NEWSLETTER: News from the HTA Agencies

JULY 2021

SUMMARY

Agency	Drug Number	Drug Name
CADTH Evidence Driven.	4	Dinutuximab, durvalumab, encorafenib + binimetinib, encorafenib.
HAS	0	No new reports.
ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW	0	No new reports.
IQWiG	9	Avatrombopag, bedaquiline, carfilzomib, fostemsavir, Nivolumab, Pembrolizumab, Remdesivir, Sodium zirconium cyclosilicate, Upadacitinib
NICE National Institute for Health and Care Excellence	6	Adalimumab + [etanercept] + [infliximab] + [abatacept], Enzalutamide, Ixekizumab, Nivolumab, Nivolumab + [Ipilimumab], Secukinumab
Scottish Medicines Consortium	5	Atezolizumab, Bempedoic acid, Ofatumumab, Pertuzumab + trastuzumab, tafamidis

CADTH Evidence Driven.

CADTH https://www.cadth.ca/

GENERIC NAME	BRAND NAME	INDICATION	TYPE OF DOCUMENT	Link	RECOMMENDATION	Info on costs
dinutuximab	Unituxin	For the treatment of high-risk neuroblastoma patients in their first relapse or determination of refractory disease, in combination with irinotecan, temozolomide, and granulocyte macrophage colony-stimulating factor.	CADTH Reimbursement Recommendation. Final Recommendation 23.07.2021	https://www.cadth.ca/sites/default/files/attachments/2021-07/PC0222%20Unituxin%20-%20CADTH%20Final%20Rec%20v4.pdf	The CADTH pCODR Expert Review Committee (pERC) recommends that dinutuximab should be reimbursed for the treatment of patients with high-risk neuroblastoma in their first relapse or determination of refractory disease, in combination with irinotecan, temozolomide, and GM-CSF, only for patients who have not had either: ● prior therapy for R/R high-risk neuroblastoma; ● a severe reaction or progressive disease with upfront anti- GD2 immunotherapy.	Reimbursement condition: reduction in price. Reason: with price reductions approaching 100%, dinutuximab is not cost-effective at a $50,000 per QALY threshold
Durvalumab	Imfinzi	First-line treatment of adult patients with ES-SCLC in combination with etoposide and either carboplatin or cisplatin.	CADTH Reimbursement Recommendation. Final Recommendation 27.07.2021	https://www.cadth.ca/sites/default/files/attachments/2021-07/PC0234%20Imfinzi%20-%20CADTH%20Final%20Rec.pdf	The CADTH pCODR Expert Review Committee (pERC) recommends that durvalumab in combination with etoposide and platinum (EP) chemotherapy (cisplatin or carboplatin) should be reimbursed for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) only if the following conditions are met: ●Patient must not have received previous treatment for ES-SCLC; ●Patient must have good performance status upon treatment initiation with durvalumab.	Reimbursement conditions: Reduction in price. Reason: Durvalumab + EP is more costly than EP alone. The ICER for durvalumab in combination with EP was $441,635 per QALY compared with EP alone. A price reduction of at least 88% for durvalumab is necessary for durvalumab + EP to be considered cost-effective at a $50,000 per QALY threshold.

encorafenib	Braftovi	In combination with cetuximab, for the treatment of patients with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by a validated test, after prior therapy.	CADTH Reimbursement Recommendation. Final Recommendation 26.07.2021	https://www.cadth.ca/sites/default/files/attachments/2021-07/PC0233%20Braftovi%20-%20CADTH%20Final%20Rec_0.pdf	The CADTH pCODR Expert Review Committee (pERC) recommends that encorafenib should be reimbursed for the treatment of patients with mCRC with a BRAF V600E mutation, as detected by a validated test, after prior therapy only if the following conditions are met: ● Patients must receive encorafenib in combination with cetuximab; ● Patients must have BRAF V600E–mutated mCRC; ● Patients must have received at least 1 previous systemic treatment for mCRC; ● Patients must have good performance status; ● Patients must not have received prior EGFR inhibitors or BRAF inhibitors; ● Patients must have adequate organ function.	Reimbursement Condition: Price reduction- Reason: The ICER for encorafenib in combination with cetuximab is $198,779 when compared with FOLFOX. Given the cost of cetuximab, there is no price for encorafenib at which an ICER of $50,000 could be achieved. If the price of cetuximab was reduced by more than 60%, encorafenib may be able to achieve an ICER of $50,000 per QALY, with a 99% price reduction.
encorafenib + binimetinib	Braftovi + Mektovi	For the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation	CADTH Reimbursement Recommendation. Final Recommendation 26.07.2021	https://www.cadth.ca/sites/default/files/attachments/2021-07/PC0232%20Braftovi%20and%20Mektovi%20Final.pdf	The CADTH pCODR Expert Review Committee (pERC) recommends that encorafenib should be reimbursed for the treatment of patients with mCRC with a BRAF V600E mutation, as detected by a validated test, after prior therapy only if the following conditions are met: ● Patients must receive encorafenib in combination with cetuximab. ● Patients must have BRAF V600E–mutated mCRC. ● Patients must have received at least 1 previous systemic treatment for mCRC. ● Patients must have good performance status. ● Patients must not have received prior EGFR inhibitors or BRAF inhibitors ● Patients must have adequate organ function.	Pricing: Reimbursement condition: 1. Encorafenib in combination with binimetinib should not be more costly than the least costly BRAFi/MEKi combination regimen. Reason: Evidence from indirect comparisons (NMAs) suggest that there is no statistically significant difference in efficacy among the 3 BRAFi/MEKi combination treatments in patients with unresected or metastatic melanoma

§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/

July 2021: No Final Reports available for any drug or condition.

ICER

https://icer.org/

July 2021: No Final Reports available for any drug or condition.

IQWIG

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

Generic name	Brand name	Indication	Type of document	link	Recommendation	Note
Avatrombopag [A21-32]	Doptelet	Treatment of primary chronic immune thrombocytopenia in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)	Dossier assessment 01/07/2021	https://www.iqwig.de/en/projects/a21-32.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.
Avatrombopag [A21-31]	Doptelet	Adult patients with severe thrombocytopenia and chronic liver disease who are scheduled to undergo an invasive procedure	Dossier assessment 01/07/2021	https://www.iqwig.de/en/projects/a21-31.html	●Moderate or high bleeding risk of the invasive procedure: proof of considerable added benefit. ●Low bleeding risk of the invasive procedure: 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.
Bedaquiline [G21-11]	Sirturo	multidrug resistant tuberculosis: children aged 5 to 11 years	Dossier assessment 01.07.2021	https://www.iqwig.de/en/projects/g21-11.html		In accordance with §35a (1) Sentence 11 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

Carfilzomib [A21-08]	Kyprolis	Adult patients with multiple myeloma who have received at least one prior therapy	Dossier assessment 15/07/2021	https://www.iqwig.de/en/projects/a21-08.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.
Fostemsavir [A21-33]	Rukobia	Adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.	Dossier assessment 01.07.2021	https://www.iqwig.de/en/projects/a21-33.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.
Nivolumab [A20-121] [A21-62]	Opdivo	Adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy	Dossier assessment and addendum 2/07/2021	https://www.iqwig.de/en/projects/a20-121.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.
Nivolumab [A21-39]	Opdivo	Adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection	Dossier assessment 01/07/2021	https://www.iqwig.de/en/projects/a21-39.html	●Stage IIIB/C and IV disease: hint of non-quantifiable added benefit. ●Stage IIIA 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.

Pembrolizumab [A21-36]	Keytruda	First-line treatment of adult patients with metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer	Dossier assessment 01/07/2021	https://www.iqwig.de/en/projects/a21-36.html	●Patients for whom intensive therapy is appropriate: hint of considerable added benefit. ●Patients for whom intensive therapy is not appropriate: 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.
Pembrolizumab [A21-34]	Keytruda	Adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumours express programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) ≥ 10	Dossier assessment 01/07/2021	https://www.iqwig.de/en/projects/a21-34.html	Indication of 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.
Pembrolizumab [A21-35]	Keytruda	Adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant or following at least two prior therapies when autologous stem cell transplant is not a treatment option	Dossier assessment 01/07/2021	https://www.iqwig.de/en/projects/a21-35.html	●Adults for whom brentuximab vedotin is the suitable therapy according to physician's choice: hint of non-quantifiable added benefit. ●Adults for whom brentuximab vedotin is not the suitable therapy according to physician's choice: added benefit not proven. ●Children and adolescents aged 3 years and older: 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.

Remdesivir [A21-38]	Veklury	COVID-19	Dossier assessment 01.07.2021	https://www.iqwig.de/en/projects/a21-38.html	Adult patients with low-flow oxygen (LFO) at start of treatment: indication of considerable benefit. Adolescent patients with low-flow oxygen (LFO) at start of treatment: added benefit not proven. Patients with high-flow oxygen (HFO)/non-invasive ventilation (NIV) at start of treatment: 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.
Sodium zirconium cyclosilicate [A21-40]	Lokelma	hyperkalaemia	Dossier assessment 01/07/2021	https://www.iqwig.de/en/projects/a21-40.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.
Upadacitinib [A21-15]	Rinvoq	Adult patients with active psoriatic arthritis	Dossier assessment 15.07.2021	https://www.iqwig.de/en/projects/a21-15.html	●Patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy: hint of minor added benefit. ●Patients who have had an inadequate response or who have been intolerant to a prior therapy with biologic disease-modifying 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 [A21-12]*

NICE National Institute for Health and Care Excellence

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

Generic name	Brand name	Indication	Type of document	link	Recommendation
Adalimumab + [etanercept] + [infliximab] + [abatacept]	Humira + [Enbrel] + [Infliximab] + [Orencia]	Moderate rheumatoid arthritis after conventional DMARDs have failed	Technology appraisal guidance [TA715] 07/07/2021	https://www.nice.org.uk/guidance/ta715/resources/adalimumab-etanercept-infliximab-and-abatacept-for-treating-moderate-rheumatoid-arthritis-after-conventional-dmards-have-failed-pdf-82611135252421	Adalimumab, etanercept and infliximab, all with methotrexate, are recommended as options for treating active rheumatoid arthritis in adults, only if: • intensive therapy with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs) has not controlled the disease well enough; • disease is moderate; • the companies provide adalimumab, etanercept and infliximab at the same or lower prices than those agreed with the Commercial Medicines Unit. The most likely estimates suggest that adalimumab, etanercept and infliximab after 2 or more conventional DMARDs are a cost-effective use of NHS resources. So, they are recommended for treating moderate rheumatoid arthritis. The most likely cost-effectiveness estimates for abatacept are higher than what NICE normally considers cost effective, so it is not recommended for moderate disease. ●The list price of originator adalimumab (Humira, AbbVie) is £352.14 per 40 mg pre-filled pen or pre-filled syringe (excluding VAT; BNF online, accessed March 2021). ●The list price of originator etanercept (Enbrel, Pfizer) is £89.38 per 25 mg prefilled pen or pre-filled syringe (excluding VAT; BNF online, accessed March 2021). ●The list price of infliximab biosimilars per 100 mg vial are £377.00 (Flixabi, Biogen) ●The list price of abatacept (Orencia, Bristol-Myers Squibb) is £302.40 per 125 mg pre-filled pen or pre-filled syringe and £302.40 per 250 mg vial (excluding VAT; BNF online, accessed March 2021).

Enzalutamide	Xtandi	hormone-sensitive metastatic prostate cancer in adults	Technology appraisal guidance [TA712] 07/07/2021	https://www.nice.org.uk/guidance/ta712/resources/enzalutamide-for-treating-hormonesensitive-metastatic-prostate-cancer-pdf-82611130213573	Enzalutamide plus androgen deprivation therapy (ADT) is recommended, within its marketing authorisation, as an option for treating hormone-sensitive metastatic prostate cancer in adults. It is only recommended if the company provides enzalutamide according to the agreed commercial arrangement. Enzalutamide plus ADT would offer another option for people with hormone-sensitive metastatic prostate cancer, especially for people who cannot have docetaxel. Trial results suggest that, compared with ADT alone, enzalutamide plus ADT increases the time until the cancer progresses and how long people live. Also, an indirect comparison suggests that, compared with docetaxel plus ADT, enzalutamide plus ADT increases the time until the cancer progresses. The cost-effectiveness estimates are within the range NICE considers an acceptable use of NHS resources. Therefore, enzalutamide plus ADT is recommended. The list price of a 112-capsule pack of 40 mg enzalutamide is £2,734.67 (excluding VAT; BNF online, accessed May 2020). The daily dose of enzalutamide is 160 mg and costs £97.67.
Ixekizumab	Taltz	axial spondyloarthritis	Technology appraisal guidance [TA718] 21/07/2021	https://www.nice.org.uk/guidance/ta718/resources/ixekizumab-for-treating-axial-spondyloarthritis-pdf-82611140291269	Ixekizumab is recommended as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy, or active non-radiographic axial spondyloarthritis with objective signs of inflammation 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 ixekizumab according to the commercial arrangement. When people cannot have TNF-alpha inhibitors or they have not worked well enough the current treatment option is conventional therapy. This includes NSAIDs and physiotherapy. Secukinumab is also an option for treating radiographic disease but there is not enough data to reliably compare it with ixekizumab. Evidence from clinical trials shows that ixekizumab is effective compared with placebo. The costeffectiveness estimates for ixekizumab compared with conventional therapy are within what NICE usually considers cost effective. Therefore, ixekizumab is recommended. The list price of ixekizumab is £1,125 for 1 pre-filled syringe containing 80 mg per 1 ml solution. The annual cost is £16,875 for 15 injections in year 1 and £14,625 for 13 injections in year 2.

Nivolumab	Opdivo	. locally advanced or metastatic non-squamous non-small-cell lung cancer (NSCLC) in adults after chemotherapy	Technology appraisal guidance [TA713] 07/07/2021	https://www.nice.org.uk/guidance/ta713/resources/nivolumab-for-advanced-nonsquamous-nonsmallcell-lung-cancer-after-chemotherapy-pdf-82611131893189	Nivolumab is recommended as an option for treating locally advanced or metastatic NSCLC in adults after chemotherapy, only if: • their tumours are PD-L1 positive, and • it is stopped at 2 years of uninterrupted treatment, or earlier if their disease progresses, and • they have not had a PD-1 or PD-L1 inhibitor before. The key clinical trial shows that people with PD-L1-positive tumours who have nivolumab live longer than those who have docetaxel, which is the most appropriate comparator. There is uncertainty about how long people should have nivolumab for, but evidence shows that there is continued benefit when treatment is stopped at 2 years. Nivolumab meets NICE's criteria to be considered a life-extending treatment at the end of life. The cost-effectiveness estimates for nivolumab compared with docetaxel are likely to be within what NICE considers an acceptable use of NHS resources. Therefore, it is now recommended in the NHS. The list price of nivolumab is £2,633 per 240 mg per 24 ml vial (excluding VAT; BNF online, accessed March 2020). 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.
Nivolumab + [Ipilimumab]	Opdivo + [Yervoy]	previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency	Technology appraisal guidance [TA716] 28/07/2021	https://www.nice.org.uk/guidance/ta716/resources/nivolumab-with-ipilimumab-for-previously-treated-metastatic-colorectal-cancer-with-high-microsatellite-instability-or-mismatch-repair-deficiency-pdf-82611136932037	Nivolumab plus ipilimumab is recommended, within its marketing authorisation, as an option for treating metastatic colorectal cancer with high microsatellite instability (MSI) or mismatch repair (MMR) deficiency after fluoropyrimidine-based combination chemotherapy. It is recommended only if the company provides nivolumab and ipilimumab according to the commercial arrangement. People with previously treated metastatic colorectal cancer that has high MSI or MMR deficiency are usually offered combination chemotherapy including FOLFOX, FOLFIRI or trifluridine–tipiracil, and best supportive care. This is the same as what is offered for most other types of metastatic colorectal cancer. Clinical trial evidence suggests that nivolumab plus ipilimumab may extend how long people live. The cost-effectiveness estimates are within what NICE normally considers acceptable use of NHS resources. So, nivolumab plus ipilimumab is recommended.

					The list price of nivolumab is £2,633 per 240mg per 24-ml vial (excluding VAT; BNF online, assessed March2021). The company has a commercial arrangement. The list price of ipilimumab is £15,000 per 200-mg vial (excluding VAT; BNF online, assessed March2021). The company has a commercial arrangement.
Secukinumab	Cosentyx	non-radiographic axial spondyloarthritis	Technology appraisal guidance [TA719] 21/07/2021	https://www.nice.org.uk/guidance/ta719/resources/secukinumab-for-treating-nonradiographic-axial-spondyloarthritis-pdf-82611141970885	Secukinumab is recommended as an option for treating active non-radiographic axial spondyloarthritis with objective signs of inflammation that is not controlled well enough with non-steroidal anti-inflammatory drugs in adults. It is recommended only if: • TNF-alpha inhibitors are not suitable or do not control the condition well enough; • the company provides secukinumab according to the commercial arrangement. Different TNF-alpha inhibitors have different costs but similar effectiveness. When more than one TNF-alpha inhibitor is suitable, the cheapest is used, currently adalimumab biosimilar. Because of this, secukinumab is not a cost-effective use of NHS resources when compared with TNF-alpha inhibitors. Secukinumab is only considered to be cost effective for people who cannot have TNFalpha inhibitors, or when TNF-alpha inhibitors have not worked well enough. Therefore, it is recommended in these situations. The list price is £1,218.78 for 2 pre-filled pens or syringes containing 150 mg per 1 ml solution (excluding VAT, BNF online accessed March 2021). Annual cost of treatment for the first year is £9,750.24 and subsequent years is £7,312.68. The company has a commercial arrangement. This makes secukinumab 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

**Esclusi dal report i seguenti medicinali valutati da NICE: Dasatinib (Sprycel), Duvelisib (Copiktra).*

Scottish Medicines Consortium

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

Generic name	Brand name	Indication	Type of document	Link	Advice	Evidences
atezolizumab **SMC2349**	Tecentriq	In combination with bevacizumab for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.	Medicine advice 12/07/2021	https://www.scottishmedicines.org.uk/media/6103/atezolizumab-tecentriq-final-june-2021-for-website.pdf	Following a full submission assessed under the end of life process: atezolizumab (Tecentriq®) is accepted for use within NHSScotland.	In a phase III study in patients with advanced or unresectable HCC who had not received prior systemic therapy, atezolizumab plus bevacizumab was associated with greater overall and progression-free survival compared with a multikinase inhibitor. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. Atezolizumab 1,200mg followed by bevacizumab 15mg/kg of body weight, administered by iv infusion every three weeks: £6,384
bempedoic acid **SMC2363**	Nilemdo	In adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:	Medicine advice 12/07/2021	https://www.scottishmedicines.org.uk/media/6104/bempedoic-acid-nilemdo-resubmission-final-june-2021-for-website.pdf	following a resubmission: bempedoic acid (Nilemdo®) is accepted for restricted use within NHSScotland.	SMC restriction: for use in combination with ezetimibe in patients who are: ● statin intolerant or for whom a statin is contra-indicated and ●where ezetimibe alone does not appropriately control LDL-C and ●where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate. In two phase III studies in patients intolerant to statins, the percentage reduction in LDL-C to 12-weeks was significantly larger with bempedoic acid compared with placebo.

		In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contra-indicated.				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. Cost per year: Bempedoic acid 180mg orally once daily 721£.
ofatumumab **SMC2357**	Kesimpta	Treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.	Medicine advice 12/07/2021	https://www.scottishmedicines.org.uk/media/6108/ofatumumab-kesimpta-final-june-2021-for-website.pdf	following a full submission: ofatumumab (Kesimpta®) is accepted for restricted use within NHSScotland.	SMC restriction: treatment of RRMS with active disease defined by clinical or imaging features. Two phase III studies demonstrated superiority of ofatumumab in reducing annualised relapse rate when compared with another disease-modifying treatment in adult patients with RMS. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.20mg administered by sc injection with initial dosing at weeks 0, 1 and 2, followed by subsequent monthly dosing, starting at week 4: First year: £22,388; Subsequent years: £17,910

pertuzumab + trastuzumab **SMC2364**	Phesgo	**-Early breast cancer** in combination with chemotherapy in: • HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence • HER2-positive early breast cancer at high risk of recurrence. **-Metastatic breast cancer** In combination with docetaxel in 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.	Medicine advice 12/07/2021	https://www.scottishmedicines.org.uk/medicines-advice/pertuzumab-and-trastuzumab-phesgo-abb-smc2364/	following an abbreviated submission: pertuzumab/trastuzumab (Phesgo®) is accepted for restricted use within NHSScotland.	SMC restriction: Restricted to use in line with previous SMC advice for pertuzumab and trastuzumab (see SMC2284; SMC2120; SMC2119; SMC No. 928/13; SMC No. 278/06). Pertuzumab/trastuzumab provides a combination injection for subcutaneous use. Pertuzumab has previously been accepted by SMC under the orphan medicine process. 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.
Tafamidis **SMC2354**	Vyndaqel	For the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)	Medicine advice 12/07/2021	https://www.scottishmedicines.org.uk/media/6112/tafamidis-vyndaqel-final-june-2021-amended-090721-for-website.pdf	following a full submission under the orphan and end of life medicine process: **tafamidis (Vyndaqel®) is not recommended for use within NHSScotland**.	In a phase III study, 30 months of treatment with tafamidis (as meglumine) significantly reduced the risk of all-cause mortality and cardiovascular-related hospitalisation compared with placebo, in patients with wild-type or hereditary ATTR-CM. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the company did not present a sufficiently robust economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The licence holder has indicated their intention to resubmit. Tafamidis: 61mg orally once daily 129,645£