Bristol, North Somerset and South Gloucestershire Integrated Care Board

Reference: FOI.ICB-2223/099

Subject: Formulary Process & Icosapent Ethyl

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

QUESTION	RESPONSE
1. Formulary process: a. The process(es) for drugs which have a NICE Technology Appraisal? b. The name of the formulary committee(s) that will be reviewing this on behalf of your organisation? c. The forthcoming dates of these committee(s) meetings as far as they have been scheduled? d. Name of the committee(s) Secretary and contact details? e. Name of the committee(s) Chair and contact details? f. Copies of the previous two minutes from the committee(s) meetings? g. Copy of the Terms of Reference for the committee(s)? h. Copy of the application form which needs to be completed, where a different form is applicable for different committees, please send over each one?	a. All NICE technology appraisal implementation is managed through the BNSSG (Bristol, North Somerset and South Gloucestershire) NICE College to ensure that the correct infrastructure is in place to deliver the technology through the approval of an implementation plan. This ensures that the patient cohort is identified, the pathway to deliver the technology safely to the patient is place and the financial implications to the system are identified. It is usual that the implementation process is completed prior to the given NICE implementation period and that NICE TAs are automatically added to the BNSSG Joint Formulary within the given timeframe. The BNSSG Joint Formulary Committee agrees and approves the formulary traffic light status (TLS) of the technology this has been assigned as Blue i.e., an option to consider after first line treatments to allow NICE compliance. b. BNSSG Joint Formulary Committee and BNSSG NICE College c. Scheduled meeting dates:

	BNSSG Joint Formulary Committee 13th December 2022 BNSSG NICE College 1st December 2022 d. BNSSG Joint Formulary Committee – Interface Pharmacists & Principal Pharmacist, Medicines Optimisation, BNSSG ICB bnssg.medicines-optimisation@nhs.net BNSSG NICE College - Principal Pharmacist, Medicines Optimisation, BNSSG ICB bnssg.medicines-optimisation@nhs.net e. BNSSG Joint Formulary Committee – Interim Chair, Deputy Director (Medicines Optimisation) BNSSG ICB BNSSG NICE College Chair - Principal Pharmacist, Medicines Optimisation bnssg.medicines-optimisation@nhs.net f. BNSSG Joint Formulary - minutes attached* for July and September 2022, the October minutes will be available following the next meeting on 13th December 2022  01 Joint Formulary Group Adult Minute  02 Sept JFG Minutes 13.09.22 Fir BNSSG NICE College – July and September minutes attached*, no minutes available for October meeting

	03 Final - NICE Minutes 21.07.22FIN 04 NICE Minutes 08.09.22.pdf g. BNSSG Joint Formulary – ToR (Terms of Reference) attached* 05 JFG ToR update Feb 22 FINAL.pdf BNSSG NICE College – ToR attached* – note these currently being updated to reflect change to ICB 06 NICE College TOR update July 201 h. BNSSG Joint Formulary – no paperwork is required to assign a TLS to a NICE TA – this is a standing agenda item. However formulary paperwork is available at: https://remedy.bnssgccg.nhs.uk/formulary-adult/formulary-process-and-paperwork/joint-formulary-paperwork/ BNSSG NICE College Implementation Plan attached*. 07 Implementation Plan Template 2021.

	*Please note that FOI requests and responses are publicly available and therefore personal information has been redacted. The ICB considers the names included in these documents to be personal information and therefore has applied a section 40 (Personal Information) exemption to this information.
2. NICE ask that this is completed within a 90-day window post the Health Technology Appraisal being published in England, this date being **11th October, 2022**. This date has now passed and from what I can see on your publicly available local formulary website, this has not happened to date, https://remedy.bnssgccg.nhs.uk/ For this reason, I am also writing to you to request the following information, i. Has Icosapent Ethyl been reviewed?... ii. …if not, has Icosapent Ethyl been allocated as an agenda item on an upcoming committee(s) meeting? iii. Name of the person who has completed the 'formulary paperwork' on behalf of the drug that will be shared with the committee(s)	We can confirm that TA805 for Icosapent ethyl has been added to the BNSSG Joint Formulary as per NICE guidance. Our records show that this was undertaken on 13th October 2022 – given that the NICE implementation plan was approved no restrictions to use were in place or communicated from 11th -13th October 2022; the time delay for publication on the BNSSG Joint Formulary of 2 days was due to staff capacity. Remedy pathway (bnssgccg.nhs.uk) - https://remedy.bnssgccg.nhs.uk/formulary-adult/chapters/2-cardiovascular-system/26-hyperlipidaemia/

The information provided in this response is accurate as of 17 November 2022 and has been approved for release by Rosi Shepherd, Chief Nurse 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 and Paediatrics

Meeting Held on: Tuesday 26th July 2022
Time: 13:00 – 16:00
Venue: Virtual – Microsoft Teams

Minutes

Present:

XXXX	XX	Principal Medicines Optimisation Pharmacist, BNSSG ICB
XXXX (Minutes)	XX	Team Administrator & Minute Taker, BNSSG ICB
XXXX	XX	GP Clinical Lead in Prescribing for BNSSG ICB
XXXX	XX	Interface Pharmacist, BNSSG ICB
XXXX	XX	Interface Pharmacist, BNSSG ICB
XXXX	XX	Interface Pharmacist, BNSSG ICB
XXXX	XX	Formulary Pharmacist, NBT
XXXX	XX	Lead for Pharmacoeconomics & High Cost Drugs, NBT
XXXX	XX	Clinical Pharmacy Manager, UHBW
XXXX	XX	Senior Medicines Optimisation Pharmacist, Diabetes Lead, BNSSG ICB
XXXX	XX	Director of Pharmacy, NBT
XXXX	XX	GP and Clinical Lead in Exceptional Funding and Policy Development, BNSSG, ICB
XXXX	XX	Consultant Rheumatologist, NBT

Apologies:

XXXX	XX	Clinical Lead Pharmacist, AWP
XXXX	XX	Head of Medicines Optimisation, Sirona
XXXX	XX	Consultant Pharmacist, Rheumatology, NBT
XXXX	XX	Deputy Director Medicines Optimisation, BNSSG ICB
XXXX	XX	Medicines Safety Officer and Senior Pharmacist, Sirona

Applicants:

XXXX	XX	Consultant Dermatology & Skin Cancer Lead, NBT
XXXX	XX	Consultant Anaesthetist, NBT
XXXX	XX	Consultant Obstetrician & Bereavement Lead, NBT
XXXX	XX	Diabetes Specialist Nurse, UHBW

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 New Drugs Request (NDR) – Adults

Tirbanibulin ointment for solar keratosis, *XXXX, Consultant Dermatology and Skin Cancer Lead, NBT*

Discussion

XX presented the new drug request for Tirbanibulin ointment to be included onto the BNSSG Adult Formulary for solar keratosis. Tirbanibulin is indicated for the treatment of non-hyperkeratotic actinic keratosis (Olsen grade 1) of the face or scalp in adults.

The current formulary options are fluorouracil 5% cream (TLS green), and diclofenac sodium 3% gel and fluorouracil 0.5% / Salicylic acid 10% cutaneous solution (both TLS blue). The applicant has advised Tirbanibulin would be considered for Olsen grade 1 solar keratosis (early mild disease) instead of diclofenac 3%. Tirbanibulin is used for 5 days versus 90 days of treatment required for diclofenac 3%. Tirbanibulin has a shorter course of treatment than other formulary options therefore this should improve patient compliance and potentially treatment efficacy. It is recommended to consider other treatment options if the treated area does not show complete clearance after 8 weeks. There are no monitoring requirements specifically for Tirbanibulin.

In terms of cost, Tirbanibulin is more expensive than the first line formulary option of fluorouracil 5% cream as well as second line option diclofenac sodium 3% gel. Depending on length of course and quantity required, Tirbanibulin may be less expensive than fluorouracil 0.5% / Salicylic acid 10% cutaneous solution. Tirbanibulin presents an additional drug cost to the system. The anticipated number of patients likely to receive treatment within BNSSG per year is 500 in secondary care and estimated 2000 within primary care. In terms of evidence, there are no head-to-head studies of Tirbanibulin versus other options for actinic keratosis however a Bayesian network meta-analysis has suggested Tirbanibulin is more effective than diclofenac 3%.

XX joined the meeting to discuss the application in further detail. Actinic Keratosis (AK), synonymous with solar keratosis, are cutaneous lesions that manifest predominantly in sun exposed areas of the skin. XX advised Actinic Keratosis is one of the most common dermatology pathologies seen by clinicians, which reflects the NICE estimation of 23% of the UK population aged 60 and above. The current treatment option is Efudix (fluorouracil 5%) cream but some patients experience difficulty tolerating Efudix due to inflammatory reaction. However, due to the high evidence of use for Efudix this treatment option will remain as the first-line treatment. Diclofenac 3% and Solaraze gel are second-line treatment options. The licensed use for Diclofenac 3% and Solaraze gel is 60-90 days twice a day, which equates to 180 applications. Therefore, there are compliance concerns relating to the second-line treatment options. Tirbanibulin is a 5 day course once daily which is more manageable for patients to support compliance. In terms of other ICB formularies, BSW have included Tirbanibulin onto their formulary as TLS green for actinic keratosis on face or scalp. Gloucestershire have included as TLS red, pending review. Tirbanibulin is non-formulary in Dorset, Somerset and Devon. In terms of treatment choice, XX advised this depends on the individual patient if the patient has significant actinic keratosis or has previously had skin cancer Efudix would be prescribed. Tirbanibulin is only licensed for face or scalp use and for Olsen grade 1 disease.

Decision Criteria used by JFG for NDR

- **Patient safety –** Associated with local skin reactions, application site pruritus and pain. Favourable safety profile, similar to other treatment options.
- **Clinical effectiveness –** More effective at complete clearance of actinic keratosis lesions than placebo. Bayesian network meta-analysis suggests superiority over diclofenac 3% and lower to similar efficacy compared with fluorouracil 5% / fluorouracil 5% + salicylic acid.

- **Strength of evidence –** Limited to two moderate strength RCTs. No head-to-head studies, comparison to existing treatments from a Bayesian network meta-analysis. No long-term efficacy or safety data, or evidence for use for re-treatment.
- **Cost effectiveness or resource impact –** Tirbanibulin represents a cost pressure to the system. SMC found the economic case was demonstrated. AWTTC report that Tirbanibulin is dominant compared to diclofenac 3%.
- **Place in therapy relative to available treatments –** Alternative to diclofenac 3% as a second line option after fluorouracil 5%.
- **National guidance and priorities –** Nil national guidance.
- **Local health priorities –** Use would enable patient choice of available licensed treatment options.
- **Equity of access –** Accepted for use as option in Scotland and Wales. TLS Green in BSW, and East Lancashire. Non-formulary in most other formulary areas. GMMMG reviewing place in pathway.
- **Other considerations -** Short 5 day treatment course compared to current options may improve compliance.

Conclusion

The group considered the application, the evidence and the information submitted. The group agreed there is sufficient evidence to support use of Tirbanibulin 1% ointment as an option for field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp. Tirbanibulin may be a useful option where there are concerns over compliance with other options or where adverse effects associated with fluorouracil are not acceptable/tolerated. The group agreed to include Tirbanibulin onto the BNSSG Adult Formulary as TLS Blue as an alternative to diclofenac 3%. This should be a second line option after fluorouracil 5%.

The group acknowledged that this is still a relatively new treatment option and that further head to head evaluation studies are in progress. The group suggested the applicant could return to the group once the evidence has been published if findings suggest a review of the formulary traffic light status is needed, in particular if there is more evidence to support improved compliance and reduced need for repeat treatment courses, which may present further cost savings to the system.

Action:

1. The Formulary team to include Tirbanibulin ointment for solar keratosis onto the BNSSG Adult Formulary as TLS blue as an alternative to diclofenac 3% and a second-line treatment option after fluorouracil 5%.

Ropivacaine for top up of epidural anaesthesia for instrumental or caesarean delivery, *XXXX, ST6 Anaesthesia and XXXX, Consultant Anaesthetist, NBT*

Discussion

XX presented the new drug request for Ropivacaine to be included onto the BNSSG Adult Formulary for top up of epidural anaesthesia for instrumental or caesarean delivery. The current BNSSG formulary option is “Fizzy lignocaine” which is used to top up an epidural to provide anaesthesia for operative delivery. Fizzy lignocaine is a mix of lignocaine, sodium bicarbonate and adrenaline. The expectation is for Ropivacaine to replace fizzy lignocaine as a first-line option on the BNSSG formulary. Ropivacaine provides surgical anaesthesia suitable for caesarean section on average in 9.5minutes whereas fizzy lignocaine has a faster onset of 6 minutes. Fizzy lignocaine would still be available to use if the priority was a faster onset e.g. emergency situation. There is a significantly lower need for supplemental analgesia with ropivacaine.

XX advised this application is primarily for NBT as UHBW have advised they would like to continue to use fizzy lignocaine. NBT advised Ropivacaine would remove significant potential risk for drug errors involved when having to mix up the fizzy lignocaine. The anticipated number of patients likely to receive treatment within BNSSG are 500-600 per year. This is based on the number of epidural top ups (with either fizzy lignocaine or 0.5% levobupivacaine) at NBT in 2021. In terms of cost, Fizzy lignocaine is £2.60 per dose and 0.75% Ropivacaine is £4.54 per dose. However due to 50-70% cases being offered co-administration with an additional cost of £1.43 with fizzy lignocaine the cost pressure to the system would be approximately £600 per year.

In terms of evidence, the evidence includes two meta-analysis who have assessed the efficacy of Ropivacaine. The evidence suggests fizzy lignocaine as the superior treatment option for onset surgical block. There is very limited evidence to compare the quality of block between Ropivacaine and fizzy

lignocaine. Although there is small evidence in a double blind randomised controlled trial which suggests there is no difference in the quality of blocks between the two options.

XX joined the meeting to discuss the application in further detail. XX noted the safety benefits with using ropivacaine and advised the current formulary option “fizzy lignocaine” involves clinicians performing ‘triple dilution’ by mixing three different drugs (18mL 2% lignocaine, 2mL 8.4% Sodium Bicarbonate, 0.1mL 1:1000 adrenaline). The cohort of patients are usually category 1 caesareans meaning the baby is required to be delivered within 30 minutes. Therefore preparing the correct mixture in an emergency situation under pressure has the potential for serious drug errors. This task is often undertaken out of hours by relatively junior anaesthetists. Fizzy lignocaine has always been used in practice due to not having an alternative product available. XX acknowledged Ropivacaine is a couple of minutes longer for onset than fizzy lignocaine, however notes this is not a clinically significant delay when factoring in the time it takes to transfer patient to the delivery suite. XX advised there have not been any local drug safety incidents relating to fizzy lignocaine, but there have been national incidents.

Decision Criteria used by JFG for NDR

- **Patient safety –** Adverse effects of anaesthesia used to top up epidural may include intraoperative nausea, vomiting, shivering, pruritis and hypotension. Evidence suggests there is no difference in the incidence of adverse effects between all the anaesthetic options.
- **Clinical effectiveness –** Overall, the evidence demonstrates lidocaine has the fastest onset of surgical block compared to ropivacaine. The quality of block of Ropivacaine, as determined by the need for intraoperative supplementation, is superior to levobupivacaine/bupivacaine but non-inferior to lidocaine.
- **Strength of evidence –** Evidence included two meta-analysis that consisted of randomised controlled trials assessing the efficacy of ropivacaine as a top up anaesthetic however, evidence is limited by both small numbers of trials and methodological variance. A review of the evidence available has highlighted the need for a multi-centre, double blinded randomised controlled trial that is powered adequately for the incidence of intraoperative supplementation and onset of surgical block.
- **Cost effectiveness or resource impact –** Ropivacaine 0.75% costs £4.54 per dose compared to £2.60 for fizzy lidocaine (lidocaine 2%, adrenaline 1:200,000, sodium bicarbonate 8.4%), with 50-70% of cases being offered co-administration with costing an additional £1.43. A switch from fizzy lidocaine +/- fentanyl to ropivacaine would be a cost pressure of approximately £600 per year for the cohort of patients at NBT.
- **Place in therapy relative to available treatments –** Ropivacaine would replace fizzy lidocaine at NBT as a top up epidural for instrumental delivery or caesarean section. Fizzy lidocaine would still be available if fastest onset of action is required, but ropivacaine would be first line due to simplicity of administration.
- **National guidance and priorities –** There is a paucity of professional guidance on which agent to use to top up epidurals. Proposed change driven by local specialists at NBT.
- **Local health priorities –** NBT only, UHBW do not wish to change choice of anaesthetic used for top up epidurals.
- **Equity of access –** Ropivacaine is included on some other local formularies although obstetric use is not specified. If approved, it would be used in NBT only therefore inequity in BNSSG.

Conclusion

The group considered the application, the evidence and the information submitted. The group agreed whilst the evidence suggests Ropivacaine is an effective option to top up epidurals for surgical block, ropivacaine has a slower onset of action, non-inferior quality of block and is slightly more expensive than the existing option of fizzy lignocaine. However Ropivacaine would minimise the perceived risk of mixing three drugs to prepare fizzy lignocaine in an emergency setting, presenting safety benefits for patients. Noting these safety risk benefits, XX has agreed to liaise with UHBW to discuss the potential of replacing fizzy lignocaine to Ropivacaine in practice for top up of epidural anaesthesia for instrumental or caesarean delivery. The group agreed to include Ropivacaine for top up of epidural anaesthesia for instrumental or caesarean delivery onto the BNSSG Adult Formulary as TLS red.

Action:

1. The Formulary team to include Ropivacaine for top up of epidural anaesthesia for instrumental or caesarean delivery onto the BNSSG Adult Formulary as TLS red.

Misoprostol for induction of labour, including patients with intrauterine foetal death, XXXX, *Consultant, Women and Children's, NBT*

Discussion

XX presented the new drug request for Misoprostol to be included onto the BNSSG Adult Formulary for induction of labour, including patients with intrauterine foetal death. In terms of dose, 25 microgram is taken orally in combination with mifepristone. The anticipated number of patients likely to receive treatment within BNSSG is 8 per year by NBT. XX advised UHBW will be reviewing their processes within the next year but currently mechanical methods will remain first line. Within NBT, oral misoprostol would be an alternative option to vaginal misoprostol and the local guideline would be amended to include oral misoprostol as an option for patients following shared decision making.

NICE guidance recommends using oral misoprostol in cases of intrauterine death, specifically if patients do not have a scarred uterus (i.e. had a previous caesarean). The RCOG guideline specific to intrauterine foetal death is out of date, therefore not fully appraised, but does show that the use of oral misoprostol at a low dose has been used for at least 12 years prior to the release of the new product. This guidance is in the process of being updated. The International Federation of Gynaecology and Obstetrics (FIGO) released recommendations for using misoprostol alone in patients in 2017. This includes information for induction of labour as well as for IUD specifically.

In terms of cost, oral misoprostol is slightly more expensive than vaginal misoprostol. This is estimated to be around £600 more expensive per trust per year. In regards to other ICB formularies, BSW have included oral misoprostol on their formulary as TLS red (25 microgram tablets for obstetric indications as per trust guideline). Dorset have included as TLS red (mention allowing use of oral tablets vaginally) and Devon TLS red (200microgram tablets).

XX joined the meeting to discuss the application in further detail. XX advised their current guidelines are out of keeping with national guidance from the RCOG, NICE and from the international guidance from FIGO, which suggest lower, oral doses of misoprostol. XX advised whilst the authors of these guidelines acknowledge there is limited data on comparison of doses, at present NBT are working at significantly higher doses of misoprostol than is recommended in guidance. XX advised inducing labour can cause uterine hyperstimulation and uterine rupture. The risk associated with a uterine rupture is maternal death. All treatments have these risks and comparing treatments show that one has a slightly higher risk of one side effect or may have a slower rate of action. Therefore choice of medicine should be a balance of these risks or benefits for the individual patient. RCOG are currently updating their guideline but XX advised the RCOG will be recommending the FIGO dosing. XX advised providers might be keen to identify lowest possible doses because of reduced adverse effects, but that it was also important to consider time to delivery: low doses have been shown to be associated with a longer induction-to-delivery interval and lower overall effectiveness, and evidence has supported the safety of the "higher" doses for women. The group acknowledged the importance of individual patient choice to allow patients to consider the risks and benefits.

Decision Criteria used by JFG for NDR

- **Patient safety –** Oral misoprostol shows the same side effect profile as vaginal with potential for fewer cases of uterine hyperstimulation. May cause more minor side effects than vaginal (as would be expected for systemic therapy).
- **Clinical effectiveness –** Shown to be equivalent to vaginal misoprostol (the product currently used).
- **Strength of evidence –** Multiple meta analyses and a Cochrane review, though this notes that there are not many strong trials.
- **Cost effectiveness or resource impact –** Will have a small resource impact though this may be balanced by ease of administration compared to others and may allow patients to start at home.
- **Place in therapy relative to available treatments –** Will change current Trust guidance on IUFD post 27 weeks
- **National guidance and priorities –** FIGO guidance/ RCOG guidance/ NICE guidance
- **Local health priorities –** To be up to date with other areas/ international guidance, will create some more staff time due to easier administration.
- **Equity of access –** Available in other local locations such as BSW

Conclusion

The group considered the application, the evidence and the information submitted. The group agreed there is good evidence, oral misoprostol is as efficacious as current treatments and allows an oral option in a

distressing time where extra privacy may be highly valued by the patient. It is supported by national and international guidance. The group agreed to include Misoprostol for induction of labour, including patients with intrauterine foetal death onto the BNSSG Adult Formulary as TLS red.

Action:

1. The Formulary team to include oral Misoprostol for induction of labour, including patients with intrauterine foetal death onto the BNSSG Adult Formulary as TLS red.

Trimbow Nexthaler for adult patients with moderate to severe chronic obstructive pulmonary disease (COPD), *XXXX, Respiratory Specialist Pharmacist, NBT*

Discussion

XX presented the new drug request for Trimbow® Nexthaler to be included onto the BNSSG Adult Formulary for adult patients with moderate to severe chronic obstructive pulmonary disease (COPD). Trimbow® NEXThaler is available as a dry powder inhaler (DPI) with a dose counter on the front. Each inhaler contains 120 doses. The addition for Trimbow® NEXThaler is due to the need for lower environmental impact inhalers. The inhaler contains the same ingredients as its MDI counterpart in the Trimbow® portfolio, but with significantly less impact on the environment. The NHS is committed to reducing the environmental impact of inhalers, which has been highlighted in the Investment and Impact Fund 2022/23. To help achieve the targets set by NHS England, expanding the DPI portfolio would be beneficial if patients are going to be switched from an MDI to a DPI, without needing to compromise the active ingredients. In terms of the current BNSSG Adult Formulary options, there is already a DPI triple therapy device available on the BNSSG Adult Formulary (Trelegy Ellipta® - Fluticasone / Umeclidinium / Vilanterol) which is a once daily formulation but there are a cohort of patients who would prefer to have a twice a day regimen due to day and night symptoms (such as Trimbow NEXThaler). Trimbow® Nexthaler would provide this option to patients.

In regards to cost, Trimbow® NEXThaler, Trimbow® MDI and Trelegy Ellipta® are all £44.50 for 30 days' treatment. Therefore, there are no cost implications with including Trimbow® NEXThaler onto the formulary compared to other triple therapy options. Trimbow® is generally well tolerated, with adverse reactions consistent with those of the individual components.

Decision Criteria used by JFG for NDR

- **Patient safety –** The most frequently reported adverse reactions to Trimbow include dysphonia, oral candidiasis, muscle spas ms and dry mouth. The safety profile of Trimbow NEXThaler is similar to that of Trimbow pMDI.
- **Clinical effectiveness –** Trimbow pMDI is already on the BNSSG Joint Formulary therefore a full critical appraisal of the evidence has not been completed.
- **Strength of evidence –** Trimbow pMDI is already on the BNSSG Joint Formulary therefore a full critical appraisal of the evidence has not been completed.
- **Cost effectiveness or resource impact –** Cost neutral as Trimbow NEXThaler is equivalent in price to existing triple therapy options.
- **Place in therapy relative to available treatments –** Trimbow NEXThaler has been included in the recently updated COPD guidelines as follows:

LABA/LAMA/ICS					
Inhaler	**Image**	**Dose**	**Device**	**Inspiratory Flow and Resistance[1]**	**Equivalent CO_2eq annual car miles[2,3]**
Trelegy® Fluticasone/umeclidinium/ vilanterol		1 puff daily	**Ellipta®** Dry powder inhaler	Hard/fast inhalation **Med Low**	25 miles
Trimbow® Beclometasone/formoterol/ glycopyrronium		2 puffs twice daily	**NEXThaler®** Dry powder inhaler	Hard/fast inhalation **Med High**	39 miles
Trimbow® Beclometasone/formoterol/ glycopyrronium		2 puffs twice daily	Metered-dose inhaler	Slow/long co-ordinated inhalation **Low**	624 miles

- **National guidance and priorities –** The Investment and Impact Fund (IIF) which focuses on creating a more sustainable NHS includes an indicator to reduce avoidable inhaler carbon emissions. The

inclusion of a triple therapy DPI with a lower environmental impact will help achieve targets set by NHSE without needing to compromise the active ingredients.

- **Local health priorities –** BNSSG recommend that DPIs and SMIs should be offered first line if clinically appropriate for any newly prescribed inhalers, through shared decision making.
- **Equity of access –** Trimbow NEXThaler is included on neighbouring CCG formularies including BSW, North and East Devon and Kernow CCG formularies.
- **Other considerations -** BNSSG does not advocate 'blanket switching' of patients from MDIs to DPIs as this could be detrimental to patients needing to use inhalers in emergencies or when their control is poor. Any decisions about inhaler choice should be made on an individual basis with the support of a healthcare professional. If the patient has no inhaler preference, consider initiating a DPI (or SMI) if clinically appropriate.

Conclusion

The group considered the application, the evidence and the information submitted. The group agreed to include Trimbow® Nexthaler onto the BNSSG Adult Formulary for adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) as TLS Green.

Action:

1. The Formulary team to include Trimbow® Nexthaler onto the BNSSG Adult Formulary for adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) as TLS Green.

Insulin Lispro (Lyumjev) for diabetes mellitus in adults. *XXXX, Diabetes Specialist Nurse, UHBW*

Discussion

XX presented the new drug request application for Insulin Lispro (Lyumjev®) to be included onto the BNSSG Adult Formulary for diabetes mellitus in adults. The applicant advised Novorapid, Humalog® and Trurapi® would be considered as a first-line treatment and Fiasp® or Lyumjev® would be considered as a second-line treatment if the first-line options are not working for the patient or not tolerated. Lyumjev® has a quicker onset of action than Humalog and Novorapid®.

In terms of cost, Lyumjev® is the same cost as Humalog. Therefore, there are no cost implications with including Lyumjev® onto the BNSSG Adults Formulary. In regards to monitoring requirements, there are no additional monitoring requirements for Lyumjev®. From a safety perspective, Lyumjev® is a high strength formulation therefore it is important to check, as with all insulin administration, that the right formulation, product and dose is being given. XX advised there is a Junior KwikPen® device for Lyumjev® which delivers 0.5 unit doses and despite the name, is only licensed for adult patients. It was agreed to provide additional information on the BNSSG Adult Formulary to advise the KwikPen® is only licensed for adult patients. This aspect has also been fed back to the Medicines Optimisation Quality and Safety group to ask whether this risk needs formally feeding back to the manufacturer.

XX joined the meeting to discuss the application in further detail. XX advised Lyumjev® would benefit patients with post prandial raised blood glucose where alternative options have not been tolerated/effective such as NovoRapid®, Humalog® and Trurapi®. XX advised Lyumjev® would not be a first-line treatment option.

Decision Criteria used by JFG for NDR

- **Patient safety –** 200units/ml is high strength insulin but there are other 'high strength insulins' included on the formulary. Formulary needs to clarify that Junior KwikPen is not suitable for children, it is licensed for adults only and refers to delivering 0.5 unit doses. Product itself reported to be safe
- **Clinical effectiveness –** N/A as critical appraisal not completed
- **Strength of evidence –** N/A as critical appraisal not completed
- **Cost effectiveness or resource impact –** Comparable cost to Humalog
- **Place in therapy relative to available treatments –** Second line option after Humalog and Novorapid
- **National guidance and priorities –** N/A
- **Local health priorities –** Provides another option for patients, where Humalog and Novorapid have not had desirable effect
- **Equity of access –** Included on other formularies, 100units/ml BSW (not 200units/ml)

Conclusion
The group considered the application, the evidence and the information submitted. The group agreed to include Insulin Lispro (Lyumjev®) for diabetes mellitus in adults onto the BNSSG Adult Formulary as TLS Amber no SCP.

Action:
1. The Formulary team to include Insulin Lispro (Lyumjev®) for diabetes mellitus in adults onto the BNSSG Adult Formulary as TLS Amber no SCP.

2. The Formulary team agreed to provide additional information onto the BNSSG Adult Formulary to advise the KwikPen is only licensed for adult patients and to provide additional information regarding the KwikPen device.

Actrapid for diabetes. XXXX, Senior Medicines Optimisation Pharmacist, Diabetes Lead, BNSSG ICB

Discussion
XX presented the new drug request for Actrapid® to be included onto the BNSSG Adult Formulary. Actrapid® is a short-acting, soluble human insulin and may be used in combination with intermediate or long-acting insulin medicinal products. Actrapid® is currently listed on the BNSSG Paediatric Formulary as TLS green but is not listed on the BNSSG Adult Formulary. A root cause analysis was reported in October 2021, in which Novorapid® was given in place of Actrapid® in the treatment of hyperkalaemia. Although this RCA highlighted larger issues around removing insulin from a pre-filled syringe and lack of clarity of guideline it did highlight the omission of Actrapid® from the Adult Chapter. By including Actrapid® in the Adult formulary we will therefore not only replicate the medication options within the Paediatric formulary, removing the potential for a patient's medication becoming non-formulary when they transfer to adult services but also reflect the insulins used within the local Trusts as part of their treatment pathways.

In terms of cost, Actrapid® (10ml vial) is £7.49, Insuman Rapid (3ml cartridges) is £17.50, Humulin S® (10ml vial) is £15.68 and Humulin R® (20ml vial) is an imported product therefore there is no NHS indicative price available. Actrapid® is a more cost effective treatment option than the other products on the BNSSG Adult Formulary.

Decision Criteria used by JFG for NDR

- **Patient safety –** No known additional safety concerns with this brand
- **Clinical effectiveness –** N/A as critical appraisal not completed
- **Strength of evidence –** N/A as critical appraisal not completed
- **Cost effectiveness or resource impact –** More cost effective than other formulary options
- **Place in therapy relative to available treatments –** Use as a short-acting, soluble human insulin
- **National guidance and priorities –** An option for treatment for diabetes
- **Local health priorities –** Formulary update would reflect local usage and ensure continuity for paediatric patients reaching adulthood
- **Equity of access –** Already prescribed in trusts and paediatrics

Conclusion
The group considered the application, the evidence and the information submitted. The group agreed by including Actrapid® onto the BNSSG Adult Formulary would not only replicate the medication options within the Paediatric formulary, removing the potential for a patient's medication becoming non-formulary when they transfer to adult services but also reflect the insulins used within the local Trusts as part of their treatment pathways. The group agreed to include Actrapid® onto the BNSSG Adult Formulary as TLS Green.

Action:
1. The Formulary team to include Actrapid® onto the BNSSG Adult Formulary as TLS Green.

Admelog for diabetes. XXXX, Senior Medicines Optimisation Pharmacist, Diabetes Lead, BNSSG ICB

Discussion

XX presented the new drug request for Admelog® to be included onto the BNSSG Adult Formulary. XX advised Admelog® is a biosimilar insulin similar to Humalog. Admelog® indication is for the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Admelog® is also indicated for the initial stabilisation of diabetes mellitus.

In terms of cost, Admelog® is more cost effective than Humalog. During the chapter review the use of biosimilars has been discussed at the Diabetes safety working group (a sub-group of the Diabetes Programme Board) and with various clinicians across the system. There have been no objections raised to the inclusion of biosimilar insulins to the BNSSG formulary in general or specifically for Admelog®. However, it is proposed that its inclusion would initially be TLS green (for new patients only). This will allow time for a wider piece of work planned, as part of the Diabetes Medicines and Devices group (a further sub-group of the Diabetes Programme Board) in conjunction with the Diabetes safety working group to facilitate a system-wide approach to a switch programme. This programme will be embedded with education and clinician support to facilitate the safe move to greater use of biosimilar insulins across the system whilst allowing the ICB to gain from the associated financial savings. XX advised the pre-filled pen device for Admelog® is a SoloStar® device and education around insulin devices is a current working priority for the Diabetes Medicines Safety working group. Whilst in the future the traffic light status for Admelog® would need to change to support the above mentioned biosimilars switch, local clinicians are keen to keep other insulin devices available to enable the ongoing individualisation of patient care with appropriate device selection for each patient.

Decision Criteria used by JFG for NDR

- **Patient safety –** Similar efficacy and safety demonstrated compared to Humalog
- **Clinical effectiveness –** N/A as critical appraisal not completed, however SORELLA-1 and 2 studies demonstrate similar efficacy as a biosimilar
- **Strength of evidence –** N/A
- **Cost effectiveness or resource impact –** Cost effective option
- **Place in therapy relative to available treatments –** First line option for new patients who require a very rapid acting insulin
- **National guidance and priorities –** Biosimilar work is a priority nationally to release savings
- **Local health priorities –** Priority as part of the biosimilar work
- **Equity of access –** Provide as an option. It is included on other formularies including Southampton, York and Scarborough, Berkshire

Conclusion

The group considered the application, the evidence and the information submitted. The group agreed to include Admelog® onto the BNSSG Adult Formulary as TLS green for new patients.

Action:

1. The Formulary team to include Admelog® onto the BNSSG Adult Formulary as TLS green for new patients.

Insuman Basal for diabetes. XXXX, Senior Medicines Optimisation Pharmacist, Diabetes Lead, BNSSG ICB

Discussion

XX presented the new drug request for Insuman Basal to be included onto the BNSSG Adult Formulary. Following a review of the BNSSG Adult diabetes chapter review it was noted that the current formulary first line option for Isophane insulin has a higher NHS indicative cost than Insuman Basal. As Isophane insulin is the first line insulin regime in patients with Type 2 diabetes this has the potential to support cost savings across the system even if just prompted as the first line choice. XX advised there may be consideration for future work if a switch were to take place as the 12month potential saving for switching (100%) Humulin I cartridges, Humulin I KwikPens® and Insulatard® cartridges over to Insuman Basal cartridges/pens is calculated to be £96,900. XX advised during a consultation with system wide providers, feedback was positive for the addition of Insuman Basal to the formulary with a note highlighting that it is a more cost-

effective option. However, clinicians were keen to keep the existing preparations on the formulary due to the different devices and the benefit of having choice available when individualizing treatment to best suit patient needs.

Decision Criteria used by JFG for NDR

- **Patient safety –** No safety concerns identified
- **Clinical effectiveness –** N/A – critical appraisal not conducted
- **Strength of evidence –** N/A – critical appraisal not conducted
- **Cost effectiveness or resource impact –** Cost effective option for isophane insulin- potential cost saving to the system
- **Place in therapy relative to available treatments –** Could be first line insulin option for type 2 diabetes
- **National guidance and priorities –** Isophane insulin included in NICE diabetes guidelines
- **Local health priorities –** Cost saving
- **Equity of access –** Provides another option for patients

Conclusion
The group considered the application, the evidence and the information submitted. The group agreed to include Insuman Basal onto the BNSSG Adult Formulary as TLS green.

Action:

1. The Formulary team to include Insuman Basal onto the BNSSG Adult Formulary as TLS green.

3 Break

4 Minutes of the Previous Meeting from Tuesday 14th June 2022 and Matters arising

The minutes of the previous Joint Formulary meeting from Tuesday 14th June 2022 were reviewed. These were agreed to be an accurate reflection of the meeting, with no amendments to be made.

5 Joint Formulary Group Adults Action Log

Ref 9.3 – Testosterone (Tostran 2% gel) / (Testogel 50mg/5g gel sachets) - *It was agreed to include Tostran and Testogel to the enhanced service for monitoring.*

- The Formulary team advised the addition of testosterone gel to onto the SMM LES was approved by PCOG and PCCC. The group agreed this action can be closed.

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 further work is being undertaken at NBT to confirm clinic capacity for botox and to scope out other users of glycopyrronium (LD) where the same issues may arise. This action is ongoing.

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 are awaiting more information from the trusts regarding one of the shared care protocols before combining all Penicillamine shared protocols into one. This action is ongoing.

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 are awaiting a shared care protocol from trusts. This action is ongoing.

Ref 15.4 – Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) (Sativex®) oromucosal spray - *XX/XX to confirm where business case needs to be presented within the system.*

- The Formulary team advised this action is ongoing.

Ref 15.6 – Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) (Sativex®) oromucosal spray - *The Formulary team to update formulary if financial approval is given for TLS Red status*

- The Formulary team advised this action is ongoing.

Ref 16.5 – Jorveza (budesonide soluble tablets) – NDR - *The Formulary team to include Jorveza for maintenance treatment of eosinophilic oesophagitis in adults onto the BNSSG Formulary as amber 3 months once a shared care protocol has been developed and approved.*

- The Formulary team advised budesonide orodispersible tablets for maintenance treatment of eosinophilic oesophagitis in adults has been included as TLS amber 3 months onto the BNSSG Formulary. The group agreed this action can be closed.

Ref 17.8 – Guanfacine m/r tablets – NDR - *The Formulary team to include Guanfacine onto the adult BNSSG Joint Formulary as TLS amber 3 months for treatment of ADHD in adults for whom stimulants are not suitable, not tolerated or ineffective as a 4th line option after atomoxetine pending development of a shared care protocol. The Formulary team to include guanfacine as TLS Red in the interim.*

- The Formulary team advised a meeting is scheduled for August to discuss the shared care protocol. This action is ongoing.

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 the Thealoz Duo shared care protocol has been developed. This will be shared with the Joint Formulary Group once the dry eye disease pathway has been finalised.

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 action is ongoing.

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 the acute trusts have concerns regarding the cost, the team are exploring using cyclogest which is also micronised. It was agreed for an SBAR to be presented at a future Joint Formulary Group to discuss trust feedback and concerns relating to cost.

Ref 21.9 – Ospemifene oral tablets - *The Formulary team to review the current vaginal atrophy pathway within the menopause guidelines to ensure the criteria for ospemifene is defined. The updated version is to be shared with the BNSSG menopause working group and to go back to a future APMOC meeting for ratification.*

- The Formulary team advised the Vulvovaginal pathway is due to be presented to the Area Prescribing Medicines Optimisation Committee (APMOC) in August. This action is ongoing.

Ref 22.2 – Sodium zirconium cyclosilicate (Lokelma®) and Patiromer sorbitex calcium (Veltassa®) – TLS – *Trusts to confirm the current spend within the system for patients on maintenance treatment for Lokelma and Veltassa so that this can be compared to the implementation plan costings in the NICE TAs. Applicants to specify spend on each drug if possible.*

- The Formulary team advised UHBW have confirmed the spend on Lokelma last year was £10,250 and £0 for Veltassa. The Formulary team are awaiting feedback from NBT. This action is ongoing.

Ref 22.3 – Sodium zirconium cyclosilicate (Lokelma®) and Patiromer sorbitex calcium (Veltassa®) – TLS – *Trusts to confirm the projected spend if these drugs were more readily available due to a traffic light status change, again specifying this for each drug.*

- The Formulary team advised the Consultants from UHBW believe the change in traffic light status will not increase the patient numbers. The Formulary team are awaiting feedback from NBT.

Ref 22.5 – Sodium zirconium cyclosilicate (Lokelma®) and Patiromer sorbitex calcium (Veltassa®) – TLS – *Applicants to provide specific monitoring recommendations, along with the evidence /rationale behind the monitoring and frequencies of monitoring for the formulary group to review for both Lokelma and Veltassa*

- The Formulary team are awaiting a response from the renal team. 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 this action is ongoing.

Ref 22.8 – Dienogest – NDR – *The Formulary team to include dienogest for adult female patients with confirmed or suspected endometriosis as TLS amber no shared care onto the BNSSG Adult Formulary.*

- The Formulary team advised Dienogest for adult female patients with confirmed or suspected endometriosis has been included onto the BNSSG Adult Formulary as TLS amber no shared care. The group agreed this action can be closed.

Ref 22.9 – Yes! vaginal moisturiser – NDR – *The Formulary team to include Yes! vaginal moisturiser onto the formulary for vaginal atrophy in post-menopausal women with oestrogen sensitive conditions as TLS green.*

- The Formulary team advised Yes! vaginal moisturiser onto the formulary for vaginal atrophy in post-menopausal women with oestrogen sensitive conditions has been included onto the BNSSG Adult Formulary as TLS green. The group agreed this action can be closed.

Ref 23 – Yes! vaginal moisturiser – NDR – *KM (applicant) to provide the formulary team with a specific sentence to include with Yes! vaginal moisturiser onto the BNSSG Formulary to support GPs prescribing vaginal moisturiser treatment for cancer patients whilst the HRT guidance is awaiting sign off.*

- The Formulary team advised the applicant (Dr Kirsty Manley) has provided specific information to include with Yes! vaginal moisturiser onto the BNSSG Formulary to support GPs prescribing vaginal moisturiser treatment for cancer patients whilst the HRT guidance is awaiting sign off. The group agreed this action can be closed.

Ref 23.1 – Dexmedetomidine – ***NDR*** **–** *The Formulary team to include Dexmedetomidine onto the BNSSG Adult Joint Formulary as TLS red for sedation during awake fibre-optic intubation for patients with opioid dependence or who are at higher risk of respiratory depression, hypoxia and over-sedation.*

- The Formulary team advised Dexmedetomidine has been included onto the BNSSG Adult Formulary as TLS red. The group agreed this action can be closed.

Ref 23.2 – Ketamine – NDR – *The Formulary team to include ketamine for management of behavioural disturbance in ED as TLS red on the BNSSG Adult Formulary.*

- The Formulary team advised Ketamine for management of behavioural disturbance in ED has been included onto the BNSSG Adult Formulary as TLS red. The group agreed this action can be closed.

Ref 23.3 – Guanfacine for ADHD – SCP – *The Formulary team, JS, XX, XX and XX to arrange a meeting to review the delivery of guanfacine shared care to ensure this considers patient safety and correct clinical practice.*

- The Formulary team advised a meeting is scheduled in August to discuss the shared care protocol. The group agreed this action can be closed.

Ref 23.4 – Budesonide orodispersible tablets – SCP – *The Formulary team to upload the budesonide orodispersible tablets for maintenance treatment of eosinophilic oesophagitis shared care protocol and pathway onto the BNSSG Formulary website.*

- The Formulary team advised the Budesonide Orodispersible tablets shared care protocol and pathway has been included onto the BNSSG Adult Formulary website. The group agreed this action can be closed.

Ref 23.5 – Colesevelam – SCP – *The Formulary team to include Colesevelam shared care protocol for treatment of bile acid malabsorption (in adults) where Colestyramine is ineffective or not tolerated onto the BNSSG Formulary website.*

- The Formulary team advised the Colesevelam shared care protocol has been included onto the BNSSG Adult Formulary website. The group agreed this action can be closed.

Ref 23.6 – Colesevelam – SCP – *The Formulary team to ensure evidence for monitoring recommendations is reviewed where these are not specified in the Summary of Product Characteristics for future shared care protocols.*

- The Formulary team will review evidence for monitoring recommendations for future shared care protocols. The group agreed this action can be closed.

Ref 23.7 – SBAR- Diabetes Chapter Review (Adults) – *AD to make the agreed amendments to the BNSSG Formulary Adult diabetes chapter.*

- The Formulary team advised the BNSSG Adult Formulary website has been updated. The group agreed this action can be closed.

Ref 23.8 – Dapsone – NDR – *The Formulary team to include dapsone for dermatoses onto the BNSSG Adult Formulary as TLS amber 3 months, once a shared care protocol has been developed and approved and, there has been clarification of the monitoring requirements.*

- The Formulary team is awaiting feedback from the applicant regarding clarification of monitoring requirements and a shared care protocol. This action is ongoing.

Ref 23.9 – Salbutamol tablets to be removed from Adult and Paediatric BNSSG Formulary – *The Formulary Team to remove salbutamol tablets from the Adult BNSSG Formulary.*

- The Formulary team advised Salbutamol tablets have been removed from the Adult and Paediatric BNSSG Formulary. The group agreed this action can be closed.

Ref 24 - iQoro device – *The Formulary Team to arrange for information about iQoro to be included in the Medicines Optimisation newsletter and on ScriptSwitch.*

- The Formulary team advised the information relating to iQoro has been included in the July Medicines Optimisation Newsletter and a message has been included to ScriptSwitch. The group agreed this action can be closed.

6 NICE New Technology Appraisals

NICE New Technology Appraisals published since June 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
Romosozumab for treating severe osteoporosis	ICS	Red
TYRX Absorbable Antibacterial Envelope for preventing infection from cardiac implantable electronic devices	Terminated appraisal	
Filgotinib for treating moderately to severely active ulcerative colitis	ICS	Red
Ibrutinib for treating Waldenstrom's macroglobulinamia	Not recommended	
Diroximel fumarate for treating relapsing-remitting multiple sclerosis	ICS	Red
Anifrolumab for treating active autoantibody-positive systemic lupus erythematosus	Terminated Appraisal	
Enfortumabvedotin for previously treated locally advanced or metastatic urothelial cancer	Terminated Appraisal	

Venetoclax for treating chronic lymphocytic leukemia	NHSE	Red
Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation	NHSE	Red
Faricimab for treating wet age-related macular degeneration	ICS	Red
Faricimab for treating diabetic macular oedema	ICS	Red
Cemiplimab for treating advanced cutaneous squamous cell carcinoma	NHSE	Red
Pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer	NHSE	Red
Teduglutide for treating short bowel syndrome	ICS	Red
Fenfluramine for treating seizures associated with Dravet syndrome	NHSE	Red
Roxadustat for treating symptomatic anaemia in chronic kidney disease	ICS	For discussion*1
Belimumab for treating lupus nephritis	Terminated appraisal	
Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides	ICS	For discussion*2
Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs	ICS	Red

*1The Resource Impact report suggests providers are primary care TA807 Resource impact report (nice.org.uk)
*2 The committee discussion section notes that icosapent is likely to be used mostly in a primary care setting

Roxadustat for treating symptomatic anaemia in chronic kidney disease

XX advised NICE College colleagues are reviewing an implementation plan for Roxadustat. XX advised the trusts have confirmed Roxadustat has a PAS and therefore would be TLS red. If the PAS is available in community the TLS could be amber. The group agreed to re-review at the next Joint Formulary meeting once an implementation plan has been reviewed.

Action

1. NBT to confirm whether the PAS applies to primary care
2. Formulary team to add to September agenda

Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides

XX advised Icosapent ethyl would be primarily a primary care drug due to these cohort of patients already on statin therapy within primary care. Icosapent ethyl would be an additional agent for these patients. Secondary care consultants have fed back that this would be a medicine considered as part of primary care management for most patients. XX advised the NICE costing template has suggested there would be 298 patients eligible which would be a £500,000 cost to the system. It was requested whether a scoping exercise can be undertaken to understand potential patient numbers locally and to assess the cost pressure, whilst noting that uptake of prescribing would not be an immediate effect and would depend on existing capacity within the system. Further work was needed before a traffic light status can be agreed.

Action

1. Further work needed, to re-discuss at September meeting.

7 Shared Care Protocols/TLS Status – Adults

New Shared Care Protocols
Nil

Updated Shared Care Protocols
Nil

Traffic Light Status Request Change

Linaclotide
XX presented the traffic light status request change for Linaclotide from amber 1 month to amber no shared care protocol. XX advised the shared care protocol for Linaclotide has recently been updated and it was identified there is no specific drug monitoring required and the BNF and BNSSG constipation guideline contains all the information that was included in the shared care protocol. Therefore it has been suggested to change the TLS to amber no shared care protocol and to provide a link to the NICE guideline and BNSSG constipation guideline and information on when to initiate on the BNSSG Formulary website. UHBW and NBT have advised they support this change. XX advised when Linaclotide was originally included onto the BNSSG Adult Formulary this was a brand new drug and now there is more experience of use clinically. The group agreed to change the TLS for Linaclotide from amber 1 month to amber no shared care protocol on the BNSSG Adult Formulary.

Action

1. The Formulary team to change the TLS for Linaclotide from amber 1 month to amber no shared care protocol on the BNSSG Adult Formulary and to link to the constipation guidelines and NICE guideline

Potassium Permanganate 400mg tablets
XX presented the traffic light status request change for Potassium Permanganate 400mg tablets. The current TLS on the BNSSG Adult Formulary is green with the following information on the formulary 'On 5th April 2022 a National Patient Safety Alert was issued on the risk of inadvertent oral administration of potassium permanganate. Please refer to the NPSA alert for more information'. The application is to change the TLS from green to TLS blue with the following information updated to 'On 5th April 2022 a National Patient Safety Alert was issued on the risk of inadvertent oral administration of potassium permanganate. Please refer to the NPSA alert for more information'.

A National Patient Safety Alert (NPSA) was published on 5 April 2022 highlighting the inadvertent oral administration of potassium permanganate. Potassium permanganate is routinely used in the NHS as a dilute solution to treat weeping and blistering skin conditions, such as acute weeping/ infected eczema and leg ulcers. Potassium Permanganate is supplied in concentrated forms, either as a 'tablet' or a solution, it requires dilution before it is used as a soak or in the bath. The NPSA alert highlighted incidents where patients had inadvertently ingested the concentrated form of potassium permanganate. Key themes identified from the incidents included healthcare staff administering potassium permanganate orally, patients taking potassium permanganate orally at home or when left on a bedside locker and potassium permanganate incorrectly prescribed as oral medication.

There is no alternative treatment to Potassium Permanganate therefore should remain on the formulary. XX advised the Medicines Optimisation Quality and Safety group are developing a system-wide risk assessment for patients who are prescribed Potassium Permanganate, which will be added to the formulary to support once approved at APMOC (August). The group agreed to change the TLS for Potassium Permanganate 400mg tablets from TLS green to blue on the BNSSG Adult Formulary.

Action

1. The Formulary team to change the TLS for Potassium Permanganate 400mg tablets from green to blue on the BNSSG Adult Formulary.

The following TLS changes are due to the Diabetes Chapter Review which was completed in June 2022

Saxagliptin

XX presented the traffic light status request change for Saxagliptin from TLS green to blue. During the Diabetes chapter review and as part of the cost saving work for the Medicines Optimisation Team a review of DPP-4 inhibitor choice was undertaken. There are currently two DPP-4 inhibitors classed as TLS green on the BNSSG Adult Formulary (Alogliptin and Saxagliptin). Alogliptin is the most cost effective DPP-4 currently on the BNSSG Adult Formulary. There has been ongoing work to promote the use of Alogliptin as the first line choice for DPP-4. There are currently 955 patients within BNSSG prescribed Saxagliptin, however it is not anticipated the TLS change will increase patient numbers. It is therefore proposed to change the TLS status from green to blue for Saxagliptin to reflect this as a second-line option. The group agreed to change the TLS for Saxagliptin from TLS green to blue.

Action

1. The Formulary team to change the TLS for Saxagliptin from green to blue on the BNSSG Adult Formulary.

Dulaglutide and Semaglutide TLS Blue to TLS Green weekly use; Lixisenatide TLS Green to TLS Blue daily use

XX presented the traffic light status request change for dulaglutide and Semaglutide weekly use and Lixisenatide daily use. The current TLS for Dulaglutide and Semaglutide is TLS blue and Lixisenatide is TLS green. The request is to change Dulaglutide and Semaglutide to TLS green for weekly use and Lixisenatide to TLS blue for current patients only, daily use.

XX advised locally within BNSSG prescribing of GLP-1 receptors agonists does not reflect the TLS of the various GLP-1 receptors agonists on the BNSSG Formulary. A patient number search took place in March 2022 which identified of the 5395 patients currently prescribed GLP-1 receptor agonists only 52 patients were prescribed Lixisenatide compared to 2036 for Dulaglutide and 2537 for Semaglutide. In May 2022 the manufacturers of Lixisenatide also announced that they were discontinuing the 10mcg strength of Lixisenatide. As there is no planned update to the license for Lixisenatide the discontinuation of the 10mcg strength removes the option of initiating Lixisenatide in new patients as initiation requires the prescribing of a 10mcg dose for 1 month before transferring to the 20mcg dose. It therefore seems sensible to change the TLS to blue (current patients only). Changing the TLS of Dulaglutide and Semaglutide to green will ensure that when choosing a GLP-1 receptor agonist the first line option is one which has positive cardiovascular outcomes. This TLS change also supports cost effective prescribing as these options are both the same price and less expensive than comparators. The group agreed to change the TLS for Dulaglutide and Semaglutide to TLS green (weekly use) and Lixisenatide to TLS blue for current patients only (daily use) on the BNSSG Adult Formulary.

Action

1. The Formulary team to change the TLS for Dulaglutide and Semaglutide to TLS green (weekly use) and Lixisenatide to TLS blue for current patients only (daily use) on the BNSSG Adult Formulary.

SGLT2 inhibitors- TLS Blue to TLS Green

XX presented the traffic light status request change for SGLT2 inhibitors from TLS blue to green for diabetes indications. The NICE NG 28 Type 2 diabetes in adults: management was updated in February 2022 prompting the offer of sequential initiation of dual first line therapy with metformin and SGLT2i with proven cardiovascular benefit to patients with type 2 diabetes who have established cardiovascular disease or chronic heart failure. The same update also promoted the consideration of this sequential initiation of dual first line therapy in those considered at high risk of cardiovascular disease. Therefore, should a patient subsequently develop cardiovascular disease or chronic heart failure or become at high risk of cardiovascular disease the same principles of offering or considering the addition of an SGLT2i apply. If metformin is contraindicated SGLT2i's may also be a suitable first line option for some patients. The prescribing of SGLT2i's is no longer a second line option and it was felt the traffic light status should be updated to reflect this.

XX advised it is acknowledged that there are significant cost pressures associated with this change in guidance and further work is planned with the Diabetes Medicines and Devices Group to review the value associated with the use of the SGLT2i and linking this to the development of the Diabetes guidelines to support the management of blood glucose in Primary care. The group agreed to change the TLS for SGLT2 inhibitors from TLS blue to green for diabetes indications.

Action

1. The Formulary team to change the TLS for SGLT2 inhibitors from TLS blue to green for diabetes indications.

Abasaglar (Insulin glargine) TLS Green to TLS Blue

XX presented the traffic light status request change for Abasaglar® from TLS green to blue. XX advised Semglee®, which is another biosimilar analogue basal insulin (insulin glargine) has a lower NHS indicative price. By changing the TLS of Abasaglar® to TLS blue, this will support the ongoing work with biosimilar insulin use locally whilst ensuring that the most cost effective option is first line in the formulary. The group agreed to change the TLS for Abasaglar® (Insulin glargine) from TLS green to blue.

Action

1. The Formulary team to change the TLS for Abasaglar® (Insulin glargine) from TLS green to blue.

Semglee (Insulin glargine) TLS Blue to TLS Green

XX presented the traffic light status request change for Semglee®. The TLS change of request is from blue to green. XX advised Semglee® has a lower NHS indicative price than Abasaglar® (Insulin glargine). Abasaglar® is currently the first line analogue basal insulin. By changing the TLS for Semglee®, this will support the ongoing work with biosimilar insulin use locally whilst ensuring that the most cost effective option is first line in the formulary. The group agreed to change the TLS for Semglee® (Insulin glargine) from TLS blue to green.

Action

1. The Formulary team to change the TLS for Semglee® (Insulin glargine) from TLS blue to green.

8 Items for Discussion

Nil

9 AOB

Cilodex® ear drops

XX advised Cilodex® ear drops were included onto the BNSSG Adult Formulary in June 2017. The brand Cilodex® has since been discontinued however a generic Ciprofloxacin with dexamethasone remains on the BNSSG Adult Formulary.

New NDR application form

XX advised there is a new ‘new drug request’ (NDR) application form. The final version of the form will be circulated to the group and UHBW/NBT agreed to use the new NDR application form for a trial for future new drug requests. XX advised the critical appraisal has been separated from the NDR form. This will then be merged into one document by the formulary team once finalised.

Imvaggis

XX advised Imvaggis® is currently on the BNSSG Adult Formulary as TLS green. A meeting took place to discuss the TLS definitions. On reflection from this meeting it is felt Imvaggis® should be TLS blue due to the other alternative options for vulva vaginal atrophy within the menopause guideline e.g. Estring® being TLS blue. The group agreed to change the TLS status for Imvaggis® from TLS green to TLS blue.

Action

1. The Formulary team change the TLS status for Imvaggis® from TLS green to TLS blue.

Anidulafungin

XX advised it has come to light that Anidulafungin was removed from the BNSSG Adult Formulary due to cost (around 6/7 years ago). XX advised NHSE is responsible for the cost. The NBT Microbiology team advised Anidulafungin should be reinstated on the BNSSG Adult Formulary. The group agreed to reinstate Anidulafungin on the BNSSG Adult Formulary.

Action

1. The Formulary team to include Anidulafungin the BNSSG Adult Formulary (TLS Red).

Tranexamic Acid

XX advised Tranexamic Acid is TLS green on the BNSSG Adult Formulary without details of the indications or formulations approved. Boots Outpatient Pharmacy at UHBW have queried whether tranexamic acid 5% mouthwash can be issued as it is not clearly listed on the formulary. This has led to a request to clarify the current formulary position and what process is needed to add tranexamic acid 5% mouthwash to the formulary. NBT confirmed that they would consider the formulary covers all licensed indications and formulations for the drug, unless specifically stated otherwise. Tranexamic acid 5% mouthwash is available as an unlicensed special product and is currently used across BNSSG for Haematology, oncology and palliative care indications. Tranexamic acid 5% mouthwash is often used in place of using oral tablets or solution for injection in an unlicensed manner e.g. crushing tablets. The group concluded that tranexamic acid mouthwash is currently not covered by the current formulary listing.

The group discussed whether all licensed preparations for Tranexamic acid should be specified on the BNSSG Adult Formulary to avoid misinterpretation but agreed this was not necessary and would not be consistent with the majority of other drugs listed on the BNSSG Formulary. Prescribers have the scope to prescribe the most appropriate product for the patient. The group agreed a NDR application form would be required for Tranexamic acid 5% mouthwash, it was agreed to trial the new NDR application form.

Action

1. XX to complete the new NDR application form for Tranexamic acid 5% mouthwash and present at a future Joint Formulary Group meeting.

Flunarizine

XX advised Flunarizine has been included on the BNSSG Paediatric Formulary under Neuropathic pain instead of Migraine. Therefore the formulary team have amended this error and Flunarizine has been moved back under the Migraine section. The group raised no concerns.

10 Potential NDRs for June Meeting (no paperwork, for information only)

Please note, some applications have not been received yet. Three spaces have been reserved for the September meeting for melatonin applications. Capacity of the team will determine which other applications are included for the September JFG meeting

- **Melatonin**- off-label in patients with dementia experiencing circadian sleep disorders, in whom conventional sedation is considered too risky
- **Melatonin**- Off-label use for sleep disorder in adult and paediatric patients with any of:
    - Attention Deficit Hyperactivity Disorder (ADHD)
    - Autism (Slenyto is licensed for this indication in 2-18 year olds)
    - Learning Disabilities (LD) (or Intellectual Disabilities)
- **Melatonin**- Off-label for use on PICU and HDU (during hospital stay only) to aid onset of sleep in patients with neurodevelopmental disorders/ASD and other conditions e.g. bone marrow transplant and renal patients who are suffering from sleep cycle disorder following prolonged stays and who have not responded to standard sleep hygiene measures.
- **IV contrast agent - Perflutren (Luminity)** for diagnostic purposes
- **Tretinoin/clindamycin gel** - acne
- **Intrarosa gel** – (application not yet received)
- **Synalar ointment/cream** - Severe inflammatory skin disorders such as eczemas, psoriasis
- **Oritavancin** -Treatment in adults of acute bacterial skin and skin structure infections (ABSSI)

XXXX/XXXX/XXXX/XXXX
July 2022

Date of Meeting	Time	Venue	Meeting Type
~~25-Jan-2022~~	~~13:00 – 16:00~~	~~Virtual, Microsoft Teams~~	~~Adults Only~~
~~15-March-2022~~	~~09:30 – 13:30~~	~~Virtual, Microsoft Teams~~	~~Adults & Paediatrics~~
~~26-April-2022~~	~~13:00 – 16:00~~	~~Virtual, Microsoft Teams~~	~~Adults Only~~
~~14-June-2022~~	~~09:30 – 13:30~~	~~Virtual, Microsoft Teams~~	~~Adults & Paediatrics~~
~~26-July-2022~~	~~13:00 – 16:00~~	~~Virtual, Microsoft Teams~~	~~Adults Only~~
13-Sept-2022	09:30 – 13:30	Virtual, Microsoft Teams	Adults & Paediatrics
01-Nov-2022	13:00 – 16:00	Virtual, Microsoft Teams	Adults Only
13-Dec-2022	09:30 – 13:30	Virtual, Microsoft Teams	Adults & Paediatrics

BNSSG Joint Formulary Group Meeting – Adults and Paediatrics

Meeting Held on: Tuesday 13th September 2022
Time: 09:30 – 13:30
Venue: Virtual – Microsoft Teams

Minutes

Present:

XXXX (Chair)	XX	Principal Medicines Optimisation Pharmacist, BNSSG ICB
XXXX (Minutes)	XX	Team Administrator & Minute Taker, BNSSG ICB
XXXX	XX	GP Clinical Lead in Prescribing for BNSSG ICB
XXXX	XX	Interface Pharmacist, BNSSG ICB
XXXX	XX	Interface Pharmacist, BNSSG, ICB
XXXX	XX	Interface Pharmacist, BNSSG, ICB
XXXX	XX	Formulary Pharmacist, NBT
XXXX	XX	Medicines Information Pharmacist, UHBW
XXXX	XX	Medicine Safety Officer, Sirona Care and Health
XXXX (joined 10:40)	XX	Chief Pharmacist, Bristol Children's Hospital, UHBW
XXXX (joined 11:30)	XX	Clinical Effectiveness Programme Officer, BNSSG, ICB
XXXX (joined 11:30)	XX	Clinical Effectiveness Programme Officer, BNSSG, ICB
XXXX (joined 11:30)	XX	Clinical Effectiveness Programme Officer, BNSSG, ICB
XXXX (joined 11:30)	XX	Associate Medical Director, Research and Evidence, BNSSG, ICB
XXXX	XX	GP and Clinical Lead in Exceptional Funding and Policy Development

Apologies:

XXXX		
XXXX	XX	Deputy Director (Medicines Optimisation), BNSSG, ICB
XXXX	XX	Clinical Pharmacy Manager, UHBW
	XX	Lead for Pharmacoeconomics & High Cost Drugs, NBT

Applicants:

XXXX	XX	Senior Pharmacist, Medicines Optimisation, BNSSG, ICB
XXXX	XX	Lead Echocardiographer, UHBW
XXXX	XX	Consultant Dermatologist, UHBW
XXXX (joined 11:30)	XX	Consultant Old Age Psychiatrist/Clinical Lead, Bristol Dementia Wellbeing Service
XXXX (joined 11:30)	XX	Consultant Psychiatrist for Older Adults, Medical Lead North Somerset
XXXX (joined 11:30)	XX	Consultant in Mental Health (Adults of all ages), Devon Partnership NHS Trust
XXXX (joined 11:30)	XX	Deputy Chief Pharmacist, AWP
XXXX (joined 11:30)	XX	Consultant Psychiatrist of Intellectual Disability for Salisbury and South Wiltshire, AWP
XXXX (joined 11:30)	XX	Consultant Psychiatrist Adult ADHD, AWP
XXXX (joined 11:30)	XX	Consultant Community Pediatrician, CCHP
XXXX (joined 11:30)	XX	Consultant Community Pediatrician and Clinical Director for Community Paediatrics, Sirona Care and Health
XXXX (joined 13:30)	XX	PICU Pharmacist and Lead Pharmacist for Paediatric Surgery

1 Welcome and Apologies

XX opened the meeting as chair. Introductions were made and apologies were noted as above. The meeting was not quorate due to no secondary care representation at the meeting, therefore any decisions made will need to be ratified via email. There were no declarations of interest recorded.

2 Minutes of the Previous Meeting from Tuesday 26th July 2022 and Matters arising

The minutes of the previous Joint Formulary meeting from Tuesday 26th July 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 the updated documents have been received and a meeting was held on 06/09/2022. The Formulary team are awaiting for updated cost and patient numbers from NBT for this year. XX will discuss with XX to determine whether the information should return to the Joint Formulary Group or to the ICS Medicines Optimisation High Cost Drugs group.

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 are awaiting information from acute trusts. This action is ongoing.

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 are awaiting a shared care protocol from NBT.

Ref 15.6 - Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) (Sativex®) oromucosal spray - *XX/XX to confirm where business case needs to be presented within the system.*

- The Formulary Team had received an updated via NBT DTC. It was agreed for the specialty to work on a business case. This action is ongoing.

Ref 17.8 - Guanfacine m/r tablets – NDR – *The Formulary team to include Guanfacine onto the adult BNSSG Joint Formulary as TLS amber 3 months for treatment of ADHD in adults for whom stimulants are not suitable, not tolerated or ineffective as a 4th line option after atomoxetine pending development of a shared care protocol. The Formulary team to include guanfacine as TLS Red in the interim.*

- A meeting took place to discuss shared care arrangements. The group agreed to update the shared care protocol and discuss at the next Joint Formulary Group meeting in November.

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.*

- XX advised there is a new consultant representative to support the dry eye disease pathway. There is a dry eye disease working group meeting arranged for September 2022. The Thealoz Duo shared care protocol is to be presented at a future Joint Formulary Group meeting, depending on the development of the dry eye disease pathway.

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.*

- XX advised there is a new consultant representative to support the dry eye disease pathway. There is a dry eye disease working group meeting arranged for September 2022.

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 are awaiting for divisional sign off from both trusts. A SBAR will be presented at a future Joint Formulary Group meeting.

Ref 21.9 - Ospemifene oral tablets - *The Formulary team to review the current vaginal atrophy pathway within the menopause guidelines to ensure the criteria for ospemifene is defined. The updated version is to be shared with the BNSSG menopause working group and to go back to a future APMOC meeting for ratification.*

- The Formulary team advised the VVA pathway has been updated and the Menopause guideline has been presented at APMOC (Area Prescribing Medicines Optimisation Committee). The pathway and guideline has been approved and uploaded to Remedy. The group agreed this action can be closed.

Ref 22.2 - Sodium zirconium cyclosilicate (Lokelma®) and Patiromer sorbitex calcium (Veltassa®) – TLS - *Trusts to confirm the current spend within the system for patients on maintenance treatment for Lokelma and Veltassa so that this can be compared to the implementation plan costings in the NICE TAs. Applicants to specify spend on each drug if possible.*

- This Formulary team advised UHBW have confirmed the spend on Lokelma last year was £10,250 and £0 for Veltassa. The Formulary team are awaiting feedback from NBT. This action is ongoing.

Ref 22.3 - Sodium zirconium cyclosilicate (Lokelma®) and Patiromer sorbitex calcium (Veltassa®) – TLS - *Trusts to confirm the projected spend if these drugs were more readily available due to a traffic light status change, again specifying this for each drug.*

- This Formulary team advised the consultants from UHBW believe the change in traffic light status will not increase the patient numbers. The Formulary team are awaiting feedback from NBT. This action is ongoing.

Ref 22.5 - Sodium zirconium cyclosilicate (Lokelma®) and Patiromer sorbitex calcium (Veltassa®) – TLS - *Applicants to provide specific monitoring recommendations, along with the evidence /rationale behind the monitoring and frequencies of monitoring for the formulary group to review for both Lokelma and Veltassa.*

- This Formulary team are awaiting a response from the renal team. 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.*

- This action is ongoing.

Ref 23.8 – Dapsone – NDR – *The Formulary team to include dapsone for dermatoses onto the BNSSG Adult Formulary as TLS amber 3 months, once a shared care protocol has been developed and approved and, there has been clarification of the monitoring requirements.*

- The Formulary team is awaiting feedback from the applicant regarding clarification of monitoring requirements and a shared care protocol. This action is ongoing.

Ref 24.1 – Tirbanibulin – NDR - *The Formulary team to include Tirbanibulin ointment for solar keratosis onto the BNSSG Adult Formulary as TLS blue as an alternative to diclofenac 3% and a second-line treatment option after fluorouracil 5%.*

- The Formulary team have included Tirbanibulin ointment for solar keratosis onto the BNSSG Adult Formulary as TLS blue as an alternative to diclofenac 3% and a second-line treatment option after fluorouracil 5%. The group agreed this action can be closed.

Ref 24.2 – Ropivacaine – NDR - *The Formulary team to include Ropivacaine for top up of epidural anaesthesia for instrumental or caesarean delivery onto the BNSSG Adult Formulary as TLS red.*

- The Formulary team have included Ropivacaine for top up of epidural anaesthesia for instrumental or caesarean delivery onto the BNSSG Adult Formulary as TLS red. The group agreed this action can be closed.

Ref 24.3 – Misoprostol – NDR - *The Formulary team to include oral Misoprostol for induction of labour, including patients with intrauterine foetal death onto the BNSSG Adult Formulary as TLS red.*

- The Formulary team have included oral Misoprostol for induction of labour, including patients with intrauterine foetal death onto the BNSSG Adult Formulary as TLS red. The group agreed this action can be closed.

Ref 24.4 – Trimbow Nexthaler – NDR - *The Formulary team to include Trimbow® Nexthaler onto the BNSSG Adult Formulary for adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) as TLS Green.*

- The Formulary team have included Trimbow® Nexthaler onto the BNSSG Adult Formulary for adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) as TLS Green. The group agreed this action can be closed.

Ref 24.5 – Insulin Lispro (Lyumjev) – NDR - *The Formulary team to include Insulin Lispro (Lyumjev®) for diabetes mellitus in adults onto the BNSSG Adult Formulary as TLS Amber no SCP.*

- The Formulary team have included Insulin Lispro (Lyumjev®) for diabetes mellitus in adults onto the BNSSG Adult Formulary as TLS Amber no SCP. The group agreed this action can be closed.

Ref 24.6 – Insulin Lispro (Lyumjev) – NDR - *The Formulary team agreed to provide additional information onto the BNSSG Adult Formulary to advise the KwikPen is only licensed for adult patients and to provide additional information regarding the KwikPen device.*

- The Formulary team have sent additional information to XXXX/Applicant and are awaiting confirmation. This action is ongoing.

Ref 24.7 – Actrapid for diabetes – NDR - *The Formulary team to include Actrapid® onto the BNSSG Adult Formulary as TLS Green.*

- The Formulary team have included Actrapid® onto the BNSSG Adult Formulary as TLS Green. The group agreed this action can be closed.

Ref 24.8 – Admelog for diabetes – NDR - *The Formulary team to include Admelog® onto the BNSSG Adult Formulary as TLS green for new patients.*

- The Formulary team have included Admelog® onto the BNSSG Adult Formulary as TLS green for new patients. The group agreed this action can be closed.

Ref 24.9 – Insuman Basal for diabetes – NDR - *The Formulary team to include Insuman Basal onto the BNSSG Adult Formulary as TLS green.*

- The Formulary team have included Insuman Basal onto the BNSSG Adult Formulary as TLS green. The group agreed this action can be closed.

Ref 25 – NICE TA - Roxadustat for treating symptomatic anaemia in chronic kidney disease - *NBT to confirm whether the PAS applies to primary care*

- The Formulary team advised the resource impact report now states that this medicine is to be supplied by hospital trust. The Formulary team to include Roxadustat as TLS red onto the BNSSG Adult Formulary.

Ref 25.1 – NICE TA - Roxadustat for treating symptomatic anaemia in chronic kidney disease - *The Formulary team to add to September agenda*

- Change to NICE TA impact statement noted at September meeting. The group agreed this action can be closed.

Ref 25.2 – NICE TA - Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides - *Further work needed, to re-discuss at September meeting.*

- The Formulary team advised this will be reviewed by NICE College. The TLS will be discussed at a future Joint Formulary Group once further work has been completed. This action is ongoing.

Ref 25.3 – Linaclotide – TLS - *The Formulary team to change the TLS for Linaclotide from amber 1 month to amber no shared care protocol on the BNSSG Adult Formulary and to link to the constipation guidelines and NICE guideline.*

- The Formulary team have changed the TLS for Linaclotide from amber 1 month to amber no shared care protocol on the BNSSG Adult Formulary and have included a link to the constipation guidelines and NICE guideline. The group agreed to close this action.

Ref 25.4 – Potassium Permanganate 400mg tablets – TLS - *The Formulary team to change the TLS for Potassium Permanganate 400mg tablets from green to blue on the BNSSG Adult Formulary.*

- The Formulary team have changed the TLS for Potassium Permanganate 400mg tablets from green to blue on the BNSSG Adult Formulary. The group agreed to close this action.

Ref 25.5 – Saxagliptin – TLS - *The Formulary team to change the TLS for Saxagliptin from green to blue on the BNSSG Adult Formulary.*

- The Formulary team have changed the TLS for Saxagliptin from green to blue on the BNSSG Adult Formulary. The group agreed to close this action.

Ref 25.6 – Dulaglutide and Semaglutide TLS Blue to TLS Green weekly use; Lixisenatide TLS Green to TLS Blue daily use - *The Formulary team to change the TLS for Dulaglutide and Semaglutide to TLS green (weekly use) and Lixisenatide to TLS blue for current patients only (daily use) on the BNSSG Adult Formulary.*

- The Formulary team have changed the TLS for Dulaglutide and Semaglutide to TLS green (weekly use) and Lixisenatide to TLS blue for current patients only (daily use) on the BNSSG Adult Formulary. The group agreed to close this action.

Ref 25.7 – SGLT2 inhibitors- TLS Blue to TLS Green - *The Formulary team to change the TLS for SGLT2 inhibitors from TLS blue to green for diabetes indications.*

- The Formulary team have changed the TLS for SGLT2 inhibitors from TLS blue to green for diabetes indications. The group agreed to close this action.

Ref 25.8 – Abasaglar (Insulin glargine) – TLS - *The Formulary team to change the TLS for Abasaglar® (Insulin glargine) from TLS green to blue.*

- The Formulary team have changed the TLS for Abasaglar® (Insulin glargine) from TLS green to blue. The group agreed to close this action.

Ref 25.9 – Semglee (Insulin glargine) - TLS - *The Formulary team to change the TLS for Semglee® (Insulin glargine) from TLS blue to green.*

- The Formulary team have changed the TLS for Semglee® (Insulin glargine) from TLS blue to green. The group agreed to close this action.

Ref 26 – Imvaggis – TLS - *The Formulary team change the TLS status for Imvaggis® from TLS green to TLS blue.*

- The Formulary team have changed the TLS status for Imvaggis® from TLS green to TLS blue. The group agreed to close this action.

Ref 26.1 – Anidulafungin - *The Formulary team to include Anidulafungin the BNSSG Adult Formulary (TLS Red).*

- The Formulary team have included Anidulafungin onto the BNSSG Adult Formulary (TLS Red). The group agreed to close this action.

Ref 26.2 – Tranexamic Acid - *XX to complete the new NDR application form for Tranexamic acid 5% mouthwash and present at a future Joint Formulary Group meeting.*

- The Formulary team advised UHBW have confirmed a new drug request application would be required. XX agreed to fed back to UHBW consultants. The group agreed to close this action.

4 NICE New Technology Appraisals

NICE New Technology Appraisals published since July 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
TA810 Abemaciclib with endocrine therapy for adjuvant treatment of hormone receptor-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence	NHSE	Red
TA809 Imlifidase for desensitisation treatment before kidney transplant in people with chronic kidney disease	NHSE	Red
TA811 Duvelisib for treating relapsed or refractory chronic lymphocytic leukaemia after 2 or more treatments	Terminated appraisal	
TA812 Pralsetinib for treating RET fusion-positive advanced non-small-cell lung cancer	Not recommended	
TA813 Asciminib for treating chronic myeloid leukaemia after 2 or more tyrosine kinase inhibitors	NHSE	Red
TA817 Nivolumab for adjuvant treatment of invasive urothelial cancer at high risk of recurrence	NHSE	Red
TA816 Alpelisib with fulvestrant for treating hormone receptor-positive, HER2-negative, PIK3CA-mutated advanced breast cancer	NHSE	Red
TA815 Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs	ICB	Red
TA819 Sacituzumab govitecan for treating unresectable triple-negative advanced breast cancer after 2 or more therapies	NHSE	Red
TA818 Nivolumab with ipilimumab for untreated unresectable malignant pleural mesothelioma	NHSE	Red
TA821 Avalglucosidase alfa for treating Pompe disease	NHSE	Red
TA820 Brolucizumab for treating diabetic macular oedema	ICB	Red

TA807 Roxadustat for treating symptomatic anaemia in chronic kidney disease
XX advised Roxadustat for treating symptomatic anaemia in chronic kidney disease is TLS red.

5 New Drugs Request (NDR) – Adults

Perflutren (Lumnity) for ultrasound contrast-enhancing agent for use in adult patients, *XXXX, Cardiologist, UHBW*

Discussion

XX presented the new drug request application for Perflutren (Lumnity). Lumnity is an ultrasound contrast-enhancing agent for use in adult patients in whom non-contrast echocardiography was suboptimal (suboptimal is considered to indicate that at least two of six segments in the 4- or 2-chamber view of the ventricular border were not evaluable) and who have suspected or established coronary artery disease, to provide opacification of cardiac chambers and improvement of left ventricular endocardial border delineation at both rest and stress. The current formulary option is SonoVue (Bracco). SonoVue is contraindicated in patients known to have right-to-left shunts, severe pulmonary hypertension (pulmonary artery pressure >90 mmHg), uncontrolled systemic hypertension, and in patients with adult respiratory distress syndrome. SonoVue must not be used in combination with dobutamine in patients with conditions suggesting cardiovascular instability where dobutamine is contraindicated. Luminity only has one contraindication which is hypersensitivity to the active substance, Perflutren, or to any of the excipients listed. It can safely be used in patients with PAH, shunts ARDS and uncontrolled systemic hypertension. Luminity can be used for a wider cohort of patients without needing to progress to a different form of imaging which is costly to the system e.g. CT and MRI. The anticipated number of patients likely to receive treatment within BNSSG are 130 at UHBW. NBT have confirmed they would like to continue to use the existing formulary treatment option (SonoVue) due to NBT not having the same equipment (imaging availability) as UHBW. NBT have confirmed they support the new drug request application. Luminity is slightly more expensive than the current formulary option (SonoVue). Luminity will cost the system £7,962 compared to £7,644 for SonoVue. This is a small cost pressure of £318 per year. Luminity is included on Nottinghamshire, Barts Hospital, Milton Keynes and Oxford University Hospitals formularies and is non-formulary in Mid and South Essex. Luminity is not identified on some formulary websites, however as this is a contrast agent it may not be listed in all joint formularies as a medicine. There is evidence to suggest Luminity is better than placebo, however there are no head to head studies between other contrast dyes available on the market. The European Association of Cardiovascular imaging advise all commercially available contrast agents are suitable and do not state a preference.

XX joined the meeting to discuss the application. XX advised Luminity will mainly be used in stress echo to investigate the patients' heart under exercise. If two continuous segments of the heart cannot be seen, an imaging contrast is required to ensure there are no inconclusive tests. Luminity and SonoVue have a similar action profile. XX advised it would be beneficial to have both agents onto the BNSSG Adult Formulary due to the possibility of supply chain issues. Luminity is delivered slightly differently to SonoVue. Luminity agitates the imaging substance which shows the linings of the cardiac structures, which provides detailed stress echo conclusions. In terms of switching, XX advised both agents will be used and this will be determined by user preference. In regard to preference, this will be determined once clinician experience and use increases.

Decision Criteria used by JFG for NDR

- **Patient safety –** Favourable safety profile. Adverse reactions usually resolve within 15 mins
- **Clinical effectiveness –** Improves imaging of cardiac structure during echocardiography compared to unenhanced ultrasound.
- **Strength of evidence –** Evidence from one RCT, one prospective cohort study and pre-marketing trials. No head-to-head studies identified.
- **Cost effectiveness or resource impact –** No studies of cost-effectiveness for use in the UK were identified. Very small additional cost.
- **Place in therapy relative to available treatments –** Alternative to current formulary option SonoVue.
- **National guidance and priorities –** European Association of Cardiovascular Imaging advise all commercially available contrast agents are suitable including Luminity and current formulary option SonoVue.
- **Local health priorities –** Requested to reduce potential need for other diagnostic tests.
- **Equity of access –** Included on a number of formularies in England but not available on any local formularies.
- **Other considerations –** UHBW only request – NBT support continued use of SonoVue.

Conclusion
The group considered the application, the evidence and the information submitted. There is sufficient evidence to support inclusion of Perflutren (Luminity®) for its licensed indication. The group agreed to include Perflutren Luminity® onto the BNSSG Joint Formulary as TLS Red as an alternative to Sulfur hexafluoride (SonoVue®).

Action:
1. The Formulary team to include Perflutren (Lumnity) for ultrasound contrast-enhancing agent for use in adult patients onto the BNSSG Adult Formulary as TLS red as an alternative to Sulfur hexafluoride (SonoVue®).

6 Shared Care Protocols/TLS Status – Adults

Traffic Light Status Request Change
Nil

New SCPs
Nil

Updated SCPs
Nil

7 Items for Discussion – Adults

SBAR – Viridal Duo
XX presented the SBAR for Viridal Duo (Alprostadil). Alprostadil is listed as TLS amber on the BNSSG Adult Formulary for erectile dysfunction. This includes intracavernosal injection as the brand Caverject. Due to recent supply problems, secondary care have been recommending and prescribing a different brand (Viridal Duo). This has been longstanding and a more permanent position is needed. The two medicines have the same mode of action but slightly different administration technique, therefore counselling is given based on the available product at the time. Caverject is the preferred brand as it is easier for the patient to use but having both available on the BNSSG Adult Formulary would enable patients who have been trained already on either formulation to continue. It would also allow for new patients to be started on either depending on availability. Caverject 40 microgram powder and solvent for injects is £21.58 for 1 vial. Viridal Duo 40 microgram continuation pack powder and solvent for injection is £27.22 for 2 cartridges. The group agreed to list all generic brands of Alprostadil (Caverject and Viridal Duo) onto the BNSSG Adult Formulary and to include a statement to advise prescribers to use the lowest acquisition cost product, but not to change brands unless the patient has received appropriate counselling.

Action
1. The Formulary team to list all generic brands of Alprostadil (Caverject and Viridal Duo) onto the BNSSG Adult Formulary and to include a statement to advise prescribers to use the lowest acquisition cost product, but not to change brands unless the patient has received appropriate counselling.

Chapter Review – Sip Feeds
XX provided a summary on the Oral Nutritional Supplements chapter review. Secondary care, primary care and the community dietetic team at Sirona care and health submitted comments on the chapter. The feedback included changes to the page layout, removal of information which has been replaced by the pathway for prescribing oral nutritional supplements in BNSSG for disease related malnutrition guideline, additional/removal of supplements, additional of pre-thickened ONS, changes to information regarding specific products recommended by dieticians and removal of oral nutritional supplement prices from the formulary a prone to going out of date.

XX provided details of the main changes within the chapter to the group.

- The primary care information section has been moved to the top of the chapter.
- Within each section, the most expensive option has been removed and replaced with cost effective options.
- Low volume (compact) powdered shakes have been included as a new section. These are the same price as the other compact powder option already on the formulary but provides another option for patients.
- Low volume (compact) milkshake style (1 bottle per day) has been included as a new section. These are once daily (patients/carers need to be able to retain the remainder of the bottle to consume second daily dose). These would be more cost effective than readymade bottles which are required two per day but may not be suitable for everyone.
- There is a new subsection for protein supplements.
- There is a new subsection for fibre supplements. This includes a powdered version and the most cost-effective bottle.
- There is a new subsection for pre-thickened ONS. This is for patients with swallowing difficulties who cannot meet nutritional needs through diet and require a supplement. These products include a range for formulations. Additional information has been included onto the formulary to reduce queries to the dietetic team from practices.
- A statement on non-formulary prescribing was proposed and the group agreed that this should be edited to ensure prescribers justify reasons for deviating from the BNSSG Formulary options and to ensure this is clearly documented.
- The Sirona leaflet library which contains useful links/sections have been included onto the formulary for prescribers. Sirona link: Nutrition and Dietetics - Sirona care & health (sirona-cic.org.uk)
- XX advised the Food First guideline is currently being updated.

It was suggested changes to the chapter are included within a newsletter to ensure primary care are aware of the changes made. The group agreed with the changes made to the BNSSG Adult Oral Nutritional Supplement guideline.

Action

1. The Formulary Team to make changes to Oral Nutritional Supplements chapter on the BNSSG Adults Formulary page as summarised.
2. The Formulary Team to edit the paragraph relating to non-formulary prescribing before publication on the Formulary website.

Bempedoic acid with ezetimibe – An update

XX presented an update relating to Bempedoic acid with ezetimibe. XX advised when bempedoic acid with ezetimibe was approved by NICE this was included onto the BNSSG Adult Formulary as TLS red until a place within the pathway was established. The group were awaiting for the publishing of the Inclisiran TA, it was felt this would be more useful and used for a wider group of patients. The formulary team have received queries in relation to bempedoic acid and ezetimibe for patients who live in BNSSG but are seen across ICS boundaries and other areas, particularly in BSW. There is a group of patients who have been seen by RUH who are asking for primary care to take over prescribing (bempedoic acid with ezetimibe is TLS green in BSW). Bempedoic acid with ezetimibe is being used in a small group of patients in BNSSG and local specialists do not have much experience with use. The specialists within BNSSG are recommending monitoring significantly over what is recommended within the SPC and other ICB areas, which is creating a barrier from changing the TLS from red to amber. The formulary team have liaised with local specialists to discuss reducing the monitoring and it was agreed there is some scope, however an evidence review is required before monitoring can be reduced. NICE do not stipulate any special prescribing/monitoring requiments for bempedoic acid with ezetimibe and monitoring requirements are not explicitly stated in the SPC. Local specialists currently recommend the following monitoring: full blood count, ferritin, uric acid, liver function tests, renal function and a full lipid profile. Some local areas have advised they will stop seeing patients from BNSSG if primary care is not able to take over the prescribing. The group agreed for bempedoic acid with ezetimibe to remain TLS red on the BNSSG Adult Formulary until further work is done on monitoring and TLS. It was agreed for XX to liaise with the 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 group discussed how the formulary team can advise the affected GP practices on managing requests for bempedoic acid and ezetimibe. It was recommended to advise practices that the decision remains with the practices and there is a plan in place to review the situation with secondary care.

Action

1. 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.

8 New Drug Requests (NDR) – Joint Adults and Paediatrics

Tretinon 0.025% / Clindamycin 1% for acne, *XXXX, Senior Medicines Optimisation Pharmacist, BNSSG ICB*

Discussion

XX presented the new drug request application for Tretinon 0.025%/Clindamycin 1% for acne. The BNSSG Community Antibiotics Guidelines contain a section on the treatment for acne. Treatment can include either tropical or oral antibiotics and good stewardship of the antibiotics used is important. NICE published guidelines on the treatment of acne (NG198) in June 2021. The new recommendations includes advice on options for first line treatment, one of which is Tretinoin/ Clindamycin for acne of any severity. Tretinoin/ Clindamycin is not currently on the BNSSG Joint Formulary therefore cannot currently follow NICE guidelines.Tretinoin/Erythromycin is on the BNSSG Adult Formulary, but this has not been advised by NICE due the increasing resistance of Cutibacterium acnes to erythromycin. The anticipated number of patients likely to receive Tretinon/Clindamycin within BNSSG per year are 126, however as the pathway changes this could increase. Treatment should be reviewed at 12 weeks and acne treatment that contains a topical treatment must not be continued for more than 6 months (as recommended by NICE). In terms of cost, Tretinon/Clindamycin is £11.94 per tube, which is more expensive than the current formulation option Tretinoin/Erythromycin (£7.05) which is not recommended by NICE. It is slightly cheaper than other NICE recommendations options such as Benzoyl peroxide + Clindamycin (£13.14) and Adapalene + Benzoyl peroxide (£19.53). The total cost for the anticipated cohort for a 6 month maximum course is £9,026. The Area Prescribing Medicines Optimisation Committee (APMOC) have allowed for Tretinon/Clindamycin to be included into the BNSSG Antimicrobial Stewardship guidelines for acne. XX advised if Tretinon/Clindamycin is approved the formulary team will remove Tretinoin/Erythromycin from the BNSSG Adult Formulary. The formulary team will also change Clindamycin monotherapy to be used for Hidradenitis suppurative and be removed from the acne section. In terms of other ICB formularies. Tretinoin/Clindamycin gel is included in BSW, Gloucestershire, Somerset, Dorset and Devon formularies but not Cornwall. In regard to evidence, the evidence does support Tretinoin/Clindamycin is the most effective treatment for acne.

XX joined the meeting to discuss the application. XX advised Tretinoin/Clindamycin has been requested to be included onto the BNSSG Adult Formulary to ensure BNSSG are following NICE recommendations when prescribing.

Decision Criteria used by JFG for NDR

- **Patient safety –** Associated with eye irritation and skin reactions. Contraindicated in pregnancy. Largely well tolerated, though topical retinoids are associated with an increased risk of discontinuation.
- **Clinical effectiveness –** Effective treatment option for acne of any severity. Combination topical clindamycin / tretinoin gel is more effective than monotherapy or placebo.
- **Strength of evidence –** Evidence from a pooled analysis of 3 RCTs and network meta-analyses (NMAs). Quality of NMAs affected by very low to moderate quality of individual studies included.
- **Cost effectiveness or resource impact –** NICE approved as cost effective first-line treatment option. Cheaper than other NICE approved options.
- **Place in therapy relative to available treatments –** First-line treatment option for acne of any severity.
- **National guidance and priorities –** NICE recommend topical tretinoin 0.025% + clindamycin 1% as a first-line treatment option for acne of any severity.
- **Local health priorities –** Important to enable adherence to NICE guidance.
- **Equity of access –** Available in most other local formulary areas.
- **Other considerations –** Important to support antimicrobial stewardship. Topical and oral antibiotics for acne should be reviewed 3-monthly and only continued for more than 6 months in exceptional circumstances. Current formulary options of clindamycin monotherapy and tretinoin / erythromycin solution are not recommended by NICE.

Conclusion

The group considered the application, the evidence and the information submitted. There is sufficient evidence to support inclusion of topical Tretinoin 0.025% + Clindamycin 1% gel as a first-line treatment option for acne of any severity onto the BNSSG Adult and Paediatric Joint Formulary as TLS Green to replace Tretinoin/Erythromycin solution to comply with NICE guidance. It was also agreed to change Clindamycin monotherapy to be used for Hidradenitis suppurative and be removed from the acne section. Tretinoin/Erythromycin will also be removed from the BNSSG Adult and Paediatric Formulary.

Actions:

1. The Formulary team to include Tretinon 0.025%/Clindamycin 1% for acne onto the BNSSG Adult and Paediatric Formulary as TLS

2. The formulary team to remove Tretinoin/Erythromycin from the BNSSG Adult and Paediatric Formulary.

3. The formulary team to change Clindamycin monotherapy on the BNSSG Adult and Paediatric Formulary to be used for Hidradenitis suppurative and be removed from the acne section.

Synalar® (fluocinolone ointment 0.025%) ointment/cream for severe inflammatory skin disorders such as eczema and psoriasis (Short Form) *XXXX, Consultant Dermatologist, UHBW and XXXX, Specialist Dermatology Pharmacist UHBW*

Discussion

XX presented the new drug request for Synalar (fluocinolone 0.025%) cream and ointment within its licensed indication for severe inflammatory skin disorders such as eczema and psoriasis. Synalar gel is already included onto the BNSSG Adult and Paediatric Formulary as TLS green. Ointment bases are useful as they provide a better emollient effect, usually contain fewer preservatives (so less irritant) plus they provide a barrier to help protect the skin from contact with irritants. Patients may be intolerant of certain excipients in the various formulations (e.g. parabens gel, lanolin ointment) and may have a preference for one formulation over another. Creams are generally more cosmetically acceptable than ointments and can feel cooling on the skin, gels may be preferable on greasy skin. Other topical steroid preparations currently on the formulary are already available in a number of different formulations. Patient choice is an important factor when considering product formulation to support patient compliance. Diflucortolone 0.1% and 0.3% oily cream and ointment (Nerisone and Nerisone Forte®) were previously on the formulary, these have now been discontinued and removed. Synalar® cream and ointment would in part replace these. Synalar would be reserved for patients who cannot use potent steroids currently on the formulary such as Betamethasone, Mometasone and Clobetasol due to class A, C or D steroid allergy or intolerance. It is recommended Synalar gel remains on the BNSSG Adult and Paediatric Formulary in addition to the cream and ointment as this formulation is particularly useful in hair bearing areas. The ointment and cream is cheaper than the gel, £0.12-£0.14 per gram for ointment and cream vs £0.17-£0.19 per gram for gel. All formulations are available in 30g pack sizes. The discontinued product (Nerisone Forte oily cream and ointment) is £0.31 per gram. Synalar cream and ointment are approximately twice the price of existing formulary topical steroid options such as Betamethasone, Mometasone and Clobetasol, but Synalar would be reserved for patients who cannot use these options such as those with a steroid allergy or intolerance. In terms of traffic light status, it has been suggested Synalar cream and ointment will be TLS blue. Synalar gel is currently TLS green on the BNSSG Adult and Paediatric formulary, therefore if Synalar cream and ointment was agreed as TLS blue, it was recommended Synalar gel should be TLS blue to ensure the BNSSG formulary is consistent.

XX joined the meeting to discuss the application. XX advised Synalar cream and ointment will be an alternative option for patients who have allergies or cannot tolerate class A, C and D steroids such as Betamethasone, Mometasone and Clobetasol. XX advised it is important for the ointment, cream and gel formulation to be included onto the BNSSG Adult and Paediatric formulary. This is due to the ointment being beneficial for patients with inflammatory skin problems. The creams have higher preservatives and some patients can tolerate the cream. The gel is helpful for hair bearing areas. The topical steroid options would be first-line and Synalar would be a second-line option if allergies present or the patient does not tolerate topical steroids.

Decision Criteria used by JFG for NDR

- **Patient safety –** Adverse reactions to Synalar are similar to that of all topical corticosteroids. Common side effects include skin reactions and telangiectasia.
- **Clinical effectiveness –** Synalar (gel) is already on the formulary in another formulation therefore a full critical appraisal of the evidence has not been completed.
- **Strength of evidence –** Synalar (gel) is already on the formulary in another formulation therefore a full critical appraisal of the evidence has not been completed.

- **Cost effectiveness or resource impact –** As the cream and ointment formulations are more cost-effective than the existing formulary gel formulation, there is potential small cost saving.
- **Place in therapy relative to available treatments –** TLS Green (in line with existing Synalar gel formulary classification). Synalar gel/ointment/cream would be offered to patients as an alternative to Betamethasone, Mometasone, Dermovate (formulary potent/very potent) or Nerisone forte (discontinued), especially for those who have an allergy to those steroids
- **National guidance and priorities –** NICE recommends choosing a topical corticosteroid that is acceptable to the person is important as it will encourage compliance with treatment
- **Local health priorities –** Due to the discontinuation of Nerisone Forte ointment and oily cream, an alternative is required. Synalar gel is already on the formulary and the inclusion of other formulations would offer another option for patients requiring alternative formulations.
- **Equity of access –** Many other neighbouring ICB formularies include Synalar cream/ointment/gel as TLS green including BSW, Gloucestershire, South and West Devon and Kernow.

Conclusion
The group considered the application, the evidence and the information submitted. The group agreed to include Synalar® (fluocinolone ointment 0.025%) ointment/cream onto the BNSSG Adult and Paediatric Formulary as TLS blue. It was also agreed to change the TLS status for Synalar® gel from TLS green to TLS blue to ensure the BNSSG Formulary is consistent.

Actions:

1. The Formulary team to include Synalar® (fluocinolone 0.025%) ointment and cream onto the BNSSG Adult and Paediatric Formulary as TLS blue.

2. The Formulary team to change the TLS status for Synalar® gel from TLS green to TLS blue to ensure the BNSSG Formulary consistent.

9 Shared Care Protocols/TLS Status – Paediatrics

Traffic Light Status Request Change
Nil

New SCPs
Nil

Updated SCPs
Nil

10 Items for Discussion – Joint Adults and Paediatrics

Nil

11 Melatonin - Joint Adults and Paediatrics

Melatonin Circadin® (MR tablets) *(Adults)*: off-label use in patients with dementia experiencing circadian sleep disorders, in whom conventional sedation is considered too risky. XXXX, Consultant Psychiatrist, Devon Partnership NHS Trust. XXXX, Consultant Psychiatrist, North Somerset Complex Intervention Team, AWP.

Discussion

XX presented the new drug request application for melatonin Circadin (Adults) for off-label use in patients with dementia experiencing circadian sleep disorders, in whom conventional sedation is considered too risky. XX advised the application is for patients with dementia experiencing sleep disturbance for more than 2 weeks. The anticipated number of patients likely to receive treatment within BNSSG is 146, with the possibility of additional patients from UHBW (estimated 8). Treatment is likely to be long-term but with programmed trial reductions to see whether patients can manage without melatonin. The aim is generally not to reset the circadian rhythm.

In terms of cost, XX advised if Circadin (preferred brand) were to be used the cost will be between £55K - £57K per year. Although it has been noted the quoted patient cohort may be an underestimate.

The ICB Research and Evidence team completed an evidence review. This identified 6 systematic reviews. based on 11 trials. The systematic reviews contained overlapping evidence from these 11 trials. There is some evidence for use of melatonin for dementia. However, this is not supported by all of the systematic reviews identified, including a recent Cochrane Review from 2020. Sleep latency was shown to be reduced slightly and sleep efficacy and total sleep time increased. The evidence is mostly for use in Alzheimer's disease and there is little evidence for other forms of dementia. The trials varied in size, length, doses and time of administration. The applicants acknowledge there is a poor evidence base, however for this cohort of patients there are no other suitable treatment options. Traditional hypnotics are not suitable due to the side effects of increased confusion, increased falls risk and behavioural disturbance. The applicants have requested that melatonin is a first-line treatment before moving to hypnotics.

The average dose in practice is 4mg at night, doses above this are uncommon. Melatonin Circadin's European patent is due to expire in August (unless extended) and a new immediate release brand has is now available. The formulary team have asked the applicant whether the new immediate release brand is appropriate and is awaiting a response.

In regard to NICE guidance, NICE guideline (2018) provides a do not use recommendation for melatonin which was based on a 2016 Cochrane review containing very low-to moderate evidence from RCTs. NICE agreed that the evidence did not show significant benefit from using melatonin to treat insomnia in people with Alzheimer's disease. NICE agreed this evidence could not be extrapolated to other subtypes of dementia e.g. REM sleep disorder in Parkinson's disease. The Cochrane review has been updated since (2020) and the updated Cochrane review continues to not recommend melatonin due to the low-quality evidence.

XX, XX, XX and XX joined the meeting to discuss the application. XX advised whilst there is low-moderate evidence for the use of melatonin for patients with dementia, patients with Alzheimer's will experience elements of vascular and Lewy body dementia in their life. Within the studies some patients have responded to treatment and some have not. XX advised the proposal would be to trial melatonin and if there is clear benefit treatment will continue. If the patient does not show any benefit treatment will be stopped.

In terms of alternative hypnotics available (benzodiazepine and z-drugs). Hypnotics work primarily through sedation leading to increased confusion, increased falls risk and behavioural disturbance. This can cause difficulty for elderly patients who are a risk to fractures/falls. Melatonin is used in preference to alternative hypnotics to avoid harm to these patients. Similarly sedating hypnotics do not induce natural sleep and are known to interfere with the normal neurochemistry of sleep, reducing its restorative value. Melatonin avoids these risks being comparatively far safer and using an entirely different mechanism of action as an endogenous compound. XX advised there is also a benefit to family and carers, where a partner, family member or carer is needing to stay awake all night due to a person with dementia being awake and trying to leave their home in a vulnerable state. Simply resolving the issue of not sleeping at night can mean the difference between remaining at home, or admission to institutional care. Similarly, wakefulness at night for some with dementia is associated with increased confusion and agitation, even aggression, and restoring sleep at night can again enable a carer to support them in the community and remove the burden of managing challenging behaviours during the night in care facilities. XX advised from clinical experience in a significant proportion of cases, using melatonin can resolve insomnia or sleep-wake reversal and avoid harmful alternatives such as benzodiazepines and z-drugs, indirectly improving patient safety through decreased falls risk and worsening cognition.

The group discussed whether it would be possible to identify which patient groups will respond and will not respond. XX advised it is difficult to determine which patients would benefit the most from melatonin. The proposal is to conduct a rigorous trial of treatment and if the patient does not benefit treatment will be

stopped. The group discussed whether it would be possible to collate local evaluation data to support evidence and clinical effectiveness. It was recommended for this data to include the number of falls experienced and the cost impact caring for patients who are experiencing lack of sleep. XX advised it would be difficult to collate data for patient falls and acute admissions as well as providing finance data. XX advised patients will be initiated on melatonin for 7-10 days and if no benefit is seen during this period, treatment will be stopped. The group discussed whether patients responding to melatonin can stop treatment and remain off treatment for a period of time or whether this is a long-term treatment. XX advised there are patients who benefit from melatonin and after 3-6 months of treatment have a successful trial of a reduced dose.

In terms of the initiation protocol which states patients should not intake caffeine after 12pm.The group recommended that patients prescribed medication for sleep should not take any caffeine though out the day. XX advised that carers and care homes are told patients should not have tea, coffee or coca cola and to consume naturally caffeine free alternatives. In terms of the trial duration for melatonin, XX advised the data suggests the treatment duration should be 4/5 weeks to see full benefit. The ideal time to titrate the dose would be 7-10 days, however due to the lack of capacity this is not possible.

Decision Criteria used by JFG for NDR

- **Patient safety –** Melatonin has not been associated with serious adverse effects and is well tolerated. Use may be preferable as associated with less risk than other sedatives.
- **Clinical effectiveness –** Statistically significant improvements in sleep efficiency, total sleep time at night and sleep latency were found but this was not reproduced in all systematic reviews including the Cochrane Review by McCleary and Sharpley (2020). See table 2 (page 7) of the evidence review for a summary of findings from the systematic reviews that included an assessment of strength / certainty of findings. Most studies were based on short-term outcome measures and long-term outcome data is limited. **Sleep efficiency:** Xu et al., 2015, found statistically significant improvement in sleep efficiency by 2.23%, measured using mean difference in wrist actigraphy, after administration of melatonin for more than 4 weeks in all dementia types. **Total Sleep Time:** Xu et al., 2015, also found a statistically significant prolongation in total sleep time due to melatonin treatment using all data of 24.36 minutes. Total sleep time was lengthened by 28.78 minutes over a 4 week follow-up. **Sleep latency:** Blackman et al., 2021, found that melatonin was associated with a statistically significant reduction in sleep latency, using actigraphy, of 14.7 and 15.25 minutes for melatonin compared to 26.08 and 34.75 for placebo.
- **Strength of evidence –** The evidence base is limited by a shortage of studies. 6 systematic reviews were included in the evidence review, relying on 11 RCTs. Most findings were of low to moderate strength / certainty. The evidence base is predominantly for patients with Alzheimer's Disease rather than other types of dementia. Longer duration studies are needed to enable analysis of long-term outcomes. There is limited evidence on the place of melatonin relative to available treatments.
- **Cost effectiveness or resource impact –** No studies of cost-effectiveness were identified. Significantly more expensive than alternative sedatives. The cost pressure for the anticipated cohort is £54,356. Some additional non-formulary prescribing may already be occurring in primary care. Most prescribing is expected to be long-term. Circadin's European patent expiry (unless extended) may precipitate a reduction in acquisition price.
- **Place in therapy relative to available treatments –** To be used if non-pharmacological treatments e.g. sleep hygiene have not been effective, instead of alternative sedatives which may be less suitable due to potential adverse effects.
- **National guidance and priorities –** NICE guidance includes a "do not offer" recommendation for melatonin for insomnia in Alzheimer's disease. This recommendation does not extend to use in other subtypes of dementia. The guideline is relatively old (published in 2018). The British Association for Psychopharmacology recommends that prolonged release melatonin should be tried first when a hypnotic is indicated in patients over 55 years.
- **Local health priorities –** High priority for local specialists to include melatonin for adults with dementia on the formulary, as shared care. It is currently non-formulary for this indication outside of REM sleep disorder. Some non-formulary prescribing for this indication is already happening in secondary care and may be occurring in primary care.
- **Equity of access –** Inclusion of melatonin, indications and TLS status on other formularies varies greatly. It is TLS Red for inpatient use for dementia / care of the elderly in two local areas and Amber in a couple of other formulary areas.

- **Other considerations –** Recommended formulations:

1. First line: Circadin m/r 2mg tablets. These may be titrated by halving the tablets, and still maintain their prolonged release properties.
2. Second line: Circadin m/r 2mg tablets use in swallowing difficulties – halved or crushed with a spoon.
3. Third line: melatonin 1mg/1ml soluble solution, preferably alcohol free, where a lactose-free product is required, and no solid-dose preparation is suitable for the patient.

Conclusion

The group considered the application, the evidence and the information submitted. The group agreed there is low quality evidence for the use of melatonin in patients with dementia, as well as a high-cost pressure to the system. The group noted anecdotal evidence of benefit to individual patients but that benefit at a population health level is not supported by the published evidence. The applicant has advised there is no resource within the clinical team to collect local evaluation data to determine efficacy and cost. The group noted that melatonin is already being used in for this indication in BNSSG on a non-formulary basis.

Based on the decision-making criteria above, the group agreed that melatonin should not be included onto the BNSSG Adult Formulary for off-label use in patients with dementia experiencing circadian sleep disorders, in whom conventional sedation is considered too risky, due to lack of clinical and cost effectiveness evidence and the cost pressure to the system. However, the Joint Formulary Group recommended that if further evidence/local data can be collected to better inform the application and model use, the group could re-review and reconsider a new drug request application if this was presented by the applicant in the future. The group advised that the resource of the BNSSG ICB Research and Evidence Team could be drawn on to support with collection of additional local evidence.

Post Meeting Note – Update from ICB Research and Evidence Team – There is a researcher within the ICB who can work with the clinical team to build up a cost-effectiveness analysis, which may include an audit/data collection to develop a simple model to project costs and savings under a range of assumptions.

The Formulary team to include the melatonin decision onto decision making page on the BNSSG formulary website.

Action:

1. The Formulary team to inform the applicant that due to the lack of clinical and cost-effectiveness evidence and the cost pressure to the system it was agreed to not include Melatonin onto the BNSSG Adult Formulary for off-label use in patients with dementia experiencing circadian sleep disorders, in whom conventional sedation is considered too risky. The Formulary team to also advise that the Joint Formulary Group recommend that if further evidence/local data can be collected to better inform the application and model use, the group could re-review and reconsider a new drug request application, if this is presented by the applicant in the future. This data collection will be supported by a researcher within the ICB.
2. The Formulary team to include the melatonin decision onto decision making page on the BNSSG formulary website.

Melatonin *(Adults and Paediatrics)*: off-label use for sleep disorder in adult and paediatric patients with any of:

- Attention Deficit Hyperactivity Disorder (ADHD)
- Autism Spectrum Disorder (ASD)
- Learning Disabilities (LD)

Discussion

XX presented the new drug request application for melatonin (Adults and Paediatrics) for use for sleep disorder in adult and paediatric patients with attention deficit hyperactivity disorder (ADHD), autism or patients with learning disabilities (LD).

XX advised melatonin is currently on the BNSSG Adult Formulary for adults with learning disabilities and sleep disturbance who also have either depression, mania, psychosis, dementia or disorder (e.g. autism, autistic spectrum, anxiety disorders, adult ADHD etc) as per shared care protocol. In terms of paediatric patients, melatonin is currently on the BNSSG Paediatric Formulary for children with neurodevelopmental disorder/disability with intrinsic sleep disorder (difficulty getting to sleep or remaining asleep) who have exhausted all behavioural sleep hygiene options. This excludes children with ADHD or autism or learning disabilities. XX advised the new drug request application is to widen the patient cohort group and to include

all patients with a sleep disorder who have ADHD or autism or learning disabilities. The typical treatment dose is 2mg-6mg per day.

In terms of patient numbers, there is a high volume of prescribing taking place already despite being non formulary. AWP estimate around 185 patients prescribed by CAMHS and 24 patients for learning disabilities. In terms of Sirona there are 433 patients prescribed within Community Paediatrics and 27 in the Adult Learning Disabilities.

In regards to melatonin's place within the pathway, the first-line option is simple sleep hygiene measures, second-line option is individualised behavioural and environmental recommendations, finally the third-line option would be a trial of melatonin.

A sleep diary is used in some adult LD services, which is left intentionally basic so that care providers/family can adapt it to their needs. The ADHD services also use sleep diaries and quality of life questionnaires to measure effectiveness.

In terms of cost, the Circadin brand is more cost effective than Slenyto, costing £1.02 for 4mg per day vs £2.75 for 4mg per day. Slenyto is licensed for autism spectrum disorder for 2-18 year olds. If everyone within a community provider setting was prescribed Circadin this would cost between £124K - £373K per year. According to EMIS data, there are 46,659 patients with a clinical code for ADHD, autism or learning disabilities. 739 patients are already being prescribed melatonin by primary care. In the last 12 months, BNSSG CCG spent £367,277 (9,192 items) on melatonin within primary care, which is approximately middle of the range comparing to other CCGs spend on melatonin. This represents the existing overall spend on melatonin in primary care over a 12-month period. It is not possible to extract details on formulary or non-formulary indications, dose or duration.

In regards to other ICB formularies. The most common indication approved is for autism. Within the 29 ICB formularies reviewed, 18 include melatonin for ASD. Of these, 5 ICBs include melatonin for adults with a shared care status (with 1 specifying unlicensed specials are considered red). 17 ICBs include melatonin for paediatrics, 16 as shared care, 1 as red. 13 ICBs include melatonin for ADHD. 6 ICBs include melatonin for ADHD in adults and of these, 5 ICBs classify this as shared care (with 1 specifying unlicensed specials are red) and 1 ICB red. For paediatrics, 11 ICBs have a shared care status (with 1 ICB specifying unlicensed specials are red) and 2 ICBs having a red status, noting some ICBs were also red but this is less clear within merged ICB formularies. In regards to learning disabilities, 10 ICBs include melatonin for learning disabilities on their formularies. Of these, 5 ICBs include melatonin for adults: 4 as shared care, 1 red (with 1 specify unlicensed specials are red). 11 ICBs include melatonin for children: 10 shared care and 1 red.

The British Association for Psychopharmacology acknowledge melatonin is used for insomnia in patients with learning disabilities and behaviour that challenges after non-pharmacological options, but melatonin is not licensed for this indication. The guidelines also acknowledge melatonin administration can be used to advance sleep onset to normal values in children with ADHD who are not on stimulant medication. NICE guideline on Challenging behaviour and learning disabilities NG11 includes melatonin to 'consider' if medication is needed, noting it's off-label use in patients aged under 55 years. Furthermore, NICE CG170 include melatonin to 'consider' if a pharmacological intervention is needed to aid sleep, following consultation with a specialist paediatrician.

The evidence review completed by the BNSSG evidence team focussed on available data from the 2020-2022 period only, however this included meta-analyses which included trials prior to this date range.

In terms of safety, melatonin is generally well tolerated, with no reports of any common or common adverse drug reactions, or reports of patients experiencing tolerance, dependence or withdrawal symptoms with Circadin.

XX, XX, XX and XX joined the meeting to discuss the application.

Paediatric cohort

XX advised melatonin is widely used within Community Paediatrics. Melatonin is useful in improving the sleep initiation phase and quality of life. The family/carers of these patients also experience distress and this affects their quality of life due to sleep disturbances. This patient cohort can be vulnerable and often already have complex needs with neurodevelopmental disorders/disability. Treatment can improve quality of life for family members and carers, with a lower risk of burnout, and lower risk of break-down of the family home. Treatment can also improve production of appropriate amount of growth hormone secretion, leading to

appropriate growth in children as well as improved behaviour and concentration during the daytime leading to better learning. XX advised there is evidence for children taking melatonin which improves sleep for children with ASD. XX advised it is difficult to conduct research and evidence trials for paediatric patients. Some patients would benefit from melatonin on a short term basis to help re-set body clocks and cycle and once stable treatment can stop, however the majority with neurodevelopmental difficulties will need treatment longer term. XX noted that individuals with neurodevelopmental disorders have been shown to have intrinsically lower melatonin levels, which is why melatonin can be helpful. Patients will have regular breaks off melatonin to determine whether treatment is still required. If symptoms do not improve treatment will be stopped.

XX noted the overlap between ADHD and ASD and other neurodevelopmental issues and concurred with the feedback from patients and families regarding the benefits of melatonin. The improvement of sleep by thirty minutes every day of a patient's life can be significant for children.

Adult service - ADHD

XX advised patients will be referred to the adult service and they will already be taking melatonin, which has helped historically. ADHD is associated with increased rates of sleep apnoea, insomnia and restless legs syndrome but most commonly sleep disorder. Most patients present with a delayed sleep phase pattern. XX advised the patient's ADHD will be optimised with medication and behavioural interventions which may improve day time functioning/sleep onset problems however, there is a cohort of patients where medication does not treat these symptoms and melatonin will be indicated. Melatonin will help re-set the patient's sleep pattern and this can improve cognition to support further education, work and quality of life. The treatment duration will be dependent on patient basis, some patients may require ongoing prescriptions subject to review.

Inclusion of melatonin to the formulary would permit clinicians to use all of the tools available to attempt to get a patient's ADHD under control.

Adult service – LD

XX advised patients with learning disabilities are a highly heterogeneous cohort in the context of the cause and severity of their disability along with individual co-morbidities. There is a lack of research into prescribing and management of these patients due to ethical concerns and many patients are unable to describe the side effects of medication due to being non-verbal. This cohort of patients are at risk of polypharmacy. The STOMP initiative is very prominent in prescribing practice and there is an emphasis on deprescribing where clinically appropriate.

XX advised the anticipated numbers prescribed melatonin for this indication are smaller than the other indications being presented but that treatment with melatonin would be long term/ lifelong. The evidence shows there is no tolerance or withdrawal concerns with melatonin compared to benzodiazepines and Z-drugs. There is a lower risk for falls. There is a minimal hangover from melatonin. In regard to evidence, the British Association for Psychopharmacology consensus states melatonin is effective in treating delayed sleep phase syndrome, treating sleep disorder in patients who are blind and treating adults with an intellectual disability. In terms of the treatment pathway melatonin will be a third-line option. First-line will be sleep hygiene methods, second-line treatment would be behavioural interventions/reviewing a wide range of health complaints which might be affecting the patient's sleep pattern or a physio sleep system. XX noted the wider implications of poor sleep such as placement breakdown, loss of carers, impact on families/carers.

Further discussion with the applicants

The group asked whether melatonin would replace benzodiazepine and Z-drugs and the risks of dual therapy. XX/XX/XX/XX advised they would not prescribe melatonin and Benzodiazepines/Z-drugs. XX confirmed that Z drugs or benzodiazepine drugs would not be an appropriate alternative for this patient cohort and are not routinely prescribed. If these drugs were to be prescribed it would be strictly short term and for a co-morbid illness not for the sleep disorder itself.
The group discussed whether it would be possible to determine which patients melatonin would be most beneficial for treatment. The applicants advised this would not be possible.

The group recognised the applicants were able to provide compelling social anecdotal evidence of benefit of melatonin for individuals and asked about whether there would be the potential for further audit work to capture this benefit locally on a population basis. Applicants noted difficulty with undertaking such work such as the learning disability patient cohort being very heterogenous, issues with consent, ethical considerations and lack of capacity within the teams.

Decision Criteria used by JFG for NDR

- **Patient safety –** Studies found melatonin to be safe and well tolerated, with less risk associated with melatonin than other sedative medicine options. However for these indications, the alternatives would not be routinely used for these patient cohorts.
- **Clinical effectiveness –** When clinical trial data was pooled together in meta-analysis, statistically significant results were found showing an improvement of sleep latency and total sleep time. A pertinent meta-analysis by McDonagh et al (2019), concluded that for children and adolescents, Melatonin significantly improved sleep latency and duration, although the range of improvement in sleep latency varied between studies (11-51 minutes, median 28 minutes) and sleep duration improved by 14-68 minutes (median 33 minutes). It was reported within this meta-analysis that children with ASD improved the most compared to other neurodevelopmental disorders (sleep latency by 37 minutes and sleep duration by 48 minutes). Evidence for improvement was stronger for younger children than adolescents. However the Evidence team noted limitations with the study as measurements of awakenings or time spent awake after sleep onset were inconsistent with each other and varied from getting worse to improving significantly leaving little confidence in the trial's findings. A systematic review conducted by Salanitro (2022) concluded that melatonin improved sleep onset latency and total sleep time in adults across sleep disorders and across all disorders including ADHD/LD/ASD. There was no evidence that melatonin improved night awakenings. It is not clear whether the reported statistically significant improvements to sleep latency and total sleep time translate to clinically significant outcomes. Further studies are recommended to explore the effects of longer term use of melatonin and the impact of improvements to sleep on function, behaviour and improvement of condition. Further studies are also needed with a larger population size and use of a controlled environment to exclude bias.
  Applicants acknowledged that whilst the evidence may only report small improvements to sleep that for these patient cohorts there is significant benefit by this improvement of sleep and that the results are perhaps skewed by being averaged out with other patient cohorts who are included in the trials. The applicants were able to share anecdotal reports of how melatonin has improved their patient's quality of life and carer/ family quality of life, noting improvements on performance at school and at home.
- **Strength of evidence –** Low quality- despite the volume of evidence and use of melatonin for nearly 30 years, the quality of studies were variable with studies often of low quality with limitations such as absence of large scale RCTs, smaller sample size; short duration (the majority are 13 weeks duration or less); subjective outcome measures and risk of bias (e.g. sleep diaries); lack of methodology detail; lack of reproducibility. The majority of evidence reviewed focussed on children, and studies did not routinely focus on ADHD, LD or ASD in isolation. The evidence review completed by the BNSSG evidence team focussed on available data from the 2020-2022 period only, however this included meta-analyses which included trials prior to this date range.
  Anecdotal evidence was provided by applicants for melatonin use for this cohort, which can be considered 'weaker' strength of evidence.
- **Cost effectiveness or resource impact –** Current prescribing of melatonin already presents a substantial cost to the system of £702,468.50 per annum (£335,191.50 for AWP and Sirona combined and £367,277 by GP Practices). If the application for these additional indications were approved as shared care on the BNSSG Formulary, the costs of prescribing currently held with AWP and Sirona would shift to primary care. Prescription administration workload currently managed by AWP and Sirona would transfer to GP Practices, which may relieve pressure in those settings, but increase pressure in GP Practices. It is expected the majority of prescribing would be longer-term.
  The applicants reported wider potential cost benefits in terms of improving sleep such as ability to work, perform better at school, retention of placements for LD, improve quality of life for patient and other family members, however these potential cost benefits are anecdotal reports and costs are not confirmed by evidence.
- **Place in therapy relative to available treatments –** 3rd line, following non-pharmacological treatments.
- **National guidance and priorities –** NICE guideline Challenging behaviour and learning disabilities NG11 includes melatonin to 'consider' if medication is needed, noting it's off-label use in patients aged under 55 years. NICE CG170 advises to 'consider' melatonin for patients with autism only if a pharmacological intervention is needed to aid sleep, following consultation with a specialist paediatrician or psychiatrist with expertise in management of autism or sleep medicine in conjunction with non-pharmacological interventions. Melatonin is recognised as an option by the British Association of Psychopharmacology for patients with LD, ASD and children with ADHD who are not on stimulant medication after behavioural strategies.

- **Local health priorities –** Considered a high priority for local specialists who wish to make melatonin shared care for the indications ADHD, ASD and LD for both adult and paediatric patients. It is currently non-formulary for the majority of these patient cohorts, meaning potentially some prescribing occurs in primary care 'non formulary' and prescribing occurs within AWP and Sirona outside of formulary recommendations.
- **Equity of access –** At a national level, the inclusion of melatonin on formularies varies greatly in terms of indications covered, traffic light status and whether it is included for adults or paediatrics or both. Of those reviewed, ASD was the most frequent indication included on formularies, followed by LD then ADHD. In comparison to neighbouring CCGs, in BSW melatonin is TLS Red for paediatric patients, restricted to patients with ASD or ASD with ADHD. It is not recommended for routine use for ADHD alone. For young people approaching 18 who will be discharged from paediatric services, melatonin is TLS Amber shared care, noting this should be for a small patient cohort.
- **Other considerations –** For cost effective prescribing:
    1) First line use for all stated off-label conditions: Circadin m/r 2mg tablets. These may be titrated by halving the tablets if needed, and still maintain their prolonged release properties. In 2022, a new immediate release formulation called Adaflex was launched and is licensed for insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient. It was noted that there would be considerable cost savings for patients on doses of 4mg or more a day and that this should be explored further to see where this may be appropriate, noting that this is an immediate release formulation compared to Circadin which is modified release.
    2) Second line: Circadin m/r 2mg tablets use in swallowing difficulties – halved or crushed with a spoon.
    3) Third line: Slenyto tablets, where the small diameter (3mm) of the tablet is a significant aid for people with swallowing difficulties, who cannot manage crushing tablets effectively.
    4) Fourth line: melatonin 1mg/1ml soluble solution that is alcohol free, low in propylene glycol and low in sorbitol (E.g. Martindale® or Kidmel® brands). For use in rare hereditary conditions of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption. Also for use in people who cannot manage any solid dose form of medication, e.g. with a percutaneous endoscopic gastrostomy (PEG) tube.

Conclusion

The group considered the application, the evidence and the information submitted.

The group acknowledged the challenges and issues that sleep disorders can present and recognised the compelling social anecdotal evidence provided by clinicians at the meeting to support melatonin use for these patients. It was noted that despite being prescribed 'non-formulary' in many cases, significant prescribing across the system for melatonin already takes place and due to this, the implications for existing patients will also need considering when decision making.

The application requested the addition of melatonin on the formulary for use in ADHD, autism and LD as independent indications. The evidence focuses on a wider patient cohort rather than focussing on individual indications, although some evidence suggests greater improvement to sleep in autism patients overall. It was noted that there is a placebo-controlled trial for use of Slenyto for ASD. Discussions took place around the value of melatonin on a population health basis. Recognising the anecdotal evidence, the group discussed the possibility of potential support from teams within the ICB to collate the evaluation data on melatonin use locally.

The group recognised that the impact of any formulary change could present a significant cost to the system and that this decision would need agreement from the appropriate senior team within the ICS.

The group recognised that the BNSSG Adult Formulary includes melatonin use for adults with Learning Disabilities and sleep disturbance who also have a co-morbid mental illness (for example Depression, Mania, Psychosis, Dementia etc.) OR disorder (for example Autism or Autistic Spectrum, Anxiety Disorders, Adult ADHD etc, however the BNSSG Paediatric formulary explicitly excludes ADHD. The paediatric formulary includes melatonin use for children with neurodevelopmental disorder/disability with intrinsic sleep disorder (difficulty getting to sleep or remaining asleep) who have exhausted all behavioural sleep hygiene options, but *not* for use in ADHD or autism or learning disabilities. The group agreed the formulary should be consistent and equitable across adults and paediatrics and a review of this should be prioritised. The group noted the importance of ensuring there are clear guidelines in terms of starting treatment, stopping treatment, duration of treatment and drug holidays/management of melatonin.

The group considered the guidelines and evidence around melatonin, acknowledging the NICE recommendations for ASD and LD patient cohorts in particular and were minded to explore including on the formulary. It was agreed that further discussion is needed for all indications and if included onto the Formulary, the traffic light status would also need to be discussed and agreed.

The group were not quorate during the meeting but also felt that due to the complexity of the application and financial impact across the system, that further reflection and wider discussion was needed at the December Joint Formulary Group meeting.

Action:

1. The Formulary team to summarise discussions from October meeting and bring back to December meeting for further discussion
2. Formulary team to find out what representation is needed at December JFG and if anyone else needs inviting

Melatonin *(Paediatrics)*: Off-label for use on PICU and HDU (during hospital stay only) to aid onset of sleep in patients with neurodevelopmental disorders/ASD and other conditions e.g. bone marrow transplant and renal patients who are suffering from sleep cycle disorder following prolonged stays and who have not responded to standard sleep hygiene measures.

Discussion

XX presented the new drug request application for melatonin for off-label for use on PICU and paediatric HDU during hospital stay only to aid onset of sleep in patients with neurodevelopmental disorders/ASD and other conditions e.g. bone marrow transplant and renal patients who are suffering from sleep cycle disorder following prolonged stays and who have not responded to standard sleep hygiene measures. The anticipated number of patients likely to receive treatment within BNSSG are 50 patients per year for short term use (1-4 weeks). XX advised approximately half of the patients who are issued melatonin on PICU/HDU are already on melatonin at home, therefore the number of new initiations would be much smaller than the estimated 50 patients per year which is based on annual dispensing data. XX advised patients who have prolonged stays at PICU and HCU can often suffer from disordered sleep once they are weaned from sedation. Careful weaning of sedative medications is undertaken to reduce the risk of any withdrawal effects that could be contributing to impaired sleep pattern. Any possible improvements in relation to sleep hygiene are the first line option for treating disordered sleeping in PICU and HDU (although not always as easy to comply with in a hospital setting where noise and light cannot be fully removed from the setting). If nursing staff and parents report significant impairment to sleep cycle such as frequent waking, prolonged time taken to get to sleep and/or daytime somnolence then this will be reported to the doctors who will decide if a short term course of melatonin may be suitable. The medication is only used short term and, in most patients, will be at a dose of 2 or 4mg every night. If there is no improvement after a few nights then a higher dose may be considered or switching to another sedating agent such as chloral hydrate may be considered. Medication will be reviewed regularly (at least weekly) with the medication stopped if sleep significantly improves and will always be stopped prior to step down to a general ward.

Decision Criteria used by JFG for NDR

- **Patient safety –** None of articles reviewed provided evidence for patient safety in the use of melatonin in a PICU/HDU setting. However, there is evidence that demonstrates a good safety profile more broadly in paediatric populations for sleep indications. The evidence on adverse events (AEs) lacks support from systematic and rigorous safety studies and meta-analyses (Kennaway, 2015). The studies identified in this review found little evidence of serious AEs. Where AEs were reported, they were minor and infrequent and included headaches, migraine, feeling cold, mood dip, decreased appetite, dizziness, bed-wetting, hyperactivity, drowsiness, agitation, and fatigue (van Geijlswijk, 2010 and McDonagh, 2019). Bruni et al (2015b) identified that there is a need for long-term safety studies as well as for studies on fertility, for which animal data are variable and human data are lacking.
- **Clinical effectiveness –** None of the articles reviewed provided evidence for clinical effectiveness in the use of melatonin in a PICU/HDU setting. Procaccini and Kudchadkar (2021) found that prescriptions of melatonin for sleep indications in paediatric inpatients of a tertiary hospital, including those on PICU, has increased substantially over a 4-year period, despite a lack of evidence. This study relied on dispensing data and did not reveal anything about the efficacy of treatment with melatonin. There is evidence to suggest that the use of melatonin in paediatric populations for sleep indications have statistically significant beneficial effects. Systematic reviews by McDonagh et al (2019), Ferracioli-Oda et al. (2013) and van Geijlswijk, (2010) all assessed the efficacy of melatonin in terms of sleep latency

and sleep duration. Results were variable and the range of improvement was variable across the studies, however overall study findings showed an improvement in sleep onset latency and sleep duration. Although, effect sizes might be too modest to be clinically significant.

	McDonagh et al (2019)	***Ferracioli-Oda et al. (2013)***	***van Geijlswijk, (2010)***
Sleep latency	28 minutes (11 - 51)	7.06 minutes (4.37 - 9.75)	16.04 minutes
Sleep duration	33 minutes (14 - 68)	8.25 minutes (1.74 - 14.75)	28.39 minutes

- **Strength of evidence –** There is a lack of evidence on the use of melatonin in PICU and HDU environments, and only one retrospective study analysed the use of melatonin in paediatric patients in these settings. This study relied on dispensing data and did not reveal anything about the safety and efficacy of treatment with melatonin. However, there is evidence that may support the use of melatonin for sleep indications in paediatric patients including systematic reviews, two randomised controlled trials and other quantitative evidence such as a retrospective analysis, consensus findings from a conference and a letter to the editor. Of the higher quality evidence available, overall, the evidence is limited to mostly small samples and heterogeneity between studies. Research questions focused on sleep latency, sleep duration and sleep quality, the effect sizes of which may be too small to be clinically significant.
- **Cost effectiveness or resource impact –** No studies of cost-effectiveness were identified. Circadin® MR tablets costs £0.30 - £1.50 per day (based on current UHBW contract price) for a dose range of 2-10mg. The most common dose is 3mg daily which costs £0.45 per patient day. It has been estimated that approximately 50 patients per year will be prescribed melatonin in PICU/HDU for up to 4 weeks. For this cohort and for the maximum treatment duration, this would have a relatively small cost implication of approximately £735 per year. Costs estimated based on common doses used in practice. Melatonin liquid, which is more expensive, has not been dispensed to any patients on PICU for this indication in the last year and would only be used in exceptional circumstances.
- **Place in therapy relative to available treatments –** Melatonin use for this indication would be offered second line following a review of any medication causing insomnia and sleep hygiene improvement. The third line option for this cohort is chloral hydrate. Use of melatonin would replace or at the very least reduce the use of other sedatives which may have a more harmful side effect profile. Melatonin for this indication would be TLS Red on the BNSSG Paediatric Formulary, restricted to use on PICU/HDU only and not to be continued on discharge.
- **National guidance and priorities –** There is no national guidance relative to the use of melatonin in paediatric patients on an ICU or HDU setting. Various NICE guidelines include melatonin as an option for sleep indications in children.
- **Local health priorities –** Formulary review of melatonin indications is a high priority locally.
- **Equity of access –** A total of 29 CCG Formularies were reviewed to determine whether other areas include melatonin for use in PICU/HDU on their formulary. No other formularies specified use for this indication/cohort, however many formularies included the use of melatonin in paediatrics for other sleep indications. In BNSSG, melatonin is already on the paediatric formulary as TLS amber 3 months for children with neurodevelopmental disorder/disability with intrinsic sleep disorder (difficulty getting to sleep or remaining asleep) who have exhausted all behavioural sleep hygiene options. In BNSSG, for adult patients, melatonin is included on the formulary for ICU to prevent delirium.

Conclusion

The group considered the application, the evidence and the information submitted. The evidence supports the use of Melatonin for short term use for the specified patient cohort. Melatonin is included onto the BNSSG Adult Formulary for ICU patients (to prevent delirium). Melatonin has a good safety profile, and there is sufficient evidence to suggest melatonin is effective in improving onset and duration of sleep, despite variation in improvement found in the evidence. The group agreed to include Melatonin onto the BNSSG Paediatric Formulary as TLS red as the perceived benefits on sleep may support healing and recovery in this cohort of patients with a small financial impact.

Action:

1. The Formulary team to include Melatonin for off-label for use on PICU and HDU (during hospital stay only) to aid onset of sleep in patients with neurodevelopmental disorders/ASD and other conditions e.g. bone marrow transplant and renal patients who are suffering from sleep cycle disorder following prolonged stays and who have not responded to standard sleep hygiene measures onto the BNSSG Paediatric Formulary as TLS red.

12 Action log – Paediatrics

The Paediatric Joint Formulary Group action log was not discussed during todays meeting.

13 New Drug Requests (NDR) Paediatrics

Nil

- **Shared Care Protocols/TLS Status – Paediatrics**

New SCPs

Mirabegron for overactive bladder syndrome in children, *XXXX, PICU Pharmacist and Lead Pharmacist for Paediatric Surgery.*

The group agreed to discuss the new shared care protocol for Mirabegron for overactive bladder syndrome in children via email due to today's meeting over running in time.

Updated SCPs

Nil

Traffic Light Status Request Change

Nil

14 Items for Discussion – Paediatrics

Nil

15 Potential NDRs for July Meeting (no paperwork, for information only)

- **Oritvancin** for acute bacterial skin and skin structure infections (ABSSI)
- **Tenecteplase** for thrombolysis in acute ischaemic stroke
- **Ameluz** for the treatment of actinic keratosis of mild to moderate severity (Olsen grade 1 to 2) and of field cancerization in adults; and the treatment of superficial and/or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment related morbidity and/or poor cosmetic outcome in adults.
- **Testim** gel for the treatment of low sexual desire in post-menopausal women as another option in addition to existing options on formulary.
- **Synalar 1 in 4** (Fluocinolone 0.00625% Ointment and Cream) for milder forms of a wide variety of inflammatory, pruritic and allergic disorders of the skin as per the licensed indications

16 AOB

Shared Care Protocols Review Plan

The group agreed to discuss the shared care protocol review plan at the next Joint Formulary Group meeting.

Date of Meeting	Time	Venue	Meeting Type
~~25-Jan-2022~~	~~13:00 – 16:00~~	~~Virtual, Microsoft Teams~~	~~Adults Only~~
~~15-March-2022~~	~~09:30 – 13:30~~	~~Virtual, Microsoft Teams~~	~~Adults & Paediatrics~~
~~26-April-2022~~	~~13:00 – 16:00~~	~~Virtual, Microsoft Teams~~	~~Adults Only~~
~~14-June-2022~~	~~09:30 – 13:30~~	~~Virtual, Microsoft Teams~~	~~Adults & Paediatrics~~
~~26-July-2022~~	~~13:00 – 16:00~~	~~Virtual, Microsoft Teams~~	~~Adults Only~~
~~13-Sept-2022~~	~~09:30 – 13:30~~	~~Virtual, Microsoft Teams~~	~~Adults & Paediatrics~~
01-Nov-2022	13:00 – 16:00	Virtual, Microsoft Teams	Adults Only
13-Dec-2022	09:30 – 13:30	Virtual, Microsoft Teams	Adults & Paediatrics

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

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

NICE College Meeting

Date of Meeting: **Thursday 21st July 2022**
Time: **10:00 – 12:00**
Venue: **Microsoft Teams, Virtual**

Minutes

Present		
XXXX	Principal Medicines Optimisation Pharmacist, BNSSG ICB	XX
XXXX	Team Administrator & Minute Taker, BNSSG ICB	XX
XXXX	Interface Pharmacist, BNSSG ICB	XX
XXXX	Interface Pharmacist, BNSSG ICB	XX
XXXX	Specialist Pharmacist, High Cost Drugs, UHBW	XX
XXXX	High Cost Drugs Pharmacist, NBT	XX
XXXX	NICE Manager, University Hospitals Bristol NHS Trust	XX
XXXX	High Cost Drugs Pharmacy Technician, BNSSG ICB	XX
XXXX	Business Intelligence Analyst, Contracting, BNSSG ICB	XX
XXXX	Contract Accountant, NBT	XX
Apologies		
XXXX	Principal Pharmacist, Specialist Commissioning, NHS England South	XX
XXXX	Deputy Director, Medicines Optimisation, BNSSG ICB	XX
XXXX	Senior Pharmacist, Pharmacoeconomics, NBT	XX
XXXX	Interface Pharmacist, NBT	XX
XXXX	Clinical Audit and Effectiveness Manager, UHBW	XX
XXXX	Pharmacy Advisor, Specialist Commissioning, NHS England South	XX
XXXX	Principal BI Analyst, BNSSG ICB	XX
XXXX	Interface Pharmacist, BNSSG ICB	XX
XXXX	Principal Pharmacist, Lead for Pharmacoeconomics & High Cost Drugs Management	XX

	Item	Action
01	**Welcome and Introductions** XXXX (XX) opened the meeting. Introductions were made and apologies were noted as above.	
02	**Previous Minutes and Action Log** The group discussed the previous meeting minutes from Thursday 23rd June 2022. The group raised some comments in relation to the minutes. It was advised on page 3 this should be Ruxolitinib oppose to Ravulizumab. It was also advised on page 4 it should be 'Saxenda Form' and not 'Sense Check Form'. XX agreed to amend the minutes in June and re-circulate to the group. The Action Log was discussed and noted below.	

	Item	Action
	Ref 110: Finance (M12) - *XX agreed to review the coding for insulin pumps for UHBW (Weston)* • XX advised the coding for insulin pumps for UHBW (Weston) is starting to take place. The group agreed this action can close. **Ref 111: Finance (M12)** - *XX check 21/22 M12 FOTs against Horizon Scanning 22/23 budget and flag and risk.* • XX has checked 21/22 M12 FOTs against Horizon Scanning. The group agreed this action can close. **Ref 112: Finance M1 22/23 -** *XX, XX and XX to link up to discuss a set of IR rules. Once rules are agreed XX will contact XX and advise her of these rules* • XX, XX and XX have met to discuss the IR rules. It was agreed to XX to share this with XX and XX. The group agreed this action can close. **Ref 113: Finance M1 22/23 -** *XX to insert additional 'proposed Horizon Scanning budget year to date' Colum to finance report.* • This action is complete. The group agreed this action can close. **Ref 114: Finance M1 22/23 -** *XX to resolve XX's drugs challenges query from last year with the Finance team.* • This action is complete. The group agreed this action can close. **Ref 115: TA792 Filgotinib UC NBT -** *XX to discuss TA792 Filgotinib UC NBT with XXXX and High Cost Drugs and report back to the group* • This action is ongoing.	
03	**Finance M2 22/23** **Presentation for Directors of Finance Summary – M2** XX advised XX and XX met XXXX who is responsible for the high cost drug budgets within the ICB. A bi-monthly report/presentation has been requested for the Directors of Finance. XX shared the presentation with the group. The presentation includes the month finance summary for NBT and UHBW (Bristol & Weston). This includes the overall 22/23 FOT budget allocated for each trust, FOT variance against allocated budget, FOT variance against NICE and the NICE YTD variance. XX has also included the risks, mitigations and actions per each trust along with a proposal/escalation section for the Directors of Finance. The presentation will be presented to the Directors of Finance on Friday 29th July. XX agreed to circulate the presentation to the group for comments/feedback. **M2 BNSSG NICE Report** The M2 BNSSG NICE report has been circulated to the group. NBT and UHBW advised there is not budget against Filgotinib which will be used this month. The YTD variance on the NICE summary for NBT does not match the YTD figure on the summary sheet. XX advised this is currently being reviewed. In terms of PbR Excl and IFR. It was agreed some drugs will need to be removed such as Dimethyl Fumarate, Dupilumab, Eltrombopag, Filgotinib and Guselkumab. XX advised	

	Item	Action
	Idarucizumab will need to be included onto the TA sheet. XX discussed Liothyronine (£9,702) which is appearing on the PbR Excl and IRF spreadsheet. It was agreed Liothyronine should be removed. Botox is also on the PbR Excl and IRF spreadsheet which should be removed. **Data Challenges** The group discussed the data challenges. The NBT data challenges were devices. XX advised the reconciliation for M1 was fine however in M2 there was a £4K difference. XX advised this is due to the classification of the diabetes consumables. These have been moved from the drug report to the devices report, as this was felt to be more suitable. As a result in M2 the tariff code was changed. XX advised for M3 this will be reverted back to the previous tariff code to ensure this aligns. XX advised the Insulin Pumps should be reported under drugs and TA151, not devices however CGM should be reported under devices. XX agreed to review this further internally within NBT. **Action:** **1.** XX to review NBTs diabetes consumables under drug and devices report internally and feedback to the group. In terms of UHBW. XX and XX have reviewed the data and advised there was a patient coded for Cardiology and Adalimumab it is believed to be coded to the wrong speciality and should be under Rheumatology. XX agreed to review the patients who do not have an allocated NICE TAG and feedback this information to XX. XX agreed to liaise with UHBW internal finance. **Action:** **1.** XX agreed to review the patients who do not have an allocated NICE TAG and feedback this information to XX. **2.** XX to change the word “proposed” to “allocated” on the budget titles for the NICE spreadsheet.	**XX** **XX** **XX**
04	**NICE Implementation Plans / Statements** **TA768 Upadacitinib** XX discussed the NICE Implementation plan for Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDS. XX advised the NICE implementation plan is to extend the cohort for other treatments. NBT and UHBW raised no concerns in the implementation of Upadacitinib. This will be included into the pathway. The group agreed to sign off the TA768 Upadacitinib NICE Implementation plan. **TA792 Filgotinib** XX discussed the NICE Implementation plan for Filgotinib for treating moderately to severely active ulcerative colitis. XX advised this was a follow up from discussions which took place during NICE College on Thursday 23rd June 2022. The group agreed to sign off the TA792 Filgotinib NICE Implementation plan.	

	Item	Action
05	**NICE TA Publications** XX discussed the NICE TA Publications for June 2022. Filgotinib for treating moderately to severely active ulcerative colitis has been discussed by the group. There will be an implementation plan in due course for Faricimab for treating diabetic macular oedema and wet AMD.	
06	**Consideration of TAGs for early implementation** There was no TAGs to consider for early implementation at todays meeting.	
07	**Items for discussion** **Report from Blueteq on incorrect TAGs** XX shared the information for incorrect reported TAGs on Blueteq with the group. XX has been analysing this data from the SLAM database to understand the reasons behind the incorrect TAGs on Blueteq. XX will be reviewing this with XX outside of the meeting. There are incorrect TAGs for Gastroenterology patients which were listed as crohn's disease but was used for UC or listed as UC when it was used for crohn's. XX advised the majority if the incorrect TAGS are from UHBW (Weston). **Rheumatology onto Blueteq** XX advised a discussion regarding Rheumatology being included onto Blueteq took place with XXXX. XX will ensure the TAGs are set up as forms over the next couple of months.	
08	**AOB** **Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides (TA805).** XX advised this will be around £1,400 per a year per patient. The group discussed whether this would be primary care or secondary care led. XX agreed to share the NICE costing template with XX for review. The NICE costing template advises there is a cost impact of £504,316. It is estimated there is currently 7,000 patients currently receiving statin across BNSSG and there are 349 patients who would be moved to Icosapent ethyl. The group felt Icosapent ethyl will predominately be initiated from primary care where the cohort would have had lipid management optimised with a few patients initiated within secondary care. The group advised there is currently a national pathway which includes Icosapent ethyl. It was agreed to discuss the TLS for Icosapent ethyl during a Joint Formulary Group meeting to confirm TLS. **Roxadustat** XX has flagged to the NBT renal team and this is currently being reviewed. XX agreed to review whether an implementation plan is required for the Joint Formulary Group. **Adalimumab** XX advised the two brands of Adalimumab are currently being used at NBT (Imraldi and Amgevita). XX raised does Imraldi still have to be used first line. It was advised NHS guidance states to use the allocated contract brand given to keep the market place open. It was recommended for NBT to discuss further with NHSE.	

	Item	Action
	Next Meeting Thursday 8th September, 10:00 – 12:00	

XXXX
Team Administrator, BNSSG ICB
July 2022

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

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

NICE College Meeting

Date of Meeting: **Thursday 8th September**
Time: **10:00 – 12:00**
Venue: **Microsoft Teams, Virtual**

Minutes

Present		
XXXX	Principal Medicines Optimisation Pharmacist, BNSSG ICB (Chair)	XX
XXXX	Team Administrator & Minute Taker, BNSSG ICB (Minute taker)	XX
XXXX	Interface Pharmacist, BNSSG ICB	XX
XXXX	Interface Pharmacist, BNSSG ICB	XX
XXXX	Interface Pharmacist, BNSSG ICB	XX
XXXX	Specialist Pharmacist, High Cost Drugs, UHBW	XX
XXXX	High Cost Drugs Pharmacist, NBT	XX
XXXX	NICE Manager, University Hospitals Bristol NHS Trust	XX
XXXX	Principal BI Analyst, BNSSG ICB	XX
Apologies		
XXXX	High Cost Drugs Pharmacy Technician, BNSSG ICB	XX
XXXX	Business Intelligence Analyst, Contracting, BNSSG ICB	XX
XXXX	Contract Accountant, NBT	XX
XXXX	Principal Pharmacist, Specialist Commissioning, NHS England South	XX
XXXX	Deputy Director, Medicines Optimisation, BNSSG ICB	XX
XXXX	Senior Pharmacist, Pharmacoeconomics, NBT	XX
XXXX	Interface Pharmacist, NBT	XX
XXXX	Clinical Audit and Effectiveness Manager, UHBW	XX
XXXX	Pharmacy Advisor, Specialist Commissioning, NHS England South	XX
XXXX	Principal Pharmacist, Lead for Pharmacoeconomics & High Cost Drugs Management	XX

	Item	Action
01	**Welcome and Introductions** XXXX (XX) opened the meeting. Introductions were made and apologies were noted as above.	
02	**Previous Minutes and Action Log** The group discussed the previous meeting minutes from Thursday 21st July 2022. There were no comments from the group for any amendments to be made to these minutes.	

	Item	Action
03	**Finance M3 22/23** XX presented M3 22/23 Finance report data with the group and provided a summary of the year to date position within BNSSG. **NBT (total drugs and devices spend)** YTD actuals is £2,464,208 YTD variance is -£284,675 Forecast outturn variance is -£1,138,699 **UHBW (Bristol) (total drugs and devices spend)** YTD actuals is £6,157,315 YTD variance is -£242,542 Forecast outturn variance is -£1,406,589 **UHBW (Weston) (total drugs and devices spend)** YTD actuals is £553,285 YTD variance is -£62,166 Forecast outturn variance is -£3,095,364 There is underspending against the allocated purposed budget within the M3 data across all trusts. There is a delay with UHBW's homecare invoicing due to staff capacity, which may create a spike in finance in due course. XX to check UHBWs unbilled home care (outstanding invoices) within the finance data and update the group. **Action** 1. XX to check UHBWs unbilled home care (outstanding invoices) within the finance data and update the group.	**XX**
04	**NICE Implementation Plans / Statements** **TA799 - Faricimab for treating diabetic macular oedema & TA800 - Faricimab for treating wet age-related macular degeneration** The group discussed TA799 and TA800 (Faricimab). It was confirmed Faricimab is already on the BNSSG Formulary. The group agreed clinicians would need to complete a Blueteq form when initiating Faricimab. The Blueteq form will contain a criteria to state if the patient is failing to extend over 6 weeks to initiate Faricimab and to conduct another Blueteq review in 6/12 months time due to the cost savings only being applicable if the patient is using Faricimab 4/5 times per year. In terms of cost, Ranibizumab biosimilar vial is £231 per vial, Aflibercept is £456 per vial and Faricimab is £546 per vial. Faricimab will need to be used less per year to be comparative to Aflibercept. XX advised 97% patients are currently on Aflibercept with an aim to make savings by switching these patients to biosimilar. If these patients were switched to Faricimab there will be no cost savings. In regards to a clinical perspective. Faricimab is non-superior to Aflibercept from an outcome point of view. Clinicians have advised Faricimab has a less frequent injections required which does support workforce capacity. NICE have recommended to use the most cost effective agent.	

	Item	Action
	The group agree with Faricimab' s place in therapy, however the group would like to support NICE and ensure patients receive the most cost effective treatment option. The group recommended for patients who are unable to extend dosing intervals on Faricimab they should be returned to treatment with a most cost-effective agent, aflibercept or ranibizumab. The group agreed to review at the ICS MO High Cost Drugs meeting on Wednesday 21st September. **TA791 - Romosozumab for treating severe osteoporosis** The group discussed TA791 (Romosozumab). XX advised the anticipated numbers of patients within BNSSG are 300 which equals to £1,147,800 per year. This includes all trusts covering Rheumatology and Orthogeriatrics. XX advised the NICE TA is for women with severe osteoporosis who are at high risk of fractures. NICE have provided detailed criteria. Romosozumab is currently not licensed for men. The treatment dosage is once per month for 12 months. XX advised Teriparatide treatment is for 24 months. XX compared costs, Romosozumab costing is similar to Teriparatide due to the difference in treatment duration. XX advised Romosozumab will be alongside Teriparatide within the treatment pathway due to Teriparatide being licensed for men. XX agreed to liaise with clinicians to understand the number of patients who would be initiated within the first 6 months. Once this information has been obtained the group agreed to review at the ICS MO High Cost Drugs meeting on Wednesday 21st September. **Action** 1. XX agreed to liaise with clinicians to understand the number of patients who would be initiated within the first 6 months. **TA803 Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs** The group discussed TA803 (Risankizumab). Risankizumab is approved by NICE. XX advised the patient is required to be assessed for psoriasis, this has been agreed by Dermatology. XX advised there has been an update for TA717 (Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs) this has been superseded to TA815. XX advised the main change is Guselkumab can now also be used first line after cSDMARDs if TNFi. The group agreed the update does not change the patient numbers/cost therefore a new implementation plan is not required. **TA807 Roxadustat for treating symptomatic anaemia in chronic kidney disease** The group discussed TA807 (Roxadustat). XX advised Roxadustat is a new class of medication, therefore it is anticipated the initial scale-up in patient numbers would be slow (3 patients first 6 months). However clinicians expect patient numbers to increase in time. Roxadustat is an oral version of subcut Erythropoietin. Erythropoietin is currently funded by NHS England. The clinicians have advised Roxadustat will be initiated to patients who are needle phobic. The group agreed to discuss at ICS MO High Cost Drugs meeting. The group agreed to sign off the implementation plan. **TA814 Abrocitinib, Tralokinumab or Upadacitinib for treating moderate to severe atopic dermatitis.** The group discussed TA814 (Abrocitinib, Tralokinumab or Upadacitinib). XX advised adult and paediatric patients are seen in UHBW. XX advised Baricitinib and Dupilumab are the current treatment options. There is unlikely to be an increase in cost due to the cohort of patients will already be on treatment. Abrocitinib, Tralokinumab or Upadacitinib is more cost effective than Baricitinib and Dupilumab. There are concerns on the number of patients increasing and is also higher than NICE's predictions. The group agreed to	**XX**

	Item	Action
	discuss at ICS MO High Cost Drugs. XX will obtain patient numbers from Dermatology and feedback to XX.	
05	**NICE TA Publications** The group discussed Icosapent Ethyl. It was advised the BNSSG Formulary team are required to review Icosapent Ethyl and determine a traffic light status for the BNSSG Formulary. It was agreed for secondary care to provide their thoughts on a traffic light status to the group. XX agreed to liaise with Alison Mundell (Principal Pharmacist, BNSSG ICB) to discuss further. It was agreed for ICB to create an Implementation Plan. **Action** 1. Secondary care to provide their thoughts on a traffic light status for Icosapent Ethyl. 2. XX to create an Implementation plan for Icosapent Ethyl and present at the next NICE college meeting.	**XX/XX** **XX**
06	**Consideration of TAGs for early implementation** There were no consideration of TAGs for early implementation to discuss during todays meeting.	
07	**Items for discussion** **Blueteq - Rheumatology draft forms** XX advised the Blueteq Rheumatology forms are currently in progress.	
08	**AOB** **Infliximab** XX advised there was the switch from Inflectra to Remsima that took place in January, which would be an estimated £250K savings per year. XX advised there have been issues with the lab who are still billing Pfizer for the testing. The lab should be billing Remsima company Celltrion. It was confirmed this is not an issue for NBT. There is now a national shortage of Remsima. UHBW have been ordering Inflectra to ensure patients receive Infliximab treatment and avoid switching. XX advised the costings will increase due to Inflectra costing more than Remsima. XX liaised with the lab manager to advise when ordering test the lab will be to submit which brand is being ordered. XX advised the prices do not include the testing, therefore there may be a bill outstanding to pay for the tests. XX agreed to discuss at ICS MO High Cost Drugs. **Filgotinib for UC** XX advised the early implementation plan was completed however further discussions were agreed to take place to discuss Filgotinib's place within the pathway. XX agreed to liaise with XXXX for an update. **Action** 1. XX agreed to liaise with XXXX for an update on Filgotinib's place within the pathway for UC and feedback to the group.	**XX**

	Item	Action
	Next Meeting Thursday 20th October, 10:00 – 12:00	

XXXX/XXXX
Team Administrator, BNSSG ICB
September 2022

BNSSG Joint Formulary Group (JFG)

Terms of Reference

1. Introduction

A local formulary is defined as 'the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a Health Economy, service or organisation' (NICE Medicines Practice guideline MPG1 'Developing and updating local formularies 2014).

The BNSSG Joint Formulary (JF) is a local formulary that is a joint venture across the care system, and recognises the needs of primary, community and secondary care and the impact that drug choice in one sector can have on the others. The BNSSG Joint Formulary Group (JFG) is the committee with responsibility for promoting appropriate, safe, rational, evidence based and cost effective use of medicines and prescribable medical devices to improve patient outcomes, promote medicines management guidance and resource decision making to the best effect for the health of the local population. The BNSSG JFG develops, manages and produces the local formulary which is evidence based, considers clinical and cost-effectiveness and reflects the needs of the local population and local affordability. It aims to cover prescribing across the BNSSG Health community (approximately 1,000,000 population) (FP10 prescriptions, Acute trust prescriptions, FP10 (HP) prescriptions, FP10D dental prescriptions and recommendations made to GPs e.g. in out-patient letters)

The JFG has delegated responsibility from all BNSSG organisations with regards to the formulary. The JFG has no delegated responsibility for resource allocation. Decisions made by the JFG are intended to guide clinical decisions.

2. Membership and Responsibilities

The JFG is a decision- making group within the remits outlined within the terms of reference, and therefore organisations will need to delegate responsibility to their representative members.

Each member of the JFG has core Roles and Responsibilities:

- Commit to regular attendance to ensure consistency and equity of decision making.

- Hold delegated responsibility to their representative members.
- Declare conflicts of interest as required at each meeting.
- Undertake work as necessary between meetings including reading papers in advance of the meetings.
- Participate in the discussions around the New Drug Requests and Shared Care Protocols.
- Ensure decisions made are consistent and equitable in line with the decision making and ethical framework (see section 7)
- Take decisions from JFG back to individual organisations and promote the formulary within them.
- Ensure agreed actions are followed up and reported back to the group

The list of roles and responsibilities are not exhaustive and members may be asked to support other roles as materialise

Organisation	Job Title	Additional Roles and Responsibilities
BNSSG Public Health	Public Health Consultant	• Chair the JFG meetings • If unable to attend, to organise a deputy • Introduce applicants • Inform applicants of decisions • Ensure decision criteria used by JFG for appraising NDRs are explicitly discussed to ensure transparency and consistency of decision making.
BNSSG CCG	Deputy Director (Medicines Optimisation)	• Hold budgetary responsibility for Primary Care Prescribing budget and the PbR excluded non-NICE, CCG commissioned budget.
	Principal Pharmacist-BNSSG system	• Support the Formulary Leads with formulary related issues as they arise. • Deputise for Deputy Director (Medicines Optimisation) where necessary.
	Interface Pharmacists (Formulary Leads)	• Manage and co-ordinate the NDRs pre and post meeting • Liaise with primary care application applicants • Secretary for the Meetings • Liaise with applicants prior to and after meetings • Inform applicants of the outcome of the application • Update the Formulary Website • Be responsible for formal minutes and action logs of the meetings. • Ensure appropriate communication of decisions upwards through the Governance structure.
	Clinical Lead for Prescribing	• Provides primary care clinical perspective • Engages with other GPs where needed. • Provides clinical support to Formulary Leads where necessary.
UHBW (Bristol)	Clinical Pharmacy Manager	• Coordinate the NDRs within the trust, ensuring it is received by the interface pharmacist 6 weeks prior to the next meeting. • Ensure internal organisational governance processes have been adhered to prior to the meeting. • Support Interface Pharmacist in liaising with applicants where needed. • To be responsible for actions relating to their Trust.

Organisation	Job Title	Additional Roles and Responsibilities
		• To ensure decisions are communicated and embedded in practice at their Trust. • Ensure that the appropriate Division is aware of the application and that the application is signed off.
	Clinician Representative from UHBW (Consultant)	• Provides secondary care clinical perspective • Engages with other clinicians in Trust where needed. • To ensure decisions are communicated and embedded in practice at their Trust.
	Senior paediatric Pharmacist from BRCH	• Coordinate the paediatric NDRs within the trust, ensuring the initial NDR is received by the interface pharmacist 6 weeks prior to the next meeting. • Support Interface Pharmacist in liaising with applicants where needed. • To provide expertise on applications for children and interpret whether any adult applications should also be applicable to children. • To be responsible for actions relating to within their Trust. • To ensure that decisions are communicated and promoted at their Trust. • Ensure that the appropriate Division is aware of the application and that the application is signed off.
	Clinician Representative from BRCH (Paediatric Consultant)	• Engages with other clinicians in Trust where needed. • To ensure that decisions are communicated and embedded in practice at their Trust. • Provides secondary care clinical perspective
North Bristol NHS Trust (NBT)	Formulary Pharmacist (or other senior pharmacist)	• Coordinate the NDRs within the trust, ensuring it is received by the interface pharmacist 6 weeks prior to the next meeting. • Ensure internal organisational governance processes have been adhered to prior to the meeting. • Support Interface Pharmacist in liaising with applicants where needed • To be responsible for actions relating to their Trust. • To ensure that decisions are communicated and promoted at their Trust. • Ensure that the appropriate Division is aware of the application and that the application is signed off.
	Clinician Representative from NBT (Consultant)	• Provides secondary care clinical perspective • Engages with other clinicians in Trust where needed. • To ensure that decisions are communicated and promoted at their Trust.

Organisation	Job Title	Additional Roles and Responsibilities
UHBW (Weston)	Deputy Chief Pharmacist	• Co-ordinate the NDRs within the trust, ensuring the initial NDR is received by the Interface Pharmacist 6 weeks prior to the next meeting. • Liaise with applicants ensuring they know when their application will be discussed. • To be responsible for actions relating to their Trust. • To ensure that decisions are communicated and promoted at their Trust. • Ensure that the appropriate division is aware of the application and that the application is signed off.
	Clinician representative from WAHT	• Provides secondary care clinical perspective • Engages with other clinicians in Trust where needed. • To ensure that decisions are communicated and embedded in practice at their Trust.
Primary Care provider	GP or Non-Medical Prescriber	• Provides primary care clinical perspective • Engages with other GPs where needed.
Avon and Wiltshire Mental Health Trust (AWP)	Formulary Pharmacist	• Provide Mental Health Provider clinical perspective • Link in with BNSSG formulary pharmacists where appropriate • Ensure that the BNSSG and AWP formularies align as closely as possible.

Members of the Committee should send a nominated deputy to the meeting. These individuals must be able to operate with full authority over any issue arising at the meeting.
Members should give 3 month's notice of resignation from the Committee to enable timely replacement of the resigning member and allow continuity of membership.

Welcome to attend and papers also circulated to

The minutes of the meetings will also be sent to other individuals for information and to inform their own governance arrangements. The individuals are welcome to attend any meetings that are relevant to their clinical practice.

Organisation	Job Titles
University Hospitals Bristol & Weston NHS Foundation Trust (UHBW)	Director of Pharmacy (Bristol)
University Hospitals Bristol & Weston NHS Foundation Trust (UHBW)	Chief Pharmacist (Weston)
North Bristol NHS Trust	Director of Pharmacy
NHS England, Area Team	Specialised Commissioning Pharmacist
Local Hospices (St Peters, Charlton Farm Childrens Hospices)	Lead Pharmacist
Sirona Care and Health (SCH)	Lead Pharmacist

Organisation	Job Titles
Childrens and Adolescent Mental Health Services (CAMHS)	Clinician
HMPs within BNSSG area (Ashfield, Bristol, Eastwood Park and Leyhill)	Lead Pharmacist

Other persons may be invited to attend to enable the Committee to discharge its functions effectively. The committee will also invite guests to attend, to present information and/or provide the expertise necessary for the committee to fulfil its responsibilities.

4. Administration

A named administrator from BNSSG CCG will be responsible for the provision of administrative support to the Committee and they will ensure that minutes of the meeting are accurately produced and agreed with members.

The agenda and papers (including the completed New Drug Request (NDR) applications) will be circulated no less than 5 working days before each meeting. Completed NDRs will need to be sent to the Formulary Leads no later than 6 weeks before each meeting. NDRs not received within this timescale will be deferred. The Formulary Leads will be responsible for executive duties to the review group and ensuring agreed actions are recorded and implemented.

Applicants are expected to attend the JFG meeting to present their New Drug Request wherever possible in order that they are able to answer any questions that the group may have. Failure to attend may mean that the application has to be deferred until the next meeting. All NDRs should be completed fully, and will be rejected if they are incomplete.

Members of the JFG will be asked to make Declarations of Interests. This will be in the form of an annual declaration by completing a form held by the BNSSG Joint Formulary Pharmacist. In addition, at the beginning of each meeting the Chair will ask any attendees to declare any additional interests. The JFG will decide what, if any effect such a declaration will have on the deliberations of the meetings and decide appropriate action.

Where the chair of the BNSSG JFG has made a declaration that could have an effect on the deliberations he/she will pass the chair to the Joint Formulary Pharmacist or a nominated acting chair.

5. Quoracy

For meetings which concern adult agenda items only, the meeting will be quorate with the attendance of the membership as below:-

- Three members from BNSSG CCG or their deputies, to include a GP Clinical lead.

- Two members from acute provider Trusts (UHBW, NBT) or their deputies preferably to include a Consultant or other medical physician.
- Two Medical physicians, the representation of this can be either, two GPs, two secondary care physicians or 1 GP and 1 secondary care physician.

For meetings which concern paediatric agenda items, the meeting will be quorate with the attendance of the above plus:-

- A paediatric medical representative from BRCH
- A paediatric senior pharmacist representative from BRCH

However, if a decision being made is predominantly affecting one area of the system where no medical representation is present in that meeting, for example, a decision affecting acute provider Trusts where no Consultant is present, then the decision will have to be delayed in that meeting and either:

i. reviewed by the missing representative outside the Committee and confirmed in an email to the secretariat whether the decision is endorsed or not, or
ii. deferred until the next meeting.

Where the Committee is assured that the appropriate input and sign-off from the lead specialist/s has been appropriately obtained for the guideline/pathway in question, the Committee may approve a decision without following the process above in point i. and ii.

The aim will be to reach consensus without the need to resort to a vote. A decision put to a vote at the meeting shall be determined by a majority of the votes of members present. In the case of an equal vote, the Chair of the Committee shall have a second and casting vote.

If the meeting is not quorate, the Chair will determine if the meeting should proceed and the interface pharmacists will secure active endorsement of any decisions post-meeting.

For meetings held virtually which are not quorate, active endorsement of any decisions will be sought post-meeting by email. The quorate membership will be required to confirm their agreement by email within the specified time frame. Decisions will not be approved until all the quorum has responded. Active response required. Agenda if not followed up refer to Chair

In the event of a participant being unable to attend a meeting, the member should nominate an appropriate deputy to represent them. The deputy must be approved by their organisation to hold delegated decision making powers. The member should notify the chair of any deputies.

Extra-ordinary virtual decision making

An extra-ordinary virtual JFG decision may be made if the following criteria are met:

a. There is an urgent Formulary issue that cannot wait until the next scheduled JFG meeting and
b. this issue is supported by an urgent clinical need and
c. the decision is required to maintain and/or improve health, reduce risk and prevent harm to patients and
d. the expedited Formulary decision has been requested to improve the patient pathway within the local healthcare system.

This will be co-ordinated by the Interface Pharmacists.

Representation of this virtual group must include Directors of Pharmacy for NBT and UHBW, Deputy Director Medicines Optimisation, GP Prescribing Lead, JFG Consultant representative and JFG Chair. In the event of absence, a Deputy must be used.

Responses from all the members (or Deputies) of the virtual group listed above must respond within the timeframe given otherwise a decision cannot be made and the application must be taken to the next JFG.
In usual circumstances, urgent use of a medicine for an individual patient should be managed through local organisational governance processes.

Decision making when a member of the committee leaves and there is a resulting delay to replacement.

If a vacancy in membership of the committee is not immediately replaced and there is a delay, every best effort will be made to find an interim representative by the respective stakeholder organisation.
If the title of the member of the committee is essential to a meeting being quorate and there is no interim representative, the JFG may agree the decisions despite non-quoracy providing that the JFG is assured:

1. that the correct formulary processes have been followed,
2. that the correct stakeholders have been involved in the application,
3. that the applicants have attended the meeting,
4. that there are representatives from the organisation(s) from which the application is made,
5. that there are no objections to the decisions made in the meeting,

If any objections to a decision are made, these must be taken to the next JFG for discussion and agreement.
This process may only be followed in exceptional circumstances to allow continuity of decision making.

6. Meetings

The BNSSG JFG meet on average every 6 weeks (8 meetings per year) the venue will mainly alternate between South Plaza and Pharmacy Department at North Bristol Trust. Meetings may be held virtually if circumstances dictate this is necessary. The decision to conduct the meeting virtually will lie with the Interface Pharmacist Team. Meetings will alternate between adults only and adults and children combined. The running time of the meeting will vary but will average 3 hours.

All member organisations must commit to regular attendance at meetings, as continuity and balance of input into decision-making is of the utmost importance. Nominated deputies should be identified and empowered, wherever possible, to ensure that a balanced complement of members is always present.

7. Guiding Principles

Meetings should encourage open, honest and challenging debate. Decisions should be reached by consensus. Once a decision has been finalised a corporate view will be presented and maintained.

In order to maintain consistency of decision making, for all new drug applications, the JFG will consider it against the criteria below, based on the NICE Guidance MPG1: Developing and updating local formularies, 2014. Each of these points should be discussed and minuted for each New Drug Applications.

Decision Criteria used by JFG for NDR

- Patient safety
- Clinical effectiveness
- Cost effectiveness or resource impact
- Strength of evidence
- Place in therapy relative to available treatments
- National guidance and priorities
- Local health priorities
- Equity of access

These criteria align with the BNSSG Ethical Framework Principles for decision making (Appendix 3) as below.

Ethical Framework Principle	JFG decision criteria
Principle 1- Rational	This will be covered by ensuring the group take into account patient safety, clinical effectiveness and strength of evidence.
Principle 2- Inclusive	This will be covered by ensuring the group take into account equity of access and national guidance and priorities.
Principle 3- Take account of the value we will get	This will be covered by ensuring the group take into account cost effectiveness and place in therapy relative to available treatments. Whilst the JFG does not manage the drug budget or make decisions on purely financial grounds, the group will take into account the cost effectiveness of any new treatment in comparison to the cost effectiveness of existing or alternate treatments.
Principle 4- Transparent and open to scrutiny	This will be covered by ensuring the decisions made by the group and the reasons behind them are clearly communicated and there is a robust appeals process (See Appendix 2)
Principle 5- Promote health for both individuals and the community	This will be covered by ensuring that the group take into account both national guidance and priorities and local health priorities.

8. Roles and Responsibilities

The main roles and responsibilities of the Committee are:

1. To develop, update and maintain the BNSSG JF by:

a) Managing all new medicine and applications for devices prescribable on FP10s, to the JF, making recommendations consistent with the BNSSG Ethical Framework (Appendix 3)
b) Managing the Traffic Light Status (TLS) of formulary medicines including approved NICE Technology Appraisals within the 90 day implementation period and reviewing the TLS of existing drugs when applications to do so are received.
c) Approving Shared Care Protocols (SCPs) for amber medicines which have been co-ordinated by the CCG Interface team with direct communication and collaborative working with all relevant stakeholders.
d) Acknowledging the chapter review process of the BNSSG Joint Formulary, drawing on appropriate specialists in key areas, in accordance with an agreed work plan.
e) Considering and acting on relevant outputs from national bodies such as National Institute for Health and Care Excellence (NICE), Regional Medicines Optimisation Committees (RMOC) and Medicines and Healthcare Regulatory Agency (MHRA).
f) Ensuring that cohorts of patients of Exceptional Funding Requests are identified, through this panel, and that steps are taken to support a JFG NDR for these.
g) Undertaking an annual horizon scanning process to determine those new drugs in the pipeline that will have a potential impact on the JF within a given financial year.
h) Acknowledge any Early Access to Medicines Schemes (EAMS) and Free Stock Schemes which have been managed by the High Cost Drugs STP as per the BNSSG EAMS and Free Stock policy.

2. Encourage and evaluate compliance with the formulary by:

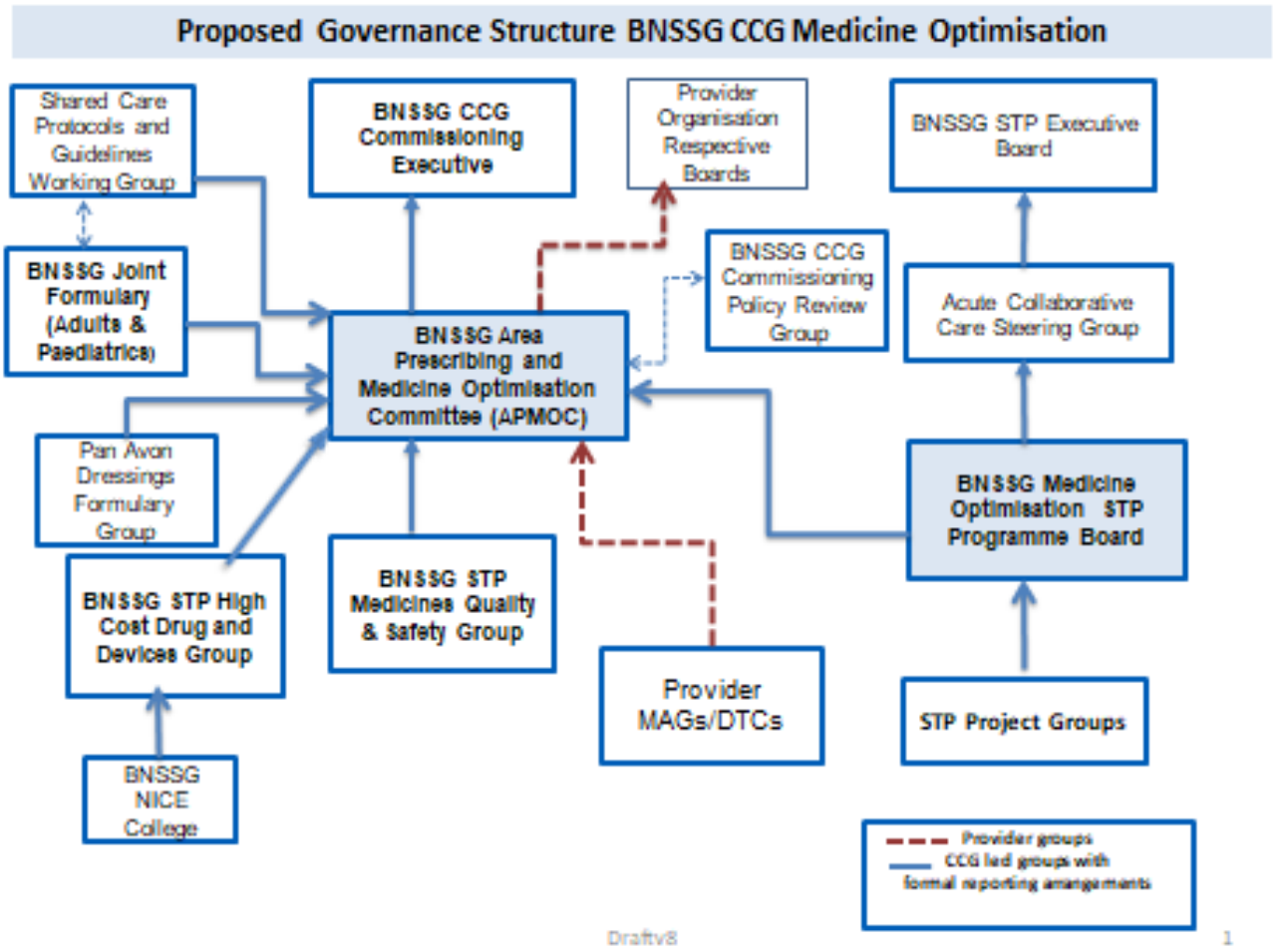
a) Preventing and assisting in the resolution of issues relating to medicine provision at the interfaces of care.
b) Monitoring the implementation and adherence to the formulary through audit and suggesting appropriate action.
c) Communicating recommendations and outputs effectively to all relevant member and stakeholder organisations and encourage implementation.
d) Providing the annual report for the JFG to provide assurance to the CCGs and Provider Trusts.

9. Governance Structure and Reporting Requirements

The Joint Formulary Group reports to and makes recommendations on the suitability of medicines for prescribing to the Area Prescribing and Medicines Optimisation Committee (APMOC) on behalf of BNSSG. Decisions made by the JFG are communicated to the local acute trusts DTCs by the Pharmacist representatives from those Trusts (NBT D&TC, UHBW Bristol MAG) The CCG will also communicate relevant decisions to other stakeholders e.g primary care. Decisions will need to be taken to the CCG Clinical Executive for agreement if they involve significant financial impact on existing system budgets.

Requires new allocated resource or signicant shift inresource – responsibility of JFG to highlight resource requirement on system budgets.

The Shared Care Protocol and Guidelines Working Group is responsible for working up Shared Care Protocols outside of the group so they can come to JFG for final approval.



9. Date to review these Terms of Reference

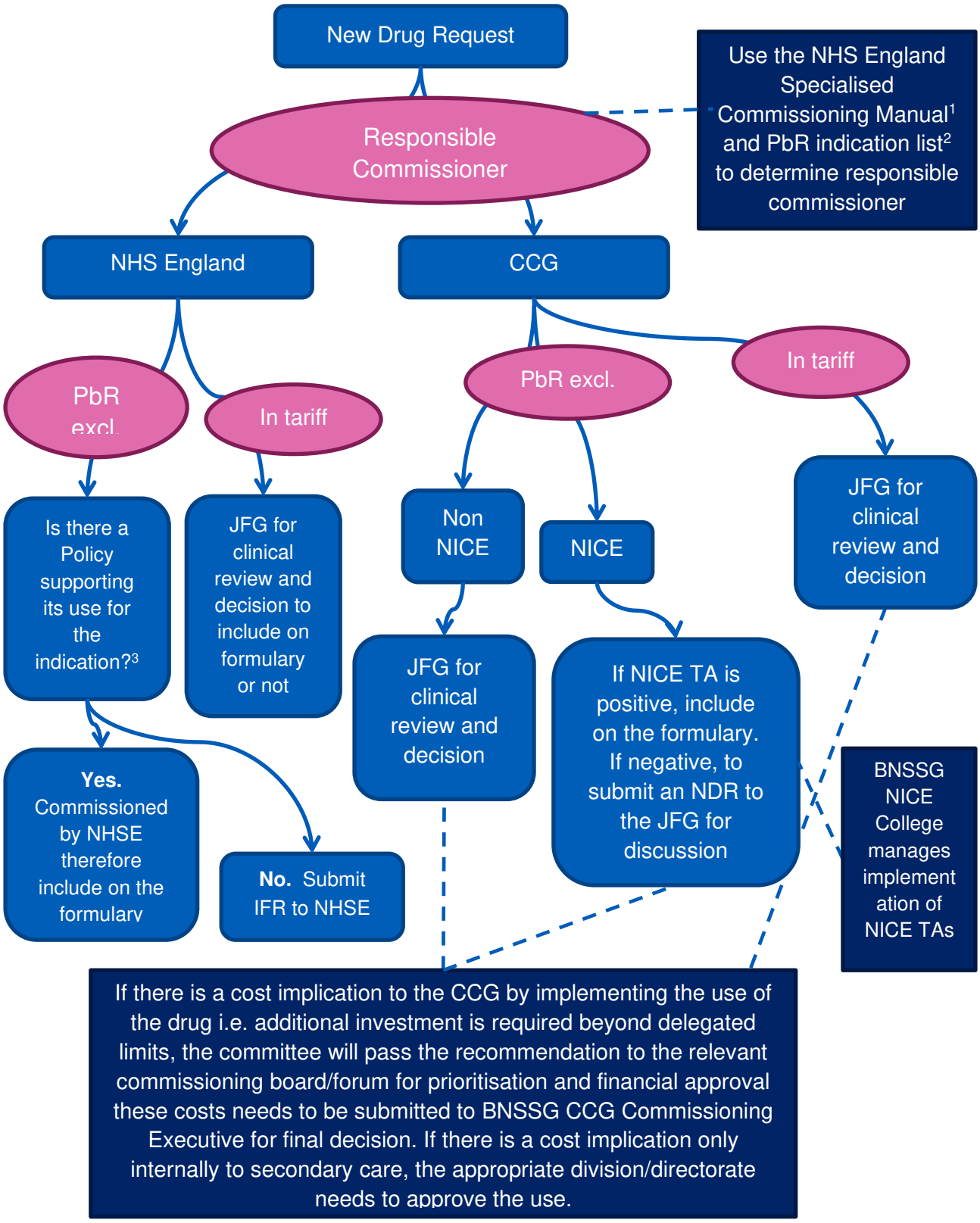
These terms of reference will be reviewed annually to coincide with publication of the JFG Annual Report.

Version	Date	Author/Reviewer	Comment
V1	17/7/2020	xxxxx xxxxx	

Appendices

Appendix 1 BNSSG JF Process for managing the introduction of New Drugs
Appendix 2 BNSSG JF process for review of a Joint Formulary Group (JFG) decision
Appendix 3 BNSSG Ethical Framework

Appendix 1 BNSSG JF Process for managing the introduction of New Drugs



1. NHS England Manual for Prescribed Specialised Services 2018/19 https://www.england.nhs.uk/wp-content/uploads/2017/10/prescribed-specialised-services-manual.pdf
2. Indications for NHS England drugs list version13 https://www.england.nhs.uk/wp-content/uploads/2018/03/nhs-england-drugs-list-v13.pdf
3. NHS England Specialised Services Clinical Reference Groups https://www.england.nhs.uk/commissioning/spec-services/npc-crg

Appendix 2 BNSSG JF process for review of a Joint Formulary Group (JFG) decision

There are two possible routes that the applicant can take to request a review of a BNSSG Joint Formulary Group decision:
1. Reconsideration of the application with further relevant information
2. Appeal the decision

1. Reconsideration

If the applicant believes that there is further relevant information that was not considered by the JFG, they may ask the JFG to reconsider the application specifically in the light of this information. This should be discussed at the next available meeting.

2. Appeal

Grounds for requesting an appeal

The applicant can make a request to the JFG Review Panel to review the decision made. The request should be made within 21 days of being informed of the decision.

The request for review must set out the grounds on which the JFG decision is being challenged. The JFG Review Panel shall consider whether:

• The process followed by the JFG was consistent with the agreed decision making processes of the JFG.
• The decision reached by the JFG:
- was taken following a process which was consistent with the agreed processes of the JFG
- had taken into account and weighed all relevant evidence.
- had not taken into account irrelevant factors
- indicated that the members of the JFG acted in good faith
- was a decision which a reasonable Formulary decision making body was entitled to reach.

In the event that JFG Review Panel consider that there was any procedural error in the decision of the JFG, the JFG Review Panel shall next consider whether there was any reasonable prospect that the JFG may have come to a different decision if the JFG had not made the procedural error.

If the JFG Review Panel considers that there was no reasonable prospect of the JFG coming to a different decision then the JFG Review panel shall approve the decision notwithstanding the

procedural error. Based on the NHS Commissioning Board Commissioning Policy: Individual Funding Request, Reference NHSCD/CP/03, November 2017

Membership of the JFG Review Panel

A CCG Clinical Lead plus two others from the clinicians listed below to include one representative of the submitting organisation:

- Medicines Optimisation Pharmacist
- Director of Pharmacy (UHB, NBT, WAHT)
- GP/Secondary care consultant

A member of the JFG will present the new drugs application in context to the Joint Formulary to the JFG Review Panel (JFGRP) only. They will not attend the review meeting.

None of these members should have been involved in the application prior to the JFGRP. The panel will be quorate if all three members are in attendance and decisions will be reached by consensus.

Purpose of the JFG Review Panel

The JFGRP will examine all the papers considered by the JFG, the reasons for the decision and the grounds of the appeal. The JFGRP will examine the process followed by the JFG and the decision made by the JFG. The JFGRP will examine the issues raised in the grounds for the appeal and the tests set out above. The JFGRP will not consider new information or receive oral representation. If there is significant new information, not previously considered by the JFG, it will be considered as set out under 'Reconsideration'.

The JFGRP will be able to reach one of two decisions:

- To uphold the decision reached by the JFG
- To refer the case back to the JFG with detailed points for reconsideration

In the event that the JFGRP consider that either:

- The decision may not have been consistent with the ToR of the JFG

OR

- The JFG may not have taken into account and weighted all the relevant evidence

OR

- The JFG may have taken into account irrelevant factors

OR

- The JFG may have reached a decision which a reasonable Formulary decision making body was not entitled to reach.

If any of these apply, the JFGRP shall refer the matter to the JFG if they consider that there is a reasonable prospect that the application will be approved by the JFG when it reconsiders. Based on the NHS Commissioning Board Commissioning Policy: Individual Funding Request, Reference NHSCD/CP/03, November 2017

If the JFG Review Panel considers that, notwithstanding their decision on the procedure adopted by the JFG, there is no reasonable prospect that the decision would have been different; the JFGRP shall uphold the decision of the JFG.

Outcome from the JFG Review Panel

The outcome of the JFGRP will be either to uphold the decision of the JFG or to refer back to the JFG for reconsideration.

The JFGRP will inform the applicant and JFG of the outcome of the JFGRP within 1 week. Reasons given should only refer to the basis on which the original decision was made.

If the original JFG decision is upheld, then the applicant will be informed that there are no further routes of appeal.

If the JFGRP determines that the JFG needs to reconsider the new drug application, the JFG will reconsider the application at the next scheduled meeting. The JFG will reconsider its decision and in doing so will formally address the detailed points raised by the JFG Review Panel. The JFG is not bound to change its decision as a result of the case being referred for reconsideration but if it confirms its original decision, then clear reasons must be given.

Appendix 3 BNSSG Ethical Framework

Updated: January 2022, BNSSG Joint Formulary Group
Approved: February 2022, BNSSG Area Prescribing Medicines Optimisation Committee
Review Date: 2 years from approval, or in light of new requirements, whichever is sooner.

Bristol CCG
South Gloucestershire CCG
North Somerset CCG
North Bristol NHS Trust
University Hospitals Bristol NHS Foundation Trust
Weston Area Health NHS Trust

BRISTOL, NORTH SOMERSET AND SOUTH GLOUCESTERSHIRE (BNSSG) HEALTH COMMUNITY

BNSSG NICE COLLEGE

TERMS OF REFERENCE

Overview
The BNSSG NICE (National Institute for Health and Care Excellence) College accepts that commissioning member organisations have a legal duty to make treatments available to patients whose clinical condition(s) come within the definitions listed in a NICE Technology Appraisal within 3 months of the date of the appraisal's publication, unless the treatments have been exempted by the Secretary of State. All other NICE Guidance shall not be treated as statutory guidance, including medical technologies guidance, but it will be carefully considered when developing strategies, planning services and prioritising resources (NHS Commissioning Board Commissioning Policy: Implementation and funding of guidance produced by the NICE, April 2013).

The BNSSG NICE College has a vital role in meeting the agenda outlined in Innovation Health and Wealth (Department of Health, December 2011). The DH publication 'Creating Change - IHW One Year On' (published December 2012) specifies that:

"NHS organisations should demonstrate their commitment to implement each element of the Comply or Explain regime, and we shall set out compliance in the NHS Standard Contract. There are four elements to Comply or Explain:

- automatic inclusion of positive NICE Technology Appraisals on local formularies in a planned way that supports safe and clinically appropriate practice;
- publication of local formularies;
- tracking of adoption of NICE Technology Appraisals through the Innovation Scorecard; and
- support to overcome the system barriers to implementation of NICE Technology Appraisal guidance and other guidance through the NICE Implementation Collaborative."

1. Purpose

a. To horizon scan NICE Technology Appraisals (TAs) and formulate a proposed budget for each financial year to support the commissioning process.
b. To scrutinise, agree and sign off Implementation Plans (IP, appendix 1) for NICE TAs.

c. To agree appropriate TAs for early implementation following publication, before 90 day mandatory deadline.
d. To monitor clinical and financial activity of funded TAs on a monthly basis and take action on any risks identified.
e. To submit NICE TA audit priorities to acute Trusts' Clinical Audit departments to be incorporated into Trusts' yearly clinical audit plans.
f. To gain implementation assurance by reviewing, and providing feedback on, audits from Trusts.
g. To provide assurance to the CCGs and Provider Trusts on the local implementation of NICE TAs in accordance with national recommendations.
h. To ensure adoption of published NICE TAs into the BNSSG Joint Formulary.

2. Membership

BNSSG NICE Lead - Interface Pharmacist Bristol CCG - Chair

Core Members

Organisation	Job Titles
Bristol Clinical Commissioning Group (CCG)	Head of Medicines Management Interface Pharmacist – NICE Lead
North Somerset CCG	Head of Medicines Management
South Gloucestershire CCG	Head of Medicines Management
University Hospitals Bristol NHS Foundation Trust (UHB)	Director of Pharmacy NICE Manager, Clinical Effectiveness
North Bristol NHS Trust (NBT	Director of Pharmacy NICE Implementation Pharmacist
Weston Area Healthcare NHS Trust (WHAT)	Director of Pharmacy
Finance South West Commissioning Support Unit (SWCSU)	NICE Finance Lead

Extended invitee meetings

Organisation	Job Titles
Bristol Clinical Commissioning Group (CCG)	Chief Financial Officer or Deputy
North Somerset CCG	Chief Financial Officer or Deputy
South Gloucestershire CCG	Chief Financial Officer or Deputy
University Hospitals Bristol NHS Foundation Trust (UHB)	Chief Financial Officer or Deputy Head of Commissioning or Deputy Chair/Clinical Lead for Clinical Effectiveness or Deputy

North Bristol NHS Trust (NBT	Chief Financial Officer or Deputy Head of Commissioning or Deputy Chair/Clinical Lead for Clinical Effectiveness or Deputy
Weston Area Healthcare NHS Trust (WHAT)	Chief Financial Officer or Deputy Head of Commissioning or Deputy Chair/Clinical Lead for Clinical Effectiveness or Deputy
South West Commissioning Support Unit (SWCSU)	Programme Director Operational Planning and Delivery or Deputy
BNSSSG Area Team	Area Team Pharmacist

Notes to membership

To be quorate members of two of the three provider Trusts, being UHB, NBT and WAHT and two of the three CCGs, being North Somerset, Bristol and South Gloucestershire, including one Head of Medicines Management, will be present. If not quorate, the NICE Lead will determine if the meeting should proceed, securing endorsement of any decisions ex-committee. In the absence of the BNSSG NICE Lead a Head of Medicines Management will take the Chair.

Extended invitee meetings
Quoracy as above plus: representation from one CCG Chief Financial Officer or Deputy and one from an acute Trust. In addition one CSU representative either finance or contract management.

Organisations submitting implementation plans should be represented by the most appropriate representative/s.

Trusts are advised that implementation plans will only be considered if there are Trust representatives present. This also applies to implementation plans that are being reconsidered.

3. Frequency/meeting arrangements

Frequency
The BNSSG NICE College will meet monthly.

Extended invitee meetings
An extended invitee meeting will occur quarterly. Dates will be set in advance. These will inform all parties of the horizon scanning process, financial monitoring, progress reports on and review of audits and support in year commissioning decision making. The extended membership for these meetings is defined in point 2.

Meeting arrangements
Implementation plans and audits wherever possible will be circulated no less than 5 working days before each meeting. Implementation plans and audits will need to be given to the BNSSG NICE Lead no later than 7 working days before each meeting.

The BNSSG NICE Lead will be responsible for executive duties to the review group and ensuring agreed actions are recorded and implemented.

CSU NICE Finance Lead will be responsible for submitting monthly finance reports, wherever possible circulating no less than 5 working days before each meeting.

4. Terms of Reference

Representing a collaborative approach between primary and secondary care:

4.1 To ensure a transparent corporate decision making process is maintained within the NICE College; inclusive discussion and agreement to ensure all parties are informed.

4.2 To perform an annual horizon scanning process to determine those TAs that will impact within a given financial year and propose a NICE budget.

4.3 To scrutinise, agree and sign-off TA implementation plans. This will ensure that patient numbers, cost of technology, pathways costs, costs to off-set, are considered against the appropriate NICE costing template and audit intentions are clearly stated.

4.4 To agree early implementation (sooner than end of 90 day window post NICE publication) of NICE TAs where the NICE College early implementation criteria are met (see appendix 2).

4.5 To monitor the implementation and uptake of NICE TAs clinically through audit.

4.6 To monitor the implementation and uptake of NICE TAs financially each month.

4.7 To monitor monthly, actual implementation costs against estimated or budgetary costs, as detailed in implementation plans and act when material variance is determined and report actions taken to the NICE College. To submit NICE TA audit priorities into acute Trusts' clinical audit plan and review audits undertaken by Trusts for assurance.

4.8 To monitor adoption into the BNSSG Joint Formulary within the 90 day window post NICE publication.

4.9 To support the conduct, evaluation and feedback of audit activity associated with the NICE work programme.

4.10 To support and maintain links with the internal NICE groups established in local acute Trusts.

4.11 To agree a decision where unavoidable variations of NICE guidance may occur.

4.12 To provide an organisational view on the implementation of NICE clinical guidelines (CG), interventional procedures (IP), diagnostic guidance (DG) and quality standards (QS) as required.

4.13 To produce an annual report for the NICE College to provide assurance to the CCGs and Provider Trusts.

5. Guiding Principles

All member organisations must commit to regular attendance at review meetings, as continuity and balance of input into decision-making is of the utmost importance. Nominated

deputies should be identified and empowered, wherever possible, to ensure that a balanced complement of members is always present.

Meetings should encourage open, honest and challenging debate. Decisions should be reached by consensus. Once a decision has been finalised a corporate view will be presented and maintained.

6. Reporting requirements

The NICE College will report to individual CCGs, partnership boards and appropriate Trust governance groups.

The College will produce an annual report, agreed in committee and signed by the Chair, to demonstrate that proceedings are appropriate and subject to adequate governance.

Minutes will be circulated within 10 working days of each meeting and will be submitted to the NICE College meetings for information.

7. Date to review these Terms of Reference

Annual review of Terms of Reference to coincide with publication of College Annual Report.

8. Specialised Commissioning

The NICE College will continue business as usual for NICE TAs which fall under the remit of NHS England. This will be reviewed when the relationship between NHS England specialised commissioning and NICE pathways with are fully established.

xxxxx xxxxx
Interface Pharmacist (BNSSG NICE Lead), Bristol CCG
April 2013

Approved by:BNSSG NICE College 11th July 2013
Date of Review: April 2015

Appendix 1

BNSSG NICE College Technology Appraisal Guidance (TAG) Implementation Plan Proforma

TAG title and number				
Publication date		**Funding date**		
Name(s) of Trust submitting				
Funding route ***(please specify)***	**Specialised Commissioning**		**Clinical Commissioning Group**	
Does this TAG supersede an existing TAG? If YES, which one?				
Recommendations of TAG				
1. Named lead (title, speciality and contact details for this TAG)				
2. What action is required to implement this TAG within the Trust?				
3. Is there any further impact on primary care, or another Trust, and if so, what?				
4a. What is the anticipated number of patients likely to receive this treatment in BNSSG? *If numbers higher than NICE costing template predicts, please state why.*				
4b. What is the anticipated number of BNSSG patients likely to receive this treatment in your local Trust? *Please detail numbers of patients involved in clinical trials, compassionate release programmes, exceptional funding etc*				
5. What is the anticipated impact on waiting lists?				
6. What are the anticipated changes in the referral patterns?				
7. What effect will implementing this TAG have in terms of human resources?				
8. What effect will implementing this TAG have in terms of training?				

9. What effect will implementing this TAG have in terms of equipment?

10a. What are the financial implications (Full year effect) over and above existing expenditure of implementing this guidance? (Please specify the costs you have considered in your estimate including cost per case, number of cases to be funded per year, baseline costs, costs off-set)

NICE Drugs:-

	Number of Patients	Drug Cost per Patient £	Total Drug cost £ (full year)

NICE Procedures:-

	Number of cases/ attendances	Tariff per Patient £	Total Cost £ (full year)	Included in PCT Service Level Agreement?
Inpatients				
Day cases				
Outpatients				
Other – please specify				
Total				

NICE Devices:-

	Number of patients	Device cost per patient £	Total cost £ (full year) Include	Included in PCT Service Level Agreement?

Costs Off-set (please describe below):

Cost of Genetic tests if applicable (please indicate if genetic testing included as part of NICE costing statement):

10b. How will you track and monitor cases treated per month so that evidence can be provided for verification? *(where separate invoicing arrangements apply)*
10c. What % cost of FYE do you expect will be implemented within this financial year (2012/13) ***(if applicable please take into account number of patients you have on waiting lists for this treatment)***
10d. What are the financial expectations for future years? Please indicate how many years you estimate it will take to reach steady state/ maximum activity *(number of cases and increase/ decrease in cost-per-case)*
10e. What factors have you offset against this cost, if any? *(NB outpatient/ day case tariffs include staff costs)*
11. Unfunded additional costs pressures to the Trusts as a result of implementing this TAG (for information only, for use in future negotiations)
12a. Is Early Implementation required and was this highlighted as part of horizon scanning
12b. Reason for / criteria met for early implementation
13. Home care – is it possible to deliver this drug via home care (please give details of patient benefits, cost savings and the home care company that would undertake delivery).
14. Will the implementation of this TAG require the production of patient information leaflets? *Please give further details.*
15. What assessment processes and patient selection criteria will be adopted to identify eligible patients when implementing NICE recommendations?
16a. What audit activity and monitoring will be undertaken as a result of this guidance?

Financial tracking of expenditure, clinical audit, other.

16b. Has this been added to Trust audit programme?

17. Specific Audit criteria highlighted by NICE College at implementation for incorporation into Trust NICE Clinical Audit (to be completed by BNSSG NICE Lead)

18. Named audit lead contact details

Audit lead:

Audit contact:

19. Named Management contact details

Name:

Contact:

20. Additional comments

21. Review date (plans will be reviewed regularly – annually through horizon scanning) and will need to be rewritten if new TAGs supersede this one if through monitoring activity appears to be significantly different to this implementation plan).

22. Declaration of conflicts of interest
http://www.nice.org.uk/media/0B2/B6/DeclaringDealingConflictInterestOct08.pdf

Please List

1. Any gifts or hospitality received from the manufacture of the product concerned (exceeding the value of £20) in the last year
2. Presentations, advisory panels, consultancy work (including retainers) or written materials for which payment has been received from the product manufacturer.
3. Shares held in the company (where known)
4. Sponsorship of research, members of staff, equipment or other materials in your department or clinical speciality funded by the manufacturer.
5. Any other forms of benefit or relationships which could be classed as a potential conflict of interest.

If NIL please state **NB You are not required to declare the actual money value of the above.**
23. Signed By:

For further details on how to complete this document, please contact your NICE Manager in your organisation and refer to the College Policy document.

Appendix 2

BNSSG NICE Commissioning College

Principles of NICE TAG Implementation

These principles only apply to CCG funded NICE technology appraisals.

Each NICE Technology Appraisal Guidance (TAG) will have an implementation plan agreed by the NICE College. This implementation plan will be in place to start three months after publication of the TAG.

TAGs will not routinely be implemented before the three months from the publication date. However, consideration will be given to implementing a TAG earlier than 3 months under any of the following circumstances **and** where the infrastructure is already in place to deliver the new TAG and the implementation plan has been agreed.

Early Implementation Criteria:

1. The TAG offers a new treatment to patients where
    a. no other evidence based treatment is available, and
    b. when the patients' condition may otherwise deteriorate irretrievably over the three month implementation period.

2. The change in treatment is cost neutral/cost saving to BNSSG CCGs.

3. The treatment package recommended in the new TAG is already part of PBR tariff and Trusts are not asking for increased funds to deliver the TAG

4. The treatment package involved is already funded by BNSSG CCGs under a pre-existing SLA.

If a new TAG meets at least one of the above 4 criteria listed above, then permission for early implementation can be sought. An early implementation proforma (appendix 3) should be completed along with an Implementation Plan (IP) and submitted to the BNSSG NICE Lead, who will ensure the criteria are met and the proforma has all relevant information. This application for early implementation will be considered at the next NICE College meeting.

Where possible the NICE College will identify those TAGs, prior to publication, for which early implementation would likely to be requested. This will be undertaken as part of the horizon scanning (HS) process. Permission will still need to be sought and an implementation plan provided and agreed once the TAG is published.

Approved by:
Date of Guideline: June 2013
Review Date : June 2015 or sooner if national guidance changes.

Appendix 3

NICE Technology Appraisal Early Implementation Proforma for BNSSG

1. Name of TA requesting early implementation

2. Name of Consultant or Group requesting Early Implementation:

3. What criteria on BNSSG Implementation Policy for Early Implementation does this fulfill?

1. The TAG offers a new treatment to patients where
    a. no other evidence based treatment is available, and
    b. when the patients' condition may otherwise deteriorate irretrievably over the three month implementation period.
2. The change in treatment is cost neutral/ cost saving to BNSSG PCTs.
3. The treatment package recommended in the new TAG is already part of PBR tariff.
4. The treatment package involved is already funded by BNSSG PCTs under a pre existing SLA.

CRITERION

4. What additional cost will this incur by implementing early?

5. Is there sufficient funding allocated in BNSSG NICE College Budget to meet this anticipated additional cost?

6. Has an Implementation Plan been received and signed off by Primary Care NICE TAG Group members (agreement may be sought via email)

Summary

- Criteria met for early implementation YES/NO
- Funding available from NICE budget – YES/NO
- Additional funding required – YES / NO
- Implementation Plan received - YES/NO

FINAL APPROVAL:

Approved by BNSSG NICE College YES/NO

Signature: Date:

Healthier Together

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

Bristol, North Somerset and South Gloucestershire CCG – NICE TA Implementation Plan

Title of guidance:		
Reference number:	Date of publication:	Implementation deadline:
Name of Trust(s) submitting:		
Is your trust commissioned to provide this service?		
If no, please specify where patients flow: ICS: Provider: Shared care: If shared care is required/in-place, please detail arrangements:		
If your trust is not commissioned to offer this treatment and you have specified where your patients flow / any intentions for shared care arrangements you do not need to proceed any further.		
Funding Route *(tick both if appropriate)*	Specialised Commissioning (including interim CDF): ☐	CCG/ICS: ☐
Does this commissioning guidance supersede an existing policy? (if yes, which one?):		
Named clinical lead for this NICE TA Title: Speciality: Contact details:		
What action is required to implement this NICE TA within the Trust?		
Is there any further impact on primary care, or another Trust and if so, what?		
Population Estimates		

Population area served by your Trust for this TA (*Please be as specific as possible, including information on populations outside of own ICS if relevant*):

What is the anticipated number of patients likely to receive treatment at your Trust? (*Please be as specific as possible, e.g. detail if there is a cohort of patients waiting to start immediately*)

From within ICS:

From outside ICS:

Additional number of year-on-year patients expected:

Additional information (*Please detail numbers of patients involved in clinical trials, compassionate use programmes etc if appropriate*):

Implementation / Finance
Please describe any barriers to implementing this NICE TA:
What are the financial implications (full year effect, FYE) over and above existing expenditure of implementing this guidance? (*Please specify the costs you have included in your estimate, including cost per case, number of cases to be funded per year, baseline costs, costs off-set*) Costs off-set compared to existing treatment options (please specify if applicable): Specify additional costs compared to existing treatments e.g. cost of genetic tests or activity costs:
Completed by: