NEWSLETTER: News from the HTA Agencies

December 2024

SUMMARY

HTA Agency	N°of Drugs	Drugs Name
CADTH Evidence Driven.	4	LISOCABTAGENE MARALEUCEL • FRUQUITINIB • VENETOCLAX • ENFORTUMAB VEDOTIN
HAS HAUTE AUTORITÉ DE SANTÉ	5	BIMATOPROST/TIMOLOL • BIMATOPROST • CONCIZUMAB • TECLISTAMAB • SOTATERCEPT
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW	0	
IQWiG Institute for Quality and Efficiency in Health Care	12	RISANKIZUMAB • INSULIN ICODEC • OLAPARIB • FARICIMAB • DURVALUMAB • INSULIN ICODEC• DURVALUMAB• SOTATERCEPT• CROVALIMAB • LINZAGOLIX • EPCORITAMAB • AXICABTAGENE CILOLEUCEL
NICE National Institute for Health and Care Excellence	6	BEVACIZUMAB GAMMA • CRIZOTINIB • TORIPALIMAB • ELAFIBRANBOR • ELRANATAMAB• UBLITUXIMAB • TIRZEPATIDE
SMC Scottish Medicines Consortium	4	LEVODOPA/CARBIDOPA/ENTACAPONE • VIBEGRON • ZANUBRUTINIB • DURVALUMAB

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
LISOCABTAGENE MARALEUCEL	BREYANZI	For the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), primary mediastinal large B-cell lymphoma (PMBCL), high-grade B-cell lymphoma (HGBCL), and DLBCL arising from follicular lymphoma, who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, and who are candidates for autologous hematopoietic stem cell transplant (HSCT)	CADTH Reimbursement Recommendation	Reimburse with conditions. Breyanzi should only be reimbursed for patients who have not yet been treated with chimeric antigen receptor (CAR) T-cell therapy, if it is prescribed and administered by clinicians with expertise in lymphomas and CAR T-cell therapy in a hospital setting with adequate resources, and if the cost of Breyanzi is not more than that of axicabtagene ciloleucel (axi-cel). It must also be feasible to administer Breyanzi	Treatment with Breyanzi is expected to cost $501,900 per patient per infusion.
FRUQUITINIB	FRUZAQLA	For the treatment of adult patients with metastatic colorectal cancer who have been previously treated with or are not considered candidates for available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-VEGF agent; an anti-EGFR agent (if RAS wild-type); and either trifluridine-tipiracil or regorafenib.	CADTH Reimbursement Recommendation	Reimburse with conditions. Fruzaqla should be prescribed by clinicians who specialize in diagnosing and treating patients with mCRC. Fruzaqla should be stopped if the disease worsens or the patient has severe side effects. The cost of Fruzaqla should be reduced.	Treatment with Fruzaqla is expected to cost approximately $6,321 per 28-day cycle.
VENETOCLAX	VENCLEXTA	Venetoclax (Venclexta), in combination with obinutuzumab, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia.	CADTH Reimbursement Recommendation	Reimburse with conditions. Venclexta in combination with obinutuzumab should only be reimbursed if prescribed by a clinician with expertise treating CLL and monitoring therapy, and if the cost of Venclexta is reduced. Patients who experience disease progression while taking Venclexta or who cannot tolerate the drug would not be eligible for continued coverage. Reimbursement of venetoclax should be discontinued after 12 months of therapy is completed.	Treatment with Venclexta in combination with obinutuzumab is expected to have a per-patient cost of $17,354 in cycle 1, $9,469 in cycle 2, $13,681 in cycles 3 to 6, and $7,930 in cycles 7 to 12

CADTH

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ENFORTUMAB VEDOTIN	PADCEV	In combination with pembrolizumab, for the treatment of adult patients with unresectable locally advanced or metastatic urothelial cancer (mUC) with no prior systemic therapy for mUC	CADTH Reimbursement Recommendation 	Reimburse with conditions. Padcev, in combination with pembrolizumab, should only be reimbursed if prescribed by a clinician who has experience treating patients with locally advanced UC or mUC and if the price of Padcev is reduced.	Treatment with Padcev is expected to cost approximately $15,747 per patient per 28-day cycle. When used in combination with pembrolizumab, the 28-day cost per patient for Padcev plus pembrolizumab is $24,547 when using a weight-based dose for pembrolizumab.

HAS

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BIMATOPROST/ TIMOLOL	**BITIFRIN**	For the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who have an insufficient response to topical beta-blockers or prostaglandine analogues.	Avis de la CT	**First registration. Favourable opinion on reimbursement. ASMR: V (absence): This specialty is a hybrid that does not provide an improvement in the medical service rendered (ASMR V) compared to the reference specialty GANFORT 0.3 mg/5 mg per mL (bimatoprost/timolol), eye drops in solution.**
BIMATOPROST	**IRICRYN**	**Reduction of high intraocular pressure in patients with chronic open-angle glaucoma and hypertension ocular (as monotherapy or as adjunctive treatment in combination beta blockers)**	Avis de la CT	**First registration. ASMR: V (absence): This specialty is a hybrid that does not bring improvement in the medical service rendered (ASMR V) compared to the reference specialty.**
CONCIZUMAB	**ALHEMO**	**Alhemo is indicated in the prophylaxis to prevent or reduce the frequency of bleeding episodes in patients aged 12 years and older: Hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors as a last resort People with hemophilia B (congenital factor IX deficiency) who have developed FIX inhibitors as a last resort**	Avis de la CT	**Renewed early access authorization for ALHEMO (concizumab)**

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
TECLISTAMAB	TECVAYLI	In monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three previous treatments including an immunomodulator, a proteasome inhibitor and an anti-antibodyCD38 and whose disease has progressed during the last treatment	Avis de la CT 	Réévaluation. Favourable opinion for reimbursement. ASMR: V (absence): The Commission considers that, in the current state of data, and pending in particular the results of the MajesTEC-3 randomized phase III study, TECVAYLI (teclistamab) 10 mg/mL or 90 mg/mL, injectable solution, does not provide any improvement in medical service rendered in the management of adult patients with relapsing and refractory multiple myeloma, who have received at least three previous treatments, including an immunomodulator, a proteasome inhibitor and an anti-antiantibodyCD38 and whose disease has progressed during the last treatment
SOTATERCEPT	WINREVAIR	Treatment of pulmonary hypertension (PAH) in adults in WHO functional class (CF) II or III, receiving standard treatment for PAH in three-way therapy including an endothelin receptor antagonist (ERA), a phosphodiesterase 5 (iPDE5) inhibitor or a stimulator of soluble guanylate cyclase (GCs) and a prostacycline analogue by parenteral route.	Avis de la CT 	Early access authorization granted.

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RISANKIZUMAB	SKYRIZI	Adults with moderately to severely active ulcerative colitis.	Dossier Assessment [A24-84]	Result of dossier assessment: 1. Patients who have had an inadequate response to, lost response to, or were intolerant to conventional therapy: added benefit not proven 2. Patients who have had an inadequate response to, lost response to, or were intolerant to a biologic therapy: added benefit not proven	The pU determines annual therapy costs per patient for Risankizumab in the amount of 19,190.36 €
INSULIN ICODEC	AWIQLI	Adult patients with type 2 diabetes mellitus.	Dossier Assessment [A24-91]	Result of dossier assessment: 1. Insulin-naive adults with type 2 diabetes mellitus without manifest cardiovascular disease who have not achieved sufficient glycaemic control with their present drug treatment consisting of at least 2 blood-glucose lowering drugs in addition to diet and exercise and for whom insulin therapy is indicated: added benefit not proven 2. Insulin-naive adults with type 2 diabetes mellitus with manifest cardiovascular disease who have not achieved sufficient glycaemic control with their present drug treatment consisting of at least 2 blood-glucose lowering drugs in addition to diet and exercise and for whom insulin therapy is indicated: added benefit not proven 3. Insulin-experienced adults with type 2 diabetes mellitus without manifest cardiovascular disease who have not achieved sufficient glycaemic control with their present insulin regimen in addition to diet and exercise: added benefit not proven 4. Insulin-experienced adults with type 2 diabetes mellitus with manifest cardiovascular disease who have not achieved sufficient glycaemic control with their present insulin regimen in addition to diet and exercise: added benefit not proven	For the subpopulations a1) and a2), pU for insulin icodec determines annual therapy costs per patient in the amount of 885.86 € to 1712.33 €.

IQWiG

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OLAPARIB	LYNPARZA	Maintenance treatment of adult patients with primary advanced or recurrent mismatch repair proficient endometrial cancer whose disease has not progressed on first-line treatment with durvalumab in combination with carboplatin and paclitaxel	Dossier Assessment [A24-88]	Result of dossier assessment: Added benefit not proven	The pU determines annual total therapy costs per patient of 128 for the initial therapy durvalumab in combination with carboplatin + paclitaxel and for the subsequent maintenance therapy to be evaluated with olaparib in combination with durvalumab 128,376.64 € to 132,508.57 € in the 1st treatment year.
FARICIMAB	VABYSMO	Adult patients with visual impairment due to macular oedema	Dossier Assessment [A24-85]	Result of dossier assessment: -Macular oedema secondary to branch retinal vein occlusion: added benefit not proven -Macular oedema secondary to central retinal vein occlusion: added benefit not proven	The pU determines annual therapy costs per patient for Faricimab in a range of 6132.06 € to 13 628.88 € for the 1st year and 3066.03 € to 13 628.88 € for the following years.
DURVALUMAB	IMFINZI	First-line treatment of adult patients with primary advanced or recurrent mismatch repair deficient endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with durvalumab	Dossier Assessment [A24-87]	Result of dossier assessment: Added benefit not proven	The pU determines for durvalumab in combination with carboplatin + paclitaxel and the subsequent maintenance therapy with Durvalumab (monotherapy) annual treatment costs per patient ranging from 87.111,40 € to 90.494,85 € in the first year of treatment.

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INSULIN ICODEC	AWIQLI	Adult patients with type 1 diabetes mellitus	Dossier Assessment [A24-90]	Result of dossier assessment: Added benefit not proven	The pU determines annual therapy costs per patient for insulin icodec in combination with bolus insulin of 1210.52 € to 1942.30 €.
DURVALUMAB	IMFINZI	First-line treatment of adult patients with primary advanced or recurrent mismatch repair proficient endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with durvalumab in combination with olaparib	Dossier Assessment [A24-86]	Result of dossier assessment: - Patients with newly diagnosed disease: hint of considerable added benefit (at the beginning of the study, the positive effects in the mortality category are indicative of a significant additional benefit. In contrast, there are indications for a lower benefit with regard to the non-serious / non-severe symptoms / follow-up complications(loss of appetite, constipation, taste change, and mainly anemia)) - Patients with recurrent disease: hint of lesser benefit (no difference between the treatment groups was observed in the overall survival endpoint. On the negative side, for these patients with non-serious / non-severe symptoms / follow-up complications (nausea and vomiting), there is a significant indication of a lower benefit with the extent. Furthermore, the endpoints loss of appetite, constipation, taste change also indicate a lower benefit with the extent considerable or, in addition, for anemia a point of evidence for a higher damage)	The pU determines annual therapy costs per patient of 128 376.64 € to 132 508.57 € in the 1st treatment year for durvalumab in combination with carboplatin + paclitaxel and the subsequent maintenance therapy with durvalumab in combination with olaparib
SOTATERCEPT	WINREVAIR	Treatment of pulmonary arterial hypertension in adult patients with WHO Functional Class II to III, to improve exercise capacity	Dossier Assessment [A24-96]	Result of dossier assessment: Added benefit not proven The data presented by pU are not suitable to derive conclusions on the additional benefit of Sotatercept compared to appropriate comparative therapy	The pU determines annual therapy costs per patient or per year for Sotatercept. Patient in the amount of € 172,384.02 to € 172,385.02, which consists of drug costs and costs for additional GKV services.

IQWiG

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CROVALIMAB	PIASKY	Adult and paediatric patients 12 years of age or older with a weight of ≥ 40 kg with paroxysmal nocturnal haemoglobinuria	Dossier Assessment [A24-94]	Result of dossier assessment: - Patients with high disease activity, characterized by clinical symptoms of haemolysis: added benefit not proven - Adult patients who have been treated with a C5 inhibitor for ≥ 6 months and are clinically stable: hint of lesser benefit - Paediatric patients 12 years of age or older who have been treated with a C5 inhibitor for ≥ 6 months and are clinically stable: added benefit not proven In the COMMODORE 2 study, crovalimab did not show any positive or negative effects compared to eculizumab. In summary, there is no evidence for an additional benefit of crovalimab compared to eculizumab for patients with PNH with high disease activity, characterized by clinical signs of hemolysis. An additional benefit is not proven. This corresponds to the assessment of pU, which also does not derive any additional benefit across all questions	The pU determines annual therapy costs per patient or per year for crovalimab. Patient in the amount of 368.309,50 €
LINZAGOLIX	YSELTY	Adult women of reproductive age with moderate to severe symptoms of uterine fibroids	Dossier Assessment [A24-92]	Result of dossier assessment: Added benefit not proven Due to the lack of comparison with the appropriate comparative therapy, the studies PRIMROSE 1 and PRIMROSE 2 are not considered suitable for evaluating the additional benefit of Linzagolix in accordance with the pU.	The pU determines annual therapy costs per patient for Linzagolix of € 1323.39, which consist of drug costs.
EPCORITAMAB	TEPKINLY	Adult patients with relapsed or refractory follicular lymphoma after 2 or more lines of systemic therapy	Dossier Assessment [A24-95]	Result of dossier assessment: Added benefit not proven The review of the completeness of the study pool did not reveal a trial for direct comparison of epcoritamab to appropriate comparator therapy.	Annual therapy cost 198.723,13€ for the first year and 102.254,88€ for the following year

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
AXICABTAGENE CILOLEUCEL	YESCARTA	Adults with diffuse large B-cell lymphoma or high-grade B-cell lymphoma that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy, and who are candidates for high-dose therapy	Dossier Assessment [A24-109] Addendum to [A24-71] 	Result of dossier assessment: Unchanged after addendum: hint of minor added benefit Compared to the analyses already used in the dossier assessment, the analyses subsequently submitted do not provide any additional information and are also incomplete, as no subgroup analyses and Kaplan-Meier curves are available (mEFS1.1 and mEFS2.1 confirm the minor added benefit of axicabtagene ciloleucel compared with the ACT in the outcome of failure of the curative treatment approach. The time-to-event analyses are still inherently biased in favour of the intervention arm and therefore still cannot) be interpreted	

NICE

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BEVACIZUMAB GAMMA	LYTENAVA	Bevacizumab gamma (Lytenava, Outlook Therapeutics) is 'indicated in adults for treatment of neovascular (wet) age-related macular degeneration (nAMD)'.	Technology appraisal [TA1022]	Bevacizumab gamma is recommended as an option for treating wet age-related macular degeneration in adults, only if: the eye has a best-corrected visual acuity between 6/12 and 6/96; there is no permanent structural damage to the central fovea; the lesion size is 12 disc areas or less in greatest linear dimension; there are signs of recent disease progression (for example, blood vessel growth as shown by fluorescein angiography, or recent visual acuity changes); the company provides it according to the commercial arrangement.	The list price of bevacizumab gamma is £470 for 1 vial of 7.5 mg per 0.3 ml solution (excluding VAT; company submission, accessed September 2024).
CRIZOTINIB	XALKORI	Crizotinib (Xalkori, Pfizer) is indicated for 'the treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC)'.	Technology appraisal [TA1021]	Crizotinib is recommended as an option for treating ROS1-positive advanced nonsmall-cell lung cancer in adults, only if: • they have not had ROS1 inhibitors • the company provides it according to the commercial arrangement.	The list price is £4,689.00 per 60-capsule pack of 200 mg or 250 mg capsules (excluding VAT; BNF online accessed October 2024).
CRIZOTINIB	LOQTORZI	Toripalimab (Loqtorzi) with chemotherapy for untreated advanced oesophageal squamous cell cancer in adults.	Technology appraisal [TA1024]	NICE is unable, at this time, to make a recommendation about the use in the NHS of toripalimab. This is because Shanghai Junshi Bioscience has requested a delay to the evidence submission.	

NICE

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ELRANATAMAB	ELREXFIO	Elranatamab as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy	Technology appraisal [TA1023]	Elranatamab is recommended with managed access as an option for treating relapsed and refractory multiple myeloma in adults, only after 3 or more lines of treatment (including an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody) when the multiple myeloma has progressed on the last treatment. It is only recommended if the conditions in the managed access agreement for elranatamab are followed.	The list price for elranatamab is £4,242.50 per 76-mg vial and £2,456.00 per 44-mg vial
UBLITUXIMAB	BRIUMVI	Ublituximab is indicated for 'the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features	Technology appraisal [TA1025]	Ublituximab is recommended as an option for treating relapsing forms of multiple sclerosis, defined as active by clinical or imaging features in adults, only if: • the multiple sclerosis is relapsing–remitting, and • the company provides it according to the commercial arrangement. 1.2 Use the least expensive option of the available treatments (including ublituximab, ocrelizumab and ofatumumab). Take account of administration costs, dosages, price per dose and commercial arrangements. If the least expensive option is unsuitable, people with the condition and their healthcare professional should discuss the advantages and disadvantages of other treatments.	The list price of ublituximab is £2,947.00 per 150-mg vial

NICE

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TIRZEPATIDE	MOUNJARO	Tirzepatide is indicated for 'weight management, including weight loss and weight maintenance, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial Body Mass Index (BMI) of: • ≥30 kg/m2 (obesity) or • ≥27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus)'.	Technology appraisal [TA1026]	Tirzepatide is recommended as an option for managing overweight and obesity, alongside a reduced-calorie diet and increased physical activity in adults, only if they have: • an initial body mass index (BMI) of at least 35 kg/m2 and • at least 1 weight-related comorbidity. Use a lower BMI threshold (usually reduced by 2.5 kg/m2) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds. If less than 5% of the initial weight has been lost after 6 months on the highest tolerated dose, decide whether to continue treatment, taking into account the benefits and risks of treatment for the person.	The list prices of tirzepatide (4-week supply of pre-filled pen devices for subcutaneous injection) are: • £92.00 for 2.5 mg and 5 mg • £107.00 for 7.5 mg and 10 mg • £122.00 for 12.5 mg and 15 mg

SMC

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LEVODOPA/ CARBIDOPA/ ENTACAPONE	LECIGON	For the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results.	Medicine Advice [SMC2507]	Following a full submission assessed under the orphan equivalent medicine process levodopa 20mg/mL + carbidopa monohydrate 5mg/mL + entacapone 20mg/mL intestinal gel (Lecigon®) is not recommended for use within NHSScotland. The submitting company did not present a sufficiently robust clinical or economic analysis to gain acceptance by SMC.	Dose regimen: 1 cartridge per day. Cost per year: £27,667
VIBEGRON	OBGEMSA	Symptomatic treatment of adult patients with overactive bladder (OAB) syndrome.	Medicine Advice [SMC2696]	Following an abbreviated submission vibegron (Obgemsa®) is accepted for use within NHSScotland.	
ZANUBRUTINIB	BRUKINSA	As monotherapy for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy.	Medicine Advice [SMC2684]	Following a full submission under the orphan medicine process zanubrutinib (Brukinsa®) is accepted for use within NHSScotland. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.	Dose regimen: 320 mg (four 80 mg capsules) once daily or 160 mg (two 80 mg capsules) twice daily. Treatment should be continued until disease progression or unacceptable toxicity. Cost per year: £ 59,801
DURVALUMAB	IMFINZI	In combination with platinum-based chemotherapy as neoadjuvant treatment, followed by durvalumab as monotherapy after surgery, is indicated for the treatment of adults with resectable (tumours ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known EGFR mutations or ALK rearrangements.	Medicine Advice [SMC2677]	Following a full submission durvalumab (Imfinzi®) is not recommended for use within NHSScotland. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	Neoadjuvant durvalumab 1,500 mg intravenously every 3 weeks in combination with chemotherapy for up to four cycles or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with durvalumab 1,500 mg intravenously every 4 weeks as monotherapy for up to 12 cycles or until disease recurrence or unacceptable toxicity. Cost per course: Up to £ 118,368