Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Reference: FOI.ICB-2223/225

Subject: Joint Formulary Group Meeting Minutes

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

QUESTION	RESPONSE
I am writing to request information under the Freedom of Information Act regarding the latest Meeting Minutes of your one committee. Could you please provide the latest meeting minutes for; 1) Bristol, North Somerset and South Gloucestershire Joint Formulary Group at NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board (ICB)?	Please find minutes enclosed. Please note: FOI requests and responses are publicly available and therefore personal information has been redacted. The ICB considers the names included in the enclosed document(s) to be personal information and therefore has applied a section 40 (Personal Information) exemption to this information. The ICB has also applied Section 43(2) to information contained in the document. Section 43(2) exempts from disclosure information which would, or would be likely to, prejudice the commercial interests of any legal person (an individual, a company, the public authority itself, or any other legal entity). Section 43(2) is a qualified exemption and therefore subject to the public interest test. The ICB considers that disclosure of the information would prejudice the commercial interests of an organisation. The information redacted outlines contract prices which are protected across the NHS.

	The public interest argument in favour of disclosing the information include the ICB's responsibility to be transparent and accountable in it's decision making processes and to promote public understanding of processes. The public interest argument in favour of maintaining the exemption includes the ICB responsibility to secure the best use of public resources and provide value for money. There are robust mechanisms to ensure the NHS obtains competitive prices for medicines whilst ensuring that the UK remains a commercially attractive marketplace for pharmaceutical companies. The ICB has considered the requirement to be transparent in its decision making processes and believes that disclosure of the minutes demonstrates how the ICB functions and makes decisions. The ICB has considered the balance of both disclosing the information and maintaining the exemption and believes that it is in the public's best interest to apply the exemption.

The information provided in this response is accurate as of 11 April 2023 and has been approved for release by Dr Joanne Medhurst, Chief Medical Officer for NHS Bristol, North Somerset and South Gloucestershire ICB.

Healthier Together

Improving health and care in Bristol, North Somerset and South Gloucestershire

BNSSG Joint Formulary Group Meeting – Adults

Meeting Held on: Tuesday 31st January 2023
Time: 13:00 – 15:00
Venue: Virtual – Microsoft Teams

Minutes

Present:

xxxxx xxxxx (Chair)	xx	Deputy Director, Medicines Optimisation, BNSSG ICB
xxxxx xxxxx (Minutes)	xx	Team Administrator & Minute Taker, BNSSG ICB
xxxxx xxxxx	xx	Principal Medicines Optimisation Pharmacist, BNSSG ICB
xxxxx xxxxx	xx	GP Clinical Lead in Prescribing for BNSSG ICB
xxxxx xxxxx	xx	Interface Pharmacist, BNSSG ICB
xxxxx xxxxx	xx	Interface Pharmacist, BNSSG ICB
xxxxx xxxxx	xx	Formulary Pharmacist, NBT
xxxxx xxxxx	xx	Lead for Pharmacoeconomics & High Cost Drugs, NBT
xxxxx xxxxx	xx	Clinical Pharmacy Manager, UHBW
xxxxx xxxxx	xx	GP Trainee, BNSSG ICB
xxxxx xxxxx	xx	Medicines Safety Officer and Senior Pharmacist, Sirona
xxxxx xxxxx	xx	Director of Pharmacy, NBT
xxxxx xxxxx	xx	Consultant Neurologist & Neurophysiologist, NBT
xxxxx xxxxx	xx	Clinical Effectiveness Programme Officer, BNSSG, ICB
xxxxx xxxxx	xx	Rotational Pharamcist, NBT
xxxxx xxxxx	xx	Rotational Pharamcist, NBT
xxxxx xxxxx	xx	Rotational Pharamcist, UHBW
xxxxx xxxxx	xx	Rotational Pharamcist, UHBW
xxxxx xxxxx	xx	GP and Clinical Lead in Exceptional Funding and Policy Development, BNSSG, ICB

Apologies:

xxxxx xxxxx	xx	Head of Medicines Optimisation, Sirona
xxxxx xxxxx	xx	Lead Pharmacist for Medicines Safety, Governance, Research and Development, AWP
xxxxx xxxxx	xx	Consultant Pharmacist, Rheumatology, NBT
xxxxx xxxxx	xx	Pharmacy Technician, Medicines Optimisation, BNSSG ICB

Applicants:

xxxxx xxxxx	xx	Consultant, Biochemistry & Metabolic Medicines, UHBW
xxxxx xxxxx	xx	Principal Pharmacist, Medicines Optimisation, BNSSG, ICB
xxxxx xxxxx	xx	Consultant, Interventional Neuroradiology, NBT

1 Welcome, Apologies and Declarations of interests

xx opened the meeting as chair. Introductions were made and apologies were noted as above. The meeting today was quorate. There were no declarations of interests recorded.

2 Minutes of the Previous Meeting from Tuesday 13th December 2022 and Matters arising

The minutes of the previous Joint Formulary meeting from Tuesday 13th December 2022 were reviewed. These were agreed to be an accurate reflection of the meeting, with no amendments to be made.

3 Joint Formulary Group Adults Action Log

Ref 10.1 - Glycopyrronium SBAR – *xx to support with implementation of a review of the Hypersalivation pathway in the context of Glycopyrronium and Botox. Requested actions were: to review how Glycopyrronium compares to total costs for Botox (including clinics) and per annum, to advise of the clinical justification for when Glycopyrronium might be more appropriate over Botox and to incorporate this into the current Botox pathway, to understand which patients could use either option or both and whether the current commissioning pathway needs amending.*

- The formulary team advised it was agreed at the Joint Formulary Group in December 2022 to approve the use of Glycopyrronium for Parkinson's Disease patients with sialorrhoea as TLS Amber 3 months SCP, once the existing SCP for use for Motor Neurone Disease patients was updated to incorporate this indication, and the most cost effective formulation included. The SCP is due to be discussed during today's meeting. It was agreed to close this action.

Ref 12.2 - Penicillamine shared care protocols – *The Formulary team are awaiting further information from the trusts regarding combining existing Penicillamine shared care protocols into a single shared care protocol. Varicella exposure information to be included in the single shared care protocol.*

- The formulary team advised this will be picked up within the shared care protocols work. The group agreed this action can be closed.

Ref 12.4 - Verapamil tablets – NDR – *xx to seek advice from Cardiologist in regards to the dose strength and the monitoring which should be required and to check The British Association for the Study of Headache guidelines for advice on the dose strength and monitoring requirements.*

- The formulary team advised Cardiology have confirmed this has been incorporated into a draft SCP which is due to be discussed during today's meeting. The group agreed this action can be closed.

Ref 18.6 – Thealoz Duo - NDR – *The Formulary team to include Thealoz Duo onto the BNSSG Adult Formulary for treatment in moderate to severe patients with signs of inflammation for a short course as TLS amber 3 months, subject to development/finalisation of the dry eye disease pathway to support primary care and shared care protocol.*

- The formulary team advised this will be picked up by the Dry Eye Disease Working Group and APMOC. The group agreed this action can be closed.

Ref 18.9 – VisuXL Gel – NDR – *The applicant to share the dry eye disease pathway with the Formulary team which will be included on the BNSSG Formulary to support primary care.*

- The formulary team advised this will be picked up by the Dry Eye Disease Working Group and APMOC. The group agreed this action can be closed.

Ref 20.2 – Utrogestan 400mg capsules – NDR – *The Formulary team to include Utrogestan 400mg capsules for treatment of women with a history of at least one previous miscarriage, with an intrauterine pregnancy confirmed by ultrasound scan with symptoms of vaginal bleeding onto the BNSSG Formulary as per NICE guidance as TLS red once internal Trust financial approval has been given.*

- The formulary team advised financial sign off for Utrogestan has not been confirmed. This action is ongoing.

Ref 22.6 – Joint Formulary Group Terms of Reference – *xx agreed to email the differences and comments regarding the Terms of Reference to the group for feedback to discuss at the next Joint Formulary Group.*

- The formulary team advised the Joint Formulary Group Terms of Reference is due to be discussed during today's meeting. The group agreed this action can be closed.

Ref 26.7 – Bempedoic acid with ezetimibe – An update – *xx to liaise with UHBW lipid specialists to check whether a SBAR can be developed and provide evidence of the monitoring which is over and above the SPC recommendations to enable the Joint Formulary Group to review the TLS.*

- The formulary team advised Bempedoic acid with ezetimibe TLS change is on the agenda for discussion during today's meeting. The group agreed this action can be closed.

Ref 27.5 – Melatonin (Adults and Paediatrics): off-label use for sleep disorder in adult and paediatric patients with any of: ADHD, ASD or LD – *The Formulary team to summarise discussions from October meeting and bring back to December meeting for further discussion*

- The formulary team advised Melatonin was discussed during the Joint Formulary Group meeting in December 2022. The group agreed this action can be closed.

Ref 27.6 - Melatonin (Adults and Paediatrics): off-label use for sleep disorder in adult and paediatric patients with any of: ADHD, ASD or LD – *The Formulary team to find out what representation is needed at December JFG and if anyone else needs inviting*

- The formulary team advised Melatonin was discussed during the Joint Formulary Group meeting in December 2022. The group agreed this action can be closed.

Ref 28.5 – Testosterone (Testim) gel – *xx to update the menopause pathway to include Testim gel as a second line option (for those who do not absorb Tostran effectively or require daily dosing).*

- The formulary team have updated the Menopause guideline. The group agreed this action can be closed.

Ref 28.6 – Morphine orodispersible tablets (Actimorph) – NDR – *xxxxx xxxxx to liaise with the ICB Medicines Safety Officers about how to safely manage the introduction of Actimorph and review the pathway for Sevredol, Oramorph and Actimorph.*

- The formulary team advised Actimorph is due to be discussed during today's meeting. The group agreed this action can be closed.

Ref 28.8 – Cyclogest SBAR – *The Formulary team to obtain clarification of financial approval for Cyclogest to be used as an alternative option to Utrogestan from NBT and UHBW.*

- The formulary team have sent an email to acute trusts regarding clarification of financial approval for Cyclogest. UHBW have confirmed they are awaiting financial sign off. This action is ongoing.

Ref 29.7 – Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids – *The formulary team to include Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids onto the Joint Formulary Group agenda in January 2023.*

- The formulary advised Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids is due to be discussed during today's meeting. The group agreed this action can be closed.

Ref 29.8 – Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids – *The formulary team to include Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids onto the BNSSG adult formulary as TLS red, pending confirmation of patient pathway which would allow discussion of whether TLS Amber is appropriate.*

- The formulary team have included Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids onto the BNSSG adult formulary as TLS red, pending confirmation of patient pathway which would allow discussion of whether TLS Amber is appropriate. The group agreed this action can be closed.

Ref 29.9 – Tenecteplase - NDR – *The formulary team to include Tenecteplase for thrombolysis of acute ischaemic stroke prior to thrombectomy onto the BNSSG adult formulary as TLS red on advice of stroke specialist only and in line with agreed criteria. It was agreed for the formulary team to note on the BNSSG adult*

formulary that Tenecteplase is only for patients eligible for both thrombolysis and thrombectomy treatment and is to be used at NBT only.

- The formulary team have included Tenecteplase for thrombolysis of acute ischaemic stroke prior to thrombectomy onto the BNSSG adult formulary as TLS red on advice of stroke specialist only and in line with agreed criteria. The formulary team have included a note on the BNSSG adult formulary that Tenecteplase is only for patients eligible for both thrombolysis and thrombectomy treatment and is to be used at NBT only. The group agreed this action can be closed.

Ref 30 – Tenecteplase - NDR – *NBT to discuss collating evidence outcome data to review in 1 years' time at the Joint Formulary Group and to confirm starting criteria.*

- xx has emailed xx to confirm the starting criteria for Tenecteplase. Applicants have also been advised of request in letter advising them of the outcome of formulary decision. The group agreed to move to 'outcome data' tab on spreadsheet for follow up January 2024. Trust to return with outcome data January 2024.

Ref 30.1 – Insulin eye drops – NDR – *The formulary team to include Insulin eye drops as TLS red for short-term use for patients with corneal persistent epithelial defects that are refractory to usual treatment in clinical practice to promote epithelisation, under the advice of a corneal specialist at Bristol Eye Hospital.*

- The formulary team have included Insulin eye drops as TLS red for short-term use for patients with corneal persistent epithelial defects that are refractory to usual treatment in clinical practice to promote epithelisation, under the advice of a corneal specialist at Bristol Eye Hospital. The group agreed this action can be closed.

Ref 30.2 – Insulin eye drops – NDR – *The formulary team to contact the applicant (xx) to request the applicant conducts review of outcomes with a plan for feeding this back to inform best practice and to ensure prescribing is clinically effective and cost effective.*

- The formulary team have contacted the applicant to request the applicant conducts review of outcomes with a plan for feeding this back to inform best practice and to ensure prescribing is clinically effective and cost effective. The group agreed this action can be closed.

Ref 30.3 – Budesonide (Cortiment®) prolonged release tablets – NDR – *The formulary team to include budesonide MMX (Cortiment®) prolonged release tablets for induction of remission in patients with mild to moderate active ulcerative colitis where 5-ASA treatment is not sufficient or not tolerated as an alternative to other topical/oral corticosteroids if these are unsuitable, onto the BNSSG adult formulary as TLS amber no shared care.*

- The formulary team have included Budesonide MMX (Cortiment®) prolonged release tablets for induction of remission in patients with mild to moderate active ulcerative colitis where 5-ASA treatment is not sufficient or not tolerated as an alternative to other topical/oral corticosteroids if these are unsuitable, onto the BNSSG adult formulary as TLS amber no shared care. The group agreed this action can be closed.

Ref 30.4 – Budesonide (Cortiment®) prolonged release tablets – NDR – *The formulary team to change the traffic light status of Clipper® tablets and Budenofalk® to ensure the formulary aligns with Formulary TLS definitions.*

- The formulary team have changed the TLS of Clipper® tablets and Budenofalk® to ensure the formulary aligns with Formulary TLS definitions. The group agreed this action can be closed.

Ref 30.5 – Budesonide (Cortiment®) prolonged release tablets – NDR – *The formulary team to annotate the formulary listings of oral budesonide to be prescribed by brand as Cortiment® and Budenofalk® should not be used interchangeably due to mode of action and licensing in IBD.*

- The formulary team have updated the formulary website. The group agreed this action can be closed.

Ref 30.6 – Lercanidipine – NDR – *The formulary team to include Lercanidipine for treatment of hypertension as a second line calcium channel blocker option when amlodipine is not tolerated or suitable onto the BNSSG adult formulary as TLS blue, reserved for patients where amlodipine is not tolerated or suitable.*

- The formulary team have included Lercanidipine for treatment of hypertension as a second line calcium channel blocker option when amlodipine is not tolerated or suitable onto the BNSSG adult formulary as TLS blue, reserved for patients where amlodipine is not tolerated or suitable. The group agreed this action can be closed.

Ref 30.7 – Lercanidipine – NDR – *xx agreed to ensure the request to review whether there is a clinical requirement for felodipine to remain on the BNSSG adult formulary is included as part of the upcoming cardiovascular chapter review.*

- xx has circulated the chapter review to secondary care clinicians and has highlighted this point for consideration. The group agreed this action can be closed.

Ref 30.8 – Emollient Chapter Review – *The formulary team to update formulary page with agreed brand changes.*

- The formulary team have updated the formulary page (Emollient Chapter) with agreed brand changes. The group agreed this action can be closed.

Ref 30.9 – Emollient Chapter Review – *xx to advise clinicians of the need for NDRs if they wish for Adex® or Doublebase Once® to be added to the formulary.*

- xxxxx xxxxx (Senior Pharmacist, Medicines Optimisation, BNSSG, ICB) has advised clinicians and NDRs are expected for Adex and Doublebase at a future Joint Formulary Group meeting. The group agreed this action can be closed.

Ref 31 – Emollient Chapter Review – *xx to update the 'First line Emollient' table guidance and take to APMOC as per guideline management process.*

- The formulary team advised the deadline for comments on emollient formulary is Thursday 26th January, then the full emollient formulary and first line emollients will be presented at APMOC in February/April. There is no further requirement from the Joint Formulary Group therefore it was agreed this action can be closed.

Ref 31.1 – Anaesthesia - Adult Chapter Review – *The formulary team to include Morphine to the Perioperative section (15.1.6).*

- The formulary team have included Morphine to the Perioperative section (15.1.6). The group agreed this action can be closed.

Ref 31.2 – Anaesthesia - Adult Chapter Review – *The formulary team to remove 'restriction for NBT ITU only' for Propofol as UHBW use Propofol on ICU within the Extra Corporeal Membrane Oxygenation service.*

- The formulary team have removed 'restriction for NBT ITU only' for Propofol as UHBW use Propofol on ICU within the Extra Corporeal Membrane Oxygenation service. The group agreed this action can be closed.

Ref 31.3 – Glycopyrronium for Parkinson's Disease patients with sialorrhoea – *The formulary team to liaise with clinicians to incorporate the indication of Glycopyrronium for Parkinson's Disease patients with sialorrhoea into the existing SCP for MND and to ensure the most cost effective formulation is recommended. The SCP will need to return to JFG for sign off.*

- The formulary team have emailed xx to request existing SCP for MND to be updated and incorporate PD indication. xx to support with cost effective formulations. SCP will need agreeing with UHBW clinicians. This action is ongoing.

Ref 31.4 – Fluocinolone 0.00625% ointment and cream (Synalar® 1 in 4) – NDR – *The Formulary team to include Fluocinolone 0.00625% ointment and cream (Synalar® 1 in 4) for use as per licensed indications onto the BNSSG adult and paediatric formulary as TLS blue.*

- The formulary team have included Fluocinolone 0.00625% ointment and cream (Synalar® 1 in 4) for use as per licensed indications onto the BNSSG adult and paediatric formulary as TLS blue. The group agreed this action can be closed.

Ref 31.5 – Melatonin – NDR – *The Formulary team to proceed with work required to seek financial approval for option 3 to be added to the adult and paediatric formulary. Option 3 to remain non-formulary until financial approval gained.*

- The formulary team is awaiting financial approval and SCP. This action is ongoing.

Ref 31.6 – Melatonin – NDR – *Formulary team to add to formulary as TLS Amber 3 months once financial approval and SCP protocol including review criteria is agreed.*

- The formulary team is awaiting financial approval and SCP. This action is ongoing.

Ref 31.7 – Biosimilar Insulins- management across adult and paediatric – *The formulary team to remove 'new patients only' and to include a section to advise 'Biosimilar insulins are not interchangeable and should only be switched during the patient's clinical review as a planned process within the BNSSG formulary.*

- The formulary team have removed 'new patients only' and to include a section to advise 'Biosimilar insulins are not interchangeable and should only be switched during the patient's clinical review as a planned process within the BNSSG formulary. The group agreed this action can be closed.

Ref 31.8 – Leuprorelin – *The formulary team to add Staladex® to BNSSG Formulary for prostate cancer only, if in agreement with NBT and UHBW specialists.*

- The formulary team advised there has been agreement from UHBW and NBT that Staladex brand can be added as an option to the formulary for prostate indications only. The formulary team have included Staladex brand onto the Adult Joint Formulary. The group agreed this action can be closed.

The group discussed action references 28.8 and 20.2. xx agreed to liaise with xx and discuss the current financial approval position for Cyclogest and Utrogestan for UHBW.

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4 NICE New Technology Appraisals

NICE New Technology Appraisals published since December 2022 – For information only. *Will be included in the BNSSG Joint Formulary once Implementation plans have been submitted and agreed within NICE TA Review Group*

NICE TA	Commissioner	TLS Status
Slow-release potassium bicarbonate–potassium citrate for treating distal renal tubular acidosis (terminated appraisal)	Terminated Appraisal	
Ruxolitinib for treating acute graft versus host disease refractory to corticosteroids (terminated appraisal)	Terminated Appraisal	
Ruxolitinib for treating chronic graft versus host disease refractory to corticosteroids (terminated appraisal)	Terminated Appraisal	
Carfilzomib with daratumumab and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)	Terminated Appraisal	
Tisagenlecleucel for treating follicular lymphoma after 2 or more therapies (terminated appraisal)	Terminated Appraisal	
Luspatercept for treating anaemia caused by beta-thalassaemia (terminated appraisal)	Terminated Appraisal	
Luspatercept for treating anaemia caused by myelodysplastic syndromes (terminated appraisal)	Terminated Appraisal	
Mepolizumab for treating severe hypereosinophilic syndrome (terminated appraisal)	Terminated Appraisal	
Mepolizumab for treating severe chronic rhinosinusitis with nasal polyps (terminated appraisal)	Terminated Appraisal	
Mepolizumab for treating eosinophilic granulomatosis with polyangiitis (terminated appraisal)	Terminated Appraisal	
Cemiplimab for untreated PD-L1-positive advanced or metastatic non-small-cell lung cancer (terminated appraisal)	Terminated Appraisal	
Cabozantinib for previously treated advanced hepatocellular carcinoma	NHSE	Red
Amivantamab for treating EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy (Not Recommended)	Not Recommended	
Pembrolizumab for neoadjuvant and adjuvant treatment of triple-negative early or locally advanced breast cancer	NHSE	Red
Trifluridine–tipiracil for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma after 2 or more treatments	NHSE	Red

Esketamine nasal spray for treatment-resistant depression (Not Recommended)	Not Recommended	
Avatrombopag for treating primary chronic immune thrombocytopenia	ICB	Red

Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids
XX advised during the last Joint Formulary Group meeting (December 2022) it was agreed for Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids to be TLS red as an interim pending clarification of patient pathway and monitoring requirements (DEXA). The gynaecologists from NBT have confirmed they would review patients at 4, 8 and 12 months and agreed to organise the DEXA scan. NBT are currently awaiting for UHBW to confirm whether this agreement is consistent across the acute trusts. The group agreed to re-review at the next Joint Formulary Group meeting.

Action

1. The Formulary team to include Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids onto the Joint Formulary Group agenda for March 2023.

5 Shared Care Protocols/TLS Status

Traffic Light Status Request Change

Bempedoic Acid (with ezetimibe) from TLS red to TLS amber no SCP for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults in line with NICE TA694.
xx presented the traffic light status request change for Bempedoic acid from TLS red to TLS amber no SCP for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. Bempedoic acid is an adenosine triphosphate citrate lyase inhibitor which inhibits cholesterol synthesis in the liver, thereby lowering LDL-cholesterol. Bempedoic acid with ezetimibe is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults in line with NICE TA694. It is recommended only if statins are contraindicated or not tolerated, ezetimibe alone does not control low-density lipoprotein cholesterol well enough and if the company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement. Bempedoic acid with ezetimibe can be used as separate tablets or a fixed-dose combination. NICE did not stipulate any special prescribing / monitoring requirements for bempedoic acid with ezetimibe. Bempedoic acid (with ezetimibe) is available to prescribe in primary care within the commercial agreement. The current TLS red status in BNSSG is at odds with commissioning arrangements in neighbouring ICS areas which have bempedoic acid with ezetimibe as TLS green or amber. Local specialists anticipate bempedoic acid will only be used infrequently for the small cohort of primary prevention patients, intolerant to statins, who do not meet the criteria for PCSK9 monoclonals / are not eligible for Inclisiran as they have no evidence of cardiovascular disease. The change to TLS amber will be particularly useful to support access to bempedoic acid for patients who are registered with a GP in BNSSG but are seen by specialists in neighbouring ICS areas where the bempedoic acid with ezetimibe is TLS green or amber.

Local specialists have recommended monitoring requirements to include full blood count, ferritin, uric acid, liver function tests, renal function and full lipid profile at 3 months, 12 months and then annually. These recommendations are based on a consensus view from local lipid specialists after review of prescribing and safety information from published data and manufacturer information.

xx explained the rationale for the recommended tests due to the recognised side effects of hyperuricaemia and gout, and a drop in haemoglobin (potentially a drop of 20g/L) which can be clinically significant, in each case there is about 1% of patients experiencing these side effects. Local specialists have advised that relying solely on the clinical presentation of gout and anaemia given the frequency of the adverse effect may not be safe. Lipid specialists recognise that specific biochemical monitoring has not been explicitly recommended by the SPC or NICE TA. Therefore, a pragmatic approach was taken to suggest biochemical monitoring no more stringent than that asked for statin therapy. xx advised the Clear OUTCOMES trial (the cardiovascular outcomes study) is anticipated to be published in the Spring. A press release was recently published. Additional safety data was not published, however, tendon rupture has been added as a noted side effect. It is hoped that further safety and

efficacy data from this study will inform the place of bempedoic acid going forward and support with revision of monitoring recommendations. The current monitoring recommendations are an interim solution.

The group discussed the purpose of U&Es and ferritin monitoring. xx agreed U&Es could be tested at baseline only. Further information is needed to support the recommendation to monitor ferritin. xx explained the mechanism for the drop in haemoglobin is unknown but it has been suggested it is due to an interference with iron metabolism. It was recommended that specific action/guidance is included in a shared care protocol to follow up from the results of these tests.

xx acknowledges that local specialists experience with this drug has been limited due to its position in the pathway i.e. for patients who are statin intolerant, not for lack of efficacy. It cannot be used as an add-on to therapy for patients not achieving target. Most secondary prevention patients who cannot take a statin would have LDL >2.6 therefore would be eligible for Inclisiran. Clear OUTCOMES recruited patients only with LDL >2.6 therefore the results of this trial will not broaden the scope.

While neighbouring ICS formularies include bempedoic acid as TLS green, the potential disadvantage of this status is there may be a risk of this drug being initiated before establishing a true statin intolerance.

The group agreed to change the TLS from red to amber 3 months shared care protocol. The group felt a shared care protocol is required due to the monitoring requirements. The group recommended to change the renal function monitoring requirements to at baseline level only with no further ongoing monitoring and to request further narrative regarding the outcome for ferritin monitoring and guidance on next steps regarding the results.

Action

1. The Formulary team to change the TLS for Bempedoic Acid (with ezetimibe) for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults from TLS red to TLS amber 3 months shared care protocol once a shared care protocol has been developed.

2. The Formulary team to feedback to the applicant the need for a shared care protocol, which should reflect the changes to the monitoring recommendations as discussed at the meeting including changing the renal function monitoring requirements to at baseline level only with no further ongoing monitoring and to request further narrative regarding the outcome for ferritin monitoring and guidance on next steps regarding the results.

New SCPs

Verapamil for cluster headache

xx presented the new shared care protocol for Verapamil immediate release tablets for cluster headaches. Verapamil was approved onto the Adults Formulary in September 2021 as TLS red pending shared care protocol. The shared care protocol outlines a dose titration schedule which exceeds the cardiac dosing. This has been published in the BMJ and has been endorsed locally by specialists. It was agreed for the group to discuss the monitoring requirements in further detail. Cardiology have recommended a small cohort of patients (elderly patients aged 75 and over, and those with longstanding hypertension) would require a repeat ECG 10 days after each dose increase until the patient is at a stable dose. The ECG would also be required on completing and restarting a course of Verapamil. xx advised this cohort requiring additional monitoring has been estimated to be 5 – 10 patients per year. xx advised the main concerns raised to date relate to the infrastructure within primary care to undertake the ECG monitoring, particularly around GP competence and confidence interpreting ECGs for the review of heart block. It is difficult to determine how many ECGs would be required as this would be patient dependent, however, there could be up to 9 dose titrations per a patient before reaching a maximum titration which means up to 9 ECGs. It is advised the patient's dose would be increased every 2 weeks, therefore most of the monitoring would take place in secondary care within the first three months of treatment as the proposed TLS is amber 3 months. The group discussed the feasibility of primary care conducting and interpreting ECGs for this cohort of patients. Even if commissioned appropriately, like the phlebotomy LES, expert advice would still be required to safely interpret abnormal ECGs and review of heart block as suggested in the SCP. It was suggested whether a practitioner who specialises in ECGs within primary care could be commissioned for this piece of work, however this is not currently in place. Cardiology advice and guidance may not provide the timely response required to continue dose titrations for patients experiencing a cluster headache. The group pointed out it may be difficult for elderly patients to routinely attend hospital for an ECG at each titration dose.

The group agreed to discuss the interface work further at the Primary Care Operational Group (PCOG). The group agreed to change the TLS to amber 3 months for patients who are <75 years old without a longstanding history of hypertension to support the majority of patients with cluster headache on verapamil access treatment. It was agreed due to the lack of suitable infrastructure in primary care to undertake and interpret ECGs for the higher risk cohort, it was agreed this proportion of patients should be managed by the specialist team in secondary care and the TLS for this cohort i.e. patients who are ≥75 years old or have a long history of hypertension, to remain red.

Action

1. xx/xx to discuss the interface work further at the Primary Care Operational Group (PCOG).

2. The Formulary team to update the adults' formulary with the TLS change to amber 3 months for cluster headache. Verapamil remains TLS red for a specific cohort of patients i.e. for patients aged 75 and over and patients with longstanding hypertension.

3. The Formulary team to update the shared care protocol to define the cohort of patients for whom verapamil is TLS amber 3 months.

Glycopyrronium for hypersalivation (sialorrhoea)/ saliva management in people with swallowing problems (bulbar dysfunction) and with neurological conditions, motor neurone disease (MND) or Parkinson's Disease (PD) in line with the hypersalivation pathway

xx presented the new shared care protocol for Glycopyrronium for hypersalivation (sialorrhoea)/ saliva management in people with swallowing problems (bulbar dysfunction) and with neurological conditions, motor neurone disease (MND) or Parkinson's Disease (PD) in line with the hypersalivation pathway. xx advised Parkinson's Disease has been included into the indications section within the shared care protocol. Due to cost and availability being variable, it was agreed to include 'Costs between formulations vary considerably. Where clinically appropriate, the most cost-effective option should be prescribed.' There is a prescribing message on ScriptSwitch as a guide to support prescribers within primary care. In terms of dose and frequency, 'Low doses may be initiated and titrated upwards to minimise the risk of adverse effects including confusion' has been included. The group approved the new shared care protocol for Glycopyrronium.

Action

1. The Formulary team to upload the new shared care protocol for Glycopyrronium for hypersalivation (sialorrhoea)/ saliva management in people with swallowing problems (bulbar dysfunction) and with neurological conditions, motor neurone disease (MND) or Parkinson's Disease (PD) in line with the hypersalivation pathway onto the formulary website.

Updated SCPs

Nil

6 Items for Discussion

Actimorph SBAR

xx presented the Actimorph SBAR to the group. The new drug request for Actimorph (morphine sulfate immediate release) orodispersible tablets for the management of pain was submitted to the Joint Formulary Group in November 2022. It was concluded that there is sufficient evidence to support the inclusion of Actimorph orodispersible table as an alternative to morphine oral solution when oral solution is not suitable due to safety concerns or where liquid medicines are not tolerated. During the Joint Formulary Group in November 2022, the group agreed in principle that Actimorph has a place in therapy and should be included onto the BNSSG adult formulary, however, before Actimorph is included onto the Formulary, the group requested further investigation to ensure there is safe introduction of Actimorph in practice, to consider the pathway and to explore whether Sevredol is still required on the BNSSG formulary. The group also requested review of bioavailability data to consider if the onset of action was similar for Actimorph and Oramorph and guide if different immediate release preparations could be used interchangeably.

xx liaised with NBT, UHBW, Weston General Hospital, Weston Hospice Care, St. Peter's Hospice and Sirona. All providers were supportive of the addition of Actimorph onto the BNSSG Formulary in line with the formulary application with emphasis on its use in specific cohorts of patients such as those requiring small doses. Actimorph is available in a wider range of strengths including 1mg, 2.5mg, 5mg, 20mg and 30mg orodispersible tablets. The lower strength would be considered a safe alternative to oral morphine sulfate solution particularly for patients who may have difficulty measuring small doses using an oral syringe. It would also remove the risk of inappropriate administration of oral morphine sulfate solution as patients may 'swig' from a bottle increasing the risk of overdose. There were concerns relating to the schedule of Actimorph compared to Oramorph and the impact this would have on staff capacity to administer a schedule 2 CD. Oramorph may continue to be used for inpatients, acknowledging Actimorph may be an appropriate formulation of choice on discharge. xx advised oral morphine sulfate solution is a more cost-effective option, therefore for patients who can safely administer with oral solution, this should remain the first line choice as TLS green and Actimorph may be considered as TLS Blue, as a safe alternative reserved for patients who not able to tolerate oral morphine sulfate solution or if this is not suitable due to safety concerns.

All providers have considered how Actimorph would be safely implemented in their local practice and have acknowledged the main risk lies at the point of discharge or transfer between settings. Suggestions were made to mitigate risk such as not adding Actimorph to ward stock, so Oramorph and Actimorph are not used interchangeably during an inpatient stay (NBT and UHBW), prescribing by brand (Weston), a trial period to assess impact and risk (UHBW) and for all providers, ensuring clinician and pharmacy team education and awareness of the different formulations to facilitate medicines reconciliation on admission and patient counselling on discharge.

Providers did not support the removal of Sevredol from the Formulary as it still well established and still has a place in practice. It is the analgesic of choice in day case joint replacements (NBT). Also, there is likely to be a cohort of patients who prefer a tablet over an orodispersible formulation e.g. dry mouth.

There is limited bioequivalence data for Actimorph compared to Oramorph, however, Martindale Pharma have provided data comparing Actimorph to Sevredol. While data on bioequivalence is limited, there are differences in the bioavailability of the different formulations of immediate release oral morphine sulfate, which may mean that clinical effect of the brands may also differ. When switching between brands patients should be counselled that they may experience changes in symptom management and what to do if this does occur.

The group discussed the TLS status for Actimorph, Oramorph and Sevredol. The group agreed for Actimorph to be included onto the Adult BNSSG formulary as TLS blue as an alternative for patients not able to tolerate oral morphine sulfate solution or if this is not suitable due to safety concerns. It was agreed for Sevredol to be TLS blue as an alternative for patients who require a solid dosage form and a higher dose. Oral morphine sulfate solution will remain TLS green as this is an appropriate formulation for most patients and is the lowest acquisition cost.

Action

1. The Formulary team to include Actimorph (morphine sulfate immediate release) orodispersible tablets for the management of pain onto the Adult BNSSG formulary as TLS blue as an alternative for patients not able to tolerate oral morphine sulfate solution or if this is not suitable due to safety concerns.

2. The Formulary team to change the TLS for Sevredol to TLS blue.

3. The Formulary team to annotate the formulary page with counselling advice "When switching between brands, patients should be counselled that they may experience changes in symptom control and it is recommended the patient contacts the prescriber if this happens".

Joint Formulary Group – Terms of Reference

xx presented the updated Joint Formulary Group Terms of Reference to the group. In terms of membership and responsibilities, Public Health Consultant is currently noted as the chair of the meeting, xx advised there are ongoing conversations to try and find a replacement Public Health Consultant to join the Joint Formulary Group. An additional sentence '*Members should give 3 months' notice of resignation from the Committee to enable timely replacement of the resigning member and allow continuity of membership*' has been included to support quoracy and replacement opportunities.

Additional information was proposed '*All NDRs should be completed fully and will be rejected if they are incomplete. The application should have been signed off by the budget holder and speciality lead from a*

financial/service resource and clinical perspective prior to submitting for inclusion to JFG.' The group discussed the process for drugs which require a system-wide budget confirmation as each trust may be working to different timelines/priorities. The group discussed the implications of the ICS budget and agreed to amend this section of the terms of reference to ensure it aligns to ICS decision making processes. The group agreed any new drug requests should be discussed as a system within the draft stage.

'Where a NICE Technology Appraisal decision is expected within the next 12 months, applications for these drugs will not be accepted by JFG' has also been added to the terms of reference. This has been proposed as there will be a national team looking at the evidence base in detail therefore there is a risk of reaching a different conclusion to the NICE recommendation as well as a duplication of work.

xx advised new drug requests would not be accepted if they are not complete. XX will be screening new drug requests to ensure they fulfil the agreement.

The group discussed quoracy for JFG meetings and agreed that for meetings which concern adult agenda items only, the meeting will be quorote with the attendance of seven members: the chair or delegated chair, three members from BNSSG ICB Medicines Optimisation team to include two Medicines Optimisation Pharmacists from the ICB, or their deputies and a GP Clinical lead or other primary care physician and three members *from acute trust providers (UHBW, NBT) to include two pharmacists or their deputies and a consultant or other medical physician.'* The group agreed to change 'deputies' to 'regular members/a named consultant.' It was recommended to change 'The chair' to 'The chair or delegated duty.'

xx advised an additional sentence has been included which is '*The aim will be to reach consensus without the need to resort to a vote. A decision put to a note at the meeting shall be determined by the vote of the quorate membership (see above) including the chair.'*

xx advised 'Environment Impact' has been included into the decision criteria for new drug request considerations. It was agreed to liaise a member of the Sustainability team to the Joint Formulary Group to clarify whether the group could include any additional questions or considerations into the new drug request forms for environment impact/sustainability. The group discussed whether it would be beneficial to invite a patient/lay representative. xx agreed to liaise with the lay representative who routinely attends the IFR panel to ask whether they would be happy to attend a Joint Formulary Group meeting.

xx agreed to update the Joint Formulary Group Terms of Reference as discussed. It was agreed if any members of the group have any additional feedback/comments to email the BNSSG ICB Formulary team.

Action

1. xx to update the Joint Formulary Group Terms of Reference. If any members of the group have any additional feedback/comments to email the BNSSG ICB Formulary team. Further work needed and to return to a future JFG meeting.

2. xx to liaise with the lay representative who routinely attends the IFR panel to ask whether they would be happy to attend a Joint Formulary Group meeting.

New Drug Request Application Paperwork

The group briefly discussed the new drug request application paperwork, but not reviewed in full due to time limits. xx advised PbR excluded is no longer the correct terminology but whether a drug is in tariff is still relevant to the new drug request application. It was agreed to amend the wording of this question on the application form. The group agreed to consider including additional information relating to health inequalities and the impact on health inequality. Due to time constraints during the meeting, it was agreed for the group to review the new drug request application paperwork and email the BNSSG ICB formulary team with any further comments/feedback. xx agreed to liaise with the ICB BNSSG Sustainability team to ask whether there is any additional information regarding suitability/environmental impact could be included within the paperwork.

Action

1. The group to review the new drug request application paperwork and email the BNSSG ICB formulary team with any comments/feedback. The formulary team to include onto the Joint Formulary Group agenda for discussion at a future meeting.

2. xx to liaise with the ICB BNSSG Sustainability team to ask whether there is any additional information regarding suitability/environmental impact could be included within the new drug request application paperwork.

7 New Drugs Requests (NDRS)

Verapamil IA for cerebral arterial vasospasm post-acute aneurysmal subarachnoid hemorrhage, causing focal neurological deficit or reduction in GCS in interventional neuroradiology. *xxxxx xxxxx, Consultant Interventional Radiologist, NBT*

Discussion

xx presented the new drug application for Verapamil IA for cerebral arterial vasospasm post-acute aneurysmal subarachnoid haemorrhage, causing focal neurological deficit or reduction in GCS in interventional neuroradiology. Aneurysmal subarachnoid hemorrhage (aSAH) is a major cause of death and disability. xx advised a proportion of patients who have an acute subarachnoid haemorrhage have vasospasm caused by blood being in the wrong place which creates narrowed blood vessels. xx advised oral Nimodipine is not as effective/quick acting and the vessels become progressively narrow which can reduce perfusion in the brain. If not treated quickly, can result into long term unsalvageable ischaemic damage. Over the past few years, clinicians have been injecting the dilators directly into the intracranial circulation. Verapamil has been shown to last longer compared to Nimodipine. xx advised Nimodipine or Verapamil will sometimes be used in conjunction with stents which would prise the narrow vessels open breaking the muscle connections and then administer the IA vasodilator. This will result in a long last effect and reduce significant morbidity that is associated with vasospasm. xx advised IA Nimodipine has been used for around 10 years within NBT and Verapamil has been in use on a case-by-case basis since 2015. CT angiography is used to determine the state of the patient's vessels and whether the patient would benefit from Nimodipine or Verapamil. There is no evidence to suggest Nimodipine is superior or inferior to Verapamil. However, based clinical experience Verapamil has a longer duration of action. Due to the longer lasting effect with Verapamil, there is a less requirement for future treatment for some patients. The choice between Nimodipine and Verapamil will be considered on a case-by-case basis.

The current formulary treatment option is GTN, Nimodipine and physical angioplasty with balloon however balloon angioplasty cannot be used for all areas of the cerebral vasculature. In terms of other ICB formularies. Verapamil injection is included onto the BSW and Dorset formulary but is not specifically listed for this indication. South East London have included Verapamil injection for Intra-radial artery injection to prevent radial artery spasm in radial access procedures as TLS red. Cambridgeshire and Peterborough, Hampshire and Isle of Wight, Sheffield Teaching Hospitals have included Verapamil injection but the specific indication has not been stated. The American Heart Association/American Stroke Association Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage recommend the use of IA vasodilators as an option.

[XXXXX]. Even if patient numbers increase or retreatment is required, the cost of the drug will be minimal. IA verapamil at doses described in the application is cheaper than alternatives, GTN or nimodipine.

In a recent 2021 retrospective cohort review of high dose IA verapamil (>20mg) to manage symptomatic vasospasm post aSAH, 86 of 188 patients were treated with verapamil. Outcomes included radiographic stroke due to cerebral vasospasm, clinical outcome, and functional status. Overall, 61.5% achieved good functional outcomes between 3 and 12-month follow-up and 25.5% had evidence of vasospasm-related delayed cerebral ischemia (includes patients who did not receive verapamil). 45 of the 86 patients (52.3%) who received verapamil experienced clinical improvement following treatment, 16 (18.6%) did not. Documentation regarding clinical improvement after IA verapamil was not present for 25 patients, if these patients are excluded from analysis, clinical improvement after IA verapamil increased to 74%. Of the 86 patients receiving IA verapamil, 68 survived to discharge, 38 of whom had a good functional outcome.

Decision Criteria used by JFG for NDR

- **1. Patient safety –** No significant safety concerns. Does not appear to compromise haemodynamic stability. Seizures and increases in intracranial pressure have been reported.
- **2. Clinical effectiveness –** Reports of beneficial effect on angiographic response and clinical and functional outcomes. A meta-analysis suggests other vasodilators may have better outcomes than verapamil and that vasodilators were not superior to other treatments.

- **3. Strength of evidence –** Weak evidence to support use - no robust clinical/functional outcome data. Data from case series (some large). No RCTs or head-to-head studies.
- **4. Cost effectiveness or resource impact** – Minimal resource impact.
- **5. Place in therapy relative to available treatments –** Alternative to IA nimodipine – applicant reports longer duration of action.
- **6. National guidance and priorities –** Nil national guidance**.**
- **7.Local health priorities –** Already in use, high priority for speciality to have additional IA option for vasospasm.
- **8.Equity of access –** Included on SE London formulary for IA injection to prevent radial artery spasm in radial access procedures. Not found on formulary websites for this indication.

- **Other considerations:** Off-label use. Treatment options for vasospasm are limited and outcomes following aSAH are poor. The American Heart Association/American Stroke Association support use of IA vasodilators as an option for symptomatic cerebral vasospasm.

Conclusion
The group considered the application, the evidence and the information submitted. There is a paucity of data to support IA verapamil for symptomatic cerebral artery vasospasm post aSAH. This reflects the patient cohort, highly specialist treatment and difficulty carrying out RCTs in this area. Patient outcomes following aSAH are poor and treating vasospasm to help prevent further complications is challenging. The available data reports benefit and there are minimal safety concerns. The group agreed to include Verapamil IA for cerebral arterial vasospasm post-acute aneurysmal subarachnoid haemorrhage, causing focal neurological deficit or reduction in GCS onto the BNSSG adult formulary as TLS red, for use by interventional neuroradiology only. The formulary team advised Nimodipine is currently TLS amber no shared care protocol on the BNSSG Adult Formulary. The group agreed to change the TLS of Nimodipine to TLS red for consistency across the BNSSG Formulary.

Action
1. The Formulary team to include Verapamil IA for cerebral arterial vasospasm post-acute aneurysmal subarachnoid haemorrhage, causing focal neurological deficit or reduction in GCS onto the BNSSG adult formulary as TLS red, for use by interventional neuroradiology only.

2. The Formulary team to change Nimodipine to TLS red for consistency across the BNSSG Formulary.

8 AOB

Sirolimus for treating angiofibroma from tuberous sclerosis complex in people 6 years and older – NDR received, NICE TA expected October 2023

xx advised the formulary team received an application in December from paediatric neurology for unlicensed sirolimus ointment for adults and children with TSC (tuberous sclerosis complex). Topical sirolimus does not currently have a marketing authorisation in the UK for treating angiofibroma from TSC, but it is possible that Hyftor (sirolimus gel) may be in the pipeline for a UK license and NICE are expected to publish a technology appraisal for this indication and potentially licensed product in October 2023. The formulary team were minded to wait for NICE to publish rather than take an application for the unlicensed topical preparation through JFG 6 months prior to publication. This scenario has now been included in the updated Terms of Reference. The group supported this approach to wait for NICE's recommendation.

Action
1. The Formulary team to advise the applicant.

9 Potential NDRs for March Meeting (no paperwork, for information only)

Please note, some applications have not been received yet.

- Ivermectin (unlicensed special) for adult and paediatric patients for treatment of hyperkeratotic scabies that do not respond to topical treatment alone or are severe, crusted or resistant scabies, or for bed-ridden patients or institutional out-breaks *(application received)*
- Biologics for psoriasis high impact sites, for use in adults and children *(application received)*
- Ciclosporin eye drops for a range of severe dry eye conditions *(application not received)*

xxxxx xxxxx/xxxxx xxxxx/xxxxx xxxxx/xxxxx xxxxx
January 2023

Date of Meeting	Time	Venue
~~Tuesday 31st January Adults only~~	~~13:00-16:00~~	~~Microsoft Teams~~
Tuesday 21st March Adult and Paediatrics	09:30 – 13:30	Microsoft Teams
Tuesday 9th May Adults only	13:00-16:00	Microsoft Teams
Tuesday 27th June Adults & Paediatrics	09:30 – 13:30	Microsoft Teams
Tuesday 29th August Adults only	13:00-16:00	Microsoft Teams
Tuesday 17th October Adult & Paediatrics	09:30 – 13:30	Microsoft Teams
Tuesday 12th December Adults only	13:00-16:00	Microsoft Teams