NHS
Devon
Clinical Commissioning Group

Meeting of the Northern and Eastern Devon Formulary Interface Group

Minutes

Thursday 11 April 2019: 9:00am – 11:00am
Old Heathcoat School, Tiverton

Present:

Tawfique Daneshmend	Consultant Gastroenterologist	RD&E
Glen Allaway	GP	NHS Devon CCG
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Susie Harris	Consultant, Elderly Care	RD&E
Andrew Harrison	GP	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Matthew Kaye	Chief Pharmacist	NDHT
Carole Knight	Clinical Pharmacist (Medicines Information and Formulary)	NDHT
Denise Lanyon	MO Pharmacist	NHS Devon CCG
Rebecca Perkins	Senior MO Pharmacist	NHS Devon CCG
Bethan Rogers	Medicines Information and Formulary Support Pharmacist	RD&E
Graham Simpole	Joint Formularies Support Pharmacist	NHS Devon CCG
Christopher Sullivan	Pharmacist	Devon Partnership NHS Trust
Darren Wright	Joint Formulary Technician	NHS Devon CCG

Guests:

Susie Earl	Consultant Rheumatologist and Clinical Lead	RD&E
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and Introductions:

Apologies

Iain Carr	Senior MO Pharmacist	NHS Devon CCG
Emma Gitsham	Joint Formularies Pharmacist	NHS Devon CCG
Simon Kay	GP	NHS Devon CCG
Jess Parker	GP	NHS Devon CCG

Declaration of Interests

Declaration of Interest forms were collected. There were no Declaration of Interests to report.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
First generation (typical) depot antipsychotics ▪ Flupentixol decanoate injection ▪ Haloperidol decanoate injection ▪ Zuclopenthixol decanoate injection	Various manufacturers
DMARDs in rheumatology (including reclassification of penicillamine to hospital only) Various medications	 Various manufacturers
Semaglutide (Ozempic®) for the treatment of type 2 diabetes	Novo Nordisk Limited
Alternative treatments:	
Other GLP-1 mimetics	
Dulaglutide (Trulicity®)	Eli Lilly and Company Ltd
Exenatide (Byetta®, Bydureon®)	AstraZeneca UK Ltd
Liraglutide (Victoza®)	Novo Nordisk Ltd
Lixisenatide (Lyxumia®)	Sanofi
Other antidiabetic medication	
Metformin, Sulfonylureas, DPP4 inhibitors, SGLT2 inhibitors, Insulins	Various manufacturers
FreeStyle Libre device for interstitial glucose monitoring in diabetes	Abbott Laboratories Ltd
Alternative treatments:	
Blood glucose monitoring devices	Various
Continuous glucose monitors	Various

Ganciclovir 0.15% w/w eye gel Alternative Treatments Aciclovir eye ointment 3.0% w/w Trifluorothymidine (trifluridine, FT3)	Thea Pharmaceuticals Ltd GlaxoSmithKline UK Unlicensed available from specialist manufacturer
Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops Alternative Treatments	Novartis Pharmaceuticals UK Ltd Various manufacturers
Management of gout Various medications	 Various manufacturers
Urinary tract infection (lower) Various medications	 Various manufacturers
Chronic pelvic pain syndrome (CPPS) Various treatments	 Various manufacturers
Chronic Obstructive Pulmonary Disease (COPD) formulary guidance update Various medications	 Various manufacturers
Lyme disease Various medications	 Various manufacturers

Items discussed by e-FIG

e-FIG Item	Company
Over the counter (OTC) items which should not routinely be prescribed in primary care. Various medications	 Various manufacturers
DEKAs® Plus and DEKAs® Essential multivitamins	Alveolus Biomedical BV
Paravit-CF® Multivitamins	ParaPharm Development Ltd
Secondary prevention of stroke and transient ischaemic attack (TIA) in primary care Various medications	 Various manufacturers

Unipolar depression augmentation strategies & QT prolongation drugs Various medications	 Various manufacturers

2. Minutes of the meeting held on Thursday 13th December 2018 and matters/actions arising

The minutes of the meeting held on Thursday 13th December 2018 were approved.

Summary of actions

Date	Action	Lead	Status
18/208	Check whether patients taking dapsone are flagged up on the trust haematology system. Patients are not flagged up on the RD&E haematology system.		Complete
18/209	Discuss Dapsone guidelines with the LMC, make agreed amendments to the draft and bring back to FIG.	Formulary Team	Ongoing
18/210	Kyleena (levonorgestrel) 19.5mg intrauterine system (IUS) to be added to the local formulary in line with the discussion.		Complete
18/211	MO to be asked to review e-PACT2 figures for the number of LNG-IUS dispensed.		Complete
18/212	MO to be asked to review e-PACT2 data for dexamfetamine and sense check it as there may be inaccuracies due to recent issues with e-PACT2.		Complete
18/213	Formulary team to look at filters being used for ePACT2 searches.		Complete
18/214	Dexamfetamine to be added to the formulary in line with the discussion.		Complete
18/215	Cholurso to be removed from the formulary as the preferred brand of urodeoxycholic acid 250mg tablets.		Complete
18/216	Cholurso to be removed from the preferred brand page of the formulary.		Complete
18/217	Manufacturers of anal irrigation systems to be contacted regarding the amount of time extension tubes and water bags can be used before they are replaced.		Complete
18/218	Contact number for South Molton NHS Bladder and Bowel Care Service to be checked and updated in the anal irrigation formulary entry.		Complete

18/219	Formulary entry for Anal Irrigation System products to be updated in line with the discussion.		Complete
18/220	Contact number for South Molton NHS Bladder and Bowel Care Service to be checked and updated in the anal inserts formulary entry.		Complete
18/221	Formulary entry for anal inserts to be updated in line with the discussion.		Complete
18/222	Podiatrists to be asked to confirm the products that should be used in Primary Care for cracked heals. Formulary team to reword statement and circulate to FIG.		Complete
18/223	Discuss the use of Script-switch for appropriate emollient products with the MO team.		Complete
18/224	Formulary entry for emollient guidance and product recommendations to be updated in line with the discussion.		Complete
18/225	Dermatologists to be asked to ensure that they exhaust formulary options before trying non-formulary products.		Complete
18/226	Formulary entry for the management of infantile colic to be updated with approved entry.		Complete
18/227	Proposed formulary entry for Lyme disease to be amended in line with the discussion and circulated to FIG members. On agenda.		Complete
18/228	Formulary guidance for unipolar depression to be updated in line with the discussion.		Complete
18/229	Notes to be added to the Rivaroxaban entry.		Complete
18/230	Add top line to ritonavir entry and link out to MHRA drug safety update for further details.		Complete
18/231	Add top line to Ponatinib (Iclusig▼) entry and link out to MHRA for further details.		Complete
18/232	Transdermal fentanyl patches: Add link to the 2018 MHRA drug safety update in Chapter 16 Palliative Care.		Complete
18/233	Systemic and inhaled fluoroquinolones – add advice for healthcare professionals to 5.1.12 quinolones page and risk to be highlighted under quinolones recommended for use and treatment guidelines.		Complete

Matters arising

Report of e-FIG decisions

January 2019

In January 2019 the FIG accepted the proposed wording for Over the Counter Items for inclusion into the formulary at appropriate locations and the slider for inclusion on the information page.

It was noted that the two Devon CCGs merged on 1st April 2019; A new website has been launched. This is likely that the formulary links will break when the old website is taken down. The formulary information for Over the Counter Items will be updated when the work on the CCG website is complete.

ACTION: Accepted wording for Over the Counter Items to be included into the formulary at appropriate locations and the slider for inclusion on the formulary page.

February 2019

In February 2019 the FIG was asked to consider four items:

- DEKAs Plus and DEKAs Essential multivitamin and mineral formulations.
- Paravit-CV multivitamins.
- An update to the formulary guidance for Secondary Prevention of Stroke and TIA in primary care.
- An update to the formulary guidance for Unipolar Depression Augmentation Strategies and QT prolongation drugs.

All the proposals were accepted, and the formulary has been updated accordingly.

March 2019

Guidance from NHS England and NHS Clinical Commissioners indicates that liothyronine is an item which should not be routinely prescribed in primary care. The Devon CCGs' Medicines Optimisation teams are working on local arrangements for initiation and review of existing patients on liothyronine and have engaged with stakeholders across the south west peninsula to develop protocols for initiation and for review of current patients.

In March an e-FIG process took place asking the FIG to consider changes to the formulary entry for liothyronine. The Formulary team subsequently amended the proposed entry accordingly for final agreement by FIG.

The FIG considered and accepted the proposed formulary entry without amendment. A link to the protocols will be added when signed off by the CCG.

There was discussion about:

- Reimbursement to trusts supplying 56 x 20mcg tablets per patient for at least the first year.

ACTION: Formulary team to add the accepted liothyronine entry for North and East Devon to the local formulary.

ACTION: Formulary team to add link to protocols following sign off by the CCG.

Acceptance of the Annual Report 2017-18

The annual report has been approved by both FIGs.

The Chair of the North and East FIG approved the annual report on behalf of the group via e-mail on 22 February 2019. South and West FIG approved the annual report at its meeting on 13 March 2019.

The annual report was also received by the Clinical Policy Committee at its meeting on 27 March 2019.

It was noted that for the 2017-218 period a change to the format of the annual report had taken place with the aim of increasing the breadth and depth of the report. This will be continued in the 2018-19 annual report which is expected to be completed over the next few months.

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

Early draft SMS prescribing guidelines for the safe prescribing and monitoring of several 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 agreed in principle 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.

It is understood that the CCG is developing a separate commissioned Local Enhanced Service (LES) to cover annual physical health monitoring for patients with serious mental illness.

The group considered the proposed updated SMS guideline. The discussion noted that:

- Rachel Ali has confirmed that the LMC have no outstanding concerns.
- a note has been added to the formulary stating that Fluphenazine decanoate (Modecate®) injections have been discontinued due to manufacturing and supply problems, not due to any safety issues. Any remaining stock of Modecate® can continue to be used, although it is expected that stock levels will be depleted shortly'. There is therefore no SMS for Fluphenazine decanoate.
- GPs practices are moving away from keeping paper copies of Shared Care Guidelines towards keeping them electronically. It was also noted that the RD&E is expected to become completely paperless in 2020. This is not the case at all Trusts. It was suggested that the possibility of electronic signing of SMS documents should be considered.
- There was discussion regarding assumptions being made that GPs are undertaking monitoring. GPs present noted that primary care does not have to take on responsibility for monitoring and that this should be made clear. This is clearly stated on the first page of the SMS guidance.
- GPs present also requested that Trusts make clear the dose being prescribed and how it has been administered (multiple injections etc).
- It was noted that there are two salts of Zuclopenthixol and that they must not be confused. A note will be added to the SMS guidance.
- Formulary team to remove fax number from documents.

ACTION: Formulary team to make amendments to the SMS guidelines in line with the discussion.

4. DMARDs in rheumatology (including reclassification of penicillamine to hospital only)

Following updated national guidelines from the British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology, specialist rheumatology teams in Northern Devon Healthcare NHS Trust and Royal Devon and Exeter NHS Foundation have worked together to undertake a clinical review of local shared care guidelines for use of Disease Modifying Anti-Rheumatic Drugs (DMARDS). Dr Susie Earl, Consultant Rheumatologist and Clinical Lead, RD&E took part in the discussion. Written comments have been received from Dr Rachel Ali, GP representative for LMC.

Updated Specialist Medicines Service (SMS) guidelines were presented for discussion and agreement. These guidelines are broadly based on similar

guidelines for West Devon rheumatology patients, that were updated last year. Hydroxychloroquine is not included; recent Royal College of Ophthalmologist guidelines recommend significant changes to the drug safety monitoring for hydroxychloroquine, and a separate piece of Devon-wide work is underway.

The current shared care guidelines for methotrexate cover both GP prescribing and monitoring of oral methotrexate, and GP monitoring of subcutaneous methotrexate. The separation of prescribing from drug safety monitoring is not routinely supported in Devon, as it represents a potential risk to patient safety. Specialist services have indicated a desire to move prescribing of subcutaneous methotrexate to primary care in north and east Devon (or to establish a primary care phlebotomy service to support secondary prescribing), however these proposals are outside the scope of the SMS and require agreement and funding at an organisational level.

Data on the number of patients is also needed. Bethan Rogers and Matt Kaye to forward patient numbers for sub-cut methotrexate to Matt Howard.

ACTION: Bethan Rogers and Matt Kaye to forward patient numbers for sub-cut methotrexate to Matt Howard.

Discussions are ongoing, but in the meantime, it is proposed that the historic guidelines will stand in respect of subcutaneous methotrexate.

Penicillamine is currently listed as amber (specialist) in the joint formulary (indicated for 'severe rheumatoid arthritis' in line with shared care guidelines). Shared care guidelines for penicillamine for rheumatoid arthritis are no longer supported by local rheumatologists due to changes in practice. These are therefore not included in the proposed updated SMS guidelines and it is proposed that the historic guidelines are archived and made available for reference only.

The FIG considered the proposed SMS guidelines – North and East Devon DMARDs in Rheumatology. There was discussion about:

- Pregnancy: If a patient becomes pregnant both the GP and specialist must always be informed.
    - Leflunomide – it was agreed that the guidance on 'wash out' should remain as written. The specialist present indicated that specialist advice would always be available to GPs.
    - Pregnancy testing for women of childbearing age and the importance of the use of effective contraception.
- Vaccination – the guidance describes which patients should not be given the shingles vaccination. Specialists indicated that for some patients shingles vaccination was appropriate the information is included in patient letters.
- The draft SMS guidelines to be updated and forwarded to Susie Earl and Stuart Kyle.

ACTION: Updated draft SMS guidelines to be forwarded to Susie Earl and Stuart Kyle.

Further discussion took place; a number of issues relating to shared care were considered. These included:

- Prescribing and monitoring of patients; including blood tests and the need for specialists to prescribe until a patient is stable and GP has accepted sharing of care.
- Interactions - GPs assume that secondary care check for drug interactions however, specialists present indicated that they do not have up to date lists of the medication that a patient is taking.
- GPs present felt that the Local Medical Committee (LMC) will highlight that the national guidance states that patients should move to shared care only after they have been stabilised.
- Trusts are switching off paper correspondence in favour of electronic communications.
- Some patients may be having blood tests for things unrelated to DMARDs.
- Consideration may be needed regarding setting up a phlebotomy service in primary care. The number of nurses needed and delays in ex-ray reporting was also raised.
- Penicillamine is not included in the shared care guidelines. Rebecca Perkins will find out how many patients are on prescribed penicillamine in primary care and under which trust and speciality they are.

ACTION: Rebecca Perkins to share information on the number of patients prescribed penicillamine in primary care and under which trust, speciality/indication with Matt Howard (and rheumatologists where appropriate).

5. Semaglutide (Ozempic®)

At its meeting on 27th March 2019 the Clinical Policy Committee made a recommendation that the routine commissioning of semaglutide be accepted in Devon for patients with type 2 diabetes mellitus. Semaglutide is a glucagon-like peptide-1 (GPL-1) reception agonist indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus, as an adjunct to diet and exercise. It was recommended for use as described for GLP-1 mimetics in NICE guideline NG28.

The FIG considered and accepted the proposed formulary entry subject to correction of some typographical errors.

ACTION: On completion of the CCG's governance processes, formulary team to add the proposed entry for semaglutide to the local formulary as per the discussion.

6. FreeStyle Libre®

NHS Devon CCG has a Clinical Commissioning Policy for FreeStyle Libre published in March 2018.

In March 2019 NHS England (NHSE) published national guidance outlining criteria, which when met by a patient, the CCGs will be reimbursed a proportion of the cost

of sensors. The criteria are estimated to represent up to 20% of England's type 1 diabetic population and therefore NHSE have set a threshold for the maximum amount that will be reimbursed. Across Devon this equates to 1,158 patients and a cap of around £783, 000.

Between December 2018 and January 2019 864 patients were prescribed FreeStyle Libre under Devon's current policy, this represents 75% of the reimbursement cap proposed by NHSE. Considerable variation in prescribing was identified across Devon, with 64% of prescribing occurring in the west, 20% in the south and 8% in both the North and East.

Although a number of the criteria proposed by NHSE were included within the current CCG policy, there were also a number of additional criteria proposed. At its meeting on 27th March 2019 the CPC considered the NHSE criteria for reimbursement.

The CPC did not recommend adoption of all the criteria proposed by NHSE. The committee recommended that two additional patient groups be added to the Devon CCG commissioning policy, patients on haemodialysis and patients with cystic fibrosis (both of whom test their glucose more than 8 times a day), were to be included in criteria 1. In addition, it was recommended that patients must demonstrate this level of testing on meter downloads over 3 months.

The committee also made a recommended to include a 12 month use of the FreeStyle Libre in pregnant women with Type 1 Diabetes.

Prescribing will still be initiated by specialists and letters will be sent to GPs explaining the criteria under which they were initiated. Specialists will continue to review patients against continuation criteria at 6 months.

The addition of these patient groups to the existing criteria is not expected to incur significant costs to the CCG as NHSE will reimburse a proportion of the cost of sensors.

The FIG considered and accepted the proposed formulary entry. There was discussion about the criterion of 'pregnant women with Type 1 Diabetes – 12 months in total inclusive of post-delivery period:

- It will be explained to pregnant women at the time of initiation that prescribing is limited to a twelve-month period.

ACTION: On completion of the CCG's governance processes, formulary team to add the proposed entry for FreeStyle Libre for interstitial glucose monitoring in diabetes as per the discussion.

7. Consideration of ganciclovir 0.15% w/w eye gel for addition to the formulary

Ganciclovir 0.15% w/w eye gel (Virgan®) is licenced for the treatment of acute herpetic keratitis (dendritic and geographic ulcers).

Currently formulary guidance for North and East Devon includes aciclovir eye ointment 3% w/w as a topical treatment for ocular herpes simplex infection. GlaxoSmithKline UK, the sole supplier of aciclovir eye ointment, discontinued it from the worldwide market in 2018 due to repeated challenges in guaranteeing a sustainable product supply. Stock is anticipated to continue to be available in the UK until the end of June 2019, subject to demand. There is no other branded or generic aciclovir eye ointment available.

It was proposed that aciclovir eye ointment 3% w/w be removed from the formulary and replaced with ganciclovir 0.15% eye gel.

The FIG considered and accepted the proposed formulary entry. A brief discussion took place:

- It was noted that ganciclovir is a more expensive than aciclovir.
- Specialists favour ganciclovir being given 'green' status in the formulary. Specialists would like GPs to be able to prescribe, particularly for recurrent cases.
- It was agreed that the first presentation would ideally be referred to specialists (as per NICE CKS) and that a note be added to the formulary entry reflecting this.

ACTION: Formulary team to add note to proposed formulary entry reflecting that patients should be referred to specialists but if not possible, seek specialist advice regarding topical antivirals.

ACTION: Formulary team to add accepted formulary entry for ganciclovir 0.15% w/w eye gel to the formulary in line with the discussion.

- Medicines Optimisation (MO) team to highlight Ganciclovir 0.15% w/w eye gel rather than aciclovir eye ointment 3% w/w, via ScriptSwitch.

ACTION: MO team to highlight Ganciclovir 0.15% w/w eye gel rather than aciclovir eye ointment 3% w/w, via ScriptSwitch.

8. Consideration of Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops for addition to the formulary

An application for the consideration of Cilodex ear drops was submitted by Mr James Rainsbury, consultant ENT surgeon (University Hospitals Plymouth NHS Foundation Trust). The application is supported by Devon-wide ENT Surgeons.

Cilodex ear drops suspension is a combination preparation containing ciprofloxacin 3mg/ml, a broad-spectrum fluoroquinolone antibacterial agent, and dexamethasone 1 mg/ml, a corticosteroid. It is indicated for the treatment of acute otitis externa (AOE) in adults and children older than 1 year and for the treatment of acute otitis media in patients with tympanostomy tubes (AOMT) in adults and children older than 6 months of age. The dose for both indications in both adults and children is 4 drops twice daily for 7 days.

The applicant has proposed that Cilodex is added to the formulary as a green, (first line) treatment option for the management of AOE in primary and secondary care in line with its product licence. The formulary inclusion of Cilodex has been accepted in South and West Devon as a blue, second line treatment option following feedback from Devon-wide microbiology specialists.

The FIG considered and accepted the proposed formulary entry for Cilodex (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops subject to minor amendement. A discussion took place:

- It was agreed that the colour status of Cilodex should be 'green' in the formulary.
- The choice of preparations is currently led by product availability rather than necessarily the 'gold standard 1st choice'.

ACTION: Formulary team to add Cilodex to the formulary in line with the discussion.

9. Management of gout

Formulary guidance for the management of gout has been considered as part of the rolling review programme. It is proposed to align formulary guidance for North and East, and South and West Devon to provide easily accessible information to primary care prescribers. It is proposed that following publication, local Clinical Referral Guidelines (CRG) will contain no management guidance and will refer to the newly drafted formulary guidance.

The FIG considered and accepted the proposed formulary guidance subject to minor amendment. Dr Susie Earl, Consultant Rheumatologist and Clinical Lead, RD&E took part in the discussion. There was discussion about:

- Management of Gout:
  - Treatment of acute gout:
    - Indometacin removed as an option for gout but retained in formulary as 'for other licenced indications'.
    - Colchicine – agreed to expand to include dose regimen. There are differences between the British National Formulary (BNF) and local specialist opinion.
- Long-term management of gout:
  - It was suggested that GPs review all medication and consider if these may be causing or contributing to gout.
  - Add reference to potential preference for losartan as antihypertensive in patients with co-morbid gout (as per BSR)

- Allopurinol 50mg was recommended in the Clinical Referral Guideline (CRG), however NICE recommend 100mg. The FIG agreed to remove the 50mg dose. The 50mg dose is not licensed and is not available; it would be necessary to divide the 100mg tablets which are not scored. It was noted that the CRG will no longer include management advice. It was noted that Devon Referral Support Services (DRSS) update the CRGs. A meeting between DRSS, the Clinical Effectiveness Team and Pathology Group is being set up.

- 10.1.4 Gout and cytotoxic-induced hyperuricaemia

  - Sulfinpyrazone - the specialist present stated that sulfinpyrazone is a useful medicine but not readily available. There has been no prescribing in primary care for a year.

ACTION: Formulary team to update the formulary guidance for the management of gout in line with the discussion.

10. Urinary tract infection (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.

The FIG considered and accepted the proposed formulary subject to minor amendment:

- Nitrofuranotin – 'Consider checking renal function when choosing to treat with nitrofurantoin, especially in elderly' remove 'especially in elderly' throughout.
- Fosfomycin – remove 'prescribe as Monuril® brand' throughout (there is no longer any financial advantage to doing so).

- Pregnant women ≥ 12 years with UTI (lower) – a query was raised regarding penicillin allergy.

ACTION: Formulary team to look into suitable options for pregnant women with penicillin allergy.

- Women and men >65 years with UTI (lower) – a slider will be brought to the FIG for discussion at a future meeting.
- Children and young people <16 years with UTI (lower) – there was discussion about the position of trimethoprim and nitrofurantoin in the guidance. It was agreed that the Formulary team check with microbiologists if nitrofurantoin could be regarded as blue (2nd line/alternative) as both appear to be equally suitable but there are significantly increased costs with nitrofurantoin and national drive away from trimethoprim in other patient groups.

ACTION: Formulary Team to check with microbiologists if nitrofurantoin could be regarded as blue (2nd line/alternative).

11. 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 Referral 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 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. It was suggested 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 will 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.

12. Lyme disease

The current formulary guidance has been revised in line with the NICE Guideline NG95, published in April 2018. A proposed draft was considered by the north and east Devon FIG in December 2018; revisions were requested, specifically in relation to the need to admit patients requiring intravenous antibiotics. In the interim, the license for several doxycycline products has been updated; use in children 8 years to less that 12 years is no longer contraindicated.

In addition, it was recently agreed that formulary guidance for Lyme disease for south and west Devon would include mention of the risk of photosensitivity with doxycycline, particularly since the prescribed courses are longer that the usual courses used for other susceptible infections.

It is noted that when using weight-based dosing, some children may require doses not easily delivered by the current formulary recommended product and other products may be more suitable. However, it is noted that the acquisition cost of the dispersible tablets is significantly higher than that of standard 100mg capsules.

The FIG considered and accepted the proposed formulary entry.

The FIG also agreed that doxycycline 50mg capsules and 100mg 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.

13. COPD formulary guidance update

The Formulary team are 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 NG115 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 and have indicated a preference for the GOLD approach to treatment.

The FIG considered the GOLD and NICE guidance. GPs present indicated a preference for the GOLD approach to treatment.

ACTION: Formulary team to produce revised formulary guidance and bring to a future FIG meeting.

14. Recent drug decisions (including NICE)

The recent drug decisions were reviewed and noted.

15. MHRA Drug Safety Updates: Dec ’18, Jan ’19, Feb ’19 and Mar ‘19

<u>December 2018</u>

- Oral lidocaine- containing products for infant teething: only to be available under the supervision of a pharmacist. It was agreed that no action was needed.
- Valproate medicines: are you in acting in compliance with the pregnancy prevention measures? This has been added to the formulary.
- Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients. This has been added to the formulary.
- Direct-acting antivirals for chronic hepatitis C: risk of hypoglycaemia in patients with diabetes. This has been added to the formulary.

- Hydrocortisone muco-adhesive buccal tablets: should not be used off-label for adrenal insufficiency in children sue to serious risk. Add top line and link to MHRA safety update.

ACTION: Formulary team to add top line to entry for hydrocortisone muco-adhesive buccal tablets and link to MHRA safety update.

January 2019

- Tapentadol (Palexia): risk of seizures and reports of serotonin syndrome when co-administered with other medications. Add MHRA advice for healthcare professionals:
  - as for all opioid medications, 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
  - 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. Add MHRA advice for healthcare professionals.

ACTION: Formulary team to add MHRA advice for healthcare professionals.

- Ipilimumab (Yervoy): reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation. Add MHRA advice for healthcare professionals:
  - colitis occurs commonly in patients treated with ipilimumab for advanced melanoma; advise patients to contact their healthcare professional immediately at the onset of symptoms of colitis (including diarrhoea, blood in stools or abdominal pain)
  - if patients on ipilimumab present with diarrhoea or colitis, investigate possible causes, including infections; perform a stool infection work-up and screen for CMV
  - for patients with immune-related colitis that is corticosteroid refractory, use of an additional immunosuppressive agent should only be considered if other causes are excluded (including with screening for CMV, culture, Clostridium difficile, ova, and parasite) using viral PCR on biopsy, and other viral, bacterial, and parasitic causes
  - report suspected adverse drug reactions associated with ipilimumab to the Yellow Card Scheme

ACTION: Formulary team to add MHRA advice for healthcare professionals.

February 2019

- Carbimazole: increased risk of congenital malformations; strengthened advice on contraception. This has been added to the formulary.
- Carbimazole: risk of acute pancreatitis. This has been added to the formulary.
- SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum). Add title and link out to MHRA drug safety update for further details.

ACTION: Formulary team to add title and link out to MHRA drug safety update for further details on SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum).

March 2019

- Fluoroquinolone antibiotics: new restrictions and precautions for use due to very rare reports of disabling and potentially long-lasting or irreversible side effects. Add title and link to MHRA Drug Safety Advise for further details.

ACTION: Formulary team to add title and link out to MHRA drug safety update for further details on fluoroquinolone antibiotics.

- Onivyde (irinotecan, liposomal formulations): reports of serious and fatal thromboembolic events. Add title and link to MHRA Drug Safety Advise for further details.

ACTION: Formulary team to add title and link out to MHRA drug safety update for further details on onivyde (irinotecan, liposomal formulations.

- Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing? It was agreed that this is useful information but potentially difficult to add to the formulary as it is not limited to any specific medicine or condition(s). The Formulary team will consider if there are any particular pages where reference to this advice may be helpful. It will also be referred to in the revised SMS guidelines for DMARDs where applicable.

ACTION: Formulary team to consider if there are any particular pages where reference to this advice may be helpful.

ACTION: This guidance will be referred to in the SMS guideline for DMARDS where applicable.

16. Any other Business

Merger of NEW Devon CCG and South Devon and Torbay CCG

Subsequent to the merger of the two previous CCGs in Devon to create NHS Devon CCG, the formulary policies have been rebranded. A new CCG website is being developed. FIG members were asked to let the Formulary team know if they noticed any information that requires updating.

A query was raised about merging the formularies. It was noted that in reality Devon has one formulary, however there are some differences between North and East Devon and South and West Devon allowing variation to reflect and support the different needs of the local healthcare communities clustered around the four major hospitals in Devon, and differences in local service configuration or provision.

Summary of actions

Date	Action	Lead	Status
18/209	Discuss Dapsone guidelines with the LMC, make agreed amendments to the draft and bring back to FIG.	Formulary Team	Ongoing
19/01	Report of e-FIG: January 2019 – accepted wording for Over the Counter items to be included into the formulary at appropriate locations and the slider included on the formulary page.	Formulary team	Outstanding
19/02	Report of e-FIG: March 2019 - Liothyronine - accepted entry to be added to the formulary.		Complete
19/03	Add link to liothyronine protocols following sign off by the CCG	Formulary team	Outstanding
19/04	Specialist Medicines Service (SMS) prescribing guidelines: First generation - Make amendments to the SMS guidelines in line with the discussion.		Complete
19/05	DMARDs in rheumatology – sub-cut methotrexate patient numbers to be forwarded to Matt Howard.	Bethan Rogers Matt Kaye	Outstanding Complete
19/06	DMARDs in rheumatology: Updated draft SMS guidelines to be forwarded to Susie Earl and Stuart Kyle.	Formulary team	Outstanding
19/07	Share information on the number of patients prescribed penicillamine in primary care and under which trust, speciality/indication with Matt Howard (and rheumatologists where appropriate).	Rebecca Perkins	Outstanding

19/08	On completion of the CCG's governance processes, add the proposed entry for semaglutide to the local formulary as per the discussion.	Formulary team	Outstanding
19/09	On completion of the CCG's governance processes, add the proposed entry for FreeStyle Libre for interstitial glucose monitoring in diabetes as per the discussion.	Formulary team	Outstanding
19/10	Consideration of ganciclovir 0.15% w/w eye gel for addition to the formulary - add note to proposed formulary entry reflecting that patients should be referred to specialists but if not possible, seek specialist advice regarding topical antivirals.		Complete
19/11	Accepted entry for ganciclovir 0.15% w/w eye gel to be added to the formulary in line with the discussion.		Complete
19/12	Highlight Ganciclovir 0.15% w/w eye gel rather than aciclovir eye ointment 3% w/w, via ScriptSwitch.	Medicines Optimisation team	Outstanding
19/13	Cilodex to be added to the formulary in line with the discussion.		Complete
19/14	Update formulary guidance for the management of gout in line with the discussion.	Formulary team	Outstanding
19/15	Urinary tract infection (lower): to look into suitable options for pregnant women with penicillin allergy.	Formulary team	Outstanding
19/16	Children and young people <16 years with UTI (lower) – check with microbiologists if nitrofurantoin could be regarded as blue (2nd line alternative).	Formulary team	Outstanding
19/17	Chronic pelvic pain syndrome (CPPS) draft management guidance to be developed and brought to a future FIG meeting.	Formulary team	Outstanding
19/18	Feedback to DRSS on issues raised by the FIG in relation to the algorithm and CRG for CPPS.	Formulary team	Outstanding
19/19	Update formulary entry for Lyme disease in line for the discussion.		Complete
19/20	Revised guidance for COPD to be produced and brought to a future FIG meeting.	Formulary team	Outstanding
19/21	MHRA Drug Safety Update December 2018: Hydrocortisone muco-adhesive buccal tablets add top line and link to update to be added to the formulary.		Complete
19/22	MHRA Drug Safety Update January 2019: Tapentadol (Palexia): risk of seizures and reports of serotonin syndrome when co-administered with other medications. Advise for healthcare professionals to be added to the formulary.		Complete
19/23	MHRA Drug Safety Update January 2019: Ipilimumab (Yervoy): reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation. Advise for healthcare professionals to be added to the formulary.		Complete

19/24	MHRA Drug Safety Update February 2019: SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum). Add title and link out to MHRA drug safety update for further details.		Complete
19/25	MHRA Drug Safety Update March 2019: Fluoroquinolone antibiotics. Add title and link out to drug safety update for further advice.		Complete
19/26	MHRA Drug Safety Update March 2019: Onivyde (irinotecan, liposomal formulations). Add title and link to drug safety update for further advice.		Complete
19/27	MHRA Drug Safety Update March 2019: Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing? – Consider whether there are any particular pages where reference to this advice may be helpful. This has been added to the Formulary team work plan.		Complete
19/28	MHRA Drug Safety Update March 2019: Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing? This guideline will be referred to in the SMS guideline for DMARDS where applicable.		Complete