapefruit juice should be avoided during treatment with guanfacine. Due to risk of blood pressure increase upon discontinuation, guanfacine should be gradually tapered at a rate of no more than 1 mg every 3 to 7 days. Blood pressure and pulse should be monitored when discontinuing treatment.

	Discontinuation should be managed by the specialist team or HCP with expertise in ADHD who conducts the annual review.

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- Drugs which prolong the QT interval. Concomitant use with guanfacine is not recommended.
- **CYP3A4 and CYP3A5 inhibitors**, e.g. ketoconazole, clarithromycin, erythromycin, ciprofloxacin, diltiazem, fluconazole, verapamil, grapefruit juice, ritonavir: increased exposure to guanfacine. Dose reduction may be required, see section 5.
- **CYP3A4 inducers**, e.g. carbamazepine, modafinil, phenytoin, rifampicin, St John's wort: reduced exposure to guanfacine. Dose increase may be required.
- **Valproic acid**: concomitant use may increase concentrations of valproic acid
- **Antihypertensive medicines**: risk of additive effects, e.g. hypotension, syncope
- **CNS depressants**, e.g. alcohol, sedatives, hypnotics, benzodiazepines, barbiturates, antipsychotics: risk of additive effects, e.g. sedation, somnolence
- **Administration with high fat meals:** increased exposure to guanfacine.

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A full assessment, as recommended by NICE guidance for ADHD. This should include a medical history and cardiovascular assessment, taking into account conditions that may be contraindications for guanfacine, and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required.
- Height, weight, and body mass index (BMI).
- Blood pressure (BP) and heart rate.

- Electrocardiogram (ECG) and cardiology opinion are recommended if the patient has any of the following:
    - history of congenital heart disease or previous cardiac surgery
    - sudden death in a first-degree relative under 40 years suggesting a cardiac disease
    - shortness of breath on exertion compared with peers
    - fainting on exertion or in response to fright or noise, palpitations
    - chest pain suggestive of cardiac origin
    - signs of heart failure, heart murmur or hypertension
- ECG is recommended if the patient has a co-existing condition treated with a medicine that may increase cardiac risk.

Initial monitoring:

- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring:

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need.

Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

In BNSSG the annual review is done in primary care for patients registered at GP practices signed up to the ADHD locally enhanced service (LES) and by the specialist team where the GP practice is not signed up to the LES.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• Blood pressure and heart rate • Weight and appetite	Every 3 months for the first year, and every 6 months thereafter. More frequent monitoring is recommended following dose adjustment, which may be done in primary care if directions have been discussed and agreed with the specialist service.
• Assessment of adherence	As required, based on the patient's needs and individual circumstances.
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD. • Review to include assessment for any new or worsening psychiatric symptoms and sleep problems.	Annually (by primary or secondary care depending on ADHD Annual Review LES uptake).
(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.	

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other signs or symptoms suggestive of cardiac disease	Refer for urgent specialist cardiac evaluation
Marked decrease from baseline in heart rate	Discuss with specialist team; dose reduction or cardiac evaluation may be required
Hypotension or orthostatic hypotension	Give lifestyle advice (e.g. drinking plenty of fluids, getting up slowly from standing or sitting) and repeat monitoring. If blood pressure decreases markedly from baseline, reduce dose by 1mg and discuss with specialist team.
Sedation and somnolence	Sedation and somnolence typically occur during the start of treatment and with dose increases. Review timing of dose; guanfacine may be taken in the morning or evening. Review lifestyle factors, and reinforce that alcohol should be avoided. Seek specialist advice if sedation persists. Dose reduction or discontinuation may be indicated.
Weight or BMI outside healthy range	Provide appropriate support on multicomponent interventions to increase physical activity levels, improve eating behaviour and quality of diet.

	Discuss with specialist if difficulty persists; dose reduction, or treatment break, or change of medicine may be required.
Psychiatric disorders Suicidal ideation or behaviour	Review patient and exclude other causes. Refer urgently for psychiatric assessment and notify the ADHD specialist team. Consider discontinuing guanfacine.

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- New or worsening psychiatric symptoms, such as suicidal ideation or behaviour
- Signs and symptoms of bradycardia or hypotension, e.g. fatigue, dizziness, palpitations, feeling faint or fainting

The patient should be advised:

- To drink plenty of fluids; dehydration can increase the risk of falls or fainting.
- Not to drive, cycle, or operate machines if guanfacine affects their ability to do so safely, e.g. by causing dizziness or drowsiness, and to inform the DVLA if their ability to drive safely is affected. See https://www.gov.uk/adhd-and-driving.
- Avoid alcohol while taking guanfacine, as it may make side effects worse.
- Avoid grapefruit juice while taking guanfacine.
- Not to stop taking guanfacine without talking to their doctor. Due to risk of side effects, it is important to gradually reduce the dose of guanfacine under medical supervision.

Patient information:

- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults
- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=guanfacine

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Guanfacine is not recommended for use during pregnancy. There are no or limited data from the use of guanfacine in pregnant women, and animal studies have shown reproductive toxicity.

Patients who become pregnant while taking guanfacine, or who plan a pregnancy, should be referred to the specialist team for review.

Breastfeeding:

There is no published evidence on the safety of guanfacine in breastfeeding. Decisions on whether to use while breastfeeding should be made on a case-by-case basis with specialist input e.g. UKTIS, taking into account the risks to the infant and benefits of therapy. The long half-life increases the risk of accumulation in breastfed infants. It may interfere with lactation, as guanfacine decreases prolactin levels in the mother. Infants should be monitored for decreased appetite/weight gain, sleep disturbances, gastrointestinal symptoms (e.g. pain, vomiting, constipation), although some of these may be difficult to detect.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/guanfacine/

Paternal exposure:

- No evidence regarding adverse outcomes following paternal exposure was identified.

13. Specialist contact information

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Name: Dr Dietmar Hank

Role and specialty: Consultant Psychiatrist and Clinical Lead Adult ADHD service, AWP

Daytime telephone number: 01275 796262 M-F 9-5

Email address: Awp.specialisedadhdservices@nhs.net

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- eBNF. Guanfacine. Accessed via https://bnf.nice.org.uk/drug/guanfacine.html on 02/06/2025
- Guanfacine hydrochloride 1 mg prolonged-release tablets (Intuniv®). Date of revision of the text 23/05/23. Accessed via https://www.medicines.org.uk/emc/product/5099 on 02/06/2025
- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 02/06/2025
- NICE NG43: Transition from children's to adults' services for young people using health or social care services. Last updated February 2016. Accessed via https://www.nice.org.uk/guidance/ng43/ on 02/06/2025

16. Other relevant national guidance

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- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Contact specialist for advice if:

- The patient finds the medication intolerable for any given reason

- If there is concern about observed mental or physical side effects (e.g. depression or hypertension)
- The side effects mentioned above, do not appear to be of a temporary and short lived nature.

Contact named responsible clinician in writing or via secure email detailed in clinic letter.

Also see BNSSG Remedy 'Adult ADHD' page ADHD (adult) (Remedy BNSSG ICB) for information for GP practices signed up to the ADHD LES.

APC board date: JFG July 2025

BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	**Guanfacine (Intuniv®)**
Amber ***three months***	

Indication	As part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children and adolescents of 5* years of age and over, where:
	• Treatment with methylphenidate or lisdexamfetamine has been considered to be:
	  ○ Inadequate (Their symptoms have not responded to separate 6-week trials of each medicine.)
	  ○ Not tolerated
	  ○ Contraindicated
	  ○ Inappropriate (e.g. concerns about misappropriation of stimulants).
	
	*Guanfacine is licensed from 6 years, 'off-label' use for 5 year old patients, but supported by NICE Guideline (NG87; 1.5.13)

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Guanfacine is a non-stimulant selective alpha2A-adrenergic receptor agonist. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or ADHD specialist non-medial prescriber. **Dose in children 5-12 years** Body-weight 25kg and above: Initially 1mg once daily, adjusted in steps of 1mg every week if needed and if tolerated. Maintenance: 0.05-0.12mg/kg (max 4mg/dose). **Dose in young people 13-17 years** Body-weight 34-41.4kg: Initially 1mg once daily; adjusted in steps of 1 mg every week if necessary and if tolerated; maintenance 0.05–0.12 mg/kg once daily (max. per dose 4 mg). Body-weight 41.5–49.4 kg Initially 1mg once daily; adjusted in steps of 1 mg every week if necessary and if tolerated; maintenance 0.05–0.12 mg/kg once daily (max. per dose 5 mg).

	<u>Body-weight 49.5–58.4 kg:</u> Initially 1mg once daily; adjusted in steps of 1 mg every week if necessary and if tolerated; maintenance 0.05–0.12 mg/kg once daily (max. per dose 6 mg). <u>Body-weight 58.5 kg and above:</u> Initially 1mg once daily; adjusted in steps of 1 mg every week if necessary and if tolerated; maintenance 0.05–0.12 mg/kg once daily (max. per dose 7 mg). *For optimal weight-adjusted dose titrations, consult product literature.* Patients who have shown clear benefit from guanfacine in childhood or adolescence may continue treatment into adulthood at the same daily dose.
Route and formulation	Oral. Guanfacine hydrochloride (Intuniv®▼) 1 mg, 2 mg, 3 mg and 4 mg modified-release tablets. Guanfacine can be taken with or without food, but should not be given with high fat meals due to increased exposure.
Duration of treatment	Long term Efficacy should be seen within four – eight weeks of therapeutic dose being reached. If no clinical benefit seen during the titration period, treatment should be stopped – this is the responsibility of secondary care. Long-term usefulness of guanfacine for extended periods (over 12 months) should be periodically re-evaluated. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
Monitoring at baseline and during initiation is the responsibility of the specialist; once the patient is optimised on the chosen medicine, with no anticipated changes expected in the immediate future, prescribing will be transferred to the GP. Monitoring will remain the with the specialist clinician in secondary care unless specific arrangements are made with GP. **Baseline investigations:** • A medical and medication history and full cardiovascular assessment (this should include consideration of any family history of sudden cardiac/unexplained death), taking into account conditions which may be contraindicated, risk of pregnancy (where applicable).

- Height, weight, and body mass index (BMI) on growth chart and risk of obesity
- Blood pressure (BP) and heart rate (including risk of hypotension, bradycardia and QT prolongation
- Risk of somnolence and sedation
- Suicidal ideation or behaviour

Blood tests, ECG and other parameters are not required unless specifically indicated for individual patients. N.B. Electrocardiogram (ECG) is recommended only if the patient has any of the following: History of congenital heart disease or previous cardiac surgery, sudden death in a first-degree relative under 40 years suggesting a cardiac disease, shortness of breath on exertion compared with peers, fainting on exertion or in response to fright or noise, palpitations, chest pain suggestive of cardiac origin, signs of heart failure, heart murmur or hypertension, or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk

Initial monitoring during dose titration:

- Weekly monitoring for signs and symptoms of somnolence, sedation, suicidal ideation or behaviour, hypotension and bradycardia during dose titration and stabilisation
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Ongoing monitoring:

- Before and after every change of dose: assess heart rate and blood pressure.
- Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This remains the responsibility of the specialist.
- Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined below remains appropriate.

Test	Frequency	Who by	Action/management For paediatric patients the use of a centile chart is recommended
Blood pressure and heart rate. **Signs or symptoms of cardiovascular adverse effects, e.g. bradycardia and hypotension**	Every 3 months for the first year of treatment, and every 6 months thereafter. N.B. More frequent monitoring is recommended following dose adjustment or discontinuation. Additional monitoring to be carried out by team initiating the dose change (usually	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care)	Compare with normal range for age. **Hypotension** Give lifestyle advice (e.g. drinking plenty of fluids, getting up slowly from standing or sitting) and repeat monitoring. If BP decreases markedly from baseline, reduce dose by 1mg and discuss with specialist team. **Hypertension** If there is a clinically significant increase in blood pressure or systolic blood pressure is greater than 95th percentile (measured on 2 occasions), refer to paediatric hypertension specialist; consider dose adjustment or alternative ADHD treatment. **Low heart rate:** Discuss with specialist team; dose reduction or cardiac evaluation may be required.

	secondary care).		**Raised heart rate:** NICE guidance suggest to investigate a resting tachycardia of > 120pbm; we suggest to monitor and possibly investigate a sustained resting tachycardia >100bpm; consider ECG; discuss with paediatric physical health colleagues as needed.
Height, weight and BMI (on growth chart)			If there is evidence of significant weight gain, loss or nil weight gain where expected, measure BMI and discuss with patient and family/ carer as appropriate. Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Somnolence and sedation			Sedation and somnolence typically occur during the start of treatment and with dose increases. Seek specialist advice if sedation persists. Dose reduction or discontinuation may be indicated.
Assessment of adherence	As required based on the patient's needs and individual circumstances	CAMHS or Community Paediatrics department and primary care	Primary care to seek advice from secondary care
Suicidal ideation or behaviour	Annually or if dose is adjusted / titrated or discontinued.	CAMHS or Community Paediatrics department unless arrangements have been made for individual patients.	Primary care to seek advice from secondary care
Monitoring for effectiveness and adverse effects.	During any dose adjustments or discontinuation and every 3 months for the first year and then at least annually.		This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods off medication to assess the patient's functioning without pharmacotherapy, preferably during times of school holidays, when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document rationale.
Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually	Primary care to confirm that review by CAMHS or Community Paediatrics has occurred.	Primary care to seek advice from secondary care

*Children and Adolescent Mental Health Service

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency/ severity	Action/management
Cardiac related	Uncommon - Severe	Refer for urgent specialist cardiac evaluation: Palpitations, exertional chest pain, syncope, dyspnoea or marked bradycardia (from baseline)
Marked decrease from baseline in heart rate	Common	Discuss with specialist team; dose reduction or cardiac evaluation may be required.
Hypotension or orthostatic hypotension	Common	Give lifestyle advice (e.g. drinking plenty of fluids, getting up slowly from standing or sitting) and repeat monitoring. If BP decreases markedly from baseline, reduce dose by 1mg and discuss with specialist team.
Sedation and somnolence	Very Common	Sedation and somnolence typically occur during the start of treatment and with dose increases. Closely monitor during initiation and stabilisation and every 3 months for first year. Seek specialist advice if sedation persists. Dose reduction or discontinuation may be indicated.
Weight increase	Common	Provide appropriate support on multicomponent interventions to increase physical activity levels, improve eating behaviour and quality of diet. Discuss with specialist if difficulty persists; dose reduction, treatment break or change of medicine may be required.
Psychiatric disorders Suicidal ideation or behaviour	Common Unknown	Review patient and exclude other causes. Refer urgently to ADHD specialist team. Consider discontinuing guanfacine
Dry mouth	Common	Supportive management. Discuss with specialist if symptoms persist.

Referral back to specialist

Refer back to specialist when:

- Patients become pregnant or starts breastfeeding while taking guanfacine.
- Suicidal behaviour or ideation, syncope, or other signs or symptoms of cardiovascular adverse effects occur (all urgent referral).
- Any loss of clinical efficacy is suspected (e.g. worsening of ADHD symptoms) or intolerance to therapy occurs.
- Any significant change in physical health and comorbidities for example hepatic or renal insufficiency

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues

Significant drug interactions of guanfacine

CNS depressants and melatonin	Enhanced sedative effect
Antihypertensives and baclofen	Risk of hypotension
Some anticonvulsants	Greater exposure to either anticonvulsant or guanfacine side effects
CYP3A4 – moderate-potent inhibitors	Reduce dose by half (e.g. with ciprofloxacin, clarithromycin, erythromycin, fluconazole and itraconazole)
CYP3A4 – potent inducers	Increase dose up to max. 7 mg daily (e.g. with carbamazepine, phenobarbital, phenytoin, rifampicin, St. John's Wort and glucocorticoids).
QT prolonging medicines	Risk of additive effect of decreased heart rate

Contraindications

- Hypersensitivity to guanfacine or to any excipients of formulation.

Cautions

- Cardiac issues, e.g. risk of torsade de pointes with bradycardia, heart block and hypokalaemia; caution in patients with history of hypotension, cardiovascular disease or of QT-interval prolongation
- Sedation and somnolence – predominantly at the start of treatment and typically lasts for 2-3weeks, closely monitor during initiation and stabilisation and every 3 months for first year
- Suicidal ideation – post-marketing reports of suicide-related events, monitor closely especially during initiation, optimisation and discontinuation
- Aggression- Behavioural changes- Hostility (predominantly aggression, oppositional behaviour and anger) - patients should closely monitor for worsening of aggressive behaviour
- Pregnancy- avoid during pregnancy
- Refer back to specialist services for advice if patient breastfeeding

Other cautions:

Periods off medication (including poor compliance) for more than 48 hours require re-titration. Do not restart at the previous dose.

Treatment cessation

Avoid abrupt withdrawal. Due to risk of blood pressure increase upon discontinuation, guanfacine should be gradually tapered at a rate of no more than 1 mg every 3 to 7 days. Blood pressure and pulse should be monitored when discontinuing treatment. This is the responsibility of the CAMHS or Community Paediatrics department managing treatment cessation.

Reminder to ask patient about specific problems	The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay: • New or worsening psychiatric symptoms, such as suicidal ideation or behaviour • Signs and symptoms of bradycardia or hypotension, e.g. fatigue, dizziness, palpitations, feeling faint or fainting

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

The patient and/or family/carer should be advised:

1. To drink plenty of fluids; dehydration can increase the risk of fainting.
2. Not to drive, cycle, or operate machines if guanfacine affects their ability to do so safely, e.g. by causing dizziness or drowsiness - review timing of dose as guanfacine may be taken in the morning or evening.
3. Avoid alcohol while taking guanfacine, as it may make side effects worse.
4. Avoid grapefruit juice while taking guanfacine (theoretical increase in guanfacine blood levels).
5. Not to stop taking guanfacine without talking to their doctor. Due to risk of discontinuation effects, it is important to gradually reduce the dose of guanfacine under medical supervision. Let your specialist or GP know if you miss more than one dose.
6. To take a pregnancy test if they think there is a possibility they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant (women of child-bearing potential).
7. Avoid taking with high fat meals as this may increase absorption.
8. Information on drug prescribed including a patient information leaflet (PIL). Information on mental health conditions, treatments and medication can be found at:

Choice and Medication
NHS – Attention Deficit Hyperactivity Disorder
Guanfacine Patient Information Leaflet

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Communicate changes of medication form, strength or dose to the GP before the next repeat prescription is due (ie within 28 days). Note that a change of dose does not itself imply instability, and is usually done as a response to patient growth. If the secondary care clinician feels the medication is not at a stable dose, the GP will be informed that the secondary care provider will supply medication until this is again stable
5. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
6. To provide advice to primary care when appropriate, including queries about medication efficacy and side effects.
7. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
8. Stopping treatment where appropriate or providing advice on when to stop.
9. Reporting adverse events to the MHRA.
10. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Initiating Clinician	AWP	As provided on correspondence	As provided on correspondence
Sarah Steel Highly Specialised Clinical Pharmacist	AWP	01249 474542	Sarah.steel6@nhs.net

Section 10: Document Details

Date prepared	28th April 2023
Prepared by	Sarah Steel
Date approved by JFG	6th Feb 2024
Date of review	Feb 2027
Document Identification: Version	V1

Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Sarah Steel - Highly Specialised Clinical Pharmacist, AWP
2. Samantha Hayer - CAMHS Consultant, AWP
3. Alfred Perrera - CAMHS Consultant, AWP
4. Richard Williams - Consultant Paediatrician, Sirona Care & Health
5. Richard Lee-Kelland - Consultant Community Paediatrician, Sirona Care & Health – from June 2023

Section 12: References

Please list references

1. Specialist Pharmacy Service. Guanfacine Lactation Safety Information. Last updated October 2022. Accessed on 15/12/2022.

2. Cortese S, Del Giovane C, Chamberlain S*, et al.* Pharmacological and non-pharmacological interventions for adults with ADHD: protocol for a systematic review and network meta-analysis *BMJ Open* 2022;**12:**e058102. Accessed May 2023.
3. eBNF. Guanfacine, last updated 14th December 2022. Accessed via on 15/12/2022.
4. SmPC: Guanfacine hydrochloride 1 mg prolonged-release tablets (Intuniv®). Date of revision of the text 2nd March 2022. Accessed on 15/12/2022.
5. NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated 13th September 2019. Accessed on 15/12/2022.
6. EMC: Guanfacine risk minimisation materials. Updated June 2022. Accessed via on 15/12/2022.
7. Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed on 15/12/2022

National shared care protocol:

Lisdexamfetamine for patients within adult services

1 January 2025, Version 1

TLS Amber – 3 Months

Review date – January 2028

This shared care protocol is based on content originally published by RMOC/NHS England in January 2022. As well as these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable them to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribe is normally for at least 12 weeks until the patient is stable and dose optimised.
- Counsel patient to contact their clinician if any new or worsening psychiatric symptoms occur at any point during treatment.

- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.
- Prescribing when a woman becomes or wishes to become pregnant can be managed in primary care with advice/input from the specialist.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist as soon as practicable if they are **unable** to support shared care (in writing or via secure email). It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into account any potential drug interactions in section 7.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Adjust the dose of lisdexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with lisdexamfetamine when starting new medicines (see section 7)
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop lisdexamfetamine and make an urgent referral for appropriate care when contra-indications are suspected.
- Seek advice/input from the specialist if the patient becomes or plans to become pregnant.

- Stop treatment as advised by the specialist. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Patient and/or carer responsibilities

- Take lisdexamfetamine as prescribed and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their GP. Seek immediate medical attention if they develop any symptoms as detailed in section 11. Any new or worsening psychiatric symptoms should be highlighted to your clinician as soon as they occur.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of lisdexamfetamine with their pharmacist before purchasing any OTC medicines.
- Be aware that lisdexamfetamine can affect cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving (see section 11).
- Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs.
- Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store lisdexamfetamine safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Lisdexamfetamine dimesylate is metabolised following administration to dexamfetamine and therefore has the same sympathomimetic mechanism of action with central stimulant and anorectic activity. It is indicated as part of a comprehensive treatment programme for the treatment of attention deficit hyperactivity disorder (ADHD) when the response to a 6-week trial of methylphenidate treatment is considered clinically inadequate. It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management).

NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Lisdexamfetamine is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated.

Pharmacological treatment of ADHD may be needed for extended periods. When lisdexamfetamine is used for extended periods (over 12 months) its usefulness should be re-evaluated at least yearly by a healthcare professional with expertise in ADHD, and consideration given to trial periods off medication to assess the patient's functioning without pharmacotherapy.

2. Indications

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Licensed indication: attention deficit hyperactivity disorder (ADHD) in adults

See SPC for full details of licensed indication.

3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)

N/A

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines.
- Glaucoma.
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment.
- Hyperthyroidism or thyrotoxicosis.

For patients with the following contraindications, lisdexamfetamine can be prescribed under certain circumstances after a risk benefit consideration by the specialist has been taken into account:

- Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder.
- Diagnosis or history of severe and episodic (Type I) bipolar (affective) disorder (that is not well-controlled).
- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include moderate hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, and structural cardiac abnormalities.
- Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke.

Cautions:

- History of substance or alcohol abuse.
- Phaeochromocytoma.
- Family history of sudden cardiac or unexplained death, ventricular arrhythmia, tics or Tourette's syndrome.
- Underlying medical conditions or concomitant drugs which can increase the QT-interval or heart rate, or elevate blood pressure (e.g. cardiac disease, electrolyte disturbance).
- History of seizure disorders (discontinue if seizures occur).
- Susceptibility to angle-closure glaucoma.
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour), tics, Tourette's syndrome, anxiety, or bipolar disorder.
- Depressive symptoms; patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Severe renal impairment; GFR 15-30mL/min/1.73m^2 or CrCl less than 30mL/min. Dose reduction is required, see section 5.
- Hepatic insufficiency (due to lack of data).
- Pregnancy or breast-feeding (see section 12).
- Potential for abuse, misuse, or diversion.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after the patient has been on treatment for at least 12 weeks, is stable and the dose optimised with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- Dose or formulation adjustments can be managed in primary care with advice/input from the specialist.
- Termination of treatment can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.

Initial stabilisation:

30 mg taken once daily in the morning, increased in increments of 20 mg at intervals no shorter than 1 week. Lower starting doses may be used if clinically appropriate (off-label use).

The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Maximum 70 mg per day.

Lisdexamfetamine must be prescribed by the initiating specialist during initiation and dose stabilisation.

Conditions requiring dose adjustment:

In severe renal impairment (GFR 15-30mL/min/1.73m^2 or CrCl less than 30mL/min), the recommended maximum dose is 50 mg per day.

Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. This should be undertaken and supervised by the specialist who will advise the patient and GP of the outcome. Alternatively, this can be managed in primary care within the competence of the prescriber (section 8).

6. Pharmaceutical aspects

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Route of administration:	Oral

Formulation:	Lisdexamfetamine dimesylate 30mg 50mg and 70mg hard capsules (Elvanse Adult®) Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg and 70mg hard capsules (Elvanse®) – use in adults may be considered off-label. See SPC for full details.
Administration details:	The dose may be taken with or without food Lisdexamfetamine capsules may be swallowed whole, or the capsule opened and the entire contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. See SPC for further information If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. Afternoon doses should be avoided because of the potential for insomnia
Other important information:	Lisdexamfetamine is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of lisdexamfetamine Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations. **In times of medicine shortages, local guidance is available to support clinicians to manage supply disruptions. Management of Stock Shortages (Remedy BNSSG ICB)**

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

The following medicines must not be prescribed without consultation with the specialist:

- **Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics** (e.g. rasagiline, selegiline, safinamide) – additive hypertensive effect

Other clinically significant interactions

- **Selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine, paroxetine)**: may increase exposure to lisdexamfetamine, risk of serotonin syndrome
- **Serotonergic drugs, bupropion, tapentadol, tramadol:** Risk of serotonin syndrome
- **Tricyclic antidepressants (TCAs) and nabilone**: may increase risk of cardiovascular adverse events.
- **Ascorbic acid and other agents and conditions (thiazide diuretics, diets high in animal protein, diabetes, respiratory acidosis)** that acidify urine increase urinary excretion and decrease the half-life of amfetamine.
- **Sodium bicarbonate and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting)** that alkalinise urine decrease urinary excretion and extend the half-life of lisdexamfetamine**.**
- **Antihypertensives, including guanethidine**: effects may be reduced by lisdexamfetamine
- **Lithium, phenothiazines, haloperidol**: may reduce the effects of lisdexamfetamine
- **Opioids** (including tapentadol and tramadol): analgesic effects may be increased by lisdexamfetamine
- **Alcohol:** Limited data is available, therefore caution is advised as alcohol may exacerbate the CNS side effects of lisdexamfetamine
- **Apraclonidine:** effects decreased by lisdexamfetamine.
- **Ritonavir, tipranavir:** may increase exposure to lisdexamfetamine
- **Safinamide:** predicted to increase the risk of severe hypertension when given with lisdexamfetamine
- **Atomoxetine**: increased risk of adverse effects

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- A risk assessment for substance misuse and drug diversion

- Blood pressure (BP) and heart rate
- Height, weight and body mass index (BMI)
- Appetite
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:
    - History of congenital heart disease or previous cardiac surgery
    - Sudden death in a first-degree relative under 40 years suggesting a cardiac disease
    - Shortness of breath on exertion compared with peers
    - Fainting on exertion or in response to fright or noise
    - Palpitations
    - Chest pain suggestive of cardiac origin
    - Signs of heart failure, heart murmur or hypertension
    - Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- After every change of dose: assess heart rate and blood pressure, changes in weight, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Monitor for aggressive behaviour or hostility
- Assessment of symptom improvement. Discontinue if no improvement is observed after reaching normal therapeutic doses.

Ongoing monitoring:

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

In BNSSG the annual review is done in primary care for patients registered at GP practices signed up to the ADHD locally enhanced service (LES) and by the specialist team where the GP practice is not signed up to the LES.

Patients should be encouraged to consider stopping the medication every 1 to 5 years, with the guidance of the specialist clinic if desired. If desired and clinically appropriate, lisdexamfetamine can be restarted by the GP, referral back into the ADHD service is not necessary.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and advice	Frequency
• Blood pressure and heart rate • Weight and appetite •	Every 6 months, and after any change of dose recommended by specialist team.
• Assessment of adherence, and for any indication of lisdexamfetamine abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD • Review to include assessment for any new or worsening psychiatric symptoms and sleep problems.	Annually (by primary or secondary care depending on ADHD Annual Review LES uptake)

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP	• In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management • In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.
New or worsening seizures	Stop treatment and discuss with specialist. Discontinuation may be indicated.
Anorexia or weight loss, weight or BMI outside healthy range	Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before • additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction	Review timing of doses and continue treatment unless severe, Give advice on sleep hygiene. Discuss with specialist if required
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required

New or worsening psychiatric or neuropsychiatric symptoms, e.g. mania, depression, paranoia, anxiety and agitation	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue lisdexamfetamine as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether lisdexamfetamine can be re-started.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient/carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Any mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania and suicidal ideation
- Palpitations, chest pain or syncope
- Cerebrovascular symptoms, such as severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language, or memory
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- Any visual changes such as difficulty with accommodation or blurring of vision
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

The patient/carer should be advised:

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue

prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.

- Lisdexamfetamine can affect impair cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving. For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including amfetamines, see drugs and driving: the law. People who drive must inform the DVLA if their ADHD, or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving
- Avoid alcohol while taking lisdexamfetamine, as it may make some side effects worse. Avoid recreational drugs. Due to the risks of severe depression, and fatigue, abrupt withdrawal after a prolonged period of intake of high doses of lisdexamfetamine should be avoided. Patients wishing to reduce their dose or stop lisdexamfetamine treatment should discuss with their specialist before doing so.
- Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store lisdexamfetamine safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences.

Patient information:

- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults
- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

The active metabolite of lisdexamfetamine, dexamfetamine, is thought to cross the placenta. The limited data available shows an increased risk of premature birth and preeclampsia. Infants may also develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion.

If a patient becomes pregnant or is planning a pregnancy during treatment they should discuss treatment options with their specialist. Ongoing prescribing in pregnancy may be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Lisdexamfetamine should only be used during pregnancy if the potential benefit outweighs the risks.

Healthcare professional information available from: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AMFETAMINES-IN-PREGNANCY/

Breastfeeding:

There is no published evidence for safety of lisdexamfetamine in breastfeeding. The manufacturers recommend against use, and the UK Drugs in Lactation Service recommend caution (see link below). Lisdexamfetamine metabolites, including dexamfetamine, are excreted in human milk, therefore a risk to infants cannot be excluded. An individual risk assessment must be made, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Healthcare professional information available from: Breastfeeding Medicines Advice service – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified. Further information for patients: https://www.medicinesinpregnancy.org/leaflets-a-z/lisdexamfetamine/

13. Specialist contact information

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Name: *Dr Dietmar Hank*

Role and specialty: Consultant Psychiatrist and Clinical Lead Adult ADHD service, AWP

Daytime telephone number: 01275 796262 M-F 9-5

Email address: *Awp.specialisedadhdservices@nhs.net*

Alternative contact: *[insert contact information, e.g. for clinic or specialist nurse]*

Out of hours contact details: *[insert contact information, e.g. for duty doctor]*

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed of any changes to the patient's GP or their contact details.

15. References

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- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 15/01/2025
- eBNF. Lisdexamfetamine, Accessed via https://bnf.nice.org.uk/ on 15/01/2025
- Lisdexamfetamine dimesylate 20 mg hard capsules (Elvanse®). Accessed via https://www.medicines.org.uk/emc/product/14091/smpc on 15/01/2025
- Lisdexamfetamine dimesylate 30 mg hard capsules (Elvanse® Adult). Accessed via https://www.medicines.org.uk/emc/product/14089/smpc on 15/01/2025
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via https://www.nice.org.uk/guidance/ng46/ on 15/01/2025
- Gov.uk: Drugs and driving: the lawGov.uk. Drugs and driving: the law. Accessed via https://www.gov.uk/drug-driving-law on 15/01/2025
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: last revised December 2024. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/ on 15/01/2025

16. Other relevant national guidance

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- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/

- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Contact specialist for advice if:

- The patient finds the medication intolerable for any given reason
- If there is concern about observed mental or physical side effects (e.g. depression or hypertension)
- The side effects mentioned above, do not appear to be of a temporary and short lived nature.

Contact named responsible clinician in writing or via secure email detailed in clinic letter.

Also see BNSSG Remedy 'Adult ADHD' page ADHD (adult) (Remedy BNSSG ICB) for information for GP practices signed up to the ADHD LES.

Approved by BNSSG JFG: May 2025
Review date: September 2027
Version 1.3

BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	**Lisdexamfetamine dimesylate (Elvanse®)**
Amber ***three months***	
Indication	Part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children and young people of 5*years and over, where: • Methylphenidate treatment has been considered to be: ○ Clinically inadequate (symptoms have not responded to adequate trials of methylphenidate.) ○ Not tolerated ○ Contraindicated ○ Inappropriate (e.g. concerns about misappropriation of stimulants). *Lisdexamfetamine is licenced from 6 years, 'off-label' use for 5 year old patients but supported by NICE Guideline (NG87; 1.5.13).

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Lisdexamfetamine is a stimulant. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or ADHD specialist non-medial prescriber. **Dose:** Initially 20-30 mg once daily, dose to be taken in the morning. Dose increased in steps of 10–20 mg every week if needed, to a maximum of 70 mg per day. Lisdexamfetamine is classed as a schedule 2 Controlled Drug under the Misuse of Dugs Regulations 2001 (MDR). Prescriptions must therefore conform to the MDR. **It is 'best practice' and AWP procedure to prescribe one month supply or less of any schedule 2 controlled drugs at a time.**

Route and formulation	Oral Elvanse® 20mg, 30mg, 40mg, 50mg, 60mg and 70mg capsules
Duration of treatment	Lisdexamfetamine should be continued for as long as it is effective.

	Discontinue after 4-6 weeks if insufficient response at maximum tolerated dose.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Monitoring at baseline and during initiation is the responsibility of the specialist; once the patient is optimised on the chosen medicine, with no anticipated changes expected in the immediate future, prescribing will be transferred to the GP. Monitoring will remain the with the specialist clinician in secondary care unless specific arrangements are made with GP. Patients will be reviewed by a specialist clinician annually as a minimum.

Baseline investigations include:

- Cardiovascular status including blood pressure, heart rate, height and weight on growth chart (see table below).
- Comprehensive history of concomitant medicines (past and present), co-morbid physical and psychiatric disorders or symptoms, and family history of sudden cardiac/unexplained death.
- Assessment of risk of diversion and/or misuse.

Blood tests, ECG and other parameters are not required unless specifically indicated for individual patients.

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	**Frequency**	**Who by**	**Action/management** **For paediatric patients the use of a centile chart is recommended**
Blood pressure (BP), pulse, weight, height	Prior to medication initiation	Initiating clinician (CAMHS* or Community Paediatrics department)	To prepare for medication titration
BP	After each dose increase, every 6 months and at annual review	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under	Compare with normal range for age, if there is a clinically significant increase in blood pressure or systolic blood pressure is greater than 95th percentile (measured on 2 occasions), refer to paediatric hypertension specialist; consider dose adjustment or alternative ADHD treatment.
Pulse			Compare with normal range for age. NICE guidance suggests to

		advice from secondary care)	investigate a resting tachycardia of > 120bpm; we suggest to monitor and possibly investigate a sustained resting tachycardia >100bpm; consider ECG; discuss with paediatric physical health colleagues as needed.
Height	Every 6 months		Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Weight	**Children 10 years and under:** 3 monthly **Children over 10 years and young people:** 3 and 6 months following initiation and 6 monthly thereafter *More often if concerns arise.*		If there is evidence of significant weight loss or nil weight gain where expected, measure BMI and discuss with patient and family/ carer as appropriate. Strategies to manage weight loss include: -Taking medication with or after food -Additional meals/snacks early morning or late evening when stimulant effects have worn off -Choosing high calorie foods of good nutritional value -Taking a planned break from treatment or changing medication. Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Assessment of adherence and monitoring for effectiveness and adverse effects including suicidal ideation or behaviour, tics, sexual dysfunction, seizures and sleep.	After each dose adjustments, at annual review and as required based on the patient's needs and individual circumstances.	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care)	This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document rationale. Seek secondary care advice. With stimulant medication, this should include review of potential misuse and diversion.

*Children and Adolescent Mental Health Service

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency	Action/management
Headache	Very Common	Usually transient. If it is persistent, consider stopping and consult the specialist team
Decreased Appetite	Very Common	Take medication after breakfast/food; Maximise food intake at times of least appetite suppression; increase snacking, introduce liquid calories (smoothies etc.)
Dry Mouth	Very Common	Contact specialist if persists
Insomnia	Very Common	This may be transient. Make sure medication is taken in the morning. Refer to the specialist team if persistent
CVS Symptoms: arrhythmias, tachycardia, hypertension, palpitations	Common	Monitor the BP, pulse, and if necessary perform an ECG. If the resting pulse is consistently > 100bpm, contact the specialist team (consideration must be given to child/young person's age and what is expected for age)
Agitation, anxiety, bruxism, restlessness, tremor, irritability, dizziness	Common	Common on initiation. Often subsides after several days. If no improvement, consult specialist
Reduced libido, erectile dysfunction	Common	Contact specialist
Dyspnoea	Common	Contact specialist if persists
GI disorders – diarrhoea, constipation, nausea, vomiting, abdominal pain	Common	Contact specialist if persists
Difficulties in visual accommodation	Rare	Usually transient. Optician to check to rule out other causes such as increased intraocular pressure. Contact specialist team if persistent
Serotonin Syndrome	Rare	Can occur when co-prescribed with antidepressants and lithium; stop Lisdexamfetamine immediately if suspected and seek expert advice. Early symptoms of serotonin syndrome include tachycardia, shivering, diarrhoea, diaphoresis, muscle cramps, agitation, and elevated body temperature
Leukopenia, thrombocytopenia and anaemia	Rare	Refer to specialist team, medicine may need to be stopped

Effects on ability to drive and use machines Lisdexamfetamine can cause dizziness, drowsiness and transient visual disturbances including difficulties with

	accommodation, diplopia and blurred vision (rare). It may have a moderate influence on the ability to drive and use machines. This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:
	• The medicine is likely to affect your ability to drive
	• Do not drive until you know how the medicine affects you
	• It is an offence to drive while under the influence of this medicine
	• However, you would not be committing an offence (called 'statutory defence') if:
	  ○ The medicine has been prescribed to treat a medical problem and
	  ○ You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
	  ○ It was not affecting your ability to drive safely.

Referral back to specialist	Contact specialist for advice if: • There is a query regarding medication efficacy • Patient finds the medication intolerable for any given reason • If there is concern about observed mental/psychological or physical side effects (e.g. depression or hypertension) • The side effects mentioned above, do not appear to be of a temporary and short-lived nature and they persist • If patient is pregnant or breastfeeding

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues

Significant Drug Interactions

MAOIs	E.g. moclobemide; risk of hypertensive crisis. Not to be given within 2 weeks of MAOIs.
Tricyclic antidepressants	Increased levels of TCA as can inhibit metabolism
Urinary PH altering agents	E.g. Ascorbic acid, thiazide diuretics and sodium bicarbonate. Agents that acidify urine increase urinary excretion and decrease the half-life of Lisdexamfetamine, decreasing over all levels of amphetamine. Agents that alkalinise urine decrease urinary excretion and extend half-life, increasing overall levels of amphetamine.
Antipsychotics and other dopaminergic drugs	E.g. Chlorpromazine and haloperidol block dopamine and norepinephrine receptors, thus inhibiting the central stimulant effects of Lisdexamfetamine.
Antihypertensives	Lisdexamfetamine may reduce the effect of antihypertensives.
Alcohol	Limited data, may increase CNS adverse reactions.
Serotonergic drugs	Potential increased risk of serotonin syndrome with co-administration – monitor and discontinue lisdexamfetamine as soon as possible if suspected.
Lithium	Anorectic and stimulatory effects of amfetamines may be inhibited by lithium carbonate
Steroids	Amfetamines can cause significant elevation in plasma corticosteroid levels. Greatest increase in the evening.

	<table><tr><td>Others</td><td>Use with caution with other sympathomimetics e.g. pseudoephedrine and decongestants.</td></tr></table> **Contraindications** • Hypersensitivity to sympathomimetic amines or any of the excipients in the particular formulation • Concomitant use of monoamine oxidase inhibitors (MAOIs) or within 14 days after treatment (due to the risk of hypertensive crisis). • Hyperthyroidism or thyrotoxicosis • Agitated states • Symptomatic cardiovascular disease • Advanced arteriosclerosis • Moderate to severe hypertension. • Glaucoma **Special Warnings and precautions** • Pre-existing cardiovascular disorders including serious structural abnormalities, cardiomyopathy, serious heart rhythm abnormalities, pre-existing hypertension, coronary artery disease or heart failure • Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke or known risk factors for cerebrovascular disorders • Diagnosis or history of recent severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder • Diagnosis or history of severe and episodic (Type 1) Bipolar (affective) disorder • Tics – stimulants can exacerbate motor and phonic tics and Tourette's Syndrome • Aggression – stimulants may cause aggressive behaviour or hostility • Seizures – stimulants may lower the seizure threshold • Pregnancy – Seek specialist advice • Breast-feeding – Seek specialist advice • Dose reduction is required in severe renal impairment – seek specialist advice. **Dose reduction and discontinuation** If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued – advice should be sought from the specialist. Patients should be carefully monitored for the risk of diversion, misuse and abuse of lisdexamfetamine. Lisdexamfetamine should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion.
Reminder to ask patient about specific problems	Ask about emergence of any possible side effects/compliance to treatment issues

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

The patient and/or family/carer should be advised:

1. It is not advisable to drink alcohol, use recreational substances or consume excessive amounts of caffeine whilst taking Lisdexamfetamine.
2. The patient should immediately report abdominal pain, unexplained nausea, malaise, darkening of the urine, jaundice, or suicidal thinking and/or self-harm to the GP.
3. Failure to attend annual reviews could result in the medication being stopped.
4. Patients can choose to try stopping the medication. Annual reviews are an ideal opportunity to discuss this but a desire to stop medication can be expressed and discussed at any time.
5. Information on drug prescribed including a patient information leaflet (PIL). Information on mental health conditions, treatments and medication can be found at:

Choice and Medication
NHS – Attention Deficit Hyperactivity Disorder
Medicines for Children leaflet: Lisdexamfetamine for ADHD
Lisdexamfetamine Patient Information Leaflet

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Communicate changes of medication form, strength or dose to the GP before the next repeat prescription is due (i.e. within 28 days). Note that a change of dose does not itself imply instability, and is usually done as a response to patient growth. If the secondary care clinician feels the medication is not at a stable dose, the GP will be informed that the secondary care provider will supply medication until this is again stable
5. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
6. To provide advice to primary care when appropriate.
7. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
8. Stopping treatment where appropriate or providing advice on when to stop.
9. Reporting adverse events to the MHRA.
10. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Initiating Clinician	AWP/Sirona	As provided on correspondence	As provided on correspondence
Sarah Steel Highly Specialised Clinical Pharmacist	AWP	01249 474542	Sarah.steel6@nhs.net

Section 10: Document Details

Date prepared	28th April 2023
Prepared by	Sarah Steel
Date approved by JFG	October 2023 (Minor update March 2025 updating clinical review frequency)
Date of review	October 2026
Document Identification: Version	V3

Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Sarah Steel highly specialised clinical pharmacist AWP
2. Samantha Hayer CAMHS consultant AWP
3. Alfred Perrera CAMHS consultant AWP
4. Richard Williams Consultant Paediatrician Sirona Care & Health
5. Richard Lee-Kelland, Consultant Community Paediatrician Sirona Care & Health – from June 2023

Section 12: References

Please list references

1. NICE Guideline [NG87]. Attention Deficit Hyperactivity Disorder: diagnosis and management. Updated 13.09.2019. Accessed Feb 2023.
2. SPC Lisdexamfetamine. Updated 14.11.2022. Accessed Feb 2023.
3. BNF Online. Lisdexamfetamine. Updated September 2022. Accessed Feb 2023.
4. Cortese S, *et al.* Pharmacological and non-pharmacological interventions for adults with ADHD: protocol for a systematic review and network meta-analysis *BMJ Open*. Accessed May 2023.

National shared care protocol:

Methylphenidate in adult services

1 January 2025, Version 1

TLS Amber – 3 Months

Review date – January 2028

The content of this shared care protocol was correct as of January 2022. As well as these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribing is normally for at least 12 weeks until the patient is stable and dose optimised.
- Counsel patient to contact their clinician if any new or worsening psychiatric symptoms occur at any point during treatment.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, brand to be prescribed, current and ongoing dose, any relevant test results and any additional monitoring. Include contact information (section 13).

- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.
- Prescribing when a woman becomes or wishes to become pregnant can be managed in primary care with advice/input from the specialist.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist as soon as practicable if they are **unable** to support shared care (in writing or via secure email). It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into account any potential drug interactions in section 7.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Adjust the dose of methylphenidate prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with methylphenidate when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop methylphenidate and make an urgent referral for appropriate care when contra-indications are suspected.
- Seek advice/input from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Patient and/or carer responsibilities

- Take methylphenidate as prescribed, and avoid abrupt withdrawal unless advised by their prescriber.

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11. Any new or worsening psychiatric symptoms should be highlighted to your clinician as soon as they occur.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of methylphenidate with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if methylphenidate affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 11).
- Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs.
- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Methylphenidate is a central nervous system stimulant licensed as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD). It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed. See NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management. NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Methylphenidate is available as immediate-release tablets, and modified-release tablets and capsules. The modified-release preparations contain both immediate-release and prolonged-release methylphenidate, and different brands have different proportions of each. Brands may therefore vary in their release characteristics and clinical effect. Modified-released preparations should therefore be prescribed by brand name.

Methylphenidate is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management. Risk of misuse can be reduced by using modified-release preparations.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated.

The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. Patients should be reviewed for ongoing need at least annually, and the manufacturers recommend a trial discontinuation at least once yearly to assess the patient's condition.
Methylphenidate is not licensed for all the indications it is used to treat below. However, its use for the indications below are established and supported by various sources and bodies including the BNF and NICE.

2. Indications

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- Attention deficit hyperactivity disorder (ADHD) in adults. Some brands are not licensed in adults (see section 6)

3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)
N/A

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to methylphenidate or to any of the excipients
- Glaucoma
- Phaeochromocytoma
- During treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Hyperthyroidism or thyrotoxicosis
- Medikinet XL only: history of pronounced anacidity of the stomach with a pH value above 5.5, or during therapy with H2 receptor blockers, proton pump inhibitors or antacids.

For patients with the following contraindications, methylphenidate can be prescribed under certain circumstances after a risk benefit consideration by the specialist has been taken into account:

- Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder.
- Diagnosis or history of severe and episodic (Type I) bipolar (affective) disorder (that is not well-controlled).

- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include moderate hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, and structural cardiac abnormalities.
- Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke.

Cautions:

- Family history of sudden cardiac or unexplained death, malignant arrhythmia.
- Cardiovascular status should be carefully monitored (see section 9 & section 10)
- Underlying conditions which might be compromised by increases in blood pressure or heart rate.
- Known drug or alcohol dependency or misuse of central nervous system (CNS) stimulants: potential for abuse, misuse or diversion.
- Alcohol consumption (not recommended during treatment)
- Epilepsy: may lower seizure threshold
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, depressive symptoms, bipolar disorder.
- Renal or hepatic insufficiency (due to lack of data)
- Leukopenia, thrombocytopenia, anaemia, or other haematological abnormalities.
- Prolonged-release tablets only: severe narrowing of the gastrointestinal tract or dysphagia; risk of obstruction
- Safety and efficacy has not been established in patients older than 60 years of age.
- Susceptibility to open-angle glaucoma.
- Pregnancy or breast-feeding (see section 12)
- Potential for abuse, misuse, or diversion.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after the patient has been on treatment for at least 12 weeks, is stable and the dose optimised with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- Dose or formulation adjustments can be managed in primary care with advice/input from the specialist.
- Termination of treatment can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.

Initial stabilisation:

Recommended starting dose in ADHD:

- Immediate release tablets: 5 mg, given 2-3 times daily
- Modified release tablets: 18 mg daily, given in the morning
- Modified release capsules: 10-20 mg daily

Adults with ADHD who have shown clear benefit from methylphenidate in childhood or adolescence may continue treatment into adulthood at the same daily dose. Consult SPC for the prescribed brand for more information.

Methylphenidate must be prescribed by the initiating specialist during initiation and dose stabilisation.

Maintenance dose (following initial stabilisation):

The dose of methylphenidate should be titrated to response, usually at weekly intervals.

Maximum dose in ADHD:

- Immediate release tablets: up to 100 mg daily in 2-3 divided doses
- Modified release tablets: up to 108 mg once daily, given in the morning
- Modified release capsules: up to 100 mg daily. May be given as a single dose in the morning or in divided doses in the morning and at midday, depending on brand.

The maximum licensed daily dose varies with formulation and brand; consult BNF and SPC.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. This should be undertaken and supervised by the specialist who will advise the patient and primary care prescriber of the outcome. Alternatively, this can be managed in primary care within the competence of the prescriber (section 8).

If there are concerns about declining renal/hepatic function, discuss and agree the need for periodic hepatic/renal monitoring on an individual patient basis with the specialist.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Methylphenidate hydrochloride. **Standard release tablets:** Medikinet®: 5mg, 10mg, 20mg

	Methylphenidate hydrochloride (generic): 5mg, 10mg, 20mg Ritalin®: 10mg Tranquilyn®: 5mg, 10mg, 20mg **NB: Methylphenidate standard release tablets are not licensed for use in adults. Use is considered off-label.** Brand name prescribing is not necessary for standard release tablets. **Prolonged-release tablets:** NB: Modified-released preparations vary in their release characteristics and guidance from the MHRA states that methylphenidate must be prescribed according to brand. Concerta XL®: 18mg, 27mg, 36mg, 54mg Delmosart®: 18mg, 27mg, 36mg, 54mg Matoride XL®: 18mg, 36mg, 54mg Xaggitin XL®: 18mg, 27mg, 36mg, 54mg Xenidate XL®: 18mg, 27mg, 36mg, 54mg Affenid XL®: 18mg, 27mg, 36mg, 54mg **NB: Not all methylphenidate prolonged-release tablets are licensed for use in adults. Please consult the relevant SPC for brand-specific licensing information, to see if prescribing is off-label.** **Modified-release capsules:** NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. The specialist must specify the brand to be prescribed. Equasym XL®: 10mg, 20mg, 30mg Medikinet XL®▼: 5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg Metyrol XL®: 10mg, 20mg, 30mg, 40mg, 60mg Meflynate XL®: 10mg, 20mg, 30mg, 40mg, 60mg Ritalin XL®: 10mg, 20mg, 30mg, 40mg, 60mg **NB: Ritalin XL, Medikinet XL, Metyrol XL and Meflynate XL modified-release capsules are licensed for initiation and continuation in adults. Equasym XL is not licensed for use in adults** **Please consult the relevant SPC for brand-specific licensing information.**
Administration details:	Methylphenidate can be taken with or without food, but patients should standardise which method is chosen. Administration requirements vary by formulation and brand. Prolonged-release tablets must be swallowed whole with the aid of liquids, and must not be

	chewed, divided, or crushed. Methylphenidate capsules can be opened and sprinkled on a small amount of soft food for administration. Please consult the relevant SPC for brand-specific information. If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose.
Other important information:	Methylphenidate is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. The choice of formulation will be decided by the treating specialist on an individual basis, and depends on the intended duration of effect. Risk of misuse can be reduced by using modified-release preparations. Alcohol may exacerbate CNS adverse effects of methylphenidate and should be avoided during use. Methylphenidate may cause false positive laboratory test results for amphetamines. **In times of medicine shortages, local guidance is available to support clinicians to manage supply disruptions. Management of Stock Shortages (Remedy BNSSG ICB)**

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- **Monoamine oxidase inhibitors (MAOIs):** risk of hypertensive crisis. The combination should be avoided, and use of methylphenidate and MAOIs should be separated by at least 14 days
- **Coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants**: metabolism may be inhibited by methylphenidate. Dose adjustment may be required when starting or stopping methylphenidate.
- **Anti-hypertensive drugs**: effectiveness may be reduced by methylphenidate
- **Other drugs which elevate blood pressure:** risk of additive effects (e.g. linezolid)
- **Alcohol:** may exacerbate adverse CNS effects of methylphenidate
- **Serotonergic drugs**, including SSRIs and MAOIs**:** increased risk of central nervous system (CNS) adverse effects, risk of serotonin syndrome
- **Halogenated anaesthetics:** risk of sudden blood pressure increase during surgery. Avoid methylphenidate on the day of planned surgery.

- **Dopaminergic drugs**, **including antipsychotics**: increased risk of pharmacodynamic interactions including dyskinesias or hypertensive crisis (e.g. risperidone, paliperidone, selegiline, rasagiline)
- **Apraclonidine:** effects decreased by methylphenidate.
- **Carbamazepine:** may decrease methylphenidate levels
- **Ozanimod:** may increase risk of hypertensive crisis
- **Clonidine):** Serious adverse events, including sudden death, have been reported in concomitant use with clonidine

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- Risk assessment for substance misuse and drug diversion
- Height, weight, and body mass index (BMI)
- Appetite
- Blood pressure (BP) and heart rate
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:
  - History of congenital heart disease or previous cardiac surgery
  - Sudden death in a first-degree relative under 40 years suggesting a cardiac disease
  - Shortness of breath on exertion compared with peers
  - Fainting on exertion or in response to fright or noise
  - Palpitations
  - Chest pain suggestive of cardiac origin
  - Signs of heart failure, heart murmur or hypertension
  - Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- After every change of dose: assess heart rate, blood pressure, changes in weight, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Assessment of symptom improvement. Discontinue if no improvement is observed after reaching normal therapeutic doses.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.
Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

In BNSSG the annual review is done in primary care for patients registered at GP practices signed up to the ADHD locally enhanced service (LES) and by the specialist team where the GP practice is not signed up to the LES.

Patients should be encouraged to consider stopping the medication every 1 to 5 years, with the guidance of the specialist if desired. If desired and clinically appropriate, Methylphenidate can be restarted by the GP, referral back into the ADHD service is not necessary.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• Blood pressure and heart rate • Weight and appetite	Every 6 months, and after any change of dose recommended by specialist team.
• Assessment of adherence, and for any indication of methylphenidate abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances.
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD. • Review to include assessment for any new or worsening psychiatric symptoms and sleep problems.	Annually (by primary or secondary care depending on ADHD Annual Review LES uptake)

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP	• In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management • In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.
Weight or BMI outside healthy range, anorexia or weight loss	Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before • additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Haematological disorders Including leukopenia, thrombocytopenia, anaemia or other alterations NB: no haematological monitoring is recommended. Haematological disorders	Contact specialist team. Discontinuation should be considered. Referral to haematology may be warranted; use clinical discretion.

would be a chance finding/due to patient reporting adverse drug reactions.	
Psychiatric disorders New or worsening psychiatric symptoms, e.g. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, depression	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present. Methylphenidate should not be continued unless the benefits outweigh the risks.
Nervous system disorders Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue methylphenidate, refer urgently for neurological assessment
New or worsening seizures	Discontinue methylphenidate. Discuss with specialist team.
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue methylphenidate as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether methylphenidate can be re-started.
Insomnia or other sleep disturbance	Review timing of methylphenidate dose and advise as appropriate. Give advice on sleep hygiene. Discuss with specialist if difficulty persists; dose reduction may be required.
Suspicion of abuse, misuse, or diversion	Discuss with specialist

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Abnormally sustained or frequent and painful erections: seek immediate medical attention.
- Signs or symptoms of serotonin syndrome (e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea)
- Any mood changes, for example. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, anxiety, depression
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory)
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

The patient should be advised:

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Not to drive or operate machines if methylphenidate affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances.
- People who drive must inform the DVLA if their ADHD, or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving or https://www.gov.uk/narcolepsy-and-driving.
- Avoid alcohol while taking methylphenidate, as it may make side effects worse. Avoid recreational drugs.
- Not to stop taking methylphenidate without talking to their doctor. Medical supervision of withdrawal is required, since this may unmask depression or chronic over-activity.
- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely.

It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences.

Patient information:

- Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults
- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Methylphenidate is not recommended for use during pregnancy unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy and/or the pregnant woman.

Evidence on exposure to methylphenidate during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks.

Patients who become pregnant while taking methylphenidate, or who plan a pregnancy, should be referred to the specialist team for review. Ongoing prescribing in pregnancy may be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Healthcare professional information available from: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-METHYLPHENIDATE-IN-PREGNANCY/

Patient information available from: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Methylphenidate/

Breastfeeding:

Methylphenidate has been found in breast milk in small amounts. Evidence for safety in breastfeeding is limited. Decisions to use while breastfeeding should be made on a case-by-case basis, taking into account the risks to the infant and benefits of therapy. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite/weight gain, sleep disturbances, irritability), although these may be difficult to detect. High doses may interfere with lactation, although this is not confirmed in practice.

Healthcare professional information available from: Breastfeeding Medicines Advice service – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Paternal exposure:
No evidence regarding adverse outcomes following paternal exposure was identified.
Further information for patients: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)

13. Specialist contact information

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Name: *Dr Dietmar Hank*
Role and specialty: Consultant Psychiatrist and Clinical Lead Adult ADHD service, AWP
Daytime telephone number: 01275 796262 M-F 9-5
Email address: *Awp.specialisedadhdservices@nhs.net*
Alternative contact:
Out of hours contact details:

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- Specialist Pharmacy Service. Medicines Q&A: Which medicines should be considered for brand-name prescribing in primary care? Prescribing by generic or brand name in primary care – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice on 15/01/2025
- Home Office. Guidance: List of most commonly encountered drugs currently controlled under the misuse of drugs legislation. Updated August 2022. Accessed via https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation on 15/01/2025
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via https://www.nice.org.uk/guidance/ng46/ on 15/01/2025
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- UKTIS. Use of methylphenidate in pregnancy. https://www.toxbase.org/poisons-index-a-z/m-products/methylphenidate-in-pregnancy/ [requires registration to access]

16. Other relevant national guidance

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- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

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Define the referral procedure from specialist to primary care prescriber & route of return should the patient's condition change.

Contact specialist for advice if:

- The patient finds the medication intolerable for any given reason
- If there is concern about observed mental or physical side effects (e.g. depression or hypertension)
- The side effects mentioned above, do not appear to be of a temporary and short lived nature.

Contact named responsible clinician in writing or via secure email detailed in clinic letter.

Also see BNSSG Remedy 'Adult ADHD' page ADHD (adult) (Remedy BNSSG ICB) for information for GP practices signed up to the ADHD LES.

Approved by BNSSG JFG: May 2025
Review date: September 2027
Version 1.3

BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	**Methylphenidate**
Amber ***three months***	
Indication	Part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children and adolescents of 5* years of age and over: • When remedial measures alone prove insufficient • Patient choice is taken into account *Methylphenidate is licenced from 6 years, 'off-label' use for 5 year old patients, but supported by NICE Guideline (NG87; 1.5.13)

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Methylphenidate is a stimulant, whose treatment must be initiated under the supervision of a specialist in childhood behaviour disorders, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Differences in response between different modified release brands have been experienced. GPs should continue prescribing the brand that has been initiated by specialists, unless otherwise instructed. **Xaggitin XL 18mg, 27mg, 36mg and 54mg tablets** (Other brands available Concerta XL*, Xenidate XL and Delmosart) – Initially 18mg once daily, the dose may be adjusted in 18mg increments (dose interval of at least one week) to a maximum licensed dose of 54mg/day (maximum 2.1mg/kg) taken once daily in the morning. Xaggitin brand is considered first line. *Concerta XL under specialist supervision can be increased to a maximum of 108mg/day, maximum licensed dose remains 54mg/day. **Equasym XL 10mg, 20mg, 30mg capsules** Initially 10mg once daily in the morning before breakfast increasing if necessary by at least weekly increments of 5-10mg to a maximum licensed dose of 60mg daily (90mg daily (off-label) may be given under specialist supervision), maximum of 2.1mg/kg. **Medikinet XL 5mg, 10mg, 20mg, 30mg, 40mg, 50mg and 60mg capsules** Initially 10mg once daily in the morning before breakfast increasing if necessary by at least weekly increments to a maximum licenced dose

	of 60mg daily (90mg daily (off-label) may be given under specialist supervision), maximum of 2.1mg/kg. **Methylphenidate immediate release tablets** Initially 5 mg 1-2 times a day, dose is increased if necessary at weekly intervals according to response, increased if necessary up to 60 mg daily in 2–3 divided doses (max licensed dose). 90mg daily in 2-3 divided doses (off-label) may be given under specialist supervision), maximum of 2.1mg/kg daily. If effect wears off in evening (with rebound hyperactivity) a dose at bedtime may be appropriate (establish need with trial bedtime dose). Methylphenidate is classed as a schedule 2 Controlled Drug under the Misuse of Drugs Regulations 2001 (MDR). Prescriptions must therefore conform to the MDR. **It is 'best practice' and AWP procedure to prescribe one month supply or less of any schedule 2 controlled drugs at a time.**
Route and formulation	Oral. Form dependent on manufacturer: • 5mg, 10mg and 20mg Immediate release tablets • 18mg, 20mg, 27mg, 36mg, 54mg, XL/MR tablets • 5mg, 10mg, 20mg, 30mg, 40mg, 50mg and 60mg XL/MR capsules
Duration of treatment	Methylphenidate should be continued for as long as it is effective. **Discontinue if no response seen after 4-6 weeks of expected effective dose.**

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
Monitoring at baseline and during initiation is the responsibility of the specialist; once the patient is optimised on the chosen medicine, with no anticipated changes expected in the immediate future, prescribing will be transferred to the GP. Monitoring will remain with the specialist clinician in secondary care unless specific arrangements are made with GP. Patients will be reviewed by a specialist clinician annually as a minimum. Baseline investigations include: • Cardiovascular status including blood pressure, heart rate, height and weight on growth chart (see table below). • Comprehensive history of concomitant medicines (past and present), co-morbid physical and psychiatric disorders or symptoms, and family history of sudden cardiac/unexplained death. • Assessment of risk of diversion and/or misuse.

Blood tests, ECG and other parameters are not required unless specifically indicated for individual patients.

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	Frequency	Who by	Action/management For paediatric patients the use of a centile chart is recommended
Blood pressure (BP), pulse, weight, height	Prior to medication initiation	Initiating clinician (CAMHS* or Community Paediatrics department)	To prepare for medication titration
BP	After each dose increase, every 6 months and at annual review	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care)	Compare with normal range for age, if there is a clinically significant increase in blood pressure or systolic blood pressure is greater than 95th percentile (measured on 2 occasions), refer to paediatric hypertension specialist; consider dose adjustment or alternative ADHD treatment.
Pulse			Compare with normal range for age. NICE guidance suggests to investigate a resting tachycardia of >120bpm; we suggest to monitor and possibly investigate a sustained resting tachycardia >100bpm; consider ECG; discuss with paediatric physical health colleagues as needed.
Height	Every 6 months		Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Weight	**Children 10 years and under:** 3 monthly **Children over 10 years and young people:**		If there is evidence of significant weight loss or nil weight gain where expected, measure BMI and discuss with patient

	3 and 6 months following initiation and 6 monthly thereafter *More often if concerns arise.*		and family/ carer as appropriate. Strategies to manage weight loss include: -Taking medication with or after food -Additional meals/snacks early morning or late evening when stimulant effects have worn off -Choosing high calorie foods of good nutritional value -Taking a planned break from treatment or changing medication. Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Assessment of adherence and monitoring for effectiveness and adverse effects including suicidal ideation or behaviour, tics, sexual dysfunction, seizures and sleep.	After each dose adjustments, at annual review and as required based on the patient's needs and individual circumstances.	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care)	This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document rationale. Seek secondary care advice. With stimulant medication, this should include review of potential misuse and diversion.

* Children and Adolescent Mental Health Service

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency	Action/management
Headache	Very Common	Usually transient. If it is persistent, consider stopping and consult the specialist team
Decreased Appetite	Very Common	Take medication after breakfast/food; Maximise food intake at times of least appetite suppression; increase snacking, introduce liquid calories (smoothies etc.)
Dry Mouth	Very Common	Contact specialist if persists
Insomnia	Very Common	This may be transient. Make sure medication is taken in the morning Refer to the specialist team if persistent
CVS Symptoms: arrhythmias, tachycardia, hypertension, palpitations	Common	Monitor the BP, pulse, and if necessary perform an ECG. If the resting pulse is consistently >100bpm, contact the specialist team (consideration must be given to child/young person's age and what is expected for age)
Agitation, anxiety, tremor, irritability, dizziness	Common	Common on initiation. Often subsides after several days. If no improvement, consult specialist
Reduced libido, erectile dysfunction	Common	Contact specialist
Dyspnoea	Common	Contact specialist if persists
GI disorders – diarrhoea, constipation, nausea, vomiting, abdominal pain	Common	Contact specialist if persists
Difficulties in visual accommodation	Rare	Usually transient. Optician to check to rule out other causes such as increased intraocular pressure. Contact specialist team if persistent
Serotonin Syndrome	Rare	Can occur when co-prescribed with antidepressants and lithium; stop methylphenidate immediately if suspected and seek expert advice. Early symptoms of serotonin syndrome include tachycardia, shivering, diarrhoea, diaphoresis, muscle cramps, agitation, and elevated body temperature
Leukopenia, thrombocytopenia and anaemia	Rare	Refer to specialist team, medicine may need to be stopped

	Effects on ability to drive and use machines Methylphenidate can cause dizziness, drowsiness and transient visual disturbances including difficulties with accommodation, diplopia and blurred vision (rare). It may have a moderate influence on the ability to drive and use machines. This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:
	• The medicine is likely to affect your ability to drive
	• Do not drive until you know how the medicine affects you
	• It is an offence to drive while under the influence of this medicine
	• However, you would not be committing an offence (called 'statutory defence') if:
	  ○ The medicine has been prescribed to treat a medical problem and
	  ○ You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
	  ○ It was not affecting your ability to drive safely.

Referral back to specialist	Contact specialist for advice if: • There is a query regarding medication efficacy. • Patient finds the medication intolerable for any given reason. • If there is concern about observed mental/psychological or physical side effects (e.g. depression or hypertension). • If medication side effects persist despite intervention. • If patient is pregnant or breastfeeding

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues

Significant Drug Interactions

MAOIs	E.g. moclobemide; risk of hypertensive crisis. Not to be given within 2 weeks of MAOIs.
Volatile liquid anaesthetics	Increased risk of hypertension
Tricyclic antidepressants	Increased levels of TCA as methylphenidate can inhibit metabolism
Antipsychotics and other dopaminergic drugs	Methylphenidate increase extracellular dopamine levels thus may be associated with pharmacodynamic interactions when co-administered with dopamine antagonists or with direct and indirect dopamine agonists.
Antihypertensives	Methylphenidate may reduce the effect of antihypertensives.
Alcohol	Limited data, may increase CNS adverse reactions.
Serotonergic drugs	Potential increased risk of serotonin syndrome with co-administration – monitor and discontinue methylphenidate as soon as possible if suspected.
Clonidine	Serious adverse events including sudden death have been reported with concomitant use.
Others	Not to be given with other sympathomimetics e.g. pseudoephedrine and decongestants.

	Contraindications • Hypersensitivity to sympathomimetic amines or any of the excipients in the particular formulation • Concomitant use of monoamine oxidase inhibitors (MAOIs) or within 14 days after treatment (due to the risk of hypertensive crisis). • Hyperthyroidism or thyrotoxicosis • Agitated states • Advanced arteriosclerosis • Glaucoma • Phaeochromocytoma *For patients with the following contraindications, methylphenidate can be prescribed under certain circumstances after a risk benefit consideration by the specialist has been taken into account:* • Pre-existing / symptomatic cardiovascular disorders including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels) • Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke or known risk factors for cerebrovascular disorders. • Diagnosis or history of recent severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder. • Diagnosis or history of severe and episodic (Type 1) Bipolar (affective) disorder **Special Warnings and precautions** • Tics – stimulants can exacerbate motor and phonic tics and Tourette's Syndrome • Family history of Tourette's syndrome • Aggression – stimulants may cause aggressive behaviour or hostility. • Seizures – stimulants may lower the seizure threshold. • Pregnancy – Seek specialist advice • Breast-feeding – Seek specialist advice • Anxiety **Dose reduction and discontinuation** If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued – advice should be sought from the specialist. Patients should be carefully monitored for the risk of diversion, misuse and abuse of Methylphenidate. Methylphenidate should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion.
Reminder to ask patient about specific problems	Ask about emergence of any possible side effects/compliance to treatment issues.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient:

The patient and/or family/carer should be advised:

1. It is not advisable to drink alcohol, use recreational substances or consume excessive amounts of caffeine whilst taking Methylphenidate.
2. The patient should immediately report abdominal pain, unexplained nausea, malaise, darkening of the urine, jaundice, or suicidal thinking and/or self-harm to the GP.
3. Failure to attend annual reviews could result in the medication being stopped.
4. Patients can choose to try stopping the medication. Annual reviews are an ideal opportunity to discuss this but a desire to stop medication can be expressed and discussed at any time.
5. Information on drug prescribed including a patient information leaflet (PIL). Information on mental health conditions, treatments and medication can be found at:

Choice and Medication
NHS – Attention Deficit Hyperactivity Disorder
Methylphenidate Patient Information Leaflet
Medicines for Children leaflet: Methylphenidate for ADHD

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Communicate changes of medication form, strength or dose to the GP before the next repeat prescription is due (i.e. within 28 days). Note that a change of dose does not itself imply instability, and is usually done as a response to patient growth. If the secondary care clinician feels the medication is not at a stable dose, the GP will be informed that the secondary care provider will supply medication until this is again stable
5. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
6. To provide advice to primary care when appropriate, including queries about medication efficacy and side effects
7. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
8. Stopping treatment where appropriate or providing advice on when to stop.
9. Reporting adverse events to the MHRA.
10. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Initiating Clinician	AWP/ Sirona	As provided on correspondence	As provided on correspondence
Sarah Steel Highly Specialised Clinical Pharmacist	AWP	01249 474542	Sarah.steel6@nhs.net

Section 10: Document Details

Date prepared	28th April 2023
Prepared by	Sarah Steel
Date approved by JFG	October 2023 (Minor update March 2024 updating clinical review frequency)
Date of review	October 2026
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Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Sarah Steel - Highly Specialised Clinical Pharmacist, AWP
2. Samantha Hayer - CAMHS Consultant, AWP
3. Alfred Perrera - CAMHS Consultant, AWP
4. Richard Williams - Consultant Paediatrician, Sirona Care & Health
5. Richard Lee-Kelland - Consultant Community Paediatrician, Sirona Care & Health – from June 2023

Section 12: References

Please list references

1. NICE Guideline [NG87]. Attention Deficit Hyperactivity Disorder: diagnosis and management. Updated 13.09.2019. Accessed Feb 2023.
2. SPC Methylphenidate. Updated 11.11.2022. Accessed Feb 2023.
3. BNF Online. Methylphenidate. Updated September 2022. Accessed Feb 2023.
4. Cortese S, *et al.* Pharmacological and non-pharmacological interventions for adults with ADHD: protocol for a systematic review and network meta-analysis *BMJ Open*. Accessed May 2023.