NEWSLETTER: News from the HTA Agencies

February 2023

SUMMARY

	N° of drugs	Drug Name
CADTH Evidence Driven.	9	Anifrolumab • axicabtagene ciloleucel • belimumab • brolucizumab • deferiprone • dupilumab (x2) • durvalumab • pembrolizumab
HAS HAUTE AUTORITÉ DE SANTÉ	20	[18F]PSMA-1007 • burosumab • corifollitropine alfa • durvalumab • elranatamab • faricimab • filgotinib • idecabtagene vicleucel • maralixibat • maribavir • nifédipine/lidocaïne chlorhydrate • olaparib • Ose2101 • pembrolizumab • régadénoson • sacituzumab govitecan • selpercatinib • sotrovimab • tébentafusp • trémélimumab
ICER	0	
IQWiG Institute for Quality and Efficiency in Health Care	10	Daridorexant [A22-123] • elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide [A22-116] • olaparib [A22-89]/[A23-02] - [A22-117] • pembrolizumab [A22-70]/[A22-135] • ravulizumab [A22-115] • tezepelumab [A22-122] • tralokinumab [A22-121] • trastuzumab deruxtecan [A22-80]/[A22-126] - [A22-81]/[A22-127]
NICE National Institute for Health and Care Excellence	9	Ataluren • nintedanib • nivolumab • Ixazomib • regorafenib • somatrogon • trastuzumab deruxtecan • upadacitinib • vutrisiran
SMC Scottish Medicines Consortium	5	Burosumab • eptinezumab • nivolumab • pembrolizumab • upadacitinib

CADTH

https://www.cadth.ca/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
anifrolumab	Saphnelo	As addition to standard therapy for the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE).	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/SR0717%20Saphnelo%20-%20CADTH%20Final%20Rec_JH_BF.pdf	The CADTH Canadian Drug Expert Committee (CDEC) recommends that anifrolumab be reimbursed for use in addition to standard therapy for the treatment of adult patients with active, autoantibody positive, SLE only if the conditions listed in the linked report are met.	Treatment with Saphnelo is expected to cost approximately $21,934 per patient per year
axicabtagene ciloleucel	Yescarta	The treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL), who are candidates for autologous stem cell transplant (ASCT)	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/PG0293REC-Yescarta-meta.pdf	The CADTH pCODR Expert Review Committee (pERC) recommends that axicabtagene ciloleucel be reimbursed for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma (HGBL) that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy and who are eligible for autologous stem cell transplant (ASCT) only if the conditions listed in the linked report are met.	Treatment with Yescarta is expected to have a 1-time cost of $485,021 per patient. Additional costs associated with pre- and postinfusion management (i.e., leukapheresis, bridging therapy, conditioning chemotherapy) and administration will also apply.
belimumab	Benlysta	In addition to standard therapy for treatment of active lupus nephritis in adult patients.	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/SR0746%20Benlysta-%20CADTH%20Final%20Recommendation%20February%207%2C%202023_For%20Publishing_KT_NA_BF_KT_BF-meta.pdf	The CADTH Canadian Drug Expert Committee (CDEC) recommends that belimumab be reimbursed in addition to standard therapy for treatment of active lupus nephritis (LN) in adult patients only if the conditions listed in the linked report are met.	Treatment with Benlysta is expected to cost approximately $20,631 to $25,938 per patient per year.

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brolucizumab	Beovu	The treatment of diabetic macular edema (DME).	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/SR0747%20Beovu%20-%20CADTH%20%20Final%20Recommendation%20KH_SC%20-%20KH-meta.pdf	The CADTH Canadian Drug Expert Committee (CDEC) recommends that brolucizumab be reimbursed for the treatment of DME only if the conditions listed in the linked report are met.	Treatment with Beovu is expected to cost between $9,730 and $11,120 per patient in the first year of use (based on 7 to 8 injections) depending on how many injections are required. In subsequent years, the annual cost per patient is expected to be between $5,560 and $9,730 (based on 4 to 7 injections per year).
deferiprone	Ferriprox	For the treatment of patients with transfusional iron overload due to sickle cell disease or other anemias.	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/SR0741%20Ferriprox%20-%20Final%20CADTH%20Recommendation%20Final-meta.pdf	The CADTH Canadian Drug Expert Committee (CDEC) recommends that deferiprone be reimbursed the treatment of patients with transfusional iron overload due to SCD or other anemias, only if the conditions in the linked report are met.	Treatment with Ferriprox is expected to cost between $6,113 and $8,151 per month.

CADTH

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dpilumab	Dupixent	As an add-on maintenance treatment in patients aged 6 to 12 years with severe asthma with a type 2 or eosinophilic phenotype characterized by: Symptoms that are not controlled despite optimal treatment, defined by the daily use of a medium or high dose ICS + 1 controller medication or high-dose ICS alone. EOS 150 or FeNO 20 or allergy driven asthma. Uncontrolled asthma having at least one severe exacerbation, defined by having experienced one or more hospitalization/emergency care visit OR treatment with a systemic corticosteroid (SCS, oral, or parenteral) in the past 12 months. A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of dupilumab treatment.	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/SR0745%20Dupixent%20-%20CADTH%20Final%20Recommendation%20Final.pdf	The CADTH Canadian Drug Expert Committee (CDEC) recommends that dupilumab be reimbursed as an add-on maintenance treatment in patients aged 6 to younger than 12 years with severe asthma with a type 2/eosinophilic phenotype if the conditions listed in the linked report are met. The CDEC recommendation for dupilumab as an add-on maintenance treatment in patients aged 12 years and older with severe asthma and with a type 2 or eosinophilic phenotype or oral corticosteroid (OCS)-dependent asthma dated June 8, 2021, continues to apply to patients who are not included in the population evaluated in the resubmission.	Treatment with Dupixent is expected to cost approximately $25,446 per patient per year for patients receiving 200 mg every 2 weeks. For those receiving
dupilumab	Dupixent	For the treatment of patients aged 12 years and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable and/or who are refractory to or ineligible for systemic immunosuppressant therapies (i.e., due to contraindications, intolerance, or need for long-term treatment).	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/SF0754REC-Dupixent-RfA.pdf	The CADTH Canadian Drug Expert Committee (CDEC) recommends that dupilumab be reimbursed for the treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, only if the conditions in the linked report are met.	Treatment with Dupixent is expected to cost approximately $25,918 per patient during the first year; the annual maintenance cost is $24,958 per patient.

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durvalumab	Imfinzi	In combination with gemcitabine-based chemotherapy is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer (BTC)	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/PC0296REC-Imfinzi_JH_GP1_KAS.pdf	The CADTH pCODR Expert Review Committee (pERC) recommends that durvalumab be reimbursed in combination with gemcitabine plus platinum-based chemotherapy for the first-line treatment of patients with locally advanced (not amenable to surgery) or metastatic BTC, only if the conditions listed in the linked report are met.	Treatment with Imfinzi is expected to cost approximately $11,733 for per cycle
pembrolizumab	Keytruda	Keytruda (pembrolizumab), as monotherapy, for the treatment of adult patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) endometrial cancer whose tumours have progressed following prior therapy, or in combination with lenvatinib for the treatment of adult patients with advanced endometrial cancer who have disease progression following prior platinum-based systemic therapy in any setting and are not candidates for curative surgery or radiation.	CADTH Reimbursement Recommendation	https://www.cadth.ca/sites/default/files/DRR/2023/PC0280%20Keytruda%20-%20Final%20CADTH%20Recommendation.pdf	The CADTH pCODR Expert Review Committee (pERC) recommends that pembrolizumab be reimbursed as monotherapy for the treatment of adult patients with unresectable or metastatic MSI-H or dMMR endometrial cancer whose tumours have progressed following prior therapy and who have no satisfactory alternative treatment options, only if the conditions listed in the linked	Treatment with Keytruda is expected to cost approximately $11,733 every 28 days.

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

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[18F]PSMA-1007	Radelumin	« Ce médicament est à usage diagnostique uniquement. RADELUMIN est destiné à la tomographie par émission de positons (TEP). La TEP après injection de RADELUMIN est indiquée chez un patient en récidive biologique d'un cancer de la prostate, traité initialement de façon radicale, avec réaugmentation de la concentration sérique d'antigène spécifique de la prostate (PSA).	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2022-05/radelumin_decision_et_avis_ct.pdf	Autorisation d'accès précoce octroyée à la spécialité RADELUMIN ([18F]PSMA-1007)
burosumab	Crysvita	le traitement de l'hypophosphatémie liée au FGF23 chez les enfants et adolescents âgés d'1 an à 17 ans et chez les adultes atteints d'ostéomalacie oncogénique associée aux tumeurs mésenchymateuses phosphaturiques qui ne relèvent pas d'une exérèse à visée curative ou ne peuvent pas être localisées.	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-19961_CRYSVITA_PIC_INS_AvisDef_CT19961.pdf	Première évaluation. Avis favorable au remboursement. ASMR: IV (mineur) la Commission de la Transparence considère que CRYSVITA (burosumab) apporte une amélioration du service médical rendu mineure (ASMR IV) dans la stratégie de prise en charge de l'hypophosphatémie liée au FGF23 chez les enfants et adolescents âgés d'1 an à 17 ans et chez les adultes atteints d'ostéomalacie oncogénique associée aux tumeurs mésenchymateuses phosphaturiques qui ne relèvent pas d'une exérèse à visée curative ou ne peuvent pas être localisées.
corifollitropine alfa	Elonva	« traitement des hommes adolescents (âgés de 14 ans et plus) atteints d'hypogonadisme hypogonadotrope (HH), en association avec la Gonadotrophine Chorionique humaine (hCG). »	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20012_ELONVA_PIC_INS_AvisDef_CT20012.pdf	Nouvelle indication. Avis favorable au remboursement d'ELONVA (corifollitropine alfa). ASMR: V (absence) La Commission considère qu'ELONVA n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la stratégie thérapeutique actuelle qui comprend les comparateurs cliniquement pertinents.

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durvalumab	Imfinzi	« IMFINZI en association avec IMJUDO dans le traitement de première ligne des patients adultes atteints d'un carcinome hépatocellulaire (CHC) avancé ou non résécable, avec une fonction hépatique préservée (stade Child-Pugh A), avec un score ECOG 0 ou 1, non éligibles aux traitements locorégionaux ou en échec à l'un de ces traitements, et non éligibles à un traitement par l'association atezolizumab bevacizumab»	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/imfinzi_aap_decision_et_avisct_ap155.pdf	Autorisation d'accès précoce octroyée à la spécialité IMFINZI (durvalumab)
elranatamab	Elranatamab pfizer	« En monothérapie pour le traitement des patients adultes atteints d'un myélome multiple en rechute et réfractaire, ayant reçu au moins trois traitements antérieurs incluant un agent immunomodulateur, un inhibiteur du protéasome et un anticorps anti-CD38 et dont la maladie a progressé pendant le dernier traitement, lorsque toutes les options thérapeutiques sont épuisées (hors thérapies cellulaires), sur avis d'une réunion de concertation pluridisciplinaire (RCP) »	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/elranatamab_pfizer_decision_et_avisct_aap142.pdf	Autorisation d'accès précoce octroyée à la spécialité ELRANATAMAB PFIZER (elranatamab).
faricimab	Vabysmo	« le traitement des patients adultes atteints de la baisse d'acuité visuelle due à un œdème maculaire diabétique (OMD), en cas de forme diffuse ou de fuites proches du centre de la macula, chez les patients adultes ayant une baisse d'acuité visuelle ≤ 5/10 et chez lesquels la prise en charge du diabète a été optimisée. »	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20042_VABYSMO_OMD_PIC_INS_AvisDef_CT20042.pdf	Nouvelle indication. Avis favorable au remboursement. ASMR: la Commission considère que VABYSMO (faricimab), solution injectable, n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport à EYLEA (aflibercept), chez l'adulte, dans le traitement de la baisse de l'acuité visuelle due à un œdème maculaire diabétique, en cas de forme diffuse ou de fuites proches du centre de la macula, chez les patients ayant une acuité visuelle inférieure ou égale à 5/10 et chez lesquels la prise en charge du diabète a été optimisée.

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filgotinib	Jyseleca	« Polyarthrite rhumatoïde : JYSELECA est indiqué dans le traitement de la polyarthrite rhumatoïde active modérée à sévère chez des patients adultes qui ont présenté une réponse inadéquate, ou une intolérance, à un ou plusieurs traitements de fond antirhumatismaux (DMARDs). JYSELECA peut être utilisé en monothérapie ou en association avec le méthotrexate (MTX). – Rectocolite hémorragique : JYSELECA est indiqué dans le traitement de la rectocolite hémorragique active modérée à sévère chez des patients adultes qui ont présenté une réponse inadéquate, une perte de réponse ou une intolérance soit au traitement conventionnel soit à un agent biologique. »	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-20059_JYSELECA_PIS_INS_AvisDef_CT20059.pdf	Avis favorable au remboursement. ASMR: V (absence) La Commission de la transparence considère que JYSELECA (filgotinib) n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la stratégie de prise en charge de: la polyarthrite rhumatoïde active modérée à sévère chez les adultes qui ont eu une réponse inadéquate, ou une intolérance, à un ou plusieurs traitements de fond, la rectocolite hémorragique.
idecabtagene vicleucel	Abecma	« traitement des patients adultes atteints d'un myélome multiple en rechute et réfractaire ayant reçu au moins trois traitements antérieurs, incluant un agent immunomodulateur, un inhibiteur du protéasome et un anticorps anti-CD38, et dont la maladie a progressé pendant le dernier traitement, lorsque toutes les options thérapeutiques ont été épuisées, sur l'avis d'une réunion de concertation pluridisciplinaire (RCP) ».	Avis de la CT	https://www.has-sante.fr/jcms/p_3412521/fr/abecma-idecabtagene-vicleucel-myelome-multiple	Renouvellement de l'accès précoce concernant le médicament ABECMA (Idecabtagene vicleucel)
maralixibat	Livmarli	« traitement du prurit cholestatique chez les patients atteints du syndrome d'Alagille (SAG) à partir de l'âge de 2 mois ».	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/livmarli_decision_et_avisct_ap132.pdf	Autorisation d'accès précoce octroyée à la spécialité LIVMARLI (maralixibat)
maribavir	Livtencity	« traitement de l'infection et/ou de la maladie à cytomégalovirus (CMV) réfractaire (avec ou sans résistance) à un ou plusieurs traitements antérieurs, y compris le ganciclovir, le valganciclovir, le cidofovir ou le foscarnet chez les patients adultes ayant reçu une greffe de cellules souches hématopoïétiques (GCSH) ou une greffe d'organe solide (GOS). Il convient de prendre en compte les recommandations officielles sur l'utilisation appropriée des agents antiviraux ».	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/livtencity_ap166_decision_et_avisct.pdf	Avis favorable à l'autorisation d'accès précoce post-AMM

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nifédipine/ lidocaïne chlorhydrate	Nifexine	« traitement des douleurs associées à la fissure anale chronique après échec aux traitements usuels des symptômes aigus de fissure anale. »	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-19998_NIFEXINE_PIC_INS_AvisDef_CT19998.pdf	Première évaluation. Avis favorable au remboursement. ASMR: V (absence) la Commission considère que NIFEXINE 0,3 g/1,50 g (nifédipine/chlorhydrate de lidocaïne), crème rectale n'apporte pas d'amélioration du service médical rendu (ASMR V) chez les adultes pour soulager les douleurs associées à la fissure anale chronique après échec aux traitements usuels des symptômes aigus de fissure anale.
Olaparib	Lynparza	« en monothérapie ou en association à une hormonothérapie pour le traitement adjuvant des patients adultes atteints d'un cancer du sein précoce à haut risque HER2-négatif et présentant une mutation germinale des gènes BRCA1/2, qui ont été précédemment traités par chimiothérapie néoadjuvante ou adjuvante ».	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-19971_LYNPARZA_PIC_EI_AvisDef_CT19971.pdf	Nouvelle indication. Avis favorable au remboursement de LYNPARZA (olaparib). ASMR: III (modéré) la Commission considère que LYNPARZA (olaparib) apporte une amélioration du service médical rendu modérée (ASMR III) dans la stratégie thérapeutique du traitement des patients adultes atteints d'un cancer du sein précoce à haut risque HER2-négatif et présentant une mutation germinale des gènes BRCA1/2, qui ont été précédemment traités par chimio-thérapie néoadjuvante ou adjuvante, n'incluant pas le comparateur KEYTRUDA (pembrolizumab) pour le sous-groupe concerné.
Ose2101	Tedopi	« En monothérapie pour des patients adultes HLA-A2 atteints de cancer bronchique non à petites cellules, localement avancé (non opérable et non éligible à la radiothérapie) ou métastatique sans altération des gènes EGFR et ALK : en 3ème ligne de traitement après échec d'une 1ère ligne de chimiothérapie puis d'une 2ème ligne de traitement avec un inhibiteur de point de contrôle immunitaire administré en monothérapie pendant au moins 12 semaines ».	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/tedopi_ap147_decision_refushas_ansm.pdf	Autorisation d'accès précoce refusée à la spécialité TEDOPI

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pembrolizumab	Keytruda	« En monothérapie dans le traitement adjuvant des patients (adultes et) adolescents âgés de 12 ans et plus atteints d'un mélanome de stade IIB, IIC, ayant eu une résection complète ; En monothérapie dans le traitement des patients adolescents âgés de 12 ans et plus atteints d'un mélanome de stade III après résection complète et d'un mélanome avancé (non résécable ou métastatique)»	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/tedopi_ap147_decision_refushas_ansm.pdf	Autorisation d'accès précoce refusée à la spécialité TEDOPI
régadénoson	Rapiscan	« Ce médicament est à usage diagnostique uniquement. RAPISCAN est un vasodilatateur coronarien sélectif destiné à être utilisé chez les adultes comme agent de stress pharmacologique pour : – l'imagerie de perfusion myocardique (IPM) chez les patients adultes ne pouvant réaliser une épreuve d'effort adéquate.	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-19808_RAPISCAN_PIC_INS_AvisDef_CT19808.pdf	Nouvelle indication. Avis favorable au remboursement. ASMR: V (absence) La Commission de la Transparence considère que RAPISCAN (régadénoson) n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la stratégie diagnostique de l'ischémie myocardique par imagerie de perfusion avec stress pharmacologique chez des patients ne pouvant pas réaliser une épreuve d'effort adéquate.
sacituzumab govitecan	Trodelvy	« en monothérapie pour le traitement des patients adultes atteints d'un cancer du sein RH positifs / HER2 négatifs (IHC 0, IHC 1+ ou IHC 2+/ISH-) non résécable ou métastatique, ayant reçu au moins deux lignes de chimiothérapie au stade métastatique »	Avis de la CT	https://www.has-sante.fr/jcms/p_3418105/fr/trodelvy-sacituzumab-govitecan-cancer-du-sein	Autorisation d'accès précoce octroyée à la spécialité TRODELVY (sacituzumab govitecan)

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

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selpercatinib	Retsevmo	RETSEVMO est indiqué en monothérapie dans le traitement des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) avancé présentant une fusion du gène RET non précédemment traités par un inhibiteur de RET.	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-19920_RETSEVMO_PIC_EI_AvisDef_CT19920.pdf	Nouvelle indication: Avis défavorable au remboursement en 1ère ligne, en monothérapie dans le traitement des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) avancé présentant une fusion positive de RET (REarranged during Transfection). Maintien de l'avis favorable au remboursement uniquement en 2ème ligne et plus, en monothérapie dans le traitement des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) avancé présentant une fusion positive de RET (REarranged during Transfection). (cf. avis de la Commission de la Transparence du 2 juin 2021). Cet avis de juin 2021 avait été conditionné à la réévaluation de cette spécialité dans un délai maximum de 3 ans sur la base des résultats de l'étude de phase III en 1ère ligne de traitement (LIBRETTO-431, analyse principale pour fin 2023) dans le CBNPC avec une fusion du gène RET, dans cette indication.
sotrovimab	Xevudy	« traitement des adultes et des adolescents (âgés de 12 ans et plus et pesant au moins 40 kg) atteints de la maladie à coronavirus 2019 (COVID-19) qui ne nécessitent pas de supplémentation en oxygène du fait de la COVID-19 et étant à risque élevé d'évoluer vers une forme grave de la maladie, sous réserve de la sensibilité de la souche de SARS-CoV-2 vis-à-vis de XEVUDY (sotrovimab) ».	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/xevudy_renouvellement_decision_et_avis ct_ap144.pdf	Autorisation d'accès précoce post AMM renouvelée concernant le médicament XEVUDY (sotrovimab)
tébentafusp	Kimmtrak	KIMMTRAK est indiqué en monothérapie pour le traitement du mélanome uvéal non résécable ou métastatique chez les patients adultes positifs à l'antigène leucocytaire humain HLA-A*02 :01.	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-19841_KIMMTRAK_PIC_INS_AvisDef_CT19841.pdf	Première évaluation. Avis favorable au remboursement en monothérapie. ASMR: III (modéré) la Commission de la Transparence considère que KIMMTRAK 100 µg/0,5 mL (tébentafusp), solution à diluer pour perfusion, apporte une amélioration du service médical rendu modérée (ASMR III) en monothérapie dans la prise en charge du mélanome uvéal non résécable ou métastatique chez les patients adultes positifs à l'antigène leucocytaire humain HLA A*02:01.

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Generic name	Brand name	Indication	Type of document	Link	Recommendation
trémélimumab	Imjudo	« en association avec IMFINZI dans le traitement de première ligne des patients adultes atteints d'un carcinome hépatocellulaire (CHC) avancé ou non résécable, avec une fonction hépatique préservée (stade Child-Pugh A), avec un score ECOG 0 ou 1, non éligibles aux traitements locorégionaux ou en échec à l'un de ces traitements, et non éligibles à un traitement par l'association atezolizumab bevacizumab »	Avis de la CT	https://www.has-sante.fr/upload/docs/application/pdf/2023-02/imjudo_aap_decision_et_avisct_ap156.pdf	Autorisation d'accès précoce octroyée à la spécialité IMJUDO (trémélimumab)

Esclusi dal report i seguenti medicinali valuati da HAS perché si tratta di rivalutazioni, di generici, ibridi, nuove presentazioni, eurogenerici: alogliptine/metformine (vipdomet), cabotégravir (vocabria), ciprofloxacine/dexaméthasone (ciloxadex), gonadotrophine ménopausique humaine/gonadotrophine chorionique humaine (fertistarkit), métronidazole (metronidazole B braun), nintédanib (ofev), nivolumab (opdivo), ofatumumab (kesimpta), olmésartan médoxomil (alteis), ozanimod (zeposia), ponésimod (ponvory), rilpivirine (rekambys), sitagliptine (januvia), Hexyon, Repevax, Tetravac, Revaxis, Filsuvez

https://icer.org/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
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IQWiG

https://www.iqwig.de/en/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Daridorexant [A22-123]	Quviviq	Adults with insomnia, characterized by symptoms present for at least 3 months, who have not responded to cognitive behavioural therapy or for whom this type of therapy is not suitable or not feasible	Dossier Assessment	https://www.iqwig.de/download/a22-123_daridorexant_nutzenbewertung-35a-sgb-v_v1-0.pdf	Added benefit not proven	The annual cost of therapy is 298.50 €
Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide [A22-116]	Genvoya	Children aged ≥ 2 to < 6 years and with a body weight of ≥ 14 kg with HIV-1 infection	Dossier assessment	https://www.iqwig.de/download/a22-116_elvitegravir-cobicistat-emtricitabin-tenofoviralafenamid_nutzenbewertung-35a-sgb-v_v1-0.pdf	1. Treatment-naive children: added benefit not proven 2. Pretreated children: added benefit not proven	The annual cost of therapy of EVG/COBI/FTC/TAF is 10,385.55 €
Olaparib [A22-89] / [A23-02]	Lynparza	Adult patients with germline BRCA-mutant, HER2-negative, high risk early breast cancer; after neoadjuvant or adjuvant chemotherapy; adjuvant treatment	Dossier Assessment + Addendum	https://www.iqwig.de/download/a22-89_olaparib_nutzenbewertung-35a-sgb-v_v1-0.pdf https://www.iqwig.de/download/a23-02_olaparib_addendum-zum-projekt-a22-89_v1-0.pdf	Indication of minor added benefit	The annual cost of therapy is 60,808.09 €
Olaparib [A22-117]	Lynparza	Maintenance therapy of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose tumour is associated with HRD-positive status	Dossier assessment	https://www.iqwig.de/download/a22-117_olaparib_nutzenbewertung-35a-sgb-v_v1-0.pdf	1. Patients without detectable tumour after primary surgery and patients without detectable tumour/with complete response following chemotherapy: indication of considerable added benefit 2. Patients without detectable tumour after interval surgery and patients with partial response: indication of lesser benefit	The annual cost of therapy is 60,808.09 €

IQWiG

https://www.iqwig.de/en/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Pembrolizumab [A22-70] / [A22-135]	Keytruda	Adult patients with persistent, recurrent, or metastatic cervical cancer whose tumours express PD-L1 with a CPS ≥ 1	Dossier Assessment + Addendum	https://www.iqwig.de/download/a22-70_pembrolizumab_nutzenbewertung-35a-sgb-v_v1-0.pdf	1. First-line patients for whom cisplatin or carboplatin + paclitaxel ± bevacizumab is a suitable therapy of physician's choice: After addendum now: indication of major added benefit 2. First-line patients for whom cisplatin or carboplatin + paclitaxel ± bevacizumab is no suitable therapy of physician's choice: Unchanged after addendum: added benefit not proven 3. Patients after first-line chemotherapy and for whom further antineoplastic therapy is an option: Unchanged after addendum: added benefit not proven	1. 107 829,10 € bzw. 108 512,49€ für Pembrolizumab + Cisplatin + Paclitaxel 2. 180 902,67€ bzw. 181 586,05€ für Pembrolizumab + Cisplatin + Paclitaxel + Bevacizumab 3. 109 197,79€ bzw. 109 881,18€ für Pembrolizumab + Carboplatin + Paclitaxel 4. 182 271,36€ bzw. 182 954,74€ für Pembrolizumab + Carboplatin + Paclitaxel + Bevacizumab
Ravulizumab [A22-115]	Ultomiris	Adults with anti-acetylcholine receptor antibody-positive generalized myasthenia gravis	Dossier Assessment	https://www.iqwig.de/download/a22-115_ravulizumab_nutzenbewertung-35a-sgb-v_v1-0.pdf	1. Adults who are still eligible for standard treatment: added benefit not proven 2. Adults with refractory disease: added benefit not proven	The annual cost of therapy is 343,015.15 - 411,000.93€
Tezepelumab [A22-122]	Tezspire	Patients with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment	Dossier Assessment	https://www.iqwig.de/download/a22-122_tezepelumab_nutzenbewertung-35a-sgb-v_v1-0.pdf	1. Adolescents aged 12 to 17 years: added benefit not proven 2. Adults: added benefit not proven	The annual cost of therapy is 19,794.97€
Tralokinumab [A22-121]	Adtralza	Adolescents 12 to < 18 years with moderate-to-severe atopic dermatitis who are candidates for systemic therapy	Dossier Assessment	https://www.iqwig.de/download/a22-121_tralokinumab_nutzenbewertung-35a-sgb-v_v1-0.pdf	Added benefit not proven	The annual cost of therapy is 8,601,88 - 17,269.94 €

IQWiG

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Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Trastuzumab deruxtecan [A22-80]/[A22-126]	Enhertu	Patients with unresectable or metastatic HER2-positive breast cancer who have previously received HER2-targeted therapy	Dossier Assessment + Addendum	https://www.iqwig.de/download/a22-80_trastuzumab-deruxtecan_nutzenbewertung-35a-sgb-v_v1-0.pdf	1. Patients < 65 years: hint of major added benefit 2. Patients ≥ 65 years: added benefit not proven	The annual cost of therapy is 159,583.83€
Trastuzumab deruxtecan [A22-81]/[A22-127]	Enhertu	Adults with unresectable or metastatic HER2-positive breast cancer who have previously received 2 or more HER2-targeted therapies	Dossier Assessment + Addendum	https://www.iqwig.de/download/a22-81_trastuzumab-deruxtecan_nutzenbewertung-35a-sgb-v_v1-0.pdf	After addendum now hint of considerable added benefit	The annual cost of therapy is 159,583.83€

NICE

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

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Ataluren	Translarna	Ataluren (Translarna, PTC Therapeutics) has a conditional marketing authorisation for 'the treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older.	Highly specialised technologies guidance Reference number: HST22	https://www.nice.org.uk/guidance/hst22/resources/ataluren-for-treating-duchenne-muscular-dystrophy-with-a-nonsense-mutation-in-the-dystrophin-gene-pdf-50216315955397	Ataluren is recommended, within its marketing authorisation, as an option for treating Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene in people 2 years and over who can walk. This is only if the company provides ataluren according to the commercial arrangement.	The price for ataluren is £2,532 per box of thirty 125-mg sachets, £5,064 per box of thirty 250-mg sachets and £20,256 per box of thirty 1,000-mg sachets (excluding VAT; BNF online accessed September 2022).
Nintedanib	Ofev	Nintedanib (Ofev, Boehringer Ingelheim) is indicated 'for the treatment of idiopathic pulmonary fibrosis.	Technology appraisal guidance [TA864]	https://www.nice.org.uk/guidance/ta864/resources/nintedanib-for-treating-idiopathic-pulmonary-fibrosis-when-forced-vital-capacity-is-above-80-predicted-pdf-82613612686021	Nintedanib is recommended as an option for treating idiopathic pulmonary fibrosis in adults, only if they have a forced vital capacity of above 80% predicted and the company provides it according to the commercial arrangement.	The price of nintedanib is £2,151.10 per pack of 60 capsules, each containing 150 mg (excluding VAT; BNF online accessed October 2022).
Nivolumab	Opdivo	Nivolumab (Opdivo, Bristol Myers Squibb) 'in combination with fluoropyrimidine- and platinum-based combination chemotherapy is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1%'.	Technology appraisal guidance [TA865]	https://www.nice.org.uk/guidance/ta865/resources/nivolumab-with-fluoropyrimidine-and-platinumbased-chemotherapy-for-untreated-unresectable-advanced-recurrent-or-metastatic-oesophageal-squamous-cell-carcinoma-pdf-82613614365637	Nivolumab with fluoropyrimidine-based and platinum-based combination chemotherapy is recommended as an option for untreated unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma in adults whose tumours express PD-L1 at a level of 1% or more. It is recommended only if: pembrolizumab plus chemotherapy is not suitable and the company provides nivolumab according to the commercial arrangement.	The list price is £1,097 for a 100-mg vial (excluding VAT; BNF online accessed September 2022). The company has a commercial arrangement. This makes nivolumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

NICE

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Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Ixazomib	Stivarga	Ixazomib citrate (Ninlaro, Takeda), in combination with lenalidomide and dexamethasone, is indicated for 'the treatment of adult patients with multiple myeloma who have had at least 1 previous therapy	Technology appraisal guidance [TA870]	https://www.nice.org.uk/guidance/ta870/resources/ixazomib-with-lenalidomide-and-dexamethasone-for-treating-relapsed-or-refractory-multiple-myeloma-pdf-82613666433733	Ixazomib, with lenalidomide and dexamethasone, is recommended as an option for treating multiple myeloma in adults, only if they have had 2 or 3 lines of therapy and the company provides ixazomib according to the commercial arrangement.	The list price is £6,336 per pack of 3 capsules (excluding VAT; BNF online, accessed November 2022).
Regorafenib	Stivarga	Regorafenib (Stivarga, Bayer) is indicated for 'the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy	Technology appraisal guidance [TA866]	https://www.nice.org.uk/guidance/ta866/resources/regorafenib-for-previously-treated-metastatic-colorectal-cancer-pdf-82613616045253	Regorafenib is recommended, within its marketing authorisation, as an option for metastatic colorectal cancer in adults who have had previous treatment (including fluoropyrimidine-based chemotherapy, anti-VEGF therapy and anti-EGFR therapy) or when these treatments are unsuitable. Regorafenib is only recommended if the company provides it according to the commercial arrangement.	The list price of regorafenib 40 mg is £3,744 per 84 tablets (excluding VAT; BNF online accessed November 2022).
Somatrogon	Ngenla	Somatrogon (Ngenla, Pfizer) is indicated for 'the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone.	Technology appraisal guidance [TA863]	https://www.nice.org.uk/guidance/ta863/resources/somatrogon-for-treating-growth-disturbance-in-children-and-young-people-aged-3-years-and-over-pdf-82613611006405	Somatrogon is recommended, within its marketing authorisation, as an option for treating growth disturbance caused by growth hormone deficiency in children and young people aged 3 years and over.	£166.08 per 1.2-ml vial containing 24 mg of somatrogon or £415.20 for a 1.2-ml vial containing 60 mg of somatrogon (excluding VAT, company submission, December 2022). At the recommended dose of 0.66 mg per kg per week the estimated annual cost for a 40 kg patient is £9,500. Costs may vary in different settings because of negotiated procurement discounts.

NICE

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

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Trastuzumab deruxtecan	Enhertu	Trastuzumab deruxtecan (Enhertu, Daiichi Sankyo) 'as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens	Technology appraisal guidance [TA862]	https://www.nice.org.uk/guidance/ta862/resources/trastuzumab-deruxtecan-for-treating-her2positive-unresectable-or-metastatic-breast-cancer-after-1-or-more-antiher2-treatments-pdf-82613609326789	Trastuzumab deruxtecan is recommended with managed access as an option for treating HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments in adults. It is only recommended if the conditions in the managed access agreement for trastuzumab deruxtecan are followed.	The list price for trastuzumab deruxtecan is £1,455 per vial containing 100 mg powder for concentrate for solution for infusion (excluding VAT; BNF online accessed October 2022)
Upadacitinib	Rinvoq	Upadacitinib (RINVOQ, AbbVie) is indicated for 'the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs)	Technology appraisal guidance [TA861]	https://www.nice.org.uk/guidance/ta861/resources/upadacitinib-for-treating-active-nonradiographic-axial-spondyloarthritis-pdf-82613607647173	Upadacitinib is recommended as an option for treating active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs) in adults. It is recommended only if: tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough and the company provides upadacitinib according to the commercial arrangement.	The list price is £805.56 per 28-tablet pack, with each tablet containing 15 mg of upadacitinib (excluding VAT; BNF online, accessed November 2022). The annual cost of treatment with one 15-mg tablet per day is £10,501.05 (excluding VAT; BNF online, accessed November 2022)
Vutrisiran	Amvuttra	Vutrisiran (Amvuttra, Alnylam) is indicated for the 'treatment of hereditary transthyretin-mediated amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy	Technology appraisal guidance [TA868]	https://www.nice.org.uk/guidance/ta868/resources/vutrisiran-for-treating-hereditary-transthyretinrelated-amyloidosis-pdf-82613619404485	Vutrisiran is recommended, within its marketing authorisation, as an option for treating hereditary transthyretin-related amyloidosis in adults with stage 1 or stage 2 polyneuropathy. It is only recommended if the company provides vutrisiran according to the commercial arrangement.	£95,862.36 per 0.5 ml solution for injection containing 25 mg of vutrisiran (excluding VAT; company submission). At the recommended dose of 25 mg administered subcutaneously every 3 months, the estimated annual cost per patient is £383,449.44.

SMC

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

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Burosumab	Crysvita	Treatment of X-linked hypophosphataemia in adults.	Medicine Advice	https://www.scottishmedicines.org.uk/media/7406/umar-burosumab-crysvita-final-jan-2023-amended-030223-for-website.pdf	Following a full submission assessed under the ultra-orphan process.	Cost per year (£): 272,272
Eptinezumab	Vyepti	For the prophylaxis of migraine in adults who have at least 4 migraine days per month.	Medicine Advice	https://www.scottishmedicines.org.uk/media/7403/eptinezumab-vyepti-abb-final-jan-2023-for-website.pdf	Following an abbreviated submission : eptinezumab (Vyepti®) is accepted for restricted use within NHSScotland.	
Nivolumab	Opdivo	As monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥1%, who are at high risk of recurrence after undergoing radical resection of MIUC.	Medicine Advice	https://www.scottishmedicines.org.uk/media/7404/nivolumab-opdivo-final-jan-2023-for-website.pdf	Following a full submission assessed under the orphan equivalent medicine process: nivolumab (Opdivo®) is accepted for use within NHSScotland.	Cost per year (£): 68,458
Pembrolizumab	Keytruda	In combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS)≥1.	Medicine Advice	https://www.scottishmedicines.org.uk/media/7405/pembrolizumab-keytruda-final-jan-2023-amended-170123-for-website.pdf	Following a full submission assessed under the end of life and orphan equivalent medicine process: pembrolizumab (Keytruda®) is accepted for restricted use within NHSScotland.	Cost per 3 week cycle(£): 5,260
Upadacitinib	Rinvoq	For the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).	Medicine Advice	https://www.scottishmedicines.org.uk/media/7407/upadacinib-rinvoq-nr-axspa-abb-final-jan-2023-for-website.pdf	Following an abbreviated submission: upadacitinib (Rinvoq®) is accepted for use within NHSScotland.	