NEWSLETTER: News from the HTA Agencies

September 2025

SUMMARY

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CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
RISPERIDONE	LONGAVO	For the treatment of schizophrenia in adults	CADTH Reimbursement Recommendation 	Reimburse with conditions Longavo should only be reimbursed when prescribed by clinicians experienced in using long-acting injectable (LAI) atypical antipsychotic drugs to treat adult patients with schizophrenia. Reimbursement for Longavo should follow the same criteria that each public drug plan uses for other LAI atypical antipsychotic drugs approved for the condition. Longavo should only be reimbursed if the total cost does not exceed the drug program cost of treatment with the least costly LAI atypical antipsychotic drugs for the treatment of schizophrenia.	Treatment with monthly Longavo is expected to cost approximately $5,930 per patient annually, with an annual administration cost of $51.
RELUGOLIX-ESTRADIOL-NORETHINDRONE ACETATE	MYFEMBREE	Management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women	CADTH Reimbursement Recommendation 	Reimburse with conditions Myfembree should only be reimbursed if prescribed by clinicians with expertise in diagnosing and managing UFs and the cost is not more than the least costly regimen of leuprolide acetate with or without add-back therapy (hormonal therapy to reduce negative side effects). When first prescribed, Myfembree should be reimbursed for 6 months, after which response to treatment should be assessed. The drug should not be reimbursed if used in combination with a gonadotropin-releasing hormone agonist or antagonist, upon successful surgery or medical procedure to treat UFs, pregnancy, menopause, or if significant bone loss occurs.	Treatment with Myfembree is expected to cost approximately $3,285 per patient per year.

CADTH

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GOSELKUMAB	TREMFYA	For the treatment of adult patients with moderately to severely active Crohn disease	CADTH Reimbursement Recommendation	Reimburse with conditions Tremfya should only be reimbursed if the cost of Tremfya is reduced so that it does not cost the drug programs more than the least costly available advanced therapy that is reimbursed for the treatment of moderately to severely active Crohn disease.	Treatment with Tremfya is expected to cost between $23,016 and $49,092 per patient in the first year and between $19,957 and $39,913 per patient in subsequent years.
AMIVANTAMAB	RYBREVANT	In combination with carboplatin and pemetrexed for the treatment of patients with locally advanced (not amenable to curative therapies) or metastatic non–small cell lung cancer with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with osimertinib	CADTH Reimbursement Recommendation	Reimburse with conditions Rybrevant should only be reimbursed if it is prescribed by clinicians with expertise in treating NSCLC and its price is reduced.	Treatment with Rybrevant is expected to cost approximately $26,816 to $33,520 per patient for the first 28 days, and $11,173 to $13,408 for each subsequent 28 days.
OSIMERTINIB	TAGRISSO	For the treatment of patients with locally advanced, unresectable (stage III) non–small cell lung cancer (NSCLC) whose tumours have EGFR exon 19 deletions or exon 21 L858R substitution mutations (either alone or in combination with other EGFR mutations) and whose disease has not progressed during or following platinum-based chemoradiation therapy	CADTH Reimbursement Recommendation	Reimburse with conditions Tagrisso should only be reimbursed if it is prescribed by clinicians with expertise in treating NSCLC and the cost of Tagrisso is reduced.	Treatment with Tagrisso is expected to cost approximately $9,020 per 28-day cycle.

CADTH

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ABEMACICLIB	VERZENIO	For the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor (HER2)-negative advanced or metastatic breast cancer, in combination with an aromatase inhibitor (AI) in postmenopausal women as initial endocrine-based therapy	CADTH Reimbursement Recommendation	Reimburse with conditions Verzenio plus NSAI should only be reimbursed if prescribed by clinicians with expertise in managing advanced or metastatic breast cancer and if the cost of Verzenio does not exceed the drug program cost of treatment with ribociclib plus NSAI, reimbursed for the indicated population.	Treatment with Verzenio as an add-on to NSAI is expected to cost $6,508 per patient for a 28-day cycle. The 28-day per patient cost of abemaciclib plus NSAI for advanced or metastatic breast cancer as initial endocrinebased therapy is predicted to be $6,535 if using anastrozole and $6,547 if using letrozole as the NSAI component of the regimen
ABEMACICLIB	VERZENIO	For the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative, advanced or metastatic breast cancer, in combination with fulvestrant in women with disease progression following endocrine therapy	CADTH Reimbursement Recommendation	Reimburse with conditions Verzenio plus fulvestrant should only be reimbursed if prescribed under the care of clinicians with expertise in the treatment of advanced breast cancer, and if the cost of Verzenio for the indicated population does not exceed the drug program cost of treatment with ribociclib, both in combination with fulvestrant.	Treatment with Verzenio as an add-on to fulvestrant is expected to cost $6,508 per patient for a 28-day cycle. The 28-day per patient cost of abemaciclib plus fulvestrant for the indicated population is expected to be $7,324 for the first cycle and $6,916 for subsequent cycles.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
TRAVOPROST	TRAVATAN	Reduction of elevated intraocular pressure in adult patients with intraocular hypertension or open-angle glaucoma; The reduction of elevated intraocular pressure in pediatric patients aged 2 months to 18 years with intraocular hypertension or pediatric glaucoma.	Avis de la CT	First-time registration Favorable opinion on 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 presentation already registered.
BENRALIZUMAB	FASENRA	In adult patients in additional treatment of recurrent or refractory forms of eosinophilic granulomatosis with polyangiitis.	Avis de la CT	Extension of indication Registration Unfavorable opinion on reimbursement ASMR: not applicable
SOTATERCEPT	WINREAVAIR	Treatment of pulmonary arterial hypertension (PAH), in combination with other PAH treatments, in adults in WHO functional class (FC) IV: receiving standard triple therapy for PAH including an endothelin receptor antagonist (ERA), a phosphodiesterase 5 inhibitor (PDE5i) or a soluble guanylate cyclase (sGC) stimulator, and a parenteral prostacyclin analog; or insufficiently controlled by oral triple therapy AND not eligible for a parenteral prostacyclin analogue; or insufficiently controlled by dual therapy AND not eligible for another standard treatment for PAH. This specialty falls under the category of drugs subject to restricted prescription.	Avis de la CT	Early access authorization granted

Generic Name	Brand Name	Indication	Type of Document	Recommendation
NORADRENALINE TARTRATE	TANOREN	In adults in the restoration and maintenance of perioperative blood pressure after hypotension induced by spinal or general anesthesia	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE): The Commission considers that TANOREN 0.5 mg/mL (noradrenaline tartrate), solution for dilution for solution for injection/infusion, does not provide an improvement in the medical service rendered (ASMR V) compared to other vasopressors available in France.
GLYCOPYRRONIUM BROMIDE	GLYCOPYRRONIUM BIOGARAN AXICA	in adults for continuous bronchodilator treatment to relieve the symptoms of chronic obstructive pulmonary disease (COPD)	Avis de la CT	First-time registration Favorable opinion on reimbursement ASMR: V (ABSENCE): This specialty is a hybrid which does not provide an improvement in the medical service rendered (ASMR V) compared to the reference specialty SEEBRI BREEZHALER (glycopyrronium bromide) 44 µg, powder for inhalation in capsules.
IVACAFTOR/TEZACAFTOR/ELEXACAFTOR + IVACAFTOR	KAFTRIO + KALYDECO	KAFTRIO (ivacaftor/tezacaftor/elexacaftor) is indicated in combination with KALYDECO (ivacaftor) for the treatment of patients with cystic fibrosis aged 2 years and older who have at least one non-class I mutation in the CFTR (cystic fibrosis transmembrane conductance regulator) gene and who do not have an F508del mutation in the CFTR gene	Avis de la CT	Extension of indication Modification of registration conditions Favorable opinion for reimbursement ASMR: II (IMPORTANT): The Commission considers that KAFTRIO 37.5 mg/25 mg/50 mg, 75 mg/50 mg/100 mg, (ivacaftor/tezacaftor/elexacaftor) film-coated tablets, KAFTRIO 60 mg/40 mg/80 mg, 75 mg/50 mg/100 mg, (ivacaftor/tezacaftor/elexacaftor) granules in sachet in combination with KALYDECO 75 mg, 150 mg (ivacaftor) film-coated tablets, KALYDECO 59.5 mg, 75 mg (ivacaftor) granules in sachet provide a substantial improvement in actual benefit (IAB II) in the current therapeutic strategy which includes the relevant comparator (see paragraph 5.2).

Generic Name	Brand Name	Indication	Type of Document	Recommendation
IVACAFTOR/TEZACAFTOR/ELEXACAFTOR + IVACAFTOR	KAFTRIO + KALYDECO	in combination with KALYDECO (ivacaftor) is indicated in combination in the treatment of patients with cystic fibrosis aged 2 years and older who carry at least one non-class I mutation of the CFTR (cystic fibrosis transmembrane conductance regulator) gene and who do not carry an F508del mutation of the CFTR gene	Avis de la CT	Early access authorization granted
DOLUTEGRAVIR + LAMIVUDINE	DOVATO	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	Favorable opinion on maintaining reimbursement The Commission takes note of these amendments, which are not of a nature to modify its previous conclusions (opinion of 09/07/2025).
DOLUTEGRAVIR/ABACAVIR/LAMIVUDINE	TRIUMEQ	treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults, adolescents and children aged at least 3 months and weighing at least 6 kg to less than 25 kg, not carrying the HLA-B*5701 allele and without previous or current evidence of resistance to one of the classes of antiretrovirals represented in the dolutegravir/abacavir/lamivudine fixed-dose combination, namely integrase inhibitors and nucleos(t)ide reverse transcriptase inhibitors.	Avis de la CT	Modification of registration conditions Favourable opinion for the continuation of reimbursement The Commission takes note of these amendments, which are not of a nature to modify its previous conclusions (opinions of 17/12/2014, 22/09/2021, 10/05/2023 and 11/09/2024)

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
DOLUTEGRAVIR	TIVICAY	treatment of human immunodeficiency virus (HIV) type 1 infection in adults, adolescents, children and infants weighing at least 3 kg.	Avis de la CT	Modification of registration conditions Favorable opinion on maintaining reimbursement The Commission takes note of these amendments, which are not such as to modify its previous conclusions (opinions of 28/05/2014, 11/10/2017 and 07/07/2021)
DOLUTEGRAVIR/RILPIVIRINE	JULUCA	treatment of human immunodeficiency virus type 1 (HIV-1) infection, in virologically controlled adults (HIV-1 RNA < 50 copies/mL) on stable antiretroviral treatment for at least 6 months, with no history of virological failure and no known or suspected resistance to non-nucleoside reverse transcriptase inhibitors or integrase inhibitors	Avis de la CT	Modification of registration conditions Favorable opinion for the continuation of reimbursement The Commission takes note of these amendments, which are not of a nature to modify its previous conclusions (opinions of 25/07/2018 and 22/09/2021).
PIRTOBRUTINIB	JAYPIRCA	as monotherapy in the treatment of adult patients with relapsed and refractory chronic lymphocytic leukemia who have been previously treated with a BTK inhibitor and venetoclax (double refractory)	Avis de la CT	Extension of indication Registration Favorable opinion for reimbursement Unfavorable opinion on reimbursement in other situations covered by the MA indication. ASMR: V (ABSENCE): The Commission considers that JAYPIRCA (pirtobrutinib) 100 mg film-coated tablet does not provide an improvement in the medical service rendered (ASMR V) compared to the comparators bendamustine + rituximab and idelalisib + rituximab.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE 21-VALENT	CAPVAXIVE	prevention of invasive infections and pneumonia caused by Streptococcus pneumoniae in people aged 18 years and over, according to the HAS vaccination recommendations of July 3, 2025	Avis de la CT	Registration Favorable opinion on reimbursement ASMR: V (ABSENCE): The Commission considers that CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent, non-adsorbed), does not provide an improvement in the medical service rendered (ASMR V) in active immunization for the prevention of invasive infections and pneumonia caused by Streptococcus pneumoniae in people aged 18 years and over.
TIRATRICOL	EMCITATE	The treatment of peripheral thyrotoxicosis in patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan-Herndon-Dudley syndrome), from birth	Avis de la CT	Registration Unfavorable opinion on reimbursement ASMR: NOT APPLICABLE
MENINGOCOCCAL CONJUGATE VACCINE GROUPS A, C, W AND Y	MENQUADFI	active immunization of subjects against invasive meningococcal diseases due to Neisseria meningitidis groups A, C, W-135, Y and B, according to the current HAS vaccination recommendations of 03/13/202 and 07/17/2025.	Avis de la CT	Modification of registration conditions following the update of the HAS recommendations of 2025 The updating of the vaccination strategy according to the HAS recommendations in force dated 03/13/2025 and 07/17/2025 is not likely to modify the previous conclusions of the CT
MENINGOCOCCAL GROUP B VACCINE	TRUMENBA	Active immunization of subjects against invasive meningococcal diseases due to Neisseria meningitidis groups A, C, W-135, Y and B, according to the current HAS vaccination recommendations of 03/13/2025 and 07/17/2025.	Avis de la CT	Modification of registration conditions following the update of the HAS recommendations of 2025 The updating of the vaccination strategy according to the HAS recommendations in force dated 03/13/2025 and 07/17/2025 is not likely to modify the previous conclusions of the CT

Generic Name	Brand Name	Indication	Type of Document	Recommendation
MENINGOGOCCAL SEROGROUPS A, C, W-135 AND Y CONJUGATE	MENVEO	Active immunization of children (from 2 years), adolescents and adults at risk of exposure to Neisseria meningitidis serogroups A, C, W-135 and Y, to prevent invasive disease.	Avis de la CT	First-time registration Favorable opinion 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.
MENINGOCOCCAL GROUP B VACCINE	BEXSERO	Active immunization of subjects against invasive meningococcal diseases due to Neisseria meningitidis groups A, C, W-135, Y and B, according to the current HAS vaccination recommendations of 03/13/2025 and 07/17/2025.	Avis de la CT	Modification of registration conditions following the update of the HAS recommendations of 2025 Favorable opinion on maintaining reimbursement ASMR: not specified: The updating of the vaccination strategy according to the HAS recommendations in force dated 03/13/2025 and 07/17/2025 is not likely to modify the previous conclusions of the CT.
GALLIUM 68Ga GOZETOTIDE	ILLUCIX	for the detection of prostate-specific membrane antigen (PSMA)-positive lesions by positron emission tomography (PET) in adults with prostate cancer (PC) in the following clinical situations: 1. initial staging of patients with high-risk PC before initial curative treatment, 2. suspected recurrence of PC in patients with increased serum prostate-specific antigen (PSA) levels after initial curative treatment, 3. Identification of patients with progressive, PSMA-positive, metastatic, castration-resistant prostate cancer (mCRPC) for whom PSMA-targeted therapy is indicated.	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (ABSENCE)

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
CODEINE/AQUEOUS DRY EXTRACT OF ERYSIMUM OFFICINALE MALTODEXTRIN	CODEINE-ERYSIMUM MAYOLY SPINDLER SUGAR-FREE	symptomatic treatment of troublesome non-productive coughs.	Avis de la CT	First-time registration Favorable opinion on 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 specialty already registered.
GLOFITAMAB	COLUMVI	Columvi in combination with gemcitabine and oxaliplatin is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS), only as second-line treatment, ineligible for autologous stem cell transplantation (ASCT) and CAR-T cell-based drugs	Avis de la CT	Early Access Authorization granted
MENINGOCOCCAL CONJUGATE VACCINE GROUPS A, C, W AND Y	NIMERNRIX	Active immunization of subjects against invasive meningococcal diseases due to Neisseria meningitidis groups A, C, W-135, Y and B, according to the current HAS vaccination recommendations of 03/13/2025 and 07/17/2025	Avis de la CT	Modification of registration conditions following the update of the HAS recommendations of 2025 Favorable opinion on maintaining reimbursement The updating of the vaccination strategy according to the HAS recommendations in force dated 03/13/2025 and 07/17/2025 is not likely to modify the previous conclusions of the CT.
OXOMEMAZINE	OXOMEMAZINE BENTA SUGAR-FREE	symptomatic treatment of troublesome non-productive coughs, particularly those predominantly at night.	Avis de la CT	First-time registration Favorable opinion for reimbursement ASMR: V (ABSENCE): This specialty is a generic which does not provide any improvement in the medical service rendered (ASMR V) compared to other oxomemazine-based specialties already registered.

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 [A25-74]	Result of dossier assessment: 1. Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: added benefit not proven 2. 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 pU estimates annual treatment costs per patient for guselkumab at €17,363.97.
GUSELKUMAB	TREMFYA	Adults with moderately to severely active Crohn's disease	Dossier Assessment [A25-75]	Result of dossier assessment: 1. Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: added benefit not proven 2. 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 pU calculates annual treatment costs per patient for guselkumab at €17,363.97.
RIMEGEPANT	VYDURA	Adults with at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine	Dossier Assessment [A25-73]	Result of dossier assessment: 1. Patients for whom conventional migraine prophylaxis is an option: added benefit not proven 2. Patients who do not respond to, are unsuitable for, or do not tolerate any of the following drug treatments/drug classes: metoprolol, propranolol, flunarizine, amitriptyline: added benefit not proven	Adults with at least 4 migraine attacks per month and indication for preventive treatment of episodic migraine Medication costs in €: 5,193.95
ASCIMINIB	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 pharmaceutical company (pU) determines annual treatment costs per patient for Asciminib to be €60,350.97.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
RIMEGEPANT	VYDURA	Adults with migraine with or without aura who require acute treatment	Dossier Assessment [A25-72]	Result of dossier assessment: Added benefit not proven	Adults with migraine with or without aura requiring acute treatment Costs for additionally required GKV services in € 28.46–1707.60
SELPECARTINIB	RETSEVMO	Adults and adolescents 12 years and older with advanced rearranged during transfection-mutant medullary thyroid cancer; first-line therapy	Dossier Assessment [A25-71]	Result of dossier assessment: Indication of major added benefit	Adults and adolescents from 12 years with advanced RET-mutated medullary thyroid carcinoma (MTC); first-line therapy Costs for additionally required GKV services (€): 35,099.70 – 46,718.70
DATOPOTAMAB 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 pharmaceutical company (pU) has determined the annual therapy costs per patient for Datopotamab deruxtecan to be between €169,754.43 and €170,121.43.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
MIRIKIZUMAB	OMVOH	Adults with moderately to severely active Crohn's disease	Dossier Assessment [A25-42]	Result of dossier assessment: 1. Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: added benefit not proven 2. 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 pharmaceutical company (pU) does not calculate annual treatment costs for mirikizumab, as at the time of dossier submission, the product was not yet listed in the Lauer-Taxe in the dosage form required for the indication.
MIRIKIZUMAB	OMVOH	Adults with moderately to severely active Crohn's disease	Dossier Assessment [A25-99] Addendum to Project [A25-42]	Result of dossier assessment: 1. Patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy: unchanged after addendum: added benefit not proven 2. 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	-
NIVOLUMAB +IPILILUMAB	OPDIVO+ YERVOY	First-line treatment of adult patients with unresectable or metastatic colorectal cancer with mismatch repair deficiency or high microsatellite instability	Dossier Assessment [A25-80]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) estimates annual treatment costs per patient for nivolumab in combination with ipilimumab, followed by nivolumab monotherapy, to be €97,890.24 to €99,190.90 for the first year and €76,871.60 to €77,870.94 for the second year.

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NIVOLUMAB	OPDIVO	First-line treatment of adult patients with unresectable or advanced hepatocellular carcinoma	Dossier Assessment [A25-79]	Result of dossier assessment: 1. Patients with Child-Pugh A or no hepatic cirrhosis: added benefit not proven 2. Patients with Child-Pugh B: added benefit not proven	The pharmaceutical company (pU) calculates annual therapy costs per patient for nivolumab + ipilimumab of €129,018.44 to €130,319.10 in year 1. In year 2, the annual therapy costs decrease to €76,871.60 to €77,870.94 because ipilimumab is only administered in year 1.
NIVOLUMAB	OPDIVO	Adult patients with resectable non-small cell lung cancer at high risk of recurrence whose tumours have programmed death ligand 1 expression ≥ 1%; neoadjuvant and adjuvant treatment	Dossier Assessment [A25-81]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) calculates annual therapy costs per patient for nivolumab in combination with platinum-based chemotherapy (neoadjuvant treatment phase) and subsequent monotherapy (adjuvant treatment phase) of €78,861.92 to €82,964.24 (for the 1st treatment year) and €96,601.52 to €100,703.84 (for the entire therapy)

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
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: 1. Patients < 65 years of age for whom everolimus is a suitable individualized treatment: hint of a minor added benefit 2. Patients ≥ 65 years of age for whom everolimus is a suitable individualized treatment: hint of a considerable added benefit 3. Patients for whom everolimus is not a suitable individualized treatment: added benefit not proven	The pU calculates annual therapy costs per patient for Belzutifan amounting to €169,927.94, which consist exclusively of drug costs.
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 [A25-107] Addendum to Project [A25-45]	Result of dossier assessment: Patients < 65 years of age for whom everolimus is a suitable individualized treatment: unchanged after addendum: hint of a minor added benefit Patients ≥ 65 years of age for whom everolimus is a suitable individualized treatment: unchanged after addendum: hint of a considerable added benefit Patients for whom everolimus is not a suitable individualized treatment: unchanged after addendum: added benefit not proven	-

NICE

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BENRALIZUMAB	FASENRA	Benralizumab (Fasenra, AstraZeneca) is indicated 'as an add-on treatment for adult patients with relapsing or refractory eosinophilic granulomatosis with polyangiitis'.	Technology appraisal [TA1096]	Benralizumab as an add-on to standard care can be used, within its marketing authorisation, as an option to treat relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) in adults. It can only be used if the company provides it according to the commercial arrangement.	Benralizumab costs £1,955 for a solution of 30 mg per 1 ml for injection (excluding VAT; BNF online accessed May 2025).
ENFORTUMAB VEDOTIN + PEMBROLIZUMAB	PADCEV + KEYTRUDA	Enfortumab vedotin (Padcev, Astellas) with pembrolizumab (Keytruda, MSD) is indicated for 'the first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy'.	Technology appraisal [TA1097]	Enfortumab vedotin with pembrolizumab can be used, within its marketing authorisation, as an option for untreated unresectable or metastatic urothelial cancer in adults when platinum-based chemotherapy is suitable. Enfortumab vedotin with pembrolizumab can only be used if the companies provide them according to their commercial arrangements.	The price of enfortumab vedotin is £578 per 20-mg vial or £867 per 30-mg vial (excluding VAT; BNF online accessed August 2025). The price of pembrolizumab is £2,630 per 100 mg in a 4-ml vial (excluding VAT; BNF online accessed August 2025).
ISATUXIMAB	SARCLISA	Isatuximab (Sarclisa, Sanofi) is indicated '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'.	Technology appraisal [TA1098]	Isatuximab plus bortezomib, lenalidomide and dexamethasone can be used, within its marketing authorisation, as an option for untreated multiple myeloma in adults when an autologous stem cell transplant is unsuitable. It can only be used if the company provides it according to the commercial arrangement.	The list price of isatuximab is £506.94 per 100 mg/5 ml vial and £2,534.69 per 500 mg/25 ml vial (excluding VAT; BNF online accessed May 2025).

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
BLINATUMUMAB	BLINCYTO	For the treatment of adult patients with Philadelphia chromosome negative CD19-positive B-cell precursor acute lymphoblastic leukaemia (ALL) in the consolidation phase	Medicine Advice [SMC2808]	following a full submission assessed under the orphan medicine process blinatumomab (Blincyto®) is accepted for restricted use within NHSScotland.	28 micrograms/day via continuous intravenous infusion for 28 days per cycle for up to four cycles (adult patients ≥45 kg) (14-day treatment-free period between cycles) Cost per cycle (£): 56,476
RUBRACA	RUCAPARIB	As monotherapy for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.	Medicine Advice [SMC2799]	Following a full submission rucaparib (Rubraca®) is accepted for use within NHSScotland.	Dose regimen: 600 mg orally twice daily Cost per 28-day cycle (£): 6,648
BELZUTIFAN	WELIREG	Treatment of adult patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with a programmed death receptor-1 (PD-1) / programmed death ligand (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).	Medicine Advice [SMC2864]	In the absence of a submission from the holder of the marketing authorisation belzutifan (Welireg®) is not recommended for use within NHSScotland.	-
ENCORAFENIB	BRAFTOVI	in combination with binimetinib for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600E mutation.	Medicine Advice [SMC2865]	In the absence of a submission from the holder of the marketing authorisation encorafenib (Braftovi®) is not recommended for use within NHSScotland	-