New Medicines Decisions for July 2024

voretigene neparvovec (Luxturna®)				
SMC Drug ID	**Conditions**	**Decision**	**Date published on SMC Website**	**Date of decision / Expected date of decision**
SMC2641	For the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.	Routinely available from a specialist centre in another health board	08/07/2024	30/09/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8464/voretigene-neparvovec-luxturna-umar-final-june-2024-for-website.pdf				

New Medicines Decisions for July 2024

empagliflozin (Jardiance®)				
SMC Drug ID	**Conditions**	**Decision**	**Date published on SMC Website**	**Date of decision / Expected date of decision**
SMC2642	in adults for the treatment of chronic kidney disease. SMC restriction: in patients having individually optimised standard care (including angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, unless these are contraindicated or not tolerated), and either, at the start of treatment: an estimated glomerular filtration rate (eGFR) of 20 mL/min/1.73m2 up to 45 mL/min/1.73m2, or an eGFR of 45 mL/min/1.73m2 up to 90 mL/min/1.73m2 and either: o A urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or o Type 2 Diabetes Mellitus (T2DM).	Available in line with local or regional guidance	08/07/2024	30/09/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8466/empagliflozin-jardiance-final-june-2024-amended-240624-for-website.pdf				

New Medicines Decisions for July 2024

pembrolizumab (Keytruda®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2644	in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1.	Not routinely available as not recommended for use in NHS Scotland	08/07/2024	19/06/2024
Other Decision Specified : The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC.				
Web Link : https://www.scottishmedicines.org.uk/media/8460/pembrolizumab-keytruda-mgc-final-june-2024-for-website.pdf				

nivolumab, relatlimab (Opdualag®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2645	first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older.	Available in line with local or regional guidance	08/07/2024	30/09/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8458/nivolumab-relatlimab-opdualag-final-june-2024-for-website.pdf				

New Medicines Decisions for July 2024

pembrolizumab (Keytruda®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2660	in combination with fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express programmed death-ligand 1 (PD-L1) with a combined positive score (CPS) ≥ 1.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	08/07/2024	30/09/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8461/pembrolizumab-keytruda-final-june-2024-for-website.pdf				

pegunigalsidase alfa (Elfabrio®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2665	for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase). SMC restriction: for use in adults with symptomatic Fabry disease who would usually be offered an enzyme replacement therapy.	Available in line with national guidance	08/07/2024	08/07/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8459/pegunigalsidase-alfa-elfabrio-final-june-2024-for-website.pdf				

New Medicines Decisions for July 2024

follitropin delta (Rekovelle®)				
SMC Drug ID	**Conditions**	**Decision**	**Date published on SMC Website**	**Date of decision / Expected date of decision**
SMC2670	controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle. SMC restriction: for use in normal responders (patients with an anti-Müllerian hormone level of >5.4 pmol/L) or high responders (patients with an anti-Müllerian hormone level of ≥25 pmol/L).	Not routinely available as there is a local preference for alternative medicines	08/07/2024	30/09/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8467/follitropin-delta-rekovelle-abb-final-june-2024-for-website.pdf				

New Medicines Decisions for July 2024

lenacapavir (Sunlenca®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2691	Film-coated tablets: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen, for oral loading prior to administration of long-acting lenacapavir injection. Solution for injection: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.	Not routinely available as not recommended for use in NHS Scotland	08/07/2024	19/06/2024
Other Decision Specified : Non-submission				
Web Link : https://www.scottishmedicines.org.uk/media/8457/lenacapavir-sunlenca-non-sub-final-june-2024-for-website.pdf				

remimazolam (Byfavo®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2692	in adults for intravenous induction and maintenance of general anaesthesia.	Not routinely available as not recommended for use in NHS Scotland	08/07/2024	19/06/2024
Other Decision Specified : Non-submission.				
Web Link : https://www.scottishmedicines.org.uk/media/8462/remimazolam-byfavo-non-sub-final-june-2024-for-website.pdf				

New Medicines Decisions for July 2024

trastuzumab deruxtecan (Enhertu®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2693	as monotherapy for the treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.	Not routinely available as not recommended for use in NHS Scotland	08/07/2024	19/06/2024
Other Decision Specified : Non-submission				
Web Link : https://www.scottishmedicines.org.uk/media/8463/trastuzumab-deruxtecan-enhertu-non-sub-final-june-2024-for-website.pdf				

tezacaftor-ivacaftor (Symkevi®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2711	in a combination regimen with ivacaftor tablets for the treatment of patients with cystic fibrosis (CF) aged 6 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T.	Available in line with national guidance	24/07/2024	
Other Decision Specified : Following SMC collaboration with NICE on TA988				
Web Link : https://scottishmedicines.org.uk/media/8489/20240724-cad-symkevi-smc2711-v10.pdf				

New Medicines Decisions for July 2024

lumacaftor-ivacaftor (Orkambi®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2712	treatment of cystic fibrosis (CF) in patients aged 1 year and older (granules in sachet) or 6 years and older (film-coated tablets) who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Available in line with national guidance	24/07/2024	
Other Decision Specified : Following SMC collaboration with NICE on TA988				
Web Link : https://scottishmedicines.org.uk/media/8488/20240724-cad-orkambi-smc2712-v10.pdf				

ivacaftor-tezacaftor-elexacaftor (Kaftrio®)

SMC Drug ID	Conditions	Decision	Date published on SMC Website	Date of decision / Expected date of decision
SMC2713	in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 2 years to less than 6 years (granules in sachet) and 6 years and older (film-coated tablets) who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Available in line with national guidance	24/07/2024	22/11/2024
Other Decision Specified : Following SMC collaboration with NICE on TA988				
Web Link : https://scottishmedicines.org.uk/media/8487/20240724-cad-kaftrio-smc2713-v10.pdf				