NEWSLETTER: News from the HTA Agencies

March 2025

SUMMARY

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CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
FARICIMAB	VABYSMO	For the treatment of macular edema secondary to retinal vein occlusion	CADTH Reimbursement Recommendation 	Reimburse with conditions. The Canadian Drug Expert Committee (CDEC) recommends that faricimab be reimbursed for the treatment of macular edema secondary to RVO only if the conditions are met. Vabysmo should only be reimbursed in a similar way to other anti-VEGF drugs currently reimbursed by public drug plans for the treatment of patients with macular edema secondary to RVO and the cost of Vabysmo should not exceed the drug program cost of treatment with other antiVEGFs reimbursed for macular edema secondary to RVO.	Treatment with Vabysmo is expected to cost between $9,450 and $13,500 per patient in the first year of use, depending on how many injections are required (between 7 and 10 injections). In subsequent years, the annual cost per patient is expected to be between $5,400 and $9,450 (based on 4 to 7 injections per year).
FERRIC CARBOXYMALTOSE	FERINJECT	For the treatment of iron deficiency in adult patients with heart failure and NYHA class II/III to improve exercise capacity.	CADTH Reimbursement Recommendation 	Reimburse with Conditions. The CDA-AMC Canadian Drug Expert Committee (CDEC) recommends that ferric carboxymaltose be reimbursed for the treatment of iron deficiency (ID) in adult patients with heart failure and New York Heart Association (NYHA) class II/III to improve exercise capacity only if the conditions are met: 1. Adult patients with heart failure and NYHA class II or III who have HF and who have all the following: 1.1. Have LVEF ≤ 40% 1.2. Have ferritin ≤ 300 µg/L with a TSAT < 15% 2. Duration of initial authorization is 24 weeks 3. For renewal after initial authorization and each subsequent annual renewal, the physician must provide proof that the criteria in condition 1 above still applies. 4. Cardiologist or clinician experienced in the management of chronic HF 5. A reduction in price	Ferric carboxymaltose, 50 mg elemental iron per mL, intravenous $45.00 per 2 mL single-use vial $225.00 per 10 mL single-use vial $450.00 per 20 mL single-use vial $800 per treatment course

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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. The CDA-AMC Canadian Drug Expert Committee (CDEC) recommends that pasireotide for injectable suspension be reimbursed 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 a first-generation somatostatin analogues only if the conditions listed are met: 1. Adult patients with a confirmed diagnosis of acromegaly and all of the following: 1.1 Patients must be ineligible, have contraindications, or demonstrated lack of response to surgery 1.2 Patients must have shown inadequate control of disease with a first generation SSA, octreotide or lanreotide for a 6 months trial 2. The maximum duration of initial authorization is 6 months. 3. For renewal after initial authorization and each subsequent annual renewal, the physician must provide proof of normalization of GH and IGF-1 as follows: random GH <1 µg/L and age normalised IGF-1 <ULN. Additionally, the patient should not have undergone surgery within the past 3 to 6 months.	Submitted prices: $5,048.76 per 40 mg vial; $5,048.76 per 60 mg vial Submitted treatment cost $65,859 annually per patient
TERLATAMAB	IMDELLTRA	The treatment of adult patients with extensive-stage small cell lung cancer with disease progression on or after at least 2 prior lines of therapy including platinum-based chemotherapy	CADTH Reimbursement Recommendation	Reimburse with conditions. Imdelltra should only be reimbursed if administered in centres with appropriate medical support to manage potentially life-threatening adverse events, such as cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), and if the cost of Imdelltra is reduced.	Treatment with Imdelltra is expected to cost approximately $32,445 per patient for the first 28-day cycle and $30,900 per patient for each subsequent 28-day treatment cycle.

CADTH

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TALQUETAMAB	TALVEY	For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an antiCD38 monoclonal antibody, and have demonstrated disease progression on or after the last therapy.	CADTH Reimbursement Recommendation	Do not reimburse.	Treatment with Talvey on a weekly dosing schedule is estimated to cost approximately $31,154 per patient for the first 28 days, followed by $29,129 every 28 days thereafter. For the biweekly dosing schedule, the estimated cost is approximately $36,878 for the first 28 days and $27,184 every 28 days thereafter, per patient.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ENFORTUMAB VEDOTIN	PADCEV	In combination with pembrolizumab, in the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma eligible for platinum-based chemotherapy.	Avis de la CT	Extension of indication. Registration. ASMR: III (moderate): the Commission considers that PADCEV (enfortumab vedotin) 20 mg and 30 mg, powder for solution to be diluted for infusion, provides a moderate improvement in medical service rendered (ASMR III) compared with platinum-based chemotherapies.
NIVOLUMAB + IPILIMUMAB	OPDIVO + YERVOY	As a first-line treatment for adult patients with unresectable or metastatic colorectal cancer (CRC) presenting a deficiency in the DNA mismatch repair system (dMMR) or high microsatellite instability (MSI-H).	Avis de la CT	Early access authorization denied.
PEMBROLIZUMAB	KEYTRUDA	KEYTRUDA, in combination with radiochemotherapy (external radiotherapy followed by brachytherapy), in the treatment of adult patients with locally advanced stage III cervical cancer (extension to the pelvic wall and/or lower third of the vagina and/or, is causing hydronephrosis or a non-functioning kidney) - IVA (involvement of the mucosa of the bladder or rectum -adjacent pelvic organs-) with or without pelvic and/or para-aortic lymph node invasion, according to FIGO 2014, who have not received prior definitive treatment.	Avis de la CT	Extension of indication. Approval for reimbursement. ASMR: III (moderate): The Commission considers that KEYTRUDA (pembrolizumab) 25 mg/ml, dilutable solution for infusion, in association with radiochemotherapy (external radiotherapy followed by brachytherapy) provides a moderate improvement in medical service rendered (ASMR III) compared with radiochemotherapy.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
PEMBROLIZUMAB	KEYTRUDA	In combination with trastuzumab and platinum-fluoropyrimidine-based chemotherapy for the first line treatment of adult patients with gastric adenocarcinoma or gastric oesus junction, locally advanced non-resectable or metastatic, HER-2 positive and whose tumors express PD-L1 with a CPS 1.	Avis de la CT	Early access authorization granted
Inactivated influenza vaccine, surface antigen, prepared on cell cultures	FLUCELVAX TIV	Prevention of influenza in adults and children aged 2 and over, in line with current vaccination recommendations	Avis de la CT	Registration. Approval of reimbursement. ASMR: V (absence): The change from tetravalent to trivalent is not likely to alter the level of improvement in medical service rendered. The Commission considers that FLUCELVAX (inactivated influenza vaccine, surface antigen, prepared on cell cultures) provides no improvement in medical service rendered (ASMR V), in adults and children aged 2 and over for whom vaccination is recommended, compared with other vaccines recommended for the prevention of seasonal influenza.
FERRIC CARBOXYMALTOSE	FERRIC CARBOXYMALTOSE	Treatment of martial deficiency when: - oral iron preparations are not effective; - oral iron preparations may not be used; - there is a clinical need to administer iron quickly. The diagnosis of martial deficiency must be based on appropriate biological examinations.	Avis de la CT	First-time registration. Approval for reimbursement. ASMR: V (absence) This speciality is a hybrid which does not provide any improvement in medical service rendered (ASMR V) compared to the reference speciality already registered. FERRIC CARBOXYMALTOSE TEVA 50 mg/mL (ferric carboxymaltose) is not likely to have an additional impact on public health compared to the reference specialty FERINJECT 50 mg/mL (ferric carboxymaltose). The Commission considers that the medical benefit provided by FERRIC CARBOXYMALTOSE TEVA 50 mg/mL (ferric carboxymaltose), injectable/infusion dispersion, is moderate in children aged 1 to 13 years, in the treatment of iron deficiency when oral iron preparations are not effective or cannot be used, or when there is a clinical need to administer iron intravenously rapidly.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ACALABRUTINIB	CALQUENCE	In combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for stem cell autotransplantation.	Avis de la CT	Early access authorization denied
DABRAFENIB + TRAMETINIB	FINLEE + SPEXOTRAS	Treatment of pediatric patients aged 1 year and older with BRAF V600E-mutated low-grade glioma (LGG) who require systemic therapy Treatment of pediatric patients aged 1 year and over with BRAF V600E-mutated high-grade glioma (GHG) who have received at least one prior course of radiotherapy and/or chemotherapy	Avis de la CT	First-time registration. Approval of reimbursement. ASMR: IV (mineur): The combination of FINLEE (dabrafenib) 10 mg, dispersible tablet, and SPEXOTRAS (trametinib) 0.05 mg/mL, powder for oral solution, provides a minor improvement in medical service rendered (ASMR IV) compared with carboplatin and vincristine chemotherapy, in the treatment of low-grade glioma carrying a BRAF V600E mutation in pediatric patients aged 1 year and over who require systemic treatment. The combination of FINLEE (dabrafenib) 10 mg, dispersible tablet, and SPEXOTRAS (trametinib) 0.05 mg/mL, powder for oral solution, provides a minor improvement in medical service rendered (ASMR IV) in the strategy for the management of high-grade glioma with a BRAF V600E mutation in pediatric patients aged 1 year and over who have received at least one prior course of radiotherapy and/or chemotherapy.
MARSTACIMAB	HYMPAVZI	For routine prophylaxis of bleeding episodes in patients aged 12 and over, weighing at least 35 kg, with severe hemophilia A (congenital factor VIII deficiency, FVIII < 1%) without factor VIII inhibitors, or severe hemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors, with difficult venous access or when alternatives are not possible	Avis de la CT	Early access authorization denied

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
EPCORITAMAB	TEPKINLY	In the treatment of adult patients with refractory or relapsed diffuse large B-cell lymphoma (DLBCL), after at least two lines of systemic treatment, who are ineligible for all available therapies or have failed CAR-T cell-based drugs	Avis de la CT	Early access authorization renewed
DANICOPAN	VOYDEYA	In combination with ravulizumab or eculizumab in the treatment of adult patients with paroxysmal nocturnal hemoglobinuria presenting symptomatic hemolytic anemia after treatment with a C5 complement inhibitor for at least 6 months	Avis de la CT	First-time registration. Approval for reimbursement only “in combination with ravulizumab or eculizumab in the treatment of adult patients with paroxysmal nocturnal hemoglobinuria presenting symptomatic hemolytic anemia after treatment with a C5 complement inhibitor for at least 6 months”. Refusal of reimbursement in other situations covered by the AMM indication. ASMR III (moderate): the Commission considers that VOYDEYA 50 mg and 100 mg (danicopan), film-coated tablet, provides a moderate improvement in medical service rendered (ASMR III) in association with ravulizumab or eculizumab in the treatment of adult HPN patients with symptomatic hemolytic anemia after treatment with a C5 inhibitor for at least 6 months, in the same way as ASPAVELI (pegcetacoplan).
BLINATUMUMAB	BLINCYTO	As monotherapy for consolidation treatment in adult patients over 30 years of age with CD19-expressing B-precursor acute lymphoblastic leukemia (ALL) with Philadelphia chromosome negative in first complete remission with negative minimal residual disease (MRD)	Avis de la CT	Early access authorization granted

Generic Name	Brand Name	Indication	Type of Document	Recommendation
IMLIFIDASE	IDEFIRIX	Desensitization treatment of hyperimmunized adult patients awaiting a kidney transplant with a positive crossmatch against an available deceased donor graft and who are not eligible for current desensitization strategies. The use of Idefirix must be reserved for patients with a low probability of being transplanted within the current graft allocation (and distribution) system, including under priorities and/or programs intended for hyperimmunized patients.	Avis de la CT	Renewal of the early access authorization granted
ODEVIXIBAT	KAYFANDA (ex BYLVAY)	Treatment of cholestatic pruritus associated with Alagille syndrome (AGS) in patients aged 6 months or over.	Avis de la CT	Registration. Approval of reimbursement. ASMR: III (moderate): the Commission considers that KAYFANDA (odevixibat) provides a moderate improvement in medical service rendered (ASMR III) in the current therapeutic strategy.
BEMPEDOIC ACID	NILEMDO	Treatment of adult patients at high or very high cardiovascular risk, with proven intolerance to statins or in whom statins are contraindicated, to reduce cardiovascular risk by lowering LDL-c levels when these are not at target despite optimized lipid-lowering therapy: - in cases of high risk of atherosclerotic cardiovascular disease (primary prevention); - or in cases of established atherosclerotic cardiovascular disease (secondary prevention).	Avis de la CT	Registration. NILEMDO (bempedoic acid) will be reimbursed only in adult patients at high or very high cardiovascular risk, with proven intolerance to statins or in whom statins are contraindicated, to reduce cardiovascular risk by lowering LDL-c levels when these are not at target despite optimized lipid-lowering therapy: in cases of high risk of atherosclerotic cardiovascular disease (primary prevention) ; or in cases of established atherosclerotic cardiovascular disease (secondary prevention). No reimbursement for NILEMDO (bempedoic acid) in other clinical situations covered by the AMM indication. The Commission considers that NILEMDO (bempedoic acid) 180 mg, film-coated tablet, does not provide an improvement in medical service rendered (ASMR V) in the current therapeutic strategy for the management of adult patients at high risk of atherosclerotic cardiovascular disease (primary prevention) or in patients with established atherosclerotic cardiovascular disease (secondary prevention).

HAS

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MARIBAVIR	LIVTENCITY	Treatment of cytomegalovirus (CMV) infection and/or disease that is refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir, or 1 foscarnet in adult patients who have received a hematopoietic stem cell transplant (HSCT) or a solid organ transplant (SOT). Consideration should be given to official recommendations on the appropriate use of antiviral agents.	Avis de la CT	Early access authorization granted.
GLUCARPIDASE	VORAXAZE	Reduction of toxic plasma methotrexate concentration in adults and children (from 28 days) with delayed methotrexate elimination or at risk of methotrexate toxicity.	Avis de la CT	Early access authorization renewed.
TRASTUZUMAB DERUXTECAN	ENHERTU	As monotherapy in the treatment of adult patients with unresectable or metastatic breast cancer with hormone receptor-positive (HR+), HER2-low or HER2-ultra-low expression, who have received at least one hormone therapy in the metastatic setting and who are not eligible for subsequent line hormone therapy.	Avis de la CT	Early access authorization refused.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
MELPHALAN	PHELINUN	A high dose of PHELINUN used alone or in combination with other cytotoxic drugs and/or total body irradiation is indicated in the treatment of the following conditions: multiple myeloma; malignant lymphoma (Hodgkin's lymphoma, non-Hodgkin's); acute lymphoblastic leukemia and acute myeloblastic leukemia; infantile neuroblastoma. PHELINUN in combination with other cytotoxic drugs is indicated as reduced intensity conditioning (RIC) prior to allogeneic hematopoietic stem cell transplantation (allo-HSCT) in adults with malignant hematologic diseases. PHELINUN in combination with other cytotoxic drugs is indicated as conditioning treatment prior to allogeneic hematopoietic stem cell transplantation in hematologic malignancies within the pediatric population, namely: Myeloablative conditioning (MAC) treatment for malignant hematologic diseases; RIC treatment for non-malignant hematologic diseases.	Avis de la CT	Registration. Favorable opinion for reimbursement. ASMR: V (absence): In the indications common to the reference specialty, the Commission considers that PHELINUN 50 mg/10 ml and 200 mg/40 ml (melphalan) does not provide an improvement in medical benefit (ASMR V) compared to melphalan-based specialties already registered. In combination with other cytotoxic drugs as reduced intensity conditioning (RIC) prior to allogeneic hematopoietic stem cell transplantation (allo-HSCT) in adults with malignant hematologic diseases, the Commission considers that PHELINUN 50 mg/10 ml and 200 mg/40 ml (melphalan) does not provide an improvement in medical benefit (ASMR V) compared to available RIC conditioning protocols. In combination with other cytotoxic drugs as myeloablative conditioning (MAC) prior to allogeneic hematopoietic stem cell transplantation (allo-HSCT) in cases of malignant hematologic diseases within the pediatric population, the Commission considers that PHELINUN 50 mg/10 ml and 200 mg/40 ml (melphalan) does not provide an improvement in medical benefit (ASMR V) compared to available MAC conditioning protocols. In combination with other cytotoxic drugs as reduced intensity conditioning (RIC) prior to allogeneic hematopoietic stem cell transplantation (allo-HSCT) in cases of non-malignant hematologic diseases within the pediatric population, the Commission considers that PHELINUN 50 mg/10 ml and 200 mg/40 ml (melphalan) does not provide an improvement in medical benefit (ASMR V) compared to available RIC conditioning protocols.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
BENRELIZUMAB	FASENRA	As an add-on therapy in adult patients with recurrent or refractory eosinophilic granulomatosis with polyangiitis.	Dossier Assessment [A24-113]	Result of dossier assessment: Added benefit not proven	The company calculated annual treatment costs per patient for benralizumab in the amount of €31,963.36.
RIBOCICLIB	KISQALI	Adjuvant treatment of patients with HR-positive, HER2-negative early breast cancer at high risk of recurrence.	Dossier Assessment [A24-124]	Result of dossier assessment: 1. Premenopausal women: added benefit not proven 2. Postmenopausal women: added benefit not proven 3. Men: added benefit not proven	The company calculates annual therapy costs per patient for Ribociclib + Aromatase Inhibitor + GnRH analog in the range of €31,642.93 to €33,191.14, and annual therapy costs per patient for Ribociclib + Aromatase Inhibitor in the range of €29,791.47 to €30,564.88.
LINZAGOLIX	YSELTY	Symptomatic treatment of endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis; with concomitant hormonal add-back therapy	Dossier Assessment [A24-123]	Result of dossier assessment: Added benefit not proven	The company calculates annual therapy costs per patient for Linzagolix at €1,323.39.

IQWiG

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
ATEZOLIZUMAB	TECENTRIQ	First-line treatment of advanced non-small cell lung cancer in adult patients for whom platinum-based chemotherapy is not an option and whose tumours have no EGFR mutations or ALK translocations.	Dossier Assessment [A24-97]	Result of dossier assessment after addendum now: 1. Patients with PD-L1 expression ≥ 50% on tumour cells: added benefit not proven 2. Patients with PD-L1 expression < 50% on tumour cells: indication of minor added benefit	The company calculates annual therapy costs per patient for Atezolizumab at €67,767.78 (s.c. administration) and €69,507.78 (i.v. administration, once every 3 weeks).
ATEZOLIZUMAB	TECENTRIQ	First-line treatment of advanced non-small cell lung cancer in adult patients for whom platinum-based chemotherapy is not an option and whose tumours have no EGFR mutations or ALK translocations.	Dossier Assessment [A25-25] Addendum to [A24-97]	Result of dossier assessment after addendum now: 1. Patients with PD-L1 expression ≥ 50% on tumour cells: added benefit not proven 2. Patients with PD-L1 expression < 50% on tumour cells: indication of minor added benefit	
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 company calculates annual therapy costs for Sotatercept per patient ranging from €172,384.02 to €172,385.02
SOTATERCEPT	WINREVAIR	Treatment of pulmonary arterial hypertension in adult patients with WHO Functional Class II to III, to improve exercise capacity	Dossier Assessment [A25-14] Addendum to [A24-96]	Result of dossier assessment: unchanged after addendum: Added benefit not proven	

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: 1. Patients with high disease activity, characterized by clinical symptoms of haemolysis: added benefit not proven 2. Adult patients who have been treated with a C5 inhibitor for ≥ 6 months and are clinically stable: hint of lesser benefit 3. 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	The company calculated annual treatment costs per patient of €97,354.70 to €103,781.50. For the subsequent pembrolizumab monotherapy in the 2nd year of treatment, the company determined annual treatment costs per patient of €91,509.10 to €92,448.70.
CROVALIMAB	PIASKY	Adult and paediatric patients 12 years of age or older with a weight of ≥ 40 kg with paroxysmal nocturnal haemoglobinuria	Dossier Assessment [A25-12] Addendum to [A24-94]	Result of dossier assessment: After addendum now: 1. Patients with high disease activity, characterized by clinical symptoms of haemolysis: added benefit not proven 2. Patients who have been treated with a C5 inhibitor for ≥ 6 months and are clinically stable: added benefit not proven	For apremilast, the company calculated annual treatment costs of €7752.08 to €11,317.61 per patient.
DUPILUMAB	DUPIXENT	Add-on maintenance treatment of adult patients with uncontrolled COPD characterized by raised blood eosinophils on a combination of an inhaled corticosteroid, a long-acting beta-2 agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if an inhaled corticosteroid is not appropriate	Dossier Assessment [A24-79]	Result of dossier assessment: Added benefit not proven	For Dupilumab, the company calculates annual therapy costs of €15,974.70.

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DARATUMUMAB	DARZALEX	In combination with Bortezomib, Lenalidomide, and Dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who 1 are eligible for autologous 2 stem cell transplantation.	Dossier Assessment [A24-114] 	Result of dossier assessment: Added benefit not proven	The company calculates annual therapy costs per patient for Daratumumab + Bortezomib + Lenalidomide + Dexamethasone of €141,061.60 in the 1st year of treatment and annual therapy costs of €76,194.23 for each subsequent year.
CILTACABTAGENE AUTOLEUCEL	CARVYKTI	Treatment of relapsed and refractory multiple myeloma in adult patients who have previously received at least 3 therapies, including 1 immunomodulator, 1 proteasome inhibitor, and 1 anti-Cluster-of-Differentiation(CD)38 antibody, and who showed disease progression during the last therapy	Dossier Assessment [A24-116] 	Result of dossier assessment: 1. for adult patients with relapsed and refractory multiple myeloma who have previously received 1 to 3 prior therapies, including 1 immunomodulator and 1 proteasome inhibitor, and who showed disease progression during the last therapy and are refractory to lenalidomide, and for whom DPd or PVd is a suitable individualized patient therapy: indication of a non-quantifiable additional benefit 2. For adult patients with relapsed and refractory multiple myeloma who have previously received 1 to 3 prior therapies, including 1 immunomodulator and 1 proteasome inhibitor, and who showed disease progression during the last therapy and are refractory to lenalidomide, and for whom DPd or PVd is not a suitable individualized patient therapy, as well as for patients who have previously received at least 4 prior therapies: Added benefit not proven	For Ciltacabtagene Autoleucel, the company calculates annual therapy costs per patient of €286,326.65.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
DUPILUMAB	DUPIXENT	Treatment of children aged 1 to 11 years with a body weight of at least 15 kg with eosinophilic esophagitis (EoE) who are inadequately treated with, intolerant to, or ineligible for conventional drug therapy.	Dossier Assessment [A24-117]	Result of dossier assessment: Added benefit not proven	The company calculates annual therapy costs for Dupilumab ranging from €15,974.70 to €31,949.41

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
12 standard quality house dust mite sublingual lyophilisate	ACARIZAX	In adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with at least one of the following conditions: • persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication • house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients'asthma status should be carefully evaluated before the initiation of treatment'. In adolescents (12-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.	Technology appraisal [TA1045]	12 standard quality house dust mite sublingual lyophilisate (SQ-HDM SLIT) is recommended, within its marketing authorisation, as an option for treating moderate to severe house dust mite allergic rhinitis in people 12 to 65 years that is: • diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test or specific immunoglobulin E [IgE]) and • persistent despite use of symptom-relieving medicine.	The list price of 12 SQ-HDM SLIT is £80.12 (excluding VAT; BNF accessed April 2024) per pack of 30 tablets
ATEZOLIZUMAB	TECENTRIQ	For untreated advanced or recurrent non-small-cell lung cancer when platinum-doublet chemotherapy is unsuitable in adults	Technology appraisal [TA1047]	NICE is unable to make a recommendation about the use in the NHS of atezolizumab for untreated advanced or recurrent non-small-cell lung cancer when platinum-doublet chemotherapy is unsuitable in adults. This is because Roche Products has confirmed that it does not intend to make an evidence submission for the appraisal. Roche Products considers that there is unlikely to be enough evidence that the technology is a costeffective use of NHS resources in this population.	

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
ZOLBETUXIMAB	VYLOY	Zolbetuximab (Vyloy, Astellas) in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.	Technology appraisal [TA1046] 	Zolbetuximab with fluoropyrimidine- and platinum-based chemotherapy is not recommended, within its marketing authorisation, for untreated, locally advanced, unresectable or metastatic, claudin-18.2-positive, HER2-negative, gastric or gastro-oesophageal junction adenocarcinoma in adults.	The list price of zolbetuximab is £410 per 100-mg vial.
FENFLURAMINE	FINTEPLA	Fenfluramine (Fintepla, UCB) is indicated for 'the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) as an add-on therapy to other antiepileptic medicines for patients 2 years of age and older'.	Technology appraisal [TA1050] 	Fenfluramine is recommended as an option for treating seizures associated with Lennox–Gastaut syndrome (LGS), as an add-on to other antiseizure medicines, for people 2 years and over. It is recommended only if: • the frequency of drop seizures is checked every 6 months, and fenfluramine is stopped if the frequency is not reduced by at least 30% compared with the 6 months before starting treatment • the company provides it according to the commercial arrangement.	The list price for fenfluramine is £1,802.88 for the 120-ml (2.2 mg/ml) bottle and £5,408.65 for the 360-ml bottle.
BLINATUMUMAB	BLINCYTO	Blinatumomab (Blincyto, Amgen) is indicated for 'the treatment of adult patients with Philadelphia chromosome negative CD19-positive B-cell precursor leukaemia ALL in the consolidation phase'.	Technology appraisal [TA1049] 	Blinatumomab with chemotherapy can be used as an option to treat Philadelphiachromosome-negative CD19-positive B-cell precursor acute lymphoblastic leukaemia (ALL) in adults, if: • the leukaemia is minimal residual disease-negative • it is used at the start of consolidation treatment • the company provides it according to the commercial arrangement.	The list price of blinatumomab is £2,017 per 38.5-microgram vial

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
LISOCABTAGENE MARALEUCEL	BREYANZI	Lisocabtagene maraleucel (liso-cel; Breyanzi, Bristol-Myers Squibb) is indicated for 'the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma (HGBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B), who relapsed within 12 months from completion of, or are refractory to, first-line chemoimmunotherapy'	Technology appraisal [TA1048]	Lisocabtagene maraleucel (liso-cel) is recommended as an option for treating large B-cell lymphoma that is refractory to, or has relapsed within 12 months after, first-line chemoimmunotherapy in adults with: • diffuse large B-cell lymphoma • high-grade B-cell lymphoma • primary mediastinal large B-cell lymphoma, or • follicular lymphoma grade 3B. Liso-cel is recommended only if: • an autologous stem cell transplant would be considered suitable, and • the company provides it according to the commercial arrangement.	The list price for a single infusion, including shipping, engineering and generation of CAR-T cells is £297,000

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CABOZANTINIB	CABOZANTINIB IPSEN	As monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.	Medicine Advice [SMC2754]	Following an abbreviated submission cabozantinib (Cabozantinib Ipsen) is accepted for use within NHSScotland.	Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.
ATEZOLIZUMAB	TECENTRIQ	As monotherapy for the first-line treatment of adult patients with advanced NSCLC who are ineligible for platinum-based therapy.	Medicine Advice [SMC2769]	In the absence of a submission from the holder of the marketing authorisation atezolizumab (Tecentriq®) is not recommended for use within NHSScotland.	
AMIVANTAMAB	RYBREVANT	In combination with carboplatin and pemetrexed for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI).	Medicine Advice [SMC2768]	In the absence of a submission from the holder of the marketing authorisation amivantamab (Rybrevant®) is not recommended for use within NHSScotland.	
SPESOLIMAB	SPEVIGO	For the treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy.	Medicine Advice [SMC2729]	Following a full submission assessed under the orphan equivalent medicine process spesolimab (Spevigo®) is not recommended for use within NHSScotland.	Dose regime: 900 mg IV infusion on Day 1, with optional extra dose on Day 8 : Cost per course (£) 15,000 to 30,000

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RIPRETINIB	QINLOCK	For the treatment of adult patients with advanced gastrointestinal stromal tumour (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib.	Medicine Advice [SMC2722]	Following a full submission assessed under the end of life and orphan medicine process ripretinib (Qinlock®) is not recommended for use within NHSScotland.	Dose regimen: 150 mg once daily, taken orally. Cost per 28 days (£): 17,173.
TALAZOPARIB	TALZENNA	In combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.	Medicine Advice [SMC2753]	Following an abbreviated submission talazoparib (Talzenna®) is accepted for use within NHSScotland.	Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.