Northern, Eastern and Western Devon
Clinical Commissioning Group
South Devon and Torbay
Clinical Commissioning Group

Meeting of the South and West Devon Formulary Interface Group

Minutes

Wednesday 13th March 2019: 2:00 pm – 4.30 pm

Future Inn, Plymouth, PL6 5ZD

Present:

Peter Rowe (Chair)	Consultant	University Hospitals Plymouth NHS Trust
Trudy Bown	Chief Pharmacy Procurement Manager	University Hospitals Plymouth NHS Trust
Emma Gitsham	Joint Formularies Pharmacist	NEW Devon CCG
Andrew Gunatilleke	Consultant	Torbay & South Devon NHS FT
Lily Hammarlund-Sim	Pharmaceutical Advisor	NHS Kernow CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Phil Melluish	GP	South Devon & Torbay CCG
Bill Nolan	GP	South Devon & Torbay CCG
Tony Perkins	Senior Medicines Optimisation Pharmacist	NEW Devon CCG
Graham Simpole	Joint Formularies Support Pharmacist	NEW Devon CCG
Christopher Sullivan	Pharmacist	Devon Partnership NHS Trust
Darren Wright	Joint Formulary Technician	NEW Devon CCG

Guests:

Larissa Sullivan	Lead Pharmacist, Long Term Conditions	Torbay & South Devon NHS FT
Rachel Ali	GP	Devon Local Medical Committee

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG

Andrew Gunatilleke joined the meeting during the discussion of Specialist Medicines Service prescribing guidelines: Torbay and South Devon NHS Foundation Trust – updated guidelines for azathioprine (AZA) and methotrexate (MTX) tablets.

Larissa Sullivan and Rachel Ali were present for the discussions on:

- First generation (typical) depot antipsychotics
- Specialist Medicines Service prescribing guidelines: Torbay and South Devon NHS Foundation Trust – updated guidelines for azathioprine (AZA) and methotrexate (MTX) tablets.

1. Welcome and announcements

Apologies

Andy Craig	GP	NEW Devon CCG
Tom Kallis	Community Pharmacist	
Nicola Joyce	Pharmacist	Livewell Southwest
Iain Roberts	Interim Head of Medicines Optimisation	NEW Devon CCG

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
First generation (typical) depot antipsychotics ▪ Flupentixol decanoate injection ▪ Haloperidol decanoate injection ▪ Zuclopenthixol decanoate injection	Various manufacturers
Torbay and South Devon NHS Foundation Trust SMS Guidelines: ▪ Oral methotrexate ▪ Azathioprine ▪ Mercaptopurine	 Various manufacturers Various manufacturers Various manufacturers
DEKAs® Plus and DEKAs® Essential multivitamins	Alveolus Biomedical BV
Paravit-CF®	ParaPharm Development Ltd
Cilique® Alternative treatments: Lizinna Cilest	Consilient Health Ltd Morningside Healthcare Ltd Janssen- Cilag Ltd
Cilodex® ear drops Alternative Treatments	Novartis Pharmaceuticals UK Ltd Various manufacturers
Dexamfetamine Various generic and branded formulations	 Various manufacturers
Chronic Obstructive Pulmonary Disease (COPD) formulary guidance update Various medications	 Various manufacturers

UTI (lower) in adults Various medications	 Various manufacturers
Chronic pelvic pain syndrome (CPPS) treatment algorithm Various treatments	 Various medications
Lyme disease Various medications	 Various manufacturers

Name	Declaration
Lily Hammarlund Sim	Attended Morph Consultancy CPD training event on men's and women's health in Nov 18 and one of the sponsors is Consilient Health.
Tony Perkins	No new interests to declare. • I have spoken at a CCG event on "pharmacist inhaler review service" no payment to me, industry paid the venue to cover food and room facilities, joint sponsorship TEVA, GSK, Cheisi, total value £450 in line with CCG industry policy. • I have discussed schemes such as IMPACT and COPD+ which provide nurse support/capacity a non- promotional service offered by TEVA and Cheisi. • I currently am on the NICE COPD guideline update committee. • I have received no payments or gifts from pharma. • Still a member of the 2019 NICE COPD update committee (reviewing triple therapy etc) https://www.nice.org.uk/guidance/indevelopment/gid-ng10128

2. Minutes of the meeting held on 16th January 2019 and matters arising

One amendment was agreed to the draft minutes of the meeting held on 16th January 2019. Under item 7, NHS England conditions for which OTC items should not be routinely prescribed in primary care, the draft minutes record that:

'It was noted that the Local Pharmaceutical Committee had been asked to support this.'

It was agreed that this be amended to read 'It was noted that the Local Pharmaceutical Committee had not been asked to support this'.

The minutes of the meeting held on 16th January 2019 were approved subject to the above amendment.

Summary of actions			
	Action	**Lead**	**Status**
19/01	*Matters arising: Title of Chapter 8 – Malignant disease to be amended in line with the discussion.* The Formulary Team is undertaking work on the format and layout of Chapter 8. The title will be amended as part of that piece of work.	Formulary team	Outstanding
19/02	*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.* 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.	Formulary team	Outstanding
19/03	Formulary entry for anti-infective preparations for the management of AOE and AOMT including the addition of Cilodex (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension to be added to the formulary in line with the discussion.	Formulary team	Complete
19/04	Antimicrobial Stewardship Group to be contacted regarding any known microbial resistance to Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension	Formulary team	Complete
19/05	Remove Cholurso as the preferred brand of ursodeoxycholic acid 250mg tables.	Formulary team	Complete
19/06	Remove Cholurso from the preferred brand page of the formulary	Formulary team	Complete
19/07	Emollients – information on the shelf-life of opened products to be forwarded to the formulary team.	Lily Hammarlund-Sim	Complete
19/08	Emollients – check what the CQCs say about open pots.	Formulary team	Complete
19/09	Formulary entry for emollients to be updated in line with the discussion	Formulary team	Complete

19/10	NHS England conditions for which OTC items should not be routinely prescribed in primary care: Clarification to be sought from Oksana Riley on the meaning of bullet point 'Patients on prescription only medication' listed in the 'Exceptions to the guidance'. It was noted that this had been taken word for word from the NHS England guidance. More detailed guidance is expected to be published in the next few weeks. Link to be forwarded to the Formulary Team when available.		Complete
19/11	NHS England conditions for which OTC items should not be routinely prescribed in primary care: update the formulary in line with the guidance.	Formulary team	Outstanding
19/12	Unipolar depression guidance review (update): Update FIG electronically following discussion with DPT.	Formulary team	Complete
19/13	Update the formulary entry for depression and associated drugs in line with the discussion.	Formulary team	Outstanding
19/14	Add new guidance on drugs that prolong the QT interval to the formulary.	Formulary team	Outstanding
19/15	Management of gout: Formulary entry to be updated in line with the discussion.	Formulary team	Outstanding
19/16	S&W Devon guidance for Lyme disease to be added to the formulary in line with the discussion.	Formulary team	Complete
19/17	Palliative care opioid tables (update): note addition of the palliative care opioid equivalency table on the recent drug decisions document.	Formulary team	Complete
19/18	Palliative care opioid tables (update): E-mail Secondary Care Pharmacists about the Palliative Care Table.	Formulary team	Complete
19/19	Agreed information from the November 2018 MHRA Drug Safety Update to be added to the Formulary.	Formulary team	Complete
19/20	Agreed information from the December 2018 MHRA Drug Safety Update to be added to the Formulary.	Formulary team	Complete

Acceptance of Annual Report 2017-2018

The Chair accepted the Annual Report on behalf of the FIG.

The Annual Report has been accepted by the North and East FIG and will be taken to the Clinical Policy Committee meeting on 27 March 2019.

3. Specialist Medicines Service (SMS) prescribing guidelines: First generation (typical) depot antipsychotics

Early draft SMS prescribing guidelines for the safe prescribing and monitoring of a number of typical (first generation) depot antipsychotics in primary care were considered by the FIGs in Devon in 2018. These were:

- Flupentixol decanoate injection for schizophrenia and other psychoses in adults
- Haloperidol decanoate injection for schizophrenia and schizoaffective disorder in adults
- Zuclopenthixol decanoate injection for schizophrenia and paranoid psychoses in adults

At that time, clinical input had not been received from Devon Partnership Trust (DPT) psychiatrists, and the guidelines were put on hold pending further commissioning discussions at an organisational level. It has since been agreed at a senior level that the development of these guidelines should continue. Input from DPT psychiatrists and the Local Medical Committee (LMC) GP representatives has been received and the guidelines have been revised.

Funding has been in principle agreed for both the primary care drug acquisition costs and additional work required in primary care; the final settlement of funding will be agreed via the LMC negotiations committee.

The FIG considered the proposed guideline. Minor amendments were agreed, including that references to 'rapid' rereferrals are not needed in the guideline and that a bullet point be added to the GP responsibilities about being aware of interactions with any new drugs prescribed. Formulary team to amend the guideline in line with the discussion and forward to Rachel Ali and Chris Sullivan.

ACTION: Formulary team to make agreed changes to the proposed guidance and forward to Rachel Ali and Chris Sullivan.

4. Specialist Medicines Service prescribing guidelines: Torbay and South Devon NHS Foundation – Updated guidelines for azathioprine (AZA) and methotrexate (MTX) tablets and new guideline for mercaptopurine

Rheumatology guidelines for AZA and MTX tablets were updated in 2018. Changes agreed included a reduction in the frequency of monitoring required for stable patients. The proposed update to the gastroenterology guidelines will ensure the same monitoring requirements for both Inflammatory Bowel Disease (IBD) and rheumatoid indications. Mercaptopurine is included in the General Practice Specialised Medicines Service Local Enhances Service (LES) for both CCGs.

Historically, Torbay and South Devon NHS Foundation Trust (TSDFT) has undertaken the prescribing and in the South Devon and Torbay CCG area and no shared care guidelines are in place. In the NEW Devon CCG area (Royal Devon and Exeter and University Hospitals Plymouth NHS Trust), shared care guidelines are in place.

South Devon and Torbay CCG and the Local Medical Committee have been consulted on plans to produce shared care guidelines for TSDFT. It is acknowledged that there will be a shift of patients from secondary care into primary care. TSDFT currently have 54 patients on mercaptopurine. In addition, some practices will be familiar with managing these patients having been involved in shared care of patients with RD&E or Plymouth. Practices also already prescribe for patients on azathioprine, which has the same monitoring schedule, side effects, interactions, cautions and contraindications. Some patients require a reduced dose of mercaptopurine using 10mg tablets, which are unlicensed. TSDFT will continue to prescribe for these patients in order to avoid unpredictable costs of supply in primary care.

The FIG considered the proposed Shared Care Guidelines. It was agreed that some minor rewording was required. It was agreed that Larissa Sullivan inform the Formulary team when the work is complete so that the Formulary can be updated.

ACTION: Larissa Sullivan to inform the Formulary Team when work on the Shared Care Guidelines is complete so that the Formulary can be updated.

5. Consideration of DEKAs® Plus and Essential vitamins for addition to the formularies

An application was submitted by Belen Romero, cystic fibrosis (CF) & Respiratory Medicine Clinical Pharmacist, Royal Devon and Exeter NHS Foundation Trust for the inclusion of the following multivitamin product range:

- DEKAs Plus Liquid (with sweeteners)
- DEKAs Plus Chewable Tablets (with sugar and sweeteners)
- DEKAs Plus Softgels
- DEKAs Essential Capsule

The application has been supported by Patrick Oades, Consultant Paediatrician, Royal Devon & Exeter NHS Foundation Trust.

It was requested that DEKAs multivitamin formulations are added to the formulary as a first line treatment for CF patients, following specialist recommendation. The vitamin and mineral composition of the formulations differ; DEKAs Essential capsules contain only the fat soluble vitamins A,D,E, and K.

The applicant indicated that these products offer a simplified regimen at a lower acquisition cost compared to current prescribing.

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

There was discussion about the patient groups requiring these vitamins and the formulations that are suitable for children and babies. It was noted that RD&E clinicians oversee patients at Torbay and South Devon NHS Foundation Trust. There was also discussion about how changes in treatment would be managed; it was suggested that some GPs would be happy to make changes if requested by CF nurses.

The FIG also discussed the issue of medication and food supplements. It was noted that vitamins are generally considered food supplements and not medications.

ACTION: Formulary team to update formulary entry for DEKAs products with approved entry.

6. Consideration of Paravit-CF® Liquid for addition to the formularies

An application was received from Belen Romero, Cystic Fibrosis (CF) and Respiratory Medicine Clinical Pharmacist, Royal Devon and Exeter NHS Foundation Trust for the inclusion of Paravit-CF Liquid for the dietary management of CF in babies and patients with swallowing difficulties. The application has been supported by Patrick Oades, Consultant Paediatrician, Royal Devon and Exeter NHS Foundation Trust.

The applicant indicated that these products offer a simplified regimen at a lower acquisition cost compared to current prescribing.

The FIG considered and accepted the proposed formulary entry.

ACTION: Formulary team to add the accepted formulary entry for Paravit-CF liquid to the formulary.

7. Consideration of Cilique® (ethinylestradiol 35micrograms / norgestimate 250micrograms) for addition to the formulary

An application for the consideration of Cilique was submitted by the Medicines Optimisation Team of NEW Devon CCG. Cilique contains 250 micrograms of norgestimate and 35 micrograms of ethinylestradiol and is indicated for hormonal contraception.

There are three equivalent brands licenced in the UK which all contain ethinylestradiol 35mcg/ norgestimate 250mcg; the current formulary first line brand is Lizinna® which has been subject to unreliability of supply, with an ongoing stock shortage since September 2018. Cilest®, the non-formulary originator brand, has been discontinued; current supplies are expected to last until mid-July 2019.

The application originally proposed that Cilique is added to the formulary as a first line (green) treatment as a replacement for Lizinna. However, it was suggested that Lizinna be reclassified as a second-line (blue) drug and retained within the formulary in case of future supply problems with Cilique.

The addition of Cilique to the formulary is currently expected to be cost neutral.

The FIG considered the proposed formulary entry. There was discussion about costs and availability of drugs. The FIG accepted the proposed formulary entry with minor amendment:

- Formulary status of Lizinna to be retained as ‘green’.

ACTION: Formulary team to add proposed formulary entry for Cilique (ethinylestradiol) 35micrograms / norgestimate 250micrograms) to the formulary in line with the discussion.

8. Reconsideration of Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops

Cilodex (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension was considered for addition to the formulary at the South and West FIG meeting held on 16th January 2019. At that time it was decided that microbiology specialist input should be sought in relation to bacterial resistance before a final decision on formulary inclusion was made.

Following feedback from consultant microbiologists it is proposed that Cilodex ear drops suspension be included in the formulary, only for the treatment of acute otitis externa (AOE), and as a second-line (blue) option rather than as a first-line (green) choice as advocated by the applicant.

Whilst Cilodex is licensed for the treatment of acute otitis media in patients with tympanostomy tubes (AOMT) it is not in line with NICE guidance, which advocates the use of oral antibiotics if microbiologically appropriate and there is no evidence that it is any better for AOMT than the current formulary recommended treatment options. It was, therefore, proposed that Cilodex was not included in the South and West formulary for the treatment of AOMT.

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

ACTION: Formulary team to add agreed formulary entry for Cilodex (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops to the formulary.

9. Dexamfetamine entry update

An application was received from Adam Zeman, Professor of Cognitive and Behavioural Neurology, Royal Devon and Exeter NHS Foundation Trust, for consideration to be given to the addition of dexamfetamine sulfate to the formulary in north and east Devon for the treatment of narcolepsy in adults. Dexamfetamine was accepted for inclusion by the North and East FIG December 2018.

Dexamfetamine is already included in the formulary for south and west Devon for narcolepsy and refractory attention deficit hyperactivity disorder, however the applicant asked that the supporting notes agreed in north and east Devon be applied to patients across Devon; therefore a revision to the south and west Devon formulary entry is proposed.

It is anticipated that there will not be a change in prescribing roles or prescribing budgets as a result of this update; the updated entry is intended to support and guide prescribers on the safe and effective use of dexamphetamine.

The FIG considered the proposed formulary entry for CNS stimulant and drugs for attention deficit hyperactivity disorder (ADHD). There was discussion about:

- The adult and child doses for ADHD and various product licences. It was agreed that adult and child doses be removed and that specialists would advise on the required dose for individual patients.

- Specialists will initiate treatment and review patients, they may stepdown treatment as required. GPs will continue treatment.
- The colour status and cost of the oral solution.

The FIG accepted the proposed formulary entry subject to minor amendment:

4.4 CNS stimulant and drugs for attention deficit hyperactivity disorder:

- Removal of oral solution 1mg/ml.
- Remove child and adult doses for refractory attention deficit hyperactivity disorder.

ACTION: Formulary team to update the formulary entry 4.4 CNS stimulation and drugs for attention deficit hyperactivity disorder in line with the discussion.

10. Chronic Obstructive Pulmonary Disease (COPD) (update)

The Formulary team are undertaking work reviewing the COPD formulary guidance. Currently the COPD management recommendations in both regions of the Devon formulary are based on guidance produced by GOLD (2017); pharmacological treatment is based on patient phenotypes (A, B, C, D). Since the guidance was last reviewed, national and international guidelines have been updated; the 2019 GOLD Report is now available alongside the 2018 publication of NICE Guideline 115. An update to NICE NG 115 is due to be published in July 2019 which considers the evidence on triple therapy (LAMA+LABA+ICS) and the duration of oral corticosteroids for managing exacerbations. There are differences in the guidance produced by NICE and GOLD focusing on the use of inhaled therapies and both differ to the current Devon formulary guidance.

Respiratory specialists across Devon have been contacted. Two responses were received. One of the specialists indicated a preference for the GOLD guidance, the other suggested waiting until NICE publish the update to NG115. Additional specialist input is being sought. This topic will continue to be looked at and brought back to FIG.

A brief discussion took place about the future direction of travel:

- It was suggested that a single set of guidance be worked towards in line with the latest national guidance.
- There was discussion about the benefits and risks of switching stable patients between inhalers.
- The Medicines Optimisation team and FIG GPs will be asked for their views as part of the review process.

The Formulary team will continue work on reviewing the COPD formulary guidance and bring to FIG for discussion as appropriate.

11. Urinary Tract Infections (UTI) lower

Previously the Primary Care Antimicrobial Guidance was reviewed annually using the Public Health England 'Management of Infection Guidance for Primary Care', NICE and PHE are now collaborating to provide guidance periodically.

The current formulary guidance has been revised in line with PHE and several NICE Clinical Guidelines. The FIG considered the proposed guidance. There was discussion about educating members of the public regarding UTIs and the default of 111 being a face to face discussion with a GP. The following minor amendments were agreed.

- Asymptomatic bacteriuria
  - Add note to the slider
- Throughout
  - Nitrofurantoin: reword notes regarding renal function for clarity and link out to MHRA Drug Safety Update.
  - Fosfomycin
    - Make 'Prescribe as Monuril® first bullet point.
- Non-pregnant women ≥ 16 years with UTI (lower)
  - Trimethoprim
    - Second bullet point to read 'Use trimethoprim only if low risk of resistance, e.g. if not used in the past 3 months, previous urine culture suggests susceptibility.
- Children and young people ≤ 16 years with UTI (lower)
  - Nitrofurantoin suspension – add note that this is non-formulary and costs around £400.00 per bottle.
  - 12 to 15 years – remove '50mg four times daily', keep dose as '100mg m/r twice a day'.

Further discussion took place. It was felt that people over 65 years of age living at home may be at increased risk of UTI. It was suggested that a section and link to Public Health England toolkit be added to the guidance for this group who have a suspected UTI.

ACTION: Formulary team to update the formulary entry for Urinary Tract Infections in line with the discussion.

ACTION: Formulary team to bring slider for people over the age of 65 to a future meeting.

12. Chronic pelvic pain syndrome (CPPS)

Consultant Urologists in Devon had produced a treatment algorithm for the initial management of Chronic Pelvic Pain Syndrome (CPPS). It was proposed that the algorithm be included in the Clinical Reference Guideline (CRG) for CPPS, under the slider, 'management', together with a text format suitable for the formulary guidance pages.

The FIG considered the proposed treatment algorithm and CRG. GPs present were keen that the management and drug treatment recommendations for CPPS remain in the formulary. The FIG agreed that a statement should be added stating that 'if a patient is on opioids these should

be stopped'. The Formulary team will develop draft management guidance and bring this to a future FIG meeting.

ACTION: Formulary team to develop draft management guidance and bring to a future FIG meeting.

The FIG did not fully support the proposed CRG as it stood. Concern was expressed that the algorithm did not fit within current clinical practice. It was noted that GPs undertake dipstick tests earlier than suggested by the algorithm and that adoption of the algorithm may significantly extend the time patients wait before referral to a specialist. It was agreed that the Formulary team would raise this with DRSS.

ACTION: Formulary team to feedback to DRSS on the issues raised by the FIG in relation to the algorithm and CRG for CPPS.

13. Lyme disease (update)

The current formulary guidance was revised in line with NICE Guideline NG95, published in April 2018. The South and West guidance was considered at the November 2018 meeting of the South and West FIG and, following some clarification and amendments, agreed at the January 2019 meeting of the South and West Devon FIG.

During initial consultation, feedback from the Devon Antimicrobial Stewardship Group indicated a strong desire to follow NICE guideline recommendations for these patients. However, feedback received from a paediatrician and a microbiologist in South and West Devon had indicated a reluctance to routinely recommend doxycycline in primary care, due to the contraindication in this age group. The South and West Devon FIG decided not to recommend doxycycline, but to favour amoxicillin first line with azithromycin as an alternative (on specialist recommendation) for these patients.

Since the current South and West Devon guidance was written, the licence for several doxycycline products has been updated and use in children aged 8 years to less than 12 years is no longer contraindicated. The FIG was asked whether, considering these license changes, it wished to adopt doxycycline as first line for children aged 9 to 12 years with single erythema migrans lesion, in line with NICE.

The FIG considered and accepted the proposed formulary entry.

The FIG also agreed that doxycycline 50mg capsules and 100 mg dispersible tablets (sugar free) be added to the formulary for the treatment of Lyme disease in children aged 9-12 years.

ACTION: Formulary team to update the formulary entry for Lyme disease in line with the discussion.

14. Recent drug decisions (including NICE)

The recent drug updates were noted.

15. MHRA Drug Safety Updates: Jan '19 & Feb '19

January 2019

- Tapentadol (Palexia®): risk of seizures and reports of serotonin syndrome when co-administered with other medicines. Add:
  - as for all opioid medicines, tapentadol can induce seizures
  - tapentadol should be prescribed with care in patients with a history of seizure disorders or epilepsy
  - tapentadol may increase seizure risk in patients taking other medicines that lower seizure threshold, for example, antidepressants such as serotonin reuptake inhibitors (SSRIs), serotonin-noradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants, and antipsychotics
  - serotonin syndrome has been reported when tapentadol is used in combination with serotoninergic antidepressants (see typical presenting symptoms below)
  - withdrawal of the serotoninergic medicine, together with supportive symptomatic care, usually brings about a rapid improvement in serotonin syndrome
  - report suspected adverse drug reactions, including those resulting from interactions between drugs, on a Yellow Card

- Ipilimumab (Yervoy): reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation. This drug is included in the formulary as a 'Red' secondary care only drug for melanoma. Add headline and link to advice for healthcare professionals.

ACTION: Formulary team to add agreed information from the MHRA Drug Safety update for January 2019 to the formulary.

February 2019

- Carbimazole: increased risk of congenital malformations; strengthened advice on contraception. Add:
  - carbimazole is associated with an increased risk of congenital malformations when used during pregnancy, particularly in the first trimester of pregnancy and at high doses (15 mg or more of carbimazole daily)
  - women of childbearing potential should use effective contraception during treatment with carbimazole
  - carbimazole should only be considered in pregnancy after a thorough individual assessment of benefits and risks of treatment, and only at the lowest effective dose without additional administration of thyroid hormones; close maternal, foetal, and neonatal monitoring is recommended
  - please report to the Yellow Card Scheme any suspected adverse reactions associated with medicines taken during pregnancy experienced by women or the baby or child

- Carbimazole: risk of acute pancreatitis. The Advice for healthcare professionals has been added to the formulary.

- SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum). Add:

- post-marketing cases of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum) have been associated with the use of sodium-glucose co-transporter 2 (SGLT2) inhibitors
- Fournier's gangrene is a rare but serious and potentially life-threatening infection
- if Fournier's gangrene is suspected, stop the SGLT2 inhibitor and urgently start treatment (including antibiotics and surgical debridement as required)
- urogenital infection or perineal abscess may precede necrotising fasciitis
- advise patients to seek urgent medical attention if they experience severe pain, tenderness, erythema, or swelling in the genital or perineal area, accompanied by fever or malaise
- report suspected adverse drug reactions to a SGLT2 inhibitor to the Yellow Card Scheme without delay

ACTION: Formulary team to add agreed information from the MHRA Drug Safety update for February 2019 to the formulary.

16. Any Other Business

Buprenorphine (Espranor®)

It was noted that a formulary request has been submitted for this product for patients with drug addiction. The application will be brought to FIG.

Erenumab for migraine

The FIG is aware that trusts are being offered free supplies of erenumab for the treatment of migraine prior to the publication of a NICE Technology Appraisal. The FIG noted that it was up to trusts to decide whether to accept the supplies. Trusts accepting the supplies will have to manage the risk in the event of NICE publishing a negative Technology Appraisal.

It was noted that Bryan Foreshew, Interface and NHSE Pharmacist, is attempting to highlight these discussions across the Sustainability and Transformation Partnership (STP).

Summary of actions

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19/01	*Matters arising: Title of Chapter 8 – Malignant disease to be amended in line with the discussion.* The Formulary Team is undertaking work on the format and layout of Chapter 8. The title will be amended as part of that piece of work.	Formulary team	Outstanding
19/02	*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.* 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.	Formulary team	Outstanding
19/11	NHS England conditions for which OTC items should not be routinely prescribed in primary care: update the formulary in line with the guidance.	Formulary team	Outstanding
19/13	Update the formulary entry for depression and associated drugs in line with the discussion.	Formulary team	Complete
19/14	Add new guidance on drugs that prolong the QT interval to the formulary.	Formulary team	Complete
19/15	Management of gout: Formulary entry to be updated in line with the discussion.	Formulary team	Complete
19/21	Specialist Medicines Service (SMS) prescribing guidelines: First generation (typical) depot antipsychotics – agreed changes to be made to the proposed guidance and guidance forwarded to Rachel Ali and Chris Sullivan	Formulary team	Complete
19/22	Specialist Medicines Service prescribing guidelines: Torbay and South Devon NHS Foundation – Updated guidelines for azathioprine (AZA) and methotrexate (MTX) tablets and new guideline for mercaptopurine. Formulary team to be informed once work on Shared Care Guidelines is complete so that the formulary can be updated.	Larissa Sullivan	Outstanding
19/23	Formulary to be updated with approved entry for DEKAs.	Formulary team	Complete
19/24	Accepted formulary entry for Paravit-CF liquid to be added to the formulary.	Formulary team	Complete
19/25	Proposed formulary entry for Cilique® (ethinylestradiol 35micrograms / norgestimate 250micrograms) to be added to the formulary in line with the discussion.	Formulary team	Complete

19/26	Agreed formulary entry for Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops to be added to the formulary.	Formulary team	Complete
19/27	Dexamfetamine: Formulary entry 4.4 CNS stimulation and drugs for attention deficit hyperactivity disorder in line with the discussion.	Formulary team	Complete
19/28	Formulary entry for Urinary Tract Infections to be updated in line with the discussion.	Formulary team	Outstanding
19/29	Urinary tract infections - Slider for people over the age of 65 to be brought to a future meeting.	Formulary team	Outstanding
19/30	Feedback to DRSS on the issues raised by the FIG in relation to the algorithm and Clinical Reference Guideline for Chronic Pelvic Pain Syndrome.	Formulary team	Complete
19/31	Draft management guidance to be developed and brought to a future FIG for patients with chronic pelvic pain syndrome.	Formulary team	Outstanding
19/32	Formulary entry for Lyme disease to be updated in line with the discussion.	Formulary team	Complete
19/33	MHRA Drug Safety Update: January 2019 - add agreed information to the formulary.	Formulary team	Outstanding
19/34	MHRA Drug Safety Update: February 2019 – add agreed information to the formulary.	Formulary team	Outstanding