NEWSLETTER: News from the HTA Agencies

January 2024

SUMMARY

	N° of drugs	Drug Name
CADTH Evidence Driven.	5	Calaspargase pegol • Efgartigimod alfa • Ibrutinib • Polatuzumab Vedotin • Upadacitinib
HAS HAUTE AUTORITÉ DE SANTÉ	10	Atogepant • Calcipotriol /Betamethasone • Ciclopirox • Clobetasol • Exagamglogene Autotemcel • Futibatinib • Linzagolix choline • Nivolumab / Relatlimab • Pegunigalsidase alfa • Salmonella enterica serovar typhi strain TY21A
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW	-	-
IQWiG Institute for Quality and Efficiency in Health Care	2	Nivolumab • Pegunigalsidase alfa
NICE National Institute for Health and Care Excellence	5	Durvalumab + Gemcitabine • Ivosidenib • Loncastuximab tesirine • Olaparib + Bevacizumab • Treosulfan
SMC Scottish Medicines Consortium	5	Axicabtagene ciloleucel • Belantamab mafodotin • Burosumab • Pembrolizumab • Setmelanotide

CADTH

https://www.cadth.ca/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Calaspargase pegol	Asparlas	As a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients age 1 to 21 years	CADHT Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2024/PC0321REC-Asparlas.pdf	Reimburse with conditions. What Are the Conditions for Reimbursement? Asparlas should only be reimbursed as part of a MAC regimen. Asparlas should be prescribed by clinicians with expertise in the management of ALL, and the cost of Asparlas should not exceed the drug program cost of treatment with pegaspargase.	Treatment with Asparlas is expected to cost approximately $52,093 per patient per treatment course
Efgartigimod alfa	Vyvgart	For the treatment of adult patients with generalized myasthenia gravis who are anti-acetylcholine receptor antibody positive	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2024/SR0782REC-Vyvgart-meta.pdf	Reimburse with conditions. What Are the Conditions for Reimbursement? Vyvgart should not be reimbursed when given during a gMG exacerbation (i.e., moment when patient experience weakness in some or all muscles, without needing assistance to breath) or crisis (i.e., moment when respiratory muscles are too weak, limiting air flow in and out of lungs, and as a result, patient is unable to breathe), or within 3 months of thymectomy (i.e., surgical removal of thymus gland). Vyvgart should only be reimbursed if prescribed by or in consultation with a neurologist with expertise in managing patients with gMG, and the cost of Vyvgart is reduced. Vyvgart should not be used concomitantly with rituximab or complement inhibitors.	Treatment with Vyvgart is expected to cost approximately $63,200 to $94,800 per patient per course, or $298,304 to $447,456 per patient per year, depending on patient weight and assuming 4.72 courses per year
Ibrutinib	Imbruvica	Ibrutinib, with or without rituximab, for the treatment of adult patients with previously treated refractory or relapsed Waldenström's macroglobulinemia	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2024/PC0328%20Imbruvica%20WM%20-%20Final%20CADTH%20Recommendation.pdf	Reimburse with conditions: CADTH recommends that Imbruvica, with or without rituximab, should be reimbursed by public drug plans for the treatment of adult patients with previously treated relapsed or refractory Waldenström's macroglobulinemia (WM) if certain conditions are met.	Treatment with Imbruvica is expected to cost approximately $8,386 per patient per 28-day cycle.

CADTH

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Polatuzumab Vedotin	Polivy	Polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients with previously untreated large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high grade B-cell lymphoma, Epstein-Barr virus-positive (EBV+) DLBCL NOS, and T-cell/histiocyte rich LBCL.	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2024/PC0313%20Polivy%20-%20CADTH%20Final%20Rec.pdf	The CADTH pan-Canadian Oncology Drug Review Expert Review Committee (pERC) recommends that polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (pola-RCHP) not be reimbursed for the treatment of adult patients with previously untreated large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high-grade B-cell lymphoma, Epstein-Barr virus (EBV)–positive DLBCL NOS, and T-cell/histiocyte-rich LBCL.	Treatment with Polivy in combination with R-CHP is expected to cost $23,480 per patient per 28 days.
Upadacitinib	Rinvoq	For the treatment of adult patients with moderately to severely active Crohn's disease who have demonstrated prior treatment failure, i.e., an inadequate response to, loss of response to, or intolerance to at least one of conventional and/or biologic therapy.	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2024/SR0775REC-Rinvoq-(Crohn's)-meta.pdf	Reimburse with conditions. What Are the Conditions for Reimbursement? Rinvoq should only be reimbursed if prescribed by a physician experienced in the diagnosis and management of CD, if it is not used in combination with biologics for CD, and if the cost of Rinvoq is reduced so that it does not cost the drug programs more than the least costly biologic therapy reimbursed for the treatment of moderately to severely active CD. Patients must respond to treatment in the first 12 weeks of starting Rinvoq to continue receiving the drug.	Treatment with Rinvoq is expected to cost between $23,074 and $30,178 per patient in the first year and $18,864 to $28,090 per patient in subsequent years.

https://www.has-sante.fr/

Generic name	Brand name	Indication	Type of document	Link	Recommendation
Atogepant	Aquipta	Pour le traitement préventif de la migraine chez les patients adultes atteints de migraine sévère avec au moins 8 jours de migraine par mois, en échec à au moins deux traitements prophylactiques et sans atteinte cardiovasculaire (patients ayant eu une maladie cardiovasculaire ou cérébrovasculaire établie, avec antécédent récent (< 6 mois) de syndrome coronarien aigu ou AVC/AIT, ou HTA).	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20443_AQUIPTA_PIC_INS_AvisDef_CT20443.pdf	Avis favorable au remboursement uniquement dans le traitement préventif de la migraine chez les patients adultes atteints de migraine sévère avec au moins 8 jours de migraine par mois, en échec à au moins deux traitements prophylactiques et sans atteinte cardiovasculaire (patients ayant eu une maladie cardiovasculaire ou cérébrovasculaire établie, avec antécédent récent (< 6 mois) de syndrome coronarien aigu ou AVC/AIT, ou HTA).
Calcipotriol / Betamethasone	Closalis	Pour le le traitement local des formes stables de psoriasis vulgaire en plaques relevant du traitement topique chez les adultes.	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20608_CLOSALIS_PIS_INS_AvisDef_CT20608.pdf	Inscription : Primo-inscription. Avis favorable au remboursement ASMR: V (absence) Cette spécialité est un hybride qui n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport à la spécialité de référence, DAIVOBET 50 µg/0,5 mg/g (calcipotriol, bétaméthasone), pommade, déjà inscrite.
Ciclopirox	Condyx	Pour le traitement des onychomycoses légères à modérées, provoquées par des dermatophytes et/ou d'autres champignons sensibles au ciclopirox, sans atteinte de la matrice unguéale.	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20624_CONYDIX_PIS_INS_AvisDef_CT20624.pdf	Inscription : Primo-inscription. Avis favorable au remboursement ASMR: V (absence) Cette spécialité est un hybride qui n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport à la spécialité de référence ONYTEC 80 mg/g (ciclopirox), vernis à ongle médicamenteux déjà inscrite.
Clobetasol	Cabesol	Pour le le traitement topique du psoriasis modéré du cuir chevelu chez l'adulte.	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20625_CABESOL_PIS_INS_AvisDef_CT20625.pdf	Inscription : Primo-inscription. Avis favorable au remboursement ASMR: V (absence) Cette spécialité est un hybride qui n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport à la spécialité de référence CLOBEX 500 µg/g (clobétasol), shampooing, et à son générique déjà inscrit.

https://www.has-sante.fr/

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Exagamglogene Autotemcel	Casgevy	« Traitement de la ß thalassémie dépendante des transfusions (TDT) chez les patients âgés de 12 ans à 35 ans éligibles à une greffe de cellules souches hématopoïétiques (CSH) et pour lesquels un donneur apparenté HLA (antigène leucocytaire humain) compatible n'est pas disponible ».	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2024-01/casgevy_decision_et_avisct_ap262.pdf	Autorisation d'accès précoce octroyée.
Futibatinib	Lytgobi	« en monothérapie pour le traitement des patients adultes atteints d'un cholangiocarcinome intrahépatique localement avancé ou métastatique avec fusion ou réarrangement du récepteur 2 du facteur de croissance des fibroblastes (FGFR2), qui ont progressé après au moins une ligne de traitement systémique et non éligibles à une chimiothérapie par FOLFOX »	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20313_LYTGOBI_PIC_INS_AvisDef_CT20313.pdf	Primo-inscription. Avis favorable au remboursement ASMR: V (absence) la Commission de la Transparence considère que LYTGOBI (futibatinib) n'apporte pas d'amélioration du service médical rendu (ASMR V) dans le traitement du sous-groupe des patients atteints d'un cholangiocarcinome intrahépatique localement avancé ou métastatique avec fusion ou réarrangement du gène du récepteur 2 du facteur de croissance des fibroblastes (FGFR2) qui ont progressé après au moins une ligne de traitement systémique et non éligibles à une chimiothérapie par FOLFOX.
Linzagolix choline	Yselty	« traitement des symptômes modérés à sévères des fibromes utérins chez la femme adulte en âge de procréer ».	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20453_YSELTY_PIC_INS_AvisDef_CT20453.pdf	Primo-inscription. Avis favorable au remboursement. ASMR: V (absence) la Commission considère qu'YSELTY 100 mg, 200 mg (linzagolix) comprimé pelliculé n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la stratégie thérapeutique actuelle qui comprend les comparateurs pertinents

https://www.has-sante.fr/

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Nivolumab / Relatlimab	Opdualag	« en première ligne de traitement du mélanome avancé (non résécable ou métastatique) chez les adultes et les adolescents âgés de 12 ans et plus avec une expression de PD-L1 au niveau des cellules tumorales inférieure à 1 %, avec un score ECOG 0 ou 1 et ne présentant pas de métastase cérébrale active ».	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20456_OPDUALAG_PIC_INS_AvisDef_CT20456.pdf	Primo-inscription. Avis favorable au remboursement uniquement « en première ligne de traitement du mélanome avancé (non résécable ou métastatique) chez les adultes et les adolescents âgés de 12 ans et plus avec une expression de PD-L1 au niveau des cellules tumorales inférieure à 1 %, avec un score ECOG 0 ou 1 et ne présentant pas de métastase cérébrale active ». ASMR: IV (mineur) la Commission considère que OPDUALAG (nivolumab/relatlimab) 240 mg/80 mg, solution à diluer pour perfusion apporte une amélioration du service médical rendu mineure (ASMR IV) par rapport au nivolumab en première ligne de traitement du mélanome avancé (non résécable ou métastatique) chez les adultes et les adolescents âgés de 12 ans et plus avec une expression de PD-L1 au niveau des cellules tumorales inférieure à 1 %, avec un score ECOG 0 ou 1 et ne présentant pas de métastase cérébrale active.
Pegunigalsidase alfa	Elfabrio	le « traitement enzymatique substitutif au long cours chez les patients adultes présentant une maladie de Fabry (déficit en alpha-galactosidase) dont le diagnostic a été confirmé ».	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20442_ELFABRIO_PIC_INS_AvisDef_CT20442.pdf	Primo-inscription. Avis défavorable au remboursement.
Salmonella enterica serovar typhi strain TY21A	Vivotif	« VIVOTIF est indiqué pour l'immunisation active par voie orale contre la fièvre typhoïde causée par Salmonella enterica sérovar typhi (S. typhi) chez les adultes et les enfants âgés de 5 ans et plus. Ce vaccin doit être utilisé conformément aux recommandations officielles "	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20462_VIVOTIF_PIC_INS_AvisDef_CT20462.pdf	Primo-inscription. Avis favorable au remboursement pour l'immunisation active par voie orale contre la fièvre typhoïde causée par Salmonella enterica sérovar typhi (S. typhi) chez les adultes et les enfants âgés de 5 ans et plus, selon les recommandations en vigueur de la HAS datant de février 2020.

ICER

https://icer.org/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
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https://www.iqwig.de/en/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Nivolumab	Opdivo	Adjuvant treatment of stage IIB or IIC melanoma after complete resection in adults and adolescents 12 years of age and older	Dossier Assessment [A23-94]	https://www.iqwig.de/download/a23-94_nivolumab_kurzfassung_nutzenbewertung-35a-sgb-v_v1-0.pdf	1. Adults: hint of minor added benefit 2. Adolescents 12 years of age and older: added benefit not proven	
Pegunigalsidase alfa	PRX-102	Adult patients with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase)	Dossier Assessment [A23-95]	https://www.iqwig.de/download/a23-95_pegunigalsidase-alfa_kurzfassung_nutzenbewertung-35a-sgb-v_v1-0.pdf	Added benefit not proven	

NICE

https://www.nice.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Durvalumab + Gemcitabine	Imfinzi	Durvalumab in combination with gemcitabine and cisplatin is indicated for 'the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer'	Technology appraisal guidance [TA944]	https://www.nice.org.uk/guidance/ta944/resources/durvalumab-with-gemcitabine-and-cisplatin-for-treating-unresectable-or-advanced-biliary-tract-cancer-pdf-82615668536005	Durvalumab plus gemcitabine and cisplatin is recommended.	The list price of durvalumab is £2,466 for a 500 mg per 10 ml vial (excluding VAT; BNF online, accessed October 2023).
Ivosidenib	Tibsovo	Ivosidenib (Tibsovo, Servier) monotherapy is indicated for 'the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy'.	Technology appraisal guidance [TA948]	https://www.nice.org.uk/guidance/ta948/resources/ivosidenib-for-treating-advanced-cholangiocarcinoma-with-an-idh1-r132-mutation-after-1-or-more-systemic-treatments-pdf-82615675254469	Ivosidenib is recommended.	The list price of a 60-tablet pack of 250 mg ivosidenib is £12,500
Loncastuximab tesirine	Zynlonta	Loncastuximab tesirine (Zynlonta, Swedish Orphan Biovitrum) is indicated for 'the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy.'	Technology appraisal guidance [TA947]	https://www.nice.org.uk/guidance/ta947/resources/loncastuximab-tesirine-for-treating-relapsed-or-refractory-diffuse-large-bcell-lymphoma-and-highgrade-bcell-lymphoma-after-2-or-more-systemic-treatments-pdf-82615673574853	Loncastuximab tesirine is recommended as an option for treating relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) after 2 or more systemic treatments in adults, only if: • they have previously had polatuzumab vedotin, or if polatuzumab vedotin is contraindicated or not tolerated, and • the company provides it according to the commercial arrangement.	The list price for loncastuximab tesirine is £15,200 per 10-mg vial (excluding VAT; company submission). An average course of loncastuximab tesirine per person is £85,562.

NICE

https://www.nice.org.uk/

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Olaparib + Bevacizumab	Lynparza + Avastin	Olaparib (Lynparza, AstraZeneca) with bevacizumab (Avastin, Roche) is indicated for the 'maintenance treatment of adult patients with advanced (FIGO stages 3 and 4) 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 in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency positive status defined by either a BRCA1/2 mutation and/or genomic instability'.	Technology appraisal guidance [TA946]	https://www.nice.org.uk/guidance/ta946/resources/olaparib-with-bevacizumab-for-maintenance-treatment-of-advanced-highgrade-epithelial-ovarian-fallopian-tube-or-primary-peritoneal-cancer-pdf-82615671895237	Olaparib with bevacizumab is recommended, within its marketing authorisation, for maintenance treatment of high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in adults whose cancer: • has completely or partially responded after first-line platinum-based chemotherapy with bevacizumab • is advanced (International Federation of Gynecology and Obstetrics [FIGO] stages 3 and 4) and • is homologous recombination deficiency (HRD) positive (defined as having either a BRCA1 or BRCA2 mutation, or genomic instability).	The list price for olaparib tablets is £2,317.50 per 14-day pack (56×150-mg tablets) or £4,635.00 per 28-day cycle
Treosulfan	Trecondi	Treosulfan with fludarabine before allogeneic stem cell transplant for people aged 1 month to 17 years with non-malignant diseases	Technology appraisal [TA945]	https://www.nice.org.uk/guidance/ta945/resources/treosulfan-with-fludarabine-before-allogeneic-stem-cell-transplant-for-people-aged-1-month-to-17-years-with-nonmalignant-diseases-terminated-appraisal-pdf-82615670215621	NICE is unable to make a recommendation. This is because Medac Pharma did not provide an evidence submission.	

SMC

https://www.scottishmedicines.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Axicabtagene ciloleucel	Yescarta	Is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy.	Medicine Advice	https://www.scottishmedicines.org.uk/media/8028/axicabtagene-ciloleucel-non-sub-final-dec-2023-for-website.pdf	In the absence of a submission from the holder of the marketing authorisation axicabtagene ciloleucel (Yescarta®) is not recommended for use within NHSScotland.	/
Belantamab mafodotin	Blenrep	Is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.	Medicine Advice	https://www.scottishmedicines.org.uk/media/8029/belantamab-blenrep-final-dec-2023-for-website.pdf	following a full submission assessed under the end of life and orphan medicine process belantamab mafodotin (Blenrep®) is not recommended for use within NHSScotland.	Cost per three-week cycle* (£): 2.5mg/kg as an intravenous infusion every three weeks until disease progression £11,415
Burosumab	Crysvita	Is indicated for the treatment of X-linked hypophosphataemia in children and adolescents aged 1 to 17 years with radiographic evidence of bone disease.	Medicine Advice	https://www.scottishmedicines.org.uk/media/8025/burosumab-crysvita-reassessment-final-dec-2023-for-website.pdf	following reassessment through the ultra-orphan framework burosumab (Crysvita®) is accepted for use within NHSScotland.	Cost per year (£) Starting dose: 0.8 mg/kg given every 2 weeks by subcutaneous injection: 77,792 to 466,752 Maximum dose: 2.0 mg/kg (maximum dose of 90mg). 700,128 (90mg)

SMC

https://www.scottishmedicines.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Pembrolizumab	Keytruda	Is indicated in deficient (dMMR) colorectal cancer in the following settings: • treatment of unresectable or metastatic colorectal cancer after previous fluoropyrimidine-based combination therapy. As monotherapy for the treatment of the following MSI-H or dMMR tumours in adults with: • advanced or recurrent endometrial carcinoma, who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation; • unresectable or metastatic gastric, small intestine, or biliary cancer, who have disease progression on or following at least one prior therapy.	Medicine Advice	https://www.scottishmedicines.org.uk/media/8026/pembrolizumab-keytruda-final-dec-2023-for-website.pdf	following a full submission pembrolizumab (Keytruda®) is accepted for use within NHSScotland.	Cost per cycle (£): 200mg every 3 weeks or 400mg every 6 weeks administered as an intravenous infusion over 30 minutes. 3 week cycle: 5,260 6 week cycle: 10,520
Setmelanotide	Imcivree	Treatment of obesity and the control of hunger associated with genetically confirmed Bardet-Biedl syndrome (BBS) in adults and children 6 years of age and above.	Medicine Advice	https://www.scottishmedicines.org.uk/media/8027/setmelanotide-imcivree-non-sub-final-dec-2023-for-website.pdf	In the absence of a submission from the holder of the marketing authorization setmelanotide (Imcivree®) is not recommended for use within NHSScotland	