The Devon Formulary and Referral

NHS Devon

http://www.devonformularyguidance.nhs.uk/

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 29th January 2025

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Glen Allaway (Chair)	GP	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Stuart Crowe	GP	NHS Devon ICB
Jess Danielson	GP	NHS Devon ICB
Lucy Harris	GP	NHS Devon ICB
Susie Harris	Consultant Physician/Geriatrician	RDUH NHS FT
Matt Howard	Senior Clinical Effectiveness Manager	NHS Devon ICB
Anne Jones	NHS Cornwall and the Isles of Scilly ICB	NHS Kernow ICB
Carole Knight	Medicines Information Pharmacist	RDUH NHS FT
James Leavy	Medicines Information Pharmacist	RDUH NHS FT
Rebecca Lowe	Joint Formulary Pharmacy Technician	NHS Devon ICB
Sarah Marner	Senior MO Pharmacist	NHS Devon ICB
Jess Parker	GP	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

Guests:

Name	Job Title	Organisation
Jonathan Digby-Bell	Consultant Gastroenterologist	RDUH NHS FT
Sarah Levy	Consultant Ophthalmologist	UHP NHS Trust

Observers:

Name	Job Title	Organisation
Rayhan Toraub	Trainee Pharmacist	RDUH NHS FT
Greeshma Babususan	Trainee Pharmacist	RDUH NHS FT

In attendance:

Name	Job Title	Organisation
Fiona Dyroff	Senior Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Glen Allaway explained the meeting etiquette.

Chairman's welcome

Attendees were welcomed to the meeting of the Devon Formulary Interface Group. Glen Allaway thanked Nick Keysell for chairing the last meeting of the Devon FIG.

Apologies

NAME	JOB TITLE	ORGANISATION
Andy Craig	GP	NHS Devon ICB
Alisha Kaliciak	GP	NHS Devon ICB
Nick Keysell	GP	NHS Devon ICB
Chris Sullivan	Deputy Chief Pharmacist	Devon Partnership NHS Trust

Declarations of Interest

The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item.

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Mycophenolate mofetil indications (thyroid eye disease / Grave's orbitopathy and bullous pemphigoid) **Mycophenolate mofetil** • 500mg tablets, 250mg capsules and 1g/5ml sugar free oral suspension **Mycophenolic acid** • 180mg and 360mg gastro-resistant tablets	 Various manufacturers Various manufacturers
Ferric Maltol (Feraccru®) **for iron deficiency anaemia in inflammatory bowel disease** Alternative treatments: **Oral iron supplements including:** Ferrous fumarate, Ferrous sulfate, Ferrous gluconate and Sodium feredetate **Parenteral iron including:** Ferinject, Venofer Diafer, CosmoFer and Ferric derisomaltose	Norgine Limited Various manufacturers Vifor Pharma UK Limited, Pharmacosmos UK Limited
Dymista (Azelastine hydrochloride and fluticasone propionate) nasal spray for allergic rhinitis Alternative treatments: Intranasal steroids Intranasal and oral antihistamines Grass pollen extract Tree pollen extract	Mylan (Viatris) Various manufacturers Various manufacturers Allergy Therapeutics (UK) Ltd, ALK-Abello Ltd Allergy Therapeutics (UK) Ltd
Thickeners, pre-thickened drinks, and desserts: • Carobel Instant • Thixo-D Original	 Nutricia Ltd Ecogreen Technologies Ltd

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
• Feed thickeners, pre-thickened drinks, and semi-solid desserts	Includes, but is not limited to: Fresenius Kabi Ltd, Nualtra Ltd, Slõ Drinks Ltd
Dienogest for endometriosis Dienogest • Dimetrum, Sawis, Zalkya Alternatives: • Various combined contraceptives (including pill, vaginal ring, transdermal patches) • Various progestogens (including pill, levonorgestrel intra-uterine device, levonorgestrel implant, depot medroxyprogesterone acetate) • Various gonadorelin agonists • Linzagolix (Yselty) • Ryego	 Besins Healthcare (UK) Ltd, Kent Pharma (UK) Ltd, Gedeon Richter (UK) Ltd Various manufacturers Various manufacturers Various manufacturers Theramex UK Ltd Gideon Ritcher (UK) Ltd
Human and animal bites • Co-amoxiclav tablets and oral suspension • Co-trimoxazole tablets and oral suspension • Doxycycline capsules • Metronidazole tablets	 Various manufacturers

Antivirals for influenza
• Oseltamivir
  ○ Elbifumin
  ○ Tamiflu
• Relenza
	
	Teva UK Ltd
	Roche Products Ltd
	GlaxoSmithKline UK Ltd

Management of scabies: • Ivermectin oral tablets • Permethrin cutaneous cream • Malathion cutaneous emulsion • Crotamiton cutaneous cream • Hydrocortisone cutaneous cream / ointment • Chlorphenamine oral tablets / oral solution	 Exeltis UK Ltd Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers
MHRA Safety Update **Topiramate containing medicines** Alternatives: • Various anti-epileptics, various medicines for migraine prophylaxis	 Various manufacturers Various manufacturers
MHRA Safety Update **Valproate containing medicines** Alternatives: • Various anti-epileptics and antipsychotics	 Various manufacturers Various manufactures

e-FIG ITEM	PHARMACEUTICAL COMPANY/ MANUFACTURER
Penicillamine updates (including withdrawal of shared care guideline) • Penicillamine tablets Alternative treatments • Other DMARDs and biologics for the treatment of rheumatoid arthritis	 Various manufacturers Various manufacturers
Sulfasalazine updates: harmonisation of formulary entry and discontinuation of Salazopyrin brand • Sulfasalazine (tablets, gastro-resistant tablets, oral suspension)	 Various manufacturers
Treatment of seborrhoeic dermatitis • Betamethasone valerate 0.025% cream/ointment **(Betnovate RD)** / 0.1% scalp application **(Betnovate)** / Clobetasone 0.05% cream/ointment **(Eumovate)** • Clotrimazole 1% cream (generic and branded **[Canesten])** • Hydrocortisone 1% cream/ointment • Ketoconazole 2% cream **(Daktarin Gold/Intensiv, Nizoral)** • Ketoconazole 2% shampoo (generic and branded **[Dandrazol, Nizoral])** • Miconzole 2% cream **(Daktarin, Daktarin Aktiv)** • Mometasone furoate 0.1% scalp application **(Elocon)** • Pimecrolimus 1% cream **(Elidel)** • Tacrolimus 0.03% ointment **(Protopic)** • Tacrolimus 0.1% ointment (generic and branded **[Protopic])**	 GlaxoSmithKline UK Ltd Various manufacturers (including Bayer Plc) Various manufacturers McNeil Products Ltd, Thornton & Ross Ltd Various manufacturers (including Crescent Pharma Ltd, Thornton & Ross Ltd) McNeil Products Ltd, Thornton & Ross Ltd Organon Pharma (UK) Ltd Viatris UK Healthcare Ltd LEO Pharma Various manufacturers (including LEO Pharma)
Latanoprost-netarsudil • Roclanda Alternatives: Various eyedrops (including prostaglandin analogues, prostamides, sympathomimetics, Carbonic anhydrase inhibitors and miotics	 Santen UK Ltd Various Manufacturers

Name	Job Title	Declaration
Rebecca Lowe	Joint Formulary Pharmacy Technician	I have secondary employment in Day Lewis Pharmacies

2. Minutes of the meeting held on Wednesday 27th November 2024 and Actions

Minutes of the meeting held on Wednesday 27th November 2024

The minutes of the meeting held on Wednesday 27th November 2024 were approved.

Action log update

The action log was reviewed.

3. Matters Arising

Recent Drug Decisions (November 2024 to December 2024)

The FIG received a report of the recent drug decisions.

NICE TA1026: Tirzepatide for managing overweight and obesity

TA1026: Tirzepatide for managing overweight and obesity was published in December 2024. Tirzepatide will be added to the Devon Formulary as a red option for use in the specialist weight management services for the purposes of weight management in line with NICE TA1026.
Implementation of TA1026 is determined by NICE and NHS England. The national plan for the future is for a phased delivery to patient cohorts in other settings, including primary care-based services, based on NHS England prioritisation criteria.

Until further communication, use of tirzepatide for weight management purposes remains with the specialist weight management service.

A discussion took place, the FIG noted:

- the importance of keeping the indications for treatment with tirzepatide separate. Tirzepatide remains blue (second-line) for use in type 2 diabetes in line with NICE TA924. The tirzepatide entry for use in diabetes and the entry for weight management are listed in separate sections of the formulary.
- that this is an evolving situation, and the drug entry for tirzepatide for weight management should indicate that the national plan is for primary-care based services to deliver tirzepatide in the future.
- Tirzepatide will be brought to a future FIG meeting with a proposal for reclassification when national plans have been communicated and discussions have taken place locally.

4. e-FIG Decisions

In December 2024 the FIG were asked to consider four items via the e-FIG process. These were:
Penicillamine updates (including withdrawal of shared care guideline)

- Sulfasalazine updates: harmonisation of the formulary entry and discontinuation of Salazopyrin brand
- Management of seborrhoeic dermatitis: update
- NICE TA1009: Latanoprost-netarsudil for previously treated primary open-angle glaucoma or ocular hypertension

Responses received indicated acceptance of the proposals.

ACTION 24/110: Withdraw the penicillamine shared care guideline and update the penicillamine formulary entry in line with the proposals.

ACTION 24/111: Update the sulfasalazine formulary entry and relevant Shared Care / SMS guidelines in line with the proposals

ACTION: 24/112: Publish the updated guidance for seborrhoeic dermatitis in line with the proposals.

ACTION: 24/113: Publish the formulary entry for latanoprost-netarsudil eye drops in line with the proposals.

5. Mycophenolate mofetil indications (thyroid eye disease / Grave's orbitopathy and bullous pemphigoid)

A consultant Ophthalmologist from UHP was present for discussion of this item.

A draft SMS guideline for patients within dermatology, ophthalmology and neurology services was presented to the FIG on Wednesday 27th November 2024. Overall, the FIG supported the proposed guideline and accepted several indications for treatment with mycophenolate mofetil in the SMS guideline.

In November, the FIG did not accept thyroid eye disease or scleritis as approved indications. Guidance from the European Group on Graves' orbitopathy (EUGOGO) includes mycophenolate as a treatment option, however a consensus statement published by the American and European Thyroid Associations (ATA and ETA) conflicts with this and as such left room for doubt regarding whether mycophenolate mofetil could be considered a standard treatment for this condition. It was noted that this applied to a very small number of patients in Devon. The FIG also requested several amendments to the guideline in relation to contraception and exclusion of pregnancy prior to treatment initiation.

During consultation on the changes requested by the FIG at the November meeting, a request was received from a consultant dermatologist for addition of bullous pemphigoid as an indication. A number of resources were identified indicating that mycophenolate mofetil is a recognised standard treatment for bullous pemphigoid. Ophthalmology specialists also requested reconsideration of thyroid eye disease. The updated guidance was presented to the FIG.

Further feedback had been received from local specialists confirming that EUGOGO guidance is routinely used in Devon.

The specialist present explained that the ATA/ETA position raised concerns about the most recent EUGOGO guidelines positioning mycophenolate as a potential first line option, whereas in practice it is usually reserved for use later in the treatment pathway. The specialist also noted that American Thyroid Association does not routinely use mycophenolate mofetil for thyroid eye disease/Grave's orbitopathy as they have other drugs available to them in the U.S.

The FIG considered and accepted the formulary guidance, including the amendments to the specialists' responsibilities with regard to contraception and the exclusion of pregnancy prior to treatment initiation.

The FIG considered and accepted the inclusion of thyroid eye disease and bullous pemphigoid as approved indications in the SMS guideline for mycophenolate mofetil.

ACTION 25/01: Update the SMS guideline for mycophenolate mofetil and mycophenolic acid for patients within adult dermatology, ophthalmology and neurology services (Devon wide) in line with the discussion and submit to LMC for negotiation of remuneration with the ICB primary care team

ACTION 25/02: Publish updated SMS guideline for mycophenolate mofetil and mycophenolic acid for patients within adult dermatology, ophthalmology and neurology services (Devon wide)

6. Ferric maltol for iron deficiency anaemia in inflammatory bowel disease

A consultant Gastroenterologist from RDUH was present for discussion of this item.

The FIG was asked to consider a proposed formulary entry for ferric maltol, following organisational sign off by NHS Devon ICB of a clinical commissioning policy. The policy committee had recommended the FIG should consider ferric maltol for an amber listing in the formulary.

Ferric maltol is an iron replacement therapy licenced for treating iron deficiency anaemia (IDA) in adults. The product is currently available as 30mg capsules, with a recommended dosage of one capsule twice daily, taken on an empty stomach.

A 4-week trial of ferric maltol is routinely commissioned for the treatment of iron deficiency anaemia in patients with inflammatory bowel disease in whom 2 standard oral iron preparations have been ineffective or not tolerated. If following a 4-week course of treatment, a clinically acceptable haematological response has been achieved, treatment may continue for a further 12 weeks.

The FIG considered and accepted, with minor amendment, the formulary entry for ferric maltol for IDA in IBD disease with an amber (specialist input) classification.

There was discussion about:

- Initiation of treatment and the formulary classification - it was agreed to embolden the note that “treatment must be initiated by a gastroenterology specialist.”
- A specialist present explained that administration of iron infusions can be difficult. Ferric maltol is safer and much easier to administer.
- Ferric maltol is significantly more expensive than standard oral iron preparations but may result in system financial savings only if the patient would otherwise have received intravenous iron.

ACTION 25/03: Publish the ferric maltol drug entry in line with the discussion

7. Fluticasone propionate and azelastine combination nasal spray (Dymista) for allergic rhinitis

The FIG was asked to consider a proposed formulary entry for fluticasone propionate and azelastine combination nasal spray, following organisational sign off by NHS Devon ICB of a clinical commissioning policy.

Fluticasone propionate and azelastine nasal spray is licenced for the management of moderate to severe allergic rhinitis in children and adults when monotherapy with either intranasal antihistamine or corticosteroid is not sufficient. The recommended dosage is one spray in each nostril twice daily.

Fluticasone propionate and azelastine nasal spray is routinely commissioned for the management of moderate to severe symptoms of allergic rhinitis where allergy specialists (adult immunology services, or specialists in paediatric allergy management) have optimised treatment with standard combination therapies. It was proposed for inclusion in the formulary as amber (specialist input).

Evidence from clinical trials demonstrates that the use of fluticasone propionate and azelastine nasal spray results in superior outcomes compared with monotherapy using either intranasal corticosteroids or antihistamines. No evidence is available which compares fluticasone propionate and azelastine nasal spray to combined therapy using both an intranasal corticosteroid and a nasal/oral antihistamine. However, fluticasone propionate and azelastine nasal spray is recommended as a treatment option for allergic rhinitis in a range of national and professional guidelines. Local specialists suggested that the use of a single spray would result in better concordance to treatment and improved outcomes compared with the use of two intranasal separate products.

The acquisition cost of fluticasone propionate and azelastine nasal spray is higher than an antihistamine and an intranasal corticosteroid, however it may prevent some patients requiring more costly treatment with immunotherapy.

Feedback received from the immunology department, University Hospitals Plymouth, after the meeting papers were distributed was presented at the meeting.

An application for the routine funding of Dymista in Devon was received from adult immunology specialists at UHP, and paediatric allergy specialists at RDUH. ENT specialists were given the opportunity to take part in the consultation on the application but did not respond to e-mails.

The FIG considered and accepted the formulary entry for Fluticasone propionate and azelastine combined nasal spray (Dymista) for allergic rhinitis with minor amendment. There was:

- Broad discussion about initiation of treatment. The policy applies to allergy specialists (adult immunology services, or specialists in paediatric allergy management) and does not allow for treatment to be initiated by ENT specialists. Allergy specialists are best placed to optimise other treatments prior to initiating Dymista. The FIG requested that it be made clear in the notes section that initiation is only to be via allergy specialists. ENT specialists will have to refer patients to Allergy Specialists for treatment with Dymista to be considered.
- It was agreed to embolden ‘secondary care allergy specialists’ in the notes section
- A Scriptswitch message was proposed to reiterate that the policy only applies to allergy specialists (adult immunology services, or specialists in paediatric allergy management)

ACTION 25/04: Publish the fluticasone propionate and azelastine hydrochloride nasal spray drug entry in line with the discussion

8. Thickeners, pre-thickened drinks and desserts

The Royal College of Speech and Language Therapists (RCSLT) published a position paper on the use of thickened fluids in January 2024. This and a preceding statement, in March 2023, were developed in response to RCSLT members requesting guidance on the use of thickened fluids in the management of dysphagia.

Following publication of the position paper, the Formulary Team received a request from Torbay and South Devon SLT teams for a change in the way that thickened fluids should be prescribed, with a recommendation that they are no longer suitable as a general prescribable aid to help dysphagia. The existing N&E Devon and S&W Devon formulary recommendations for thickeners, prethickened drinks, and desserts differ in their supporting information and product recommendations. The formulary team undertook a review of this subsection with local SLT teams, with the intention of providing harmonised Devon-wide recommendations. This includes a proposal to classify all thickeners/thickened fluids as amber (specialist input) prior to continuation in primary care. Local SLT and dietitian specialists were consulted; responses received indicated broad acceptance of the proposals (recognising that there may be increased SLT workload to ensure clinically appropriate use of these products).

It was noted that patients already being prescribed thickened fluids in primary care need not be reviewed by specialists unless GPs felt that the patient required intervention.

During the consultation, specialists noted that the formulary does not include thickening products suitable for children under 3 years of age or supporting information for paediatric patients; they proposed addition of Carobel Instant and Thixo-D Original. It was noted that Carobel may be considered for reflux in infants/babies without specialist input. Inclusion of the proposed products in the formulary is not expected to have a significant impact on expenditure.

The FIG considered and accepted the proposed amendments to the formulary pre-thickened drinks and desserts, including the addition of the thickeners Carobel Instant and Thixo-D Original for paediatric patients, to the Devon formulary.

There was discussion about prescribing during end-of-life care. It was agreed that a pragmatic approach be taken, and that GPs will use their own judgement regarding starting thickeners without specialist input.

ACTION 25/05: Publish updates to thickeners, pre-thickened drinks and deserts in line with the discussion.

9. Dienogest for endometriosis

An application for the addition of dienogest 2mg tablets to the Devon Formulary has been received from Consultant Gynaecologists and Joint Leads for Endometriosis, RDUH NHS Foundation Trust. Support for the addition of dienogest to the formulary was also received from a specialist at UHP and at T&SD NHS Foundation Trust.

Dienogest is a progestogen licensed for the treatment of endometriosis. It has been proposed for addition to the Devon Formulary as amber (specialist-input) for endometriosis when initial hormonal therapy (for example, the combined oral contraceptive pill or a progestogen) is ineffective or not tolerated or contraindicated.

NICE considers there is no difference in the effectiveness of hormonal treatment for endometriosis based on evidence from clinical trials. The European Society of Human Reproduction and Embryology (ESHRE) guidance states that in clinical practice the efficacy and side-effect profiles of hormonal therapies are highly individual.

The treatment pathway following first-line therapy for endometriosis varies between patients and may involve surgery. GnRH agonists are a second-line pharmacological option; however, they are licensed for six months use only due to concerns about loss of bone mineral density.

Two RCTs supporting the licensing of dienogest, were conducted in patient groups without a primary need for surgery. Dienogest was found to be non-inferior compared with a gonadotropinreleasing hormone (GnRH) agonist for endometriosis associated pelvic pain and to be well tolerated with few patients discontinuing treatment prematurely due to adverse events in the comparison with the GnRH agonist and in a placebo-controlled trial.

Dienogest offers a long-term second-line oral option which is cost saving compared with GnRH agonists. The annual cost of dienogest per patient is £266.50 OpenPrescribing data indicate that in the 12 months from November 2023 to October 2024, 197 items were issued for dienogest in primary care in Devon, at a total actual cost of £5,318.

The FIG considered and accepted the addition of dienogest 2mg tablets to the Devon formulary with an amber (specialist) classification with minor amendments to the order of the notes section.

The discussion included that:

- It is important to make it clear in the formulary entry that dienogest 2mg tablets are not a contraceptive. This should be highlighted in the indication and the notes. The entry should also highlight that any additional hormone treatments should be stopped when dienogest 2mg tablets are initiated. • There was discussion on the applicant's request for an amber classification given that hormonal products are well established as a first-line option and there are no additional requirements for treatment with dienogest. However, it was noted that discussion with a specialist is required if a first-line treatment is ineffective, contraindicated or not tolerated to determine the appropriate treatment (pharmacological or surgery) according to the patient's priorities and severity of their condition.
- The FIG considered that prescribing in primary care on the advice of a specialist would be acceptable as the use of hormonal treatments, including progestogens, as a first-line option is well established.

ACTION 25/06: Add dienogest tablets to the formulary as an amber (specialist input) option in line with the discussion.

10. Human and animal bites

It is part of NHS England's "National medicines optimisation opportunities 2024/25" to reduce the course length of antimicrobial prescribing to address antimicrobial resistance and decrease their carbon footprint. This prompted a review of the formulary guidance on human and animal bites to ensure recommendations are in line with NHS England's priorities and NICE NG184: Human and animal bites: antimicrobial prescribing (NICE, 2020).

Feedback received from specialists after the meeting papers were circulated was shared with the FIG.

The FIG accepted a proposal to restructure this section of the formulary; moving the individual subsections from the 'Skin and soft tissue infections' page into their own sub-pages; the FIG agreed for the information about streptococcal infections to be duplicated at the top of each sub-page.

The FIG considered and accepted the formulary guidance without amendment. There was discussion about:

- Virtual rather than face to face assessments of bites. This was considered to be acceptable with safety netting.
- The availability of co-trimoxazole in community pharmacy as it is not currently routinely used. However, it was noted that there is already some prescribing of co-trimoxazole in primary care in Devon and it is stocked by local wholesalers, so should be available with minimal delay.
- Clarification of the dose of doxycycline.

ACTION 25/07: Publish updates to guidance on human and animal bites in line with the discussion.

11. Section 5.3.4 Influenza: Reclassification of oseltamivir and zanamivir

The FIG was asked to consider a proposal for the harmonisation and updating of section 5.3.4 Influenza, including the reclassification of oseltamivir and zanamivir for the treatment and prophylaxis of influenza. Currently, oseltamivir and zanamivir are blue (second-line) in North & East Devon and amber (specialist-input) in South & West Devon. The current traffic light classifications for oseltamivir and zanamivir reflect the decisions of the predecessor FIGs.

The proposal included that oseltamivir and zanamivir are both reclassified to green (first-line) and a link to the UK Health Security Agency (UKHSA) guidance for the prescribing of these drugs is added to the formulary entries.

A review of the traffic light classification for oseltamivir and zanamivir in other formularies in the NHSE south-west England region found that five of the six formularies list oseltamivir as green and four formularies list zanamivir for inhalation as green. Zanamivir is not listed in the Cornwall & Isles of Scilly Formulary. Oseltamivir and zanamivir are not listed in the Gloucester Formulary.

The FIG considered and accepted the update to Section 5.3.4 Influenza: Reclassification of oseltamivir and zanamivir of the formulary with minor amendment. A discussion took place and it was agreed that the wording be made clearer on when GPs can prescribe antivirals and when they should be prescribed only via a commissioned service.

ACTION 25/08: Reclassify oseltamivir and zanamivir oral preparations to green (first line) and publish updates to section 5.3.4 influenza in line with the discussion

12. Management of scabies (including application of oral ivermectin 3mg tablets)

An application was received from a specialist dermatology pharmacist, supported by a consultant dermatologist and clinical lead of dermatology at RDUH for the addition of oral ivermectin 3mg tablets to the Devon formulary, for the treatment of human sarcoptic scabies.

Existing Devon Formulary recommended topical agents for the treatment of scabies are permethrin cream as first line and malathion liquid second line, if permethrin is not suitable. Additional guidance notes are limited. The product application prompted a review of Devon Formulary guidance on the

management of scabies, which included consideration of updated guidance from NICE CKS, the British Association of Dermatologists (BAD), UK Health Security Agency (UKHSA), and the British Association for Sexual Health and HIV (BASHH).

The applicant proposed that oral ivermectin tablets should be included as a blue (second line) option, for use in the following circumstances:

- If first line topical treatments (permethrin and/or malathion) have not resolved the symptoms and there is evidence of ongoing infestation with the presence of burrows, etc.
- If topical treatments are difficult to access or are unavailable.
- In conditions where topical treatments may be difficult to apply effectively, e.g. in care home settings, patients who cannot use creams or lotion and where treatment of large numbers of persons is required.

The applicant also proposed that oral ivermectin tablets should be used first line together with topical treatments for crusted scabies.

Ivermectin has been available as an unlicensed medicine in the UK on a named-patient basis from 'special order' manufacturers or specialist importing companies. A licensing application for ivermectin 3mg generic tablets was approved by the MHRA in 2024. The MHRA Public Assessment Report (PAR) for the licensed product was identified. The licensing of the 3mg generic tablets was supported by a study demonstrating bioequivalence of the generic tablets with the European reference product (Stromectol).

Oral ivermectin 3mg tablets cost £49.20 for 4 tablets. The dose is 200 micrograms/kg, with a second dose advised after 7 days to deal with recently hatched mites. Depending on the dose required, use of oral ivermectin tablets would be expected to increase drug acquisition costs in excess of £113.00 per patient per treatment course.

For the period of October 2023 to September 2024 prescribing data (ePACT2) show a total expenditure of over £350,000 for scabicides, including £159,352 of oral ivermectin. It is not possible to make a reasonable estimation of the current spend on drugs for scabies as these medicines are also used for other infestations.

NICE CKS, BAD and BASHH all recommend oral ivermectin within the treatment pathway for scabies.

Local dermatology and microbiology specialists were asked for their views on the proposed addition of ivermectin oral tablets to the formulary and were in support of inclusion, whilst also recognising the potential for increased expenditure.

Specialists proposed additional (unlicensed) second line treatments during the consultation; however, they were made aware that many of these did not appear to be routinely available in primary care and it was agreed to not make specific recommendations for these product(s) where there are likely to be difficulties in obtaining supplies of unlicensed specials. It was recognised that topical permethrin and malathion, and oral ivermectin will be appropriate for most cases, but that there may an occasional need for conversations between the specialist and GP on an individual patient basis to enable supply of an appropriate unlicensed, non-formulary alternative treatment in severe cases.

The FIG considered and accepted the proposed formulary guidance for the management of scabies with minor amendment. The discussion included:

- A suggestion that a link be added to the Myhealth Devon website to support compliance with the topical permethrin regime.

- Clarification of the wording on dosing.
- If topical treatment and one course of ivermectin (two doses) fails a specialist referral should be made.

The FIG considered and accepted the addition of oral ivermectin 3mg tablets to the Devon Formulary as a 'blue' option for the treatment of classical and crusted scabies.

ACTION 25/09: Publish updates to guidance on management of scabies in line with the discussion

ACTION 25/10: Add ivermectin 3mg tablets to the formulary as a blue (second line) option and publish updates to other drug entries in section 13.10.4 in line with the discussion

13. MHRA Drug Safety Updates (December 2024)

The FIG received the MHRA Drug Safety Update for December 2024. There were no articles on specific safety issues.

Letters sent to healthcare professionals

Welireg (belzutifan) Patient alert cards

Belzutifan is included in the formulary as red in line with NICE TA1011 for treating von Hippel-Lindau (VHL) disease. A patient alert card should be provided to all patients to provide guidance on the risks of treatment associated hypoxia. A link to the patient alert card will be added to the formulary entry for belzutifan.

The MHRA Drug Safety Updates for January 2025 will be brought to the next FIG meeting.

14. Any other business

It was noted that consultant recruitment to the group is needed. The Formulary team is escalating this issue within the health system.

END