BNSSG Joint Formulary Group
Meeting held on: Tuesday 16th January 2018
Conference Room, Level 5, South Plaza

Minutes

Present:

		Public Health Consultant, Bristol City Council
		Deputy Lead Pharmacist, Weston General Hospital
		Deputy Chief Pharmacist, AWP
Sasha Beresford	SBe	Deputy HoMM, NHS Bristol CCG
		GP, North Somerset
		Consultant Neurology Physician, NBT
Debbie Campbell	DC	HoMM, NHS North Somerset CCG
Emily Knight	EK	Interface Pharmacist, NHS Bristol CCG
Tash Mogford	TM	Interface Pharmacist, Bristol CCG
		Lead Medicines Information Pharmacist, UHBristol NHS Foundation Trust
		Pre-registration pharmacists, UHBristol NHS Foundation Trust (observing)

Apologies:

Formulary and Interface Pharmacist, NBT

1 Welcome, Apologies and Declaration of Interests

Declarations of Interest

None

2 Minutes of the meeting of 28th November 2017 and Matters arising

The minutes from the Joint Formulary Group (JFG) meeting on the 28th November 2017 had been circulated by TM following the meeting. The minutes were approved.

Matters arising from 28th November 2017 meeting

2.1 Action log

- Degarelix SCP- TM emailed specialist regarding monitoring of bone density.
- Dymista SCP- TM emailed applicant for further information about incidence of referrals and evidence it is more effective individual preparations.
- Acamprosate SCP- TM confirming specifics of duration SCP.

3 NICE New Technology Appraisals

Published

3.1 Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (TA496) RED

3.2 Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (TA495) RED

3.3 Naltrexone–bupropion for managing overweight and obesity (TA494) NOT APPROVED

3.4 Cladribine tablets for treating relapsing–remitting multiple sclerosis (TA493) RED

3.5 Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable (TA492) RED

Adopted into the BNSSG Joint Formulary – November/December 2017

- Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma (TA462)
- Roflumilast for treating chronic obstructive pulmonary disease (TA461)
- Adalimumab and dexamethasone for treating non-infectious uveitis (TA460)
- Collagenase clostridium histolyticum for treating Dupuytren's contracture (TA459)
- Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane (TA458)
- Carfilzomib for previously treated multiple myeloma (TA457)
- Ustekinumab for moderately to severely active crohn's disease after previous treatment (TA456)
- Cetuximab for treating recurrent or metastic squamous cell cancer of the head and neck (TA473)
- Obinutuzumab with bendamustine for treating follicular lymphoma refactory to rituximab (TA472)
- Eluxadoline for treating irritable bowel syndrome with diarrhoea (TA471)
- Baricitinib for moderate to severe rheumatoid arthritis (TA466)
- Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma (TA465)
- Bisphosphonates for treating osteoporosis (TA464)
- Cabozantinib for previously treated advanced renal cell carcinoma (TA463)
- Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic

pancreatic cancer (TA476)

- Dimethyl fumarate for treating moderate to severe plaque psoriasis (TA475)
- Sorafenib for treating advanced hepatocellular carcinoma (TA474)

4 New Drug Requests (NDRs)

SUMMARY

4.1 Liraglutide (Saxenda) as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with obesity

On balance, although there was some good evidence that Saxenda causes a statistically significant weight loss compared to placebo for the duration of the treatment, there is no evidence comparing it to Orlistat, the obvious comparator, and no evidence that the effect is sustained after cessation of treatment. In light of the resource implications of such treatment, and the potentially wide cohort that this could be applied to, it was decided it could not be approved as there was insufficient evidence that this would be a cost-effective use of NHS resources.

4.2 Trelegy triple inhaler, Maintenance treatment for COPD in adult patients who have symptoms and is at risk of exacerbation

The group felt the evidence for Trelegy was average for this type of inhaler. Trelegy Elipta provides another option in the Elipta family to improve patient choice and acceptability. It was agreed it would accepted on the formulary as TLS green.

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

Full Discussion

4.1 Liraglutide (Saxenda) as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with obesity

Please see application form for full details. The applicant was not able to attend the meeting, however EK presented the application.

The application is for Saxenda (Liraglutide) a GLP-1 antagonist licensed for weight management in overweight and obese patients. This application originated as a query from a GP who sought to prescribe this for a patient with high BMI who has failed to lose weight with diet and lifestyle measures and orlistat. It was noted this is probably not an exceptional case and there probably is a

cohort of patients therefore it was decided to come to JFG for appraisal.

NICE evidence summary ES14 was published in June which appraises 4 well designed, robust RCTs comparing liraglutide with placebo with various end points including weight loss, sleep apnoea ratings and time to development of diabetes in prediabetic patients. When viewed together there is good evidence that liraglutide produces a significant weight loss over the study duration. However there is no evidence that this treatment effect is sustained after treatment is ended. In fact there is some evidence from two trials (Davies et al and Pi-Sunyer et al) that weight is gained after cessation of liraglutide.

This raises the question of the intended duration of such a treatment. In the licensing information it is stated that if 5% of body weight is not lost after 12 weeks then treatment should be stopped, mirroring instructions for Orlistat. However there doesn't seem to be any evidence for this recommendation and no recommendations for stopping criteria thereafter.

There was discussion around the weight loss in the trials being in the context of good structured diet and lifestyle support, which may not be reproducible in the real world.

Although the trials were well designed, there was a high drop out rate in all studies and this data was managed using the "Last Observation Carried Forward" method, which may overestimate treatment effect.

The safety and tolerability profile of Saxena largely follows that of Victoza, with GI effects being reported as "very common" In people without T2DM no severe hypoglycaemic events were reported however in those with T2DM, severe hypos were reported in 0.7% of those treated with 3mg dose. There is currently insufficient data to assess if uncommon events (pancreatitis/neoplasms) occur more frequently with liraglutide 3.0mg (Saxenda) rather than 1.8mg (Victoza)

The manufacturer has stated they are not actively promoting within the NHS and forsee it being used primarily in a private setting.

It was noted that the request has not originated from the weight management service, who would be considered experts in this. It was also noted that the product is licensed from BMI 30 or 27 (with co-morbidities) which is a large proportion of the population and therefore would potentially represent a huge cost pressure if it were to be approved onto the formulary.

- **Patient safety** – Largely safe, gastro side effects common.
- **Clinical effectiveness** – Some degree of effectiveness demonstrated however no evidence that these are sustained after treatment cessation.
- **Cost effectiveness or resource impact** – A potentially large cost pressure given the number of potentially eligible patients and the cost of treatment.
- **Strength of evidence –** As above, largely good quality evidence with some methodological flaws however no evidence this effect is sustained.
- **Place in therapy relative to available treatments** – Only other pharmacological treatment option is orlistat.
- **National guidance and priorities** – NICE guidance on obesity recommends considering pharmacological treatment for people who have not
- **Local health priorities** – Cost effective treatment of obesity and prevention of weight related co-morbidities such as diabetes could be considered a local priority.
- **Equity of access** – Not approved on other local formularies.

The JFG considered the application, the evidence and information submitted. On balance, although there was some good evidence that Saxenda causes a statistically significant weight loss compared to placebo for the duration of the treatment, there is no evidence comparing it to Orlistat, the obvious comparator, and no evidence that the effect is sustained after cessation of treatment. In light of the resource implications of such

treatment, and the potentially wide cohort that this could be applied to, it was decided it could not be approved as there was insufficient evidence that this would be a cost-effective use of NHS resources.

Action:

1. ***EK*** *to inform applicant.*

The group also discussed how to reflect on the formulary when a drug has been reviewed and not accepted by the JFG. It was decided a commissioning statement would be the best way to do this and this can be taken forward once the CCGs have merged.

4.2 **Trelegy triple inhaler,** Maintenance treatment for COPD in adult patients who have symptoms and is at risk of exacerbation

Please see application form for full details. The applicant was not able to attend the meeting, however TM presented the application. Trelegy Ellipta is a dry powder triple inhaler comprised of fluticasone fuorate 92mcg/umeclidinium 55mcg/vilanterol 22mcg licensed for moderate to severe COPD.

Evidence was discussed. There are two main trials. FULFIL compared to Symbicort (budesonide/formeterol) and found treatment with Trelegy led to improved lung function, quality of life and reduced exacerbations. IMPACT trial compared to Relvar (fluticasone/vilanterol) and Anoro (umeclidinium/vilanterol) and found Trelegy reduced the annual rate of moderate to severe exacerbations. There are no studies which compare Trelegy as a fixed triple therapy inhaler to the individual component inhalers.

This device would provide patients who are already on the Elipta inhalers to step up and down through the pathway without switching devices, which may aid compliance and be more acceptable to patients.

There was discussion whether a fixed triple therapy inhaler might prevent stepping patients down however it was decided that patient education and empowerment of practice staff to confidently step patients down was key. It was emphasised that adherence to the BNSSG COPD guidelines should be encouraged.

- **Patient safety** – No patient safety concerns.
- **Clinical effectiveness** – Clinically effective compared to double therapy.
- **Cost effectiveness or resource impact** – Cost effective compared to the three constituent inhalers.
- **Strength of evidence –** Strong evidence
- **Place in therapy relative to available treatments** – Could replace triple therapy with individual constituent inhalers.
- **National guidance and priorities** – Effective management of COPD remains a national priority.
- **Local health priorities** – Effective management of COPD remains a local priority.
- **Equity of access –** Yet to be accepted onto many local formularies.

The JFG considered the application, the evidence and information submitted. The group felt the evidence for Trelegy was average for this type of inhaler. Trelegy Elipta provides another option in the Elipta family to improve patient choice and acceptability. It was

agreed it would accepted on the formulary as TLS green.

Action:

1. ***EK*** *to inform applicant.*

2. ***EK*** *to include on the formulary as TLS green.*

5 Shared Care Protocols/TLS status

5.1 Ciclosporin eye drops TLS change (red to amber) and new SCP

Ciclosporin eye drops for dry eye, historically has been a red drug due to being an unlicensed preparation. Now a licensed product (Ikervis) is available. The change reflects NICE TA369 suggesting patients be initiated in secondary care and followed up in primary care.

Action:

1. ***EK*** *change website and upload SCP.*

5.2 Leflunomide for Rheumatoid Arthritis updated SCP and concise drug information sheet

SCP updated in same format as previously approved SCPs. Further detail in cautions, side effects and monitoring added. Primary care monitoring changed to bring it in line with other DMARDs for rheumatology. Some increased in frequency of monitoring but the monitoring will be standardised across the DMARDs, hopefully making it more simple for GPs to manage.

Clarification around the wording “anaemia- avoid if significant” in section 6 needed.

Action:

1. ***EK*** *to clarify anaemia with applicant.*

2. ***EK*** *to upload SCP.*

5.3 Sulfasalazine for Rheumatoid Arthritis updated SCP and concise drug information sheet.

SCP updated in same format as previously approved SCPs. Further detail in cautions, side effect, monitoring added.

Action:

1. ***EK*** *to upload SCP.*

5.4 Ferracru new SCP

Weston not included- this was an oversight, to be added. Some discussion over whether the review at 12 weeks should be from GP or secondary care. It was previously agreed that it should be an amber 1 month SCP. Some discussion over whether it should be an amber 3 month SCP as there is no management/review before 3 months. Would it be more sensible for 3 months prescription to be given by secondary care and then for patient to be

reviewed by GP or secondary care at 3months.

Action:

1. ***TM*** *to go back to secondary care with amber 3 month proposal and clarify monitoring responsibilities and confirm.*
2. ***EK*** *to upload amended SCP when agreed.*

5.5 Galantamine amended SCP

General discussion around difference in dementia service between NS/SG, where GPs to refer into the memory service and in Bristol where a local dementia scheme is in place which allows GPs to act as "specialists" This SCP change therefore would apply only to prescribing within NS/SG.

Discussion about what is currently happening within the service- SCP states specialist review at 1 month. EK to clarify what is actually going on in the service and whether a review at one month is necessary. Discussion about whether it needs to be an amber 3 month drug at all or whether it could be on specialist recommendation only (amber no SCP)

Action:

1. ***EK*** *to clarify current pathway in secondary care in initial 3 months and relay to group.*

5.6 Methylphenidate M/R amended SCP

SCP amended to include preferred brands.

Action:

1. ***EK*** *to upload SCP.*

5.7 Rotigotine TLS change of request form (amber 1 month to amber no SCP)

Request to change from amber 1 month to amber no SCP due to problems caused by current amber 1 month status. Currently when patient needs to start rotigotine urgently due to swallowing disorders, the first prescription needs to come from secondary care which can delay treatment. It was proposed it should be changed to amber no SCP so that GPs can start rotigotine after discussion with a specialist. The group was clear that the clinical decision to start rotigotine or the dosing should not lie with the GP, rather that this was a logistical change to facilitate timely access to the appropriate therapy.

Discussion around whether "amber no SCP" is the correct terminology for these drugs- potentially "amber specialist recommendation only" is more appropriate.

Action:

1. ***EK*** *to convert current SCP to "prescribing guidance"*
2. ***EK*** *to amend website to reflect change.*

5.8 Semi-sodium valproate SCP update

General discussion around the risks of valproate in pregnancy and how best to highlight this to prescribers. Agreed to make these warnings clearer in the SCP and to add wording to website alongside links to MHRA warnings. Wording agreed “Use only in exceptional circumstances in women of child-bearing age” SCP and formulary to be updated with this wording.

AWP confirmed the clinicians initiating this are using the valproate checklist. Unsure if a copy of this goes to GPs. SB to confirm. AWP are keeping lists of all women of child-bearing age on valproate and are recalling back for yearly reviews.

1. ***EK*** *to amend SCP and upload*

6 Individual Funding Requests

Nil to review. To be reviewed at next meeting.

7 Items for Discussion

7.1 NHSE list of drugs of low clinical value

NHSE published a list of items which should not routinely be prescribed in primary care. Of these- liothyronine, lidocaine patches, tadalafil OD and dosulepin are on the BNSSG formulary. This was brought to group to discuss how to manage this advice locally and what actions, if any, are needed.

Liothyronine

NHSE advice- prescribers in primary care should not initiate new patients, any current patients should be reviewed by an endocrinologist and consider switching to levothyroxine where appropriate, ongoing prescribing of liothyronine should only be done in exceptional circumstances.

Currently red on the formulary for specific indications- hypothyroid coma and in combination with levothyroxine for severe thyroid deficiency. Non-formulary as monotherapy.

£168k spend in BNSSG, approximately 100 patients. It was suggested the formulary wording should be strengthened with reference to NHSE guidance. It was also suggested that the existing patients should be reviewed. The original applicant for liothyronine to the JF (Andrew Johnson) had suggested he would be happy to review any existing patients. It was decided that he and counterparts at BRI/Weston could be contacted in light of the guidance to discuss patient reviews. The logistics of reviewing these patients was discussed. For further work up outside of JFG.

Lidocaine plasters

NHSE advice-prescribers in primary care should not initiate new patients and support deprescribing. This recommendation excludes the advice in NICE CG173 neuropathic pain guidelines for management of post-herpetic neuralgia.

Discussed local usage for both formulary and non formulary indications.

£60k spend in BNSSG, approximately 130 patients. Benchmark well compared to other CCGs.

Decided action should be to strengthen wording on formulary to reference NHSE guidance and to contact pain teams to remind them of formulary indications.

Tadalafil OD

NHSE advice- prescribers should not initiate any new OD tadalafil and support deprescribing.

Current BNSSG formulary status of tadalafil is amber no SCP (no distinction made for dosing schedule) Generic sildenafil is first line and is very cheap.

£250k spent in BNSSG, 628 patients. Nationally we benchmark one of the highest in the country. There has been a historic issue with the urology department treating particularly post-prostatectomy patients. It was suggested if NBT want to continue prescribing it for these patients it could be made red.

Agreed to take off formulary and if urology want it to go back on they can bring an application to the group for it to go on as a red drug.

It was noted there are plenty of other treatment options and there was some discussion about the PRN tadalafil preparation coming off patent which may bring it in line with the pricing of generic sildenafil.

Dosulepin (for pain indications)

NHSE advice- prescribers should not initiate any new dosulepin and support deprescribing.

Currently blue for neuropathic pain (unlicensed) and non-formulary for depression. It was noted it is practically difficult to deprescribe in these patients, who tend to have tried lots of things and are reluctant to stop or switch. Nationally, BNSSG benchmarks averagely. Discussion about changing to amber no SCP to limit any primary care initiation. To change wording on formulary to reflect NHSE guidance.

8 NDRs for October meeting (no papers, for information only)

Currently no NDR received. Some SCPs for review. It was agreed that the meeting on 27th February could be cancelled and of the SCPs, any which are urgent could be reviewed by email and others could wait until the following meeting on 10th April.

9 AOB

Nil

Emily Knight
Interface Pharmacist
January 2018

BNSSG JFG

Action Log for 16th January 2018

Date of Meeting	Minute No.	Subject	Action Required	Responsible Officer	Deadline	Date of Update	Update
17/9/17	4.2	Alteplase NDR	Ask applicants to bring back local audit data in 1 year for the group to review	EK	October 2018	Done	
28/11/07	5.1	Degarelix SCP	Contact specialist pharmacist regarding monitoring bone density. Upload SCP on the website when confirmed.	TM	December		Emailed specialised pharmacist
28/11/07	5.2	Dymista	Contact the applicant for further information	TM	December		Emailed applicant
28/11/07	5.4	Acamprosate SCP update	Obtain more information regarding psychosocial support	TM	December		Emailed for more information
16/1/18	4.1	Saxenda	Inform applicant	EK	February		
16/1/18	4.2	Trelegy inhaler	Inform applicant and add to website	EK	February		
16/1/18	5.1	Ciclosporin SCP	Change website, upload SCP.	EK	February		
16/1/18	5.2	Lefluonomide SCP	Confirm definition of “anaemia” with applicant and upload SCP	EK	February		
16/1/18	5.3	Sulfasalazine SCP	Upload SCP	EK	February		
16/1/18	5.4	Ferracru SCP	Contact specialist pharmacists to discuss change to amber 3 month	TM	February		
16/1/18	5.5	Galantamine SCP	Clarify current pathway of reviews in first 3 months for	EK	February		

			amber 3 month memory drugs and email group with findings.				
16/1/18	5.6	Methylphenidate SCP	Upload SCP	EK	February		
16/1/18	5.7	Rotigotine SCP	Convert current SCP to prescribing guidance and amend website	EK	February		
16/1/18	5.8	Sodium/Semi-sodium valproate SCP	Amend website and SCP to further highlight teratogenic risk and upload	EK	February		
16/1/18	7.1	NHSE drugs of low clinical value	Prepare briefing paper with JFG recommended actions to take to STP, DTC etc for action.	TM	23/1/18		

MEETING DATES 2018

All Tuesday meetings

Date	Cut off for NDRs and SCPs	Time	Venue
16th January (AM)	12th December	9:30 to 12:30	South Plaza, Conference room (5th floor)
~~27th February (PM)~~	~~16th January~~	~~14:00 to 16:30~~	~~Southmead, Pharmacy meeting room~~
10th April (AM)	27th February	9:30 to 12:30	South Plaza, Conference room (5th floor)
22nd May (PM)	10th April	14:00 to 16:30	Southmead, Pharmacy meeting room
26th June (AM)	22nd May	9:30 to 12:30	South Plaza, Bevan room (6th floor)
4th September (PM)	26th June	14:00 to 16:30	Southmead, Pharmacy meeting room
16th October (AM)	4th September	9:30 to 12:30	South Plaza, Conference room (5th floor)
27th November (PM)	16th October	14:00 to 16:30	Southmead, Pharmacy meeting room