NEWSLETTER: News from the HTA Agencies

November 2025

SUMMARY

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HAS HAUTE AUTORITÉ DE SANTÉ	21	IPTACOPAN • APRACLONIDINE • TRAMADOL• GADOBUTROL • PARACETAMOL • LECANEMAB • LONAFARNIB • MELATONIN • TUBERCULIN • EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL • TISLELIZUMAB • DOSTARLIMAB • ENCORAFENIB/BINIMETINIB • RIOCIGUAT • ACETYLSALICYLIC ACID • DARATUMUMAB • NORMAL HUMAN IMMUNOGLOBULIN • BREXPIPRAZOLE • ZOLBETUXIMAB
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CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
RISANKIZUMAB	SKYRIZI	For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, loss of response, or were intolerant to conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor	CADTH Reimbursement Recommendation	Reimburse with conditions Skyrizi should only be reimbursed if it is prescribed by a physician experienced in the diagnosis and management of UC if it is not used in combination with other advanced therapies for UC and if the cost of Skyrizi is reduced so that it does not cost the drug programs more than the least costly relevant advanced therapy reimbursed in this patient population. A patient's disease must respond to treatment within the first 12 weeks of starting Skyrizi to continue receiving the drug.	Treatment with Skyrizi is expected to cost approximately $50,627 per patient in year 1 and $29,958 per patient per year thereafter.
DAROLUTAMIDE	NUBEQA	In combination with androgen deprivation therapy for the treatment of metastatic castration-sensitive prostate cancer	CADTH Reimbursement Recommendation	Reimburse with conditions Nubeqa should only be reimbursed in accordance with the criteria used by each of the participating drug programs for other ARPI plus ADT regimens and if the drug program cost of Nubeqa does not exceed that of the least costly ARPI plus ADT regimen for the treatment of mCSPC	At the submitted price of $28.34 per tablet, the 28-day cycle cost of darolutamide is expected to be $3,175 per patient, based on the Health Canada–recommended dosage. When used in combination with ADT, the 28-day cost of darolutamide plus ADT is expected to be $3,427 to $3,603 per patient.

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
GUSELKUMAB	TREMFYA	For the treatment of adult patients with moderately to severely active ulcerative colitis	CADTH Reimbursement Recommendation	Reimburse with conditions Tremfya should only be reimbursed if it is prescribed by a physician experienced in the diagnosis and management of UC, and if it is not used in combination with other advanced therapies for UC. A patient's disease must respond to treatment in the first 24 weeks of starting Tremfya to continue receiving the drug. The cost of Tremfya should not exceed the drug program cost of treatment with the least costly advanced therapy reimbursed for the treatment of UC	Treatment with Tremfya is expected to cost between $23,016 and $39,913 per patient per year in year 1 and between $19,957 and $39,913 per patient per year in subsequent years, depending on the frequency with which maintenance doses are received.
TALAZOPARIB	TALZENNA	Talazoparib in combination with enzalutamide for the treatment of adult patients with homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer	CADTH Reimbursement Recommendation	Reimburse with conditions Talzenna plus enzalutamide should only be reimbursed if it is prescribed by a clinician with expertise in treating prostate cancer and should not be reimbursed when used in combination with other anticancer drugs.	Treatment with Talzenna is expected to cost $5,564 per patient per 28 days. When Talzenna is used in combination with enzalutamide, the expected cost is $8,833 per patient per 28 days.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
IPTACOPAN	FABHALTA	Treatment of adult patients with C3 deposition glomerulopathy (GC3) in combination with a renin-angiotensin system (RAS) inhibitor or in patients intolerant to RAS inhibitors or in whom an RAS inhibitor is contraindicated	Avis de la CT	Registration Adverse opinion for reimbursement ASMR: NOT APPLICABLE
APRACLONIDINE	IOPIDINE	In the prevention of post-surgical elevations of intraocular pressure in patients who have just undergone laser intervention at the level of the anterior segment of the eye	Avis de la CT	Registration Adverse opinion for reimbursement ASMR: NOT APPLICABLE
TRAMADOL	TOPALGIC	Treatment of moderate to severe pain in adults (adults and adolescents over 15 years of age)	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (absence): These specialties are a range complement which does not provide any improvement in the medical service provided (ASMR V) compared to the presentations already registered.
GADOBUTROL	GADOVIST	GADOVIST is indicated in adults and in children of all ages (including full-term newborns) for: - Contrast enhancement in magnetic resonance imaging (MRI) of the cranial and spinal regions. - Contrast enhancement in MRI of the liver or kidneys in patients with strong suspicion or clear evidence of focal lesions, in order to classify these lesions as benign or malignant. - Contrast enhancement in magnetic resonance angiography (MRA). - GADOVIST may also be used for magnetic resonance imaging of whole-body pathologies.	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE): GADOVIST 1.0 mmol/mL, injectable solution in pre-filled syringe (plastic), is a range addition which does not provide any improvement in the medical service provided (ASMR V) compared to the presentations already registered.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
PARACETAMOL	PARACETAMOL BASI	In adults, adolescents and children weighing more than 33 kg, in the short-term treatment of moderate pain, particularly after surgery and in the short-term treatment of fever	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE): This specialty does not provide any improvement in the medical service provided (ASMR V) compared to presentations already registered.
LECANEMAB	LEQEMBI	Treatment of adult patients with a clinical diagnosis of mild cognitive impairment and early-stage dementia due to Alzheimer's disease (early Alzheimer's disease), who are not carriers or heterozygous for the ε4 allele of the apolipoprotein E (ApoE ε4) gene and who have confirmed amyloid pathology	Avis de la CT	Registration Adverse opinion for reimbursement ASMR: NOT APPLICABLE
LONAFARNIB	ZOKINVY	Treatment of patients aged 12 months and older with a genetically confirmed diagnosis of Hutchinson-Gilford syndrome (progeria) or progeroid laminopathy with a heterozygous inactivating LMNA mutation with accumulation of progerin-like proteins or a homozygous or heterozygous ZMPSTE24 mutation	Avis de la CT	Early access authorization renewed

Generic Name	Brand Name	Indication	Type of Document	Recommendation
MELATONIN	ADAFLEX	In insomnia in children and adolescents aged 6 to 17 years with attention deficit hyperactivity disorder (ADHD) when sleep hygiene measures have been insufficient	Avis de la CT	Registration Favorable opinion for reimbursement in insomnia Unfavorable opinion for reimbursement in other situations covered by the marketing authorization indication ASMR: V (ABSENCE): The Commission considers that ADAFLEX (immediate release melatonin) does not provide any improvement in the medical service provided (ASMR V) in the current therapeutic strategy.
TUBERCULIN	TUBERCULIN PPD RT 23 AJV	tuberculin skin test or Mantoux test	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE): This specialty does not provide any improvement in the medical service provided (ASMR V) compared to the already registered TUBERTEST (tuberculin) specialty.
EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL	EFAVIRENZE/EMTRICITABINE/TENOFOVIR DISOPROXIL ZENTIVA KS	adult patients with HIV already using triple therapy based on efavirenz/emtricitabine/tenofovir disoproxil and who are virologically controlled.	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE): This specialty is a generic which does not provide any improvement in the medical service provided (ASMR V) compared to the reference specialty.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
TISLELIZUMAB	TEVIMBRA	in combination with platinum-based and fluoropyrimidine-based chemotherapy, for the first-line treatment of adult patients with locally advanced, unresectable or metastatic, HER-2-negative gastric or esophagogastric junction (G/EGJ) adenocarcinoma whose tumors express PD-L1 with a TAP (tumor area positivity) score ≥ 5% (see section 5.1 of the SmPC)" in combination with platinum-based chemotherapy, for the first-line treatment of adult patients with unresectable, locally advanced or metastatic esophageal squamous cell carcinoma (ESC) whose tumors express PD-L1 with a TAP score ≥ 5% (see section 5.1 of the SmPC)	Avis de la CT	Extension of indication Favorable opinion for reimbursement ASMR: III (MODERATE): TEVIMBRA (tislezizumab), in combination with platinum-based and fluoropyrimidine-based chemotherapy, provides a moderate improvement in the medical benefit (ASMR III) compared to chemotherapy alone, in the first-line treatment of adult patients with locally advanced, unresectable or metastatic, HER-2-negative gastric or esophagogastric junction (G/EGJ) adenocarcinoma whose tumors express PD-L1 with a TAP score ≥ 5%. TEVIMBRA (tislelizumab), in combination with platinum-based chemotherapy, provides a moderate improvement in the medical benefit (ASMR III) compared to chemotherapy alone, in the first-line treatment of adult patients with unresectable, locally advanced or metastatic esophageal squamous cell carcinoma (ESC) whose tumors express PD-L1 with a TAP score ≥ 5%.
DOSTARLIMAB	JEMPERLI	in combination with carboplatin and paclitaxel for the treatment of adult patients with newly diagnosed or recurrent advanced endometrial cancer, who do not have a deficiency in the base mismatch repair/microsatellite instability (pMMR/MSS) system or whose status with regard to this deficiency is unknown, and who are candidates for systemic therapy.	Avis de la CT	Early access authorization renewed for the specialty

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ENCORAFENIB/BINIMETINIB	BRAFTOVI/MEKTOVI	the treatment of adult patients with advanced non-small cell lung cancer carrying a BRAF V600E mutation, as second-line treatment and beyond after failure of chemotherapy and/or immunotherapy	Avis de la CT	Extension of indication Favorable opinion for reimbursement ASMR: V (ABSENCE): The Commission considers that the combination of BRAFTOVI (encorafenib) 75 mg, capsule, and MEKTOVI (binimetinib) 15 mg and 45 mg, film-coated tablet, does not provide any improvement in the medical service provided (ASMR V) in the management of patients with NSCLC carrying the BRAF V600E mutation, in second line of treatment and beyond, after failure of chemotherapy and/or immunotherapy.
RIOCIGUAT	ADEMPAS	in combination with an endothelin receptor antagonist in children and adolescents aged 6 years to less than 18 years with pulmonary arterial hypertension (PAH) in WHO functional class II to III		Unsolicited extension of indication
ACETYLSALICYLIC ACID	ARROW ASPIRIN	In secondary prevention within the framework of chronic treatment for the indications of the Marketing Authorization: - Secondary prevention of myocardial infarction. - Prevention of cardiovascular morbidity in patients with stable angina. - History of unstable angina, outside of the acute phase. - Prevention of graft occlusion after Coronary Artery Bypass Surgery (CABS). - Coronary angioplasty, outside the acute phase. - Secondary prevention of transient ischemic attacks (TIAs) and cerebrovascular accidents (CVAs), provided that intracerebral hemorrhages have been excluded.	Avis de la CT	Registration Favorable opinion for reimbursement in secondary prevention within the framework of chronic treatment ASMR: V (ABSENCE): This specialty is a range complement which does not provide any improvement in the medical service provided (ASMR V) compared to the presentations of ASPIRIN ARROW (acetylsalicylic acid) at dosages of 75 mg and 100 mg, gastro-resistant tablet, already registered.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
DARATUMUMAB	DARZALEX	In combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplantation	Avis de la CT	Extension of indication Favorable opinion for reimbursement ASMR: V (ABSENCE): The Commission considers that DARZALEX 1800 mg (daratumumab), injectable solution, in combination with bortezomib, lenalidomide and dexamethasone (D-VRd protocol), does not provide any improvement in the medical service provided (ASMR V) in the current strategy for the first-line treatment of newly diagnosed multiple myeloma in adults ineligible for an autologous stem cell transplant
NORMAL HUMAN IMMUNOGLOBULIN	IG VENA	IG VENA is indicated for replacement therapy in adults, children and adolescents (0-18 years) with: - Primary immunodeficiencies (PID) with impaired antibody production. - Secondary immunodeficiencies (SID) in patients suffering from severe or recurrent infections, who have failed antimicrobial treatment and have either a proven specific antibody production defect (SIPD)* or serum IgG levels < 4 g/l. *SID = inability to increase the IgG antibody titre against the polysaccharide and polypeptide antigens of pneumococcal vaccines by at least 2-fold. IG VENA is also indicated for immunomodulatory treatment in adults, children and adolescents (0-18 years) with: - Primary immune thrombocytopenia (PIT), in patients with a high risk of bleeding or prior to surgery to correct platelet levels. - Guillain Barré syndrome. - Kawasaki disease (in combination with acetylsalicylic acid). - Chronic inflammatory demyelinating polyradiculoneuritis (CIDP). - Multifocal motor neuropathy (MMN)	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE): IG VENA (normal human immunoglobulin) 50 g/L does not provide any improvement in the medical service provided (ASMR V) compared to other listed normal human immunoglobulins administered intravenously or subcutaneously.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
BREXPIPRAZOLE	RXULTI	Treatment of schizophrenia in adults and adolescents aged 13 years and over	Avis de la CT	Registration Unfavorable opinion regarding reimbursement ASMR: NOT APPLICABLE
ZOLBETUXIMAB	VYLOY	In combination with fluoropyrimidine and platinum-based chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER-2 negative gastric or esophagogastric junction adenocarcinoma whose tumors are CLDN 18.2 positive and do not express PD-L1 or express PD-L1 with a Combined Positive Score (CPS) < 5 or are not eligible for PD-1/PD-L1 inhibitor therapy	Avis de la CT	Early access authorization granted

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
DURVALUMAB	IMFINZI	Adults with resectable non-small cell lung cancer at high risk of recurrence and without epidermal growth factor receptor mutations or anaplastic lymphoma kinase rearrangements; neoadjuvant and adjuvant therapy	Dossier Assessment [A25-98]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) calculates total therapy costs per patient for durvalumab in combination with platinum-based chemotherapy (neoadjuvant therapy phase) followed by durvalumab as monotherapy (adjuvant therapy phase) to range from €27,131.93 to €104,424.64.
ODRONEXTAB	ORDSPONO	Adults with relapsed or refractory diffuse large B-cell lymphoma, after at least 2 prior systemic therapies	Dossier Assessment [A25-100]	Result of dossier assessment: Patients who are eligible for CAR T-cell therapy or stem cell transplantation: added benefit not proven Patients who are ineligible for CAR T-cell therapy or stem cell transplantation: added benefit not proven	The pharmaceutical company (pU) calculates annual treatment costs for odronextamab per patient ranging from €332,277.26 to €366,978.58.
ODRONEXTAB	ORDSPONO	Adults with relapsed or refractory follicular lymphoma, after at least 2 lines of systemic therapy	Dossier Assessment [A25-101]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) calculates annual treatment costs for odronextamab per patient amounting to €169,986.27 to €187,644.75, which refer to the first year of treatment.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
DURVALUMAB	IMFINZI	Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy	Dossier Assessment [A25-96]	Result of dossier assessment: Indication of a minor added benefit	The pharmaceutical company (pU) calculates annual treatment costs for durvalumab per patient amounting to €79,038.57.
EFGARTIGIMOD ALFA	VYVGART	Adults with progressive or recurrent active chronic inflammatory demyelinating polyneuropathy after previous treatment with corticosteroids or immunoglobulins	Dossier Assessment [A25-95]	Result of dossier assessment: Added benefit not proven	The PU determines annual therapy costs per patient for efgartigimod alfa ranging from €435,887.49 to €870,104.91.
DURVALUMAB	IMFINZI	Adults with resectable muscle-invasive bladder cancer (MIBC) for whom platinum-based chemotherapy is suitable; neoadjuvant and adjuvant therapy after radical cystectomy	Dossier Assessment [A25-97]	Result of dossier assessment: Indication of a minor added benefit	Neoadjuvant Treatment Phase: The pU calculates annual therapy costs per patient for durvalumab + gemcitabine + cisplatin at €27,649.39 to €27,684.66. Adjuvant Treatment Phase: The pU calculates annual therapy costs per patient for durvalumab monotherapy at €6,079.89 to €48,639.12.
LETERMOVIR	PREVYMIS	Prophylaxis of cytomegalovirus reactivation and disease in paediatric patients with a body weight of at least 5 kg who are cytomegalovirus-seropositive recipients of an allogeneic haematopoietic stem cell transplant	Dossier Assessment [A25-126] Addendum to Project A25-67	Result of dossier assessment: Unchanged after addendum: added benefit not proven	-

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
UPADACITINIB	RINVOQ	Adults with giant cell arteritis	Dossier Assessment [A25-66]	Result of dossier assessment: Patients who are candidates for therapy with glucocorticoids alone: added benefit not proven Patients who are not candidates for therapy with glucocorticoids alone: added benefit not proven	The pharmaceutical company (pU) calculates annual therapy costs per patient for Upadacitinib monotherapy at €14,166.34.
UPADACITINIB	RINVOQ	Adults with giant cell arteritis	Dossier Assessment [A25-125] Addendum to Project A25-66	Result of dossier assessment: Patients who are candidates for therapy with glucocorticoids alone: unchanged after addendum: added benefit not proven Patients who are not candidates for therapy with glucocorticoids alone: unchanged after addendum: added benefit not proven	-
ISATUXIMAB	SARCLISA	Adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant	Dossier Assessment [A25-105]	Result of dossier assessment: Added benefit not proven	Induction therapy: The pharmaceutical company (pU) calculates the annual therapy costs per patient for induction therapy with Isatuximab + Bortezomib + Lenalidomide + Dexamethasone at €35,276.12 to €35,277.63Consolidation therapy: The pU calculates the annual therapy costs for consolidation therapies with Daratumumab + Bortezomib + Thalidomide + Dexamethasone or Daratumumab + Bortezomib + Lenalidomide + Dexamethasone at €26,643.52 to €26,644.07 or €25,599.56 to €25,600.11, respectively

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
DARATUMUMAB	DARZALEX	Adult patients with smouldering multiple myeloma who are at high risk of developing multiple myeloma	Dossier Assessment [A25-109]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) determined annual treatment costs for Daratumumab of €133,586.30 per patient for the first year of treatment and €75,505.30 per patient for each subsequent year.
DAROLUTAMIDE	NUBEQA	Adult men with metastatic hormone-sensitive prostate cancer	Dossier Assessment [A25-106]	Result of dossier assessment: Added benefit not proven	Annual therapy costs in € 47,230.10–50,529.53
INAVOLISIB	ITOVEBI	Adult patients with PIK3CA-mutated, oestrogen receptor-positive, HER2-negative, locally advanced or metastatic breast cancer, following recurrence during or within 12 months of completing adjuvant endocrine treatment	Dossier Assessment [A25-104]	Result of dossier assessment: Female patients < 65 years of age: indication of a minor added benefit Female patients ≥ 65 years of age: added benefit not proven Male patients: added benefit not proven	For Inavolisib + Palbociclib + Fulvestrant, the pU estimates annual therapy costs of €217,657.41
DARATUMUMAB	DARZALEX	Adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant	Dossier Assessment [A25-108]	Adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant	Annual Therapy Costs in € 120,163.01

IQWiG

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
ASCIMIB	SCEMBLIX	Adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) previously treated with ≥ 2 tyrosine kinase inhibitors	Dossier Assessment [A25-70]	Result of dossier assessment: Added benefit not proven	The MAH calculates annual treatment costs per patient for Nilotinib of €57,674.54, for Dasatinib of €10,562.61, for Bosutinib of €26,513.47, and for Ponatinib of €76,811.57.
DAPOTOMAB DERUXTECAN	DATROWAY	Adults with unresectable or metastatic HR-positive, HER2-negative breast cancer who have received endocrine therapy and at least one line of chemotherapy in the advanced setting	Dossier Assessment [A25-130]	Result of dossier assessment: Added benefit not proven	-
ASCIMIB	SCEMBLIX	Adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) previously treated with ≥ 2 tyrosine kinase inhibitors	Dossier Assessment [A25-129] Addendum to Project A25-70	Result of dossier assessment: Unchanged after addendum: added benefit not proven	-
DAPOTOMAB DERUXTECAN	DATROWAY	Adults with unresectable or metastatic HR-positive, HER2-negative breast cancer who have received endocrine therapy and at least one line of chemotherapy in the advanced setting	Dossier Assessment [A25-69]	Result of dossier assessment: Patients with HER2-0 breast cancer, one line of chemotherapy in the advanced setting: added benefit not proven Patients with HER2-low breast cancer, one line of chemotherapy in the advanced setting: added benefit not proven Patients with HER2-0 or HER2-low breast cancer, at least 2 lines of chemotherapy in the advanced setting: added benefit not proven	The MAH calculates the annual treatment costs per patient for Datopotamab deruxtecan at €169,754.43 to €170,121.43

IQWiG

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
GUSELKUMAB	TREMFYA	Adults with moderately to severely active ulcerative colitis	Dossier Assessment [A25-69]	Result of dossier assessment: Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: added benefit not proven Patients who have had an inadequate response with, lost response to, or were intolerant to a biologic agent (TNFα antagonist or integrin inhibitor or interleukin inhibitor): added benefit not proven	The MAH calculates annual treatment costs per patient for Guselkumab of €17,363.97. These consist of drug costs and are plausible as a lower bound.
GUSELKUMAB	TREMFYA	Adults with moderately to severely active ulcerative colitis	Dossier Assessment [A25-132] Addendum to Project A25-74	Result of dossier assessment: Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: unchanged after addendum: added benefit not proven Patients who have had an inadequate response with, lost response to, or were intolerant to a biologic agent (TNFα antagonist or integrin inhibitor or interleukin inhibitor): unchanged after addendum: added benefit not proven	-
GUSELKUMAB	TREMFYA	Adults with moderately to severely active Crohn's disease	Dossier Assessment [A25-75]	Result of dossier assessment: Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: added benefit not proven Patients who have had an inadequate response with, lost response to, or were intolerant to a biologic agent (TNFα antagonist or integrin inhibitor or interleukin inhibitor): hint of minor added benefit	The MAH calculates annual treatment costs for Guselkumab per patient at €17,363.97.
GUSELKUMAB	TREMFYA	Adults with moderately to severely active Crohn's disease	Dossier Assessment [A25-131]	Result of dossier assessment: Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: unchanged after addendum: added benefit not proven Patients who have had an inadequate response with, lost response to, or were intolerant to a biologic agent (TNFα antagonist or integrin inhibitor or interleukin inhibitor): after addendum now: indication of a minor added benefit	-*

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
MIRABEGRON	BETMIGA	For treating neurogenic detrusor overactivity in people aged 3 to 17 years	Technology appraisal [TA1100]	NICE is unable to make a recommendation about the use in the NHS of mirabegron for treating neurogenic detrusor overactivity in people aged 3 to 17 years. This is because Astellas Pharma has confirmed that it does not intend to make a submission for the appraisal. Astellas Pharma considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources in this population.	-
DURVALUMAB	IMFINZI	Durvalumab (Imfinzi, AstraZeneca) is indicated as monotherapy for 'the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.'	Technology appraisal [TA1099]	Durvalumab can be used, within its marketing authorisation, as an option to treat limited-stage small-cell lung cancer that has not progressed after platinum-based chemoradiotherapy in adults. Durvalumab can only be used if the company provides it according to the commercial arrangement.	The list price is £592 for a 120-mg vial and £2,466 for a 500-mg vial (excluding VAT; BNF online accessed June 2025).
GARADACIMAB	ANDEMBRY	Garadacimab (Andembry, CSL Behring) is indicated for the 'routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older'.	Technology appraisal [TA1101]	Garadacimab can be used as an option to prevent recurrent attacks of hereditary angioedema in people 12 years and over, only if: • they have 2 or more attacks a month, and • the company provides garadacimab according to the commercial arrangement	The list price of garadacimab for the subcutaneous injection is £20,625 for each prefilled pen (200 mg/1.2 ml).
BUDESONIDE	KINPEYGO	Targeted-release budesonide (Kinpeygo, Britannia) is indicated for 'the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram'.	Technology appraisal [TA937]	We updated recommendation 1.1 to change the unit for urine protein-to-creatinine ratio (UPCR) to mg/mmol from g/g. A UPCR of 170 mg/mmol or more equates to the 1.5 g/g or more measurement specified in the marketing authorisation indication for targeted-release budesonide.	

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
TARLAMAB	IMDYLLTRA	Treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after at least two prior lines of therapy including platinum-based chemotherapy.	SMC Advice [SMC2816]	Following a full submission tarlatamab (Imdylltra®) is not recommended for use within NHSScotland. The Committee considered the benefits of tarlatamab in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and agreed that as tarlatamab is an orphan medicine, SMC can accept greater uncertainty in the economic case. After considering all the available evidence, the Committee was unable to accept tarlatamab for use in NHSScotland.	The base case economic analysis indicated that tarlatamab was associated with increased health outcomes, as measured by quality adjusted life years, but also higher healthcare costs. Results for the comparison between tarlatamab and SOC cannot be presented here as they are considered commercial in confidence (CiC) by the submitting company.
RIBOCICLIB	KISQALI	In combination with an aromatase inhibitor for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer at high risk of recurrence. In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.	SMC Advice [SMC2803]	Following a full submission ribociclib (Kisqali®) is accepted for use within NHSScotland.	400 mg orally once daily for 21 consecutive days followed by seven days off treatment, resulting in a complete cycle of 28 days. Treatment is continued for 36 months or until disease recurrence or unacceptable toxicity.

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
MERCAPTAMINE	PROCYSBI	Treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure.	SMC Advice [SMC2824]	Following a third resubmission assessed under the orphan equivalent medicine process mercaptamine (Procysbi®) is accepted for use within NHSScotland. The Committee considered the benefits of mercaptamine (Procysbi®) in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and agreed that as mercaptamine (Procysbi®) is an orphan equivalent medicine, SMC can accept greater uncertainty in the economic case. After considering all the available evidence and the output from the PACE process, and after application of the appropriate SMC modifiers, the Committee accepted mercaptamine (Procysbi®) for use in NHSScotland.	1.3 g/m2 per day orally in two divided doses Cost per year (£): 32,612 to 163,058
MELATONIN	SLENYTO	Treatment of insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been insufficient.	SMC Advice [SMC2882]	in the absence of a submission from the holder of the marketing authorisation melatonin (Slenyto®) is not recommended for use within NHSScotland.	
ISATUXIMAB	SARCLISA	In combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.	SMC Advice [SMC2804]	Following a full submission assessed under the orphan equivalent medicine process isatuximab (Sarclisa®) is accepted for use within NHSScotland.	10 mg/kg by intravenous infusion according to treatment cycle. Cycle one: days 1, 8, 15, 22, and 29 Cycles two to four: days 1, 15, and 29 Cycles five to 17: days 1 and 15 Cycles 18 onwards: day 1 only Cost per cycle (£(: Cycle 1: 17,743 Cycles 2 to 4: 10,646 Cycles 5 to 17: 7,097 Cycle 18 onwards: 3,549

SMC

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GUSELKUMAB	TREMFYA	For the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment.	SMC Advice [SMC2850]	Following an abbreviated submission guselkumab (Tremfya®) 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.
GUSELKUMAB	TREMFYA	Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor.	SMC Advice [SMC2848]	Following an abbreviated submission guselkumab (Tremfya®) 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.
ELACESTRANT	KORSERDU	as monotherapy for the treatment of postmenopausal women, and men, with estrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer with an activating ESR1 mutation who have disease progression following at least one line of endocrine therapy including a CDK 4/6 inhibitor.	SMC Advice [SMC2807]	Following a full submission assessed under the end of life and orphan equivalent medicine process elacestrant (Korserdu®) is not recommended for use within NHSScotland.	

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DURVALUMAB	IMFINZI	In combination with tremelimumab for the first-line treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC).	SMC Advice [SMC2857]	Following a resubmission assessed under the end of life medicine process durvalumab (Imfinzi®) is accepted for use within NHSScotland. After considering all the available evidence and the output from the PACE process the Committee accepted durvalumab for use in NHSScotland	SMC considered results for decision-making that took into account all relevant PAS. SMC is unable to present these results due to competition law issues. Durvalumab plus tremelimumab was compared with atezolizumab plus bevacizumab, lenvatinib and sorafenib. Durvalumab plus tremelimumab Durvalumab 1,500 mg intravenously every four weeks Tremelimumab 300 mg intravenously on day 1 of cycle 1 First cycle (4-WEEK CYCLE): £28,008 Subsequent cycles: £7,398
BUDESONIDE SUPPOSITORY	BUDENOFALK	Short-term treatment of mild to moderate acute ulcerative colitis limited to the rectum (ulcerative proctitis) in adult patients.	SMC Advice [SMC2855]	Following an abbreviated submission budesonide suppository (Budenofalk®) 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.