NEWSLETTER: News from the HTA Agencies

October 2025

SUMMARY

HTA Agency	N°of Drugs	Drugs Name
CADTH Evidence Driven.	11	VENETOCLAX • GLOFITAMAB • PEMBROLIZUMAB • ACALABRUTINIB • ASCIMINIB • PEMBROLIZUMAB • NIVOLUMAB PLUS IPILILUMAB • DARIDOREXANT • BELANTAMAB MAFODOTIN, POMALIDOMIDE, DEXAMETHASONE • BELANTAMAB MAFODOTIN, BORTEZOMIB, DEXAMETHASONE • MIRVETUXIMAB SORAVTANSINE
HAS HAUTE AUTORITÉ DE SANTÉ	34	PRETOMANIDE • BECLOMETASONE + FORMOTEROL• IVACAFTOR/TEZACAFTOR/ELEXACAFTOR • BEDAQUILINE • BEREMAGENE GEPERPAVEC • IPTACOPAN • TRIVALENT INFLUENZA VACCINE • LATANOPROST • TIBOLONE • ESTRIOL • ESTRADIOL HEMIHYDRATE • ESTRADIOL/ESTRADIOL HEMIHYDRATE • ESTRADIOL VALERATE/CYPROTERONE ACETATE • DYDROGESTERONE/ESTRADIOL • ESTRADIOL HEMIHYDRATE • MEDROGESTONE • ESTRADIOL HEMIHYDRATE/NORETHISTERONE ACETATE • PROGESTERONE • ESTRADIOL HEMIHYDRATE • ESTRADIOL HEMIHYDRATE/LEVONORGESTREL • MEDROXYPROGESTERONE ACETATE/ESTRADIOL VALERATE • EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL • LISDEXAMPHETAMINE • SPESOLIMAB • IPILILUMAB/NIVOLUMAB • LIPOSOMAL AMPHOTERICIN B • CABOTEGRAVIR • RILPIVIRINE • GLOFITAMAB • TECLISTAMAB • COAGULATION FACTORS WITH FACTOR VIII AND IX INHIBITOR BYPASS ACTIVITY • ACETYLSALICYLIC ACID • ATIDARSAGENE AUTOTEMCEL • DURVALUMAB
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW	0	
IQWiG Institute for Quality and Efficiency in Health Care	14	ACALABRUTINIB • ACALABRUTINIB • ACALABRUTINIB • NIVOLUMAB • ANDEXANET ALFA • OMAVELOXOLONE • ACALABRUTINIB PLUS VENETOCLAX • SELPERCATINIB • VUTRISIRAN • REMDESIVIR • CONCIZUMAB • TRASTUZUMAB DERUXTECAN • TRASTUZUMAB DERUXTECAN • CONCIZUMAB
NICE National Institute for Health and Care Excellence	9	MIRABEGRON • DURVALUMAB • GARADACIMAB • BUDESONIDE • SPARSENTAN • LORLATINIB • CLASCOTERONE • SARILUMAB • IPTACOPAN
SMC Scottish Medicines Consortium	8	NUSINERSEN • NIVOLUMAB • LINZAGOLIX • FRUQUINTINIB • DURVALUMAB • CAPIVASERTIB • BELANTAMAB MAFODOTIN • SARILUMAB • BELANTAMAB MAFODOTIN

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
VENETOCLAX	VENCLEXTA	Venclexta in combination with ibrutinib, is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)	CADTH Reimbursement Recommendation 	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Venclexta, in combination with ibrutinib (Venclexta plus ibrutinib), be reimbursed by public drug plans for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) if certain conditions are met. Venclexta should only be reimbursed if it is prescribed by clinicians with expertise in managing MCL and monitoring therapy, and the cost of Venclexta is reduced.	Treatment with Venclexta is expected to cost approximately $7,930 per patient per 28-day cycle (Venclexta plus ibrutinib = $19,111 per cycle).
GLOFITAMAB	COLUMVI	Columvi (glofitamab), 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) who are not candidates for autologous stem cell transplant (ASCT)	CADTH Reimbursement Recommendation 	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Columvi in combination with gemcitabine and oxaliplatin be reimbursed by public drug plans for the treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are not candidates for autologous stem cell transplant (ASCT), if certain conditions are met. Columvi in combination with gemcitabine and oxaliplatin should only be reimbursed if prescribed by clinicians experienced in the treatment of aggressive lymphomas and the side effects of treatment, and if the cost of Columvi is reduced	Treatment with Columvi is expected to cost approximately $12,480 (cycles 2 to 12) per patient per 21-day cycle. When used in combination with gemcitabine and oxaliplatin, the 21-day cost is expected to be $13,200 per patient in cycles 2 to 8 and $12,480 per patient in cycles 9 to 12.
PEMBROLIZUMAB	KEYTRUDA	Treatment of adult patients with FIGO 2014 Stage III-IVA cervical cancer, in combination with chemoradiotherapy	CADTH Reimbursement Recommendation 	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Keytruda in combination with chemoradiotherapy be reimbursed by public drug plans for the treatment of Fédération Internationale de Gynécologie et d'Obstétrique (FIGO) 2014 stage III to IVA cervical cancer if certain conditions are met. Keytruda in combination with chemoradiotherapy should only be reimbursed if prescribed by clinicians with experience with immunooncology and chemoradiotherapy and in treating cervical cancer, and the cost of Keytruda is reduced.	Treatment with Keytruda is expected to cost approximately $11,733 per patient per 28 days, based on a fixed-based dosage following the Health Canada–recommended dosing schedule.

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
ACALABRUTINIB	CALQUENCE	Acalabrutinib in combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma who are ineligible for autologous stem cell transplant	CADTH Reimbursement Recommendation	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Calquence should be reimbursed by public drug plans for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous stem cell transplant (ASCT) in combination with bendamustine and rituximab (BR), if certain conditions are met Calquence plus BR should only be reimbursed if prescribed by clinicians with expertise in managing MCL and monitoring therapy, and if the cost of Calquence is reduced.	Treatment with Calquence is expected to cost approximately $7,995 per patient per 28-day cycle. Treatment with Calquence plus BR is expected to cost $13,574 per patient per 28-day cycle, and Calquence plus maintenance rituximab is expected to cost $9,035 per patient per 28-day cycle.
ASCIMINIB	SCEMBLIX	Adult patients with newly diagnosed Philadelphia chromosomepositive chronic myeloid leukemia in chronic phase	CADTH Reimbursement Recommendation	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Scemblix be reimbursed by public drug plans for the treatment of adults with newly diagnosed Philadelphia chromosome (Ph)-positive (which happens when a person has a changed chromosome called the Ph) chronic myeloid leukemia (CML) (a cancer of the bone marrow and blood cells) in the chronic phase (CP) (when the disease is present but usually progresses slowly and causes few or no symptoms) if certain conditions are met. Scemblix should only be reimbursed if it is prescribed by clinicians with expertise and experience in treating CML and the cost of Scemblix is reduced.	Treatment with Scemblix is expected to cost approximately $4,760 per patient per 28-day cycle.

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
PEMBROLIZUMAB	KEYTRUDA	For the treatment of adult patients with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumours express PD-L1 [Combined Positive Score (CPS) ≥ 1], as neoadjuvant treatment as monotherapy, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as monotherapy	CADTH Reimbursement Recommendation 	Canada's Drug Agency (CDA-AMC) recommends that Keytruda should be reimbursed by public drug plans for the treatment of adult patients with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumours express PD-L1 (combined positive score [CPS] ≥ 1), as determined by a validated test, as neoadjuvant treatment (before surgery) as monotherapy, continued as adjuvant treatment (after surgery) in combination with radiotherapy (RT) with or without cisplatin, and then as monotherapy, if certain conditions are met.	Treatment with Keytruda is expected to cost approximately $11,733 per patient per 28-day cycle using a fixed dosage (200 mg every 21 days) or $8,917 per patient per 28 days using a weight-based dosage (2 mg/kg [up to 200 mg] every 21 days). When pembrolizumab is used in combination with cisplatin, the expected 28-day cost is $12,399 per patient using fixed dosage and $9,583 per patient using weight-based dosage.
NIVOLUMAB PLUS IPILILUMAB	OPDIVO PLUS YERVOY	For the first-line treatment of adult patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer	CADTH Reimbursement Recommendation 	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Opdivo in combination with Yervoy be reimbursed by public drug plans for the first-line treatment of adult patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer, if certain conditions are met. Opdivo in combination with Yervoy should only be reimbursed if prescribed by clinicians with expertise in the diagnosis and treatment of patients with mCRC and if the cost of Opdivo in combination with Yervoy is reduced.	Treatment with Opdivo in combination with Yervoy is expected to cost approximately $21,724 in the 12-week initiation phase and $8,604 to $9,387 for each subsequent 28-day cycle.

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
DARIDOREXANT	QUVIVIQ	Daridorexant is indicated for the management of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	CADTH Reimbursement Recommendation	Do not reimburse Canada's Drug Agency (CDA-AMC) recommends that Quviviq not be reimbursed by public drug plans for the management of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	Quviviq is available as 25 mg and 50 mg tablets. At the submitted price of $2.36 per tablet, both the 25 mg and 50 mg strengths are priced equally. The annual cost of Quviviq is expected to be approximately $861.99 per patient per year.
BELANTAMAB MAFODOTIN, POMALIDOMIDE, DEXAMETHASONE	BLENREP AND BPd	Belantamab mafodotin is indicated, in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including lenalidomide	CADTH Reimbursement Recommendation	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Blenrep in combination with pomalidomide and dexamethasone be reimbursed by public drug plans for the treatment of adults with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, including lenalidomide, if certain conditions are met. Blenrep in combination with pomalidomide and dexamethasone should only be reimbursed if it is prescribed under the care of a clinician with expertise in the diagnosis and management of patients with multiple myeloma, and the cost of Blenrep is reduced.	Treatment with Blenrep in combination with pomalidomide and dexamethasone is expected to cost approximately $58,249 per 28 days per patient in the first cycle, and $49,909 per 28 days per patient in subsequent cycles.

CADTH

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
BELANTAMAB MAFODOTIN, BORTEZOMIB, DEXAMETHASONE	BLENREP AND BVd	Belantamab mafodotin is indicated for the treatment of multiple myeloma in combination with bortezomib and dexamethasone (BVd) in adult patients who have received at least one prior therapy.	CADTH Reimbursement Recommendation	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Blenrep in combination with bortezomib and dexamethasone be reimbursed by public drug plans for the treatment of adults with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, if certain conditions are met. Blenrep in combination with bortezomib and dexamethasone should only be reimbursed if it is prescribed under the care of clinicians with expertise in the diagnosis and management of patients with multiple myeloma, and if the cost of Blenrep in combination with bortezomib and dexamethasone is reduced.	Treatment with Blenrep in combination with bortezomib and dexamethasone is expected to cost approximately $77,656 per 28 days per patient in the first cycle, and $74,133 per 28 days per patient in subsequent cycles.
MIRVETUXIMAB SORAVTANSINE	ELAHERE	As monotherapy indicated for the treatment of adult patients with folate receptor-alpha positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens	CADTH Reimbursement Recommendation	Reimburse with conditions Canada's Drug Agency (CDA-AMC) recommends that Elahere be reimbursed by public drug plans for the treatment of adults with FR-alpha–positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens if certain conditions are met. Elahere should only be reimbursed if the patient is under the care of a physician with expertise in managing gynecological malignancies, if the treatment is administered in an oncology health facility with access to ophthalmic services and FR-alpha testing, and if the cost of Elahere is reduced.	Treatment with Elahere is expected to cost approximately $29,307 per patient per 28-day cycle.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
PRETOMANIDE	DOVPRELA	in combination with bedaquiline and linezolid for the treatment of adults with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to isoniazid, rifampicin, a fluoroquinolone, and a second-line injectable antibiotic; and for adults with pulmonary tuberculosis due to M. tuberculosis resistant to isoniazid and rifampicin, with intolerance or lack of response to standard treatment.	Avis de la CT	Registration Favorable opinion for reimbursement ASMR III (moderate): The Commission considers that DOVPRELA (pretomanide), in combination with other antibiotics, provides a moderate improvement in the medical service provided (ASMR III) in adults with multidrug-resistant tuberculosis.
BECLOMETASONE + FORMOTEROL	BECLOMETASONE + FORMOTEROL TEVA	In asthma: 1. For continuous asthma treatment, in situations where inhaled administration of a combination drug containing a corticosteroid and a long-acting beta-2 agonist bronchodilator is justified: a. in patients not adequately controlled by inhaled corticosteroid therapy and the use of a short-acting inhaled beta-2 agonist bronchodilator "as needed"; b. or in patients controlled by the administration of inhaled corticosteroid therapy combined with an inhaled long-acting beta-2 agonist In chronic obstructive pulmonary disease (COPD): Symptomatic treatment of patients with severe COPD (FEV1 < 50% of predicted) and a history of repeated exacerbations, and in whom significant respiratory symptoms persist despite regular treatment with a long-acting bronchodilator.	Avis de la CT	First registration Favorable opinion for reimbursement ASMR V (absence): These specialties are hybrids which do not provide any improvement in the medical service provided (ASMR V) compared to the reference specialties INNOVAIR 100/6 µg/dose and 200/6 µg/dose (beclomethasone/formoterol), pressurized bottle solution.

Generic Name	Brand Name	Indication	Type of Document	Recommendation
IVACAFTOR/TEZACAFTOR/ELEXACAFTOR	KAFTRIO PLUS KALYDECO	KAFTRIO (ivacaftor/tezacaftor/elexacaftor) is indicated in combination with KALYDECO (ivacaftor) in the treatment of cystic fibrosis patients aged 2 years and over carrying at least one F508del mutation of the CFTR (cystic fibrosis transmembrane conductance regulator) gene	Avis de la CT	Reassessment at the request of the CT Favorable opinion to maintain reimbursement ASMR I (MAJOR): 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 sachets in combination with KALYDECO 75 mg, 150 mg (ivacaftor) film-coated tablets, KALYDECO 59.5 mg, 75 mg (ivacaftor) granules in sachets provide a major improvement in the medical benefit (ASMR I) in the current therapeutic strategy which includes the relevant comparators (see paragraph 5.2).
BEDAQUILINE	SIRTURO	in appropriate combination with other medications for adult and pediatric patients (aged 5 to under 18 years and weighing at least 15 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampicin and isoniazid.	Avis de la CT	Indication extension / Registration Favorable opinion for reimbursement ASMR III (moderate): The Commission considers that SIRTURO (bedaquiline), in combination with other antibiotics, provides a moderate improvement in the medical service provided (ASMR III) in adult and pediatric patients (patients aged 5 years to less than 18 years and weighing at least 15 kg) with multidrug-resistant tuberculosis.
BEREMAGENE GEPERPAVEC	VYJUVEK	treatment of wounds in patients with dystrophic epidermolysis bullosa (EBD) with one or more mutations in the type VII collagen alpha 1 chain gene (COL7A1), from birth.	Avis de la CT	Early access authorization granted
IPTACOPAN	FABHALTA	Treatment of adult patients with C3 deposition glomerulopathy (GC3), with a urinary protein/creatinine ratio (UPCR) ≥1g/g or in relapse after transplantation, after optimized standard treatment (except in case of contraindication or intolerance)	Avis de la CT	Early access authorization refused

Generic Name	Brand Name	Indication	Type of Document	Recommendation
TRIVALENT INFLUENZA VACCINE	FLUARIX	prevention of influenza in adults and children from 6 months, according to the vaccination recommendations of the HAS in force (HAS opinion of July 8, 2025).	Avis de la CT	Registration Favorable opinion for reimbursement ASMR V (absence): The switch from tetravalent to trivalent does not alter the level of improvement in medical benefit. The Commission considers that FLUARIX (trivalent, split-virion, inactivated influenza vaccine) does not provide any improvement in medical benefit (ASMR V) for adults and children from 6 months of age for whom vaccination is recommended, compared to other vaccines recommended for the prevention of seasonal influenza.
LATANOPROST	XALATAN	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma and ocular hypertension in adults (including the elderly). Reduction of elevated IOP in pediatric patients with elevated IOP and pediatric glaucoma	Avis de la CT	First registration Favorable opinion for reimbursement ASMR: V (absence): This specialty is a hybrid which does not provide any improvement in the medical service provided (ASMR V) compared to the reference specialty XALATAN 50 µg/ml (latanoprost), eye drops solution.
TIBOLONE	LIVIAL	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in women who have been menopausal for more than 1 year	Avis de la CT	Reassessment following referral to the Ministries Negative opinion regarding reimbursement ASMR: NOT APPLICABLE
ESTRIOL	PHYSIOGINE	Correction of symptoms related to estrogen deficiency in primary or secondary ovarian insufficiency, whether natural or artificial, as part of a short-term treatment	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)

Generic Name	Brand Name	Indication	Type of Document	Recommendation
LATANOPROST	XALATAN	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma and ocular hypertension in adults (including the elderly). Reduction of elevated IOP in pediatric patients with elevated IOP and pediatric glaucoma	Avis de la CT	First registration Favorable opinion for reimbursement ASMR: V (absence): This specialty is a hybrid which does not provide any improvement in the medical service provided (ASMR V) compared to the reference specialty XALATAN 50 µg/ml (latanoprost), eye drops solution.
TIBOLONE	LIVIAL	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in women who have been menopausal for more than 1 year	Avis de la CT	Reassessment following referral to the Ministries Negative opinion regarding reimbursement ASMR: NOT APPLICABLE
ESTRIOL	PHYSIOGINE	Correction of symptoms related to estrogen deficiency in primary or secondary ovarian insufficiency, whether natural or artificial, as part of a short-term treatment	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)
ESTRADIOL HEMIHYDRATE	DERMESTRIL SEPTEM	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: IV (minor)

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ESTRADIOL/ESTRADIOL HEMIHYDRATE	ESTROGEL/ESTRODOSE/THAIS/THAISSEPT	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: IV (minor)
ESTRADIOL VALERATE/CYPROTERONE ACETATE	CLIMENE	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women Prevention of postmenopausal osteoporosis in women at increased risk of osteoporotic fracture and with intolerance or contraindication to other treatments indicated for the prevention of osteoporosis	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)
DYDROGESTERONE/ESTRADIOL	CLIMASTON	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women Prevention of postmenopausal osteoporosis in women at increased risk of osteoporotic fracture and with intolerance or contraindication to other treatments indicated for the prevention of osteoporosis	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ESTRADIOL HEMIHYDRATE	OESCLIM/OROMONE	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women Prevention of postmenopausal osteoporosis in women at increased risk of osteoporotic fracture and with intolerance or contraindication to other treatments indicated for the prevention of osteoporosis	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)
MEDROGESTONE	COLPRONE	Artificial cycle in association with an estrogen	Avis de la CT	Reassessment following referral to the Ministries Negative opinion regarding reimbursement ASMR: NOT APPLICABLE
ESTRADIOL HEMIHYDRATE/NORETHISTERONE ACETATE	ACTIVELLE/KLIOGEST/NOVOFEMME	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women Prevention of postmenopausal osteoporosis in women at increased risk of osteoporotic fracture and with intolerance or contraindication to other treatments indicated for the prevention of osteoporosis	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)
PROGESTERONE	PROGESTOGEL/UTROGESTAN	Préménopause, traitement substitutif de la ménopause (en complément du traitement estrogénique)	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ESTRADIOL HEMIHYDRATE	PROVAMES	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women Prevention of postmenopausal osteoporosis in women at increased risk of osteoporotic fracture and with intolerance or contraindication to other treatments indicated for the prevention of osteoporosis	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)
ESTRADIOL HEMIHYDRATE/LEVONORGESTREL	ESTREVA - FEMSEPT - FEMSEPTEVO - FEMSEPTCOMBI	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: IV (minor)
MEDROXYPROGESTERONE ACETATE/ESTRADIOL VALERATE	DIVINA/DUOVA	Hormone replacement therapy (HRT) for the symptoms of estrogen deficiency in postmenopausal women	Avis de la CT	Reassessment following referral to the Ministries Favorable opinion to maintain reimbursement ASMR: V (absence)

Generic Name	Brand Name	Indication	Type of Document	Recommendation
EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL	EFAVIRENZE /EMTRICITABINE/TENOFOVIR	in 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 only in adult patients with HIV already using triple therapy based on efavirenz/emtricitabine/tenofovir disoproxil and who are virologically controlled. Unfavorable opinion for reimbursement in other situations covered by the marketing authorization indication. ASMR: V (absence): These specialties are generics which do not provide any improvement in the medical service provided (ASMR V) compared to the reference specialty.
LISDEXAMPHETAMINE	XURTA	Within the framework of a comprehensive management of attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over when the response to previous treatment with methylphenidate is deemed clinically insufficient The framework of a comprehensive approach to attention deficit hyperactivity disorder (ADHD) in adults with pre-existing ADHD symptoms in childhood	Avis de la CT	Registration Favorable opinion for reimbursement ASMR: V (absence): XURTA (lisdexamphetamine) 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg capsules, does not provide any improvement in the medical service provided (ASMR V): 1. as part of a comprehensive approach to ADHD in children aged 6 years and older when the response to previous treatment with methylphenidate is deemed clinically inadequate, 2. as part of a comprehensive approach to ADHD in adults with pre-existing ADHD symptoms from childhood.
SPESOLIMAB	SPEVIGO	prevention of flare-ups of generalized pustular psoriasis (PPG) in adults and adolescents from 12 years of age.	Avis de la CT	Registration Favorable opinion for reimbursement 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 specialty SPEVIGO 150 mg, injectable solution in pre-filled syringe already registered.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
IPILILUMAB/NIVOLUMAB	YERVOY/OPDIVO	first-line treatment in adult patients with metastatic colorectal cancer (CRC) that is not initially resectable with DNA mismatch repair (dMMR) deficiency or high microsatellite instability (MSI-H)	Avis de la CT	Extension of indication Favorable opinion for reimbursement only in "first-line treatment in adult patients with metastatic colorectal cancer (CRC) that is not initially resectable with DNA mismatch repair (dMMR) deficiency or high microsatellite instability (MSI-H)". Unfavorable opinion for reimbursement in other situations covered by the marketing authorization indication. ASMR: IV (minor): The Commission considers that the combination of OPDIVO (nivolumab) & YERVOY (ipilimumab) provides a minor improvement in the medical benefit (ASMR IV) compared to chemotherapy ± targeted therapy in the first-line treatment of adult patients with metastatic colorectal cancer with high microsatellite instability (MSI-H) or deficiency of the DNA mismatch repair system (dMMR) that is not initially resectable
CABOTEGRAVIR	VOCABRIA	n the treatment of HIV-1 infection, in combination with rilpivirine, only in adolescents (aged at least 12 years and weighing at least 35 kg) virologically controlled (viral load < 50 copies/mL) on stable antiretroviral therapy for at least 6 months, with more than 200 CD4/mm3, without evidence of current or past resistance and without history of virological failure to agents of the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs) and integrase inhibitors (INIs).	Avis de la CT	Extension of indication Favorable opinion for reimbursement Unfavorable opinion for reimbursement in other situations covered by the marketing authorization indication. ASMR: V (absence): The Commission considers that VOCABRIA (cabotegravir) 30 mg tablets and VOCABRIA (cabotegravir) 600 mg injectable suspension do not provide any improvement in the medical service provided (ASMR V) in the management of adolescents (aged 12 years and over, and weighing at least 35 kg) infected with HIV-1, virologically controlled (viral load < 50 copies/mL) on stable antiretroviral treatment for at least 6 months, with more than 200 CD4/mm3, without evidence of current or past resistance and without a history of virological failure to agents of the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs) and integrase inhibitors (INIs) compared to available alternatives (oral triple and dual therapies, see section 2.2).

Generic Name	Brand Name	Indication	Type of Document	Recommendation
RILPIVIRINE	REKAMBYS	treatment of HIV-1 infection, in combination with cabotegravir, only in virologically controlled adolescents (aged at least 12 years and weighing at least 35 kg) (viral load < 50 copies/mL) on stable antiretroviral therapy for at least 6 months, with more than 200 CD4/mm3, without evidence of current or past resistance and without a history of virological failure to agents of the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs) and integrase inhibitors (INIs).	Avis de la CT	Extension of indication Favorable opinion for reimbursement Unfavorable opinion for reimbursement in other situations covered by the marketing authorization indication. ASMR: V (absence): The Commission considers that REKAMBYS (rilpivirine) 900 mg, injectable suspension, does not provide any improvement in the medical service provided (ASMR V) in the management of adolescents (aged 12 years and over, and weighing at least 35 kg) infected with HIV-1, virologically controlled (viral load < 50 copies/mL) under stable antiretroviral treatment for at least 6 months, with more than 200 CD4/mm3, without evidence of current or previous resistance and without a history of virological failure to agents of the class of non-nucleoside reverse transcriptase inhibitors (NNRTI) and integrase inhibitors (INI) compared to available alternatives (triple therapies and dual therapies by oral route, see section 2.2).
GLOFITAMAB	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 specified (DLBCL NOS), ineligible for autologous stem cell transplantation (ASCT)	Avis de la CT	Registration Favorable opinion for reimbursement of COLUMVI ASMR III: (moderate): The Commission considers that COLUMVI (glofitamab) provides a moderate improvement in the medical service provided (ASMR III) compared to the combination of rituximab, gemcitabine and oxaliplatin.
TECLISTAMAB	TECVALY	as monotherapy, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, and whose disease has progressed during the last therapy, when all therapeutic options (excluding cell therapies) have been exhausted, based on the opinion of a multidisciplinary tumor board (MTB).	Avis de la CT	Early access authorization has been granted

Generic Name	Brand Name	Indication	Type of Document	Recommendation
COAGULATION FACTORS WITH FACTOR VIII AND IX INHIBITOR BYPASS ACTIVITY	FEIBA	In the treatment of bleeding and in surgical situations in constitutional factor VIII deficiency (hemophilia A), in "strong responder" patients who have developed an inhibitor directed against factor VIII; In case of failure by factor VIIa, in the treatment of hemorrhages and in surgical situation in constitutional deficiency of factor IX (hemophilia B), in "strong responder" patients who have developed an inhibitor directed against factor IX; Depending on the medical assessment, in prophylaxis to prevent or reduce the frequency of bleeding in patients with very frequent bleeding episodes and hemophilia A "strong responders" who have developed an inhibitor directed against factor VIII or hemophilia B "strong responders" who have developed an inhibitor directed against factor IX, after failure with factor VIIa; In the treatment of bleeding and in surgical situations in patients with acquired hemophilia due to anti-factor VIII autoantibodies.	Avis de la CT	Registration Favorable opinion for reimbursement within the indications of the Marketing Authorization 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.
ACETYLSALICYLIC ACID	ASARED	Secondary prevention of myocardial infarction, transient ischemic attacks (TIAs) and cerebrovascular accidents (CVAs). 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.	Avis de la CT	Registration Favorable opinion for reimbursement in secondary prevention within the framework of chronic treatment for the indications of the Marketing Authorization: Secondary prevention of myocardial infarction, transient ischemic attacks (TIAs) and cerebrovascular accidents (CVAs). 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. ASARED is not recommended in emergency situations. ASMR: V (absence): These specialties do not provide any improvement in the medical service provided (ASMR V) compared to other available acetylsalicylic acid-based specialties.

HAS

Generic Name	Brand Name	Indication	Type of Document	Recommendation
ATIDARSAGENE AUTOTEMCEL	LIBMELDY	Treatment of metachromatic leukodystrophy characterized by biallelic mutations of the ARSA gene resulting in a reduction of ARSA enzymatic activity: In asymptomatic children, without clinical manifestation of the disease, whether in terms of motor, cognitive and/or behavioral impairment, affected by the late infantile form (manifesting before 30 months) or early juvenile form (manifesting between 30 months and 6 years inclusive) In symptomatic children with early clinical manifestations of the disease, who have retained the ability to walk independently and before the onset of cognitive decline, affected by the early juvenile form (manifesting between 30 months and 6 years inclusive).	Avis de la CT	Early access authorization renewed
DURVALUMAB	IMFINZI	in combination with platinum-based chemotherapy in neoadjuvant therapy, followed by IMFINZI monotherapy in adjuvant therapy, is indicated for the treatment of adult patients with resectable non-small cell lung cancer (NSCLC) at high risk of recurrence and without EGFR mutations or ALK rearrangements (for selection criteria, see section 5.1) whose tumors express PD-L1 at the threshold < 1%	Avis de la CT	Early access authorization has been refused

Generic Name	Brand Name	Indication	Type of Document	Recommendation
LIPOSOMAL AMPHOTERICIN B	AMPHOTERICIN B LIPOSOMAL MEDIPHA	AMPHOTERICIN B LIPOSOMAL MEDIPHA is an antifungal medicinal product indicated in adults and children as follows: 1. Treatment of invasive Aspergillus infections as an alternative therapy in cases of failure or intolerance to voriconazole. 2. Treatment of neuro-meningeal cryptococcosis in HIV-infected patients, and treatment of invasive Candida infections in cases of: • Renal insufficiency developed under amphotericin B, defined by: Serum creatinine above 220 µmol/L, or Creatinine clearance below 25 mL/min; • Pre-existing and persistent renal impairment, defined by: Serum creatinine above 220 µmol/L, or Creatinine clearance below 25 mL/min. 3. Empirical treatment of presumed fungal infections in febrile neutropenic patients. The maximum benefit was observed in allogeneic bone marrow transplant patients, and in adult patients with neutropenia lasting ≥7 days from the start of antifungal therapy, receiving concomitant nephrotoxic agents. 4. Treatment of visceral leishmaniasis in cases of proven or probable resistance to antimonials.	Avis de la CT	Registration Favorable opinion for reimbursement within the indications of the MA (see RCP) ASMR: V (absence): This specialty is a hybrid which does not provide any improvement in the medical service provided (ASMR V) compared to the reference specialty AMBISOME LIPOSOMAL 50 mg, powder for dispersion for infusion, already registered.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
ACALABRUTINIB	CALQUENCE	Adult patients with previously untreated chronic lymphocytic leukaemia	Dossier Assessment [A25-91]	Result of dossier assessment: Added benefit not proven	The pU determines the annual therapy costs per patient for Acalbrutinib in combination with Venetoclax and Obinutuzumab as follows: €168,287.32 in the first year of treatment and €11,930.86 in the second year.
ACALABRUTINIB	CALQUENCE	Adult patients with relapsed or refractory mantle cell lymphoma not previously treated with a Bruton tyrosine kinase inhibitor	Dossier Assessment [A25-90]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) estimates the annual therapy costs per patient for Acalabrutinib as monotherapy at €75,192.58.
ACALABRUTINIB	CALQUENCE	Adults with previously untreated mantle cell lymphoma who are not eligible for autologous stem cell transplant	Dossier Assessment [A25-89]	Result of dossier assessment: Patients for whom bendamustine + rituximab is a suitable individualized treatment: hint of a lesser benefit Patients for whom bendamustine + rituximab is not a suitable individualized treatment: added benefit not proven	The pharmaceutical company (pU) estimates annual therapy costs per patient for acalabrutinib + bendamustine + rituximab, including a potential maintenance therapy with rituximab, to range from €99,213.52 to €107,661.05.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
NIVOLUMAB	OPDIVO	Adjuvant treatment of adult patients with oesophageal or gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy	Dossier Assessment [A25-88]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) estimates annual therapy costs per patient for nivolumab to range from €76,871.60 to €77,271.60.
ANDEXANET ALFA	ONDEXXYA	Adult patients treated with a direct factor Xa inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrollable bleeding	Dossier Assessment [A25-87]	Result of dossier assessment: Patients with intracerebral haemorrhage: hint of a lesser benefit All other patients in the therapeutic indication: added benefit not proven	The marketing authorization holder (pU) calculates the annual treatment costs per patient for Andexanet alfa at €11,007.50 (low dose) and €19,813.50 (high dose).
OMAVELOXOLONE	SKYCLARYS	Patients ≥ 16 years with Friedreich's ataxia	Dossier Assessment [A25-86]	Result of dossier assessment: Added benefit not proven	The marketing authorization holder (MAH) estimates the annual treatment costs per patient for Omaveloxolone in the first year of treatment to be €326,512.00 (270 hard capsules) to €326,965.33 (90 hard capsules).

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
NIVOLUMAB	OPDIVO	Adjuvant treatment of adult patients with oesophageal or gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy	Dossier Assessment [A25-88]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) estimates annual therapy costs per patient for nivolumab to range from €76,871.60 to €77,271.60.
ANDEXANET ALFA	ONDEXXYA	Adult patients treated with a direct factor Xa inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrollable bleeding	Dossier Assessment [A25-87]	Result of dossier assessment: Patients with intracerebral haemorrhage: hint of a lesser benefit All other patients in the therapeutic indication: added benefit not proven	The marketing authorization holder (pU) calculates the annual treatment costs per patient for Andexanet alfa at €11,007.50 (low dose) and €19,813.50 (high dose).
OMAVELOXOLONE	SKYCLARYS	Patients ≥ 16 years with Friedreich's ataxia	Dossier Assessment [A25-86]	Result of dossier assessment: Added benefit not proven	The marketing authorization holder (MAH) estimates the annual treatment costs per patient for Omaveloxolone in the first year of treatment to be €326,512.00 (270 hard capsules) to €326,965.33 (90 hard capsules).

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
ACALABRUTINIB PLUS VENETOCLAX	CALQUENCE PLUS VENCLYXTO	Adult patients with previously untreated chronic lymphocytic leukaemia	Dossier Assessment [A25-85]	Result of dossier assessment: Added benefit not proven	The MAH calculates annual therapy costs per patient for acalabrutinib in combination with venetoclax of €147,345.20 in the first treatment year and €11,930.86 in the second treatment year.
SELPERCATINIB	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	Drug costs in € 35,099.70 – 46,718.70
VUTRISIRAN	AMVUTTRA	Wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)	Dossier Assessment [A25-93]	Result of dossier assessment: Added benefit not proven	The MAH calculates annual therapy costs per patient for vutrisiran at €300,962.00.
REMDESIVIR	VEKLURI	Children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with COVID-19 who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19	Dossier Assessment [A25-92]	Result of dossier assessment: Added benefit not proven	The pU determines the annual therapy costs for Remdesivir to be between €821.10 and €1,642.20.

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
CONCIZUMAB	ALHEMO	Routine prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency) and factor IX inhibitors and of 12 years of age or more	Dossier Assessment [A25-115] Addendum to Project A25-56	Result of dossier assessment: Unchanged after addendum: Added benefit not proven	-
TRASTUZUMAB DERUXTECAN	ENHERTU	Adult patients with unresectable or metastatic HR-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment	Dossier Assessment [A25-116] Addendum to Project A25-54	Result of dossier assessment: Unchanged after addendum: Added benefit not proven	-
TRASTUZUMAB DERUXTECAN	ENHERTU	Adult patients with unresectable or metastatic HR-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment	Dossier Assessment [A25-54]	Result of dossier assessment: Added benefit not proven	The pharmaceutical company (pU) calculates annual therapy costs per patient for trastuzumab deruxtecan ranging from €102,906.64 to €103,271.13.
CONCIZUMAB	ALHEMO	Routine prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency) and factor IX inhibitors and of 12 years of age or more	Dossier Assessment [A25-56]	Result of dossier assessment: Added benefit not proven	The pU calculates the annual therapy costs per patient for concizumab to be €369,114.94 to €859,718.80.

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.	

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
SPARSENTAN	FILSPARI	Sparsentan (Filspari, Vifor) is indicated for 'the treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥ 1.0 g/day (or urine protein-to-creatinine ratio ≥ 0.75 g/g)'.	Technology appraisal [TA1074]	We updated recommendations 1.1 and 1.2 to change the unit for urine protein-to-creatinine ratio (UPCR) to mg/mmol from g/g. A UPCR of 85 mg/mmol or more equates to the 0.75 g/g or more measurement specified in the marketing authorisation indication for sparsentan. A UPCR of 199 mg/mmol or more equates to 1.76 g/g or more.	-
LORLATINIB	LORLATINIB	Lorlatinib (Lorviqua, Pfizer) is indicated for the 'treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC) previously not treated with an ALK inhibitor or whose disease has progressed after prior treatment with an ALK inhibitor'.	Technology appraisal [TA1103]	Lorlatinib can be used as an option for ALK-positive advanced non-small-cell lung cancer in adults who have not had an ALK inhibitor. Lorlatinib can only be used if the company provides it according to the commercial arrangement.	The list price of 30 lorlatinib 100-mg tablets and 90 lorlatinib 25-mg tablets is £5,283 (excluding VAT; BNF online accessed July 2025).
CLASCOTERONE	WINLEVI	Topical treatment for acne vulgaris in people 12 years and over	Technology appraisal [TA1105]	NICE is unable to make a recommendation about the use in the NHS of clascoterone as a topical treatment for acne vulgaris in people 12 years and over. This is because Glenmark Pharmaceuticals has confirmed that it does not intend to make an evidence submission for the appraisal. Glenmark Pharmaceuticals' view, which it has corroborated in consultation with healthcare professionals and other relevant decision makers, is that an appraisal will not add value.	The list price of garadacimab for the subcutaneous injection is £20,625 for each prefilled pen (200 mg/1.2 ml).
SARILUMAB	KEVZARA	For treating polyarticular or oligoarticular juvenile idiopathic arthritis in people 2 to 17 years	Technology appraisal [TA1104]	NICE is unable to make a recommendation about the use in the NHS of sarilumab for treating polyarticular or oligoarticular juvenile idiopathic arthritis in people 2 to 17 years. This is because Sanofi has confirmed that it does not intend to make a submission for the appraisal. Sanofi considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources in this population.	

NICE

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
IPTACOPAN	FABHALTA	treating complement 3 glomerulopathy in adults	Technology appraisal [TA1102]	NICE is unable to make a recommendation about the use in the NHS of iptacopan for treating complement 3 glomerulopathy in adults. This is because Novartis has withdrawn from the appraisal.	-

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
NUSINERSEN	SPINRAZA	For the treatment of 5q spinal muscular atrophy.	Medicine Advice [SMC2805]	Following a reassessment through the ultra-orphan framework nusinersen (Spinraza®) is accepted for restricted use within NHSScotland. SMC restriction: Patients with symptomatic type 2 or type 3 (later-onset) 5q spinal muscular atrophy.	12 mg loading dose on days 0, 14, 28 and 63 followed by 12 mg maintenance dose every 4 months by intrathecal injection Cost per year (£): Year 1: 450,000 Subsequent years: 225,000
NIVOLUMAB	OPDIVO	In combination with platinum-based chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgical resection, for the treatment of adults with resectable (tumours ≥4 cm or node positive) non-small cell lung cancer and no known EGFR mutations or ALK rearrangements.	Medicine Advice [SMC2874]	In the absence of a submission from the holder of the marketing authorisation nivolumab (Opdivo®) is not recommended for use within NHSScotland. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result, we cannot recommend its use within NHSScotland.	Dose regimen: 600 mg orally twice daily Cost per 28-day cycle (£): 6,648
LINZAGOLIX	YSELTY	In adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis.	Medicine Advice [SMC2841]	Following an abbreviated submission linzagolix (Yselty®) 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.

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
FRUQUINTINIB	FRUZAQLA	Treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with available therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, with or without an anti-VEGF therapy, and if RAS wildtype and medically appropriate, an anti-EGFR therapy.	Medicine Advice [SMC2858]	Following a resubmission assessed under the end of life and orphan equivalent medicine process fruquintinib (Fruzaqla®) is accepted for use within NHSScotland.	Fruquintinib 5 mg orally each day for first 21 days in 28-day cycle Cost per cycle (£): 3,950
DURVALUMAB	IMFINZI	in combination with carboplatin and paclitaxel for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with: 1. durvalumab as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR) 2. durvalumab in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR).	Medicine Advice [SMC2797]	Following a full submission assessed under the end of life and orphan equivalent medicine process durvalumab (Imfinzi®) is accepted for use within NHSScotland	durvalumab + carboplatin + paclitaxel Cost per cycle (£): 6,530 per 3-week cycle followed by maintenance durvalumab (+olaparib inpMMR only) Cost per cycle (£): 7,398 (+ 4,635) per 4-week cycle
CAPIVASERTIB	TRUQAP	In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following recurrence or progression on or after an endocrine-based regimen.	Medicine Advice [SMC2823]	Following a full submission assessed under the end of life and orphan equivalent medicine process capivasertib (Truqap®) is not recommended for use within NHSScotland.	

SMC

Generic Name	Brand Name	Indication	Type of Document	Recommendation	Info on Costs
BELANTAMAB MAFODOTIN	BLENREP	in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	Medicine Advice [SMC2727]	Following a full submission assessed under the orphan equivalent medicine process belantamab mafodotin (Blenrep®) is accepted for restricted use within NHSScotland. SMC restriction: Patients with relapsed or refractory multiple myeloma eligible for second line treatment for whom lenalidomide is an unsuitable treatment option.	Belantamab mafodotin (in combination with daratumumab plus dexamethasone) 30-minute intravenous infusion once every three weeks, at a starting dose of 2.5 mg/kg Cost per cycle (£): £23,568
BELANTAMAB MAFODOTIN	BLENREP	in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy including lenalidomide.	Medicine Advice [SMC2747]	Following a full submission assessed under the orphan equivalent medicine process belantamab mafodotin (Blenrep®) is not recommended for use within NHSScotland.	Belantamab mafodotin (in combination with pomalidomide plus dexamethasone) 30-minute intravenous infusion once every four weeks, with a starting dose of 2.5 mg/kg given once in cycle 1 (each cycle is a 28-day period). From cycle 2 onwards, belantamab mafodotin is dosed at 1.9 mg/kg Cycle 1: £23,568 Cycle 2 onwards: £20,033