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ADTC Newsletter

New Drugs and Therapeutic Advances

Outlined in this newsletter are the recommendations for new drugs which have been through the locally agreed process (see appendix 1).
Please remember that the ADTC advises prescribers **not** to prescribe any drug that has not been recommended by Scottish Medicines Consortium (SMC) or has not yet been considered by SMC.

Where a medicine is not recommended for use by the Scottish Medicines Consortium (SMC) for use in NHS Scotland, including those medicines not recommended due to non-submission, this will be noted by the Area Drug and Therapeutics Committee New Drugs & Formulary Sub Group and the medicine will not be added to the NHS Forth Valley Formulary.

Where a medicine that has not been accepted by the SMC or NHS Health Improvement Scotland (HIS) following their appraisal on clinical and cost-effectiveness, there are Individual Patient Treatment Request (IPTR) and Peer Approved Clinical System (PACS) processes which provides an opportunity for clinicians i.e. hospital Consultants or General Practitioners to pursue approval for prescribing, on a “case by case” basis for individual patients

A copy of these policies can be found at the Pharmacy page on the Quality Improvement Website on the following link: https://guidelines.staffnet.fv.scot.nhs.uk/pharmacy-and-precribing/

GUIDELINES AND POLICIES

All guidelines and policies approved by the Area Drug and Therapeutics Committee can be found on the Quality Improvement Website on the link below.

http://guidelines.staffnet.fv.scot.nhs.uk/

Drugs Not Approved By the Scottish Medicines Consortium

Prescribing of SMC non-recommended drugs is monitored nationally by the Information Services Directorate (ISD) of the NHS National Services Scotland and reported to the Forth Valley Primary Care Pharmacy Services. As part of our locally agreed process, practices will be routinely notified on a quarterly basis of any items which are not recommended for use, and advised to review therapy.

The Acute Services will similarly be monitoring the use of SMC non-recommended drugs and will feedback usage to their Executives via the Finance Report.

All information provided by this newsletter constitutes the most current advice of the Forth Valley Area Drug and Therapeutic Committee. All SMC information and decisions are correct at time of issue, but may be liable to change in the future. For full **SMC advice** on specific drugs please refer to the SMC website www.scottishmedicines.org

Category Classification

Drugs Approved / Not Recommended By SMC

Category 1	Available in line with national guidance (link to SMC Detailed Advice Document (DAD) included)
Category 2	Available in line with local guidance for prescribing
Category 3	Available from a specialist centre in another NHS Board
Category 4	Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Category 5	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance if appropriate)
Category 6	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
MICROBIOLOGY			
Oritavancin 400mg powder for concentrate for solution for infusion (Tenkasi®) SMC Number 2285 https://www.scottishmedicines.org.uk/media/6858/oritavancin-orvactiv-resubmission-final-september-2020-amended-140222-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. SMC restriction: patients with confirmed or suspected methicillin-resistant Staphylococcus aureus (MRSA) infection who are eligible for early discharge. Use should be on the advice of local microbiologists or specialists in infectious disease.	Category 5 – not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	**N/A**
Delafloxacin 450mg tablets and 300mg powder for concentrate for solution for infusion (Quofenix®) SMC Number 2453 https://www.scottishmedicines.org.uk/media/6983/delafloxacin-quofenix-final-june-2022-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of this infection.	Category 5 – not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	**N/A**
RENAL			
Dapagliflozin 10mg film-coated tablets (Forxiga®) SMC Number 2428 https://www.scottishmedicines.org.uk/media/6871/dapagliflozin-forxiga-final-april-2022-amended-290422-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: in adults for the treatment of chronic kidney disease. SMC Restriction: • in patients with an estimated glomerular filtration rate of ≥25 to ≤75mL/min/1.73m2 at treatment initiation, and • are receiving an angiotensin converting enzyme inhibitor or angiotensin receptor blocker (unless these are not tolerated or contraindicated), and • have a urine albumin creatinine ratio of at least 23mg/mmol, or type 2 diabetes mellitus or both.	Category 1 – available in line with national guidance for prescribing Suitable for initiation in Primary Care *A West of Scotland guideline on the management of CKD in primary care is being developed to ensure appropriate prescribing*	**Acute Specialist Services & Primary Care**
Potassium citrate and potassium hydrogen carbonate 8mEq and 24mEq prolonged-release granules (Sibnayal®) SMC Number 2409 https://www.scottishmedicines.org.uk/media/7046/potassium-citrate-potassium-hydrogen-carbonate-sibnayal-	Accepted for use within NHSScotland. Indication under review: for the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one year and older.	Category 3 – available from a specialist centre in another NHS board	**N/A**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
final-march-2022-amended-080722-for-website.pdf			
SPECIALIST TERTIARY CENTRE			
Odevixibat 200, 400, 600 and 1,200 microgram hard capsules (Bylvay®) SMC Number 2411 https://www.scottishmedicines.org.uk/media/6986/umar-odevixibat-bylvay-final-march-2022-amended-5522-for-website.pdf	The Scottish Medicines Consortium (SMC) has completed its initial assessment of the evidence for the above product using the ultra-orphan framework: Indication under review: For the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older.	Category 3 – available from a specialist national centre in NHS England	**N/A**

SMC NOT RECOMMENDED – The following drugs for the indication stated are all classified as **Category 4** i.e. Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)	
Enfortumab vedotin 20mg and 30mg powder for concentrate for solution for infusion (Padcev®) SMC Number 2505 https://www.scottishmedicines.org.uk/media/6984/enfortumab-vedotin-padcev-non-sub-final-june-2022-for-website.pdf	Indication under review: As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor.
Remimazolam 20mg powder for solution for injection (Byfavo®) SMC Number 2454 remimazolam-byfavo-final-july-2022-for-website.pdf (scottishmedicines.org.uk)	Indication under review: in adults for procedural sedation.
Vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®) SMC Number 2506 https://www.scottishmedicines.org.uk/media/6987/vedolizumab-entyvio-non-sub-final-june-2022-for-website.pdf	Indication under review: treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy.
Zanubrutinib 80mg hard capsules (Brukinsa®) SMC Number 2452 https://www.scottishmedicines.org.uk/media/7095/zanubrutinib-brukinsa-final-july-2022-amended-030822-for-website.pdf	Indication under review: as monotherapy for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
Bimekizumab 160mg solution for injection in pre-filled syringe and pre-filled pen (Bimzelx®) SMC Number 2410 https://www.scottishmedicines.org.uk/media/6429/bimekizumab-bimzelx-abb-final-october-2021-for-website.pdf	Indication under review: treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 2 – Available in line with local guidance for prescribing	Hospital Specialist use only. *Will be used 3rd line or beyond in line with local treatment pathway for plaque psoriasis*
Tralokinumab 150mg solution for injection in pre-filled syringe (Adtralza®) SMC Number 2403 https://www.scottishmedicines.org.uk/media/6589/tralokinumab-adtralza-final-december-2021docx-for-website.pdf	Indication under review: treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. SMC restriction: patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 2 – Available in line with local guidance for prescribing	Hospital Specialist use only. *Will be used 2nd line after dupilumab in line with local treatment pathway for atopic dermatitis*
Upadacitinib 15mg and 30mg prolonged-release tablets (Rinvoq®) SMC Number 2417 https://www.scottishmedicines.org.uk/media/6797/upadacitinib-rinvoq-final-march-2022-for-website.pdf	Accepted for use within NHSScotland Indication under review: For the treatment of moderate to severe atopic dermatitia in adults and adolescents 12 years and older who are candidates for systemic therapy SMC restriction: Patients who have had an inadequate response to at least one conventional systemic immunosuppressant such as ciclosporin, or whom such treatment is considered unsuitable.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 2 – Available in line with local guidance for prescribing	Hospital Specialist use only. *Will be used as the 2nd line JAK inhibitor after abrocitinib in line with local treatment pathway for atopic dermatitis*
Abrocitinib 50mg, 100mg, and 200mg film-coated tablets (Cibinqo®) SMC Number 2431 abrocitinib-cibinqo-final-may-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. SMC restriction: for use in patients who have not responded to, or have lost response to, at least one systemic immunosuppressant therapy, or in whom these are contraindicated or not tolerated.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 2 – Available in line with local guidance for prescribing	Hospital Specialist use only. *Will be used as the 1st line JAK inhibitor after dupilumab and tralokinumab in line with local treatment pathway for atopic dermatitis*

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
Olopatadine hydrochloride 600 micrograms / mometasone furoate monohydrate 25 micrograms per actuation nasal spray (Ryaltris®) SMC Number 2418 https://www.scottishmedicines.org.uk/media/6536/olopatadine-hydrochloride_mometasone-furoate-monohydrate-ryaltris-abb-final-nov-2021-for-website.pdf	Indication under review: in adults and adolescents 12 years of age and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis. SMC restriction: for use where monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 5 – Not routinely available as local experts do not wish to add the medicine to the formulary at this time or there is local preference for alternative medicines	**Not Applicable**
Risankizumab 150mg solution for injection in a pre-filled syringe or pen (Skyrizi®) SMC Number 2459 risankizumab-skyrizi-abbreviated-final-march-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use restricted use with NHSScotland Indication under review: Alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs) SMC restriction: (i) patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drugs (DMARDs) therapies but have not received biologic DMARD therapy (biologic-naïve population); (ii) patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and (iii) patients in whom TNF inhibitors are contraindicated or not tolerated	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision pending	
Cenobamate 12.5mg, 25mg, 50mg, 100mg, 150mg, and 200mg film-coated tablets (Ontozry®) SMC Number 2408 cenobamate-ontozry-final-jan-2022-amended-180122-for-website.pdf (scottishmedicines.org.uk)	Accepted for restricted use within NHSScotland. Indication under review: for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite treatment with at least 2 anti-epileptic medicinal products. SMC restriction: in patients with drug-resistant epilepsy as a second-line adjunctive anti-seizure medicine, after	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 1 – available in line with national guidance for prescribing	Hospital Specialist initiation and then continued in primary care *Will be used as the preferred 2nd line adjunctive therapy in patients with*

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
	the failure of the first adjunctive anti-seizure medicine			*resistant epilepsy*
Solriamfetol 75mg and 150mg film-coated tablets (Sunosi®) SMC Number 2439 solriamfetol-sunosi-final-june-2022docx-for-website.pdf (scottishmedicines.org.uk)	Accepted for restricted use within NHSScotland. Indication under review: to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy). SMC restriction: for use in patients who have failed modafinil or have a contraindication or intolerance to modafinil.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 3 – available from a specialist centre in another NHS board	**N/A**
Crizanlizumab 10mg/mL concentrate for solution for infusion (Adakveo®) SMC Number 2438 crizanlizumab-adakveo-final-june-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: for the prevention of recurrent vaso-occlusive crises in sickle cell disease patients aged 16 years and older. It can be given as an add-on therapy to hydroxycarbamide or as monotherapy in patients for whom hydroxycarbamide is inappropriate or inadequate.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 3 – available from a specialist centre in another NHS board	**N/A**
Pegcetacoplan 1,080mg solution for infusion (Aspaveli®) SMC Number 2451 pegcetacoplan-aspaveli-final-june-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for restricted use within NHSScotland. Indication under review: in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months. SMC restriction: under the advice of the national PNH service.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 3 – available from a specialist centre in another NHS board	**N/A**
Empagliflozin 10mg film-coated tablets (Jardiance®) SMC Number 2396 https://www.scottishmedicines.org.uk/media/6334/empagliflozin-jardiance-abbreviated-final-sept-2021-for-website.pdf	Accepted for use within NHSScotland. Indication under review: in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 5 – Not routinely available as local experts do not wish to add the medicine to the formulary at this time or there is local preference for alternative medicines	**N/A**
Fedratinib 100mg hard capsule (Inrebic®) SMC Number 2462 fedratinib-inrebic-abbreviated-final-march-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland Indication under review: For further treatment of disease-related splenomegaly or symptoms in adult patients with primary myelobibrosis, post polycythaemia vera myelofibrosis	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for	Category 5 – Not routinely available as local experts do not wish to add the medicine to the formulary at this	**N/A**

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
	or post essential thrombocythaemia myelofibrosis who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib	further advice from local clinical experts	time or there is local preference for alternative medicines	
Liraglutide 6mg/mL solution for injection in pre-filled pen (Saxenda®) SMC Number 2455 liraglutide-saxenda-resubmission-final-april-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for restricted use within NHSScotland. Indication under review: as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of: • ≥30kg/m² (obese), or • ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea SMC restriction: BMI ≥35kg/m²* (obesity class II and above) with: • Non-diabetic hyperglycaemia (prediabetes) at high risk of type 2 diabetes which is defined as having either: o Fasting plasma glucose level of 5.5 to 6.9mmol/L or o HbA_{1c} of 6.0 to 6.4% (42 to 47mmol/mol), and • High risk of cardiovascular disease (CVD): o Total cholesterol >5mmol/L, or o High-density lipoprotein (HDL) <1.0mmol/L for men and <1.3mmol/L for women, or o Systolic blood pressure (SBP) >140mmHg. Patients should be treated in a specialist weight management service.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 1 – available in line with national guidance for prescribing	See line noted below
Liraglutide - Initiation/recommendation by the weight management service (WMS) and then continued in primary care. Once dietician has qualified as a supplementary prescriber then prescribing will be brought back in-house into the weight management service. WMS will produce a local treatment pathway to aid GPs and the WMS to ensure appropriate prescribing. Patients should be treated for a maximum of 2 years with ongoing review by the WMS to ensure weight targets are reached. Patients will not be allowed to re-trial liraglutide for a 5 year period. As liraglutide is available as the brand (Victoza®) for Type 2 diabetes, and as Saxenda®, (for weight management), prescribers should ensure prescriptions are issued as the brand Saxenda® if prescribed for weight management. Community pharmacists should check indication for use for any generically written prescriptions and issue the appropriate brand. Patients who have initially been prescribed Saxenda® via private clinics and who wish to receive on the NHS must be referred to the local weight management service and will only be prescribed Saxenda®, if they meet the same criteria as SMC restrictions and meet the ongoing weight loss targets. Otherwise, any prescribing will need to be continued privately.				

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
Apalutamide 60mg film-coated tablets (Erleada®) SMC Number 2472 https://www.scottishmedicines.org.uk/media/7096/apalutamide-erleada-final-august-2022-for-website.pdf	Accepted for use within NHS Scotland. Indication under review: treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium 172mcg / 5mcg / 9mcg (Trimbow®) SMC Number 2334 https://www.scottishmedicines.org.uk/media/7044/beclomestasone-trimbow-hd-abbreviated-final-feb-2021-amended-30622-for-website.pdf	Accepted for use within NHSScotland. Indication under review: maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Atezolizumab 840mg and 1,200mg concentrate for solution for infusion (Tecentriq®) SMC Number 2492 atezolizumab-tecentriq-final-july-2022-amended-130722-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: as monotherapy as adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7th edition of the UICC/AJCC staging system) non-small cell lung cancer (NSCLC) whose tumours have PD-L1 expression on ≥50% of tumour cells and whose disease has not progressed following platinum-based adjuvant chemotherapy.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Delta-9-tetrahydrocannabinol 2.7mg and cannabidiol 2.5mg per 100 microlitre spray (Sativex® Oromucosal Spray) SMC Number 2473 https://www.scottishmedicines.org.uk/media/7097/delta-9-tetrahydrocannabinod-	Accepted for use within NHSScotland. Indication under review: As treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
sativex-final-aug-2022-for-website.pdf				
Estradiol 1mg / micronised progesterone 100mg capsules (Bijuve®) SMC Number 2502 https://www.scottishmedicines.org.uk/media/7098/estradiol-micronised-progesterone-bijuve-abb-final-aug-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses. The experience in treating women older than 65 years is limited.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Imlifidase 11mg powder for concentrate for solution for infusion (Idefirix®) SMC Number 2445 https://www.scottishmedicines.org.uk/media/7099/imlifidase-idefirix-final-july-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC Number 2458 https://www.scottishmedicines.org.uk/media/7091/nivolumab-opdivo-final-aug-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: In combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with HER2-negative advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Tofacitinib 5mg film-coated tablets (Xeljanz®) SMC Number 2463 https://www.scottishmedicines.org.uk/media/7092/tofacitinib-xeljanz-final-aug-2022-amended-070922-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Trifarotene 50 microgram/g cream (Aklief®) SMC Number 2441 https://www.scottishmedicines.org.uk/media/7093/trifarotene-aklief-abbreviated-	Accepted for use within NHSScotland. Indication under review: for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when	Category 6 – Not routinely available as local implementation plans are being developed or the	Decision Pending	

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
final-jan-2022-amended-130722-for-website.pdf	many comedones, papules and pustules are present.	ADTC is waiting for further advice from local clinical experts		

Formulary Changes/Additions/Amendments

The following key changes to the Forth Valley Formulary have been agreed by the New Drugs & Formulary Group following recent formulary section reviews. Relevant *ScriptSwitch*® messages to support prescribers in primary care have been added to the clinical system and relevant changes will be reflected in the EMIS FV e-Formulary when it is next updated.

The Forth Valley Formulary can be accessed from the staff net homepage under quick links - click on clinical resources then FV formulary or access via the intranet link Forth Valley Formulary « Staff Net or via the Forth Valley Formulary internet site https://pharmacies.nhsforthvalley.com/local-guidance/forth-valley-formulary/

Formulary Review

- Chapter 6
  - HRT section – Key changes – Novofem®, Zumenon® are no longer formulary choices. Estradot® patches replace Estraderm MX® patches as a formulary choice.
  - Obstetrics & Gynaecology section - Key changes – Danazol, buserelin, bromocriptine and quinagolide are now considered non formulary.

Formulary addition

- Secukinumab for use in paediatrics
  For the treatment of severe plaque psoriasis in children and adolescents.

Change to Formulary Status

- Vancomycin
  Following a change in recommendation from SAPG and updated NICE guidance, the 1st line treatment of C. Diff. infection is now oral vancomycin irrespective of severity.
  GP's can now prescribe this if they identify a patient with C. Diff. infection rather than requiring a recommendation or initiation by the microbiology team.

- Febuxostat
  Change of the Formulary status for febuxostat from specialist initiation to general prescribing in primary care as well. To be used second line after allopurinol.
  Febuxostat to be used with caution in patients with underlying CV disease.

Gluten Free Food Formulary Product List

- ❖ Addition of pizza bases to the list

Testosterone use in women with reduced sexual desire - Formulary addition not supported

- Although NICE Menopause guidance and the British Menopause Society suggest the use of testosterone when HRT alone is not effective. The evidence base for the use of testosterone in women is limited. Study data shows that testosterone would give one extra episode of satisfying sexual contact in one month. There is no benefit for any other symptoms.
- It has been agreed, that due to the off-label use of testosterone, the limited evidence of benefit and need for ongoing monitoring, testosterone for use in women with reduced sexual desire will not be added to the

FV Formulary at this stage and it is not supported for prescribing in Primary Care. Specialists may prescribe to suitable patients if considered appropriate.

- There is a factsheet for patients, produced by the British Menopause Society that can be used to inform patients on the benefits/risks to the use of testosterone.

Process Flowchart (Appendix 1)

NHS FORTH VALLEY PRESCRIBING OF NEW MEDICINES FLOWCHART

This flowchart outlines the NHS Forth Valley process for the prescribing of new medicines. This follows guidance from the Scottish Government for the managed introduction and availability of newly licensed medicines in NHS Scotland