NEWSLETTER: News from the HTA Agencies

MAY 2021

SUMMARY

Agency	Drug Number	DrugName
CADTH Evidence Driven.		Dabrafenib + [trametinib]; Ranolazine.
HAS		Acalabrutinib; Carfilzomib; Crizanlizumab; **Dapagliflozin**; Dexamethasone; Lacosamide; Olaparib; Osilodrostat; **Upadacitinib**.
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW		No new reports
IQWiG		Atezolizumab; Baloxavir marboxil; Beclometasone + formoterol + glycopyrronium; Blinatumumab; **Dapagliflozin**; Dolutegravir; Fenluramine; Inclisiran; **Niraparib**; Nusinersen; Pertuzumab; **Tafamidis**; **Upadacitinib**.
NICE National Institute for Health and Care Excellence		Andexanet alfa; Ofatumumab; **Ravulizumab**; **Tafamidis; Trastuzumab deruxtecan.**
Scottish Medicines Consortium		Chlormethine hydrochloride; Encorafenib; Indacaterol + glycopyrronium + mometasone furoate; Indacaterol + mometasone furoate; **Niraparib**; **Ravulizumab; Upadacitinib**.

CADTH- https://www.cadth.ca/

GENERIC NAME	BRAND NAME	INDICATION	TYPE OF DOCUMENT/ Date	Link	RECOMMENDATION	Info on costs
ranolazine	Corzyna	Indicated as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies, including beta-blockers and calcium channel blockers.	Reimbursement Review	https://cadth.ca/sites/default/files/cdr/complete/SR0655%20Corzyna%20-%20CDEC%20Final%20Recommendation%20May%2031%2C%202021_For%20Posting.pdf	The CADTH Canadian Drug Expert Committee (CDEC) recommends that ranolazine not be reimbursed as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies, including beta-blockers and calcium channel blockers.	Ranolazine is available as a 500 mg and1,000mg tablet, at a submitted price of $3.50 per tablet(regardless of the dose). The recommended initial dosage is 500 mg twice daily. The annual per patient drug acquisition cost of ranolazineis $2,555
dabrafenib + [trametinib]	Tafinlar+ [Mekinist]	In combinationfor the treatment of patients with metastatic non–small cell lung cancer (NSCLC) with a v-Raf murine sarcoma viral oncogene homolog B (BRAF) V600 mutation and who have not received any prior anticancer therapy for metastatic disease	Reimbursement review-pERC FINAL RECOMMENDATION	https://cadth.ca/sites/default/files/pcodr/Reviews2021/10226Dabrafenib-TrametinibNSCLC_FnRec_pERC%20Chair%20Approved_Post28May2021_final.pdf	pERC conditionally recommends reimbursement of dabrafenib in combination with trametinib as treatment for patients with metastatic non–small cell lung cancer (NSCLC) with a v-Raf murine sarcoma viral oncogene homolog B (BRAF) V600 mutation who have not received any prior anticancer therapy for metastatic disease	Dabrafenib costs $44.88 per 50 mg capsule and $67.32 per 75 mg capsule. Trametinib costs $76.98 per 0.5 mg tablet and $307.94 per 2.0 mg tablet. At the recommended dose of 150 mg twice daily (300 mg) of dabrafenib and 2 mg once daily of trametinib, the combination regimen costs $16,162 per 28-day course.

§When the label relates to two separate drugs, the second or third drug is written into brackets, e.g.: nivolumab + [ipilimumab]; when the label relates to a fixed dose association it is represented without brackets,ie: sacubitril + valsartan.

HAS

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

Genericname	**Brand name**	**Indication**	**Type of document/ Date**	**link**	**Avis et Ammelioration du Service Medical Rendu**
acalabrutinib	Calquence	●Indiqué, en monothérapie ou en association avec l'obinutuzumab, dans le traitement des patients adultes attaints d'une leucémie lymphoïde chronique (LLC) non précédemment traités; ● Indiqué, en monothérapie, dans le traitement des patients Adultes attaints d'une leucémie lymphoïde chronique (LLC) ayantreçu au moins un traitement antérieur.	Avis de la CT 07.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19009_CALQUENCE_PIC_INS_AvisDef_CT19009.pdf	**Première évaluation.** Avis favorable au remboursement dans : ●le traitement de 1ère ligne de la LLC, en monothérapie ou en association à l'obinutuzumab uniquement: - délétion 17p ni de mutation TP53; - inéligibles à un traitement à base de fludarabine à pleine dose; - statut cytogénétique de mauvaispronostic (délétion 17p ou mutation TP53). ●le traitement de 2ème ligne et plus de la LLC, enmonothérapie, uniquement: - pas de délétion 17p ni de mutation TP53. Avis défavorable au remboursement dans les autres situations cliniques. **la Commission considère que CALQUENCE en monothérapie ou en association avec l'obinutuzumab, en 1ère ligne de traitement de la LLC, chez les patients ne présentant pas de délétion 17p ni de mutation TP53 et inéligibles à un traitement à base de fludarabine à pleine dose, ou chez les patients presentant une délétion 17p ou une mutation TP53, n'apporte pas d'amélioration du service medical rendu (ASMR V) dans la stratégie thérapeutique incluant l'ibrutinib.**

carfilzomib	Kyprolis	en association au daratumumab et à la dexaméthasone dans le traitement du myélome multiple chez les patients adultes qui ontreçu au moins un traitement antérieur.	Avis de la CT 12.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19047_KYPROLIS_PIC_EI_AvisDef_CT19047.pdf	**Nouvelle indication.** Avis favorable au remboursementen association au daratumumab et à la dexaméthasonedans le traitement du myélome multiple chez les patients adultes qui ontreçu au moins un traitementantérieur. **la Commission considère par défaut que KYPROLIS, en association à DARZALEX et à la dexaméthasone, n'apporte pas d'amélioration du service médical rendu (ASMR V) DANS LA STRATEGIE.**
crizanlizumab	Adakveo	Indiqué dans la prévention des crises vaso-occlusives (CVO) récurrentes chez les patients atteints de drépanocytose âgés de 16 ans et plus.	Avis de la CT 07.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19011_ADAKVEO_PIC_INS_AvisDef_CT19011_EPI729.pdf	**Première évaluation.** Avis favorable au remboursement dans la prévention des CVO récurrentes chez les patients atteints de drépanocytose âgés de 16 ans et plus. Il peut être administer en association avec de l'hydroxyurée/de l'hydroxycarbamide (HU/HC) ou en monothérapie chez les patients chez qui le traitement par HU/HC est inapproprié ou inadéquat. **La Commission considère qu'ADAKVEO n'apporte pas d'amélioration du service medical rendu (ASMR V) dans la prévention des CVO récurrentes chez les patients atteints de drépanocytose âgés de 16 ans et plus, en association avec de l'HU/HC ou en monothérapie chez les patients chez qui le traitement par HU/HC est inapproprié ou inadéquat.**
dapagliflozine	Forxiga	Indiqué chez les adultes pour le traitement de l'insuffisance cardiaque chronique symptomatique à fraction d'éjection réduite.	Avis de la CT 07.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-18989_FORXIGA_PIC_EI_AvisDef_CT18989.pdf	**Nouvelle indication.** Avis favorable au remboursement uniquement en traitement de recours, enajout d'un traitement standard optimisé chez les patients adultes attaints d'insuffisance cardiaque chronique avec fraction d'éjection réduite (FEVG ≤ 40%) qui restent symptomatiques (classe NYHA II à IV) malgré ce traitement. Avis défavorable au remboursement dans les autres populations de l'indication « insuffisance cardiaque ». **La Commission considère que l'ajout de FORXIGA à un traitement standard optimize apporte une amélioration du service medical rendu mineure (ASMR IV) dans la prise en charge des patients adultes attaints d'insuffisance cardiaque chronique avec fraction d'éjection réduite restant symptomatiques malgré ce traitement.**

dexamethasone	Dexamethasone MYLAN	Traitement de l'infection a coronavirus SARS-CoV-2 (COVID-19)	Avis de la CT 07.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19171_DEXAMETHASONE_MYLAN_PIS_INS_AvisDef_CT19171.pdf	**Mise à disposition d'une nouvelle présentation.** Avis favorable au remboursement dans le traitement de l'infection COVID-19 chez les adultes et les adolescents (âgés de 12 ans et pesant plus de 40 kg) qui nécessitent une oxygénothérapie. **La spécialité Dexamethasone MYLAN apporte une amélioration du service medical rendu modérée (ASMR III) dans la prise en charge des patients adultes et adolescents atteints de la COVID-19 qui nécessitent une oxygénothérapie.**
dexamethasone	Dexamethasone PANPHARMA	Traitement de l'infection a coronavirus SARS-CoV-2 (COVID-19)	Avis de la CT 07.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19251_DEXAMETHASONE_PANPHARMA_PIS_INS_AvisDef_CT19251&19252.pdf	**Nouvelle indication.** Avis favorable au remboursement dans le traitement de l'infection à coronavirus SARS-CoV-2 (COVID-19) chez les patients adultes et les adolescents (âgés de 12 ans et plus avec un poidscorporeld'aumoins 40 kg) qui nécessitent une oxygénothérapie complémentaire. **les spécialités Dexamethasone PANPHARMA apporte une amélioration du service medical rendu modérée (ASMR III), au meme titre que les spécialités DEXAMETHASONE MYLAN et DEXAMETHASONE KRKA dans la prise en charge des patients adultes et adolescents atteints de la COVID-19 qui nécessitent une oxygénothérapie complémentaire.**
lacosamide	Vimpat	Traitement, en association, des crises generalize est onico-cloniques primaires chez les adultes, les adolescents et les enfants à partir de 4 ans présentant une épilepsie généralisée idiopathique.	Avis de la CT 07.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19070_VIMPAT_PIC_EI_AvisDef_CT19070.pdf	**Nouvelle indication.** Avis favorable au remboursement dans le traitement, en association, des crises generalize tonico-cloniques primaires chez les adultes, les adolescents et les enfants à partir de 4 ans présentant une épilepsie généralisée idiopathique. **la Commission considère que VIMPAT n'apporte pas d'amélioration du service médicalrendu (ASMR V) dans la stratégie thérapeutique de prise en charge des crises generalize tonico-cloniques primaires.**

olaparib	Lynparza	Indiqué en monothérapie pour le traitement des patients adultes atteints d'un cancer de la prostate métastatique résistant à la castration, avec mutation des gènes BRCA1/2 (germinale et/ousomatique) et qui ont progressé après un traitement antérieur incluantune hormonothérapie de nouvelle génération.	Avis de la CT 07.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19057_LYNPARZA_prostate_PIC_EI_AvisDef_CT19057.pdf	**Nouvelle indication.** Avis favorable au remboursement dans l'indication « en monothérapie pour le traitement des patients adultes atteints d'un cancer de la prostate métastatique résistant à la castration, avec mutation des gènes BRCA1/2 et qui ont progressé après un traitement antérieur incluant une hormonothérapie de nouvelle génération ». **la Commission considère que LYNPARZA apporte une amélioration du service médical rendu mineure (ASMR IV) par rapport à une hormonothérapie par acétate d'abiratérone ou enzalutamide**
upadacitinib	Rinvoq	Traitement de la spondylarthrite ankylosante active chez les patients adultes qui ont Présenté une réponse inadéquate au traitement conventionnel.	Avis de la CT 18.05.2021	https://www.has-sante.fr/upload/docs/evamed/CT-19044_RINVOQ_SA_PIC_EI_AvisDef_CT19044.pdf	**Nouvelle indication.** Avis favorable au remboursementdans le traitement de la spondylarthriteankylosante active chez les patientsadultes qui onteuuneréponseinadéquate au traitementconventionnel. **la Commission de la Transparence considère que RINVOQ n'apporte pas d'amélioration du service medical rendu (ASMR V) dans la stratégie de prise en charge de la spondylarthrite ankylosante active chez l'adulte en cas de réponse inadéquate au traitement conventionnel**.

**Esclusi dal report i seguenti medicinali valuati da HAS:lucilia sericata (Serilia), pemetrexed (Pemetrexed HOSPIRA) monoxyde d'azote (Monoxyde d'Azote MESSER), tartrate de varénicline (Champix), acide gadotérique (Dotarem), gadotéridol (Prohance), sunitinib (Sunitinib Biogara), cellules autologues CD3+ transduites anti-CD19 (Tecartus), dimethyle fumarate (Tecifedra), fingolimod (Gilenya), dexamethasone (Dexamethasone MEDISOL), melatonine (Slenyto), cabergoline (Dostinex)*

May 2021: No Final Reports available for any drug or condition

Ongoing assessments:

Condition	Drug	Type of Report	Final document Date	Draft Evidence Report
Alzheimer Disease	Aducanumab	Final Evidence Report	05.08.2021	Available
Atopic Dermatitis	Abrocitinib	Final Evidence Report Report at a Glance Final Policy Recommendations	17.08.2021	Available
	Baricitinib			
	Ruxolitinib			
	Tralokinumab			
	Upadacitinib			
Hereditary Angioedema	Lanadelumab	Real World Evidence (RWE) UPDATE: Final Updated Assessment	27.07.2021	RWE UPDATE: Research Protocol available
	C1 estearase inhibitors (Haegarda®; Cinryze®)			

IQWIG

https://www.iqwig.de/en/home.2724.html

Generic name	Brand name	Indication	Type of document/Date	link	Recommendation	Note
Atezolizumab [A21-45]	Tecentriq	Adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy	Addendum to Commission [A20-97] 20.05.2021	https://www.iqwig.de/en/projects/a21-45.html	Unchanged after addendum: Patients with Child-Pugh A or no liver cirrhosis: ●with viral aetiology of HCC: indication of major added benefit, ●with non-viral aetiology of HCC: hint of considerable added benefit. Patients with Child-Pugh B: added benefit not proven.	If the need for additional work on a project commissioned by the G-BA arises during consultations, then IQWiG presents a report in the form of an "addendum". The G-BA subsequently decides on the extent of the added benefit, thus completing the early benefit assessment.
Baloxavir marboxil [A21-22]	Xofluza	Adult and adolescent patients aged 12 years and above with influenza exposure	Dossier assessment 17.05.2021	https://www.iqwig.de/en/projects/a21-22.html	●Affected people without risk of influenza-related complications: indication of considerable added benefit. ●Affected people with risk of influenza-related complications: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Baloxavir marboxil [A21-21]	Xofluza	Patients aged 12 years and above with uncomplicated influenza	Dossier assessment 17.05.2021	https://www.iqwig.de/en/projects/a21-21.html	●Without risk of influenza-related complications: added benefit not proven. ●If there is an increased risk of a severe course of the disease: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

Beclometasone+ formoterol + glycopyrronium [A21-18]	Trimbow	Adult patients with asthma whose disease is not adequately controlled with a combination of medium- or high-dose ICS and LABA, and who experienced one or more asthma exacerbations in the previous year	Dossier assessment 17.05.2021	https://www.iqwig.de/en/projects/a21-18.html	●Medium-dose ICS/LABA therapy: added benefit not proven. ●High-dose ICS/LABA therapy: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Blinatumomab [G21-04]	Blincyto	Acute lymphoblastic leukaemia	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/g21-04.html		In accordance with Social Code Book (SGB) V, the added medical benefit of orphan drugs is deemed as proven by the fact that they have been approved. On behalf of the Federal Joint Committee (G-BA), IQWiG therefore solely assesses the information on patient numbers and costs in the pharmaceutical company's dossier. After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. The resolution on the extent of added benefit is passed by the G-BA after the hearing. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA Website.
Dapagliflozin [A21-44]	Farxiga	Patients with symptomatic chronic heart failure with reduced ejection fraction	Addendum to Commission [A20-113] 20.05.2021	https://www.iqwig.de/en/projects/a21-44.html	Hint of non-quantifiable added benefit.	If the need for additional work on a project commissioned by the G-BA arises during consultations, then IQWiG presents a report in the form of an "addendum". The G-BA subsequently decides on the extent of the added benefit, thus completing the early benefit assessment.
Dolutegravir [A21-14]	Tivicay	HIV infection in children aged ≥ 4 weeks to < 6 years	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/a21-14.html	●Treatment-naive children aged ≥ 4 weeks to < 6 years: added benefit not proven. ●Treatment-experienced children aged ≥ 4 weeks to < 6 years: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

Fenfluramine [G21-06]	Fintepla	Dravet syndrome	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/g21-06.html		In accordance with Social Code Book (SGB) V, the added medical benefit of orphan drugs is deemed as proven by the fact that they have been approved. On behalf of the Federal Joint Committee (G-BA), IQWiG therefore solely assesses the information on patient numbers and costs in the pharmaceutical company's dossier. After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. The resolution on the extent of added benefit is passed by the G-BA after the hearing. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA Website.
Inclisiran [A21-13]	Leqvio	Primary hypercholesterolaemia or mixed dysipidaemia	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/a21-13.html	●Patients in whom dietary and drug options for lipid lowering have not been exhausted: added benefit not proven. ●Patients in whom dietary and drug options for lipid lowering (except evolocumab) have been exhausted: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Niraparib [A21-17]	Zejula	Ovarian cancer	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/a21-17.html	Hint of lesser benefit	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Nusinersen [A21-43] [A20-114]	Spinraza	Spinal muscolar atrophy	Dossier assessment and addendum 20.05.2021	https://www.iqwig.de/en/projects/a20-114.html	●Early onset of disease (infantile form, type 1): indication of major added benefit. ●Later onset of disease (type 2, type 3 and type 4): added benefit not proven. ●Pre-symptomatic patients: hint of non-quantifiable added benefit.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

Pertuzumab + trastuzumab [A21-11]	Phesgo	Adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/a21-11.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Pertuzumab + trastuzumab [A21-10]	Phesgo	Neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/a21-10.html	Hint of lesser benefit	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Pertuzumab + trastuzumab [A21-09]	Phesgo	Adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease	Dossier assessment	https://www.iqwig.de/en/projects/a21-09.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Tafamidis [A20-102] [A21-42]	Vyndaqel	Wild-type or hereditary transthyretin amyloid cardiomyopathy in adult patients	Dossier assessment and addendum 20.05.2021	https://www.iqwig.de/en/projects/a20-102.html	●Patients with NYHA class I + II cardiac failure: hint of considerable added benefit. ●Patients with NYHA class III cardiac failure: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

Upadacitinib [A21-16]	Rinvoq	Ankylosing spondylitis	Dossier assessment 3.05.2021	https://www.iqwig.de/en/projects/a21-16.html	●Patients who have had an inadequate response to conventional therapy: added benefit not proven. ●Patients who have an inadequate response or intolerance to a prior therapy with biologic antirheumatic drugs (bDMARDs): added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

**Esclusi dal report i seguenti medicinali valuati da IQWIG: levofloxacin + [dexamethasone]*

NICE National Institute for Health and Care Excellence

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

Genericname	Brand name	Indication	Type of document/Date	link	Recommendation
andexanet alfa	**Ondexxya**	reversing anticoagulation from apixaban or rivaroxaban	Technology appraisal guidance [TA697]	https://www.nice.org.uk/guidance/ta697	Because of the limitations of the clinical evidence, the cost-effectiveness estimates for andexanet alfa are uncertain. They are likely to be within what NICE considers a cost-effective use of NHS resources for gastrointestinal bleeding, but not for ICH or bleeds in other parts of the body. Therefore, andexanetalfa for reversing anticoagulation is recommended for routine use only in gastrointestinal bleeding. It is recommended only in research in ICH. The list price for andexanetalfa is £11,100 per 4-vial pack of 200 mg of powder for solution for infusion (excluding VAT, BNF online accessed March 2021). The average cost of a course of treatment at list price is £15,000 per patient. The company has a commercial arrangement. This makes andexanetalfaavailable 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.
ofatumumab	**Kesimpta**	relapsing multiple sclerosis	Technology appraisal guidance [TA699]	https://www.nice.org.uk/guidance/ta699	Clinical trial evidence shows that, in people with relapsing–remitting multiple sclerosis,ofatumumab reduces the number of relapses and slows disease progression when compared with teriflunomide. The most likely cost-effectiveness estimates suggest ofatumumabis cost effective and an acceptable use of NHS resources, so it is recommended. The list price for ofatumumab is £1,492.50 (excluding VAT) per unit pack (prefilled autoinjector pen). The company has a commercial arrangement. This makes ofatumumab 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.

ravulizumab	**Ultomiris**	paroxysmal nocturnal haemoglobinuria	Technology appraisal guidance [TA698]	https://www.nice.org.uk/guidance/ta698	Clinical trial evidence shows that ravulizumab is similarly as effective as eculizumab and is just assafe. Ravulizumabis given less often than eculizumab so there is some benefit on quality of life. Also, it may save costs because people need to have it less often. Ravulizumab is as effective and costs less than eculizumab so it is recommended as an option for treating paroxysmal nocturnal haemoglobinuria. The list price is £4,533 per 300 mg/3 ml concentrate for solution for infusion vial; £16,621 per 1,100 mg/11 ml concentrate for solution for infusion vial (excluding VAT; company submission). The company has a commercial arrangement. This makes ravulizumab availableto 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 detailsof the discount.
tafamidis	**Vyndaqel**	transthyretin amyloidosis with cardiomyopathy	Technology appraisal guidance [TA696]	https://www.nice.org.uk/guidance/ta696	The cost-effectiveness estimates are higher than what NICE normally considers an acceptable useof NHS resources. This is because there is not enough evidence that recommending tafamidis would reduce diagnosis delays and uncertainty about how long the treatment works after it is stopped. So, tafamidisis not recommended. The price of tafamidis is £10,685.00 per 30-capsule pack of 61 mg capsules (excluding VAT; company submission) giving an annual cost of £130,089.88. The company has a commercial arrangement, which would have applied if thetechnology had been recommended.
Trastuzumab deruxtecan	**Enhertu**	HER2-positive unresectable or metastatic breast cancer after 2 or more anti-HER2 therapies	Technology appraisal guidance [TA704]	www.nice.org.uk/guidance/ta704	Clinical trial evidence is limited. Indirect comparisons of trastuzumabderuxtecan with chemotherapy suggest that it may increase how long before disease progresses and how long people live. However, how much longer people live is uncertain. Because of this, the estimates of cost effectiveness are very uncertain and trastuzumabderuxtecancannot be recommended for routine use in the NHS. The company's list price is £1,455 per vial containing 100mg powder for concentrate for solution for infusion (company's submission). The average cost of a course of treatment at list price is £117,857.55.

Scottish Medicines Consortium

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

Genericname	Brand name	Indication	Type of document/Date	Link	Advice	Evidences
Chlormethine hydrochloride **SMC2318**	Ledaga	Topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) in adult patients.	Medicine advice 10.05.2021	https://www.scottishmedicines.org.uk/medicines-advice/chlormethine-hydrochloride-ledaga-full-smc2318/	is accepted for use within NHSScotland..	Cost per year of chlormethine 0.02% gel (once daily) is 17,000£
encorafenib **SMC2312**	Braftovi	In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, who have received prior systemic therapy.	Medicine advice 10.05.2021	https://www.scottishmedicines.org.uk/medicines-advice/encorafenib-braftovi-full-smc2312/	is accepted for use within NHSScotland..	Price for a cycle therapy with encorafenib (300 mg tablets, once daily) and cetuximab (400 mg/m2 initially dose, then 250 mg/m2 weekly by IV injection) = 7,829£ first cycle, then 7,295£.
indacaterol + glycopyrronium + mometasone furoate **SMC2355**	EnerzairBreezhaler	As a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long acting beta2 agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.	Medicine Advice 10.05.2021	https://www.scottishmedicines.org.uk/media/5939/indacaterol-glycopyrronium-mometasone-furoate-enerzair-breezhaler-abb-final-april-2021docx-for-website.pdf	following an abbreviated submission*: indacaterol + glycopyrronium + mometasone furoate (Enerzair Breezhaler®) is accepted for use within NHSScotland.	Indacaterol + glycopyrronium + mometasone furoate (EnerzairBreezhaler®) offers an additional treatment choice of high dose inhaled corticosteroid (ICS), long-acting beta2-agonist (LABA) and long-acting muscarinic antagonist (LAMA) in a single inhaler. SMC has previously accepted an alternative LAMA as an add-on treatment to ICS and LABA in asthma.

indacaterol + mometasone furoate **SMC2356**	Atectura Breezhaler	As a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short acting beta2-agonists	Medicine Advice 10.05.2021	https://www.scottishmedicines.org.uk/media/5940/indacaterol-mometasone-atectura-breezhaler-abb-final-april-2021docx-for-website.pdf	following an abbreviated submission* indacaterol + mometasone furoate (AtecturaBreezhaler®) is accepted for use within NHSScotland.	Indacaterol + mometasone furoate (AtecturaBreezhaler®) offers an additional treatment choice of inhaled corticosteroid (ICS) and long-acting beta2-agonist (LABA) in a singleinhaler. SMC has previously accepted alternative LABA / ICS combinations for use in asthma.
niraparib **SMC2338**	Zejula	As monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.	Medicine advice 10.05.2021	https://www.scottishmedicines.org.uk/medicines-advice/niraparib-zejula-full-smc2338/	is accepted for use within NHSScotland.	The cost per year of niraparib (200mg to 300mg orally oncedaily) ranges from 58,500 £ to 87,750 £.
ravulizumab **SMC2330**	Ultomiris	For the treatment of patients with a body weight of 10kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab.	Medicine advice 10.05.2021	https://www.scottishmedicines.org.uk/medicines-advice/ravulizumab-ultomiris-full-smc2330/	is accepted for restricted use within NHSScotland.	SMC restriction: under the advice of the national renal complement therapeutics service. Two single-arm, phase III studies demonstrated the beneficial treatment effect of ravulizumab on complete thrombotic microangiopathy (TMA) response, defined as normalisation of haematological parameters and improvement in renal function. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS / list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

upadacitinib **SMC2361**	Rinvoq	For the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. Upadacitinib may be used as monotherapy or in combination with methotrexate	Medicine advice 10.05.2021	https://www.scottishmedicines.org.uk/media/5944/upadacitinib-rinvoq-abbreviated-final-april-2021docx-for-website.pdf	following an abbreviated submission*:upadacitinib (Rinvoq®) is accepted for restricted use within NHSScotland.	SMC restriction: for use in patients with psoriatic arthritis whose disease has not responded adequately to at least two conventional DMARDs (cDMARDs), given either alone or in combination. Upadacitinib offers an additional treatment choice in the therapeutic class of Janus Kinase (JAK) inhibitors in this setting. Upadacitinib offers an additional treatment choice in the therapeutic class of Janus Kinase (JAK) inhibitors in this setting.

**__Abbreviated submission__: an abbreviated process may be made for some new medicines when a company considers that a full submission is not required due to a low net budget impact or if similar clinical effectiveness can be demonstrated briefly, in simple terms.*