NEWSLETTER: News from the HTA Agencies

February 2024

SUMMARY

HTA Agency	N° of Drugs	Drugs Name
CADTH Evidence Driven.	5	Nivolumab + Relatitlimab • Glofitanamb • Niraparib + Abiraterone Acetate • Sacituzumab Govitecan • Olaparib
HAS HAUTE AUTORITÉ DE SANTÉ	8	Angiotensin Acetate II • Apomorphine Hydrochloride • Ciclopirox Substipharm • Foslevodopa + Foscabidopa • Elacestrant • Apadamtase Alfa • Eravacycline • Mirikizumab
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW	-	
IQWiG Institute for Quality and Efficiency in Health Care	17	Baricitinib (x4) • Midostaurin • Migalastat (x2) • Niraparib + Abiraterone Acetato • Nivolumab (x2) • Sacituzumab Govitecan (x2) • Tirzepatide • Trifluridine + Tipiracil (x2) • Vosoritide (x2)
NICE National Institute for Health and Care Excellence	4	Olaparib + Abiraterone • Nivolumab + Relatlimab • Belumsudil • Talazoparib
SMC Scottish Medicines Consortium	7	Loncastuximab Tesirine • Ravulizumab (x2) • Difelikefalin • Cabozantinib • Secukinumab • Dupilumab

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
NIVOLUMAB + RELATLIMAB	OPDUALAG	For the treatment of adult and pediatric patients 12 years or older with unresectable or metastatic melanoma who have not received prior systemic therapy for unresectable or metastatic melanoma	CADTH Reimbursement Recommendation 	CADTH recommends that Opdualag be reimbursed for the treatment of adult and pediatric patients 12 years or older with unresectable or metastatic melanoma who have not received prior systemic therapy for unresectable or metastatic melanoma if certain conditions are met.	Treatment cost: $16,630 every 28 days
GLOFITAMAB	COLUMVI	For the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, trFL, or PMBCL, who have received 2 or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy	CADTH Reimbursement Recommendation 	CADTH recommends that Columvi be reimbursed by public drug plans for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from follicular lymphoma (trFL), or primary mediastinal B-cell lymphoma (PMBCL), who have received 2 or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T-cell therapy or have previously received CAR-T-cell therapy if certain conditions are met.	Treatment cost First cycle: $5,200 Subsequent cycles: $12,480 Pretreatment (with obinutuzumab), and premedication (with acetaminophen, diphenhydramine and prednisolone) for first dose of first cycle: $5,479
NIRAPARIB + ABIRATERONE ACETATE	AKEEGA	With prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA mutated (germline and/or somatic) mCRPC, who are asymptomatic/mildly symptomatic, and in whom chemotherapy is not clinically indicated	CADTH Reimbursement Recommendation 	CADTH recommends that Akeega be reimbursed by public drug plans for the first-line treatment of metastatic castration-resistant prostate cancer (mCRPC) if certain conditions are met.	Treatment cost: $8,239 per 28-day cycle

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
SACITUZUMAB GOVITECAN	TRODELVY	For the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least 2 additional systemic therapies in the metastatic setting.	CADTH Reimbursement Recommendation 	CADTH recommends that Trodelvy should be reimbursed by public drug plans for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least 2 additional systemic therapies in the metastatic setting, if certain conditions are met.	Treatment cost: $15,765 per 28 days assuming a weight of 70 kg
OLAPARIB	LYNPARZA	In combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. BRCA mutation must be confirmed before olaparib treatment is initiated.	CADTH Reimbursement Recommendation 	CADTH recommends that Lynparza, in combination with abiraterone with prednisone or prednisolone, should be reimbursed by public drug plans for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) if certain conditions are met	Treatment cost: The annual per-patient cost of olaparib is $102,194. In combination with abiraterone and prednisone or prednisolone, the annual per-patient cost of the combination regimen is $140,147.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ANGIOTENSIN ACETATE II	GIAPREZA	For the treatment of refractory hypotension in adults with septic shock or other distributive shock with persistent hypotension despite adequate vascular filling, catecholamines and other available vasopressors	Avis de la CT	First-registration. Favourable opinion of reimbursement of GIAPREZA (angiotensin II) in the treatment of refractory hypotension in adults with septic shock or other distributive shock with persistent hypotension despite adequate vascular filling, the administration of catecholamines and other available vasopressors. The Commission considers that GIAPREZA 2,5 mg/ml (angiotensin II), a solution to be diluted for infusion, does not provide an improvement in the medical service provided (ASMR V) in the current therapeutic strategy of last resort treatment of refractory hypotension in adults with septic shock or other distributive shock despite adequate vascular filling and after administration of catecholamines and others vasopressors available.
APOMORPHINE HYDROCHLORIDE	KYNMOBI	For the treatment of intermittent treatment of "OFF episodes" in adult patients with Parkinson's disease (PD) insufficiently controlled by oral antiparkinsonian therapy.	Avis de la CT	First-registration. Opinion in favour of reimbursement in the «intermittent treatment of "OFF" episodes in adult patients with Parkinson's disease (PD) insufficiently controlled by oral antiparkinsonian treatment. the Commission considers that KYNMOBI (apomorphine hydrochloride) 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, sublingual film and treatment initiation pack do not provide an improvement in the medical service rendered (ASMR V) compared to the reference specialty APOKINON (apomorphine hydrochloride) 30 mg/3 mL, prefilled pen solution.
CICLOPIROX SUBSTIPHARM	CICLOPIROX	Treatment of mild to moderate onychomycosis, caused by dermatophytes and/or other ciclopirox-sensitive fungi, without affecting the nail matrix	Avis de la CT	First-registration. Favourable opinion of reimbursement in the treatment of mild to moderate onychomycoses, caused by dermatophytes and/ or other fungi sensitive to ciclopirox, without affecting the nail matrix. This specialty is a hybrid drug that does not provide an improvement in medical service rendered (ASMR V) compared to the reference specialty (ONYTEC)

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
FOSLEVODOPA + FOSCABIDOPA	SCYOVA	For the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia and responding to levodopa, when the available combinations of antiparkinsonians have not yielded satisfactory results.	Avis de la CT	First-registration. Favourable opinion of reimbursement in treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia and responding to levodopa, when the available combinations of antiparkinsonians have not yielded satisfactory results. the Commission considers that SCYOVA (foslevodopa/foscarbidopa) 240 mg/mL + 12 mg/mL, solution for infusion does not provide an improvement in the medical service rendered (ASMR V) in the therapeutic strategy of the treatment of advanced stage Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia and responding to levodo-pa, when the available combinations of antiparkinsonians have not given satisfactory results.
ELACESTRANT	ORSERDU	For the monotherapy treatment of postmenopausal women and men with locally advanced or metastatic breast cancer, positive for estrogen receptors (ER), HER2-negative, with ESR1 gene activator mutation, in progression after at least one hormone therapy line in combination with a 4/6 CDK inhibitor and not eligible for treatment with a selective inhibitor of poly (ADP-ribose) polymerases (PARP)	Avis de la CT	Rejection of authorisation for early access
APADAMTASE ALFA	TAK - 755	TAK-755 is indicated in enzyme replacement therapy (TES) in patients aged 12 years and older, with congenital thrombotic thrombocytopenic purpura (PTTc) due to ADAMTS13 deficiency	Avis de la CT	Early access granted to the specialty TAK-755 (apadamtase alfa) in the indication: enzyme replacement therapy (TES) in patients aged 12 years and older with congenital thrombocytopenic thrombotic purpura (PTTc) due to ADAMTS13 deficiency.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ERAVACYCLINE	XERAVA	For the treatment of complicated intra-abdominal infections (IIAc) in adults	Avis de la CT	First-registration. Opinion in favor of reimbursement in the treatment of complicated intra-abdominal infections only in case of bacterial infections sensitive to eravacycline and when the therapeutic alternatives are deemed inadequate. The Transparency Committee considers that XERAVA (eravacycline) concentrate per infusion solution does not bring any improvement of the medical service rendered (ASMR V) in the management of complicated intra-abdominal infections
MIRIKIZUMAB	OMVOH	For treatment of moderate to severe ulcerative colitis (RCD) in adults who do not respond (insufficient response, loss of response, intolerance or contraindication) to conventional treatments and at least one biological medicine between anti-TNFα and veddolizumab	Avis de la CT	First-registration. Opinion in favour of reimbursement in the treatment of moderate to severe active ulcerative colitis in adult patients with insufficient response, loss of response or intolerance to conventional treatments, at least an anti-TNFα and veddolizumab. The Commission considers that OMVOH 300 mg concentrate per infusion solution and OMVOH 100 mg injectable solution (mirikizumab) do not bring an improvement of the medical service rendered (ASMR V) in the current therapeutic strategy.

ICER

Generic Name	Brand Name	Indication	Type of Document	Link	Recommendation	Info on Costs

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
BARICITINIB	OLUMIANT	Children and adolescents 2 years and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis)	Dossier Assessment [A23-108]	Result of dossier assessment: i) Patients who have had an inadequate response or intolerance to one or more prior conventional synthetic disease-modifying antirheumatic drugs (DMARDs): added benefit not proven ii) Patients who have had an inadequate response or intolerance to one or more prior biologic disease-modifying antirheumatic drugs (DMARDs): added benefit not proven	Annual therapy costs per patient amount of 66.82 € to 197.28 €
BARICITINIB	OLUMIANT	Children and adolescents 2 years and older with active juvenile psoriatic arthritis who have had an inadequate response or intolerance to one or more conventional synthetic or biologic disease-modifying antirheumatic drugs (DMARDs)	Dossier Assessment [A23-113]	Added benefit not proven	Annual therapy costs per patient amount of 66.82 € to 197.28 €
BARICITINIB	OLUMIANT	Children and adolescents with active enthesitis-related psoriatic arthritis who have had an inadequate response or intolerance to one or more conventional synthetic or biologic disease-modifying antirheumatic drugs (DMARDs)	Dossier Assessment [A23-114]	Result of dossier assessment: i) Children 2 to 5 years: added benefit not proven ii) Children and adolescents 6 years and older: added benefit not proven	
BARICITINIB	OLUMIANT	Paediatric patients 2 years and older with moderate to severe atopic dermatitis who are candidates for systemic therapy	Dossier Assessment [A23-109]	Result of dossier assessment: i) Children 2 to 5 years with moderate to severe atopic dermatitis: added benefit not proven; ii) Children 6 to 11 years with moderate atopic dermatitis: added benefit not proven; iii) Children 6 to 11 years with severe atopic dermatitis: added benefit not proven; iv) Adolescents 12 to 17 years with moderate to severe atopic dermatitis: added benefit not proven	Annual therapy costs 8 485.23 € per patient for children with 60 kg body weight.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
MIDOSTAURIN	RYDAPT	Adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated haematological neoplasm, or mast cell leukaemia	Dossier Assessment [A23-111]	Result of dossier assessment: Added benefit not proven	Annual therapy costs per patient in the amount of 11 212.20 € to 22 424.40 €
MIGALASTAT	GALAFOLD	Adults and adolescents aged 12 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation	Dossier Assessment [A23-88]	Result of dossier assessment: Added benefit not proven	Annual therapy costs 234 689,26€ per patient
MIGALASTAT	GALAFOLD	Adults and adolescents aged 12 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation	Dossier Assessment [A24-10] Addendum to [A23-88]	Result of dossier assessment: Unchanged after addendum: added benefit not proven	
NIRAPARIB + ABIRATERONE ACETATE	AKEEGA	Adults with metastatic castration-resistant prostate cancer (mCRPC) and breast cancer susceptibility gene 1/2 mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated	Dossier Assessment [A23-107]	Result of dossier assessment: i) Patients with treatment-naive mCRPC without prior taxane-containing chemotherapy: hint of considerable added benefit ii) Patients with treatment-naive mCRPC with prior taxane-containing chemotherapy: added benefit not proven iii) Patients with pretreated mCRPC: added benefit not proven	Annual therapy costs per patient in the amount from 78940.68 to 81208.03 €

IQWiG

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
NIVOLUMAB	OPDIVO	Neoadjuvant treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%	Dossier Assessment [A23-74]	Result of dossier assessment: Added benefit not proven	Annual therapy costs per patient in the amount of 15 278,01 to 19 366.95
NIVOLUMAB	OPDIVO	Neoadjuvant treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%	Dossier Assessment [A23-131] - Addendum to [A23-74]	Result of dossier assessment: Unchanged after addendum: added benefit not proven	
SACITUZUMAB GOVITECAN	TRODELVY	Adult patients with unresectable or metastatic triple-negative breast cancer who have had two or more prior systemic therapies including at least one of them for advanced disease.	Dossier Assessment [A23-86]	Result of dossier assessment: Hint of minor added benefit	Annual therapy costs per patient in the amount of 161055.79€
SACITUZUMAB GOVITECAN	TRODELVY	Adult patients with unresectable or metastatic triple-negative breast cancer who have had two or more prior systemic therapies including at least one of them for advanced disease.	Dossier Assessment [A24-07] Addendum to [A23-86]	Result of dossier assessment: After addendum now: proof of considerable added benefit	
TIRZEPATIDE	MOUNJARO	Adults with type 2 diabetes mellitus	Dossier Assessment [A23-112]	Result of dossier assessment: Added benefit not proven	Annual therapy costs per patient for tirzepatid for patient amount of 2.979,70 € to 3.994,64 €

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
TRIFLURIDINE + TIPIRACIL	LONSURF	Combination therapy with bevacizumab for the treatment of adults with metastatic colorectal cancer who have received 2 prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents, and/or anti-epidermal growth factor receptor agents	Dossier Assessment [A23-85]	Result of dossier assessment: Indication of an unquantifiable, but at least considerable added benefit	Annual therapy costs 42230,98 € per patient
TRIFLURIDINE + TIPIRACIL	LONSURF	Combination therapy with bevacizumab for the treatment of adults with metastatic colorectal cancer who have received 2 prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents, and/or anti-epidermal growth factor receptor agents	Dossier Assessment [A24-09] Addendum to [A23-85]	Result of dossier assessment: After addendum now: indication of major added benefit	
VOSORITIDE	VOXZOGO	Patients with achondroplasia 2 years and older whose epiphyses are not closed	Dossier Assessment [A23-92]	Result of dossier assessment: indication of non-quantifiable added benefit	Annual therapy costs 216 263,73€ per patient
VOSORITIDE	VOXZOGO	Patients with achondroplasia 2 years and older whose epiphyses are not closed	Dossier Assessment [A24-08] Addendum to [A23-92]	Result of dossier assessment: Unchanged after addendum: indication of non-quantifiable added benefit	

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
OLAPARIB + ABIRATERONE	LYNPARZA	Olaparib (Lynparza) with abiraterone for untreated hormone-relapsed metastatic prostate cancer in adults.	Technology appraisal guidance [TA951]	Olaparib with abiraterone and prednisone or prednisolone is recommended, within its marketing authorisation, as an option for untreated hormone-relapsed metastatic prostate cancer in adults who cannot have or do not want chemotherapy. It is only recommended if the company provides it according to the commercial arrangements.	The list price is £2,317.50 per pack of 56 tablets.
NIVOLUMAB + RELATLIMAB	OPDUALAG	Nivolumab–relatlimab (Opdualag) for untreated advanced (unresectable or metastatic) melanoma in people 12 years and over.	Technology appraisal guidance [TA950]	Nivolumab–relatlimab is recommended as an option for untreated advanced (unresectable or metastatic) melanoma in people 12 years and over, only if: I) nivolumab–relatlimab is stopped after 2 years of treatment, or earlier if the cancer progresses, and II) the company provides it according to the commercial arrangement.	The list price is £6,135 per 16 mg/ml vial (company submission)
BELUMOSUDIL	REZUROCK	Belumosudil (Rezurock) for chronic graft-versus-host disease in people 12 years and over after 2 or more systemic treatments.	Technology appraisal guidance [TA949]	Belumosudil is recommended, within its marketing authorisation, for treating chronic graft-versus-host disease in people 12 years and over after 2 or more systemic treatments. It is recommended only if the company provides it according to the commercial arrangement.	The list price of 30 belumosudil 200mg tablets is £6,708.00
TALAZOPARIB	TALZENNA	Talazoparib is indicated '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	Technology appraisal guidance [TA952]	Talazoparib is recommended, within its marketing authorisation, for treating HER2-negative, locally advanced or metastatic breast cancer with germline BRCA1 or BRCA2 mutations in adults who have had: I) an anthracycline or a taxane, or both, unless these treatments are not suitable, and II) endocrine therapy if they have hormone receptor (HR)-positive breast cancer, unless this is not suitable. Talazoparib is only recommended if the company provides it according to the commercial arrangement.	The list price is £4,965 for a 30 pack of 1 mg capsules and £1,655 for a 30 pack of 0.25 mg capsules

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
LONCASTUXIMAB TESIRINE	ZYNLONTA	Monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy.	Medicine advice	Following a full submission assessed under the end of life and orphan equivalent medicine process: loncastuximab tesirine (Zynlonta®) is accepted for restricted use within NHSScotland. SMC restriction: where chimeric antigen receptor (CAR) T-cell therapy is unsuitable, not tolerated or ineffective.	Cost per cycle (£): 0.15 mg/kg every 21 days for 2 cycles, followed by 0.075 mg/kg every 21 days. - First 2 cycles: £30,400 - Subsequent cycle: £15,200
RAVULIZUMAB	ULTOMIRIS	As an add-on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.	Medicine advice	In the absence of a submission from the holder of the marketing authorisation ravulizumab (Ultomiris®) is not recommended for use within NHSScotland.	
RAVULIZUMAB	ULTOMIRIS	Treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive.	Medicine advice	In the absence of a submission from the holder of the marketing authorisation: ravulizumab (Ultomiris®) is not recommended for use within NHSScotland.	
DIFELIKEFALIN	KAPRUVIA	Treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis.	Medicine advice	Following a full submission: difelikefalin (Kapruvia®) is accepted for restricted use within NHSScotland. SMC restriction: for use in patients with an inadequate response to best supportive care for reducing itch.	Dose regimen: 0.5micrograms/kg intravenously three times per week Cost per year (£): 5,460

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
CABOZANTINIB	CABOMETYX	As monotherapy for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC), refractory or not eligible to radioactive iodine (RAI) who have progressed during or after prior systemic therapy.	Medicine advice	Following a full submission assessed under the end of life and orphan equivalent medicine process: cabozantinib (Cabometyx®) is not recommended for use within NHSScotland.	Dose regimen: 60mg orally once daily Cost per year (£): 62,402
SECUKINUMAB	COSENTYX	For the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy.	Medicine advice	Following a full submission: secukinumab (Cosentyx®) is accepted for restricted use within NHSScotland. SMC restriction: for use in adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.	Cost per year (£): First year: 19,500 to 29,250 Subsequent years: 14,625 to 29,250
DUPILUMAB	DUPIXENT	For the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy.	Medicine advice	Following a full submission assessed under the orphan equivalent medicine process: dupilumab (Dupixent®) is accepted for use within NHSScotland.	Dose regimen: 600 mg then 300 mg every other week by subcutaneous injection. Treatment should be reviewed if there is no response after 24 weeks. Cost per year(£): 17,708