NHS
Devon
Clinical Commissioning Group

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 23rd June 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
Nicola Diffey	Pharmacist	Livewell Southwest
Susie Harris	Consultant (Elderly Care)	RD&E NHS FT
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
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
Jamie Smith	Consultant in Diabetes and Endocrinology	T&SD NHS FT
Vivek Soni	Deputy Director Pharmacy – Pharmacoeconomics	UHP NHS Trust
Christopher Sullivan	Deputy Chief Pharmacist - Clinical Services	DP NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formularies Technician	NHS Devon CCG

Guests:

Dr Rachel Ali	GP Representative	Devon LMC
Emma Gitsham	Clinical Effectiveness Pharmacist	NHS Devon CCG
Catherine Hill	Neurodiversity Professional Nurse Lead	DP NHS Trust
Mel Hucker	Lead Nurse Tissue Viability	NDHC
Rachel Webb	Operational and Strategic Neurodiversity Lead	DP NHS Trust

Observers:

Kemi Gibson	Medicines Optimisation Pharmacist	NHS Devon CCG

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.

Register of participants

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

Apologies

Dr Andrew Craig, NHS Devon CCG
Matthew Kaye, Chief Pharmacist, NDHT

Declarations of Interest

Declarations of Interest were collected. All declarations of interest are reported in the minutes.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Lisdexamfetamine (Elvanse® / Elvanse Adult®) for attention deficit hyperactivity disorder (ADHD) in adults	Shire Pharmaceuticals
Alternative treatments:	
Methylphenidate	Various manufacturers
Atomoxetine	Various manufacturers
Lixisenatide (Lyxumia®) for the treatment of type 2 diabetes	Sanofi
Alternative treatments:	
Exenatide (Byetta®, Bydureon®)	AstraZeneca
Semaglutide (Ozempic®, Rybelsus®)	Novo Nordisk
Liraglutide (Saxenda®, Victoza®)	Novo Nordisk
Dulaglutide (Trulicity®)	Eli Lilly

Larval therapy Alternative debridement therapies: Enzymatic Debridement, Autolytic Debridement, Mechanical Debridement (incl. monofilament pads), Conservative sharp and surgical sharp Debridement	BioMonde Various manufacturers/private providers
Levetiracetam for palliative care: Levetiracetam solution for infusion Desitrend® Keppra® Various brands Alternative treatments: Midazolam solution for infusion	 Desitin Pharma Ltd UCB Pharma Ltd Various manufacturers Various manufacturers
Eye infections: Chloramphenicol 0.5% eye drops Chloramphenicol eye ointment Fusidic acid 1% eye drops Alternative treatments: Various antibiotic eye drops	 Various manufacturers Various manufacturers Advanz Pharma Various manufacturers
CNS stimulants and drugs for ADHD: Methylphenidate modified release (Xenidate XL, Concerta XL, Medikinet XL, Equasym XL) Alternative brands: (Delmosart XL, Matoride XL, Xaggitin XL, Ritalin XL) Methylphenidate moderate release (generic) Lisdexamfetamine (Elvanse, Elvanse Adult) Atomoxetine (generic) Alternative brands: (Strattera) Dexamfetamine (generic) Alternative brand: (Amfexa) Modafinil	 Mylan, Janssen-Cilag Ltd, Flynn Pharma Ltd, Shire Pharmaceuticals Ltd/Takeda UK Ltd Janssen-Cilag, Sandoz Ltd, Ethylpharm UK Ltd Various manufacturers Takeda UK Ltd Various manufacturers Eli Lilly and Company Limited Various manufacturers Flynn Pharma Ltd Various manufacturers

Bempedoic acid with ezetimibe Bempedoic acid (Nilemdo®) Bempedoic acid/ezetimibe (Nustendi®) Alternative: Ezetimibe Alirocumab (Praluent®) Evolocumab (Repatha Sureclick®)	 Daiichi Sankyo UK Ltd Daiichi Sankyo UK Ltd Various manufacturers Sanofi Amgen Ltd

e-FIG Item	Company
Dapagliflozin (Forxiga®)	Astra Zeneca Ltd

Name of attendee	Role	Declaration
Rachel Ali	GP Representative	Chair of Devon LMC GPC UK Representative GP Partner
Jamie Smith	Consultant in Diabetes and Endocrinology	Received honoraria from AZ, Sanofi, Boehringer, novonordisk, Lilly, Amgen for speaker meetings within last 3yrs. Advisory board meeting for Daiichi Sankyo UK Ltd 2021. Conference registration fees paid by Daiichi Sankyo UK, Novonordisk, Lilly, Astra-Zeneca within last 3 yrs. PI for clinical trials involving praluent, empagliflozin, canagliflozin, semaglutide within last 3 yrs.
Rachel Webb	Operational and Strategic Neurodiversity Lead	non- interest. Trustee of Board for Somerset Child Contact Centres. Charity no. 1190163. Don't see this as an influence.

2. Minutes of the meeting held on Wednesday 28th April 2021 and Matters Arising

Minutes of the meeting held on Wednesday 28th April 2021

The minutes of the meeting held on Wednesday 28th April 2021 were approved.

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

Matters Arising

- Report of e-FIG decisions:
    - Dapagliflozin (May 2021)

      A proposed update to the Devon Formulary entry for dapagliflozin to incorporate NICE TA679 for dapagliflozin for chronic heart failure was considered at the meeting in April.

      The FIG took a 'decision in principle' to accept the proposed formulary entry subject to consultation with the heart failure teams in Devon

      One change was proposed to the draft formulary entry:

        - Through the e-FIG process the FIG was asked whether it agreed with the proposal to change the draft formulary entry from dapagliflozin should be started "on the advice of a heart failure consultant" to "on the advice of a heart failure specialist" in line with the wording of the recommendation from NICE TA679?

Responses received indicated acceptance of the proposed formulary entry.

The formulary has been updated.

- Reclassification of acamprosate (N&E FIG)

  There was an outstanding action from the final meeting of the predecessor North and East Devon FIG meeting to update the formulary classification for acamprosate from blue to amber in line with NICE guidance and the South and West Devon formulary entry. The process for updating the North and East Devon formulary entry was paused following a communication from the commissioning manager for drug and alcohol services for Public Health Devon who was concerned about the potential impact of an amber classification on service models for the Together service. The commissioner manager has since indicated that he is satisfied with the Formulary team's explanation of the amber formulary classification and the decision-making process The North and East Devon Formulary classification for acamprosate has been updated. The public health commissioner was asked whether there was an arrangement in place to reimburse the CCG for the cost of prescribing acamprosate by GPs; no response was received on this point.

  ACTION: Formulary team to contact the Head of the CCG's Medicines Optimisation Team regarding the communication from the Public Health commissioner and reimbursement for acamprosate prescribing in primary care

- Report of COVID-19 related changes to the formulary - (April 2021 – June 2021)

  Since the last Devon FIG meeting (28th April) 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.

  An update has been made to shared care / SMS drug safety monitoring during the COVID-19 pandemic. Attention was drawn to the West Devon gastroenterology statement; specialists have requested that usual frequency monitoring is undertaken for all patients. GPs in West Devon should seek specialist advice if they are unable to provide the routine monitoring requirements.

3. Lisdexamfetamine for the management of attention deficit hyperactivity disorder (ADHD) in adults

At its meeting in May 2021 the Clinical Policy Committee made a recommendation for the routine commissioning of lisdexamfetamine for the treatment of ADHD in adults who have failed to gain an adequate response or tolerate methylphenidate.

The FIG considered and accepted in principle the proposed formulary entry for lisdexamfetamine without amendment, subject to ratification of the policy decision by the CCG's Commissioning Committee.

ACTION: Formulary Team to publish the accepted formulary entry for lisdexamfetamine for the treatment of ADHD in adults subject to ratification of the policy decision by the CCGs Commissioning Committee.

4. Policy withdrawal: Lixisenatide for the treatment of type 2 diabetes

At its meeting in May 2021 the Clinical Policy Committee made a recommendation to withdraw the Commissioning Policy for lixisenatide for type 2 diabetes.

The FIG considered and accepted in principle the proposed removal of lixisenatide from the formulary entry for glucagon-like peptide-1 receptor agonists, subject to ratification of the policy withdrawal by the CCG's Commissioning Committee.

ACTION: Formulary Team to remove lixisenatide from the formulary subject to ratification of the policy withdrawal by the CCG's Commissioning Committee.

5. Larval therapy

Larvae are classified as an Unlicensed Medicine (ULM) and clinicians should be aware of and follow advice in a ULM policy and MHRA guidance.

In March 2020, the MHRA completed a routine inspection of BioMonde, a wound care company specialising in the manufacture and distribution of larval debridement therapy and directed them to obtain additional information on top of the current requirements, at the point of ordering. Subsequently, BioMonde issued a request that for future orders, accompanying information must include the name of the prescribing clinician and the clinician's authorisation to prescribe. Historically, BioMonde only requested the name of the prescriber. As a result, the Formulary Team were asked by the Tissue Viability Team in Livewell Southwest to review the existing formulary guidance to reflect the additional requirements.

There are differences in the existing guidance provided in the two presentations of the Devon formulary: In North & East Devon larval therapy is listed as an amber (specialist input) medicine, in South & West Devon larval therapy does not have a specific product entry, but there is some supporting guidance. For both presentations the information relating to larval therapy has been principally unchanged since the merger of the predecessor formularies in 2013/14.

ePACT2 data suggests in the last 5 years in primary care there is relatively low levels of prescribing of larval therapy in Devon, (39 prescriptions at a cost of just over £8,500). 92% of all primary care prescribing of larval therapy is within North & East Devon, with the remaining 8% within West Devon only.

The Formulary Team consulted with local Tissue Viability specialist services across Devon to find out how larval therapy is currently assessed, managed, reviewed, and who has financial responsibility for treatment. In addition, specialists were asked if they ever request

that GPs in primary care prescribe larval therapy. Considering specialist responses, financial considerations, and the position of other formularies in South West England, the FIG was asked to consider next steps for larval therapy within the Devon Formulary.

To aid discussions the potential options that may be considered were set out in the meeting papers. Mel Hucker, Lead Nurse Tissue Viability, NDHC attended for discussion of this item to provide support and additional information to answer questions.

The FIG was asked to consider the approach to be taken regarding the inclusion and classification of larval therapy in the Devon Formulary. The discussion included the following points:

- Across Devon several different approaches are currently taken. Specialists, GPs and community nurses need clarification of what is expected from them. It was noted that larval therapy can be prescribed by non-medical prescribers. The FIG GP members noted that larval therapy is not a medicine and GPs are not familiar with its use or prescribing requirements. To be asked to do so is time-consuming and costly in terms of GP resource when there are nurses with expertise in the area. Alternative means of obtaining larval therapy for community patients should be explored.
- The lead nurse was of the opinion that use of larval therapy may reduce hospital admissions and there is emerging evidence that larval therapy is useful for immunocompromised patients.
- Further investigation by the Tissue Viability teams in Devon is needed into:
    - Options for the supply of larval therapy in the community setting
    - Funding and budget implications for supply of larval therapy
    - Utilising non-medical prescribers in the tissue viability teams
    - Rather than requesting GP prescribing, specialist teams could write two separate outpatient prescriptions or provide two FP10 prescription forms. It was noted that Biomonde will only deliver to hospitals or a dispensing pharmacy.
- Livewell have contacted the CCG's Medicines Optimisation team saying that they have no prescribers and GPs are not happy to prescribe. It was agreed that Nicola Diffey will talk to colleagues at Livewell regarding their difficulties in prescribing larval therapy.

ACTION: Nicola Diffey to talk to colleagues at Livewell regarding their difficulties in prescribing larval therapy.

It was agreed that the Formulary Team will undertake additional work with specialists and seek clarification of the issues identified during the discussion.

ACTION: Formulary team to feedback the outcome of the discussion to the specialists.

6. Palliative care: Levetiracetam 100mg/ml concentrate solution for intravenous infusion

This paper was brought for an initial discussion of a proposal from the palliative care specialists in Devon for levetiracetam concentrate solution for intravenous infusion to be included in the Devon Formulary as an amber medicine for use in a syringe driver in the community setting. The palliative care consultants are using levetiracetam as a continuous

subcutaneous infusion (CSCI) in hospitals and hospices for patients with primary or secondary brain tumours who are no longer able to take oral levetiracetam and have an ongoing risk of seizures. Treatment is started during the last few weeks of life. Levetiracetam is preferred over midazolam at this stage because it is non-sedating. The place in therapy is supported by the Scottish Palliative Care Guidelines.

The FIG GPs and FIG members were asked for their views on this proposal. It was recognised that GPs are not familiar with prescribing levetiracetam for this purpose.

The following areas were raised during the discussion which would need to be addressed satisfactorily before the FIG is able to take a final decision on the proposal:

- Availability from community pharmacies. Tom Kallis has been asked to look into this.
- Identification of patients and planning of care.
- Support for GPs.
- Areas relevant to administration, including education and support for community nurses).

ACTION: Formulary team to feedback the outcome of the discussion to the palliative care consultants and undertake further work in this area.

ACTION: Tom Kallis to respond to questions from the Formulary team on the availability of levetiracetam concentrated solution for IV infusion from community pharmacies

7. Helicobacter Pylori *(H. Pylori)* retesting in Dyspepsia and Gastro-oesophageal reflux disease (GORD)

Following discussions and a consultation period with local gastrointestinal specialists in Devon, Devon Referral Support Service (DRSS) has updated the clinical referral guideline (CRG) for upper gastrointestinal dyspepsia / GORD.

Generally, the changes in the CRG do not affect the formulary guidance for dyspepsia and GORD, except where *H. Pylori* testing is mentioned. The formulary guidance currently states: “do not retest even if dyspepsia remains, unless there is a strong clinical need”. As part of the CRG update, the CCG is recommending repeat testing using stool antigen tests for specific patient groups.

Based on a 2004 evidence review, NICE guidance states that retesting for *H. pylori* should be via a carbon-13 urea breath test as “there is currently insufficient evidence to recommend the stool antigen test as a test of eradication”. It is apparent that this recommendation was not reviewed when the publication was updated in 2014. Public Health England (PHE) published a quick reference guide for primary care for testing and treating *H. pylori* in dyspepsia in 2017, which states that urea breath tests are the most accurate, but that a stool antigen test is an alternative option. This recommendation was based on three references, however these do not appear to substantiate the position taken by PHE. A rapid literature review revealed there is still a paucity of evidence in post-eradication accuracy.

At the request of local specialists, NHS Devon CCG has agreed to diverge from NICE guidance and recommend stool antigen tests for repeat testing following *H. Pylori* infection in patients with a defined clinical need.

An update to formulary guidance has been proposed to reflect this, providing clarity on the patient groups who have a strong clinical need for retesting

The FIG considered the proposed formulary entry. There was discussion about the availability of H_2-receptor antagonists (H_2RAs) and washout after antibiotic use:

- A GP in North Devon had suggested that obtaining H_2RAs may be difficult. This was checked during the meeting; it was found that nizatidine and famotidine are currently available in all strengths.
- One minor amendment was agreed. This was that the four-week wash out period should be after 'any' antibiotic use.

ACTION: Formulary Team to update the formulary entry for *H. Pylori* retesting for Dyspepsia and Gastro-oesophageal reflux disease (GORD) in line with the discussion.

8. Eye infections: update

Due to time constraints the updated guidance on eye infections was not discussed. This item may be brought to a future FIG meeting or progressed via the e-FIG process.

Post meeting note: the MHRA issued a Drug Safety Update on the use of chloramphenicol eye drops in children under 2 years of age on 7th July which is of direct relevance to the proposed update to the formulary guidance for conjunctivitis. The Formulary team has updated the existing formulary guidance for conjunctivitis and the formulary entries for chloramphenicol eye drops with the new safety advice and will be contacting specialists regarding the proposed alignment of the relevant sections of the formulary.

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

There are currently three ADHD Specialised Medicines Service (SMS) prescribing guidelines in Devon, these are 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.

A service agreement is currently being negotiated with Devon Partnership NHS Trust (DPT) and Livewell Southwest to provide adult ADHD services across Devon. In order to support the commissioning of adult services, SMS prescribing guidelines for adults were produced and updates to the child and adolescent guidelines proposed.

The guidelines were first considered by the FIG on the 28th April 2021. A significant amount of feedback was received immediately prior to and during the April meeting, including a request to produce separate guidelines for adults and for children/young people. The guidelines for adults have been prioritised to support the timeframe for the introduction of

newly commissioned services. Revised guidelines for children will be considered at a separate FIG meeting.

Based on feedback received, and discussions at the April FIG meeting, the guidelines were redrafted and circulated amongst ADHD specialists for feedback; comments were received from DPT but not Livewell Southwest.

The CCG met with Devon LMC negotiations committee in May to discuss renumeration via SMS; this was agreed in principle. Some minor adjustments were requested to the draft guidelines.

Following the meeting of the LMC negotiations committee, further amendments were made to the guidelines based on LMC and DPT feedback. The guidelines were then circulated once more to adult ADHD specialists for comment. Both DPT and Livewell Southwest responded during the final consultation and the draft guidelines were broadly agreed in principle prior to the FIG meeting on the 23rd June.

Two outstanding issues remained unresolved:
- The need for regular specialist review
- The need for baseline physical assessments (including occasional ECGs)

Emma Gitsham, Clinical Effectiveness Pharmacist, NHS Devon CCG presented the proposed guidance to the FIG for discussion and agreement. Dr Rachel Ali, Catherine Hill and Rachel Webb joined the meeting for discussion of this item.

The FIG considered and agreed the proposed SMS guidelines; subject to some minor amendments the guidelines were considered clinically appropriate. There was discussion about:

<u>Specialist responsibilities and the need for regular specialist review</u>

It had been suggested by DPT that GPs could undertake an annual review (including consideration of stopping treatment), however both the FIG and LMC had indicated that this should be undertaken by the specialist, not the GP. This is in line with existing practice locally and the recommendation of NICE guideline NG87.

The FIG discussed the form of the review, the following points were noted:

- Annual review is currently commissioned locally from specialist services. It was noted that reviews are undertaken by specialists but not always at twelve monthly intervals, as recommended by NICE (NG87); sometimes the interval between reviews is thirteen or fourteen months.
- Mental health providers expressed concern that proposed changes to the service specification do not include an annual review.
- It was acknowledged that due to the pressures of COVID-19, annual review poses significant challenges. Unless there are specific issues, patients are often not seen annually, particularly those who are stable on their treatment. The importance of good communication for new initiations and during any upcoming reviews to ensure all parties are aware of realistic timeframes and ongoing review frequency was noted. It was agreed that there should be some leeway regarding the intervals between reviews and

that this should be based on clinical appropriateness. It is the role of specialists to manage patient expectations and determine the frequency of specialist reviews which will in turn be agreed with the GP and the patient.

- There may be a point at which GPs are not happy to continue without a specialist review. It was suggested that a virtual review could be undertaken if appropriate.
- It was agreed that the Clinical Effectiveness Team will feed back to mental health commissioners on the need to ensure that the commissioned service is suitably resourced to provide the level of follow up required.

ACTION: Clinical Effectiveness to feed back to mental health commissioners on the need to ensure that the commissioned service is suitably resourced to provide the level of follow up required in the SMS guidelines.

General practitioner responsibilities

The way in which the possibility of adverse effects should be assessed was discussed. The FIG agreed the following amendment:

- "Ask the patient and/or the patient's carer about adverse effects at every contact" to be amended to "Be alert to the possibility of adverse effects at every contact".

Monitoring requirements – baseline assessment to be completed by the specialist

The FIG agreed the following amendments:

- Add "before initiating treatment" to the end of the statement "Baseline assessment to be completed by the specialist."
- Replace "If low body mass index (BMI)" with "If body mass index (BMI) is below 18.5kg/m2".
- Women of child-bearing potential – The FIG agreed to replace "confirm" with "exclude" in the following sentence: "If there is any possibility that the individual may be pregnant it is important to confirm this prior to starting treatment. Refer also to supporting information below."

Previously DPT specialists have indicated that the adult ADHD service does not have the clinical skills and equipment to undertaken and interpret baseline ECGs. Both FIG and LMC had indicated that the necessary baseline physical assessments should be undertaken by the specialist service.

A discussion took place. It was noted ECGs are not commonly required and are usually only undertaken if new symptoms of cardiovascular disease (CVD) are identified. The DPT specialists reported that they undertake very few ECGs per year; on-going issues including lack of space, equipment and maintaining expertise in undertaking and interpreting ECGs were noted.

The FIG considered the approach required following identification of new cardiac issues during baseline assessment (prior to initiation of ADHD medication). The FIG agreed that if a baseline assessment identifies new signs or symptoms of cardiovascular disease or arrhythmias that warrant further investigation and/or management, the GP should oversee the patient and undertake any further investigations which may include an ECG. If the signs

and symptoms indicate an urgent issue, ADHD specialists should refer the patient to cardiology. It was noted that GPs would want to be made aware of any new symptoms identified.

For other patients requiring an ECG prior to initiation of ADHD medication (e.g. known CVD, or patients with no signs / symptoms but a family history of CVD and major lifestyle risk factors), the FIG agreed that the ECG should be the responsibility of the specialist initiating treatment. Specialists suggested that this would be a very small cohort of patients. Mental health providers may wish to consider sub-contracting these services; there may be alternative solutions, however it was noted that service configuration is beyond the scope of the individual SMS guidelines or the FIG.

The FIG accepted the proposed wording:

- "Electrocardiogram (ECG) to be carried out if clinically indicated based on medical history, cardiovascular assessment or if the patient is being treated with a medicine that may pose an increased cardiac risk. Specialist cardiovascular evaluation to be requested if the ECG shows abnormality or if the cardiovascular assessment raises concerns."

<u>High blood pressure and how this should be managed</u>

There was discussion about the management of high blood pressure and the threshold for drug treatment. It was agreed that high blood pressure should be managed by GPs in the usual way, based on clinical judgement. Treatment for high blood pressure may be required before treatment for ADHD is initiated.

It was agreed that Emma Gitsham will update the guidelines in line with the discussion. These will be forwarded for negotiation of remuneration with the Local Medical Committee.

ACTION: Emma Gitsham to update the proposed guidelines in line with the discussion, to be forwarded for negotiation of remuneration with the Local Medical Committee.

10. CNS Stimulants and drugs for attention deficit hyperactivity disorder (ADHD)

Due to time constraints CNS stimulants and drugs for ADHD were not discussed. This item will be progressed through the e-FIG process or brought to a future meeting.

11. Bempedoic acid with ezetimibe (NICE TA694)

A briefing paper addressing the proposed formulary entry for NICE TA694: Bempedoic acid with ezetimibe and the reclassification of ezetimibe alone from an amber (specialist-input) to a blue (second-line) formulary option was circulated with the meeting papers.

Bempedoic acid is an oral lipid lowering agent licensed for the treatment of hypercholesterolaemia (heterozygous familial and non-familial) and mixed hyperlipidaemia. Bempedoic acid lowers low density lipoprotein cholesterol (LDL-C) by reducing cholesterol biosynthesis through a novel mechanism of action and up-regulates the LDL receptor. Although bempedoic acid and statins both inhibit cholesterol synthesis in the liver, unlike

statins, bempedoic acid is inactive in skeletal muscle. Bempedoic acid is available alone or in combination with ezetimibe. The daily dose is bempedoic acid 180mg (Nilemdo) or bempedoic acid 180mg / ezetimibe 10mg (Nustendo). Bempedoic acid and ezetimibe have complementary mechanisms of action. Ezetimibe acts by inhibiting gastrointestinal cholesterol absorption and upregulation of the LDL receptors.

A brief overview of the clinical trials supporting the licensing of bempedoic acid and the rationale for the NICE TA recommendations for bempedoic acid with ezetimibe was provided in the briefing paper.

In addition, for consideration was a revised entry for ezetimibe and minor amendments to the formulary guidance for the management of blood lipids to reflect the addition of bempedoic acid with ezetimibe and the reclassification of ezetimibe monotherapy.

In order to facilitate compliance with statutory responsibilities for the commissioning of NICE technology appraisals the FIG was asked to consider the following questions:

- Does the FIG agree with the inclusion of bempedoic acid with ezetimibe as an amber formulary option? Is the proposed formulary entry clinically appropriate and clear?
- Does the FIG agree with the reclassification of ezetimibe alone from an amber to a blue formulary medicine? Is the proposed update to the entry clinically appropriate and clear?
- Does the FIG accept the updates to the formulary guidance for management of blood lipids?

The FIG considered and accepted the proposed formulary entry for bempedoic acid with ezetimibe subject to one amendment to note 1.

It was agreed that note 1 should state, “To be initiated by specialists, GPs may be asked to write subsequent prescriptions.” The FIG noted that in this context, specialists are not limited to the specialists who run lipid clinics.

The FIG considered and accepted the reclassification of ezetimibe alone from an amber to a blue formulary medicine.

The FIG considered and accepted the updates to the formulary guidance for management of blood lipids.

ACTION: Formulary Team to publish the formulary entry for Bempedoic acid with ezetimibe for treating hypercholesterolaemia or mixed dyslipidaemia within 3 months of publication of NICE TA694.

12. MHRA Drug Safety Updates April to May 2021

The MHRA Drug Safety Updates for April and May 2021 were discussed and noted.

April 2021

- Polyethylene glycol (PEG) laxatives and starch-based thickeners: potential interactive effect when mixed, leading to an increased risk of aspiration. Information has been included under the formulary section 1.6.4 Osmotic laxatives and under the feed thickeners, swallowing difficulties, section 9.4.2 Formulary choice oral nutritional supplements. The advice added to the latter section includes a list of PEG based laxatives.

  Sarah Marner confirmed that nursing homes were likely to be aware of this safety information.

  Letters sent to healthcare professionals:

  Atezolizumab: Risk of Severe Cutaneous Adverse Reactions (SCARs). The summary of product characteristics (SPC) will be updated to include guidelines for discontinuation and further description of the risk. This is addressed in the June safety update which was issued after the meeting papers were completed. The formulary will be updated accordingly.

May 2021

- Levothyroxine: the MHRA has indicated that generic prescribing of levothyroxine remains appropriate for the majority of patients. If a patient reports persistent symptoms when switching between different levothyroxine tablet formulations, and symptoms or poor control of thyroid function persists despite adhering to a specific product, levothyroxine oral solution should be considered. The FIG considered this advice was not new and it was not necessary to include a reference to the safety update in the formulary. It was noted that levothyroxine oral solution is included in the Devon Formulary as a green (first-line) formulary option alongside levothyroxine tablets. It will be proposed that levothyroxine oral solution is reclassified to a blue (second-line) option in line with the safety update as part of the work on updating the formulary guidance for thyroid disorders.

  Letters sent to healthcare professionals:

  No updates to the formulary were required.

  Medical Device Safety Information:

- Dexcom G6 sensor: untested barrier methods to reduce skin rash. The Dexcom G6 is included under section 6.1.8 Continuous glucose monitors for the Devon Formulary. A link to the medical device safety information and the actions for clinicians have been added to the formulary entry for Dexcom G6 sensor.

13. Recent drug decisions (including NICE publications)

The recent drug decisions were noted.

Summary of actions			
	Action	**Lead**	**Status**
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	Complete
21/19	Prescribing for Alzheimer's disease: progress guidance through the e-FIG process	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	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
21/29	Oral nutritional supplements - update the proposed ONS guidance in line with the discussion at the FIG meeting and further feedback from specialists.	Liz Fleming	Complete
21/30	Oral nutritional supplements - bring updated proposed formulary ONS guidance back to a future meeting for final agreement.	Liz Fleming	On agenda
21/32	Reclassification of acamprosate (N&E FIG) – contact Head of CCG's Medicines Optimisation Team regarding the communication from the Public Health Commissioner and reimbursement for acamprosate prescribing in primary care.	Formulary Team	Complete
21/33	Lisdexamfetamine for the management of ADHD - publish the accepted formulary entry for lisdexamfetamine for the treatment of ADHD in adults subject to ratification of the policy decision by the CCGs Commissioning Committee.	Formulary Team	Complete
21/34	Lixisenatide for the treatment of type 2 diabetes – remove lixisenatide from the formulary subject to ratification of the policy withdrawal by the CCG's Commissioning Committee.	Formulary Team	Complete
21/35	Talk to colleagues at Livewell regarding their difficulties in prescribing larval therapy.	Nicola Diffey	Outstanding
21/36	Larval Therapy – feedback the outcome of the discussion to the specialists.	Formulary Team	Outstanding
21/37	Levetiracetam in a syringe pump for palliative care: Formulary team to feedback outcome of discussion to consultants and undertake further work in this area	Formulary team	Complete
21/38	Levetiracetam in a syringe pump for palliative care: Respond to questions from the Formulary team on availability from community pharmacies	Tom Kallis	Complete

21/39	Update the formulary entry for Helicobacter Pylori (*H. Pylori*) retesting for Dyspepsia and Gastro-oesophageal reflux disease (GORD) in line with the discussion.	Formulary Team	Complete
21/40	ADHD in adults. Clinical Effectiveness to feed back to mental health commissioners on the need to ensure that the commissioned service is suitably resourced to provide the level of follow up required in the SMS guidelines.	Formulary Team	Complete
21/41	ADHD in adults. Update proposed guidelines in line with the discussion, to be forwarded for negotiation of remuneration with the Local Medical Committee.	Emma Gitsham	Complete
21/42	Publish the formulary entry for Bempedoic acid with ezetimibe for treating hypercholesterolaemia or mixed dyslipidaemia within 3 months of publication of NICE TA694.	Formulary Team	Complete