NHS
Devon
Clinical Commissioning Group

Meeting of the Northern and Eastern Devon Formulary Interface Group

Minutes

Thursday 16th July 2020: 9:00am – 11:30 am
By Microsoft Teams

Present:

Tawfique Daneshmend (Chair)	Consultant Gastroenterologist	RD&E
Glen Allaway	GP	NHS Devon CCG
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Iain Carr	MO Pharmacist	NHS Devon CCG
Susie Harris	Consultant, Elderly Care	RD&E
Andrew Harrison	GP	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Matt Kaye	Chief Pharmacist	NDHT
Carole Knight	Clinical Pharmacist (Medicines Information and Formulary)	NDHT
James Leavy	Medicines Information and Formulary Support Pharmacist	RD&E
Jess Parker	GP	NHS Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon CCG
Darren Wright	Joint Formulary Technician	NHS Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and Announcements:

Welcome and Introductions

Attendees were welcome to the meeting.

The previous North and East Devon FIG meeting was held on 19th March 2020. Following this meeting, a decision was made to postpone the Formulary Interface Group meetings due to the Coronavirus (COVID-19) pandemic; this was to allow clinicians time to direct their full focus towards combating the effects of the virus. During this time, the Formulary team were engaged in developing temporary new governance processes for urgent COVID-19 related actions and in supporting the development and dissemination of temporary COVID-19 related guidance from local and national groups. The work undertaken is detailed under Matters Arising, MHRA Safety Updates and Recent Drug Decisions below.

Meeting etiquette

Due to the COVID-19 outbreak the meeting took place via Microsoft Teams. The group Chair outlined the meeting etiquette.

Register of participants (for the minutes)

All expected attendees joined the meeting.

Apologies

No apologies had been received.

Declaration of Interests

All participants had completed a DoI prior to the meeting. No declarations were made.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Non-CF Bronchiectasis (acute exacerbation): antimicrobial prescribing guidance (NICE) Various medications	 Various manufacturers
Gonorrhoea: update Various antibiotics	 Various manufacturers
Pelvic Inflammatory Disease (PID): update Moxifloxacin (Avelox) Various antibiotics	 Bayer PLC Various manufacturers
Management of suspected deep vein thrombosis (DVT) and pulmonary embolism (PE) Apixaban Rivaroxaban Various medications	 Bristol-Myers Squibb Pharmaceuticals Limited Bayer PLC Various manufacturers

Sativex® for the treatment of spasticity in multiple sclerosis	GW Pharma Ltd
Alternative treatments:	
Botulinum toxin injections (Botox®, Dysport®, Xeomin®)	Allergan Ltd, Ipsen Ltd, Merz Pharma UK Ltd
Intrathecal baclofen pumps	Various
Pitolisant hydrochloride (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults	Lincoln Medical Limited
Alternative treatments:	
Modafinil	Various
Dexamfetamine	Various
Sodium oxybate (Xyrem®)	UCB Pharma Limited
Invicorp® for erectile dysfunction	Evolan Pharma AB
Alternative treatments:	
Alprostadil (Caverject®, Muse®, Viridal Duo®, Vitaros®)	Pfizer Limited, Mylan, UCB Pharma Limited, Ferring Pharmaceuticals Ltd
Penile prosthesis	Various
Palliative Care: Updating formulary guidance for diamorphine 5mg and 10mg injection	EthyPharm Limited
Morphine sulfate injection	Hamelyn Pharma Limited
Actinic keratosis: management of mild and moderate lesions	
5-FU 5% cream (Efudix)	Mylan
Alternative: Diclofenac 3% in sodium hyaluronate gel	
Solareze	Almirall Limited
Solacutan	Mibe Pharma Limited

Paediatric gastro-oesophageal reflux / omeprazole for paediatric patients Omeprazole powder for oral suspension Omeprazole dispersible gastro-resistant tablets • Losec MUPS • Mezzopram Other PPIs	 Xeolas Pharmaceuticals Limited, Rosemont Pharmaceuticals Limited Astra Zeneca Limited Sandoz Limited Various manufacturers
H2 receptor antagonists PPIs Various other treatments	 Various manufacturers Various manufacturers
Consideration of UrgoClean Ag wound dressing for addition to the formulary	Urgo Limited

Items discussed via e-FIG or COVID related changes

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Zemtard XL capsules Alternative treatments: Slozem Adizem XL Tildiem LA	Galen Limited Merck Napp Pharmaceuticals Limited SANOFI
Just In Case Bags Replacing diamorphine injection with morphine sulfate injection	EthyPharm Limited Hamelyn Pharma Limited
Report of COVID Related changes to the formulary Remdesivir – national commissioning policy	 Gilead Sciences

2. Minutes of the meeting held on Thursday 19th March 2020, including action list update

Minutes of the meeting held on 19th March 2020

The minutes of the meeting held on 19th March were approved.

Action list

Summary of actions

Number	Action	Lead	Status
19/84	The need for a system to enable secondary care to prescribe medicines to patients without them having to attend a hospital appointment to be raised with relevant people at RD&E.	Susie Harris	Outstanding
19/95	MHRA Drug Safety update: December 2019 – update for domperidone for nausea and vomiting to be added to the formulary.	Formulary team	Complete
20/01	*Cluster headache – work with Ali Round to develop formulary guidance and liaise with specialists. Proposed formulary guidance to be brought back to future FIG meeting for discussion.* It is hoped that this can be included on the agenda for the meeting scheduled for September.	Formulary team	Outstanding
20/02	*Management of adult malnutrition – redraft the guidelines in line with the discussion and bring back to a future formulary meeting for agreement.*	Formulary team/Ann Ashworth	Outstanding
20/03	Gonorrhoea and Pelvic Inflammatory Disease (PID) – Formulary team to redraft guidance in line with the FIG discussion and specialists' input, and bring to a future FIG meeting	Formulary Team	On agenda
20/04	Develop draft osteoporosis guidance, circulate to specialists for comment and bring to a future FIG meeting.	Formulary Team	Outstanding
20/05	DMARDS SMS guidelines – feedback to specialists regarding the publication date for the updated guidelines.	Formulary Team	Closed

	This action was superseded by the need for temporary guidance during the pandemic.		
20/06	Paediatric GORD – amend proposed formulary guidance in line with the discussion and circulate to specialists for their views. Bring back to a future FIG meeting for final consideration and agreement	Formulary Team	On agenda
20/07	Proton Pump Inhibitors (PPI) – amend proposals in line with the discussion and circulate to specialists for their views. Bring back to a future FIG meeting for final consideration and agreement.	Formulary Team	On agenda
20/08	Add the UrgoStart Contact Layer, UrgoStart Plus Pad and UrgoStart Plus Border to the formulary as amber for the management of diabetic foot ulcers.	Formulary Team	Complete
20/09	MHRA Drug Safety Update – January 2020: Ondansetron – add appropriate links to the formulary.	Formulary Team	Complete
20/10	MHRA Drug Safety Update – February 2020: Ingenol Mebutate gel (Picato) – draw up guidance on alternatives and circulate to specialists and FIG members for comment.	Formulary Team	On agenda
20/11	MHRA Drug Safety Update – February 2020 – Lemtrada (alemtuzumab): appropriate updates to be made to the formulary.	Formulary team	Complete
20/12	MHRA Drug Safety Update – February 2020 – Nexplanon (etonogestrel) contraceptive implants. Update formulary	Formulary team	Complete
20/13	*MHRA Drug Safety Update – February 2020 – include safety update for Nexplanon in Formulary News and formulary updates provided to Medicines Optimisation team for inclusion in the Medicines Optimisation Bulletin* This will be included in the Formulary News.	Formulary team	Outstanding

<u>Annual Report for the Devon Formulary Interface Groups (FIGs)</u>

The annual report covers the work of the two Devon FIGs between April 2019 and March 2020. It highlights not only the amount of work these committees have undertaken, but also its breadth and depth.

Growth in formulary content, and website traffic, has continued. This is testament to the quality of the final product, thanks in no small part to the advice, suggestions and scrutiny of all those involved in the FIGs.

The excellent work of Darren and Hilary, who put in a great deal of effort into preparing the board packs, maintaining the formulary day to day, dealing with enquiries, providing stats and analytics and supporting other teams was acknowledged. The excellent work of Fiona in supporting and reviewing the governance processes, maintaining the minutes and drafting large sections of the annual report was also acknowledged.

The committee were asked to approve the annual report which will now be submitted to the CCG's Clinical Policy Committee for assurance.

The FIG accepted the 2019-20 Annual Report of the Devon Formulary Interface Groups.

Matters Arising

- Report of e-FIG decisions – March 2020
    - Zemtard XL capsules

      Slozem modified release capsules were discontinued and it was proposed to replace these with Zemtard XL capsules.

      The FIG was asked if it accepted Zemtard XL capsules as an additional formulary option for diltiazem modified release alongside Adizem XL and Tildiem LA.

      Responses received indicated acceptance of the proposal.

      Comments received were with regard to acute trust contracts. These issues were resolved, and the formulary has been updated.

- Report of decisions taken through the COVID-19 FIG process for the Devon Formulary
    - Standard Just In Case bags for patients without COVID-19: replacing diamorphine injection with morphine sulphate injection

      The Formulary Team used the temporary new governance arrangements for urgent COVID-19 related action and brought the membership of the North and East Devon FIG and South and West Devon FIG together to make decisions as a single committee to agree that morphine sulphate 10mg injection should replace diamorphine 10mg injection in the list of medicines for standard Just In Case bags under the palliative care chapter of the formulary. This is an existing section of the formulary for patients without COVID-19.

      In February 2020 a supply disruption alert (SDA) was issued by DSHC and NHSE advising of a temporary shortage of diamorphine 5mg and 10mg powder for injection. In March 2020 further advice was released advising that due to the unpredictability of supply of these diamorphine injections the actions recommended in February should

be made permanent. The Formulary team liaised with specialists over proposed changes to this section, the FIG was then asked if they agreed with the proposal for the list of medicines included in standard Just In Case Bags for patients without COVID-19:

1. Replace two ampoules of diamorphine 10mg injection with two ampoules of morphine sulphate 10mg/1ml injection.
2. The proposed wording for the entry for morphine sulphate injection.
3. Remove water for injection (which was included to reconstitute diamorphine powder for injection).

Responses received indicated acceptance of the proposal.

No comments were received other than to indicate acceptance of the proposals.

The formulary section on standard Just In Case Bags for patients without Covid-19 has been updated in line with the proposal.

The update to the formulary was communicated via formulary news on the homepage of the formulary website, via the Coronavirus formulary page and the CCG's COVID-19 bulletin.

- <u>Report of COVID-19 related changes to the formulary – March 2020 to July 2020</u>

Since the last North & East FIG meeting in March 2020, the Formulary Team has supported the development and dissemination of temporary COVID-19 related guidance from various local and national groups, and as such the formulary now contains some specific COVID-19 related information to support healthcare professionals.

A temporary Devon Formulary page was created that provides a summary of formulary updates specific to the COVID-19 pandemic. This page can be accessed via the Devon Formulary homepages by clicking on the interactive image "Coronavirus – What you need to know". This temporary guidance will be removed (or absorbed into current guidance where relevant) depending on the outcomes of the pandemic. Formulary updates specific to the COVID-19 pandemic were outlined in the meeting papers, they covered:

- Shared Care/Specialist Medicines Service drug safety monitoring during the COVID-19 pandemic
- End of life symptom control for patients dying of COVID-19
- Managing pneumonia in the community during the COVID-19 pandemic
- Antibiotic treatment for pneumonia for adults in hospital during the COVID-19 pandemic
- Management of anticoagulation during the COVID-19 pandemic
- Treatment of patients requiring vitamin B12 during the COVID-19 pandemic
- Contraception guidance during the COVID-19 pandemic
- Rheumatological autoimmune inflammatory and metabolic bone disorders during the COVID-19 pandemic

- Advice for GPs regarding patients presenting in alcohol or opioid withdrawal to general practice during the COVID-19 pandemic
- Valproate pregnancy prevention programme temporary advice for management during the COVID-19 pandemic
- Advice regarding the prevention and treatment of skin damage beneath personal protective equipment (PPE) during the COVID-19 pandemic
- Routine immunisation programmes during the COVID-19 pandemic
- Routine access to remdesivir in treatment of COVID-19

3. Non-Cystic Fibrosis Bronchiectasis (acute exacerbation): antimicrobial prescribing guidance (NICE)

In December 2018 NICE published an antimicrobial prescribing guideline for acute exacerbation of non-cystic fibrosis (CF) bronchiectasis. The guideline sets out an antimicrobial prescribing strategy for managing and preventing acute exacerbation and aims to optimise antibiotic use and reduce antibiotic resistance. Currently there is no guidance within the formulary for acute exacerbation of non-CF bronchiectasis.

Draft formulary guidance was produced by the Formulary team and circulated to specialists who have provided feedback which was included in the meeting papers. The proposed guidance includes sample details, referral advice, treatment options for adults and children and prophylaxis treatment, and temporary COVID-19 information. The FIG was asked to consider the proposed guidance and comments received from specialists.

The FIG considered and accepted the proposed formulary guidance, including that:

- Antibiotic treatment should commence empirically when an exacerbation starts, without waiting for sputum cultures results,
- IV antibiotics can be given at home or in the community where it is appropriate, and services are available to support this
- COVID-19 specific information should be included in the guidance and can be removed as appropriate without further input from the FIG
- Antibiotic treatment duration should be 10 to 14 days
- Clarithromycin to be retained in the formulary as a second line (blue) drug. Specialists had indicated that amoxicillin and doxycycline are first line treatments. Amoxicillin and doxycycline are included in the formulary as 'green' drugs.
- The recommended dose of amoxicillin be 500mg to 1g three times a day for 10 to 14 days
- For patients at higher risk of treatment failure, for whom co-amoxiclav is not suitable, specialist advice should be sought regarding the use of fluoroquinolones
- Advice on (re)referral to specialist clinic for review of physiotherapy/mucolytics and/or prophylactic antibiotics be added for agreed indications.

ACTION: Formulary team to publish Non-CF Bronchiectasis (acute exacerbation): antimicrobial prescribing guidance in line with the discussion.

4. Gonorrhoea: update

Following publication in January 2019 of the British Association for Sexual Health and HIV (BASHH) Guideline for Gonorrhoea, work has been underway to update the Devon Formulary gonorrhoea guidance.

Early input into the development of the primary care guidelines was sought from N&E Devon FIG members at the March meeting, while Devon-wide Genito-Urinary Medicine (GUM) service specialists were asked to review the guidance and provide additional feedback and comments on the updated guidance and antibiotic recommendations.

The proposed guidance was presented to FIG members with the additional feedback from the GUM specialists for final consideration and agreement. New changes or amendments to the guidance that had not previously been considered by FIG were highlighted in the meeting papers.

The FIG considered and accepted the proposed changes or amendments including those for recommended antibiotic treatment for uncomplicated anogenital and pharyngeal infection, oral regimens, complicated infections and pregnancy and Test of Cure.

- Specialists recommend that if gonorrhoea infection is suspected or confirmed, patients should attend clinic but understand that instances may occur when a patient may not attend, and that primary care should treat in liaison with them.
- Oral antibiotics ciprofloxacin, cefixime and azithromycin have been amended to "specialist input" (amber) as antimicrobial susceptibility should be known prior to use, and specialist input is to be sought.
- Specialists agreed that patients with complicated infections and pregnant women suspected to have gonorrhoea should be managed in clinic and are happy with the proposed formulary statement.
- Test of Cure information has been amended to state that testing should be performed from all originally positive sites, 3 weeks after completion of treatment.

The FIG also agreed a number of additional amendments to the proposed formulary entry including that:

- 'and contact tracing' to be added to the recommendations to refer to GUM clinic for management when gonorrhoea infection is suspected or confirmed
- Wording around 'swabs' to be revised for clarity and confirmed with specialists, if there are any significant changes these will be brought back to FIG prior to publication.

ACTION: Formulary team to progress gonorrhoea guidance in line with the discussion.

5. Pelvic Inflammatory Disease (PID): update

Work has been underway to update the Devon Formulary Pelvic Inflammatory Disease (PID) guidance; this follows publication of the 2019 British Association for Sexual Health (BASHH) Guidance for PID.

Early input into the development of the primary care guidelines was sought from N&E Devon FIG members at the March 2020 meeting, while Devon-wide Genito-Urinary Medicine (GUM) service specialists were asked to review the guidance and provide additional feedback and comments on the updated guidance and antibiotic recommendations.

The proposed guidance was presented to FIG with the additional feedback from the GUM specialists for final consideration and agreement. New changes or amendments to the guidance that had not previously been considered by FIG were highlighted in the meeting papers.

Moxifloxacin is not currently listed in the Formulary for use in North and East Devon; it is recommended for use in South and West Devon. It was proposed that moxifloxacin tablets 400mg are added for use in N&E Devon as an amber (specialist input) drug for the treatment of mild to moderate PID when initial testing for *Mycoplasma genitalium* is positive.

Moxifloxacin is recommended within the BASHH guidance, NICE Clinical Knowledge Summary (CKS) for PID, and has support from local GUM specialists, it is indicated for mild to moderate PID and is currently already being prescribed in primary care in N&E Devon. It is not expected that an inclusion of moxifloxacin would increase expenditure.

The FIG considered and accepted the addition of moxifloxacin as an amber drug for PID.

The FIG accepted the proposed formulary information for Symptoms, Recommendations and Test of Cure. However, it was agreed that further consideration be given to testing for *Mycoplasma genitalium* and referral of patients to sexual health clinics. It was noted that primary care testing for *M.genitalium* is not currently routinely available in Devon.

It was agreed that the Formulary team will go back to specialists for further advice on testing for *Mycoplasma genitalium*.

ACTION: Formulary team to go back to specialists for advice on testing for mycoplasma genitalium and progress guidance accordingly

6. Management of suspected deep vein thrombosis and pulmonary embolism

Work has been underway to update the anticoagulation prescribing guidance for deep vein thrombosis (DVT) and pulmonary embolism (PE) within the Devon Joint Formulary. The review was prompted by a recent addition of information regarding the clinical guide for the management of anticoagulant services during the coronavirus pandemic published by NHS England.

Following the addition, it was noted that the current formulary guidance for DVT and PE was not in line with recently published guidance (March 2020) from NICE, NG158: Venous thromboembolic diseases: diagnosis, management and thrombophilia testing, which is referenced by the NHS England guidance.

It is proposed to update the formulary Devon-wide to align with the national COVID-19 specific guidance and the recently published NICE guidance. The proposed guidance was circulated for comment to Devon-wide haematology consultants. Feedback was received from Torbay Hospital and UHPNT. No response was received from consultants in North and East Devon.

The proposed guidance was circulated with the meeting papers. The treatment recommendations for DVT are in line with the previous primary care prescribing guidance and there are no planned changes to the drug monographs, which are linked to in the guidance.

The FIG considered and accepted the proposed formulary guidance subject to minor amendments.

ACTION: Formulary team to update the formulary guidance for the Management of suspected DVT and PE in line with the discussion.

There was discussion about the lack of engagement from consultants in North and East Devon. It was suggested this may be due to this work being undertaken by a pharmacist-led anticoagulation clinic in NDHT, and that trust consultants contacted may not have felt they had ownership. The Formulary Team will contact the pharmacist responsible for the anticoagulation clinics at NDHT.

ACTION: Formulary Team to contact the pharmacist responsible for the anticoagulation clinic at NDHT, and proceed according to feedback received on proposed guidance

7. Sativex® for the treatment of spasticity in multiple sclerosis

At its meeting in March 2020 the CCG's Clinical Policy Committee (CPC) made a recommendation to accept the routine commissioning of Sativex for the treatment of moderate to severe spasticity due to multiple sclerosis if other pharmacological treatments for spasticity are not effective, **and** treatment is initiated and supervised by a physician with specialist expertise in treating spasticity due to multiple sclerosis, **and** the patient achieves at least a 20% reduction in spasticity-related symptoms (on a 0-10 patient numeric rating scale) following a 4-week trial during which the company provides Sativex according to its pay-for-responders scheme.

It was noted that since receiving specialists' comments on the proposed formulary entry, the Formulary Team had added a note on contraception based on the SPC for Sativex.

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

ACTION: Formulary Team to add the accepted formulary entry for Sativex for the treatment of spasticity in multiple sclerosis to the formulary.

<u>Post meeting note</u>: The minutes of the North and East FIG meeting held on 16th July were accepted at the FIG meeting on 17th September 2020. Subsequently, it was noticed that the section above erroneously referred to 'mild to moderate' spasticity. This has been corrected to read 'moderate to severe'.

8. Pitolisant hydrochloride for the treatment of narcolepsy with or without cataplexy in adults

At its meeting in March 2020 the CPC made a recommendation to accept the routine commissioning of pitolisant hydrochloride. The routine commissioning of pitolisant hydrochloride is only accepted in Devon for the treatment of narcolepsy with cataplexy in adults aged 19 years and over who would otherwise be eligible for treatment with sodium oxybate in line with the NHS Devon CCG clinical commissioning policy for sodium oxybate for narcolepsy with cataplexy.

Pitolisant is not routinely commissioned for the treatment of patients with narcolepsy without cataplexy.

It was noted that since receiving the specialist's comments on the proposed formulary entry, the Formulary Team had added a note on contraception based on the SPC for pitolisant.

The FIG considered the proposed formulary entry. It was agreed that a note be added stating that patients will be stabilised, and their dose titrated by a secondary care specialist.

ACTION: Formulary team to add the formulary entry for pitolisant to the formulary in line with the discussion.

9. Invicorp® for erectile dysfunction

At its meeting in March 2020 the CPC made a recommendation to accept the routine commissioning of Invicorp for the management of erectile dysfunction when a patient meets the NHS Selected List Scheme criteria **and** has failed to respond to eight doses at the maximum tolerated dose with sexual stimulation of two different PDE-5 inhibitors or is unable to take PDE-5 inhibitors due to a contraindication.

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

It was noted that initiation with Invicorp should be commenced under specialist advice.

ACTION: Formulary team to add the formulary entry for Invicorp for erectile dysfunction to the formulary.

10. MHRA Drug Safety Updates: March to June 2020

The MHRA has issued four Drug Safety Updates since the last meeting of the North and East Devon FIG on 19th March 2020. The Formulary team has reviewed the updates and incorporated the relevant recommendations into the Devon Formulary. The articles noted in each of the Drug Safety Updates are listed under items 11, 12, 13 and 14 below.

The letters and drug alerts sent to healthcare professionals include recalls, safety issues, supply-related issues and medicines defect information/alerts. Supply-related issues generally fall outside the scope of the formulary unless they are anticipated to be long term and will have a significant impact on formulary guidance, or GPs are advised to identify patients receiving the medication and take appropriate action in which case the formulary will be updated to highlight this. Supply issues are considered by the CCG's Medicines Optimisation team.

11. MHRA Drug Safety Update: March 2020

The following items were noted:

- Esmya (Ulipristal acetate): suspension of licence due to risk of serious liver injury
- Tofacitinib (Xeljanz): new measures to minimise risk of venous thromboembolism and of serious and fatal infections
- Baricitinib (Olumiant): risk of venous thromboembolism
- SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious infections
- Benzodiazepine and opioids: reminder of risk of potentially fatal respiratory depression.

12. MHRA Drug Safety Update: April 2020

The following item was noted:

- Coronavirus (COVID-19): latest guidance for medicines safety

13. MHRA Drug Safety Update: May 2020

The following items were noted:

- Coronavirus (COVID-19): new dedicated yellow card reporting site for medicines and medical devices
- Valproate pregnancy prevention programme: temporary advice for management during coronavirus (COVID-19)

14. MHRA Drug Safety Update: June 2020

The following items were noted:

- Cyproterone acetate: new advice to minimise risk of meningioma
- Direct-acting oral anti-coagulants (DOACs): reminder of bleeding risks including availability of reversal agents.

15. Palliative care: Updating formulary guidance for diamorphine 5mg and 10mg injection

On 25 March 2020, the DHSC and NHSE issued an update for diamorphine 5mg and 10mg injection advising that the supply of diamorphine 5mg and 10mg injections will be unpredictable for the foreseeable future, and actions recommended in a supply update issued in February 2020 should be made permanent. This included primary and secondary care moving permanently away from the use of diamorphine 5mg and 10mg injection to morphine sulfate injection if clinically appropriate.

The formulary websites were searched to identify relevant guidance and product entries. The replacement of diamorphine 10mg injection in standard Just In Case Bags with morphine sulfate injection was agreed by the FIG via the COVID-19 FIG process in April 2020.

The remaining guidance to be addressed falls under the palliative care chapter in the North and East Devon Formulary. The Formulary team has worked with specialists in palliative medicine to update guidance which currently includes diamorphine injection.

The proposed changes to the formulary were highlighted in the meeting papers and apply to sections 16.2 pain management in palliative care, 16.9 Breathlessness in palliative care, 16.15 Just in Case Bags: suggested medications for end stage kidney disease and 16.16 syringe drivers.

It was noted that the consultants were in the final stages of discussions on revised Devon wide formulary guidance for palliative care earlier in the year, but these discussions were paused so the specialists could focus on the COVID-19 pandemic.

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

ACTION: Formulary team to update the formulary guidance including diamorphine 5mg and 10mg injection with the accepted formulary guidance.

16. Actinic keratosis: management of mild and moderate lesions

The temporary suspension of ingenol mebutate products in January 2020 by the European Medicines Agency (EMA) had previously been reported to the FIG. The suspension of ingenol mebutate, which is licensed for the treatment of actinic keratosis (AK), was a precautionary measure while a possible link between the use of ingenol mebutate and the development of skin cancer was reviewed. The company subsequently withdrew the products and in April 2020 the EMA made the suspension permanent.

This left the Devon Formulary without any treatment options for mild to moderate AK field changes. For moderate to severe AK field changes, two options, namely fluorouracil (5-FU) 5% cream and Metvix cream® with photodynamic therapy, are available.

It was proposed that the formulary indication for 5-FU 5% cream is extended to include the treatment of mild to moderate field changes. This proposal is based on guidance for the treatment of AK from the British Association of Dermatology and views of dermatology consultants in Devon. Preliminary views of FIG GPs on 5-FU 5% cream for mild to moderate field changes were sought by e-mail and verbally at the last FIG meeting; no objections were raised.

The clinical evidence comparing 5-FU 5% cream with other treatment options was discussed. It was noted that in terms of financial impact, a course of 5-FU 5% cream is less expensive than a course of ingenol mebutate.

The FIG considered and accepted the proposal to extend the use of 5-FU 5% cream to a first line treatment option for mild to moderate field changes for patients with AK.

ACTION: Formulary team to update the formulary guidance for actinic keratosis: management of mild and moderate lesions in line with the discussion.

17. Paediatric gastro-oesophageal reflux / omeprazole for paediatric patients

Paediatric gastro-oesophageal reflux

Proposed amendments to the North and East Devon Formulary guidance for paediatric gastro-oesophageal reflux were considered at the meeting on 19th March 2020. The amendments were proposed as the result of an update to the NICE NG1 Gastro-oesophageal reflux disease in children and young people: diagnosis and management. Recommendation 1.3.7 for the use of metoclopramide, domperidone and erythromycin was clarified to include conditions which should be met before these medications are prescribed.

The FIG agreed in principle to the proposed changes to the guidance pending review by specialists.

Consultation with the specialists resulted in agreement with the proposed wording, with the exception of one specialist from Torbay Hospital who asked for the wording regarding specialist agreement for use to be clarified and that all prescriptions for these drugs should be issued by a hospital specialist, making them 'red' drugs.

At the time of the meeting no responses had been received from specialists at Northern Devon Healthcare NHS Trust or Royal Devon and Exeter NHS Foundation Trust. The Formulary team will ask specialists at these trusts for their views on whether domperidone, metoclopramide or erythromycin should be "specialist input" or "hospital only" drugs in the context of paediatric reflux. If there is a clear response, the Formulary team would like to finalise the wording of the recommendation by e-FIG. If the responses require discussion, the proposals will be brought back to the next FIG meeting.

ACTION: Formulary Team to seek the views of specialists regarding the formulary classification for domperidone, metoclopramide and erythromycin in the context of paediatric GORD. The proposed formulary entry will then be updated and brought back to the next FIG meeting or completed via the e-FIG process

Since the FIG meeting in March, it has been necessary to address the option for offering a trial of either a Proton Pump Inhibitor (PPI) or a H2 reception antagonist (H2RA) to infants and children before referral to specialists. Current formulary guidance proposes a trial of PPIs or H2RAs under certain circumstances. Following the suspension of all formulations of ranitidine by the European Medicines Agency in April 2020, stocks of other H2RAs in the UK were reported to be depleted, and no new supplies of these medicines were expected until 2021. Therefore, in order to prevent prescriptions being issued for H2RAs which cannot be dispensed, it was proposed that H2RAs were temporarily removed from the guidance.

The specialists were in agreement with this. The FIG considered the proposed amendments to the formulary guidance for paediatric reflux. The proposal to temporarily remove H2RAs was accepted.

Post meeting note: Following the meeting, a further supply notification for H2RAs was issued by the DSHC on 03 August 2020. There is stock available in the UK of cimetidine 200mg/5ml solution which is licensed for use in children more than one year of age. It was therefore decided not to remove H2RAs as a treatment option from the formulary guidance for paediatric GORD, but to include a statement advising prescribers to check for availability before prescribing a H2RA.

ACTION: Formulary team to update the formulary guidance for paediatric GORD with a statement to check for availability of H2RAs before prescribing

<u>Omeprazole for paediatric patients</u>

At the meeting of the North and East FIG on 19th March 2020, proposed changes to the Proton Pump Inhibitors (PPIs) product entries were discussed which would provide licensed PPI options for paediatric patients, namely the licensed omeprazole 2mg/ml powder for oral suspension and omeprazole dispersible tablets. The FIG reviewed the evidence in support

of these medicines and requested additional changes to the proposed product entry. The FIG agreed in principle to the changes to the omeprazole products pending consultation with paediatric specialists in Devon.

Specialists agreed to the addition of the licensed omeprazole 2mg/ml powder for oral suspension to the formulary for patients aged from 1 month of age who require a dose less than 10mg, and for administration via enteral feeding tubes. This would be in place of the existing advice that an unlicensed omeprazole suspension could be considered in these circumstances.

Specialists agreed with the proposal to add omeprazole dispersible tablets for paediatric use to the North and East Devon Formulary.

The FIG had also agreed in principle to reformatting of the introductory text to section 1.3.5 Proton Pump Inhibitors, The FIG considered and accepted the proposed changes without amendment.

The Formulary team will respond to Dr Graham regarding the points raised in response to the consultation and patients on long term PPI.

ACTION: Formulary team to respond to Dr Graham regarding the points raised in response to the consultation and patients on long term PPI.

ACTION: Formulary team to update the formulary section 1.3.5 Proton Pump Inhibitors and the entry for omeprazole in line with the discussion.

18. H2 receptor antagonists

Following the suspension of all formulations of ranitidine by the European Medicines Agency in April 2020, stocks of other H2 receptor antagonists (H2RAs) in the UK have been depleted, and no new supplies of these medicines are expected until 2021. Therefore, in order to prevent prescriptions being issued for H2RAs which cannot be dispensed, it was proposed that H2RAs are temporarily removed as a treatment option from all Devon formulary guidance.

Consultant gastroenterologists at the acute trusts in Devon were contacted by e-mail on 18th June 2020 and on 2nd July 2020, as no response was received to the first e-mail. The specialists were asked to provide advice for GPs on how to manage patients who were taking H2RAs. No proposals have been received despite the second e-mail indicating that GPs have reported that prescriptions issued for H2RAs were not being dispensed as no stocks of H2RAs are available.

A useful discussion took place as to the circumstances which lead to patients being prescribed a H2RA. Factors which were raised included adverse effects to PPIs, and that PPIs were not effective for some patients. Comparable doses of PPIs and ranitidine, and indications for treatment were also covered. It was agreed that a member of the Formulary

team would work with Dr Daneshmend to draft advice for GPs. Dr Daneshmend would then discuss the advice with the gastroenterology team at the RD&E Hospital.

ACTION: Formulary team to work with Dr Daneshmend to discuss the advice with the gastroenterology team at the RD&E Hospital.

Post meeting note: Following the meeting, a further supply notification for H2RAs was issued by the DSHC on 03 August 2020. This indicated that with the exception of cimetidine tablets, stocks of other H2RAs were available or expected during August 2020.

ACTION: Formulary team to liaise with gastroenterologists over recent supply notification and agree appropriate course of action with Dr Daneshmend.

19. Consideration of UrgoClean Ag wound dressing for addition to the formulary

UrgoClean Ag are single-use silver impregnated dressings, indicated for the local treatment of exuding wounds at risk or with signs of local infection.

Tissue viability nurse teams in North and East Devon have suggested they would like to use UrgoClean Ag dressings as an' amber' (specialist input) option for the management of exuding wounds with signs of local infection that also require debridement.

Currently the formulary includes one other silver antimicrobial dressing option: Aquacel Ag + Extra ('green', first line). Both Aquacel Ag + Extra and UrgoClean Ag, are recommended for the same indications, but have differing frequency of change / wear time and dressing features. It has been suggested that Aquacel Ag + Extra remain in the formulary.

No published comparative evidence of UrgoClean Ag and current formulary treatment options was identified. Reference was made to NICE Evidence summary (ESMPB2) Chronic wounds: advanced wound dressings and antimicrobial dressings. BNF advice on the use of dressings containing silver was proposed for addition to the formulary section for silver dressings.

The inclusion of UrgoClean Ag dressing is not expected to increase primary care expenditure as prescribing is already apparent in North and East Devon, it has been suggested that it may release savings compared to some of the current non-formulary prescribing during a future review of silver dressing usage by the tissue viability teams, although actual figures cannot be determined.

The FIG considered and accepted the proposed formulary entry for silver dressings (17.3.3 Silver) including the addition of UrgoClean Ag® as an 'amber' (specialist input) option for the management of exuding wounds with signs of local infection that also require debridement.

ACTION: Formulary team to add the accepted entry for Urgoclean Ag to formulary section 17.3.3 Silver.

20. Recent drug decisions (including NICE)

Drug decisions made in March, April, May and June 2020 were reviewed.

Since the last meeting there were no decisions resulting from Clinical Policy Committee recommendations that were of relevance to the formulary, North Devon District Hospitals Drugs and Therapeutics Committee or the Royal Devon and Exeter New Drugs Group.

NICE had published a number of pieces of guidance and guidelines, including new COVID-19 rapid guidelines on the care of people suspected and confirmed to have COVID-19 and in-patients without COVID-19, Technology Appraisals and NICE guidelines.

The Formulary team has updated the Devon formulary in line with its statutory responsibilities for NICE Technology Appraisals. Other appropriate additions and changes have been made, including the removal of discontinued products. These changes were detailed in the meeting papers. Additions to the Devon formulary include Remdesivir concentrate for solution for infusion 5mg/ml vial and powder for concentrate for solution for infusion 100mg have been added to the formulary as 'red' (hospital only) drugs for patients hospitalised with COVID-19 (adults and children aged 12 years and older) following publication of an UK interim commissioning policy.

Changes to the Medicines Optimisation Team preferred brands for specific products in Chapter 3 - Respiratory and Chapter 11 – Eye were noted.

21. Any other business

Future FIG meetings

A discussion took place. The committee noted the benefits of utilising Microsoft Teams for the conduct of future FIG meetings. It was suggested that the majority of meetings take place via Microsoft teams. The benefits include saving on travel time, reduced costs, and environmental benefits through reduced car use.

Date of next meeting

The next meeting will be held on Thursday 17th of September 2020 from 9:00 am to 11:30 am via Microsoft Teams/telephone conference

Summary of actions

Number	Action	Lead	Status
19/84	The need for a system to enable secondary care to prescribe medicines to patients without them having to attend a hospital appointment to be raised with relevant people at RD&E.	Susie Harris	Outstanding
20/01	*Cluster headache – work with Ali Round to develop formulary guidance and liaise with specialists. Proposed formulary guidance to be brought back to future FIG meeting for discussion.* It is hoped that this can be included on the agenda for the meeting scheduled for September.	Formulary team	On agenda
20/02	*Management of adult malnutrition – redraft the guidelines in line with the discussion and bring back to a future formulary meeting for agreement.* The Formulary Team have raised a question regarding the advice for obese patients with a MUST score of 1 or higher to eat additional fatty foods, such as cheese, butter and full cream. As a result, this advice is being reviewed. The MO dieticians have raised this issue with the authors of the national guidance. This work has been moved to the Formulary Team workplan and will be revisited when dieticians have had wider discussions on appropriate advice for this patient group.	Formulary team/Ann Ashworth	Closed
20/03	Gonorrhoea and Pelvic Inflammatory Disease (PID) – Formulary team to redraft guidance in line with the FIG discussion and specialists input and bring to a future FIG meeting. This was included on the meeting agenda.	Formulary Team	Complete
20/04	Develop draft osteoporosis guidance, circulate to specialists for comment and bring to a future FIG meeting.	Formulary Team	Outstanding

20/06	Paediatric GORD – amend proposed formulary guidance in line with the discussion and circulate to specialists for their views. Bring back to a future FIG meeting for final consideration and agreement This was included on the meeting agenda.	Formulary Team	Complete
20/07	Proton Pump Inhibitors (PID) – amend proposals in line with the discussion and circulate to specialists for their views. Bring back to a future FIG meeting for final consideration and agreement. This item was included on the meeting agenda.	Formulary Team	Complete
20/10	MHRA Drug Safety Update – February 2020: Ingenol Mebutate gel (Picato) – draw up guidance on alternatives and circulate to specialists and FIG members for comment. This item was included on the meeting agenda.	Formulary Team	Complete
20/13	*MHRA Drug Safety Update – February 2020 – include safety update for Nexplanon in Formulary News and formulary updates provided to Medicines Optimisation team for inclusion in the Medicines Optimisation Bulletin* This will be included in the Formulary News.	Formulary team	Complete
20/14	Publish Non-CF Bronchiectasis (acute exacerbation): antimicrobial prescribing guidance in line with the discussion.	Formulary Team	Complete
20/15	Formulary team to progress gonorrhoea guidance in line with the discussion.	Formulary Team	Complete
20/16	Pelvic Inflammatory Disease (PID) update. *Formulary team to go back to specialists for advice on testing for mycoplasma genitalium and progress guidance accordingly.* Post meeting discussions with specialists suggested that mycoplasma genitalium testing for suspected PID was an essential requirement. Currently this is not widely available in Devon in primary care, patients would be expected to attend genitourinary medicine clinics for full testing and management. The current formulary guidance will be updated to adopt a holding position to	Formulary Team	Closed

	refer all patients with suspected PID to attend GUM clinics, until such a time that service provisions allow regular testing in primary care.		
20/17	Update the formulary guidance for the Management of suspected Deep Vein Thrombosis and Pulmonary Embolism in line with the discussion.	Formulary Team	Complete
20/18	*Formulary Team to contact the pharmacist responsible for the anticoagulation clinic at NDHT, and proceed according to feedback received on proposed guidance.* Post meeting communications indicated that the pharmacist led anticoagulation clinic in NDDH had received the proposed guidance and were in agreement with it. No amendments required.	Formulary Team	Complete
20/19	Add the accepted formulary entry for Sativex® for the treatment of spasticity in multiple sclerosis to the formulary	Formulary Team	Complete
20/20	Add the formulary entry for Pitolisant hydrochloride for the treatment of narcolepsy with or without cataplexy to the formulary in line with the discussion.	Formulary Team	Complete
20/21	Formulary team to add the formulary entry for Invicorp® for erectile dysfunction to the formulary.	Formulary Team	Complete
20/22	Palliative Care: Update the formulary guidance including diamorphine 5mg and 10mg injection with the accepted formulary guidance.	Formulary Team	Complete
20/23	Actinic keratosis: management of mild and moderate lesions – Formulary guidance to be updated in line with discussion.	Formulary Team	Complete
20/24	Formulary Team to seek the views of specialists regarding the formulary classification for domperidone, metoclopramide and erythromycin in the context of paediatric GORD. The proposed formulary entry will then be updated and brought back to the next FIG meeting or completed via the e-FIG process.	Formulary Team	Outstanding
20/25	Omeprazole for paediatric patients – respond to Dr Graham regarding the points raised in response to the consultation and patients on long term PPI .	Formulary Team	Outstanding
20/26	Update the formulary section 1.3.5 Proton Pump Inhibitors and the entry for omeprazole in line with the discussion.	Formulary Team	Complete

20/27	*H2 receptor antagonists - work with Dr Daneshmend to discuss the advice with the gastroenterology team at the RD&E Hospital* Post meeting note: a further supply notification for H2RAs issued by the DHSC after the meeting has led to a revision of the action: Formulary team to liaise with gastroenterologists over recent supply notification and agree appropriate course of action with Dr Daneshmend	Formulary Team	Complete
20/28	UrgoClean Ag for wound dressing – Add accepted entry for Silver (17.3.3) to the formulary.	Formulary Team	Complete