

## Meeting of the South and West Devon Formulary Interface Group Minutes

Wednesday 12<sup>th</sup> August 2020: 2:00 pm – 4.30 pm

Via Microsoft Teams

### Present:

Peter Rowe (Chair)	Consultant	University Hospitals Plymouth NHS Trust
Trudy Bown	Chief Pharmacy Procurement & IT Manager	University Hospitals Plymouth NHS Trust
Heidi Campbell	Pharmacy Advisor	NHS Kernow CCG
Andy Craig	GP	NHS Devon CCG
Laura Hauser	Advanced Clinical Pharmacist	Livewell Southwest
Paul Humphriss	MO Pharmacist	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Bill Nolan	GP	South Devon & Torbay CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Iain Roberts	Head of MO	NHS Devon CCG
Larissa Sullivan	Pharmacist	Torbay and South Devon NHS FT
Darren Wright	Joint Formularies Technician	NHS Devon CCG

### Guests:

Reshma Gandecha	Deputy Chief Pharmacist	University Hospitals Plymouth NHS Trust
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### In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
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## 1. Welcome and announcements

Attendees were welcomed to the meeting.

The previous South and West Devon FIG meeting was held on 12th February 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

Tips for a successful virtual meeting had been circulated to participants prior to the meeting.

### Register of participants

Meeting attendees are noted above.

### Apologies

Apologies had been received from:

Sally Mayell	Clinical Director of Pharmacy	University Hospitals Plymouth NHS Trust
Chris Sullivan	Pharmacist	Devon Partnership NHS Trust

Deputies attending:

Laura Hauser attended in place of Amy Rice  
Iain Roberts attended in place of Sarah Marnier

### Declaration of Interests

Declarations of Interest were collected and reported. The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item. All Declarations of Interest are reported in the minutes.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
<p>Sativex® for the treatment of spasticity in multiple sclerosis</p> <p>Alternative treatments:            Botulinum toxin injections (Botox®, Dysport®, Xeomin®)</p> <p>Intrathecal baclofen pumps</p>	<p>GW Pharma Ltd</p> <p>Allergan Ltd, Ipsen Ltd, Merz Pharma UK Ltd</p> <p>Various</p>
<p>Pitolisant hydrochloride for the treatment of narcolepsy with or without cataplexy in adults</p> <p>Alternative treatments:            Modafinil            Dexamfetamine            Sodium oxybate (Xyrem®)</p>	<p>Lincoln Medical Limited</p> <p>Various</p> <p>Various</p> <p>UCB Pharma Limited</p>
<p>Invicorp® for erectile dysfunction</p> <p>Alternative treatments:            Alprostadil (Caverject®, Muse®, Viridal Duo®, Vitaros®)            Penile prosthesis</p>	<p>Evolan Pharma AB</p> <p>Pfizer Limited, Mylan, UCB Pharma Limited, Ferring Pharmaceuticals Ltd</p> <p>Various</p>
<p>Non-CF Bronchiectasis (acute exacerbation): antimicrobial prescribing guidance (NICE)</p> <p>Various medications</p>	<p>Various manufacturers</p>
<p>Gonorrhoea: update</p> <p>Various antibiotics</p>	<p>Various manufacturers</p>
<p>Management of suspected deep vein thrombosis (DVT) and pulmonary embolism (PE)</p> <p>Apixaban            Rivaroxaban</p> <p>Various medications</p>	<p>Bristol-Myers Squibb Pharmaceuticals Limited            Bayer PLC</p> <p>Various manufacturers</p>
<p>Azathioprine for autoimmune hepatitis for (West Devon)</p>	<p>Various manufacturers</p>
<p>Actinic keratosis: management of mild and moderate lesions</p> <p>5-FU 5% cream (Efudix)</p>	<p>Mylan</p>

Alternative: Diclofenac 3% in sodium hyaluronate gel Solareze Solacutan	Almirall Limited Mibe Pharma Limited
Paediatric gastro-oesophageal reflux / omeprazole for paediatric patients  Omeprazole powder for oral suspension  Other PPIs	Xeolas Pharmaceuticals Limited, Rosemont Pharmaceuticals Limited  Various manufacturers

Items discussed by e-FIG

<b>e-FIG Item</b>	<b>Company</b>
Zemtard XL capsules  Alternative treatments:  Slozem Adizem XL Adizem SR	Galen Limited  Merck Napp Pharmaceuticals Limited Napp Pharmaceuticals Limited
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

<b>Name of Attendee</b>	<b>Role</b>	<b>Declaration</b>
Peter Rowe	Chair	I have received unconditional honoraria for educational sessions on use of NOAC in CKD; funded by Bristol Myers Squibb; now more than 1 year ago.

## 2. Minutes of the meeting held on Wednesday 12<sup>th</sup> February 2020 and matters arising

### Minutes of the meeting held on Wednesday 12<sup>th</sup> February 2020

The minutes of the meeting held on Wednesday 12<sup>th</sup> February 2020 were approved.

<b>Summary of actions</b>			
	<b>Action</b>	<b>Lead</b>	<b>Status</b>
19/02	<p><i>Hydroxychloroquine for rheumatological and dermatological conditions: LMC and specialists to be asked for their views. Draft guidance to be brought back to FIG together with the outcome from the forthcoming CPC meeting.</i></p> <p><i>The Clinical Effectiveness team is working with providers on identifying patients who may be at risk of hydroxychloroquine retinopathy and where such patients should be referred for testing, who will do this and how it will be resourced.</i></p> <p><i>It was noted that the risk for patients of getting hydroxychloroquine retinopathy is low. The Formulary Team is also looking at the prescribing guidance.</i></p> <p><i>Draft SMS Guidance will be brought to a future FIG meeting.</i></p> <p>It was noted that the position agreed at the Clinical Policy Committee meeting remains in place. There was discussion about the role of GPs and opticians in prescribing and screening. Currently, GPs are continuing to prescribe, patients can see an optician for routine eye tests only. For a number of reasons, it has not been possible to date to commission the necessary monitoring services. This will be discussed by the Devon Joint Clinical Effectiveness Group on 13 February.</p> <p>Progressing with the development of services in Devon for ophthalmological monitoring of hydroxychloroquine retinopathy has been escalated to the Devon Joint Clinical Effectiveness Group under the leadership of Dr Rob Dyer.</p> <p>There are no outstanding actions for the FIG to progress at the moment.</p>		Complete
19/94	<p><i>Wound management review – ascertain whether a similar process for supply of dressings exists in Devon.</i></p> <p><i>Status of action to be followed up.</i></p>		

	<p>The formulary team had followed this up. The MO representative present reported that an arrangement is in place with Livewell in Western Devon. It is hoped that this will be rolled out on a wider scale.</p> <p>This is a complex issue. However it was noted that significant savings may be made. It was agreed that an update on progress would be reported at the next meeting.</p> <p>12.08.20 Sarah Marner was not at the meeting. Sarah to be contacted to provide an update.</p>	<p>Sarah Marner</p> <p>Formulary Team</p>	<p>Outstanding</p>
19/115	<p>Forward the link to Torbay and South Devon patient leaflet for lidocaine plasters to the Formulary team.</p> <p>12.08.20 Andrew Gunatilleke had forwarded a leaflet rather than a link. Andrew and the Medicines Optimisation team to be contacted to ascertain whether they are happy for the information to be added to the formulary.</p>	<p>Formulary Team</p>	<p>Outstanding</p>
19/116	<p>Link to patient leaflet for lidocaine plasters to be added to the Devon Formulary.</p> <p>This is linked to action 19/115.</p>	<p>Formulary Team</p>	<p>Outstanding</p>
20/18	<p>Osteoporosis guidance – develop draft formulary guidance and circulate to specialists for comment. The final draft will be brought to a later FIG meeting for discussion.</p> <p>12.08.20 It was noted that new guidance has been produced for Scotland. The Formulary Team will investigate whether any other guidance exists.</p>	<p>Formulary Team</p>	<p>Outstanding</p>
20/19	<p>Hypertension in pregnancy guidance (NICE NG133) – update the formulary guidance in line with the discussion.</p>	<p>Formulary Team</p>	<p>Complete</p>

### Annual Report for the Devon Formulary Interface Groups

The 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. It was noted that 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.

Darren and Hilary were thanked for their excellent work and the great deal of effort they put into preparing the board packs, maintaining the formulary day to day, dealing with enquiries, providing stats and analytics and supporting other teams. Fiona was thanked for her excellent work supporting and reviewing the governance processes, maintaining the minutes and drafting large sections of the annual report.

The FIG received the 2019-20 Annual Report of the Devon Formulary Interface Groups which had been included in the meeting Board Pack. No changes or areas of concern were noted.

The annual report will now be submitted to the CCG's Clinical Policy Committee for assurance.

### Matters arising

#### Report of e-FIG decisions

Two requests for decisions to be taken through the e-FIG process had been circulated between March and July 2020. The full report of e-FIG decisions had been circulated with the meeting papers.

The first request was for Zemtard XL capsules. Responses received indicated acceptance of the proposal. The formulary has been updated.

The second request was for the Specialised Medicines Service (SMS) prescribing guideline for Azathioprine for Autoimmune hepatitis in adults – West Devon. No responses had been received. This item was included on the meeting agenda.

#### Report of decisions taken through the COVID-19 FIG process for the Devon Formulary

A report of decisions taken through the COVID-19 FIG process for the Devon Formulary had been circulated with the meeting papers. The main points were as follows.

- 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 would 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.

### Report of COVID-19 related changes to the formulary – March 2020 to July 2020

A report of COVID-19 related changes to the formulary – March 2020 to July 2020 had been circulated with the meeting papers. The main points were as follows:

Since the last South & West Devon 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
- Updated guidance for the management of musculoskeletal and rheumatic conditions with corticosteroids during the Covid-19 pandemic

### 3. 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 with a minor amendment. There was discussion about GP prescribing. It was noted that patients will be under specialist review.

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

### 4. 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. Patients will be stabilised, and their dose titrated by a secondary care specialist (this is usually undertaken by Prof. Adam Zeman at RD&E).

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

## 5. 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.**

## 6. Non-CF 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 culture 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.**

## 7. Palliative care: replacing guidance including diamorphine injection

On 25 March 2020, the DSHC 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 sulphate injection was agreed by the FIG via the COVID-19 FIG process in April 2020. The remaining formulary guidance to be addressed falls under the palliative care Chapter of the South and West Devon Formulary. The Formulary team has worked with Dr Sarah Human, consultant in palliative medicine, Rowcroft Hospice (Torbay) and Dr Doug Hooper, consultant in palliative medicine at University Hospitals Plymouth who supports St Luke's Hospice (Plymouth).

The majority of the changes are to replace recommendations for diamorphine injection with morphine sulfate injection.

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 section 16.2 Treatment of pain in palliative care and section 16.5 Malignant gastrointestinal obstruction with minor amendment.

**ACTION: Formulary team to update Palliative care guidance section 16.2 and 16.5 of the palliative care chapter in line with the discussion.**

## 8. Gonorrhoea

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.

Devon-wide Genito-Urinary Medicine (GUM) service specialists were asked to review the guidance and provide feedback and comments on the updated guidance and antibiotic recommendations.

The proposed guidance was presented to FIG members with the feedback from the GUM specialists for consideration and agreement.

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

The FIG was happy with the increase in the dose of ceftriaxone intramuscular injection from a single dose of 500mg in the current formulary guidance to 1g. The FIG also agreed the change in the formulary status of oral regimens to 'amber' as guidance suggests these should only be used after sensitivities are known and advice has been sought from the GUM clinics. A minor amendment was agreed to the oral regimens for clarity.

**ACTION: Formulary team to add the accepted formulary entry for gonorrhoea guidance in line with the discussion.**

## 9. Management of suspected deep vein thrombosis (DVT) and pulmonary embolism (PE)

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 fully 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 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 with minor amendment.

There was discussion about treatment for people who are intravenous drug users. Some of these patients may not eat regularly which can affect the absorption of rivaroxaban, and compliance may be a problem which has implications for apixaban which has to be taken twice a day. It was agreed that the Formulary Team will look into information on DOACs and people who are intravenous drug users.

GPs confirmed that the proposed guidance was in line with current practice in primary care.

**ACTION: Formulary Team will look into information on Direct Oral Anticoagulants (DOACs) and people who are intravenous drug users.**

**ACTION: Formulary Team to update the formulary guidance for the Management of suspected DVT in line with the discussion.**

## 10. Azathioprine for the treatment of autoimmune chronic active hepatitis (AIH) in adults

At the February 2020 meeting of the S&W Devon FIG, consideration was given to draft Specialised Medicines Service (SMS) prescribing guidelines for the safe prescribing and monitoring of azathioprine for the treatment of autoimmune chronic active hepatitis (AIH) in adults in West Devon.

The draft guidelines were prepared by the specialist hepatology team at University Hospitals Plymouth NHS Trust. GP representatives from Devon LMC have also provided feedback which has informed the production of these guidelines.

During FIG discussions in February, a number of minor amendments to the draft guidelines were proposed. Specialists were contacted on these points and a revised draft was presented to the committee via e-FIG on 16<sup>th</sup> March 2020. No responses were received, and the subsequent face to face South and West FIG meetings were cancelled due to the COVID-19 pandemic. The revised draft was circulated with the meeting papers with tracked changes.

The FIG considered and accepted the Specialist Medicines Service (SMS) prescribing guidelines: Azathioprine for the treatment of autoimmune chronic active hepatitis (AIH) in adults (West Devon) without amendment.

The Formulary team will liaise with the CCG Primary Care Team to present the guidelines to the Local Medical Committee for negotiation of GP remuneration.

**ACTION: Formulary team to liaise with the CCG Primary Care Team to present the guidelines to the Local Medical Committee for negotiation of GP remuneration.**

## 11. MHRA Drug Safety Updates February to July 2020

The MHRA has issued six Drug Safety Updates since the last meeting of the South and West Formulary Interface Group (FIG) meeting on 12th February 2020. The Formulary team has reviewed the updates and incorporated the relevant recommendations into the South and West Devon Formulary.

The Drug Safety Updates and a summary of the actions taken relating to the formulary were included in the meeting papers. 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.

There was discussion about the format of future summaries. The FIG appreciated the clarity of the summaries and it was agreed that the Formulary team will continue to produce these in the same way.

## 12. Actinic keratosis: Fluorouracil 5% cream for mild to moderate field changes

In January 2020, the European Medicines Agency (EMA) suspended ingenol mebutate gel (Picato) which is licensed for the treatment of actinic keratosis (AK). The suspension 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 confirmed that the product may increase the risk of skin cancer and the suspension was made permanent.

This left the Devon Formulary without any treatment options for mild to moderate field changes for patients with AK. A proposal was submitted to the FIG that the current formulary position of fluorouracil (5-FU) 5% cream be extended in the South and West Devon Formulary to a first line treatment option for mild to moderate field changes for patients with actinic keratosis.

Consideration of the possible options to replace ingenol mebutate gel for mild to moderate field changes took into account guidance published by the British Association of Dermatology Guidance for AK (2017), and the views of dermatology consultants in Devon were also taken into consideration.

There was discussion about the distinction between mild and moderate disease. GPs present indicated that they were happy with the distinction. There was also discussion about the size of the area of skin to be treated at one time and how larger areas would be treated. GPs present stated that they would only treat patients who had small areas of field changes and were happy to do so, those with more extensive areas of change are referred to specialists. It was agreed that the entry for 5-FU cream would be clarified with regard to the SPC statement on the maximum area which can be treated at one time.

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 subject to minor amendment. The formulary team will align the guidance for actinic keratosis with the product entries.

**ACTION: Formulary team to update the formulary guidance and product entries for Actinic keratosis in line with the discussion.**

### 13. Paediatric GORD / omeprazole for paediatric patients

#### Paediatric GORD

The south and west Devon formulary guidance for paediatric reflux disease is largely based on the NICE Guideline NG1: Gastro-oesophageal reflux disease in children and young people: diagnosis and management. The guideline was updated in October 2019. The recommendation for the use of metoclopramide, domperidone and erythromycin was amended to clarify when these medicines can be offered.

It was proposed that the current formulary statement is amended taking into account the new NG1 recommendation for domperidone, erythromycin and metoclopramide, the December 2019 Drug Safety Update for domperidone and the November 2014 Drug Safety Update for metoclopramide which is referred to in NG1.

Paediatric specialists were contacted and asked for their view on whether the proposed changes to the recommendation for metoclopramide, domperidone and erythromycin are acceptable.

The FIG was asked for their view of the proposed changes pending the outcome of consultation with specialists which is ongoing following initial responses.

The FIG considered the proposed changes to the formulary entry for Paediatric gastro-oesophageal reflux disease. Issues discussed included that:

- specialists may be concerned to make sure that GPs are not prescribing without specialist agreement. The Formulary Team can add the colour of the drug to the text of the formulary guidance for paediatric GORD to make it more obvious. If it is amber, prescribing can be continued in primary care after initiation by specialists.
- the supply of H2RAs is unpredictable, this is expected to be the case until 2021. It was agreed that a statement be added regarding this and that availability should be checked before prescribing. However it was also noted it is not the function of the formulary to own temporary fluctuations in supplies of drugs.
- patient numbers are small.
- the wording around liquid preparations be amended to reflect the addition of omeprazole suspension for paediatric patients (see below): Remove '(liquid PPIs are non-formulary items).
- the Formulary Team will add the link to the MHRA safety updates to the current formulary text whilst the consultation with specialists is ongoing.

**ACTION: Formulary team to update the proposed formulary entry in line with the discussion and circulate to the FIG for approval via the e-FIG process.**



### Omeprazole for paediatric patients

The Formulary team has been contacted by Dr James Hart, paediatric gastroenterologist at the RD&E hospital (via the paediatric pharmacist), with regard to adding guidance to the formulary on prescribing and administering doses of omeprazole less than 10mg for paediatric patients. Subsequently, a licensed omeprazole powder for oral suspension was marketed which is approved for use from 1 month of age. The paediatric pharmacist at Derriford Hospital has raised the licensed omeprazole 2mg/ml powder for oral suspension with the Formulary team. These requests have promoted a review of the proton pump inhibitor (PPI) formulary options for paediatric patients. The changes align the PPI options for paediatric patients in Devon. The proposed formulary entries were included in the meeting papers.

Specialists had been consulted. Jonathan Graham (Torbay Hospital) responded regarding the diagnosis of GORD in infants and the potential harms associated with medicines. There was a discussion of the points raised. The Formulary team will respond to Dr Graham.

The FIG considered the proposed guidance for omeprazole 2mg/ml powder for oral suspension. There was discussion about the expiry dates on made up bottles and the costs of 'specials'. It was agreed that the formulary team will undertake an e-PACT search and circulate the data to the FIG.

**ACTION: Formulary Team to undertake an e-PACT search and circulate the data to the FIG.**

The FIG accepted the addition of omeprazole 2mg/ml powder for oral suspension to the formulary.

### 1.3.5 Proton Pump Inhibitors (PPI)

The FIG considered the proposed formulary entry, there was discussion about percutaneous endoscopic gastronomy (PEG) tubes.

The FIG accepted the proposed reformatting to the introductory section 1.3.5.

The FIG accepted the proposed formulary entries for omeprazole and lansoprazole with a minor amendment and the addition of the paediatric indications to the notes for omeprazole dispersible tablets and suspension.

**ACTION: Formulary Team to update the proposed amendments to section 1.3.5 Proton pump inhibitors in line with the discussion.**

## 14. Recent drug decisions (including NICE)

The recent drug decisions were reviewed.



## 15. Future FIG meetings

### 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 Wednesday 14<sup>th</sup> October from 2:00 pm to 4.30 pm via Microsoft Teams/telephone conference.

## Summary of actions

	Action	Lead	Status
19/94	<p><i>Wound management review – ascertain whether a similar process for supply of dressings exists in Devon.</i></p> <p><i>Status of action to be followed up.</i></p> <p>The formulary team had followed this up. The MO representative present reported that an arrangement is in place with Livewell in Western Devon. It is hoped that this will be rolled out on a wider scale.</p> <p>This is a complex issue. However, it was noted that significant savings may be made. It was agreed that an update on progress would be reported at the next meeting.</p> <p>12.08.20 Sarah Marner was not at the meeting. Sarah to be contacted to provide an update.</p> <p>Update received from Sarah Marner - As far as I am aware there is no plan to centralise the ordering of wound dressings across Devon.</p>	<p>Sarah Marner</p> <p>Formulary Team</p>	<p>Complete</p> <p>Complete</p>
19/115	<p>Forward the link to Torbay and South Devon patient leaflet for lidocaine plasters to the Formulary team.</p> <p>12.08.20 Andrew Gunatilleke had forwarded a leaflet rather than a link. Medicines Optimisation team to be contacted to ascertain whether the leaflet meets their needs and for a link to be added to the formulary.</p>	<p>Formulary Team</p>	<p>Complete</p>
19/116	<p>Link to patient leaflet for lidocaine plasters to be added to the Devon Formulary.</p> <p>This is linked to action 19/115. The MO team are considering the Lidocaine plaster leaflet as part of a wider piece of work.</p>	<p>MO team</p>	<p>Closed</p>
20/18	<p>Osteoporosis guidance – develop draft formulary guidance and circulate to specialists for comment. The final draft will be brought to a later FIG meeting for discussion.</p> <p>12.08.20 It was noted that new guidance has been produced for Scotland. The Formulary Team will investigate whether any other guidance exists.</p>	<p>Formulary Team</p>	<p>Ongoing</p>
20/20	<p>Sativex® for the treatment of spasticity in multiple sclerosis – accepted formulary entry to be added to the formulary.</p>	<p>Formulary Team</p>	<p>Complete</p>
20/21	<p>Pitolisant hydrochloride for the treatment of narcolepsy with or without cataplexy in adults. Formulary team to add the formulary entry to the formulary in line with the discussion.</p>	<p>Formulary Team</p>	<p>Complete</p>

20/22	Add accepted formulary entry for Invicorp for erectile dysfunction to the formulary.	Formulary Team	Complete
20/23	Non-CF Bronchiectasis (acute exacerbation): antimicrobial prescribing guidance (NICE) – add formulary guidance in line with the discussion.	Formulary Team	Complete
20/24	Palliative care: replacing guidance including diamorphine injection – publish accepted guidance section 16.2 and 16.5 in line with the discussion	Formulary Team	Complete
20/25	Gonorrhoea – add accepted formulary entry to the formulary in line with the discussion.	Formulary Team	Complete
20/26	Management of suspected deep vein thrombosis (DVT) and pulmonary embolism (PE) – follow-up on information on DOACs and people who are intravenous drug users.  The NICE Guideline Committee noted a lack of good comparative evidence on treatments and doses for VTE in this population. The committee made a research recommendation for this area.	Formulary Team	Complete
20/27	Management of suspected DVT and PE – update formulary guidance for the management of suspected DVT in line with the discussion.	Formulary Team	Complete
20/28	Azathioprine for the treatment of autoimmune chronic active hepatitis (AIH) in adults. Liaise with the CCG Primary Care Team and LMC for negotiation of GP remuneration.  Remuneration has been agreed, the guideline has been published on the CCG website and linked to from the drug entry in the formulary.	Formulary Team	Complete
20/29	Actinic keratosis: Fluorouracil 5% cream for mild to moderate field changes – update formulary guidance and product entries for the management of mild to moderate lesions in line with the discussion.	Formulary Team	Complete
20/30	Paediatric GORD – Update proposed formulary entry in line with the discussion and circulate to the FIG for approval via the e-FIG process.	Formulary Team	On agenda
20/31	Paediatric GORD/omeprazole for paediatric patients – undertake an e-PACT search for omeprazole suspension and circulate the data to the FIG.	Formulary Team	Outstanding
20/32	Paediatric GORD/omeprazole for paediatric patients: Update section 1.3.5 Proton pump inhibitors in line with the discussion.	Formulary Team	Complete