Meeting of the South and West Devon Formulary Interface Group

Minutes

Wednesday, 10th July 2019: 2:00 pm – 4.30 pm

Future Inn Plymouth, William Prance Road, Plymouth International Business Park, Plymouth, PL6 5ZD

Present:

Peter Rowe (Chair)	Consultant	University Hospitals Plymouth NHS Trust
Trudy Bown	Chief Pharmacy Procurement & IT Manager	University Hospitals Plymouth NHS Trust
Heidi Campbell	Pharmacist	Kernow CCG
Andy Craig	GP	NHS Devon CCG
Emma Gitsham	Joint Formularies Pharmacist	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Bill Nolan	GP	NHS Devon CCG
Tony Perkins	Senior Medicines Optimisation Pharmacist	NHS Devon CCG
Amy Rice	Advanced Clinical Pharmacist	Livewell Southwest
Graham Simpole	Joint Formularies Support Pharmacist	NHS Devon CCG
Chris Sullivan	Pharmacist	Devon Partnership NHS Trust
Darren Wright	Joint Formularies Technician	NHS Devon CCG

Guests:

Theresa Mitchell	Tissue Viability CNS	Livewell Southwest
Sara Stylianou	Lower Limb Therapy Service Lead	Torbay & South Devon NHS Foundation Trust

1. Welcome and announcements

Apologies

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
Andrew Gunatilleke	Consultant	Torbay & South Devon NHS Foundation Trust
Tom Kallis	Community Pharmacist	
Phil Melluish	GP	NHS Devon CCG
Iain Roberts	Lead MO Pharmacist	NHS Devon CCG

Declaration of Interests

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

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Noqdirna® 25mcg/50mcg (Desmopressin) Oral Lyophilisate	Ferring Pharmaceutics Ltd
Alternative treatment options: Other formulations of desmopressin Loop diuretics, Alpha blockers, Antimuscannics	Various manufacturers
Urgostart Plus® Pad	Urgo medical
Consideration of Buprenorphine oral lyophilisates (Espranor®)	Martindale Pharma
Consideration of ibandronic acid 150mg tablets – change in formulary status	Various manufacturers
Items which should not routinely be prescribed in primary care – updated guidance	
Aliskiren (Rasilez®)	Noden Pharma DAC
Alternative treatments: Other antihypertensive medications	Various manufacturers
Amiodarone	Various manufacturers
Alternative treatments: Other antiarrhythmic medications	Various manufacturers

Bath and Shower Preparations for dry and pruritic skin conditions	Various manufacturers
Alternative emollients	Various manufacturers
Dronedarone (Multaq®)	Sanofi
Alternative treatments: Other antiarrhythmic medications	Various manufacturers
Minocycline for acne	Various manufacturers
Alternative treatments: Other acne treatments	Various manufacturers
Needles for Pre-filled and Reusable Insulin Pens GlucoRx CarePoint®	GlucoRx Ltd
Alternative treatments: BD Viva® GlucoRx FinePoint® Microdot Droplet® Omnican Fine® Other pen needles	Becton Dickinson UK Ltd GlucoRx Ltd Cambridge Sensors Ltd BBraun Medical Ltd Various manufacturers
Rubefacients (excluding topical NSAIDs and capsaicin)	Various manufacturers
Alternative treatments: Various oral and topical analgesics	Various manufacturers
Silk Garments DermaSilk® DreamSkin® Skinnies Silk®	 Espère Healthcare Ltd DreamSkin Health Limited Skinnies UK
Alternative treatments: Other treatments for eczema or dermatitis	Various manufacturers
Psoriasis guidance and products	
Various treatments	Various manufacturers

Chronic Obstructive Pulmonary Disease (COPD) formulary guidance update Various medications	 Various manufacturers
Non-steroidal anti-inflammatory drugs (NSAIDS) – formulary entry update Various treatments	 Various manufacturers
Revision to stroke and transient ischaemic attack guidance Various treatments	 Various manufacturers

Items discussed by e-FIG

e-FIG Item	Company
FreeStyle Libre device for interstitial glucose monitoring in diabetes	Abbott Laboratories Ltd
Alternative treatments: Blood glucose monitoring devices Continuous glucose monitors	 Various manufacturers Various manufacturers

Name	Declaration
Tony Perkins	NICE COPD update committee member 2016 - 2019

2. Minutes of the meeting held on 8th May 2019 and matters arising

The minutes of the meeting held on 8th May 2019 were approved.

Summary of actions

	Action	Lead	Status
19/01	*Matters arising: Title of Chapter 8 – Malignant disease to be amended in line with the discussion.* *The Formulary Team is undertaking work on the format and layout of Chapter 8. The title will be amended as part of that piece of work.* It was suggested that this work will be complete by the end of the summer.	Formulary team	Outstanding
19/02	*Hydroxychloroquine for rheumatological and dermatological conditions: LMC and specialists to be asked for their views. Draft guidance to be brought back to FIG together with the outcome from the forthcoming CPC meeting.* *The Clinical Effectiveness team is working with providers on identifying patients who may be at risk of hydroxychloroquine retinopathy and where such patients should be referred for testing, who will do this and how it will be resourced.* It was noted that the risk for patients of getting of hydroxychloroquine retinopathy is low. The Formulary Team is also looking at the prescribing guidance.	Formulary team	Outstanding
19/11	NHS England conditions for which OTC items should not be routinely prescribed in primary care: update the formulary in line with the guidance. The NHS Devon CCG website is now live, it was noted that the content is currently limited. The old NEW Devon CCG website remains live, however the old South Devon and Torbay CCG website has been taken down. Some concern was expressed that the South Devon and Torbay information is now unavailable. A brief discussion took place about what to do about the South Devon and Torbay information. It was agreed to wait until for it to be added to the new NHS Devon CCG website, before adding links from the Devon formulary website.	Formulary team	Outstanding

19/28	*Formulary entry for Urinary Tract Infections to be updated in line with the discussion.* The Formulary team is awaiting additional guidance from microbiologists.	Formulary team	Outstanding
19/29	Urinary tract infections - Slider for people over the age of 65 to be brought to a future meeting.	Formulary team	Outstanding
19/35	Matters arising: Liothyronine – Contact Steve Cooke and ascertain whether an audit is going to be undertaken.	Formulary team	Complete
19/36	Foodlink complete with fibre – Update formulary entry for constipation and low fibre intake supplements with the accepted formulary entry	Formulary team	Complete
19/37	Consideration of Flexitol 25% Urea Heel Balm and Dermatonics Once Heel Balm (25% Urea) – accepted formulary entry to be added to the formulary.	Formulary team	Complete
19/38	Removal of aciclovir 3% w/w eye ointment and reclassification of ganciclovir 0.15% w/w eye gel from red to amber. Formulary to be updated in line with the discussion.	Formulary team	Complete
19/39	International Dysphagia Diet Standardisation Initiative (IDDSI) framework migration. Accepted entry to be added to the Formulary in line with the discussion.	Formulary team	Complete
19/40	Secondary prevention of stroke and transient ischaemic attack in primary care. Formulary entry to be updated in line with the discussion.	Formulary team	On agenda
19/41	Secondary prevention of stroke and transient ischaemic attack in primary care. Any further comments to be forwarded to the Formulary team.	FIG members	Complete
19/42	Secondary prevention of stoke and transient ischaemic attack in primary care. South west Devon specialists to be contacted for comments relating to guidance.	Formulary team	Complete
19/43	Continence formulary guidance – undertake further work in line with the discussion to rationalise and reduce the number of products available.	Formulary team	Outstanding
19/44	Semaglutide – On completion of the CCG governance processes proposed formulary entry to be added to the formulary.	Formulary team	Complete
19/45	FreeStyle Libre – Proposed formulary entry to be amended in line with the discussion and agreed through the e-FIG process.	Formulary team	Complete
19/46	Free-Style Libre – On completion of e-FIG and CCG Governance Processes agreed formulary entry to be added to the formulary.	Formulary team	Complete
19/47	Recent drug decisions (including NICE): Monuril to be added back into the formulary for the South and West Devon area.	Formulary team	Complete
19/48	MHRA Drug Safety Update: Fluoroquinolone advice for healthcare professionals to be added to the formulary.	Formulary team	Complete

19/49	MHRA Drug Safety Update: Onivyde (irinotecan, liposomal formulations): title and link to advice for healthcare professionals to be added to the formulary.	Formulary team	Complete
19/50	MHRA Drug Safety Update: Belimumab (Benlysta) title and link to advice for healthcare professionals to be added to the formulary.	Formulary team	Complete
19/51	MHRA Drug Safety Update: agreed information for pregabalin and gabapentin to be added to the formulary	Formulary team	Complete
19/52	MHRA Drug Safety Update: title and link for elvitegravir boosted with cobicistat to be added to the formulary.	Formulary team	Complete

Matters arising

Report of e-FIG decisions July 2019

FreeStyle Libre

The FIG was asked to consider the revised proposed formulary entry for the FreeStyle Libre interstitial glucose monitor following the FIG meeting in May. The e-FIG was quorate, and the proposal was accepted by those responding. The formulary entry has been updated accordingly.

3. Consideration of desmopressin acetate oral lyophilisates (Noqdirna®)

Desmopressin is currently included in the Devon formulary, it is recommended in north and east Devon for diabetes insipidus, nocturnal enuresis, and nocturnal polyuria; and in south and west Devon for diabetes insipidus and nocturnal enuresis. For south and west Devon there is limited formulary guidance for the management of nocturia, and there is no recommended licensed treatment for idiopathic nocturnal polyuria in adults.

Noqdirna is the only licensed desmopressin formulation for idiopathic nocturnal polyuria, and is available in two strengths: 25microgams; recommended for women, and 50micrograms; recommended for men.

Urologists in Devon requested inclusion of desmopressin 25micrograms and 50micrograms in the formulary as an amber (specialist) drug, for use after simple conservative measures have been tried and failed.

Desmopressin is currently listed as a green (first line) drug for south and west Devon and it was suggested that the nature of the indications for use mean it would be more suited to an amber (specialist) classification, for use on the advice of a specialist.

The FIG considered and accepted the proposal to include desmopressin 25micrograms and 50micrograms for idiopathic nocturnal polyuria and agreed to reclassify desmopressin to amber in line with current practice.

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

ACTION: Formulary team to update the formulary entry for desmopressin with the accepted formulary entry.

4. Consideration of UrgoStart® Plus Pad dressings

UrgoStart Plus Pads are interactive dressings consisting of polyester mesh impregnated with hydrocolloid polymers within a petroleum jelly. They are indicated for treating diabetic foot ulcers, leg ulcers, pressure ulcers, and long-standing acute wounds.

The Wound Formulary Action Group; consisting of members from specialist nursing and podiatry teams requested inclusion of UrgoStart Plus Pad as an amber (specialist) option.

Currently there are no comparative products in the formulary; although UrgoStart Non-Adhesive dressings are included as an amber (specialist) product, used for low to moderately exuding wounds.

NICE Medical Technology Guidance supports the use of UrgoStart products in venous leg ulcers and diabetic foot ulcers and NICE cost modelling shows that, compared with standard care, using UrgoStart dressings to treat diabetic foot ulcers is associated with cost savings.

UrgoStart 12cm x 19cm (heel) dressings are currently included in the formulary but had zero primary care prescribing in the last year (May ’18 – Apr ’19). Specialists present, (Theresa Mitchell and Sara Styliano), agreed that these could be removed from the formulary and highlighted that guidance does not recommend sacral or shaped dressings.

The FIG considered and accepted the proposed formulary entry for UrgoStart Plus Pad and the removal of UrgoStart 12cm x 19cm (heel) dressing.

ACTION: Formulary team to add UrgoStart Plus Pad dressings to the formulary in line with the discussion

ACTION: Formulary team to remove UrgoStart 12cm x 19cm (heel) dressings from the formulary

5. Consideration of buprenorphine oral lyophilisates (Espranor®)

Buprenorphine hydrochloride 2mg and 8mg oral lyophilisates (Espranor) are licensed for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction.

Espranor is not interchangeable with other buprenorphine products. Different buprenorphine products have different bioavailability, therefore the required dose in milligrams can differ between products.

The oral lyophilisate should be placed whole on the tongue until dispersed, which usually occurs within 15 seconds; it is then absorbed through the oromucosa.

The current Devon Formulary entry for S&W Devon lists buprenorphine sublingual tablets (400microgram, 2mg, 8mg) as an amber, specialist-initiated substitution treatment for opioid dependence.

An application for inclusion of Espranor was submitted by Devon Partnership Trust and the applicants proposed that Espranor will replace sublingual buprenorphine in substance misuse services for specific appropriate individuals. Espranor would be added alongside sublingual buprenorphine.

It was noted that Local Authorities are the responsible commissioners for drug and alcohol services, and therefore the decision whether to fund Espranor sits with them; they had been consulted with regards to this application and raised no objections.

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

- Whether or not there was guidance from the NHS England Controlled Drugs Accountable Officer with regards to Espranor

ACTION: Formulary team to contact the NHS England Controlled Drugs Accountable Officer regarding inclusion

- The capacity for a ScriptSwitch message to highlight message to prescribe by brand as Espranor is not interchangeable with other buprenorphine products
- An inclusion of the higher bioavailability compared to Subutex (25-30%) and a note to highlight that Espranor is not recommended for prescribing for the management of pain

ACTION: Formulary team to amend proposed entry in line with the discussion and circulate for agreement via the e-FIG process

6. Consideration of ibandronic acid 150mg tablets – change in formulary status

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.

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.

There is no rationale to prescribe one oral bisphosphonate in preference to another based on efficacy and national guidance recommends that choice of 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.

The FIG considered the proposed entry and accepted a change to blue (second line) for ibandronic acid 150mg tablets.

There was discussion about:

- Cost pressures with the once daily risedronate sodium 5mg tablets and whether it would possible to promote the use of the once weekly risedronate sodium or other bisphosphonates
- Currently recommended indications for risedronate sodium

ACTION: Formulary team to review risedronate sodium entry indications and formulations

ACTION: Formulary team to update risedronate sodium entry in line with the discussion and circulate for agreement via the e-FIG process

7. Items not routinely prescribed in primary care (2019 update)

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. The proposed guidance builds on prior guidance issued in November 2017.

The original guidance was primarily considered and accepted by FIG during 2018. The updated (2019) guidance includes 7 further treatments that NHSE and NHSCC recommend should not be routinely prescribed in primary care; and updates the previous recommendations on rubefacients.

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.

There were discussions about:

- The use of aliskiren in certain situations when other therapies have failed
- Whether aliskiren can be used in exceptional circumstances under hospital supervision

The FIG considered the recommendations and agreed to remove aliskiren from the Devon Formulary, and to include a new entry linking to the NHSE/NHSCC guidance and highlighting safety issues for those exceptional cases when aliskiren is still used.

ACTION: Formulary team to amend proposed aliskiren entry in line with the discussion and circulate for agreement via the e-FIG process

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.

The FIG considered the recommendations and agreed to retain the current amiodarone entry, whilst local "shared care" type guidelines are developed.

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 S&W FIG meeting on 16th January 2019, 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. Following public consultation, NHSE/NHSCC did not feel it necessary to amend the proposed recommendations significantly but did make minor changes to the wording.

ACTION: Formulary team to amend current bath and shower preparations entry to add a link to NHSE/NHSCC guidance

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.

The FIG considered the recommendations and agreed to retain the current dronedarone entry.

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.

The NHS Devon CCG Medicines Optimisation (MO) Team has proposed that all Microdot Droplet needles and 31G Omnican Fine needles be **removed** from the Devon Formulary, since their acquisition cost is greater than £5 per 100; 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.

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.

Responses to a further consultation with local Paediatric Diabetes Specialist Nurses (DSNs) are pending and will inform any program to switch individuals to lower cost needles.

The FIG considered the recommendations and proposals and agreed to proposed entries in line with the discussion.

ACTION: Formulary team to amend pen needles entry to add NHSE/NHSCC recommendation and add a link to NHSE/NHSCC guidance

ACTION: Formulary team to add GlucoRx Care Point needles in line with the discussion

ACTION: Formulary team to reclassify BD Viva and GlucoRx Finepoint needles to blue

ACTION: Formulary team to remove Microdot Droplet (all sizes) and Omnican Fine (31G) needles in line with the discussion

There were discussions about:

- Including a separate statement being added to highlight that prescribing of safety needles is not recommended, this was also agreed.

ACTION: Formulary team to add an entry stating that safety needles should not be prescribed on FP10 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 S&W Devon FIG in January 2018 and are reflected in the Devon formulary.

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 Devon FIGs had already agreed to exclude capsaicin from these recommendations (because of the NICE guideline recommendations) when the NHSE/NHSCC guidance was considered in 2017. 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.

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

8. Psoriasis management review

The current formulary guidance has been revised in line with NICE Guideline CG153, and the British Association of Dermatologists (BAD) Clinical Guideline on psoriasis.

A section review was proposed by dermatology consultants who indicated that there is an increase in referrals to specialists that could be managed in a primary care setting. The proposed guidance is intended to be Devon-wide to align practice across Devon and has been expanded to include the typical presentations of psoriasis, and specific guidance with updated treatment options for primary care management.

The FIG was asked to consider whether the guidance was clear and easy to follow and whether there was agreement with the proposed management.

FIG agreed to amend Dithranol to amber (specialist input) option for psoriasis in line with specialist comments. FIG was asked if there was a requirement for unlicensed special products for psoriasis to be included in the formulary, responses indicated that they were not necessary. Trust pharmacy representatives wanted to keep 25% betamethasone ointment and coal tar paste as a hospital only option, but the others could be removed.

FIG agreed to remove Tazarotene as an option for psoriasis, and asked the formulary team to contact specialists to see if there was a need for Neutrogena and T/Gel shampoos (not specifically recommended in the guidance) to be retained in the formulary.

ACTION: Formulary team to contact dermatologists regarding Neutrogena and T/Gel shampoo preparations for psoriasis

The FIG considered and accepted the proposed formulary guidance.

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

9. Chronic Obstructive Pulmonary Disease (COPD) guidance update

Work is currently ongoing in relation to updating the formulary COPD guidance; this follows publication of the 2019 GOLD Report and the 2018 NICE Guideline 115. Early consultation with Devon wide respiratory consultants and Formulary Interface Group (FIG) members, including GP representatives, has identified a consensus in opinion to revise formulary guidance in line with the 2019 GOLD Report.

There was discussion about whether GPs routinely request full blood counts and consider eosinophils as part of the initial clinical assessment of a patient diagnosed with COPD. It was noted that in current practice these are not part of the routine assessment and would be an extra test; it was unclear whether the results of these tests would impact on treatment choice. It was noted that any guidance would need to be very clear as there are several factors that could affect eosinophil count.

FIG was asked to provide any specific recommendations or requests for changes to inhaler options for the treatment of COPD, so they may be considered in the guidance review without delay.

ACTION: FIG members to provide any specific recommendations or requests for changes to inhaler options for the treatment of COPD to the Formulary team during the next month.

10. Non-steroidal anti-inflammatory drugs (NSAIDs) formulary entry update

Following the recent review of formulary gout guidance, the formulary entry for non-steroidal anti-inflammatory drugs has been reviewed and updated. There have been no changes to the products listed or the formulations included in the formulary, apart from those that had already been agreed in the gout guidance review. The entries have been reformatted and expanded for clarity; and some indications were reclassified to amber or red to reflect the need for specialist input or hospital only use.

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

ACTION: Formulary team to update the non-steroidal anti-inflammatory drugs (NSAIDs) formulary entry in line with discussion

11. Secondary prevention of stroke and transient ischaemic attack in primary care

The updated guidance on the management of secondary prevention of stroke and TIA was presented to FIG in May 2019. Whilst the majority of the changes to the guidance were previously accepted, it was noted that some points required clarification prior to publication.

Stroke specialists in S&W Devon had provided additional input and these minor revisions were discussed, including:

- In patients who have had a haemorrhagic stroke, blood pressure lowering medication will usually have been initiated by the stroke team during the acute phase, in hospital
- In ischaemic stroke and TIA; for people with severe bilateral carotid artery stenosis a systolic blood pressure target of 140-150mmHg is appropriate; and some frail, elderly patients may not require blood pressure reduction.

The FIG considered and accepted the proposed formulary entry for secondary prevention of stroke and transient ischaemic attack in primary care without further amendment.

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

12. 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 the proposed formulary entry. It was noted that the Devon Local Medical Committee had raised concerns that the guidance was not in line with the British Medical Association (BMA) position. FIG members acknowledged that GPs were often put in a difficult position in respect of balancing their competency in prescribing in this specialist area, with risks to the individual of not prescribing. FIG members considered that the guidance was a good summary of publicly available information, and that having this in the formulary would allow GPs quick access and would be helpful.

It was noted that national clinical guidance is in development, and contractual discussions between NHS England and the BMA are ongoing; the FIG agreed that the information was a useful addition to the formulary in the interim, until national guidance and contractual discussions are completed.

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

13. Recent drug decisions (including NICE)

The recent drug updates were noted.

It was noted that Roflumilast tablets 250micrograms were added to the formulary as a red (hospital only) drug as the starting dose for treatment of severe COPD (covered by NICE TA461), and that Trimbow and Trelegy Ellipta entries had note 1 amended to reflect a change to the licensing in the SPCs.

14. MHRA Drug Safety Updates: May 2019 & June 2019

May 2019

- Lemtrada (alemtuzumab) and serious cardiovascular and immune-mediated adverse reactions: new restrictions to use and strengthened monitoring requirements. Currently the formulary includes the EMA safety review statement. Add title and link to MHRA Drug Safety Update.

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

- Tofacitinib (Xeljanz▼): restriction of 10 mg twice-daily dose in patients at high risk of pulmonary embolism while safety review is ongoing. Add title and link to MHRA Drug Safety Update and additional information from EMA safety review statement.

ACTION: Formulary team to add title and link to advice for healthcare professionals for Tofacitinib (Xeljanz) and EMA safety review statement to the formulary.

- Magnesium sulfate: risk of skeletal adverse effects in the neonate following prolonged or repeated use in pregnancy. This is a hospital only drug. Add title and link out to MHRA Drug Safety Advice for further details.

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

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.

ACTION: Formulary team to add 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.

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. Add information from the MHRA Drug Safety Update. It was noted that olaratumab is currently recommended under a NICE TA; the entry will be removed when the NICE TA has been withdrawn

ACTION: Formulary team to add a note that the EU marketing authorisation has been withdrawn / remove olaratumab from the formulary when the TA has been withdrawn

- Oral retinoid medicines▼: revised and simplified pregnancy prevention educational materials for healthcare professionals and women.
- 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.

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

15. Any Other Business

It was noted for information, that University Hospitals Plymouth NHS Trust Medicines Utilisation and Assurance Committee (MUAC) has changed its name to Medicines Governance Committee and would be having bi-monthly meetings from now on.

Invicorp® (Aviptadil 25 microgram/phentolamine mesilate 2mg) solution for injection

The procedure for the consideration of Invicorp solution for injection for erectile dysfunction was clarified as requiring a positive commissioning policy (via the Clinical Policy Committee) prior to inclusion in the Devon Formulary. No formal application has been received by the Formulary Team.

Summary of actions

	Action	**Lead**	**Status**
19/01	*Matters arising: Title of Chapter 8 – Malignant disease to be amended in line with the discussion.* *The Formulary Team is undertaking work on the format and layout of Chapter 8. The title will be amended as part of that piece of work.* *It was suggested that this work will be complete by the end of the summer.* Title of Chapter 8 has been amended in line with discussion, and reformatting has been added to the workstream.	Formulary team	Complete
19/02	*Hydroxychloroquine for rheumatological and dermatological conditions: LMC and specialists to be asked for their views. Draft guidance to be brought back to FIG together with the outcome from the forthcoming CPC meeting.* *The Clinical Effectiveness team is working with providers on identifying patients who may be at risk of hydroxychloroquine retinopathy and where such patients should be referred for testing, who will do this and how it will be resourced.* It was noted that the risk for patients of getting of hydroxychloroquine retinopathy is low. The Formulary Team is also looking at the prescribing guidance.	Formulary team	Outstanding

19/11	NHS England conditions for which OTC items should not be routinely prescribed in primary care: update the formulary in line with the guidance. *The NHS Devon CCG website is now live, it was noted that the content is currently limited. The old NEW Devon CCG website remains live, however the old South Devon and Torbay CCG website has been taken down. Some concern was expressed that the South Devon and Torbay information is now unavailable. A brief discussion took place about what to do about the South Devon and Torbay information. It was agreed to wait until for it to be added to the new NHS Devon CCG website, before adding links from the Devon formulary website.* OTC information has been added to the NHS Devon CCG website and links from the formulary will direct to this information.	Formulary team	Complete
19/28	*Formulary entry for Urinary Tract Infections to be updated in line with the discussion.* The Formulary team is awaiting additional guidance from microbiologists.	Formulary team	Outstanding
19/29	Urinary tract infections - Slider for people over the age of 65 to be brought to a future meeting.	Formulary team	Outstanding
19/35	*Matters arising: Liothyronine – Contact Steve Cooke and ascertain whether an audit is going to be undertaken.* *Steve Cooke had contacted the team to say that there was no formal audit plan, but a tracking document was in circulation that would allow MO Team to track prescribing and monitor uptake.* It was asked if the formulary team could share the tracking document with representatives from Kernow CCG for information.	Formulary team	Complete
19/40	Secondary prevention of stroke and transient ischaemic attack in primary care. Formulary entry to be updated in line with the discussion.	Formulary team	Complete
19/43	*Continence formulary guidance – undertake further work in line with the discussion to rationalise and reduce the number of products available.* Drafts have been sent for comments to specialists, with responses to be brought back to FIG.	Formulary team	Outstanding
19/53	Consideration of desmopressin acetate oral lyophilisates (Noqdirna®): Update the formulary entry for desmopressin with the accepted formulary entry.	Formulary team	Complete
19/54	Consideration of UrgoStart Plus Pad: add UrgoStart Plus Pad dressings to the formulary in line with the discussion	Formulary team	Complete

19/55	Consideration of UrgoStart Plus Pad: Remove UrgoStart 12cm x 19cm (heel) dressings from the formulary	Formulary team	Complete
19/56	Consideration of Buprenorphrine (Espranor®) oral lyophilisates: Contact the NHS England Controlled Drugs Accountable Officer regarding inclusion	Formulary team	Complete
19/57	Consideration of Buprenorphrine (Espranor®) oral lyophilisates: Amend proposed entry in line with the discussion and circulate for agreement via the e-FIG process	Formulary team	Complete
19/58	Consideration of ibandronic acid classification – change in formulary status: Review risedronate entry indications and formulations	Formulary team	Complete
19/59	Consideration of ibandronic acid classification – change in formulary status: Amend proposed entry in line with the discussion and circulate proposed changes to risedronate sodium entry for agreement via the e-FIG process	Formulary team	Complete
19/60	Items not routinely prescribed in primary care (2019 update): Amend proposed aliskiren entry in line with the discussion and circulate for agreement via the e-FIG process	Formulary team	Outstanding
19/61	Items not routinely prescribed in primary care (2019 update): Amend current bath and shower preparations entry to add a link to NHSE/NHSCC guidance	Formulary team	Complete
19/62	Items not routinely prescribed in primary care (2019 update): 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	Complete
19/63	Items not routinely prescribed in primary care (2019 update): Amend pen needles entry to add NHSE/NHSCC recommendation and add a link to NHSE/NHSCC guidance	Formulary team	Complete
19/64	Items not routinely prescribed in primary care (2019 update): add GlucoRx Care Point needles in line with the discussion	Formulary team	Complete
19/65	Items not routinely prescribed in primary care (2019 update): Reclassify BD Viva and GlucoRx Finepoint needles to blue	Formulary team	Complete
19/66	Items not routinely prescribed in primary care (2019 update): Remove Microdot Droplet (all sizes) and Omnican Fine (31G) needles in line with the discussion	Formulary team	Complete
19/67	Items not routinely prescribed in primary care (2019 update): Add an entry stating that safety needles should not be prescribed on FP10 in line with the discussion	Formulary team	Complete
19/68	Items not routinely prescribed in primary care (2019 update): Add the NHSE/NHSCC recommendation for silk garments and a link to NHSE/NHSCC guidance	Formulary team	Complete

19/69	Psoriasis management review: Contact dermatologists regarding Neutrogena and T/Gel shampoo preparations for psoriasis	Formulary team	Outstanding
19/70	Psoriasis management review: Update the psoriasis formulary guidance section in line with discussion	Formulary team	Outstanding
19/71	Chronic Obstructive Pulmonary Disease (COPD) guidance update: Provide any specific recommendations or requests for changes to inhaler options for the treatment of COPD to the Formulary team during the next month	FIG members	Outstanding
19/72	Non-steroidal anti-inflammatory drugs (NSAIDs) formulary entry update: Update the non-steroidal anti-inflammatory drugs (NSAIDs) formulary entry in line with discussion	Formulary team	Complete
19/73	Gender dysphoria and transgender prescribing: add the formulary information for gender dysphoria and transgender prescribing in line with the discussion	Formulary team	Complete
19/74	MHRA Drug Safety Update: Add title and link to advice for healthcare professionals for Lemtrada (alemtuzumab) to the formulary	Formulary team	Complete
19/75	MHRA Drug Safety Update: Add title and link to advice for healthcare professionals for Tofacitinib (Xeljanz) and EMA safety review statement to the formulary	Formulary team	Complete
19/76	MHRA Drug Safety Update: add title and link to advice for healthcare professionals for Magnesium sulfate to the formulary.	Formulary team	Complete
19/77	MHRA Drug Safety Update: Direct-acting oral anticoagulants (DOACs) – add information from the MHRA Drug Safety Update	Formulary team	Complete
19/78	MHRA Drug Safety Update: GLP-1 receptor agonists – add information from the MHRA Drug Safety Update	Formulary team	Complete
19/79	MHRA Drug Safety Update: add a note that the EU marketing authorisation has been withdrawn / remove olaratumab from the formulary when the TA has been withdrawn	Formulary team	Complete
19/80	MHRA Drug Safety Update: Oral retinoid medicines – add information from the MHRA Drug Safety Update. Where appropriate, information will also be added to the topical retinoid products in the formulary	Formulary team	Complete