New Medicines Decisions for March 2024

tocilizumab (RoActemra)				
SMC Drug ID	**Conditions**	**Decision**	**Date of ADTC**	**Date of decision / Expected date of decision**
SMC2552	Treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation	Available in line with local or regional guidance	20/03/2024	29/03/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8176/20240313-collaborative-advice-document-for-nice-mta878-v40.pdf				

Casirivimab and imdevimab (Ronapreve) UK Conditional Marketing Authorisation revoked				
SMC Drug ID	**Conditions**	**Decision**	**Date of ADTC**	**Date of decision / Expected date of decision**
SMC2553	Treatment of acute COVID-19 infection	Not routinely available as not recommended for use in NHS Scotland	20/03/2024	26/03/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/medicines-advice/casirivimab-and-imdevimab-ronapreve-full-smc2553/				

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sotrovimab (Xevudy®)				
SMC Drug ID	**Conditions**	**Decision**	**Date of ADTC**	**Date of decision / Expected date of decision**
SMC2555	Treatment of symptomatic adults and adolescents (aged 12 years and over and weighing at least 40kg) with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID infection SMC restriction: patients with increased risk for progression to severe COVID-19, as defined in section 5 of NICE final guidance, and nirmatrelvir and ritonavir is contraindicated or unsuitable.	Available in line with local or regional guidance	20/03/2024	30/06/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8176/20240313-collaborative-advice-document-for-nice-mta878-v40.pdf				

New Medicines Decisions for March 2024

nirmatrelvir and ritonavir (Paxlovid)				
SMC Drug ID	**Conditions**	**Decision**	**Date of ADTC**	**Date of decision / Expected date of decision**
SMC2557	treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19. SMC restriction: Patients with any of the following increased risk for progression to severe COVID-19, as defined in section 5 of NICE final guidance age 70 years and over a body mass index (BMI) of 35 kg/m2 or more diabetes heart failure	Available in line with local or regional guidance	20/03/2024	
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8176/20240313-collaborative-advice-document-for-nice-mta878-v40.pdf				

New Medicines Decisions for March 2024

foslevodopa-foscarbidopa (Produodopa®)				
SMC Drug ID	**Conditions**	**Decision**	**Date of ADTC**	**Date of decision / Expected date of decision**
SMC2574	treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. SMC restriction: for use in patients not eligible for deep brain stimulation (DBS).	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/03/2024	30/06/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8162/foslevodopa-foscarbidopa-produodopa-abb-final-feb-2024-for-website.pdf				

New Medicines Decisions for March 2024

talazoparib (Talzenna®)				
SMC Drug ID	**Conditions**	**Decision**	**Date of ADTC**	**Date of decision / Expected date of decision**
SMC2607	as monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy. In a phase III study in patients with germline BRCA1/2-mutations and HER2-negative locally advanced or metastatic breast cancer who had received previous treatment with an anthracycline and/or a taxane), talazoparib significantly improved radiographic progression-free survival compared with physician's choice of chemotherapy.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/03/2024	30/06/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8166/talazoparib-talzenna-final-feb-2024-for-website.pdf				

New Medicines Decisions for March 2024

ivosidenib (Tibsovo®)				
SMC Drug ID	**Conditions**	**Decision**	**Date of ADTC**	**Date of decision / Expected date of decision**
SMC2615	in combination with azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy. Addition of ivosidenib to azacitidine improved event-free and overall survival in untreated adults with newly diagnosed AML and IDH1 R132 mutation who were ineligible for intensive induction chemotherapy.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/03/2024	30/06/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8163/ivosidenib-tibsovo-final-feb-2024-for-website.pdf				

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olaparib (Lynparza®)

SMC Drug ID	Conditions	Decision	Date of ADTC	Date of decision / Expected date of decision
SMC2617	in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. In a phase III study, radiographic progression-free survival was significantly improved with the addition of olaparib to abiraterone plus prednisone or prednisolone compared with the addition of placebo in patients with mCRPC who had received no previous systemic therapy for metastatic disease.	Available in line with local or regional guidance	20/03/2024	30/06/2024
Other Decision Specified :				
Web Link : https://www.scottishmedicines.org.uk/media/8172/olaparib-lynparza-final-feb-2024-amended-070324-for-website.pdf				

axicabtagene ciloleucel (Yescarta®)

SMC Drug ID	Conditions	Decision	Date of ADTC	Date of decision / Expected date of decision
SMC2628	for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy.	Not routinely available as not recommended for use in NHS Scotland	20/03/2024	
Other Decision Specified : The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.				
Web Link : https://www.scottishmedicines.org.uk/media/8169/axicabtagene-ciloleucel-yescarta-final-amended-060324-for-website.pdf				

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pitolisant (Wakix®)

SMC Drug ID	Conditions	Decision	Date of ADTC	Date of decision / Expected date of decision
SMC2662	To improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP).	Not routinely available as not recommended for use in NHS Scotland	20/03/2024	
Other Decision Specified : Non-submission				
Web Link : https://www.scottishmedicines.org.uk/media/8164/pitolisant-wakix-non-sub-final-feb-2024-for-website.pdf				

satralizumab (Enspryng®)

SMC Drug ID	Conditions	Decision	Date of ADTC	Date of decision / Expected date of decision
SMC2663	As a monotherapy or in combination with immunosuppressive therapy (IST) for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in adult and adolescent patients from 12 years of age who are anti-aquaporin-4 IgG (AQP4-IgG) seropositive.	Not routinely available as not recommended for use in NHS Scotland	20/03/2024	
Other Decision Specified : Non-submission				
Web Link : https://www.scottishmedicines.org.uk/media/8165/satralizumab-enspryng-non-sub-final-feb-2024-for-website.pdf				