NEWSLETTER: News from the HTA Agencies

JANUARY 2021

SUMMARY

Agency	Drug Number	Drug Name
CADTH Evidence Driven.	5	Acalabrutinib, Dapagliflozin, **Entrectinib**, Galsdegib; Vedolizumab;
HAS	15	Alpelisib, Avatrombopag, Céfidérocol, Immunoglobuline humaine normale, Formotérol+budésonide, acétate d'Indacatérol+furoate de mométasone, Isatuximab, Lévonorgestrel+éthinylestradiol, Lidocaine, Mitomycine C, Nintédanib, Ribociclib, Rituximab, Pemetrexed, **Sécukinumab**.
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW	5	Belimumab, Bempedoic Acid, Inclisiran, Roxadustat, Voclosporin,
IQWiG	6	Cannabidiol [G20-24 e G20-25] , Durvalumab, Filgotinib, Ibrutinib, Ozanimod, Sofosbuvir/Velpatasvir.
NICE National Institute for Health and Care Excellence	5	**Brigatinib,** Encorafenib, Sarilumab, Tocilizumab, Trifluridine–tipiracil
Scottish Medicines Consortium	11	Apalutamide, Brentuximab vedotin, **Brigatinib,** Daratumumab, Daratumumab subcutaneous injection, Dupilumab, **Entrectinib,** Fostamatinib, Melatonin prolonged-release, **Secukinumab**, Talazoparib,

Rispetto al numero 1 di dicembre, in questo numero sono state aggiunte: **CADTH**: le informazioni sui costi del trattamento. **HAS:** l'informazione su "amelioration du service medical rendue" (o valore terapeutico aggiunto). Per quanto riguarda **ICER:** i documenti riportati non sono le raccomandazioni finali.

CADTH Evidence Driven.

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

GENERIC NAME	BRAND NAME	INDICATION	TYPE OF DOCUMENT	Link	RECCOMANDATION	Info on costs
Acalabrutinib	**Calquence**	previously untreated chronic lymphocytic leukemia	Reimbursement review- Final Recommendation	https://cadth.ca/sites/default/files/pcodr/Reviews2020/10210AcalabrutinibCLL%28previously%20untreated%29_FnRec_pERC%20Chair%20Approved_REDACT_Post08Jan2021_final.pdf	pERC conditionally recommends reimbursement of acalabrutinib as monotherapy in adult patients with previously untreated CLL for whom a fludarabine-based regimen is inappropriate, if the following conditions are met: • cost-effectiveness improved to an acceptable level • feasibility of adoption (budget impact) is addressed.	Acalabrutinib costs $135.98 per 100 mg capsule. At the recommended dose of 100 mg twice daily, acalabrutinib monotherapy costs $275 per day and $7,615 per 28-day cycle.
Dapagliflozin	**Forxiga**	Heart failure with reduced ejection fraction		https://cadth.ca/dapagliflozin-1	Reimburse as an adjunct to standard of care therapy only in adults with New York Heart Association class II and III heart failure. Standard of care therapies include beta-blockers, angiotensin converting enzyme inhibitors or angiotensin receptor blockers, plus a mineralocorticoid receptor antagonist.	Dapagliflozin is available as a 5mg and 10 mg tablets. At a recommended dose of 10 mg daily, at the submitted price of $2,73 per 10 mg tablet, the annual per patient cost is $996
Entrectinib	**Rozlytrek**	ROS1-positive Non-Small Cell Lung Cancer		https://www.cadth.ca/entrectinib-rozlytrek-ros1-positive-non-small-cell-lung-cancer	pERC conditionally recommends reimbursement of entrectinib for the firstline treatment of patients with ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) if the following conditions are met: • cost-effectiveness being improved to an acceptable level • the public drug plan costs of treatment with entrectinib should not exceed the public drug plan costs of the least costly tyrosine kinase inhibitors (TKIs) currently reimbursed for treatment-naive ROS1-positive locally advanced or metastatic NSCLC.	Entrectinib costs $95.33 per 200 mg and $48.67 per 100 mg capsule. At the recommended dose of 600 mg administered orally, once daily, entrectinib costs $8,008 per 28-day cycle

Glasdegib	**Daurismo**	acute myeloid leukemia		https://cadth.ca/sites/default/files/pcodr/Reviews2020/10207GlasdegibAML_FnRec_approvedbyChair_REDACT_Post08Jan2021_final.pdf	pERC **does not recommend reimbursement** of glasdegib in combination with low-dose cytarabine (LDAC) for the treatment of adult patients with newly diagnosed and previously untreated acute myeloid leukemia (AML), who are 75 years or older or who are not eligible to receive intensive induction chemotherapy.	Glasdegib costs $286.41 and $572.82 per 25 mg and 100 mg tablet, respectively. At the recommended dose of 100 mg administered orally once daily on days 1 to 28 of each 28-day cycle, glasdegib costs $16,039.00 per 28-day cycle. Glasdegib in combination with low-dose cytarabine costs $16,143.00 per 28-day cycle.
Vedolizumab	**Entyvio**	adult patients with moderately to severely active Crohn's disease		https://www.cadth.ca/sites/default/files/cdr/complete/SR0647%20Entyvio%20-%20CDEC%20Final%20Recommendation%20January%2022%2C%202021_for%20posting.pdf	The CADTH Canadian Drug Expert Committee recommends that vedolizumab subcutaneous be reimbursed for the treatment of adult patients with moderately to severely active Crohn disease, only if the following conditions are met.	The drug acquisition cost of a 108 mg pre-filled syringe of vedolizumab SC is $822.50, leading to an annual cost per patient of $21,458 for maintenance treatment with 108 mg every two weeks.

ICER
https://icer.org/

Generic name	Brand name	Indication	Type of document	link	Summary of evidence
Belimumab	Benlysta	Lupus Nephritis	Draft Evidence Report	https://icer.org/wp-content/uploads/2020/11/ICER_Lupus-Nephritis_Draft-Evidence-Report_012221.pdf	Assessment status: Ongoing Currently available a draft evidence report. Final recommendations will be published on April
Voclosporin	Lupkynis				

Bempedoic Acid	Nexletol®; Nexlizet™ (with ezetimibe)	Heterozygous Familial Hypercholesterolemia and for Secondary Prevention of ASCVD	Evidence Report	https://icer.org/wp-content/uploads/2020/10/ICER_High-Cholesterol_Evidence-Report_012221.pdf.pdf	Assessment Status: Closed. Currently available an Evidence Report. Also the response to Public Comments. Final Policy Recommendations due on 26.02.2021
Inclisiran					
Roxadustat	FibroGen	Treating Anemia in Chronic Kidney Disease	Evidence Report	https://icer.org/wp-content/uploads/2020/10/ICER_CKD_Revised_Evidence_Report_012821.pdf	Assessment Status: Ongoing. Available an Evidence Report. Final Policy Recommendations due on 05.03.2021

HAS

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

Generic name	Brand name	Indication	Type of document	link	Avis et Ammelioration du Service Medical Rendu
Acétate d'indacatérol+fumarate de mométasone	ATECTURA BREEZHALER	Traitement continu de l'asthme chez les adultes et adolescents âgés de 12 ans	AVIS de la CT	https://www.has-sante.fr/jcms/p_3227239/fr/atectura-breezhaler	Avis favorable au remboursement en traitement continu de l'asthme chez les adultes et adolescents âgés de 12 ans et plus insuffisamment contrôlés par la prise d'un corticoïde inhalé (CSI) et d'un bêta-2-agoniste de courte durée d'action inhalé (SABA). **la Commission de la Transparence considère qu'ATECTURA BREEZHALER n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport aux autres associations à base d'un corticoïde inhalé (CSI) et d'un bêta-2-agoniste de longue durée d'action (LABA) dans le traitement continu de l'asthme chez les adultes et adolescents âgés de 12 ans et plus insuffisamment contrôlés par la prise d'un corticoïde inhalé et d'un bêta-2-agoniste de courte durée d'action inhalé.**
Alpelisib	PIQRAY	En association au fulvestrant pour le traitement des hommes et des femmes ménopausées atteints d'un cancer du sein localement avancé ou métastatique.	AVIS de la CT	https://www.has-sante.fr/jcms/p_3233140/fr/piqray	Première évaluation. Avis défavorable au remboursement en association au fulvestrant pour le traitement des hommes et des femmes ménopausées atteints d'un cancer du sein localement avancé ou métastatique, RH+/HER2-, ayant une mutation PIK3CA, et ayant progressé après une hormonothérapie en monoterapie. **Sans object**
Avatrombopag	DOPTELET	Dans le traitement de la thrombocytopénie sévère chez les patients adultes atteints d'une maladie hépatique chronique pour lesquels une procédure invasive est programmée.	AVIS de la CT	https://www.has-sante.fr/jcms/p_3234198/fr/doptelet	Première évaluation. Avis défavorable au remboursement dans le traitement de la thrombocytopénie sévère chez les patients adultes atteints d'une maladie hépatique chronique pour lesquels une procédure invasive est programmée. **Sans objet**

Céfidérocol	FETCROJA	Traitement des patients atteints d'infections à bactéries à Gram négatif multirésistantes	AVIS de la CT	https://www.has-sante.fr/jcms/p_3234207/fr/fetcroja	Première évaluation. Avis favorable au remboursement dans l'indication de l'AMM uniquement en dernier recours pour le traitement des patients atteints d'infections à bactéries à Gram négatif multirésistantes (notamment en cas d'entérobactéries et Pseudomonas aeruginosa, avec un mécanisme de résistance de type KPC, oxacillinase ou métallo-β-lactamases [NDM, VIM, IMP]) et lorsque le recours aux autres options disponibles n'est pas envisageable. Avis défavorable au remboursement dans les autres situations. **FETCROJA (céfidérocol) apporte amélioration du service médical rendu mineure (ASMR IV) dans la prise en charge des patients atteints d'infections à bactéries à Gram négatif multirésistantes (notamment en cas d'entérobactéries et Pseudomonas aeruginosa, avec un mécanisme de résistance de type KPC, oxacillinase ou métallo-ß-lactamases [NDM, VIM, IMP]) lorsque le recours aux autres options disponibles n'est pas envisageable.**
Immunoglobuline humaine normale	GAMUNEX	Traitement des poussées myasthéniques aigues sévères.	AVIS de la CT	https://www.has-sante.fr/jcms/p_3232152/fr/gamunex	Avis favorable au remboursement en association avec le pomalidomide et la dexaméthasone pour le traitement des patients adultes atteints de myélome multiple (MM) en rechute et réfractaire, qui ont reçu au moins deux traitements antérieurs incluant le lénalidomide et un inhibiteur du protéasome (IP) et dont la maladie a progressé lors du dernier traitement. **Compte tenu de l'absence de données comparatives de GAMUNEX (immunoglobuline humaine normale) versus TEGELINE (immunoglobuline humaine normale), seule IGIV ayant une AMM ou versus les autres spécialités à base d'immunoglobuline humaine dans le traitement des poussées myasthéniques aigues sévères, la Commission considère que GAMUNEX (immunoglobuline humaine normale) n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la prise en charge des poussées aigües de myasthénie**.
Formotérol + budésonide	GIBITER EASYHALER	Asthme; Broncho-pneumopathie chronique obstructive (BPCO)	AVIS de la CT	https://www.has-sante.fr/jcms/p_3234201/fr/gibiter-easyhaler	Mise à disposition de nouvelles présentations. Avis favorable au remboursement : Chez l'adulte et l'adolescent âgé de 12 et plus, pour le traitement régulier de l'asthme lorsque l'utilisation d'une association d'un corticoïde inhalé et d'un bronchodilatateur bêta-2 agoniste de longue durée d'action est justifiée; Chez l'adulte (à partir de 18 ans) en traitement symptomatique chez les patients présentant une BPCO avec un volume expiratoire maximal par seconde (VEMS) post-bronchodilatateur < 70 % de la valeur théorique et des antécédents d'exac **Ces spécialités sont un complément de gamme qui n'apportent pas d'amélioration du service médical rendu (ASMR V) par rapport aux présentations déjà inscrites.**

isatuximab	SARCLISA	En association avec le pomalidomide et la dexaméthasone pour le traitement des patients adultes atteints de myélome multiple (MM) en rechute et réfractaire,	AVIS de la CT	https://www.has-sante.fr/jcms/p_3223297/fr/sarclisa	Avis favorable au remboursement en association avec le pomalidomide et la dexaméthasone pour le traitement des patients adultes atteints de myélome multiple (MM) en rechute et réfractaire, qui ont reçu au moins deux traitements antérieurs incluant le lénalidomide et un inhibiteur du protéasome (IP) et dont la maladie a progressé lors du dernier traitement. **la Commission considère que SARCLISA (isatuximab) en association à IMNOVID (pomalidomide) plus dexaméthasone (protocole Isa-Pd), apporte une amélioration du service médical rendu mineure (ASMR IV) par rapport à l'association IMNOVID (pomalidomide) plus dexaméthasone dans le traitement des patients adultes ayant un myélome multiple en rechute et réfractaire, qui ont reçu au moins deux traitements antérieurs incluant le lénalidomide et un inhibiteur du protéasome et dont la maladie a progressé lors du dernier traitement.**
lévonorgestrel+ éthinylestradiol	ASTERLUNA / ASTERLUNA CONTINU	Contraception orale	AVIS de la CT	https://www.has-sante.fr/jcms/p_3229927/fr/asterluna	Avis favorable au remboursement dans la contraception orale.Pas de progrès par rapport aux autres spécialités à base de lévonorgestrel / éthinylestradiol déjà remboursables. **Cette spécialité est un générique qui n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport autres spécialités à base de lévonorgestrel/éthinylestradiol déjà remboursables**.
lidocaine	XYLOCARD	Dans l'analgésie périopératoire en chirurgie abdominale par voie laparoscopique ou ouverte	AVIS de la CT	https://www.has-sante.fr/jcms/p_3232149/fr/xylocard	Extension d'indication: Avis favorable au remboursement dans l'analgésie périopératoire en chirurgie abdominale par voie laparoscopique ou ouverte (telle que chirurgie colorecta la Commission considère que XYLOCARD 20 mg/ml . **INTRAVEINEUX (chlorhydrate de lidocaïne) n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la stratégie d'analgésie péri-opératoire en chirurgie abdominale par voie laparoscopique ou ouverte (telle que chirurgie colorectale, prostatectomie, cholécystectomie.le, prostatectomie, cholécystectomie).**
mitomycine C	MITOMYCINE SUBSTIPHARM	Administration par voie intravésicale pour la prévention des récidives dans le cancer superficiel de la vessie après une résection transurétrale.	AVIS de la CT	https://www.has-sante.fr/jcms/p_3118588/fr/mitomycine-substipharm	Nouvelle indication: Avis favorable au remboursement dans l'indication: administration par voie intravésicale pour la prévention des récidives dans le cancer superficiel de la vessie après une résection transurétrale. Pas de progrès par rapport aux autres spécialités à base de mitomycine C déjà inscrites dans cette indication. **Ces spécialités sont un générique qui n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport aux autres spécialités à base de mitomycine C déjà inscrites dans cette indication.**

nintédanib	OFEV	Traitement de la pneumopathie interstitielle diffuse associée à la sclérodermie systémique.	AVIS de la CT	https://www.has-sante.fr/jcms/pprd_2984523/fr/ofev	Nouvelle indication. Avis favorable au remboursement dans le traitement de la pneumopathie interstitielle diffuse associée à la sclérodermie systémique. **la Commission considère qu'OFEV apporte une amélioration du service médical rendu mineure (ASMR IV) dans la stratégie thérapeutique actuelle de prise en charge des patients atteints de pneumopathies interstitielles diffuses associée à la sclérodermie systémique.**
ribociclib	KISQALI	Traitement du cancer du sein localement avancé ou métastatique, RH+/HER2-, chez les femmes ménopausées, en l'absence d'atteinte viscérale symptomatique menaçant le pronostic vital à court terme, comme traitement initial à base d'hormonothérapie ou après traitement antérieur par hormonothérapie.	AVIS de la CT	https://www.has-sante.fr/jcms/p_3229924/fr/kisqali	Réévaluation. Avis favorable au remboursement en association au fulvestrant dans le traitement du cancer du sein localement avancé ou métastatique, RH+/HER2-, chez les femmes ménopausées, en l'absence d'atteinte viscérale symptomatique menaçant le pronostic vital à court terme, comme traitement initial à base d'hormonothérapie ou après traitement antérieur par hormonothérapie. **la Commission considère que l'ajout de KISQALI au fulvestrant apporte une amélioration du service médical rendu mineure (ASMR IV) par rapport au fulvestrant seul dans la prise en charge en 1ère ou 2ème ligne d'hormonothérapie du cancer du sein avancé HR+/HER2- en l'absence d'atteinte viscérale symptomatique menaçant le pronostic vital à court terme chez les femmes ménopausées.**
rituximab	MABTHERA	En association à une chimiothérapie pour le traitement des patients pédiatriques (âgés de ≥ 6 mois à < 18 ans) non précédemment traités présentant à un stade avancé: un lymphome diffus à grandes cellules B (LDGCB) CD20 positif, un lymphome de Burkitt (LB)/une leucémie de Burkitt (leucémie aiguë à cellules B matures) (LA-B) ou un lymphome Burkitt-like (LB-like).	AVIS de la CT	https://www.has-sante.fr/jcms/p_3229921/fr/mabthera-ldgcb-/-lb-/-la-b-/-lb-like-pediatriques	Nouvelle indication. Avis favorable au remboursement de MABTHERA (rituximab) en association à une chimiothérapie pour le traitement des patients pédiatriques (âgés de ≥ 6 mois à < 18 ans) non précédemment traités présentant à un stade avancé : un lymphome diffus à grandes cellules B (LDGCB) CD20 positif, un lymphome de Burkitt (LB)/une leucémie de Burkitt (leucémie aiguë à cellules B matures) (LA-B) ou un lymphome Burkitt-like (LB-like). **la Commission de Transparence considère que MABTHERA (rituximab) apporte une amélioration du service médical rendu mineure (ASMR IV) par rapport à la chimiothérapie seule chez les enfants et adolescents (âgés de = 6 mois à < 18 ans) non précédemment traités ayant à un stade avancé : un lymphome diffus à grandes cellules B (LDGCB) CD20 positif, un lymphome de Burkitt (LB)/une leucémie de Burkitt (leucémie aiguë à cellules B matures) (LA-B) ou un lymphome Burkitt-like (LB-like).**

pemetrexed	PEMETREXED EVER PHARMA	Mésothéliome pleural malin; Cancer bronchique non à petites cellules	AVIS de la CT	https://www.has-sante.fr/jcms/p_3230201/fr/pemetrexed-ever-pharma	Avis favorable au remboursement dans les indications de l'AMM. BIOSIMILARE. **Cette spécialité est un hybride qui n'apporte pas d'amélioration du service médical rendu (ASMR V) par rapport à la spécialité de référence, ALIMTA, poudre pour solution à diluer pour perfusion**.
sécukinumab	COSENTYX	Traitement du psoriasis en plaques chronique sévère de l'enfant à partir de 6 ans et de l'adolescent	AVIS de la CT	https://www.has-sante.fr/jcms/p_3233061/fr/cosentyx-enfant	Extension d'indication: Avis favorable au remboursement uniquement dans le traitement du psoriasis en plaques chronique sévère de l'enfant à partir de 6 ans et de l'adolescent, défini par:un échec (réponse insuffisante, contre-indication ou intolérance) à au moins deux traitements parmi les traitements systémiques non biologiques et la photothérapie et une forme étendue et/ou un retentissement psychosocial important. **la Commission de la Transparence considère que la spécialité COSENTYX 150 mg (sécukinumab), solution injectable en seringue préremplie et en stylo prérempli et poudre pour solution injectable, n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la prise en charge du psoriasis en plaques chronique sévère de l'enfant à partir de 6 ans et de l'adolescent.**

IQWIG

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

Generic name	Brand name	Indication	Type of document	link	Recommendation	Note
Cannabidiol [G20-24]		Treatment of Dravet syndrome in children from the age of 2 years	Dossier Assessment	https://www.iqwig.de/download/g20-24_cannabidiol_bewertung-35a-absatz-1-satz-11-sgb-v_v1-0.pdf		In accordance with § 35a (para. 1, sentence 11) Social Code Book V, the added medical benefit of orphan drugs is deemed as proven by the fact that they have been approved. For the Cannabidiol report commissioned by 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.
Cannabidiol [G20-25]		Treatment of Lennox-Gastaut syndrome in children from the age of 2 years	Dossier Assessment	https://www.iqwig.de/download/g20-25_cannabidiol_bewertung-35a-absatz-1-satz-11-sgb-v_v1-0.pdf		
Durvalumab [A20-87]	Imbruvica	First-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC)	Extract of Dossier assessment	https://www.iqwig.de/download/a20-87_durvalumab_kurzfassung_nutzenbewertung-35a-sgb-v_v1-0.pdf	Men: hint of considerable added benefit; women: hint of non-quantifiable, at most considerable 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.

Filgotinib [A20-90]	Jyseleca	Adults with moderate to severe active rheumatoid arthritis who have responded inadequately to, or who are intolerant to one or more DMARDs	Extract of Dossier assessment	https://www.iqwig.de/download/a20-90_filgotinib_kurzfassung_nutzenbewertung-35a-sgb-v_v1-0.pdf	First-time therapy with bDMARDs or tsDMARDs indicated: in combination with MTX, hint of minor added benefit. Other constellations: 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.
Ibrutinib [A20-88]	Imbruvica	Adults with previously untreated chronic lymphocytic leukaemia (CLL)	Extract of Dossier assessment	https://www.iqwig.de/download/a20-88_ibrutinib_kurzfassung_nutzenbewertung-35a-sgb-v_v1-0.pdf	Patients in good general health for whom therapy with fludarabine + cyclophosphamide + rituximab is an option: indication of major added benefit. Other research questions: 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.
Ixekizumab [A20-65] [G20-31]	Taltz	Children from the age of 6 years and adolescents (body weight of at least 25 kg) with moderate to severe plaque psoriasis who are candidates for systemic therapy	Dossier assessment and addendum	https://www.iqwig.de/download/a20-65_ixekizumab_kurzfassung_nutzenbewertung-35a-sgb-v_v1-1.pdf?rev=174083	Transfer of added benefit from adults not appropriate; added benefit not proven.	Transfer of added benefit from adults not appropriate; added benefit not proven. [G20-31] is the Addendum to Commission A20-65
Ixekizumab [A20-66] [G20-32]	Taltz	Adults with active axial spondyloarthritis in 3 subindications with inadequate response or intolerance to prior therapies	Dossier assessment and addendum	https://www.iqwig.de/download/g20-32_ixekizumab_addendum-zum-auftrag-a20-66_v1-0.pdf?rev=174863	Added benefit not proven for any of the 3 research questions	[G20-32] is Addendum to Commission A20-66
Sofosbuvir/ Velpatasvir [A20-86]	Epclusa	Children and adolescents aged 6 to < 18 years (body weight of at least 17kg) with chronic hepatitis C	Extract of Dossier assessment	https://www.iqwig.de/download/a20-86_sofosbuvir-velpatasvir_kurzfassung_nutzenbewertung-35a-sgb-v_v1-0.pdf	Patients aged 6 to 11 years with genotype 1 or 3: hint of non-quantifiable added benefit. Older patients and other genotypes: 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.

NICE National Institute for Health and Care Excellence

NICE

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

Generic name	Brand name	Indication	Type of document	link	Recommendation
Brigatinib	Alunbrig	ALK-positive advanced non-small-cell lung cancer that has not been previously treated with an ALK inhibitor	Technology appraisal guidance [TA670]	https://www.nice.org.uk/guidance/ta670	Brigatinib is recommended, within its marketing authorisation, as an option for treating anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC) that has not been previously treated with an ALK inhibitor in adults. It is recommended only if the company provides brigatinib according to the commercial arrangement.
Encorafenib	Braftovi	plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer	Technology appraisal guidance [TA668]	https://www.nice.org.uk/guidance/TA668	Encorafenib plus cetuximab is recommended, within its marketing authorisation, as an option for treating BRAF V600E mutation-positive metastatic colorectal cancer in adults who have had previous systemic treatment. It is recommended only if the company provides it according to the commercial arrangements.
Sarilumab		COVID-19 rapid evidence summary: Sarilumab for COVID-19	Evidence summary [ES34]	https://www.nice.org.uk/advice/es34/chapter/Product-overview	https://www.nice.org.uk/advice/es34/resources/covid19-rapid-evidence-summary-sarilumab-for-covid19-pdf-1158236274373 (ADVICE: documento pdf)

Tocilizumab		COVID-19 rapid evidence summary: Tocilizumab for COVID-19	Evidence summary [ES33]	https://www.nice.org.uk/advice/es33/chapter/Product-overview	https://www.nice.org.uk/advice/es33/resources/covid19-rapid-evidence-summary-tocilizumab-for-covid19-pdf-1158234594757 (ADVICE: documento pdf)
Trifluridine–tipiracil	Lonsurf	metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma	Technology appraisal guidance [TA669]	https://www.nice.org.uk/guidance/ta669	Trifluridine–tipiracil **is not recommended,** within its marketing authorisation, for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma in adults who have had 2 or more systemic treatment regimens. This recommendation is not intended to affect treatment with trifluridine–tipiracil that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Scottish Medicines Consortium

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

Generic name	Brand name	Indication	Type of document	Link	Advice	Evidences
Apalutamide	Erleada	In adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).	Non submission	https://www.scottishmedicines.org.uk/medicines-advice/apalutamide-erleada-nonsub-smc2323/	in the absence of a submission from the holder of the marketing authorisation. Apalutamide (Erleada®) is not recommended for use within NHSScotland.	The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.
Brentuximab vedotin	Adcetris®	In combination with cyclophosphamide, doxorubicin and prednisone (CHP) for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL).	Medicine advice	https://www.scottishmedicines.org.uk/media/5705/brentuximab-vedotin-adcetris-final-december-2020docx-for-website.pdf	brentuximab vedotin (Adcetris®) is accepted for use within NHSScotland.	In a phase III study, brentuximab vedotin in combination with CHP was associated with a significant improvement in progression-free survival compared with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) chemotherapy.This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.
Brigatinib	Alunbrig	As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.	Medicine advice	https://www.scottishmedicines.org.uk/media/5706/brigatinib-alumbrig-final-dec-2020docx-for-website.pdf	brigatinib (Alunbrig®) is accepted for use within NHSScotland.	Brigatinib offers an additional treatment choice in the therapeutic class of tyrosine kinase inhibitors for this indication. Medicines within this therapeutic class have been accepted via the orphan process for this indication. 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.

Daratumumab	Darzalex	In combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.	Medicine advice	https://www.scottishmedicines.org.uk/media/5707/daratumumab-darzalex-final-dec-2020docx-for-website.pdf	daratumumab (Darzalex®) is accepted for use within NHSScotland.	The addition of daratumumab to bortezomib, thalidomide and dexamethasone was associated with a significant improvement in stringent complete response rates in patients with newly diagnosed multiple myeloma who were eligible for autologous stem cell transplant. 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.
Daratumumab subcutaneous injection	Darzalex®	In combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.	Medicine advice	https://www.scottishmedicines.org.uk/media/5718/daratumumab-darzalex-abb-final-december-2020docx-for-website.pdf	daratumumab subcutaneous injection (Darzalex®) is accepted for use within NHSScotland.	Following a submission under the orphan medicine process, SMC has previously accepted daratumumab concentrate for solution for infusion in combination with bortezomib, thalidomide and dexamethasone is indicated for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (SMC2302). 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.
Dupilumab	Dupixent	As an add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyposis for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.	Non submission	https://www.scottishmedicines.org.uk/media/5708/dupilumab-dupixent-non-sub-final-dec-2020docx-for-website.pdf	in the absence of a submission from the holder of the marketing authorisation dupilumab (Dupixent®) is not recommended for use within NHSScotland.	The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

Entrectinib	Rozlytrek	As monotherapy for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.	Medicine advice	https://www.scottishmedicines.org.uk/media/5709/entrectinib-rozlytrek-nsclc-final-dec-2020docx-for-website.pdf	entrectinib (Rozlytrek®) is accepted for use within NHSScotland	In a phase II study in patients with ROS1-positive advanced NSCLC, the objective response rate was 72%. 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 views from a Patient and Clinician Engagement (PACE) meeting.
Fostamatinib	Tavlesse®	Treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.	Medicine advice	https://www.scottishmedicines.org.uk/media/5710/fostamatinib-tavlesse-final-dec-2020docx-for-website.pdf	fostamatinib (Tavlesse®) is accepted for **restricted use** within NHSScotland.	SMC restriction: for the treatment of patients with severe symptomatic ITP or with a high risk of bleeding who have not had a suitable response to other therapies, including a thrombopoietin receptor-agonist (TPO-RA), or where use of a TPO-RA is not appropriate. Fostamatinib has been shown to be significantly more effective than placebo in raising and maintaining platelet counts at (or above) a minimum target level in previously-treated patients with ITP. 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 views from a Patient and Clinician Engagement (PACE) meeting.
Melatonin prolonged-release	Slenyto®	Treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.	Medicine advice	https://www.scottishmedicines.org.uk/media/5711/melatonin-slenyto-resub-final-dec-2020docx-for-website.pdf	**melatonin prolonged-release (Slenyto®) is not recommended for use within NHSScotland.**	Melatonin prolonged-release (Slenyto®), compared with placebo, increased total sleep time and sleep onset latency in children aged 2 to 17.5 years with sleep problems and autism spectrum disorder and / or Smith-Magenis syndrome who had an insufficient response to sleep hygiene measures. The company did not present a sufficiently robust economic analysis to gain acceptance by SMC.

Secukinumab	Cosentyx®	Treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non steroidal anti inflammatory drugs.	Medicine advice	https://www.scottishmedicines.org.uk/media/5712/secukinumab-cosentyx-final-december-2020docx-for-website.pdf	is accepted for use within NHSScotland.	In a randomised phase III study, secukinumab, compared with placebo, significantly improved symptoms in adults with active non-radiographic axial spondyloarthritis. 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.
Talazoparib	**Talzenna**	As monotherapy for the treatment of adult patients with germline BRCA1/2 mutations, who have HER2-negative locally advanced or metastatic breast cancer.	Non submission	https://www.scottishmedicines.org.uk/medicines-advice/talazoparib-talzenna-nonsub-smc2325/	in the absence of a submission from the holder of the marketing authorisation talazoparib (Talzenna®) is not recommended for use within NHSScotland.	The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.