NHS
Devon
Clinical Commissioning Group

Meeting of the Northern and Eastern Devon Formulary Interface Group

Minutes

Thursday 5 September 2019: 9:00am – 11:30 am
Old Heathcoat School, Tiverton

Present:		
Susie Harris (Chair)	Consultant, Elderly Care	RD&E
Glen Allaway	GP	NHS Devon CCG
Emma Gitsham	Joint Formulary Pharmacist	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Matt Kaye	Chief Pharmacist	NDHT
Carole Knight	Clinical Pharmacist (Medicines Information and Formulary)	NDHT
Denise Lanyon	MO Pharmacist	NHS Devon CCG
James Leavy	Medicines Information Pharmacist	RD&E NHS FT
Jess Parker	GP	NHS Devon CCG
Graham Simpole	Joint Formulary Support Pharmacist	NHS Devon CCG
Darren Wright	Joint Formulary Technician	NHS Devon CCG
Guests:		
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
In attendance:		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and Announcements:

Welcome and Introductions

Attendees introduced themselves. James Leavy had joined the group as pharmacy representative for RD&E NHS FT.

Apologies

Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Tawfique Daneshmend	Consultant Gastroenterologist	RD&E NHS FT
Iain Carr	MO Pharmacist	NHS Devon CCG
Andrew Harrison	GP	NHS Devon CCG
Simon Kaye	GP	NHS Devon CCG
Christopher Sullivan	Pharmacist	DPT

Declaration of Interests

There were no Declarations of Interest.

2. Minutes of the meeting held on Thursday 13th June 2019, including action list update and matters arising

Minutes of the meeting held on Thursday 13th June 2019

The minutes of the meeting held on Thursday 13th June 2019 were approved.

Action list

Summary of actions

Number	Action	Lead	Status
18/209	Discuss Dapsone guidelines with the LMC, make agreed amendments to the draft and bring back to FIG. This item was included on the agenda.	Formulary team	Complete
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. The new Devon NHS CCG website has been launched. This work is expected to be completed shortly.	Formulary team	Outstanding
19/12	Highlight Ganciclovir 0.15% w/w eye gel rather than aciclovir eye ointment 3% w/w, via ScriptSwitch.	Medicines Optimisation team	Complete
19/15	Urinary tract infection (lower): look into suitable options for pregnant women with penicillin allergy. Responses are awaited from specialists.	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). Responses are awaited from specialists.	Formulary team	Outstanding

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 December 2019.	Formulary team	Outstanding
19/39	Formulary guidance for psoriasis to be updated in line with the agreed discussion.	Formulary team	Complete
19/42	COPD guidance – comments relating to COPD guidance and inhaled therapies to be forwarded to the Formulary team during the next month. This item was included on the agenda.		Complete

Matters arising

- Reports of e-FIG Decisions

  The group received a report of the e-FIG decisions taken in June, July and August.

  June decisions

  - Specialist Medicines Services (SMS) Guidelines for Dapsone – Remuneration has been agreed with Devon Local Medical Committee, the guideline has been published on the CCG website, and the formulary has been updated.

  July decisions

  - SMS Guidelines: Disease Modifying Anti-Rheumatic Drugs (DMARDS) in rheumatology partial guideline update. Item included on meeting agenda.

  August 2019

  - Nebulised colistimethate sodium for non-Cystic Fibrosis bronchiectasis. The formulary has been updated.
  - Items which should not routinely be prescribed in primary care: Needles for Prefilled and Reusable Insulin Pens. Item included on the meeting agenda.
  - Nifedipine update. The formulary has been updated.
  - Psoriasis management review. The formulary team has sought clarification from specialists regarding the difference in potency of steroids recommended for flexures in adults and children.

- Refreshed Terms of Reference (ToR)

  The ToR had been refreshed following the merger of the two CCGs in Devon in April 2019. The group received the updated ToR. These will be updated on the website.

ACTION: Formulary team to update ToR on website.

3. Sialanar 320mcg/ml Glycopyrronium (400mcg/ml Glycopyrronium Bromide) Oral Solution

At its meeting on 24th July 2019 the CCG's Clinical Policy Committee (CPC) made a recommendation for the routine commissioning of glycopyrronium bromide oral solution for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.

Evidence from clinical trials demonstrates that glycopyrronium bromide is more efficacious than placebo and failed to find a significant difference in efficacy compared to transdermal hyoscine for this indication.

Specialists may wish to initiate either glycopyrronium oral solution or hyoscine patches as first choice. Glycopyrronium bromide is currently being used for this indication, the preparations being dispensed include the two licensed formulations and a number of unlicensed special formulations.

CPC accepted that glycopyrronium oral solution would not become the first-choice treatment, purely by virtue of being licensed. There is not expected to be any change in the prescribing levels of glycopyrronium bromide liquid formulations compared to hyoscine patches and the formulary inclusion is primarily to ensure clinical consistency. There are currently, two glycopyrronium-containing products available, that are licensed for this indication, namely, Sialanar® and an unbranded generic manufactured by Colonis Pharma. These two licenced formulations are not bioequivalent nor has bioequivalence been demonstrated between these and unlicensed special formulations.

The CCG policy does not specify a particular brand of glycopyrronium oral solution with the intention that this aspect should be managed through routine formulary and medicines optimisation processes to ensure best value for money and patient safety.

Assuming that prescribing is in accordance with the manufacturers average estimated dose, Sialanar would cost £5,606 per patient each year and the Colonis Pharma product would cost £6,636. Sialanar is cost-neutral to cost-saving compared to the unlicensed specials currently dispensed in Devon. It was therefore proposed that the preferred formulary option should be the branded Sialanar formulation and an amber entry was proposed. It was also proposed to link the hyoscine hydrobromide entry to this page.

Specialists have also been consulted for advice in relation to dose amendments when switching to sialanar (due to bioequivalence differences).

The FIG were asked to consider the proposed formulary entry.

The FIG considered and accepted the proposed formulary entry without amendment. There was discussion about the length of the studies undertaken and the transition of patients from childhood to adulthood.

ACTION: Formulary team to add the accepted entry for glycopyrronium bromide oral solution for the treatment of severe sialorrhoea in children and adolescents aged 3 years and older on the completion of the CCGs governance processes.

4. Continuous Glucose Monitoring in diabetes

At its meeting on 24th July 2019 the CCG's Clinical Policy Committee (CPC) made a recommendation for the routine commissioning of a 6 month trial of continuous glucose monitoring (CGM) for patients with type 1 diabetes who despite optimised use of insulin and conventional blood glucose monitoring and having undertaken, or being on the waiting list for, structured education, and where necessary, receiving specialist psychological support to manage their diabetes, have been assessed by a multidisciplinary specialist diabetes team to meet one of the two criteria. Specifically that the patient has impaired awareness, as defined using the GOLD or Clarke hypoglycaemia unawareness scales or hypoglycaemia unawareness plus recent episodes of severe hypoglycaemia (have experienced two or more severe hypoglycaemic episodes within 12 months where they have been unable to take oral treatments).

The CPC recommendation includes continuation criteria. The first of these relates to a reduction in the number of severe hypoglycaemic events, the frequency of use and calibration of the device, regular attendance at follow up appointments with specialists, being incapable of self-management of their diabetes and unable to recognise, or communicate about, symptoms of hypoglycaemia. The second requires an improvement of 0.5% or more in HbA1c, or a reduction in the severity or frequency of hypoglycaemic events, or a reduction in parental/carer or young person anxiety around hypoglycaemia plus are using their device at least 70% of the time, calibrate it as needed and has not miss two consecutive specialist follow up appointments.

An initial review of the continuation criteria should take place at a 6-month clinic assessment, and if it is met then reviews should be annually thereafter. It is expected that at each review consideration is given to stepping down to less intensive forms of glucose monitoring wherever clinically appropriate or where the ability to recognise and/or communicate about symptoms of hypoglycaemia has significantly improved.

A range of CGMs are available, it is expected that a clinically appropriate device with the lowest cost is chosen (taking into account acquisition cost and impact on blood glucose testing).

The FIG considered the proposed formulary entry. There was discussion about:

- The supply of sensors – these will be supplied by trusts

The proposed formulary entry was accepted without amendment.

ACTION: Approved entry for Continuous glucose monitoring in diabetes to be added to the formulary on completion of the CCG governance processes.

5. DMARDs in rheumatology: partial guideline update

Following updated national guidelines from the British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (Ledingham et at., 2017), specialist rheumatology teams in Northern Devon Healthcare NHS Trust and Royal Devon and Exeter NHS Foundation Trust have worked together to undertake a clinical review of local shared care guidelines for the use of Disease Modifying Anti-Rheumatic Drugs (DMARDs). Updated Specialised Medicines Service (SMS) guidelines for azathioprine, ciclosporin, leflunomide, methotrexate, mycophenolate mofetil, sodium aurothiomalate, and sulfasalazine were considered at the N&E Devon FIG meeting in April 2019.

At that time, some minor amendments to clinical content were agreed, however several issues regarding service provision and individual clinician responsibilities (such as responsibility for writing the first prescription) were raised by specialists and GP representatives. Discussions are ongoing between stakeholders to address these concerns.

Since those discussions may take time to reach a satisfactory conclusion, in July 2019 a N&E Devon e-FIG was undertaken to consider a partial update of the monitoring requirements in the current guidelines in order to reduce the burden and risks to the patient of unnecessary testing. Other information (including individual clinician responsibilities and any references to initial prescribing etc.) will remain unchanged. This approach is supported by rheumatology specialists, the CCG and the Chair of the LMC, and will allow sufficient time for discussion of any proposed changes to service provision etc. without unduly delaying clinical updates to the guidelines.

The e-FIG resulted in some requests for clarification with specialists, responses were received from Dr Susie Earl and Dr Stuart Kyle. The responses received were included in the meeting paper. The FIG was asked to consider how the responses received may best be reflected in the proposed partially updated guidelines and whether the partially updated guidelines were easy to follow.

The FIG considered the proposed shared care guidelines for DMARDS in rheumatology. It was agreed that the Formulary Team will make minor changes to the draft guidelines and forward to the LMC. If the LMC accepts the guidelines they will be brought back to FIG.

ACTION: Formulary Team to make minor amendments to the draft guidelines for DMARDs in rheumatology and forward to the Local Medical Committee.

6. Items which should not routinely be prescribed in primary care – updated guidance

On 27th June 2019, following public consultation NHS England (NHSE) and NHS Clinical Commissioners (NHSCC) published updated guidance for CCGs on items which should not be routinely prescribed in primary care. This guidance builds on an earlier version that was issued to CCGs in November 2017.

The updated (2019) guidance includes 7 further treatments and updates the previous recommendations on rubefacients. CCGs are expected to "take this guidance into account in formulating local policies, and prescribers to reflect local policies in their prescribing practice."

Aliskiren (New 2019)

The NHSE/NHSCC guidance identifies aliskiren as a product which is "clinically effective but where more cost-effective products are available, this includes products that have been subject to excessive price inflation" and recommends the following:

- Advise CCGs that prescribers in primary care should not initiate aliskiren for any new patient
- Advise CCGs to support prescribers in deprescribing aliskiren in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Aliskiren tablets are currently listed as amber (specialist) in the Devon Formulary.

The FIG was asked to consider whether to reclassify aliskiren to red (hospital only), whether to facilitate repatriation of prescribing to secondary care (and the impact of this on both the patient and cardiology services), and whether the formulary entry requires any additional information, or reference to the NHSE/NHSCC guidance.

A discussion took place:

- FIG agreed to remove aliskiren from the formulary.
- E-PACT2 data shows that 54 patients Devon wide were prescribed aliskiren in the 12 months (May 2018 – April 2019). It was agreed that a copy of the data be sent to trust pharmacies with a breakdown of prescribing.
- It was agreed that patients currently being prescribed aliskiren by their GP need not be repatriated to secondary care prescribing.
- The Formulary team will discuss with cardiology and renal specialists.

ACTION: Formulary team to discuss aliskiren with cardiology and renal specialists.

- It was noted that there is only one cardiologist in North Devon and that aliskiren is not commonly used.

ACTION: Formulary team to update the formulary in line with the discussion, pending agreement of cardiology and renal specialists.

Amiodarone (New 2019)

The NHSE/NHSCC guidance states that amiodarone "has potential major toxicity and its use requires monitoring both clinically and via laboratory testing" and that it "must be initiated by a specialist and only continued under a shared care arrangement for patients where other treatments cannot be used, have failed, or is in line with NICE Guidance CG180." Based on this, the NHSE/NHSCC recommendation is:

- Advise CCGs that prescribers in primary care should not initiate amiodarone for any new patient
- Advise CCGs that if, in exceptional circumstances, there is a clinical need for amiodarone to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

It was noted that new Devon-wide "shared-care" type Specialised Medicines Services (SMS) guidelines have been prioritised for development.

A discussion took place:

- Developing Shared Care arrangements will be complicated and may require a lot of work; it was highlighted that currently amiodarone is initiated by consultants in several different specialties, and inpatients may move between teams prior to discharge. This may make it more difficult for a specific named consultant to share the care of a patient with their GP long term.
- It was suggested that the views of other specialities (e.g. elderly care, EMU) be sought together with the views of pharmacists and cardiologists. Susie Harris agreed to help identify specialists or teams who may currently initiate amiodarone at RD&E.
- Matt Howard will identify cardiologists who are happy to be involved in further discussion and contact all the relevant groups identified by FIG.

The FIG agreed to leave the formulary entry for Amiodarone as is for the time being.

Bath and shower preparations for dry and pruritic skin conditions (New 2019)

The NHSE/NHSCC guidance identifies bath and shower preparations for dry and pruritic skin conditions as "products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns".

The NHSE/NHSCC rationale cites RCT evidence that "showed that there was no evidence of clinical benefit for including emollient bath additives in the standard management of childhood eczema". Soap avoidance and 'Leave-on' emollient moisturisers can still be used for treating eczema. These emollients can also be used as a soap substitute. The NHSE/NHSCC rationale recognises that the trial evidence "looked at use in children however in the absence of other good quality evidence it was agreed that it is acceptable to extrapolate this to apply to adults until good quality evidence emerges".

Based on this, the NHSE/NHSCC recommendation is:

- Advise CCGs that prescribers in primary care should not initiate bath and shower preparations for any new patient

- Advise CCGs to support prescribers in deprescribing bath and shower preparations in this category and substitute with “leave-on” emollients and, where appropriate, ensure the availability of relevant services to facilitate this change.

At the N&E FIG meeting in September 2018, it was agreed that the NHSE/NHSCC guidance relating to bath and shower preparations for dry and pruritic skin (which was available in draft format for consultation at that time) should be adopted upon publication, unless it had changed significantly from the draft.

The Devon Formulary guidance on emollients has therefore already been updated to include reference to the NHSE/NHSCC guidance.

The FIG considered that no further changes are required.

Dronedarone (NEW 2019)

The NHSE/NHSCC guidance states dronedarone is a product of “low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns”.

The NHSE/NHSCC recommendation is:

- Advise CCGs that prescribers in primary care should not initiate dronedarone for any new patient
- Advise CCGs that if, in exceptional circumstances, there is a clinical need for dronedarone to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

Dronedarone is currently included in the Devon formulary as a red (hospital only) drug for use in line with NICE TA197. There are currently no plans to develop “shared-care” type prescribing guidelines for use in Devon. 12-month ePACT2 data (May ’18 to April ’19 show no prescribing of dronedarone in primary care in Devon).

The FIG considered the formulary entry for dronedarone. It was agreed that no change was needed.

Minocycline for acne (New 2019)

The NHSE/NHSCC guidance identifies minocycline for acne a product of “low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns”. The NHSE/NHSCC recommendation is:

- Advise CCGs that prescribers in primary care should not initiate minocycline for any new patient with acne
- Advise CCGs to support prescribers in deprescribing minocycline in all patients with acne and, where appropriate, ensure the availability of relevant services to facilitate this change.

This is consistent with current Devon formulary guidance, which does not recommend minocycline for the treatment of acne due to the lack of therapeutic advantage over tetracyclines and concerns over its safety.

The FIG considered the recommendations and agreed to strengthen the formulary notes and add an entry linking to the NHSE/NHSCC guidance.

ACTION: Formulary team to add the NHSE/NHSCC recommendation to the current acne guidance and include a separate minocycline entry on the drug pages with a link to NHSE/NHSCC guidance

Needles for Pre-filled and Reusable Insulin Pens (New 2019)

The NHSE/NHSCC guidance identifies needles for pre-filled and reusable insulin pens as "products which are clinically effective but where more cost-effective products are available, this includes products that have been subject to excessive price inflation". The NHSE/NHSCC rationale states that "some pen needles will fit all major insulin delivery pen devices currently available" and that costs for insulin pen needles vary from £2.75 to £30.08 for 100".

Based on this, the NHSE/NHSCC recommendation is:

- Advise CCGs that prescribers in primary care should not initiate insulin pen needles that cost >£5 per 100 needles for any diabetes patient
- Advise CCGs to support prescribers in deprescribing insulin pen needles that cost >£5 per 100 needles and, where appropriate, ensure the availability of relevant services to facilitate this change.

Four brands of insulin pen needles are currently recommended in the Devon Formulary. The NHS Devon CCG Medicines Optimisation Team (MO) requested that needles for pre-filled and reusable insulin pens be considered via the e-FIG process. The MO team proposed that all Microdot Droplet needles and 31G Omnican Fine needles be removed from the Devon Formulary, due to their cost and that GlucoRx CarePoint needles (4mm/31G; 5mm/31G; and 6mm/31G be added to the Devon Formulary as a green (first line) option. The acquisition cost for GlucoRx CarePoint needles is £2.75 per 100 for all sizes.

It was proposed that the retained BD Viva and GlucoRx Finepoint pen needles would be reclassified as blue (second line) options.

The total primary care expenditure on pen needles in Devon during the financial year 2018/19 was almost £500,000 (including over £150,000 spent on pen needles with an acquisition cost > £5 per 100). Annual savings of over £100,000 could be made if all pen needles with an acquisition cost >£5 per 100 were switched to GlucoRx CarePoint needles. This money could be reinvested in other treatments or services.

Around 1,000 patients across Devon might be affected by the proposed changes.

Needles for Pre-Filled and Reusable Insulin Pens were considered via the e-FIG process in August 2019. Responses received highlighted some areas requiring further discussion and clarification around the removal of higher cost needles and the ease with which patients can switch from one type of needle to another. In addition, although there was broad support for safety needles not being prescribed for use by NHS staff it was suggested that there may be some circumstances where prescribing on FP10 is appropriate, further discussions are needed.

The FIG considered the proposed Formulary entry.

The was discussion about block switching patients to the proposed formulary options and the ease with which this could be done. It was noted that patient/carer training would not be needed as the needles are very similar and compatible with all insulin pens. The FIG noted that some patients may switch back.

There was also discussion about the possibility of an increase in the level of pain experienced by adults and children changing to the shorter needles. It was suggested that children and adolescents may be more affected by their perception of this. GPs present stated that assurance around this would be needed if GPs are requested to switch patients. It was noted that MO have given assurance that paediatric patients would not be included in the change.

It was agreed that the formulary entry be updated in line with the proposal.

ACTION: Formulary Team to update the formulary entry for Needles for Pre-filled and Reusable Insulin Pens in line with the discussion

Rubefacients (excluding topical NSAIDs and capsaicin) (updated 2019)

The NHSE/NHSCC guidance identifies rubefacients as "products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns". These recommendations were originally considered and accepted by the N&E Devon FIG in February 2018 and are reflected in the formulary guidance for north and east Devon.

The NHSE/NHSCC recommendations were updated in 2019 to formally exclude capsaicin cream (as well as topical NSAIDs) "i.e. capsaicin can now be prescribed as per NICE guidance". Capsaicin cream falls within NICE guidelines on neuropathic pain and osteoarthritis.

The FIG had already agreed to exclude capsaicin from these recommendations (because of the NICE guideline recommendations) when the NHSE/NHSCC guidance was considered in 2018.

The FIG agreed that no further action was necessary.

Silk Garments (NEW 2019)

The NHSE/NHSCC guidance identifies silk garments (typically prescribed for eczema or dermatitis) as "products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns". The NHSE/NHSCC rationale indicates that these products are relatively expensive and the evidence relating to the use of silk garments for eczema and atopic dermatitis is weak and of low quality.

Based on this, the NHSE/NHSCC recommendation is:

- Advise CCGs that prescribers in primary care should not initiate silk garments for any patient

- Advise CCGs to support prescribers in deprescribing silk garments in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Silk garments are not routinely recommended in the Devon Formulary for any indication.

The FIG considered the recommendations and agreed to add a statement for silk garments and a link to the NHSE/NHSCC guidance.

ACTION: Formulary team to add the NHSE/NHSCC recommendation for silk garments and a link to NHSE/NHSCC guidance

7. Removal of Gynest/Estriol 0.01% cream from the formulary

The Devon formulary currently recommends two topical estriol products: estriol 0.01% cream and Ovestin® 0.1% intravaginal cream. Both are included in the formulary for vaginal atrophy and both provide 0.5mg estriol per applicatorful.

An application for the removal from the formulary of estriol 0.01% cream has been received from the MO team with support from Obstetrics & Gynaecology specialists in North and East Devon, and the clinical lead for contraception in North Devon. The applicant has proposed that estriol 0.01% cream is removed from the formulary as there is no clear reason to have two intravaginal oestrogen-only preparations delivering 0.5mg estriol/dose and there is potential to save around £190,000 per annum if all prescriptions for estriol cream are issued as the 0.1% formulation (Ovestin 0.1%).

It was proposed that estriol 0.01% cream is removed from the formulary and the formulary entry 7.2.1 is updated. Proposed changes to the pages were highlighted in the meeting papers.

One addition to the dose of estriol cream was proposed. The British National Formulary (BNF) states “treatment should be evaluated after 12 weeks” and it is proposed to include this statement in the entry.

The FIG was asked whether it accepted the removal of Gynest/Estriol 0.01% from the formulary and, if the proposed changes to the formulary entry are acceptable.

The FIG considered and accepted the proposed formulary entry. It was agreed that a sentence indicating that a review of treatment be undertaken 12 weeks after initiation at the top of the entry.

ACTION: Formulary team to update the formulary entry 7.2.1 Preparations for vaginal and vulval changes in line with the discussion.

8. Ibandronic acid 150mg tablets and risedronate sodium – change in formulary status

Ibandronic acid 150mg tablets were added to the Devon formulary following publication of NICE TA464: Bisphosphonates for treating osteoporosis (August 2017). Ibandronic acid 150mg tablets are currently classified as a red (hospital only) treatment. Medicines optimisation teams in Devon have requested a traffic light classification change to facilitate and support GP prescribing. Alongside this application a proposal has been made to update the colour status of risedronate sodium due to current acquisition costs.

Ibandronic acid 150mg tablets are licensed for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. The recommended dose is one 150mg tablet once a month. The solution for injections formulation is also included in the formulary but it will remain 'Red'.

National osteoporosis guidance recommends that choice of bisphosphonate treatment should be made on an individual patient basis considering the advantages and disadvantages of the treatments available. If generic products are available treatment should be started with the least expensive formulation.

According to the current price list alendronic acid 70mg administered once weekly has the lowest monthly acquisition cost and risedronate sodium 5mg administered once daily is associated with the greatest monthly acquisition cost. Based on the evidence of efficacy available and current acquisition cost the FIG was asked to consider the proposal to change Ibandronic acid 150mg tablets to blue, (second line) risedronate sodium reclassified from green (first line) to blue (second line). It is also proposed that a note is added to the risedronate sodium entry to highlight the increase in acquisition cost in comparison to alternative oral bisphosphonates.

The FIG was also asked to consider whether it was in support of the proposed updates to the formulary entry.

The Chair confirmed that orthogeriatricians at the RD&E were in support of the proposed changes.

The proposed formulary entry was considered and accepted subject to the following amendments:

- Bullet points relating to MHRA Drug Safety Update (November 2009) be reordered for clarity.

- <u>Risedronate sodium</u>
  - Tablets to be listed in price order, and 30mg strength to be given 'amber' specialist status.

- <u>Indications dose - Risedronate sodium:</u>
  - Paget's disease to be given 'Amber' specialist status.

It was agreed that the Formulary team will update the formulary entry in line with the discussion.

ACTION: Formulary team to update the formulary entry 6.6.2 Bisphosphonates and other drugs affecting bone metabolism in line with the discussion.

9. COPD review

Currently the Devon formulary COPD management recommendations are based on guidance produced by GOLD (2017). 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 (updated 2019).

Following publication of these documents, work has been underway to update the Devon formulary COPD guidance. Consultation earlier this year with Devon wide respiratory consultants and Formulary Interface Group (FIG) members, including GP representatives, identified a consensus in opinion towards a revision of the formulary guidance in line with the 2019 GOLD Report.

A first draft of the proposed formulary guidance was circulated with the meeting papers. The draft considers the management of stable COPD and acute exacerbations predominantly in accordance with the GOLD 2019 Report but takes into consideration aspects of NICE Guideline 115 (including the July 2019 update). The draft guidance on the management of acute exacerbations includes revision of formulary recommended antimicrobials based on NICE Guideline 114. In addition to the guidance review, the formulary product entries were also circulated prior to the meeting with the proposed changes highlighted.

The draft formulary guidance and product entries had also been circulated to Devon wide respiratory consultants, CCG Medicines Optimisation colleagues and the anti-microbial stewardship group. Feedback has been limited and it was proposed that specialists be contacted again in order to address the outstanding questions. Feedback was received from the Medicines Optimisation team following circulation of the meeting papers. Some of the comments received were considered during the discussion.

FIG members were asked to consider whether they agreed with the general structure and layout of the guidance and whether it is easy to follow.

The FIG considered the draft COPD guidance. There was discussion about reordering of drugs and the format of follow-up sliders:

- Management of Chronic Obstructive Pulmonary Disease (COPD)
  A guide to GOLD 2019
  - Initial inhaled therapy. Agreed to add a table of patient characteristics.
  - Follow-up inhaled therapy. Move and embolden sentence ‘Follow-up treatment does not depend on the ABCD assessment at diagnosis’.

Sliders

- Non inhaled prevention and maintenance strategies
  - Smoking cessation:
    - MO have confirmed that self-management plans and rescue pack leaflets will be updated for Devon.

  - Pulmonary rehabilitation:
    - Agreed to use Medical Research Council (MRC) breathlessness scale rather than mMRC.
    - Agreed to add link to Clinical Referral Guidelines (CRG)

- Initial inhaled therapy: Group A
  - The MO team had noted the large choice of treatment in each class. The Formulary team will undertake further work to rationalise the choice. It was suggested that a refined list of Metered dose inhalers (MDI) and dry powder inhalers (DPI) be produced with more options included on the product pages compared to treatment pages thus aiding prescribers.
  - Serevent® Accuhaler® It has been suggested that Serevent Accuhaler brand be stated to support brand prescribing of inhalers. The MO team agreed.

- Initial inhaled therapy: Group D
  - Recommended inhaled treatment.
    - Keep – 'if a patient displays asthmatic features, or features suggesting a steroid responsiveness consider ICS plus LABA.
    - FIG GPs confirmed that they do often use monotherapy first.
- Follow-up maintenance inhaled therapy – dyspnoea
  - Agreed to reformat section for clarity.
  - De-escalation – add guidance on how to step down from Inhaled corticosteroids (ICS).
- Follow-up maintenance inhaled therapy – exacerbations
  - Agreed to reformat section for clarity.
  - De-escalation – add guidance on how to step down from Inhaled corticosteroids (ICS).
- Inhaled corticosteroids and pneumonia.
  - Include link to guidance on how to stop treatment.
- Other pharmacological treatments
  - Oral prophylactic antibiotic therapy
    - "Refer to respiratory consultant before commencing prophylactic antibiotic therapy." Amend first sentence to read 'Before offering prophylactic antibiotics, ensure that the person has been considered for…'
    - Add azithromycin as 'amber' (subject to response from Devon Antimicrobial Stewardship Group).
  - Oxygen therapy
    - Link to existing oxygen pages including the home oxygen order form (HOOF).
- Management of acute exacerbations
    - Query over how often sputum samples are taken was raised. It was noted that generally samples are taken if patients have required multiple courses of antibiotics.

- Glucocorticoids – GPs agreed to retain 'consider prednisolone 30mg-40mg daily for 5-7 days.'

- Acute exacerbation of COPD
  - Make clear which treatment is for penicillin allergy patients.
  - Agreed to discuss colour status of Co-trimoxazole with microbiologists; 'amber' may be appropriate. Warnings to be added if included in guidance.

The FIG was requested to feedback any further comments to the Formulary team generic e-mail inbox.

ACTION: Formulary team to 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.

There was also discussion about consideration of the environmental impact of different types of treatment.

10. Chlamydia guidance review

Following an update to the Chlamydia trachomatis guideline from the British Association for Sexual Health and HIV (BASHH) in September 2018, formulary guidance has been reviewed and a proposed update was produced and presented to the FIG.

As a result of its macrolide resistance in mycoplasma genitalium (MGen) and its inadequacy as a treatment for rectal chlamydia trachomatis, BASHH no longer recommends single use azithromycin for treatment of uncomplicated chlamydia infection at any site, regardless of the gender of the infected individual and it is proposed that Devon formulary guidance is amended to reflect this.

It is proposed that Epidiymitis guidance, included in the current chlamydia guidance, be removed to a separate slider and be reviewed at a later date. The proposed formulary entry had been considered by the Devon Antimicrobial Stewardship Group and Genito-Urinary Medicines Clinicians in Devon.

The FIG considered the proposed formulary guidance. It was agreed that:

- It is useful to retain screening in the guideline.
- Amoxcillin be included as a 'blue' second line treatment.
- The links be updated and provider details to be updated to include Devon Sexual Health.

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

11. Gender dysphoria and transgender prescribing

Following requests from stakeholders, some brief general guidance on the responsibilities in respect of gender dysphoria and transgender prescribing was drafted for inclusion in the formulary. This guidance does not provide clinical guidance but summarises the prescribing responsibilities described by NHS England (the responsible commissioner for this service), alongside advice from NHS England for GPs regarding requests by private online medical service providers. The guidance also signposts to further resources to support GPs who may be asked to prescribe for individuals with gender dysphoria.

The FIG considered and accepted the proposed formulary entry.

ACTION: Formulary team to add the formulary information for gender dysphoria and transgender prescribing in line with the discussion.

12. Recent drug decisions (including NICE)

The recent drug decisions were reviewed.

13. MHRA Drug Safety Updates: June, July and August 2019

June 2019

- Direct-acting oral anticoagulants (DOACs): increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome. Add information from the MHRA Drug Safety Update to the formulary.

ACTION: Formulary team to add agreed information from the MHRA Drug Safety Update.

- GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued. Add information from the MHRA Drug Safety Update to the formulary.

ACTION: Formulary team to add information from the MHRA Drug Safety Update.

- Lartruvo▼ (olaratumab): withdrawal of the EU marketing authorisation due to lack of efficacy. It was noted that this is a 'red' hospital only drug. It was noted that olaratumab is currently recommended under a NICE TA; but will be removed from the formulary when the NICE TA has been withdrawn.

- Oral retinoid medicines▼: revised and simplified pregnancy prevention education materials for healthcare professionals and women. Add information from the MHRA Drug Safety Update in line with the S&W area.

ACTION: Formulary Team to add information from the MHRA Drug Safety Update in line with the S&W area.

- For topical retinoids (adapalene, alitretinoin, isotretinoin, tazarotene, and tretinoin), the review concluded that data show systemic exposure is negligible following topical application and is unlikely to be associated with an increased risk of neuropsychiatric disorders. Add information from the MHRA Drug Safety Update to the formulary.

ACTION: Formulary team to add information from the MHRA Drug Safety Update.

<u>July 2019</u>

- Febuxostat (Adenuric): increased risk of cardiovascular death and all-cause mortality in clinical trial in patients with a history of major cardiovascular disease. This has already been added to the formulary.
- Toclizumab (RoActemra): rare risk of serious liver injury including cases requiring transplantation. Add title and link to advice for healthcare professionals to be added to the formulary.

ACTION: Formulary team to add title and link to advice for healthcare professionals to the formulary.

- Rivaroxaban (Xarelto▼): reminder that 15 mg and 20 mg tablets should be taken with food. Add title and link to advice for healthcare professionals to the formulary.

ACTION: Formulary team to add title and link to advice for healthcare professionals to the formulary.

<u>August 2019</u>

- Daratumumab (Darzalex▼): risk of reactivation of hepatitis B virus. Add title and link to advice for healthcare professionals.

ACTION: Formulary team to add title and link to advice for healthcare professionals.

- Nalrexone/bupropion (Mysimba▼) risk of adverse reactions that could affect ability to drive. This is not in the formulary. No action required.

- Carfilzomib (Kyprolis ▼): reminder of risk of potentially fatal cardiac events. This has been added to the formulary.

14. Any other business

Denise Lanyon reported that this was her last FIG meeting as she was leaving the CCG to take up a role in another organisation. The FIG thanked Denise for all her hard work and participation in the N&E FIG and wished her well in her new role.

Summary of actions

Number	Action	Lead	Status
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. The new Devon NHS CCG website has been launched. This work is expected to be completed shortly.	Formulary team	Complete
19/15	*Urinary tract infection (lower): look into suitable options for pregnant women with penicillin allergy.* This has been followed up. Responses are awaited from specialists.	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).* This has been followed up. Responses are awaited from specialists.	Formulary team	Outstanding
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 December 2019.	Formulary team	Outstanding

19/43	Terms of Reference to be updated on the website.	Formulary Team	Complete
19/44	Add the accepted entry for glycopyrronium bromide oral solution for the treatment of severe sialorrhoea in children and adolescents aged 3 years and older to the formulary on the completion of the CCGs governance processes.	Formulary Team	Outstanding
19/45	Approved entry for Continuous glucose monitoring in diabetes to be added to the formulary on completion of the CCG governance processes.	Formulary Team	Outstanding
19/46	Formulary Team to make minor amendments to the draft guidelines for DMARDs in rheumatology and forward to the Local Medical Committee.	Formulary Team	Complete
19/47	Discuss aliskiren with cardiology and renal specialists.	Formulary Team	Outstanding
19/48	Formulary entry for aliskiren to be updated in line with the discussion, pending agreement of cardiology and renal specialists	Formulary Team	Outstanding
19/49	Add the NHSE/NHSCC recommendation to the current acne guidance and include a separate minocycline entry on the drug pages with a link to NHSE/NHSCC guidance	Formulary Team	Outstanding
19/50	Update formulary entry for needles for pre-filled and reusable insulin pens in line with the discussion.	Formulary Team	Outstanding
19/51	Add the NHSE/NHSCC recommendation for silk garments and a link to NHSE/NHSCC guidance.	Formulary Team	Outstanding
19/52	Update formulary entry 7.2.1 preparations for vaginal and vulval changes to be updated in line with the formulary.	Formulary Team	Outstanding
19/53	Update formulary entry 6.6.2 bishosphonates and other drugs affecting bone metabolism in line with the discussion.	Formulary Team	Outstanding
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.	Formulary Team	Outstanding
19/55	Update formulary guidance for chlamydia in line with the discussion.	Formulary Team	Outstanding
19/56	Add formulary information for gender dysphoria and transgender prescribing in line with the discussion.	Formulary Team	Outstanding

19/57	Add DOAC information from the June MHRA Drug Safety Update to the formulary.	Formulary Team	Outstanding
19/58	Add GLP-1 information from the June MHRA Drug Safety Update to the formulary.	Formulary Team	Outstanding
19/59	Add Oral retinoid medicines information from the June MHRA Drug Safety Update to the formulary in line with the South and West area.	Formulary Team	Outstanding
19/60	Add information for topical retinoids from MHRA Drug Safety Update to the formulary.	Formulary Team	Outstanding
19/61	Add Toclizumab (RoActemra) title and link from the July MHRA Drug Safety to be added to the formulary.	Formulary Team	Outstanding
19/62	Add title for Rivaroxaban from the July MHRA Drug Safety Update to the formulary.	Formulary Team	Outstanding
19/63	Add title and link to advice to the Daratumumab MHRA Drug Safety Update to the formulary.	Formulary Team	Outstanding