NEWSLETTER: News from the HTA Agencies

July 2025

SUMMARY

HTA Agency	N°of Drugs	Drugs Name
CADTH Evidence Driven.	9	SEMAGLUTIDE • PASIREOTIDE • LEUPROLIDE MESYLATE • LAZERTINIB + AMIVANTAMAB • BELZUTIFAN • PEMBROLIZUMAB • POLATUZUMAB VEDOTIN • ELAFIBRANOR • OMAVELOXOLONE
HAS HAUTE AUTORITÉ DE SANTÉ	26	CROVALIMAB • GARDASIL • CHOLECALCIFEROL • NORMAL HUMAN IMMUNOGLOBULIN • ZICONOTIDE • TETRAVALENT LIVE ATTENUATED DENGUE VACCINE • BELZUTIFAN • GADOXETIC ACID • BLINATUMUMAB • BLINATUMUMAB • NEMOLIZUMAB • SELADELPAR • LEUPRORELIN • BECLOMETASONE + FORMOTEROL • FLUTICSONE PROPIONATE + SALMETEROL • DOLUTEGRAVIR + LAMIVUDINE • NITROUS OXIDE / OXIGEN • LEVOFOLIC ACID • RUXOLITINIB • POLISTE SPP WASP VENOM • RIBOCICLIB • PARACETAMOL • LEVETIRACETAM • VIBEGRON • EPLOTERSEN • BELUMOSUDIL
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW	0	
IQWiG Institute for Quality and Efficiency in Health Care	10	ACORAMIDIS • BELZUTIFAN • BELZUTIFAN • OSIMERTINIB • PIRTOBRUTINIB • LISOCABTAGENE MARALEUCEL • AMIVANTAMAB • LAZERTINIB • LAZERTINIB • AMIVANTAMAB
NICE National Institute for Health and Care Excellence	9	NEMOLIZUMAB • ADAGRASIB • DAPAGLIFLOZIN • ZANUBRUTINIB • LETERMOVIR • LISOCABTAGENE MARALEUCEL • IDECABTAGENE VILEUCEL • FRUQUINTINIB • MIRIKIZUMAB
SMC Scottish Medicines Consortium	7	FEZOLINETANT • AMIVANTAMAB • SELPERCATINIB • OSIMERTINIB • ABALOPARATIDE • PEMBROLIZUMAB • LECANEMAB

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
SEMAGLUTIDE	WEGOVY	As an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obesity), or • 27 kg/m2 or greater (overweight) in the presence of at least one weightrelated comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidemia, or obstructive sleep apnea.	CADTH Reimbursement Recommendation	Reimburse with conditions Wegovy should only be reimbursed if a patient is also on a reduced-calorie diet, has increased physical activity for chronic weight management, and the cost of Wegovy is reduced. For continuation of reimbursement after the first year of treatment, at least a 5% reduction in BMI or total body weight must be documented. Thereafter, patients should be reassessed each year.	Treatment with Wegovy is expected to cost approximately $5,066 per patient per year.
PASIREOTIDE	SIGNIFOR LAR	For the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue	CADTH Reimbursement Recommendation	Reimburse with conditions Signifor LAR should only be reimbursed if prescribed by specialists who have expertise in the diagnosis and management of acromegaly and if the cost of Signifor LAR does not exceed the drug program cost of treatment with a first-generation SSA for the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative.	Treatment with Signifor LAR is expected to cost approximately $65,859 per patient per year.
LEUPROLIDE MESYLATE	CAMCEVI	For the treatment of adult patients with advanced prostate cancer	CADTH Reimbursement Recommendation	Reimburse with conditions The cost of Camcevi should not exceed the drug program cost of treatment with the least costly alternative treatment.	Treatment with Camcevi is expected to cost approximately $2,998 per patient annually.
LAZERTINIB + AMIVANTAMAB	LAZCLUZE + RYBREVANT	For the first-line treatment of adult patients with locally advanced (not amenable to curative therapy) or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations	CADTH Reimbursement Recommendation	Reimburse with conditions Lazcluze plus Rybrevant should only be reimbursed for patients who have not had any prior anticancer treatment for advanced or metastatic disease, if prescribed by clinicians with expertise in treating NSCLC, and the cost of Lazcluze plus Rybrevant does not exceed the total cost of treatment with osimertinib plus platinum-based chemotherapy (PBC).	Treatment with Lazcluze plus Rybrevant is expected to cost approximately $12,135 per 28-day cycle.

CADTH

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BELZUTIFAN	WELIREG	For the treatment of adult patients with advanced renal cell carcinoma following a programmed death receptor-1 or programmed deathligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor	CADTH Reimbursement Recommendation	Reimburse with conditions Welireg should only be reimbursed if it is prescribed by clinicians with expertise in treating advanced RCC and if the cost of Welireg is reduced.	Treatment with Welireg is expected to cost approximately $17,920 per patient per 28-day cycle.
PEMBROLIZUMAB	KEYTRUDA	In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma	CADTH Reimbursement Recommendation	Reimburse with conditions Keytruda plus pemetrexed and platinum chemotherapy should only be reimbursed if it is prescribed by clinicians with experience in immuneoncology and in treating MPM, and if the cost is not higher than the drug program cost of treatment with nivolumab plus ipilimumab.	Treatment with Keytruda plus pemetrexed and platinum chemotherapy is expected to cost between $9,655 and $10,235 per patient every 21 days.
POLATUZUMAB VEDOTIN	POLIVY	Polivy (polatuzumab vedotin for injection) in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated for the treatment of adult patients with previously untreated large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high grade B-cell lymphoma, Epstein-Barr viruspositive (EBV+) DLBCL NOS, and T-cell/histiocyte rich LBCL that are classified as activated B-cell-like (ABC) lymphoma subtype	CADTH Reimbursement Recommendation	Reimburse with conditions Polivy in combination with R-CHP should only be reimbursed if prescribed by clinicians with experience in the management of aggressive lymphomas and the side effects of treatment with curative intent and the cost of Polivy is reduced	Treatment with Polivy in combination with R-CHP is expected to cost approximately $23,605 per patient per 28 days.

CADTH

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ELAFIBRANOR	IQIRVO	For the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA	CADTH Reimbursement Recommendation 	Reimburse with conditions Iqirvo should only be reimbursed if prescribed by or in consultation with a specialist, such as a gastroenterologist, a hepatologist, or other physicians with expertise in managing PBC, and if the cost of Iqirvo is reduced. For renewal after the initial authorization, Iqirvo should follow the same renewal criteria as obeticholic acid, in accordance with the reimbursement criteria of each public drug plan for treating PBC. For ongoing renewals, physicians must confirm that the patient's initial response to Iqirvo achieved during the first 12 months has been maintained. Renewal of coverage should be assessed on an annual basis.	Treatment with Iqirvo is expected to cost approximately $76,220 per patient per year.
OMAVELOXOLONE	SKYCLARYS	For the treatment of Friedreich's ataxia in patients 16 years of age and older	CADTH Reimbursement Recommendation 	Reimburse with conditions Skyclarys should only be reimbursed if the patient is under the care of a clinician experienced in treating ataxias and if the cost of Skyclarys is reduced. Treatment with Skyclarys should be stopped if the patient's mFARS score increases by more than 2 points in a year, or if their score increases to more than 80.	Treatment with Skyclarys is expected to cost approximately $399,180 per patient per year

Generic Name	Brand Name	Indication	Type of Document	Recommendation
CROVALIMAB	PIASKY	As monotherapy for the treatment of adult and pediatric patients aged 12 years and older, weighing 40 kg or more, with paroxysmal nocturnal hemoglobinuria (PNH): - in patients with hemolysis accompanied by clinical symptoms indicating high disease activity, - in patients who are clinically stable after having been treated with a C5 complement inhibitor for at least the past 6 months.	Avis de la CT	Registration. Negative opinion on reimbursement.
GARDASIL	HUMAN PAPILLOMA VIRUS 9-VALENT VACCINE, RECOMBINANT, ADSORBED	Prevention of infections and lesions caused by certain oncogenic types of Human Papillomavirus (HPV), in girls and boys	Avis de la CT	Modification of registration conditions following the update of the HAS 2025 guidelines Favorable opinion for reimbursement ASMR: III (moderate): The update of the vaccination strategy according to the HAS recommendations in force as of April 30, 2025, does not alter the level of improvement in the medical benefit (opinion of February 19, 2020), which remains moderate (Level III) within the prevention strategy for precancerous and cancerous anogenital lesions related to certain HPV types in the target populations (girls and boys), in accordance with the current vaccination schedule and the HAS recommendations of April 30, 2025.
CHOLECALCIFEROL	UVEDOSE	Treatment and/or prevention of vitamin D deficiency.	Avis de la CT	First registration Favorable opinion for reimbursement ASMR: V (absence): This product is a range supplement that does not provide any improvement in medical benefit (ASMR V) compared to the already listed presentations.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
NORMAL HUMAN IMMUNOGLOBULIN	PANZYGA	Substitution treatment in adults, children, and adolescents (0-18 years): • Primary immunodeficiencies (PID) with impaired antibody production. • Secondary immunodeficiencies (SID) in patients with severe or recurrent infections, for whom antimicrobial treatment is ineffective and who have proven specific antibody deficiency (PSAF) * or a serum IgG level < 4 g/L. *PSAF = inability to achieve at least a twofold increase in IgG antibody titer with pneumococcal polysaccharide vaccines and polypeptide antigens. • Pre/post-exposure prophylaxis against measles in adults, children, and adolescents (0 to 18 years) at risk for whom active immunization is contraindicated or not recommended. Official guidelines regarding the use of intravenous human immunoglobulins for pre/post-exposure prophylaxis and active immunization against measles should be followed.	Avis de la CT 	First-registration Positive opinion for reimbursement in the indications of the marketing authorization (MA). ASMR: V (absence): PANZYGA (normal human immunoglobulin) 100 mg/mL provides no improvement in the medical service rendered (ASMR V) compared to other registered normal human immunoglobulins administered intravenously or subcutaneously.
ZICONOTIDE	PRIALT	Treatment of severe, chronic pain in adults requiring intrathecal analgesia.	Avis de la CT 	Reassessment at the request of the laboratory Positive opinion for reimbursement ASMR: V (ABSENCE): The Commission considers that PRIALT 100 mcg/mL (ziconotide), injectable solution for infusion, does not provide an improvement in the medical service rendered (ASMR V) in the management strategy of severe chronic pain in adults requiring intrathecal analgesia, particularly with opioids.

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TETRAVALENT LIVE ATTENUATED DENGUE VACCINE	QDENGA	Dengue prevention	Avis de la CT	Registration Positive opinion for reimbursement for dengue prevention, according to the HAS vaccination recommendations of December 12, 2024, in the French territories of the Americas (Antilles and Guyana), as well as in Mayotte and Réunion. ASMR: IV (MINOR): The Transparency Committee considers, based on the current data, that the (tetravalent live attenuated dengue vaccine) provides a minor improvement in the medical service rendered (ASMR IV) within the therapeutic strategy, according to the HAS vaccination recommendations of December 12, 2024.
BELZUTIFAN	WELIREG	As monotherapy for the treatment of adult patients requiring therapy for renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNETs) associated with von Hippel-Lindau disease, for whom localized interventions are not suitable.	Avis de la CT	Registration Positive reimbursement opinion ASMR: IV (MINOR): The Committee considers that WELIREG (belzutifan) 40 mg, film-coated tablet, provides a minor improvement in the medical service rendered (ASMR IV) within the current therapeutic strategy and for patients for whom localized interventions are not suitable.
GADOXETIC ACID	PRIMOVIST	PRIMOVIST is indicated for the detection of focal liver lesions and provides information on the nature of the lesions using T1-weighted sequences in magnetic resonance imaging (MRI). PRIMOVIST should be used only when diagnosis is necessary and when this diagnosis cannot be obtained by MRI without contrast enhancement, and when delayed-phase imaging is required. This medicine is for diagnostic use only, administered intravenously.	Avis de la CT	First registration Positive reimbursement opinion ASMR: V (ABSENCE): PRIMOVIST 0.25 mmol/mL (gadoxetic acid), injectable solution in a prefilled (plastic) syringe, is an additional formulation that does not provide any improvement in the medical service rendered (ASMR V) compared to the already registered presentations (in glass).

HAS

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BLINATUMUMAB	BLINCYTO	As monotherapy for the treatment of pediatric patients aged 1 month to 1 year with CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) that is Philadelphia chromosome-negative, refractory or in relapse after at least two prior treatments, or in relapse after a prior allogeneic hematopoietic stem cell transplant	Avis de la CT	Extension of indication Positive reimbursement opinion ASMR: IV (MINOR): the Commission considers that BLINCYTO (blinatumomab) 38.5 micrograms, powder for solution for dilution and solution for infusion, provides a minor improvement in the medical service rendered (ASMR IV) in the historical management—based on chemotherapy salvage treatments—of CD19-positive B-cell precursor acute lymphoblastic leukemia that is Philadelphia chromosome-negative, refractory or in relapse after at least two prior treatments, or in relapse after a prior allogeneic hematopoietic stem cell transplant in children aged 1 month to 1 year.
BLINATUMUMAB	BLINCYTO	As monotherapy for the treatment of pediatric patients aged 1 month to 1 year with CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) that is Philadelphia chromosome-negative, in high-risk first relapse as part of consolidation therapy.	Avis de la CT	Extension of indication Positive reimbursement opinion ASMR: III (MODERATE): the Commission considers that BLINCYTO (blinatumomab) 38.5 micrograms, powder for solution for dilution and solution for infusion, provides a moderate improvement in the medical service rendered (ASMR III) compared to conventional chemotherapy in the treatment of children aged 1 month to 1 year with CD19-positive B-cell precursor ALL, Philadelphia chromosome-negative, in first high-risk relapse, as part of the third consolidation block.
NEMOLIZUMAB	NEMLUVIO	Treatment of adults with moderate to severe nodular prurigo requiring systemic therapy	Avis de la CT	Registration Positive reimbursement opinion La Commission considère que NEMLUVIO 30 mg (némolizumab), solution injectable en stylo prérempli, apporte une amélioration du service médical rendu modérée (ASMR III) dans la prise en charge du prurigo nodulaire modéré à sévère de l'adulte qui nécessite un traitement systémique, au même titre que DUPIXENT (dupilumab)

HAS

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SELADELPAR	LYVDELZI	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA alone, or as monotherapy in patients who cannot tolerate UDCA	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE): The Commission considers that, given the current state of the data, LYVDELZI 10 mg, capsule (seladelpar), does not provide an improvement in the medical service rendered (ASMR V) in the current therapeutic strategy, in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in patients who do not tolerate UDCA.
LEUPRORELIN	CAMCEVI	In the treatment of advanced hormone-dependent prostate cancer; in combination with radiotherapy in the treatment of high-risk, locally advanced, hormone-dependent localized prostate cancer.	Avis de la CT	First registration Favorable opinion on reimbursement ASMR: V (ABSENCE): This specialty is a hybrid which does not provide any improvement in the medical service rendered (ASMR V) compared to the reference specialty already registered.
DOLUTEGRAVIR + LAMIVUDINE	DOVATO	treatment of HIV-1 infection only in adults and adolescents aged over 12 years and weighing at least 40 kg: treatment-naive, with more than 200 CD4/mm3, a viral load (VL) less than 500,000 copies/mL and without known or suspected resistance to one of the two molecules; pre-treated, having a stable CV < 50 copies/mL for at least one year, more than 350 CD4/mm3 and without known or suspected resistance to one of the two molecules.	Avis de la CT	Re-evaluation at the request of the laboratory Favorable opinion on reimbursement in the treatment of HIV-1 infection only in adults and adolescents aged over 12 years and weighing at least 40 kg. Unfavorable opinion on reimbursement in other situations covered by the MA indication. ASMR: IV (MINOR): The update of the reimbursement scope in light of the long-term follow-up data from the GEMINI 1 and 2 studies, and in line with the current HAS recommendations, is not likely to modify the level of improvement in the medical service rendered by DOVATO (dolutegravir/lamivudine) according to the opinion of January 8, 2020: ASMR IV in the management of patients infected with HIV-1, from the age of 12, treatment-naïve, with more than 200 CD4/mm3, a CV < 500,000 copies/mL and without known or suspected resistance to one of the two molecules, ASMR: V (ABSENCE): The update of the reimbursement scope in light of the long-term follow-up data from the GEMINI 1 and 2 studies, and in line with the current HAS recommendations, is not likely to modify the level of improvement in the medical service provided by DOVATO (dolutegravir/lamivudine) according to the opinion of January 8, 2020: ASMR V in the management of patients infected with HIV-1, pre-treated and virologically controlled, compared to the JULUCA specialty.

HAS

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BECLOMETASONE + FORMOTEROL	BECLOMETASONE + FORMOTEROL	In asthma: In continuous treatment of asthma, in situations where inhaled administration of a drug combining a corticosteroid and a long-acting beta-2 agonist bronchodilator is justified: in patients inadequately controlled by inhaled corticosteroid therapy and taking an inhaled short-acting beta-2 agonist bronchodilator "on demand"; or in patients controlled by inhaled corticosteroid therapy combined with an inhaled long-acting beta-2 agonist In chronic obstructive pulmonary disease (COPD): Symptomatic treatment of patients with severe COPD (FEV1 < 50% of predicted) and a history of repeated exacerbations, and in whom significant respiratory symptoms persist despite regular treatment with a long-acting bronchodilator.	Avis de la CT	First registration. Favorable opinion on reimbursement ASMR: V (ABSENCE): These specialties are hybrids which do not provide any improvement in the medical service rendered (ASMR V) compared to the reference specialties INNOVAIR 100/6 µg/dose and 200/6 µg/dose (beclometasone/formoterol), solution in pressurized bottle.
FLUTICSONE PROPIONATE + SALMETEROL	FLUTICSONE PROPIONATE + SALMETEROL ELC CIPHALER	In asthma, for all dosages: In continuous treatment of asthma, in situations where inhaled administration of a drug combining a corticosteroid and a long-acting β2 agonist bronchodilator is justified: in patients inadequately controlled by inhaled corticosteroid therapy and taking an inhaled short-acting β2 agonist bronchodilator "on demand" Or in patients controlled by the administration of inhaled corticosteroid therapy combined with continuous treatment with inhaled long-acting β2 agonist. In chronic obstructive pulmonary disease (COPD), only for the 500 µg / 50µg / dose dosage: For the symptomatic treatment of COPD in patients whose FEV1 (measured after administration of a bronchodilator) is less than 60% of the predicted value and who have a history of repeated exacerbations and significant symptoms despite continuous bronchodilator treatment.	Avis de la CT	First-time registration Favorable opinion on reimbursement ASMR: V (ABSENCE): These specialties are hybrids which do not provide any improvement in the medical service rendered (ASMR V) compared to the reference specialties SERETIDE DISKUS (fluticasone propionate / salmeterol) already registered.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
NITROUS OXIDE / OXIGEN	KALINOX	- Short-term analgesia for painful procedures or in cases of mild to moderate pain in adults and children over one month old (e.g., lumbar puncture, bone marrow aspiration, minor superficial surgery, burn dressings, reduction of simple fractures, reduction of certain peripheral dislocations, venipuncture, emergency medical aid – trauma, burns, transport). - Sedation in dental care for infants, children, and adolescents, anxious patients, or patients with disabilities. - Analgesia in obstetrics, exclusively in a hospital setting, while awaiting epidural analgesia, or in case of refusal or impossibility to perform it.	Avis de la CT	First-time registration Favorable opinion on reimbursement within the MA indications. ASMR V (ABSENCE): These specialties are a range supplement which does not provide any improvement in the medical service rendered (ASMR V) compared to the presentations already listed.
LEVOFOLIC ACID	CALCIUM LEVOFOLINATE ZENTIVA	For the specialties LEVOFOLINATE DE CALCIUM ZENTIVA 10 mg/ml and 25 mg/2.5 ml: in association with 5-fluorouracil in cytotoxic therapy; to reduce the toxicity and counteract the action of folic acid antagonists such as methotrexate when used in cytotoxic therapy and in cases of overdose in adults and children. In cytotoxic therapy, this procedure is commonly referred to as "folinic acid rescue." Only for the specialty LEVOFOLINATE DE CALCIUM ZENTIVA 25 mg/2.5 ml: in the prevention and treatment of folate deficiencies during major malabsorption and prolonged total parenteral nutrition.	Avis de la CT	First registration. Favorable opinion on reimbursement. ASMR: V (ABSENCE): These specialties are range complements that do not provide an improvement in the medical service rendered (ASMR V) compared to the presentations already registered. Registration in the city is not likely to modify the previous conclusions of the Transparency Commission.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
RUXOLITINIB	JAKAVI	The treatment of adult and pediatric patients aged 28 days and older with acute graft-versus-host disease who have an inadequate response to corticosteroids or other systemic therapies and in the treatment of adult and pediatric patients aged 6 months and older with chronic graft-versus-host disease who have an inadequate response to corticosteroids or other systemic therapies.	Avis de la CT	Primary registration and extension of indication Favorable opinion for reimbursement ASMR: IV (MINOR): The Transparency Commission considers that the specialties JAKAVI 5 mg/mL, oral solution (ruxolitinib), and JAKAVI 5 mg, tablet (ruxolitinib), provide a minor improvement in actual benefit (IAB IV) in the management strategy for patients aged 28 days to less than 12 years with acute graft-versus-host disease who have an inadequate response to corticosteroids or other systemic treatments and patients aged 6 months to less than 12 years with chronic graft-versus-host disease who have an inadequate response to corticosteroids or other systemic treatments. ASMR: V (ABSENCE): JAKAVI 5 mg/ml oral solution is a product line extension that does not provide an improvement in actual benefit (IAB V) in adults and adolescents (>12 years) compared to the 5 and 10 mg film-coated tablet presentations of ruxolitinib already registered. In accordance with the SPC, this presentation can be used in patients who have difficulty swallowing film-coated tablets.
POLISTE SPP WASP VENOM	ALBEY POLISTE SPP WASP VENOM	The diagnosis of hypersensitivity to Polistes spp. wasp venom and treatment by allergen immunotherapy of subjects allergic to Polistes spp. wasp venom	Avis de la CT	Registration Favorable opinion on reimbursement ASMR: V (ABSENCE): The Commission considers that ALBEY WASP VENOM Polistes spp., powder and solvent for injectable solution, does not provide an improvement in the medical service rendered (ASMR V) in the current therapeutic strategy.
RIBOCICLIB	KISQALI	In combination with an aromatase inhibitor in patients in the adjuvant treatment of early-stage breast cancer with hormone receptor (HR) positive and human epidermal growth factor receptor 2 (HER2) negative, at high risk of relapse.	Avis de la CT	Extension of indication - Registration Unfavorable opinion on the reimbursement ASMR: NOT APPLICABLE

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Generic Name	Brand Name	Indication	Type of Document	Recommendation
PARACETAMOL	PARACETAMOL BGR	Symptomatic treatment of mild to moderate pain and/or fever	Avis de la CT	First registration Favorable opinion for reimbursement ASMR: V (ABSENCE): This specialty is a range supplement which does not provide any improvement in the medical service rendered (ASMR V) compared to the presentations already registered.
LEVETIRACETAM	KEPPRA	Treatment of partial seizures with or without secondary generalization only in infants and young children from 6 months to less than 4 years of age with epilepsy	Avis de la CT	First-time registration Favorable opinion for reimbursement ASMR: V (ABSENCE): This specialty is a range supplement which does not provide any improvement in the medical service rendered (ASMR V) compared to the presentations already registered.
VIBEGRON	OBGEMSA	Symptomatic treatment of overactive bladder syndrome (OAB) in adults	Avis de la CT	Registration Favorable opinion on reimbursement ASMR: V (ABSENCE): The Commission considers that OBGEMSA (vibegron) 75 mg, film-coated tablet, does not provide an improvement in the medical service rendered (ASMR V, non-existent) in the symptomatic treatment of overactive bladder syndrome (OAB) in adults.
EPLOTERSEN	WAINZUA	Treatment of hereditary transthyretin amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy, which cannot be satisfactorily treated with other available therapeutic options.	Avis de la CT	Early access authorization refused
BELUMOSUDIL	REZUROCK	Treatment of patients aged 12 years and older with chronic graft-versus-host disease (chronic GvHD) after failure of at least two prior lines of systemic treatment	Avis de la CT	Early access authorization refused

Generic Name	Brand Name	Indication	Type of Document	Recommendation
AMIVANTAMAB + LAZERTINIB	RYBREVANT + LAZCLUZE	RYBREVANT, in combination with lazertinib, as first-line treatment for adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR mutations by deletions in exon 19 or L858R substitution in exon 21 LAZCLUZE, in combination with amivantamab, as first-line treatment for adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR mutations by deletions in exon 19 or L858R substitution in exon 21	Avis de la CT	Registration Favorable opinion on reimbursement ASMR: IV (MINOR): The Commission considers that the combination of RYBREVANT (amivantamab) 350 mg, solution for dilution for infusion, with LAZCLUZE (lazertinib) 80 mg and 240 mg, film-coated tablets, provides a minor improvement in actual benefit (IAB IV) compared to TAGRISSO (osimertinib).
CAPIVASERTIB	TRUQAP	TRUQAP is indicated in combination with fulvestrant for the treatment of adult patients with estrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations following recurrence or progression during or after endocrine therapy (see section 5.1 of the SmPC). In pre- or perimenopausal women, TRUQAP and fulvestrant should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist. For men, administration of an LHRH agonist according to standard clinical practice should be considered.	Avis de la CT	First-time registration Favorable opinion on reimbursement ASMR: V (ABSENCE): The Commission considers that TRUQAP 160 mg and 200 mg (capivasertib) film-coated tablets, in combination with fulvestrant, do not provide an improvement in actual benefit (IAB V) compared to fulvestrant alone in the treatment of adult patients with estrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations following recurrence or progression during or after hormone therapy.

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Generic Name	Brand Name	Indication	Type of Document	Recommendation
AMIVANTAMAB + LAZERTINIB	RYBREVANT + LAZCLUZE	RYBREVANT, in combination with lazertinib, as first-line treatment for adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR mutations by deletions in exon 19 or L858R substitution in exon 21 LAZCLUZE, in combination with amivantamab, as first-line treatment for adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR mutations by deletions in exon 19 or L858R substitution in exon 21.	Avis de la CT	Registration Favorable opinion on reimbursement ASMR: IV (MINOR): The Commission considers that the combination of RYBREVANT (amivantamab) 350 mg, solution for dilution for infusion, with LAZCLUZE (lazertinib) 80 mg and 240 mg, film-coated tablets, provides a minor improvement in actual benefit (IAB IV) compared to TAGRISSO (osimertinib).
EPIRUBICIN HYDROCHLORIDE	EPIRUBICINE VIATRIS	in the treatment: transitional papillary cell carcinoma of the bladder, carcinoma in situ, and for intravesical prophylaxis of recurrence of non-muscle-invasive bladder tumor after transurethral resection.	Avis de la CT	Extension of indication Favorable opinion on reimbursement ASMR: V (ABSENCE): This specialty is a new generic which does not provide any improvement in the medical service rendered (ASMR V) compared to the epirubicin-based specialties already available and having this same indication.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
BELZUTIFAN	WELIREG	Adult patients with von Hippel-Lindau disease who require therapy for associated localized renal cell carcinoma, central nervous system haemangioblastomas or pancreatic neuroendocrine tumours, and for whom localized procedures are unsuitable	Dossier Assessment [A25-44]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) estimates the annual treatment costs per patient for Belzutifan at €169,927.94. These annual treatment costs include only drug costs and represent an underestimation. Based on the initial listing in the Lauer-Taxe as of April 1, 2025, recalculations result in annual treatment costs per patient amounting to €204,564.74.
BELZUTIFAN	WELIREG	Adult patients with advanced clear cell renal cell carcinoma that has progressed following 2 or more lines of therapy that included a PD-(L)1 inhibitor and at least 2 vascular endothelial growth factor-targeted therapies	Dossier Assessment [A25-45]	Result of dossier assessment: Patients < 65 years of age for whom everolimus is a suitable individualized treatment: hint of a minor added benefit Patients ≥ 65 years of age for whom everolimus is a suitable individualized treatment: hint of a considerable added benefit Patients for whom everolimus is not a suitable individualized treatment: added benefit not proven	The pU estimates annual treatment costs per patient for Belzutifan at €169,927.94, which consist solely of drug costs. However, the drug cost stated by the pU is underestimated. Based on the initial listing in the Lauer-Taxe on April 1, 2025, the recalculated annual treatment costs per patient amount to €204,564.74.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
ACORAMIDIS	BEYONTTRA	Wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)	Dossier Assessment [A25-46]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) determines annual treatment costs per patient for Acoramidis at €134,189.33.
OSIMERTINIB	TAGRISSO	Adults with locally advanced, unresectable non-small cell lung cancer whose tumours have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy	Dossier Assessment [A25-03]	Result of dossier assessment: Patients whose tumours express PD-L1 in ≥ 1% of tumour cells: added benefit not proven Patients whose tumours express PD-L1 in < 1% of tumour cells: added benefit not proven	The pharmaceutical company (pU) calculates the annual treatment costs per patient for Osimertinib at €66,095.17.
PIRTOBRUTINIB	JAYPIRCA	Adult patients with relapsed or refractory chronic lymphocytic leukaemia	Dossier Assessment [A25-50]	Result of dossier assessment: Patients who have been previously treated with a Bruton's tyrosine kinase inhibitor and not with a B-cell lymphoma 2 inhibitor: added benefit not proven Patients who have been previously treated with a Bruton's tyrosine kinase inhibitor and a B-cell lymphoma 2 inhibitor: added benefit not proven	The pU calculates annual therapy costs per patient for Pirtobrutinib at €143,849.63, which consist of drug costs and are plausible.
LISOCABTAGENE MARALEUCEL	BREYANZI	Adult patients with relapsed or refractory follicular lymphoma after 2 or more lines of systemic therapy	Dossier Assessment [A25-47]	Result of dossier assessment: Added benefit not proven	For lisocabtagene maraleucel, the pharmaceutical company (pU) estimates annual therapy costs per patient at €228,795.05.

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Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
AMIVANTAMAB	RYBREVANT	Adult patients with advanced non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitution mutations; first-line treatment	Dossier Assessment [A25-78] Addendum to project [A25-08]	Result of dossier assessment: Patients < 65 years: hint of a minor added benefit Patients ≥ 65 years: hint of a lesser benefit	-
LAZERTINIB	LAZCLUZE	Adult patients with advanced non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitution mutations; first-line treatment	Dossier Assessment [A25-77] Addendum to project [A25-11]	Result of dossier assessment: Patients < 65 years: hint of a minor added benefit Patients ≥ 65 years: hint of a lesser benefit	-
LAZERTINIB	LAZCLUZE	Adult patients with advanced non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitution mutations; first-line treatment	Dossier Assessment [A25-11]	Result of dossier assessment: Patients < 65 years: hint of a non-quantifiable added benefit Patients ≥ 65 years: hint of lesser benefit	The pU determines annual therapy costs per patient for amivantamab and lazertinib for the first treatment year amounting to €268,278.00 and annual therapy costs of €257,620.12 for each subsequent year.
AMIVANTAMAB	RYBREVANT	Adult patients with advanced non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitution mutations; first-line treatment	Dossier Assessment [A25-08]	Result of dossier assessment: Patients < 65 years: hint of a non-quantifiable added benefit Patients ≥ 65 years: hint of lesser benefit	The applicant calculates annual therapy costs per patient for Amivantamab and Lazertinib of €268,278.00 for the first year of treatment and annual therapy costs of €257,620.12 for each subsequent year.

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
NEMOLIZUMAB	NEMLUVIO	Nemolizumab (Nemluvio, Galderma) is indicated for 'the treatment of moderateto-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors in adults and adolescents 12 years and older with a body weight of at least 30 kg, who are candidates for systemic therapy'.	Technology appraisal [TA1077]	Nemolizumab with topical corticosteroids or calcineurin inhibitors, or both, can be used as an option to treat moderate to severe atopic dermatitis. It can be used in people 12 years and over with a body weight of 30 kg or more when systemic treatment is suitable, only if: • the atopic dermatitis has not responded to at least 1 systemic immunosuppressant, or these treatments are not suitable, and • a biological medicine would otherwise be offered, and • the company provides nemolizumab according to the commercial arrangement.	The list price of nemolizumab is £2,257 per 30-mg unit (company submission).
ADAGRASIB	KRAZATI	For previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer in adults.	Technology appraisal [TA1076]	NICE is unable to make a recommendation about the use in the NHS of adagrasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer in adults.	
DAPAGLIFLOZIN	FORXIGA	Dapagliflozin (Forxiga, AstraZeneca) is 'indicated in adults for the treatment of chronic kidney disease.'	Technology appraisal [TA1075] This guidance replaces TA775	Dapagliflozin can be used as an option to treat chronic kidney disease (CKD) in adults, if: • it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-2 receptor antagonists, unless these are contraindicated, and • people have an estimated glomerular filtration rate (eGFR) of: — 20 ml/min/1.73 m2 to less than 45 ml/min/1.73 m2 or — 45 ml/min/1.73 m2 to 90 ml/min/1.73 m2, and either: ◇ a urine albumin-to-creatinine ratio of 22.6 mg/mmol or more, or ◇ type 2 diabetes.	The list price of dapagliflozin is £36.59 for 28 tablets (5 mg and 10 mg) (excluding VAT; BNF online, accessed April 2025).

NICE

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ZANUBRUTINIB	BRUKINSA	Zanubrutinib (Brukinsa, BeiGene) is indicated for the 'treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy'.	Technology appraisal [TA1081]	Zanubrutinib can be used as an option to treat relapsed or refractory mantle cell lymphoma in adults who have had 1 line of treatment only. Zanubrutinib can only be used if the company provides it according to the commercial arrangement.	The list price for zanubrutinib is £4,928.65 for a 120 pack of 80-mg capsules (excluding VAT, BNF online, accessed May 2025).
LETERMOVIR	PREVYMIS	For preventing cytomegalovirus infection after a kidney transplant in adults	Technology appraisal [TA1082]	NICE is unable to make a recommendation about the use in the NHS of letermovir for preventing cytomegalovirus infection after a kidney transplant in adults. This is because Merck Sharp & Dohme has confirmed that it does not intend to make an evidence submission for the appraisal. The company considers that there is unlikely to be enough cost-effectiveness evidence to support a decision.	
LISOCABTAGENE MARALEUCEL	BREYANZI	For treating relapsed or refractory large B-cell lymphomas after first-line chemotherapy in adults when a stem cell transplant is unsuitable.	Technology appraisal [TA1083]	NICE is unable to make a recommendation about the use in the NHS of lisocabtagene maraleucel for treating relapsed or refractory large B-cell lymphomas after first-line chemotherapy in adults when a stem cell transplant is unsuitable. This is because BristolMyers Squibb has confirmed that it does not intend to make an evidence submission for the appraisal. Bristol-Myers Squibb considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources in this population.	
IDECABTAGENE VILEUCEL	ABECMA	Treating relapsed or refractory multiple myeloma after 2 to 4 treatments in adults.	Technology appraisal [TA1084]	NICE is unable to make a recommendation about the use in the NHS of idecabtagene vicleucel for treating relapsed or refractory multiple myeloma after 2 to 4 treatments in adults. This is because Bristol-Myers Squibb has confirmed that it does not intend to make an evidence submission for the appraisal. Bristol-Myers Squibb considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources in this population.	

NICE

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FRUQUINTINIB	FRUZAQLA	Fruquintinib (Fruzaqla, Takeda) is indicated for 'the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with available therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, with or without an anti-VEGF therapy, and, if RAS wildtype and medically appropriate, an anti-EGFR therapy'.	Technology appraisal [TA1079]	Fruquintinib can be used as an option at third line or later to treat metastatic colorectal cancer in adults when previous treatment has included: • fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, with or without anti-vascular endothelial growth factor (VEGF) treatment, and • anti-epidermal growth factor receptor (EGFR) treatment if the cancer is RAS wild-type, unless this was not suitable. Fruquintinib can only be used if: • trifluridine–tipiracil with bevacizumab is not suitable • the company provides it according to the commercial arrangement.	The list price of fruquintinib is £3,950.00 per 21-pack of 5-mg capsules and £790.00 per 21-pack of 1-mg capsules (excluding VAT; BNF online accessed June 2025).
MIRIKIZUMAB	OMVOH	Mirikizumab (Omvoh, Eli Lilly) is indicated for the treatment of 'adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment'.	Technology appraisal [TA1080]	Mirikizumab can be used as an option to treat moderately to severely active Crohn's disease in adults, only if: • the disease has not responded well enough or stopped responding to a previous biological treatment, or • a previous biological treatment was not tolerated, or • tumour necrosis factor (TNF)-alpha inhibitors are not suitable. Mirikizumab can only be used if the company provides it according to the commercial arrangement.	The list price of the 300-mg concentrate solution for infusion used for induction treatment is £2,056.56 (excluding VAT, BNF online, accessed April 2025). The list price of 1 pre-filled pen of 200 mg plus 1 pre-filled pen of 100 mg for subcutaneous injection as maintenance treatment is £2,398.33 (excluding VAT, company communication).

NICE

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VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR	ALYFTREK	Vanzacaftor-tezacaftor-deutivacaftor (Vnz-Tez-Diva; Alyftrek, Vertex) is indicated for 'the treatment of cystic fibrosis (CF) in people aged 6 years and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene'.	Technology appraisal [TA1085]	Vanzacaftor-tezacaftor-deutivacaftor (Vnz-Tez-Diva) can be used as an option to treat cystic fibrosis in people 6 years and over who have at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Vnz-Tez-Diva can only be used if the company provides it according to the commercial arrangement.	The list price for Vnz-Tez-Diva (excluding VAT; company submission) is £16,110.00 per: • 84-tablet pack of Vnz 10 mg, Tez 50 mg and Diva 125 mg • 56-tablet pack of Vnz 4 mg, Tez 20 mg and Diva 50 mg

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FEZOLINETANT	VEOZA	For the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.	Medicine Advice [SMC2798]	Following a full submission, fezolinetant (Veoza®) is not recommended for use within NHSScotland.	45 mg orally once daily Cost per year (£) 582
AMIVANTAMAB	RYBREVANT	In combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon20 insertion mutations.	Medicine Advice [SMC2758]	Following a full submission assessed under the end of life and orphan equivalent medicine process amivantamab (Rybrevant®) is not recommended for use within NHSScotland.	Body weight <80 kg: 1,400 mg once weekly for first 4 doses or 1,750 mg every 3 weeks from week 7 onwards ≥80 kg: 1,750 mg once weekly for first 4 doses 2,100 mg every 3 weeks from week 7 onwards Cost per 21-day cycle (£): 17,264 to 21,580 for first 4 doses then 5,395 to 6,474
SELPERCATINIB	RETSEVMO	As monotherapy for the treatment of adults and adolescents 12 years and older with advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory (if radioactive iodine is appropriate)	Medicine Advice [SMC2733]	Following a full submission assessed under the orphan equivalent medicine process selpercatinib (Retsevmo®) is accepted for restricted use within NHSScotland. SMC restriction: patients who require systemic therapy who have not previously received systemic therapy.	120 or 160 mg orally twice daily Cost per year (£) 85,176 to 113,568
ABALOPARATIDE	ELADYNOS	Treatment of osteoporosis in postmenopausal women at increased risk of fracture	Medicine Advice [SMC2764]	Following a full submission abaloparatide (Eladynos®) is accepted for restricted use within NHSScotland.	Medicine: abaloparatide Dose regimen: 80 micrograms subcutaneously once daily for a maximum duration of 18 months. Cost per 30 days (£): 295

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PEMBROLIZUMAB	KEYTRUDA	In combination with carboplatin and paclitaxel, for the first-line treatment of primary advanced or recurrent endometrial carcinoma in adults.	Medicine Advice [SMC2767]	Following a full submission pembrolizumab (Keytruda®) is accepted for use within NHSScotland.	Medicine: Pembrolizumab; Carboplatin; Paclitaxel Dose regimen: 200 mg IV every three weeks for six doses then 400 mg IV every six weeks for 14 doses; AUC 5 mg/mL/minute IV every three weeks for six doses; 175 mg/m2 BSA IV every three weeks for six doses Cost per course (£): 184,544
LECANEMAB	LEQEMBI	For the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients that are apolipoprotein E ε 4 (ApoEε4) heterozygotes or non-carriers.	Medicine Advice [SMC2811]	Following a resubmission lecanemab (Leqembi®) is not recommended for use within NHSScotland.	Medicine: lecanemab Dose regimen: 10 mg/kg intravenous infusion every 2 weeks Cost per year (£): 21,320