NHS
Devon
Clinical Commissioning Group

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 28th April 2021

Via Microsoft Teams

Present:

Tawfique Daneshmend (Chair)	Consultant Gastroenterologist	RD&E NHS FT
Glen Allaway	GP	NHS Devon CCG
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Heidi Campbell	Pharmacist	NHS Kernow CCG
Andy Craig	GP	NHS Devon CCG
Nicola Diffey	Pharmacist	Livewell Southwest
Susie Harris	Consultant (Elderly Care)	RD&E NHS FT
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Matthew Kaye	Chief Pharmacist	NDHT
Nick Keysell	GP	NHS Devon CCG
Carole Knight	Formulary Pharmacist	NDHT
James Leavy	Medicines Information Pharmacist	RD&E NHS FT
Sarah Marner	Senior MO Pharmacist	NHS Devon CCG
Bill Nolan	GP	NHS Devon CCG
Jess Parker	GP	NHS Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon CCG
Vivek Soni	Deputy Director Pharmacy – Pharmacoeconomics	UHP NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Christopher Sullivan	Deputy Chief Pharmacist, clinical services	DPT NHS Trust
Darren Wright	Joint Formularies Technician	NHS Devon CCG

Guests:

Emma Gitsham	Clinical Effectiveness Pharmacist	NHS Devon CCG
Liz Fleming	Specialist MO Dietitian	NHS Devon CCG

Observers:

Desi Kaneva	Foundation Pharmacist	T&SD NHS FT
Mishel Mathew	Foundation Pharmacist	T&SD NHS FT
Professor Tim McDonald	Laboratory Director	RD&E

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and announcements

Meeting etiquette

Tawfique Daneshmend explained the meeting etiquette.

Chairman's welcome

Tawfique Daneshmend welcomed attendees to the meeting of the Devon Formulary Group.

It was noted that Andrew Harrison had retired. Andrew was thanked for his hard work and significant contribution to the Devon FIG's predecessor group, the North and East Devon FIG, over a number of years.

Register of participants

Tom Kallis did not join the meeting. All other expected attendees were present.

Apologies

Apologies were received from Jamie Smith, Consultant in Diabetes and Endocrinology T&SD NHS FT.

Declarations of Interest

Declarations of Interest were collected. No attendees reported an interest.

Dr Jamie Smith, the applicant for dulaglutide has indicated that he has the following interests to declare:

'I would like to disclose that I've received financial support from both Novo Nordisk and Lilly for registration fees to attend virtual conferences over the last year and have been in receipt of speaker fees for educational meetings from Novo Nordisk, Lilly and Sanofi over the last 2 years.'

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Oral semaglutide (Rybelsus®) for the treatment of type 2 diabetes	Novo Nordisk Limited
Alternative treatments:	
Other GLP-1 mimetics	
• Dulaglutide (Trulicity®)	Eli Lilly and Company Ltd
• Exenatide (Byetta®, Bydureon®)	AstraZeneca UK Ltd
• Liraglutide (Victoza®)	Novo Nordisk Limited
• Lixisenatide (Lyxumia®)	Sanofi
• Semaglutide (Ozempic®)	Novo Nordisk Limited
Other antidiabetic medication	
Metformin, Sulfonylureas, DPP4 inhibitors, SGLT2 inhibitors, Insulins	Various manufacturers
FreeStyle Libre device for interstitial glucose monitoring in diabetes	Abbott Laboratories Ltd
Alternative treatments:	
• Blood glucose monitoring devices	Various manufacturers
Continuous glucose monitors	Various manufacturers including Dexcom Inc and Medtronic Ltd
Medicines for attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults:	
• Atomoxetine	Various manufacturers
• Lisdexamfetamine	
○ Elvanse and Elvanse Adult	Shire Pharmaceuticals Limited
• Methylphenidate	
○ Concerta XL	Janssen-Cilag Ltd
○ Equasym XL	Shire Pharmaceuticals Limited
○ Medikinet XL	Flynn Pharma Ltd
○ Xenidate XL	Mylan
Immediate release formulations:	
Various brands	Various manufacturers
Prescribing for Alzheimer's disease	
Donepezil, Galantamine, Memantine, Rivastigmine	Various manufacturers
Pelvic Inflammatory disease (PID)	
Various antibiotics	Various manufactures

Thyroid disorders Carbimazole, Propylthiouracil, Levothyroxine, Liothyronine	 Various manufacturers
Heart Failure (including dapagliflozin) Dapagliflozin (Forxiga®) Sacubitril valsartan (Entresto®) Various medicines	 Astra Zeneca UK Ltd Novartis Pharmaceuticals UK Ltd Various manufacturers
Methenamine hippurate 1g tablets (Hiprex®) for the treatment of UTI	Mylan
Dulaglutide (Trulicity®) Other GLP-1 mimetics • Exenatide (Byetta®, Bydureon®) • Liraglutide (Victoza®) • Lixisenatide (Lyxumia®) • Semaglutide (Ozempic®) Insulins	Eli Lilly and Company Ltd AstraZeneca UK Ltd Novo Nordisk Limited Sanofi Novo Nordisk Limited Various manufacturers
Oral Nutritional Supplements Any branded or generic oral nutritional supplements	 Various manufacturers

e-FIG Item	Company
Toujeo Doublestar Alternative treatments: • Lantus • Abasaglar	Sanofi Sanofi Eli Lilly and Company Ltd

2. Minutes of the meeting held on Wednesday 24th February 2021 year and Matters Arising

Minutes of the meeting held on Wednesday 24th February 2021

The minutes of the meeting held on Wednesday 24th February 2021 were approved.

Summary of actions			
	Action	**Lead**	**Status**
21/01	Terms of Reference – add Devon Partnership NHS Trust Drugs and Therapeutics Committee to the list of local decision-making groups.	Formulary Team	Complete
21/02	The environmental impact of inhalers – update the formulary entry for the Environmental Impact of Inhalers with the accepted formulary entry	Formulary Team	Complete
21/03	Toujeo Doublestar – contact nurse specialists in North Devon to seek their views.	Formulary Team	Complete
21/04	Toujeo Doublestar – on finalisation of wording for the formulary entry circulate to FIG members via e-FIG.	Formulary Team	Complete
21/05	Sumatriptan 3mg injection for migraine – progress the inclusion of sumatriptan 3mg subcutaneous injection for migraine into the formulary in line with the discussion.	Formulary Team	Outstanding
21/06	Sumatriptan 3mg injection for migraine – following publication of the formulary entry for sumatriptan 3mg injection the CCG's Medicines Optimisation team will be asked to add a Scriptswitch message indicating that sumatriptan 3mg injection is included in the formulary for migraine only.	Formulary Team	Outstanding
21/07	FreeStyle Libre 2 – update the formulary entry for FreeStyle Libre in line with the discussion.	Formulary Team	Complete
21/08	FreeStyle Libre 2 – inform specialists about the formulary changes.	Formulary Team	Complete
21/09	MHRA Drug Safety Updates December 2020 - contact specialists to ask whether erythromycin should be removed as a treatment option from the guidance for paediatric GORD.	Formulary Team	Outstanding
21/10	MHRA Drug Safety Updates December 2020 – Add to the formulary in line with the discussion.	Formulary Team	Complete
21/11	MHRA Drug Safety Updates January 2021 – contact Exeter genomics laboratory regarding recommendations for aminoglycosides	Formulary Team	Complete
21/12	MHRA Drug Safety Updates January 2021– Add to the formulary in line with the discussion.	Formulary Team	Complete
21/13	Technical issues with the Devon Formulary app - update FIG members and other Devon Formulary and Referral App users when the fix provided has been updated.	Formulary Team	Complete

Matters arising

Report of e-FIG decisions – Toujeo DoubleStar (April 2021)

In February 2021 the Devon FIG discussed a proposal to include Toujeo DoubleStar (insulin glargine) prefilled disposable injection device 3ml in the Devon Formulary. The proposal was accepted in principle subject to minor amendment. There was discussion over whether Toujeo Solostar should remain in the formulary. A subsequent consultation with specialists indicated support for Toujeo SoloStar to remain a formulary option.

In April 2021 the Devon FIG were asked to consider acceptance of the proposed changes to the Toujeo DoubleStar entry. Responses received indicated acceptance of the proposed formulary entry for the addition of Toujeo DoubleStar.

ACTION: Formulary Team to publish the accepted formulary entry for Toujeo DoubleStar.

Report of COVID-19 related changes to the formulary – February 2021-April 2021

The Formulary Team has continued to support the development and dissemination of temporary COVID-19 related guidance from various local and national groups. The temporary Devon Formulary page, "COVID-19 Updates", remains relevant to the current pandemic status and has been updated with important information related specifically to the COVID- 19 pandemic.

The Devon FIG received a report of COVID-19 related changes to the formulary since the last Devon FIG meeting on 24th February 2021.

The FIG was reminded that the page can be accessed via the Devon Formulary homepages by clicking on the interactive image "Coronavirus – What you need to know".

The latest update to the page is the inclusion of the national interim position statement for inhaled budesonide for adults with COVID-19.

3. Oral semaglutide (Rybelsus®) for the treatment of type 2 diabetes

The Clinical Policy Committee made a recommendation at its meeting on 24th March 2021 for the routine commissioning of oral semaglutide in Devon for patients with type 2 diabetes who are suitable for treatment with a GLP-1 mimetic, as described in NICE guideline NG28, but for whom injectable therapy is not suitable.

Semaglutide is a GLP-1 receptor agonist licensed for the treatment of type 2 diabetes mellitus. It is available as a subcutaneous injection or an oral tablet. The subcutaneous injection is the current formulary first choice option. There are four other GLP-1s currently licensed for the treatment of type 2 diabetes mellitus, all of which are only available as subcutaneous injections.

The Clinical Policy Committee's recommendation is now being taken through the CCG's governance processes; the policy recommendation is being considered by the CCG commissioning committee on 13th May, and FIG was therefore asked to take a decision in principle on the proposed formulary entry.

Concerns over variable bioavailability and the absence of a significant reduction in the incidence of cardiovascular outcomes limit the appropriateness of oral semaglutide as a first line treatment option. However, it may provide a treatment option for patients who are suitable for treatment with a GLP-1 mimetic but for whom injectable therapy is not suitable. It was therefore proposed that oral semaglutide is classified as second line (blue).

It was proposed that the entry is separate from the subcutaneous semaglutide entry to allow differences in classification and associated notes. The entries will list the products by brand. The notes of the entry highlight that it is to be limited to those patients for whom injectable therapy is not suitable and provide a rationale for that recommendation. Additional notes highlight the potential issues relating to bioavailability of the oral preparation.

The FIG considered and accepted in principle the proposed formulary entry for oral semaglutide without amendment subject to ratification of the policy decision by the commissioning committee on 13th May.

The FIG noted the clarity of the proposed entry.

ACTION: Formulary Team to publish the accepted formulary entry for oral semaglutide for the treatment of type 2 diabetes subject to ratification of the policy decision by the CCG's Commissioning Committee on 13 May.

4. FreeStyle Libre for interstitial glucose monitoring in diabetes

The CCG has had a policy in place for the FreeStyle Libre device since 2018, specifying the circumstances in which its use is accepted in Devon for interstitial glucose monitoring in diabetes. In March 2019 the Clinical Policy Committee (CPC) made a recommendation to update the CCG policy to include criteria relating to additional patient groups identified by NHS England.

In November 2020 NHS England added "People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability as recorded on their GP Learning Disability register" to the criteria for reimbursement. CPC made a recommendation at its meeting on 24th March 2021 to include this patient group in the criteria for those eligible for a six-month trial of FreeStyle libre as set out in the CCG's policy. This would be continued if the patient demonstrates the applicable continuation criteria at a six-month clinical assessment.

FreeStyle Libre is an interstitial glucose monitoring device that features a sensor applied to the back of the upper arm. Once the sensor is applied readings can be taken non-invasively, potentially reducing the need for finger pricking. To collect these measurements, patients hold the reader 1 to 4cm above the sensor for 1 second. Free Style Libre 2 is also available and has the added feature of an optional alarm that will sound when glucose levels exceed individualised high or low thresholds. FreeStyle Libre 2 is sufficiently similar to the original FreeStyle Libre that it is covered by the existing commissioning policy.

The Clinical Policy Committee's recommendation is now being taken through the CCG's governance processes; the policy recommendation is being considered by the CCG commissioning committee on 13th May, and FIG was therefore asked to take a decision in principle on the proposed changes to the existing formulary entry.

The proposed formulary entry had been circulated to specialists who were involved in the commissioning discussions. Specialists highlighted that they may not routinely be involved in the care of patients with a learning disability who are receiving insulin for type 2 diabetes

and therefore suggested that GPs could initiate the Libre for these individuals. However, the Libre reader is not prescribable on FP10 and patients or their carers may require training and advice on setting up the reader and setting optional alarms.

The FIG was asked to consider how best to support access to FreeStyle Libre for patients with a learning disability who are receiving insulin. The FIG agreed that:

- patients with a learning disability who have diabetes undergo an annual review in primary care. There are well established links between primary care and the diabetes nurses in the hospitals,
- experience with FreeStyle Libre lies in secondary care; patients with a learning disability may need additional support from specialist teams,
- the route to access FreeStyle Libre for patients with a learning disability should be the same as for other eligible patients which is that they are referred into specialist teams in secondary care,
- in the context of the proposed entry "diabetes specialist" refers to any suitably qualified member of the secondary care specialist diabetes team. The Formulary team will make this clear in the formulary entry.

ACTION: Formulary Team to publish the formulary entry for FreeStyle Libre for interstitial glucose monitoring in diabetes in line with the discussion subject to ratification of the policy decision by the CCG's Commissioning Committee on 13 May.

5. Medicines for attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults. Methylphenidate, Lisdexamfetamine and Atomoxetine

There are currently three attention deficit hyperactivity disorder (ADHD) Specialised Medicines Service (SMS) prescribing guidelines in Devon for methylphenidate, lisdexamfetamine and atomoxetine. The guidelines were last updated in 2016 (excluding the temporary COVID-19 arrangements in place) and apply to children and adolescents aged 6 years to 18 years. Devon Partnership NHS Trust (DPT) have produced a prescribing guideline for the pharmacological management of ADHD in adults, although a Devon-wide service has not been commissioned previously.

A service agreement is currently being negotiated with DPT and Livewell Southwest to provide adult ADHD services across Devon. In order to support the arrangements which are due to be finalised in the coming months, the "shared care" type SMS prescribing guidelines have been updated using NICE Guideline NG87 (2018) Attention deficit hyperactivity disorder: diagnosis and management and standard reference sources. The revised guidelines will cover children aged 6 years and over, adolescents and adults.

Key updates to the guidelines include monitoring, including baseline assessments and the frequency of monitoring. Actions for GPs have been added to offer support when the patient presents with unfavourable monitoring results or adverse events. Supporting information has also been updated or added.

Currently lisdexamfetamine is accepted in Devon for the management of ADHD in children aged 6 years of age and over for whom previous drug treatment for ADHD, including methylphenidate, has been unsatisfactory. Its use in adults is not routinely commissioned.

Alongside the update to the SMS guidelines, the Devon Clinical Policy Committee (CPC) will be considering an application for the routine commissioning of lisdexamfetamine for ADHD in adults at its meeting in May.

Remuneration will be as per the General Practice SMS framework: the final settlement of funding will be agreed via the Local Medical Committee (LMC) negotiations committee.

The FIG considered the proposed updates to the SMS prescribing guidelines for medicines for ADHD. Additional comments from specialists had been circulated to FIG members ahead of the meeting. Comments from Child and Family Health Devon were received on the morning of the meeting which did not give sufficient time for review and reporting to the FIG.

Further work to the guidelines was agreed including:

- separation of the guidelines for adults and children,
- add clarity to the timeframes and thresholds for action and for monitoring,
- baseline physical health assessments (including ECGs where necessary) should be conducted by the specialist teams. GPs should not be asked to undertake this work,
- specialists should provide regular reviews, at clinically appropriate intervals, including discussion of whether to continue treatment (NICE recommends annually); for children this should continue to be on an annual basis, for adults there may be limited scope for the interval between specialist reviews to be extended for individual patients if clinically appropriate.

The following points were also agreed:

- The focus should be on producing the guidelines for adults to support the CCG's timeline for commissioning of adult services and SMS funding allocation.
- Organisational versus individual responsibility was discussed. Where care is shared between a GP and secondary care, there should be a named GP and a named specialist.

Emma Gitsham to redraft the guidelines in line with the discussion and circulate to specialists and the Devon LMC. A final draft will be circulated to FIG members via the e-FIG process for agreement.

ACTION: Emma Gitsham to update the proposed guidelines in line with the discussion and circulate to specialists and the Devon LMC.

ACTION: Circulate final draft to FIG members via the e-FIG process for agreement.

6. Alzheimer's disease and Behavioural and Psychological Symptoms of Dementia: Update

Prescribing for Alzheimer's disease

The proposed communication from Devon Partnership Trust (DPT) to GPs regarding the initiation of memantine in primary care for patients diagnosed with mild or moderate Alzheimer's disease was discussed. The FIG GPs considered that a GP would be able to recognise a deterioration in a patient diagnosed with mild Alzheimer's disease as the point to initiate treatment with memantine. However, as GPs are not familiar with initiating treatment with memantine, further information on the titration of memantine and use in patients with renal impairment is required in the communication from DPT. The representative from DPT noted that currently a memantine titration pack is prescribed. It was noted that the feedback from the specialists at Livewell Southwest did not address the introduction of memantine for patients with Alzheimer's disease, and that this was needed before the draft formulary guidance could be agreed by the FIG.

It was noted that the specialists did not propose an alternative to the MMSE which can no longer be used due to copyright. A FIG member, who is an elderly care specialist, uses the Neuropsychiatric Inventory as a means of assessing patients with Alzheimer's disease and the impact on their carer. A list of tools for assessing patients will be included in the formulary guidance.

It was agreed that the decision on final guidance could be taken using the e-FIG process.

ACTION: Formulary team to progress guidance through the e-FIG process.

Behavioural and psychological symptoms of dementia

The guidance for behavioural and psychological symptoms of dementia (BPSD) was discussed by the two predecessor FIGs. No amendments to the draft guidance were required following consultation with specialists at Livewell and DPT. The draft guidance was brought to the FIG meeting for a decision on inclusion in the formulary.

The FIG considered and accepted the proposed guidance for BPSD and the proposed amendment to the entry for risperidone without amendment.

There was discussion about whether there should be greater advice for GPs on the deprescribing of antipsychotic drugs in the DPT guidance Pharmacological Management of Severe Behavioural and Psychological Symptoms of Dementia (BPSD)

ACTION: Formulary team to enquire via Nicola Diffey whether there is a weblink for Livewell leaflet for BPSD

ACTION: Formulary team to add the accepted formulary entry for BPSD and amendment to risperidone entry to the formulary.

7. Pelvic Inflammatory Disease (PID): Update

At the last meeting in February FIG members were asked to provide early input into draft guidance on PID which was based on feedback from the specialists at UHP in response to requests for an additional antibiotic option for GPs to prescribe. It was agreed by FIG that a "gold standard" and "silver standard" approach, suggested by the specialists, was the most appropriate direction for this guidance. Specialists across Devon were consulted on the draft guidance.

Subsequent feedback from specialists since February has been very limited. A response received from Dr Jonathan Shaw, indicated support for the proposed formulary entry with some additional points for consideration; these were included in the draft formulary entry.

The FIG considered and accepted the proposed draft guidance in the knowledge that:

- it is in line with the national guidance from British Association for Sexual Health and HIV (BASHH),
- at least one specialist has provided feedback in agreement,
- the initial gold and silver standard proposed was based on previous specialist input,
- there was previous agreement with the specialists regarding antibiotic regimens.

The FIG considered and accepted the proposed formulary guidance without amendment.

The formulary team will now send final communications to specialists with a statement that the guidance is to be published, unless specialists indicate that the proposed guidance is not considered suitable.

ACTION: Formulary team to send final communications to specialists with a statement that the guidance will be published, unless specialists indicate that the proposed guidance is not considered suitable.

8. Thyroid disorders: Update

The current formulary guidance for thyroid disorders required updating as a result of the publication of NICE guidance NG145 for thyroid disorders.

The proposed formulary guidance brought to the meeting for discussion was the result of two consultations with specialists from UHP, Torbay hospital and RD&E hospital. The RD&E team currently provide the consultant service for NDHT. The briefing paper included an outline of the proposed changes to the sections for hypothyroidism and hyperthyroidism and areas for discussion:

The FIG discussed and agreed the following changes:

- Update to the guidance for hypothyroidism
- Additional wording on monitoring for natural thyroid extract.
- The section for hypothyroidism in pregnancy should refer to individual trust guidance for management.
- Treatment of symptoms associated with hyperthyroidism to be added as an indication for propranolol.

- There was discussion about inclusion of the starting dose of propylthiouracil. The FIG agreed that the starting dose should not be included as propylthiouracil is not a first line treatment due to the risk of hepatic failure. Specialists from Torbay Hospital have indicated that it should be started on the advice of specialists.
- The NICE statement on checking full blood count and liver function tests prior to starting an antithyroid drug should be included without amendment.
- There was discussion of the approach to subclinical hyperthyroidism. It was noted that these cases are rarely seen by GPs and they would always seek advice. It was agreed that this section should identify patients who are suitable for monitoring in primary care and recommend seeking advice from specialists for other patients.
- To align the formulary across Devon, it was agreed for carbimazole to be reclassified from amber (specialist-input) to green (first-line) in the South and West Devon Formulary and for propylthiouracil to be reclassified from blue (second-line) to amber (specialist-input) in the North and East Devon Formulary pending discussion with the specialists
- It was also noted that an outstanding area to address was the difference between the trust laboratory reference values for thyroid function tests and thyroid stimulating hormone. This will be discussed with specialists after the FIG meeting.

The formulary team will redraft the proposed formulary guidance for thyroid disorders in line with the discussion and consult with specialists. The guidance will be finalised through the e-FIG process in due course.

ACTION: Formulary team to redraft the proposed formulary guidance in line with the discussion and consult with specialists.

ACTION: Circulate final draft via e-FIG process for agreement.

9. Chronic Heart Failure (including NICE TA679 for dapagliflozin)

This topic was brought to the FIG meeting for an initial discussion.

An update is required to the Devon Formulary guidance for chronic heart failure in line with NICE guideline NG106 (Chronic heart failure: diagnosis and management). The key differences between the current formulary guidance and NICE guideline NG106 were outlined in a briefing paper. The FIG GPs were asked if there were any areas where additional information was required for the formulary.

It was noted that mineralocorticoid receptor antagonists are no longer considered a specialist treatment. GPs agreed that the top line and monitoring guidance were helpful, particularly for new GPs. It was suggested information on monitoring from the NICE guideline be included in the formulary rather than a link out to the guidance.

<u>Dapagliflozin</u>

A briefing paper explaining the background to NICE TA679 for dapagliflozin for chronic heart failure was submitted to the FIG. A proposed update to the formulary entry for dapagliflozin to incorporate the technology appraisal was discussed. The CCG has a statutory obligation to comply with the recommendations in TA679 within 3 months of publication; the only

opportunity to discuss the proposed formulary entry for dapagliflozin "face-to-face" was during the April FIG meeting.

The FIG took a 'decision in principle', to accept the proposed formulary entry. This decision was taken in the knowledge that there would be a subsequent consultation with the heart failure teams in Devon before the update to the formulary was published. It was agreed that any proposed changes to the formulary entry following consultation with the heart failure teams would be considered through the established e-FIG decision process before the deadline for publishing the TA.

There was discussion about the changes to the introductory text for SGLT-2 inhibitors and the changes under indication and dose. It was noted that the proposed formulary guidance states that dapagliflozin should be started 'on the advice of a heart failure consultant' whereas the NICE guidance states 'on the advice of a heart failure specialist'. It was agreed that the formulary team seek clarity from heart failure teams in Devon on the meaning of the term 'specialist'

ACTION: Formulary team to seek clarification from heart failure teams in Devon on the meaning of the term 'specialist'.

ACTION: Formulary Team to publish the formulary entry for dapagliflozin within 3 months of publication of NICE TA679.

10. Methenamine Hippurate for Urinary Tract Infections (UTI)

Proposed recurrent UTI guidance was presented to N&E Devon FIG members and S&W Devon FIG members with feedback from the specialists for final consideration and agreement at meetings in 2020. At the time both FIGs considered the proposed formulary guidance and accepted it, subject to minor amendments.

At these meetings, FIG members discussed the inclusion of methenamine hippurate, a urinary antibacterial agent with a wide antibacterial spectrum, which is licensed for the prophylaxis and treatment of urinary tract infections. However, GPs had suggested that they had not been asked to prescribe it.

It was noted that during the specialist consultation period no responses were received from specialists on the use of methenamine hippurate in recurrent UTIs. Based on this and the information provided in NICE Guideline NG112, where evidence suggested that methenamine hippurate was less effective than antibiotic prophylaxis with nitrofurantoin, N&E and S&W Devon FIGs opted not to include it.

FIG members subsequently made a strengthened recommendation with a statement to not routinely recommend methenamine hippurate for use in recurrent UTIs, based on the NICE committee summary. Prior to publication of the guidance on the formulary website, the formulary team was contacted by a specialist from the RD&E hospital, to ask if the FIG could reconsider the strengthened statement, as it was suggested that it does not reflect current practice and methenamine hippurate may routinely be recommended in certain circumstances by a specialist or the bladder and bowel care teams in Devon.

The Formulary team looked again at the NICE guidance and contacted specialists for their opinion on the place in therapy of methenamine hippurate, and to find out whether a less stringent recommendation was more acceptable. Although there is no recommendation for methenamine hippurate in NICE NG112, local specialist opinion suggests it may have a place in therapy for the management of recurrent UTI.

An application form was received from a consultant urologist at the RD&E, requesting methenamine hippurate for recurrent uncomplicated UTIs where 1st, 2nd or even 3rd line treatments have failed. The application was supported by urology colleagues and microbiologists Devon-wide.

It was proposed to the FIG that methenamine hippurate is included in the Devon Formulary as an amber (specialist input) option for the management of recurrent UTIs, where alternative options are not appropriate. A summary of the literature review conducted for methenamine for the treatment of recurrent uncomplicated UTI was presented. It was noted that two randomised controlled trials (RCT) are underway in the UK and Scandinavia investigating methenamine for recurrent UTI.

Specialists were asked what they advise patients to do while taking methenamine hippurate to maintain acidic urine. Based on the comments received, it is proposed that the specialists will provide individual advice to the patient on monitoring and maintaining acidic urine.

The FIG considered and accepted the proposed formulary entry for the inclusion of methenamine hippurate into the Devon Formulary for the treatment of urinary-tract infections. It was agreed that the dose be added under section 5.1.13.

It was agreed that the decision should be reconsidered when the findings of the two ongoing RCTs are published.

ACTION: Formulary team to add the accepted drug entry for methenamine hippurate for the treatment of urinary-tract infections to the formulary in line with the discussion.

11. Dulaglutide 3mg and 4.5mg injection for the treatment of type 2 diabetes

Dulaglutide subcutaneous 0.75mg and 1.5mg injection is included in the Devon Formulary as a blue (second line) GLP-1 RA option in accordance with the criteria set out in NICE guideline 28 (Type 2 diabetes in adults: management). An extension to the dosing regimen for dulaglutide injection to include a 3mg and 4.5mg dose was recently licensed. The request to include the higher strengths of injection was received from a consultant endocrinologist at Torbay Hospital. Inclusion of the higher strengths of dulaglutide in the formulary would allow patients who do not have sufficient control of their diabetes on dulaglutide 1.5mg injection to continue receiving dulaglutide injection and avoid the need to switch to an alternative GLP-1 RA.

The clinical evidence for dulaglutide 3mg and 4.5mg injection was presented. It was noted that dulaglutide 3mg and 4.5mg injection is the same price as the 0.75mg and 1.5mg injection. In response to the consultation with the diabetes specialists and lead diabetes

nurses in Devon, two diabetes specialists at UHP supported the application for dulaglutide 3mg and 4.5mg injection on the grounds of clinical efficacy and no additional cost.

The FIG considered and accepted the proposed formulary entry for dulaglutide 3mg and 4.5mg injection for the treatment of type 2 diabetes without amendment.

ACTION: Formulary team to add the accepted formulary entry for dulaglutide 3mg and 4.5mg injection for the treatment of type 2 diabetes to the formulary.

12. Oral nutritional supplements

Work is currently underway to update the Devon formulary ONS guidance. The guidance is being reviewed by Liz Fleming, Specialist Medicines Optimisation Dietitian, NHS Devon CCG, with the intention of harmonising the formulary recommendations between North & East and South & West Devon. The review does not include products for swallowing difficulties.

Aligning the guidance will provide consistent advice to primary care prescribers across Devon on appropriate ONS choices and is intended to support cost efficient prescribing for the local NHS. Devon-wide consultation with local dietitian specialists is ongoing and additional feedback on the proposed formulary ONS recommendations and supporting information is expected.

Liz Fleming presented a paper to gather early input from FIG members on the development of this guidance section.

The FIG considered and accepted the proposed changes to formulary products. There was discussion about the number of first line products that should be available. The FIG agreed that there should me more than one option available in most cases. The FIG also agreed that product information should be included in a table rather than a bullet point format.

Liz Fleming will revise the guidance with support from the Medicines Optimisation team and additional feedback from dieticians. The revised guidance will be brought to a future FIG meeting, for final consideration and agreement.

ACTION: Liz Fleming to update the proposed ONS guidance in line with the discussion at the FIG meeting and further feedback from specialists.

ACTION: Liz Fleming to bring updated proposed formulary ONS guidance back to a future meeting for final agreement.

13. MHRA Drug Safety Updates February and March

The MHRA Drug Safety Updates for February and March 2021 were discussed and noted.

February 2021

- Ulipristal acetate 5mg (Esmya): further restrictions due to risk of serious liver injury.

  The temporary suspension of ulipristal acetate 5mg tablets has been lifted by the European Medicines Agency, however, the indication for ulipristal 5mg tablets has been further restricted. Ulipristal 5mg tablet was a red (hospital) drug in the Devon Formulary before the temporary suspension of the licence. As there may be occasions when a specialist considers the use of ulipristal 5mg tablets is appropriate, the formulary entry for ulipristal 5mg tablet was updated to reflect the new indication and to incorporate the advice from the MHRA Drug Safety Update issued in February 2021. There is no change to the formulary classification of ulipristal 5mg tablet, it continues to be a red drug in the Devon Formulary.

  The Formulary team contacted gynaecologists in Devon to inform them of the update to the formulary entry for ulipristal 5mg tablets including that the benefits and risks of treatment must be discussed with patients before prescribing ulipristal 5mg tablets, and monitoring of liver function tests is required before, during and after treatment. The specialists were reminded that the prescriber is responsible for undertaking any drug safety monitoring.

  The specialists were asked if they had any comments on the updated formulary entry for submission to the FIG for discussion. Mr Alexander Taylor, a consultant obstetrician and gynaecologist from UHP, responded the addition to the formulary with all the advice and instructions on use is clear.

  The FIG members were asked if the approach taken with ulipristal 5mg tablet was acceptable. They indicated that they were happy with the approach taken.

- Pregabalin (Lyrica): reports of severe respiratory depression. The Devon Formulary entry for pregabalin has been updated to reflect the safety update and a link to the safety update is included. Cross references to the drug monograph for safety updates have been added to the formulary guidance for neuropathic pain and generalised anxiety disorder.

- Gabapentinoids: reminder of advice for dependence and addiction. No further action is required.

- Alkindi granules (hydrocortisone granules) risk of acute adrenal insufficiency in children when switching from hydrocortisone tablet to granules. Alkindi granules are not included in the Devon Formulary. No further action is required.

- Medicines in pregnancy and breastfeeding: new initiative for consistent guidance; report on optimising data for medicines used during pregnancy. The MHRA has a new guidance page to assist users in finding MHRA information on drugs in pregnancy and

breastfeeding. A link to this guidance page has been added to the Devon formulary webpage "Resources for: contraception for drugs with teratogenic potential and prescribing in pregnancy and lactation". In addition, the e-mail address for reporting inconsistencies in UK advice on the use of medicines in pregnancy and lactation has been added to the formulary page.

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- Bendamustine (Levact): increased risk of non-melanoma skin cancer and progressive multifocal encephalopathy (PML). The Devon Formulary entry for bendamustine has been updated to reflect the safety update and a link to the safety update has been included.

Update on articles from previous Drug Safety Updates

- Clozapine and other antipsychotics: monitoring blood concentrations for toxicity (Drug Safety Update issued 26th August 2020). Following feedback from the hospital trust laboratories in Devon, which was reported to the predecessor FIGs, an amendment to the current Devon Formulary entry for this article under section 4.2.1 Antipsychotics has been agreed with Nicola Diffey (clinical pharmacist, Livewell Southwest) and Chris Sullivan (Deputy Chief Pharmacist, Devon Partnership Trust). The published update to the formulary will be sent to the trust laboratories for information.

ACTION: Formulary Team to send the published update to the formulary to trust laboratories for information.

14. Recent drug decisions (including NICE publications)

The recent drug decisions were noted.

Summary of actions			
	Action	**Lead**	**Status**
21/05	Sumatriptan 3mg injection for migraine – progress the inclusion of sumatriptan 3mg subcutaneous injection for migraine into the formulary in line with the discussion.	Formulary Team	Complete
21/06	Sumatriptan 3mg injection for migraine – following publication of the formulary entry for sumatriptan 3mg injection the CCG's Medicines Optimisation team will be asked to add a Scriptswitch message indicating that sumatriptan 3mg injection is included in the formulary for migraine only.	Formulary Team	Complete
21/09	MHRA Drug Safety Updates December 2020 - contact specialists to ask whether erythromycin should be removed as a treatment option from the guidance for paediatric GORD.	Formulary Team	Complete
21/14	Report of e-FIG decisions – Toujeo DoubleStar April 2021) – publish the accepted formulary entry for Toujeo DoubleStar.	Formulary Team	Complete
21/15	Publish the accepted formulary entry for Oral semaglutide for the treatment of type 2 diabetes subject to ratification of the policy decision by the CCG's Commissioning Committee on 13 May.	Formulary Team	Complete
21/16	Publish the formulary entry or FreeStyle Libre for interstitial glucose monitoring in diabetes in line with the discussion subject to ratification of the policy decision by the CCG's Commissioning Committee on 13 May.	Formulary Team	Complete
21/17	Medicines for attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults - Methylphenidate, Lisdexamfetamine and Atomoxetine: update the proposed guidelines in line with the discussion and circulate to specialists and the Devon LMC.	Emma Gitsham	Complete
21/18	Medicines for attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults - Methylphenidate, Lisdexamfetamine and Atomoxetine: Circulate final draft to FIG members via the e-FIG process for agreement.	Emma Gitsham	On agenda
21/19	Prescribing for Alzheimer's disease: progress guidance through the e-FIG process	Formulary team	Outstanding
21/20	Behavioural and Psychological Symptoms of Dementia: enquire via Nicola Diffey whether there is a weblink for the Livewell leaflet for BPSD	Formulary team	Complete
21/21	Behavioural and Psychological Symptoms of Dementia – add accepted entry for BPSD and amendment to risperidone entry to the formulary.	Formulary Team	Outstanding
21/22	Pelvic Inflammatory Disease (PID): Update - send final communications to specialists with a statement that the guidance will be published, unless specialists indicate that the proposed guidance is not considered suitable.	Formulary Team	Complete

21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists	Formulary Team	Outstanding
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement	Formulary Team	Outstanding
21/25	Chronic Heart Failure (including NICE TA679 for dapagliflozin) seek clarification from heart failure teams in Devon on the meaning of the term 'specialist'.	Formulary Team	Complete
21/26	Publish the formulary entry for dapagliflozin within 3 months of publication of NICE TA679.	Formulary Team	Complete
21/27	Methenamine Hippurate for Urinary Tract Infections (UTI) - add the accepted drug entry for methenamine hippurate for the treatment of Urinary-tract infections to the formulary in line with the discussion.	Formulary Team	Complete
21/28	Dulaglutide – add accepted formulary entry for 3mg and 4.5mg injection for the treatment of type 2 diabetes to the formulary.	Formulary Team	Complete
21/29	Oral nutritional supplements - update the proposed ONS guidance in line with the discussion at the FIG meeting and further feedback from specialists.	Liz Fleming	Outstanding
21/30	Oral nutritional supplements - bring updated proposed formulary ONS guidance back to a future meeting for final agreement.	Liz Fleming	Outstanding
21/31	MHRA Safety Updates - Clozapine and other antipsychotics: monitoring blood concentrations for toxicity (Drug Safety Update issued 26th August 2020). Send the published update to the formulary to trust laboratories for information.	Formulary Team	Complete