

Meeting of the Northern and Eastern Devon Formulary Interface Group

Minutes

Thursday 23rd January 2020: 9:00am – 11:00 am Old Heathcoat School, Tiverton

Present:

Susie Harris (Chair)	Consultant, Elderly Care	RD&E
Glen Allaway	GP	NHS Devon CCG
lain Carr	MO Pharmacist	NHS Devon CCG
Andrew Harrison	GP	NHS Devon CCG
Simon Kay	GP	NHS Devon CCG
Matt Kaye	Chief Pharmacist	NDHC NHS Trust
Carole Knight	Clinical Pharmacist (Medicines Information and Formulary)	NDHC NHS Trust
James Leavy	Medicines Information and Formulary Support Pharmacist	RD&E
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Darren Wright	Joint Formulary Technician	NHS Devon CCG
Guests:		
Tom Baddick	Pre-registration Pharmacist	NDHC NHS Trust
James Benzimra	Consultant Ophthalmologist Surgeon	RD&E
Ellis Dudley	Medicines Optimisation Pharmacist	NHS Devon CCG
Maria Glover	Pre-registration Pharmacist	NDHC NHS Trust
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
In attendance:		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and Announcements:

Welcome and Introductions

Attendees were welcomed to the meeting.

Apologies

Beverley Baker
Tawfique Daneshmend
Matt Howard
Jess Parker
Christopher Sullivan

Non-Medical Prescribing Lead Consultant Gastroenterologist Clinical Evidence Manager GP Pharmacist NHS Devon CCG RD&E NHS Devon CCG NHS Devon CCG Devon Partnership Trust

Declaration of Interests

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Thealoz duo eye drops	Thea Pharmaceuticals Ltd
Specialised Medicines Service (SMS) prescribing guidelines: Typical (first generation) depot antipsychotics:	
 Flupentixol decanoate injection for schizophrenia and other psychoses in adults 	Lundbeck Limited, Mylan
 Haloperidol decanoate injection for schizophrenia and schizoaffective disorder in adults 	Janssen-Cilag Ltd
 Zuclopenthixol decanoate injection for schizophrenia and paranoid psychoses in adults 	Lundbeck Limited
Hypertension in pregnancy guidance review	
Various medications	Various manufacturers
Community acquired pneumonia	
Various medications	Various manufacturers
Urinary Tract Infection (UTI) lower guidance review: antimicrobial guidance (NICE NG109) update	
Various medications	Various manufacturers
Perinatal Mental Health guidance	
Various medications	Various manufacturers
Prostatitis (acute) guidance review: antimicrobial guidance (NICE NG110)	
Various medications	Various manufacturers
Chronic Pelvic Pain Syndrome (CPPS) guidance review	
Various medications	Various manufacturers

There were no Declarations of Interest.

2. Minutes of the meeting held on Thursday, 7th November 2019, including action list update

Minutes of the meeting held on Thursday 7th November 2019

The minutes of the meeting held on Thursday 7th November 2019 were approved.

Action list

Number	Action	Lead	Status
19/17	Chronic pelvic pain syndrome (CPPS) draft management guidance to be developed and brought to a future FIG meeting.	Formulary Team	On agenda
	It is anticipated that this will be brought to the meeting due to take place in January 2020.		
19/54	Update draft guidance on the Management of Chronic Obstructive Pulmonary Disease (COPD) in line with the discussion and continue to develop guidance over the coming months. This was included on the agenda.		Complete
19/64	Fixapost 50micrograms/ml latanoprost and 5mg/ml timolol preservative free eye drops to be added to the formulary in line with the discussion.		Complete
19/65	Formulary entry for Nausea and vomiting in pregnancy and hyperemesis gravidarum to be updated in line with the agreed information for ondansetron.		Complete
19/66	Add One-Alpha capsules to the formulary as the preferred brand of alfacalcidol once the stock situation has been resolved.		Complete
19/67	Formulary team to ask the MO team to consider how they wish to proceed with the proposal for Valupak colecalciferol (vitamin D3) 1,000 unit tablets to be an additional preferred brand.		Complete

19/68	Formulary to be updated with the accepted formulary guidance for cough.		Complete
19/69	Chair of Antimicrobial Stewardship Group to be asked for the group's views on the proposed formulary guidance on pneumonia.		Complete
19/70	Pneumonia guidance: antimicrobial guidance (NICE) – re-draft in line with the discussion and circulate via e-FIG.	Formulary Team	On agenda
19/71	Update vaccines guidance in line with the proposed update.		Complete
19/72	Accepted resources for contraception for drugs with teratogenic potential and prescribing in pregnancy and lactation to be included in the formulary as per the discussion.	Formulary Team	Outstanding
19/73	Formulary team to update formulary COPD guidance in line with the discussion.		Complete
19/74	Hormone replacement therapy - refresh link to advice for healthcare professionals in the formulary.	Formulary Team	Outstanding
19/75	Fingolimod (Gilenya $\mathbf{\nabla}$) – add advice for healthcare professionals to the formulary product page.	Formulary Team	Outstanding
19/76	Pentosan polysulfate sodium (Elmiron) – add advice for healthcare professionals when TA610 is added to the formulary.	Formulary Team	Outstanding
19/77	Montelukast (Singulair) - add advice for healthcare professionals to the formulary product page.	Formulary Team	Outstanding
19/78	Ingenol mebutate gel (Picato $\mathbf{\nabla}$) – add advice for healthcare professionals to the formulary product page and guidance.	Formulary Team	Outstanding
19/79	Nivolumab (Opdivo) – add advice for healthcare professionals to the formulary product page and guidance.	Formulary Team	Outstanding
19/80	Prescribing medicines in renal impairment – advice for healthcare professionals to be added to the Urology chapter.	Formulary Team	Outstanding
19/81	Formulary team to add MHRA advice for adrenaline auto-injectors to product pages and contact DRSS regarding adding MHRA advice to referral page.	Formulary Team	Outstanding
19/82	Consider chairing arrangements for the meeting due to take place on Thursday 23 January 2020.		Complete

Matters Arising

There were no matters arising.

3. Thealoz Duo® eye drops

Thealoz Duo eye drops contain trehalose 3% and sodium hyaluronate 0.15% in a bottle which delivers calibrated drops. The application for Thealoz Duo was submitted by James Benzimra, consultant ophthalmologist, at the Royal Devon and Exeter hospital. The application is also supported by a consultant at Torbay Hospital and a consultant at University Hospitals Plymouth.

The proposed place in therapy is in moderate to severe dry eye for patients who cannot tolerate Evolve HA, (sodium hyaluronate 0.2%) or who have been diagnosed with moderate to severe dry eye and Evolve HA is not sufficient. As Evolve HA is for severe symptoms of dry eye in the Devon formulary, the proposed formulary entry considers Thealoz Duo for use in severe symptoms. Evolve HA is the only formulary option for sodium hyaluronate. The formulary application outlined the potential benefits of Thealoz Duo but also the substantial volume of prescribing of Hyloforte and the fact that there is no second line sodium hyaluronate formulary option.

The evidence for Thealoz Duo was presented, and the claims made by the applicant in relation to primary care prescribing data were examined. It was also noted that in the absence of an alternative formulary option to Evolve HA, specialists are recommending alternative sodium hyaluronate products or other options including cyclosporin eye drops are considered.

The FIG considered and accepted the proposed addition of Thealoz Duo eye drops to the formulary without amendment.

Formulary team to add the accepted formulary entry for Thealoz Duo eye drops to the formulary.

ACTION: Formulary team to add the accepted formulary entry for Thealoz Duo eye drops to the formulary.

4. Loteprednol eye drops for the treatment of steroid responsive inflammatory eye conditions

The routine commissioning of loteprednol (Lotemax®) was recommended by the Clinical Commissioning Group's Clinical Policy Committee at its meeting on 20th November 2019. Loteprednol is accepted in Devon for the treatment of steroid responsive inflammatory eye conditions in patients who have a known clinically significant rise in intraocular pressure with other steroid eye drops. Loteprednol does not have a UK product licence for the treatment of steroid responsive inflammatory eye conditions and the patient must be made fully aware of the unlicensed nature of the treatment and the rationale for its proposed use.

Patients with inflammatory eye conditions such as uveitis and vernal keratoconjunctivitis often require long term or frequent courses of steroid eye drops.

Prolonged use of steroid eye drops may cause an increase in intraocular pressure (IOP) in some patients. In patients who have experienced clinically significant rises in IOP on first line steroid treatment, loteprednol offers an alternative which may result in a lower rise in IOP in some individuals and permit continued treatment with topical steroid drops. Loteprednol is not commissioned as a first line option as the evidence that it has a meaningfully lower incidence of raised IOP is of poor quality and loteprednol is more expensive than alternative first line options.

The FIG was asked to consider the formulary position for loteprednol eye drops for this indication. James Benzimra, Consultant Ophthalmologist Surgeon, Royal Devon and Exeter NHS Foundation Trust took part in the discussion. There was discussion about:

- Evidence and classification in the formulary: Specialist opinion was that loteprednol is particularly useful for children and that children are at a greater risk of increased IOP. Specialist opinion suggested that 'amber' status would be appropriate as this treatment is safer than others. The specialist noted that classification as an 'amber' drug in the formulary would help to avoid unnecessary repeat attendance at hospital appointments as a means of supplying patients with loteprednol. However, it was also suggested that there should be other ways for the patient to receive a supply of loteprednol from the hospital, and that specialists should remain responsible for prescribing loteprednol. If prescribing was transferred to GPs, the GP would be accepting legal responsibility for loteprednol but the GP is not able to monitor the patient's IOP which is a requirement for long term treatment with loteprednol. Therefore, it was appropriate for loteprednol to remain a "red" drug particularly as loteprednol is prescribed for patients who have developed raised IOP from the first line corticosteroid, and evidence that loteprednol has a lower incidence of raised IOP is lacking
- Safety the specialist present stated that there was no concern about the safety profile of loteprednol and that monitoring will continue to be provided by secondary care.
- It was noted that a number of drugs are supplied to patients from secondary care. It was evident from discussions at the meeting that there were differing methods of supplying patients, and a standard approach to this should be discussed by the system. It was agreed that Susie Harris would raise this with relevant people at RD&E NHS FT.
- ACTION: Susie Harris to raise the need for a system to enable secondary care to prescribe medicines to patients without them having to attend a hospital appointment with the relevant people at Royal Devon and Exeter NHS FT.
- ACTION: Formulary Team to add the accepted entry for Loteprednol etabonate to the formulary.

- 5. Specialised Medicines Services (SMS) prescribing guidelines: Typical (first generation) depot antipsychotics:
 - Flupentixol decanoate injections 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

Specialised Medicines Services (SMS) prescribing guidelines for typical (first generation) depot antipsychotics had previously been discussed by the two Devon Formulary Interface Groups (FIGs). The guidelines have now been agreed with Devon Partnership Trust and the Local Medical Committee. The guidelines are being brought to the FIGs for final agreement.

The FIG considered and accepted the proposed formulary guidelines without amendment. There was discussion about baseline measures. It was agreed that specialists are responsible for taking baseline measures.

ACTION: Approved Specialised Medicines Services (SMS) prescribing guidelines for typical (first generation) depot antipsychotics to be added to the CCG website with links to the Devon Formulary.

6. Management of hypertension in pregnancy

Previous formulary guidance was based on NICE CG107: Hypertension in pregnancy: diagnosis and management (August 2010) – this guidance has been updated and replaced by NICE guideline NG133. Subsequently, the current formulary guidance has been revised in line with NICE NG133 Hypertension in pregnancy: diagnosis and management (June 2019). The notable changes to the guidance are as follows:

- Amended dose information for aspirin use in pre-eclampsia considering current national guidance and local specialist advice.
- Expanded advice on the risks of angiotensin-converting enzyme (ACE) inhibitors to treat hypertension in pregnancy and included the MHRA Drug Safety Update.
- Expanded and amended advice on chlorothiazide to thiazide and thiazide-like diuretics because chlorothiazide is no longer widely used.
- Updated the advice on continuing antihypertensive treatment after birth, including treatment with methyldopa.
- Updated advice on antihypertensives in the postnatal period and during breastfeeding.

The FIG considered and accepted the proposed formulary guidance.

There was discussion about switching drugs for patients who are already hypertensive who become pregnant. It was agreed that the formulary status of drugs used to treat hypertension in pregnancy should be 'blue' rather than 'amber' in order that GPs can change drugs before referring patients to a specialist. This has been agreed with Obstetrics and Gynaecology specialists during the consultation process for this update.

Formulary team to update the formulary guidance for the management of hypertension in pregnancy with the approved guidance.

ACTION: Formulary team to update the formulary guidance for the management of hypertension in pregnancy with the approved guidance.

7. Community-acquired pneumonia

At the November 2019 meeting of the North and East Devon FIG, a revised formulary section on community acquired pneumonia (CAP) was discussed. This section was based on the recently published NICE/PHE guidance for antimicrobial prescribing for community-acquired pneumonia. At the time of the FIG meeting, no responses had been received from the Devon Antimicrobial Stewardship Group (DASG). Comments on the initial draft formulary guidance were subsequently received from Dr Cressida Auckland, consultant microbiologist at the Royal Devon and Exeter (RD&E) hospital. Clarification of several points was requested from Dr Auckland, and this was received towards the end of December.

A revised draft of the guidance for CAP was presented to the FIG which incorporated comments from the previous FIG meeting and from Dr Auckland. The rationale for the NICE Guideline Development Group's recommendation for timing of initiation of antibiotics was discussed. It was decided that no change would be made to the statement proposed by the FIG at the previous meeting which was considered to be more pragmatic in terms of initiating treatment in a community setting.

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

ACTION: Formulary team to update the formulary guidance on community-acquired pneumonia with the accepted formulary guidance.

8. Urinary Tract Infections (lower) update

Currently the Devon formulary UTI management recommendations are based on guidance produced by Public Health England (PHE); 'Management of Infection Guidance for Primary Care'. NICE and PHE are now collaborating to provide guidance periodically, when these are published the formulary team will systematically review the current formulary guidance.

Work has been underway to update the Devon formulary UTI guidance; this follows publication of the October 2018 NICE Guideline NG109: Urinary tract infection (lower): antimicrobial prescribing. Consultation in late 2018 and early 2019 with Devon wide microbiologists identified a consensus to revise the formulary guidance in line with NICE

Guideline NG109. The first draft of this guidance was considered by the N&E Devon FIG in April 2019, and S&W Devon FIG in March 2019.

Upon review of the revised guideline in April 2019, the N&E Devon FIG considered and accepted the proposed formulary guidance subject to minor amendments.

The proposed formulary update for discussion at this meeting contains a new additional guidance slider; 'Women and men >65 years with UTI (lower)', which was recommended by microbiologists post-FIG discussion. In addition the slider for 'Children and young people <16 years with UTI (lower)', which required further clarification to support prescribers between the two 1st line options (and whether it was appropriate to favour 1 treatment over the other routinely). There were supporting comments for additional notes to direct use based on previous infections and to highlight the cost of Nitrofurantoin suspension.

Specialists suggested that Trimethoprim only be recommended in children and removed as an option in other patient groups. It was suggested that there were sufficient alternative options if Nitrofurantoin were not suitable in these patient groups and with higher than national average resistance rates in Devon, Trimethoprim should be removed as an option.

The FIG was asked to consider the proposed formulary guidance. The FIG considered and accepted the proposed formulary guidance without amendment. There was discussion about the cost of Nitrofurantoin suspension.

ACTION: Formulary team to update the formulary guidance with the accepted formulary guidance for UTI (lower).

9. Perinatal Mental Health

NICE issued CG192: antenatal and postnatal mental health – clinical management and service guidance in 2014. CG192 covers recognising, assessing and treating mental health problems in women who are planning to have a baby, are pregnant, or have had a baby or been pregnant in the past year.

Relevant sections of the formulary were updated at the time CG192 was issued. Since then, there has been recognition nationally of the importance of GPs in improving care for those women and families affected by perinatal mental illness, and the need to better involve GPs across the care pathway.

The formulary team was contacted by Dr Laura Davies, a GP champion in perinatal mental health based in East Devon, who is working in conjunction with Dr Laurie Windsor, consultant perinatal psychiatrist, Devon Partnership Trust (DPT). They would like to work with the formulary team to update the formulary guidance on depression in pregnancy and the postnatal period.

The objective for the FIG was to discuss possible approaches to a revised section on depression in pregnancy and the postnatal period in order to bring the views of the FIG into discussions with Dr Davies and Dr Windsor at an early stage in the process of redrafting

the formulary guidance. There was discussion about patients presenting with depression for the first time; in such cases GPs should make early contact with DPT for advice. There was also discussion on the management of patients with existing depression. It was agreed to include a link to 'best use of medicine in pregnancy' (BUMPS) advice/patient leaflets and to continue to link to DPT guidance on prescribing for perinatal mental health for recommendations for individual drugs.

The formulary team will work with Dr Davies on proposed guidance taking into account the discussion and bring back to a future meeting.

ACTION: Formulary team will work with Dr Davies on proposed guidance taking into account the discussion and bring back to future meeting.

10. Prostatitis (acute) guidance review: antimicrobial guidance (NICE)

Previously the Primary Care Antimicrobial Guidance was reviewed annually using the Public Health England (PHE) '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 NICE Guideline NG110 Prostatitis (acute): antimicrobial prescribing (October 2018).

The proposed guidance includes the addition of reference to appropriate NICE guidance, self-care advice, signs and symptoms, referral guidelines links and reassessment criteria.

Antibiotic treatment has been based on NICE guidance.

Ofloxacin has been added as a first-line treatment option, alongside the current formulary guidance options, ciprofloxacin (first line) and trimethoprim (second line).

Alternative antibiotic choices have not been included, but if worsening of symptoms on firstand second-line antibiotic treatment options, a statement has been added to a consult local microbiologist.

The FIG were asked to consider whether the proposed guidance is clear and easy to follow and whether the committee agreed with the proposed guidance. It was noted that microbiologists have stated that they can be contacted with regard to choice of treatment.

The FIG considered and accepted the proposed guidance without amendment.

The formulary team will update the formulary guidance with the accepted formulary guidance.

ACTION: Formulary team to update the formulary guidance for acute prostatitis with the accepted formulary guidance.

11. Chronic Pelvic Pain Syndrome (CPPS)

Devon Referral Support Services (DRSS) received a request from urologists Devon-wide, for an algorithm for the initial management of CPPS in primary care. The request proposed inclusion of the treatment algorithm in a new Clinical Referral Guideline (CRG) for CPPS, which would coincide with a text format suitable for the formulary guidance pages.

Subsequently work was undertaken to create formulary guidance for the management of CPPS in men. The first draft of this guidance was considered by the N&E Devon FIG in April 2019, and S&W Devon FIG in March 2019. 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 and not within the CRG. The FIG did not fully support the proposed CRG as it stood and 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.

The formulary team provided feedback to DRSS on the issues raised by the FIG in relation to the algorithm and CRG for CPPS, and have worked closely with DRSS and the original urologist to create draft management guidance.

The proposed guidance is based on NICE Clinical Knowledge Summary Prostatitis – Chronic (February 2019), and the European Association of Urology Guideline for Chronic Pelvic Pain (2019). The proposed guidance includes information on self-care advice, considerations when prescribing antibiotics, CPPS definitions, alternative diagnoses that may be causing symptoms, referral links to CRGs, antibiotic treatment recommendations based on NICE Clinical Knowledge Summary for chronic prostatitis.

The FIG was asked to consider whether the proposed guidance is clear and easy to follow and whether the committee agreed with the proposed version.

The FIG considered the proposed formulary guidance. It was agreed that doxycycline be added as a 'blue' second line treatment. With this addition the FIG accepted the proposed formulary guidance.

ACTION: Formulary team to update the formulary guidance in line with the discussion.

12. Recent drug decisions (including NICE)

The recent drug decisions were reviewed.

In addition, it was noted that Slozem capsules had been discontinued.

13. MHRA Drug Safety Updates: November 2019 and December 2019

November 2019

• Yellow fever vaccine: stronger precautions in people with weakened immunity and in those aged 60 years or older. Formulary team to add MHRA advice for Yellow fever to the formulary.

ACTION: Formulary team to add MHRA advice for Yellow fever vaccine to the formulary.

• Carfilzomib (Kyprolis): risk of reactivation of hepatitis B virus. Formulary team to add link to MHRA Drug Safety Update to the formulary.

ACTION: Formulary team to add link to MHRA advice for Carfilzomib (Kyprolis): risk of reactivation of hepatitis B virus to the formulary.

Letters and drug alerts sent to healthcare professionals in October 2019

• Ranitidine: pharmacy-level recalls: It was noted that there has been a number of pharmacy level recalls for ranitidine-containing products as a precautionary measure due to possible contamination with N-nitrosodimethylamine.

December 2019

- Domperidone for nausea and vomiting: lack of efficacy in children; reminder of contraindications in adults and adolescents. Formulary team to add the MHRA drug safety information to the formulary.
- ACTION: Formulary team to add MRHA drug safety update for domperidone for nausea and vomiting to the formulary.

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Number	Action	Lead	Status
19/17	Chronic pelvic pain syndrome (CPPS) draft management guidance to be developed and brought to a future FIG meeting. It is anticipated that this will be brought to the meeting due to take place in January 2020.	Formulary Team	Complete
19/70	 Pneumonia guidance: antimicrobial guidance (NICE) – re-draft in line with the discussion and circulate via e-FIG. This item was discussed at the FIG meeting on 23rd January 2020. 	Formulary Team	Complete
19/72	Accepted resources for contraception for drugs with teratogenic potential and prescribing in pregnancy and lactation to be included in the formulary as per the discussion.	Formulary Team	Complete
19/74	Hormone replacement therapy - refresh link to advice for healthcare professionals in the formulary.	Formulary Team	Complete
19/75	Fingolimod (Gilenya $\mathbf{\nabla}$) – add advice for healthcare professionals to the formulary product page.	Formulary Team	Complete
19/76	Pentosan polysulfate sodium (Elmiron) – add advice for healthcare professionals when TA610 is added to the formulary.	Formulary Team	Complete
19/77	Montelukast (Singulair) - add advice for healthcare professionals to the formulary product page.	Formulary Team	Complete
19/78	Ingenol mebutate gel (Picato $\mathbf{\nabla}$) – add advice for healthcare professionals to the formulary product page and guidance.	Formulary Team	Complete
19/79	Nivolumab (Opdivo) – add advice for healthcare professionals to the formulary product page and guidance.	Formulary Team	Complete
19/80	Prescribing medicines in renal impairment – advice for healthcare professionals to be added to the Urology chapter.	Formulary Team	Complete
19/81	Formulary team to add MHRA advice for adrenaline auto-injectors to product pages and contact DRSS regarding adding MHRA advice to referral page.	Formulary Team	Complete

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19/95 MHRA Drug Safety update: December 2019 – Formulary update for domperidone for nausea and vomiting to be added to the formulary.	19/95	update for domperidone for nausea and vomiting		On agenda