NHS Borders: New Medicines Decisions APRIL 2020 – MARCH 2021

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In Scotland, a newly licensed medicine is routinely available in a health board only after it has been:

- accepted for use in NHSScotland by the Scottish Medicines Consortium (SMC), and
- accepted for use by the health board's Area Drug and Therapeutics Committee (ADTC).

All medicines accepted by SMC are available in Scotland, but may not be considered 'routinely available' within a particular health board because of available services and preferences for alternative medicines. 'Routinely available' means that a medicine can be prescribed by the appropriately qualified person within a health board.

Each health board has an ADTC. The ADTC is responsible for advising the health board on all aspects of the use of medicines.
Medicines routinely available within a health board are usually included in the local formulary. The formulary is a list of medicines for use in the health board that has been agreed by ADTC in consultation with local clinical experts. It offers a choice of medicines for healthcare professionals to prescribe for common medical conditions. A formulary can help improve safety as prescribers are likely to become more familiar with the medicines in it and also helps make sure that standards of care are consistent across the health board.

How does the health board decide which new medicines to make routinely available for patients?
The ADTC in a health board will consider national and local guidance before deciding whether to make a new medicine routinely available.

What national guidance does the ADTC consider?

- SMC advice: The SMC considers newly licensed medicines and advises health boards in Scotland whether they should be available. When SMC considers a new medicine for the NHS in Scotland, it looks at:
  - how well the medicine works,
  - which patients might benefit from it ,
  - whether it is as good or better than medicines the NHS already uses to treat the medical condition, and
  - whether it is good value for money.

  In the table below, national guidance usually refers to SMC advice. Links to SMC advice for individual medicines are also included in the table.
- In some cases, other agencies may also provide guidance on how medicines should be used. For example, Healthcare Improvement Scotland issues alerts to advise if National Institute for Health and Care Excellence Multiple Technology Appraisals (NICE MTAs) are applicable in Scotland.

What local guidance does the ADTC consider?

- Advice from local clinical experts who would be expected to prescribe a particular medicine, where that service is available in a health board.

Why is a particular medicine not routinely available in my health board?

- This is usually because the medicine is not recommended for use in NHSScotland by the SMC.
- The medicine may not be routinely available in a health board, particularly in smaller health boards, because there is not a suitable specialist who may use the medicine.
- There may also be differences in which medicines are preferred in health boards. Sometimes SMC accepts more than one medicine for treating a specific medical condition. Clinical experts in each health board consider whether to add new medicines to their formulary and advise the ADTC. Sometimes it is agreed that established medicines are a better choice than new medicines.

What happens if a particular medicine is not routinely available in my health board?

- If a medicine is not routinely available and included on your health board's formulary and there are no suitable alternatives on the formulary, a healthcare professional can request to prescribe a medicine that is not on the formulary if they think you will benefit from using it. All health boards have procedures in place to consider requests when a healthcare professional feels a medicine that is not on the formulary would be right for a particular patient.

NHS Borders board decisions – six options:

- Routinely available in line with national guidance (link to SMC advice)
- Routinely available in line with local guidance for prescribing (link, if desired, to local or regional guidance)
- Routinely available from a specialist centre in another NHS board
- Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice)
- Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local or regional guidance)
- Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by *(enter date)*

The following table lists NHS Borders decisions on new medicines, ordered by MONTH of decision and then A-Z.
If you need more information on medicines decisions in NHS Borders, please email Formulary Pharmacist liz.leitch@borders.scot.nhs.uk.

APRIL 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
SMC Meetings suspended due to the need to support NHSScotland in the early stages of the COVID-19 pandemic				

MAY 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
SMC Meetings suspended due to the need to support NHSScotland in the early stages of the COVID-19 pandemic				

JUNE 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
SMC Meetings suspended due to the need to support NHSScotland in the early stages of the COVID-19 pandemic				

JULY 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
SMC Meetings suspended due to the need to support NHSScotland in the early stages of the COVID-19 pandemic				

AUGUST 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Hydroxycarbamide Xromi SMC2271	ADVICE: following assessment under the abbreviated process **hydroxycarbamide oral solution (Xromi®)** is accepted for restricted use within NHSScotland. Indication under review: for the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over 2 years of age. SMC restriction: children who are too young to be able to swallow capsules / tablets and adults and adolescents who have difficulty in swallowing solid oral dosage forms. The availability of hydroxycarbamide oral solution (Xromi®) provides a licensed	10/08/2020	Routinely available in line with national guidance (link to SMC advice) https://www.scottishmedicines.org.uk/medicines-advice/hydroxycarbamide-xromi-abbreviated-smc2271/	19/08/2020

	alternative to unlicensed liquid preparations.			
Neratinib Nerlynx SMC2251	ADVICE: following a full submission **neratinib (Nerlynx®)** is accepted for use within NHSScotland. Indication under review: for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago. In the relevant subgroup of a phase III study neratinib, given less than one year after adjuvant trastuzumab-based therapy, improved invasive disease-free survival in patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer compared with placebo. 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.	10/08/2020	Routinely available in line with national guidance (link to SMC advice) https://www.scottishmedicines.org.uk/medicines-advice/neratinib-nerlynx-full-smc2251/	19/08/2020
Vedolizumab Entyvio SMC2276 (UC)	ADVICE: following an abbreviated submission **vedolizumab (Entyvio®)** is accepted for use within NHSScotland. Indication under review: the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. SMC has previously accepted vedolizumab powder for concentrate for solution for intravenous infusion for use in NHSScotland for this indication (SMC1045/15). 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.	10/08/2020	Routinely available in line with national guidance (link to SMC advice) https://www.scottishmedicines.org.uk/medicines-advice/vedolizumab-entyvio-abb-smc2276/	19/08/2020
Vedolizumab Entyvio SMC2277 (CD)	ADVICE: following an abbreviated submission **vedolizumab (Entyvio®)** is accepted for restricted use within NHSScotland. Indication under review: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. SMC restriction: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNFα antagonist. SMC has previously accepted vedolizumab powder for concentrate for solution for intravenous infusion for restricted use in NHSScotland for this indication (SMC1064/15). This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS)	10/08/2020	Routinely available in line with national guidance (link to SMC advice) https://www.scottishmedicines.org.uk/medicines-advice/vedolizumab-entyvio-abb-smc2277/	19/08/2020

	arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.			

SEPTEMBER 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Andexanet alfa Ondexxya® SMC2273	ADVICE: following a full submission **andexanet alfa (Ondexxya®)** is accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. In an open-label single-arm study andexanet alfa reduced anti-FXa activity and improved haemostatic efficacy in adults with major bleeds. 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.	07/09/2020	Routinely available in line with national guidance (link to SMC advice) https://www.scottishmedicines.org.uk/medicines-advice/andexanet-alfa-ondexxya-full-smc2273/	21/10/2020
Brolucizumab Beovu® SMC2272	ADVICE: following a full submission **brolucizumab (Beovu®)** is accepted for use within NHSScotland. Indication under review: in adults for the treatment of neovascular (wet) age-related macular degeneration (AMD). Non-inferiority of brolucizumab versus another anti-vascular endothelial growth factor medicine was demonstrated for mean change in best corrected visual acuity from baseline to week 48 in two phase III studies in patients with neovascular AMD. 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.	07/09/2020	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time https://www.scottishmedicines.org.uk/medicines-advice/brolucizumab-beovu-full-smc2272/	21/10/2020
Cannabidiol Epidyolex SMC2262	ADVICE: following a full submission considered under the orphan process **cannabidiol (Epidyolex®)** is accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older. In two phase III,	07/09/2020	Routinely available in line with national guidance (link to SMC advice) https://www.scottishmedicines.org.uk/medicines-advice/cannabidiol-epidyolex-full-smc2262/	21/10/2020

	placebo-controlled studies cannabidiol reduced convulsive seizure frequency in the clobazam-treated subgroup of children (aged 2 to 18 years) with Dravet syndrome that was inadequately controlled by other anti-epileptic drugs. 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.			
Cannabidiol Epidyolex SMC2263	ADVICE: following a full submission considered under the orphan process **cannabidiol (Epidyolex®)** is accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older. In two phase III, placebo-controlled studies cannabidiol reduced drop seizure frequency in the clobazam-treated subgroup of children and adults (aged 2 to 55 years) with Lennox-Gastaut syndrome that was inadequately controlled by other anti-epileptic drugs. 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.	07/09/2020	Routinely available in line with national guidance (link to SMC advice) https://www.scottishmedicines.org.uk/medicines-advice/cannabidiol-epidyolex-full-smc2263/	21/10/2020
Caplacizumab Cablivi® SMC2266	ADVICE: following a full submission **caplacizumab (Cablivi®)** is accepted for use within NHSScotland. Indication under review: Treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression. Caplacizumab, compared with placebo, decreased the time to platelet count response and reduced the risk of thrombotic thrombocytopenic purpura recurrence in adults receiving plasma exchange and immunosuppression for aTTP. 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.	07/09/2020	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/caplacizumab-cablivi-full-smc2266/	21/10/2020
Esketamine	ADVICE: following a full submission **esketamine (Spravato®)** is accepted for use within NHSScotland.	07/09/2020	Not routinely available as local clinical	21/10/2020

Spravato SMC2258	Indication under review: In combination with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI), for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode. In a phase III study in adults (aged 18 to 64 years) with treatment resistant depression, esketamine plus newly initiated antidepressant significantly reduced the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to week 4 compared with placebo plus newly initiated antidepressant. A significantly lower rate of relapse in patients who received esketamine plus antidepressant over placebo plus antidepressant was demonstrated in a further phase III study. 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.		experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local or regional guidance) https://www.scottishmedicines.org.uk/medicines-advice/esketamine-spravato-full-smc2258/	
Ex vivo expanded autologous human corneal epithelial cells containing stem cells Holoclar® SMC2261	ADVICE: following a full submission for an orphan medicine **ex vivo expanded autologous human corneal epithelial cells containing stem cells (Holoclar®)** is accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: Treatment of adult patients with moderate to severe limbal stem cell deficiency (defined by the presence of superficial corneal neovascularisation in at least two corneal quadrants, with central corneal involvement, and severely impaired visual acuity), unilateral or bilateral, due to physical or chemical ocular burns. In a retrospective uncontrolled case series study, Holoclar was associated with transplant success in the majority of patients with limbal stem cell deficiency due to chemical or physical ocular burns. 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.	07/09/2020	Not routinely available – would not be used in NHS Borders – corneal specialist use only https://www.scottishmedicines.org.uk/medicines-advice/ex-vivo-holoclar-full-smc2261/	21/10/2020
Fluocinolone acetonide Iluvien	ADVICE: following a full submission **fluocinolone acetonide (Iluvien®)** is accepted for use within NHSScotland. Indication under review: prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye. In a double-blind, phase III study in patients with recurrent non-infectious uveitis affecting the posterior segment of the eye,		Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time (October 2020) https://www.scottishmedicines.org.uk/medicines-advice/fluocinolone-acetonide-iluvien-full-smc2260/	

SMC2260	fluocinolone acetonide intravitreal implant reduced the number of recurrences of uveitis compared with sham injection. 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.			
Gilteritinib Xospata SMC2252	ADVICE: following a full submission assessed under the end of life and orphan medicine process **gilteritinib (Xospata®)** is accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia with a FLT3 mutation. In an open-label, phase III study, gilteritinib improved overall survival compared with salvage chemotherapy in patients with relapsed or refractory acute myeloid leukaemia with a FLT3 mutation. 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.	07/09/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/gilteritinib-xospata-full-smc2252/	21/10/2020
Pembrolizumab RCC Keytruda SMC2247	ADVICE: following a full submission assessed under the end of life process: **pembrolizumab (Keytruda®)** is accepted for restricted use within NHSScotland. Indication under review: in combination with axitinib, for the first-line treatment of advanced renal cell carcinoma in adults. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In an open-label, phase III study, first-line treatment with pembrolizumab plus axitinib significantly improved progression-free and overall survival in adults with advanced renal cell carcinoma compared with a vascular endothelial growth factor (VEGF)-targeting tyrosine-kinase inhibitor (TKI). 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 views from a Patient and Clinician Engagement (PACE) meeting.	07/09/2020	Routinely available in line with national guidance *Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for pembrolizumab (Keytruda®) in combination with axitinib, for the first-line treatment of advanced renal cell carcinoma in adults. The DAD will published on Monday 7 September 2020.* https://www.scottishmedicines.org.uk/medicines-advice/pembrolizumab-keytruda-full-smc2247/	21/10/2020
Pembrolizumab HNSCC Keytruda	ADVICE: following a full submission assessed under the end of life process: **pembrolizumab (Keytruda®)** is accepted for restricted use within NHSScotland.	07/09/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-	21/10/2020

SMC2257	Indication under review: as monotherapy or in combination with platinum and fluorouracil chemotherapy, for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express programmed cell death ligand-1 (PD-L1) with a combined positive score (CPS)≥1. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. Overall survival was longer in patients who received pembrolizumab as monotherapy or in combination with chemotherapy compared with a monoclonal antibody plus chemotherapy in a phase III study in patients with untreated, locally incurable, recurrent or metastatic HNSCC with PD-L1 CPS≥1. 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.		advice/pembrolizumab-keytruda-full-smc2257/	
Pertuzuma Perjeta® SMC2284	ADVICE: following a resubmission assessed under the orphan medicine process **pertuzumab (Perjeta®)** is accepted for restricted use within NHSScotland. Indication under review: for use in combination with trastuzumab and chemotherapy in the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence. SMC restriction: for use in patients with lymph node-positive disease. The addition of pertuzumab to trastuzumab and chemotherapy improved invasive disease-free survival in patients with HER2-positive early breast cancer at high risk of recurrence. 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.	07/09/2020	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/pertuzumab-perjeta-resub-smc2284/	21/10/2020
Polatuzumab vedotin Polivy® SMC2282	ADVICE: following a full submission for an end of life and orphan medicine **polatuzumab vedotin (Polivy®)** is accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: in combination with bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant. In a phase Ib/II study	07/09/2020	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/polatuzumab-vedotin-polivy-full-smc2282/	21/10/2020

	polatuzumab vedotin in combination with bendamustine and rituximab significantly increased complete response rate compared to bendamustine and rituximab alone. 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.			
Semaglutide tablets Rybelsus® SMC2287	ADVICE: following assessment under the abbreviated process **semaglutide (Rybelsus®)** is accepted for restricted use within NHSScotland. Indication under review: for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise • As monotherapy when metformin is considered inappropriate due to intolerance or contraindications • In combination with other medicinal products for the treatment of diabetes. SMC restriction: In addition to other oral anti-diabetic medicines, or as an add-on to basal insulin, as an alternative glucagon-like peptide-1 receptor agonist option. SMC has previously accepted semaglutide solution for subcutaneous injection (Ozempic®) for restricted use (SMC2092). Oral semaglutide (Rybelsus®) costs the same per day as subcutaneous semaglutide (Ozempic®). Prescribers should note that the effect of switching between oral and subcutaneous semaglutide cannot easily be predicted because of high pharmacokinetic variability of oral semaglutide. Clinical effectiveness should be considered when making switching decisions between formulations. The company's submission related only to use in addition to other medicinal products for the treatment of diabetes, therefore SMC cannot recommend semaglutide tablets as monotherapy.	07/09/2020	Approved for use in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/semaglutide-rybelsus-abbreviated-smc2287/	21/10/2020
Sodium zirconium cyclosilicate Lokelma® SMC2288	ADVICE: following a resubmission **sodium zirconium cyclosilicate (Lokelma®)** is accepted for restricted use within NHSScotland. Indication under review: treatment of hyperkalaemia in adult patients. SMC restriction: patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level	07/09/2020	New medicines application in progress (May 2020) https://www.scottishmedicines.org.uk/medicines-advice/sodium-zirconium-cyclosilicate-lokelma-resub-smc2288/	21/10/2020

	(normokalaemia). Sodium zirconium cyclosilicate, compared with placebo, reduced serum potassium in two and four-week studies in adults with hyperkalaemia. In an uncontrolled one-year study sodium zirconium cyclosilicate produced normal serum potassium in a proportion of adults with hyperkalaemia. 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.			

OCTOBER 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Avelumab Bavencio SMC2248	ADVICE: following a full submission assessed under the end of life process **avelumab (Bavencio®)** is accepted for use within NHSScotland. Indication under review: in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC). Avelumab plus axitinib, compared with a vascular endothelial growth factor (VEGF)-targeting tyrosine-kinase inhibitor (TKI), improved progression-free survival in adults with advanced RCC. 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.	12/10/2020	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/avelumab-bavencio-full-smc2248/	21/10/2020
Budesonide Jorveza SMC2158	ADVICE: following a full submission **budesonide (Jorveza®)** is accepted for restricted use within NHSScotland. Indication under review: Treatment of eosinophilic oesophagitis (EoE) in adults (older than 18 years of age). SMC restriction: For patients unsuccessfully treated with proton pump inhibitors. One randomised, double-blind phase III study, demonstrated superiority of budesonide over placebo in inducing clinico-histologic remission in adult patients with EoE, refractory to treatment with a proton pump inhibitor. The case presented to SMC was for induction of remission. The marketing authorisation for budesonide (Jorveza®) has subsequently been extended to include maintenance of remission. SMC does not plan to assess this licence extension.	12/10/2020	Approved for use in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/budesonide-jorveza-full-smc2158/	21/10/2020

Carfilzomib Kyprolis SMC2290	ADVICE: following a second resubmission assessed under the orphan medicine process **carfilzomib (Kyprolis®)** is accepted for restricted use within NHSScotland. Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. SMC restriction: for patients who have received only one prior therapy. Carfilzomib in combination with lenalidomide and dexamethasone improved progression free survival and overall survival compared with lenalidomide and dexamethasone in adults with relapsed and / or refractory multiple myeloma who had received one to three prior therapies. 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.	12/10/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/carfilzomib-kyprolis-resub-smc2290/	21/10/2020
Cerliponase alfa Brineura SMC2286	The Scottish Medicines Consortium (SMC) has completed its initial assessment of the evidence for the above product using the ultra-orphan framework: Indication under review: for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency. Key points: • CLN2 disease is a severe, neurodegenerative condition, diagnosed in childhood with devastating symptoms affecting multiple aspects of the child's life. There are no other medicines licensed for this condition; • A phase I/II study reported a clinically relevant treatment effect with cerliponase alfa, measured by the CLN2 motor/language (ML) scale at 48 weeks. This treatment effect was maintained through to week 96 in an extension study. Cerliponase alfa was also associated with significant treatment benefits when indirectly compared to standard of care from a historical control group; • The quality of life data are potentially difficult to interpret but can be considered positive. The stabilisation observed may be beneficial considering the decline in quality of life typically observed with CLN2 disease; • A model-based health economic evaluation suggests that cerliponase alfa is associated with a substantial gain in quality-adjusted life years compared to standard of care. However, the following issues add to the uncertainty of the results: assumptions regarding long term disease stabilisation;	12/10/2020	ULTRA-ORPHAN MEDICINE WITH PAS Scottish Government will notify Health Boards when this medicine is available for prescribing within the ultra-orphan pathway. Meantime any requests to access treatment should be considered through local non-formulary processes. https://www.scottishmedicines.org.uk/medicines-advice/cerliponase-alfa-brineura-ultra-orphan-pathway-smc2286/	21/10/2020

	the distribution of patients in different starting health states; utility value estimates and the long time horizon; • Despite a Patient Access Scheme (PAS) that improves the cost-effectiveness of cerliponase alfa, the treatment's cost in relation to its health benefits remains high.			
Daratumumab Darzalex SMC2301 (MM) SMC2304 (RRMM)	ADVICE: following an abbreviated submission **daratumumab subcutaneous injection (Darzalex®)** is accepted for restricted use within NHSScotland. Indication under review: in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. SMC restriction: in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received one prior therapy only. Following a submission under the orphan medicine process, SMC has previously accepted daratumumab 20mg/mL concentrate for solution for infusion for restricted use in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received one prior therapy only (SMC2180). 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.	12/10/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/daratumumab-darzalex-abbreviated-smc2301/ https://www.scottishmedicines.org.uk/medicines-advice/daratumumab-darzalex-abbreviated-smc2304/	21/10/2020
Ibrutinib Imbruvica SMC2259	ADVICE: following a full submission assessed under the orphan medicine process **ibrutinib (Imbruvica®)** is accepted for restricted use within NHSScotland. Indication under review: in combination with rituximab for the treatment of adult patients with Waldenström's macroglobulinaemia. SMC restriction: for use in patients who have received at least one prior therapy. Progression-free survival was longer in patients with Waldenström's macroglobulinaemia who received ibrutinib plus rituximab compared with placebo plus rituximab in a phase III study. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. 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.	12/10/2020	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/ibrutinib-imbruvica-full-smc2259/	21/10/2020
Lenalidomide	ADVICE: following a full submission assessed under the orphan medicine process **lenalidomide hard capsules (Revlimid®)** is	12/10/2020	Not routinely available https://www.scottishmedicines.org.uk/medicines-	21/10/2020

Revlimid (MM) SMC2289	accepted for use within NHSScotland. Indication under review: as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT). In phase III, randomised studies, lenalidomide maintenance treatment improved progression-free survival in patients with newly diagnosed multiple myeloma who had undergone ASCT compared with placebo or observation. Median overall survival data were supportive of lenalidomide maintenance treatment. 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.		advice/lenalidomide-revlimid-full-smc2289/	
Lenalidomide Revlimid (FL) SMC2281	ADVICE: following a full submission considered under the orphan process **lenalidomide (Revlimid®)** is accepted for use within NHSScotland. Indication under review: In combination with rituximab (anti-CD20 antibody) for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 to 3a). In a double-blind phase III study lenalidomide in combination with rituximab, compared with placebo plus rituximab, increased progression-free survival in adults with relapsed or refractory follicular lymphoma (Grade 1 to 3a). 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.	12/10/2020	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/lenalidomide-revlimid-full-smc2281/	21/10/2020
Meropenem/ vaborbactam Vaborem SMC2278	ADVICE: following a full submission **meropenem/vaborbactam (Vaborem®)** is accepted for restricted use within NHSScotland. Indication under review: for the treatment of the following infections in adults: • Complicated urinary tract infection (cUTI), including pyelonephritis; • Complicated intra-abdominal infection (cIAI); • Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP). Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Meropenem/vaborbactam is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options. SMC restriction: for adults with confirmed carbapenem-resistant Enterobacteriaceae (CRE),	12/10/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/meropenemvaborbactam-vaborem-full-smc2278/	21/10/2020

	which is involved in the production of Klebsiella pneumoniae carbapenemase (KPC) associated with cUTI (including acute pyelonephritis [AP]), cIAI, HAP (including VAP) and bacteraemia that occurs in association with, or is suspected to be associated with any of the infections previously mentioned. Use should be on the advice of local microbiologists or specialists in infectious disease. In a randomised, double-blind, phase III study, meropenem/vaborbactam was non-inferior to a beta-lactamase/beta-lactamase inhibitor for the treatment of adults with cUTI, including AP. A smaller, randomised, open-label, phase III study suggested that meropenem/vaborbactam compared favourably with best available therapy for the treatment of adults with infections due to confirmed/suspected CRE.			
Siponimod Mayzent SMC2265	ADVICE: following a full submission **siponimod (Mayent®)** is accepted for use within NHSScotland. Indication under review: treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity. In a randomised, double-blind, placebo-controlled phase III study, siponimod was associated with a reduction in disability progression confirmed after 3 months in patients with SPMS. 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.	12/10/2020	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/siponimod-mayzent-full-smc2265/	21/10/2020

NOVEMBER 2020				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Atezolizumab Tecentriq SMC2267	ADVICE: following a full submission assessed under the end of life and orphan medicine process **atezolizumab (Tecentriq®)** is accepted for use within NHSScotland. Indication under review: Atezolizumab in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have programmed death-ligand 1 [PD-L1] expression ≥1% and who have not received	09/11/2020	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/atezolizumab-tecentriq-full-smc2267/ *Atezolizumab 840mg concentrate for solution for infusion*	16/12/2020

	prior chemotherapy for metastatic disease. In a randomised, double-blind, phase III study, the addition of atezolizumab to nab-paclitaxel significantly improved progression-free survival and numerically improved overall survival in patients with locally advanced or metastatic triple-negative breast cancer with PD-L1 expression ≥1% who had not received prior chemotherapy for metastatic disease. 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 views from a Patient and Clinician Engagement (PACE) meeting.		*(Tecentriq) Roche Products Ltd SMC2267 - Due to comments from the company, minor amendments have been made to the Detailed Advice Document (DAD) for atezolizumab (Tecentriq), in combination with nab-paclitaxel, for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have programmed death-ligand 1 [PD-L1] expression ≥1% and who have not received prior chemotherapy for metastatic disease. The DAD will published on Monday 9 November 2020*	
Atezolizumab Tecentriq SMC2279	ADVICE: following a full submission assessed under the end of life and orphan medicine process **atezolizumab (Tecentriq®)** is accepted for use within NHSScotland. Indication under review: Atezolizumab, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). In one randomised, double-blind phase III study, the combination of atezolizumab with carboplatin and etoposide was associated with modest significant improvements in progression free survival and overall survival compared with chemotherapy alone in adult patients with untreated ES-SCLC. 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 views from a Patient and Clinician Engagement (PACE) meeting.	09/11/2020	Routinely available in line with national guidelines https://www.scottishmedicines.org.uk/medicines-advice/atezolizumab-tecentriq-full-smc2279/	16/12/2020
Darolutamide Nubeqa SMC2297	ADVICE: following a full submission **darolutamide (Nubeqa®)** is accepted for use within NHSScotland. Indication under review: Darolutamide is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease. In a phase III study in men with high risk nmCRPC, treatment with darolutamide was superior to placebo for metastasis-free survival. High risk was defined as prostate specific antigen (PSA) doubling time ≤10 months and PSA ≥2 nanograms/mL. Both groups received on-going androgen-deprivation therapy or had undergone bilateral orchiectomy. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-	09/11/2020	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/darolutamide-nubeqa-full-smc2297/	16/12/2020

	effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.			
Patiromer Veltassa SMC2264	ADVICE: following a resubmission **patiromer (Veltassa®)** is not recommended for use within NHSScotland. Indication under review: for the treatment of hyperkalaemia in adults. In a clinical study, patients with chronic kidney disease (CKD) and hyperkalaemia who were taking at least one renin angiotensin aldosterone system (RAAS) inhibitor, were treated with patiromer for four weeks. Patients who had responded to patiromer (with normalisation of serum potassium concentrations) were then randomised to either continue patiromer, or placebo. Patiromer treatment during this withdrawal phase was associated with a significant change in serum potassium concentrations after four weeks, when compared with placebo. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	09/11/2020	Not Recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/patiromer-veltassa-resub-smc2264/	16/12/2020
Romosozumab Evenity SMC2280	ADVICE: following a full submission **romosozumab (Evenity®)** is accepted for restricted use within NHSScotland. Indication under review: treatment of severe osteoporosis in postmenopausal women at high risk of fracture. SMC restriction: to use in patients who have experienced a fragility fracture and are at imminent risk of another fragility fracture (within 24 months). In a phase III study in post-menopausal women with osteoporosis who were at high risk of fracture, romosozumab for 12 months followed by an oral bisphosphanate reduced the risk of fractures compared with an oral bisphosphonate alone. 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.	09/11/2020	Approved for use in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/	16/12/2020
Trabectedin Yondelis SMC2283	ADVICE: following a resubmission assessed under the orphan and end of life process **trabectedin (Yondelis®)** is accepted for use within NHSScotland. Indication under review: Treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. Trabectedin, compared with an alkylating chemotherapy, increased progression-free survival but not overall survival in patients with advanced liposarcoma or	09/11/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/trabectedin-yondelis-resub-smc2283/	16/12/2020

	leiomyosarcoma who had previously been treated with an anthracycline-based 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. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.			
Trastuzumab emtansine Kadcyla SMC2298	ADVICE: following a full submission **trastuzumab emtansine (Kadcyla®)** is accepted for use within NHSScotland. Indication under review: As a single agent, for the adjuvant treatment of adult patients with human epidermal growth factor-2 (HER2) positive early breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2 targeted therapy. Trastuzumab emtansine was associated with a statistically significant improvement in invasive disease-free survival compared with a HER2 targeted agent in patients with HER2 positive early breast cancer with residual invasive disease in the breast and/or axillary lymph nodes after completion of neoadjuvant treatment containing a HER2 targeted agent. 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.	09/11/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/trastuzumab-emtansine-kadcyla-full-smc2298/	16/12/2020
Volanesorsen Waylivra SMC2299	The Scottish Medicines Consortium (SMC) has completed its initial assessment of the evidence for the above product using the ultra orphan framework: Indication under review: As an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate.	09/11/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/volanesorsen-sodium-waylivra-uo-pathway-smc2299/	16/12/2020

DECEMBER 2020

Medicine	Condition being treated	Date SMC Advice Published	NHS BORDERS decision	Date NHSB Decision
Avatrombopag Doptelet	ADVICE: following a full submission **avatrombopag (Doptelet®)** is accepted for use within NHSScotland. Indication under review: treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to	07/12/2020	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local	16/12/2020

SMC2296	undergo an invasive procedure. In two phase III studies in patients with severe thrombocytopenia with chronic liver disease who were scheduled to undergo an invasive procedure, avatrombopag was superior to placebo for the proportion of patients who did not require a platelet transfusion or any rescue procedure for bleeding after randomisation and up to 7 days following the procedure.		preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/avatrombopag-doptelet-full-smc2296/	
Bempedoic acid Nilemdo SMC2292	ADVICE: following a full submission **bempedoic acid (Nilemdo®)** is not recommended for use within NHSScotland. Indication under review: in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:• In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach 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. In four phase III studies, the percentage reduction in LDL-C to 12-weeks was significantly larger with bempedoic acid compared with placebo.The submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.	07/12/2020	Not Recommended for use within NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/bempedoic-acid-nilemdo-full-smc2292/	16/12/2020
Mexiletine Namuscla SMC2307	ADVICE: following a resubmission assessed under the orphan process **mexiletine (Namuscla®)** is accepted for use within NHSScotland. Indication under review: for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders. In a short-term, phase III, crossover study, mexiletine significantly improved muscle stiffness compared with placebo when measured on a visual analogue scale. 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.	07/12/2020	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/mexiletine-namuscla-resubmission-smc2307/	16/12/2020
Venetoclax Venclyxto SMC2293	ADVICE: following a full submission considered under the orphan equivalent process **venetoclax (Venclyxto®)** is accepted for restricted use within NHSScotland. Indication under review: In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). Venetoclax-obinutuzumab,	07/12/2020	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/venetoclax-venclyxto-full-smc2293/	16/12/2020

	compared with chlorambucil-obinutuzumab, significantly improved progression-free survival in adults with CLL and co-morbidities. SMC restriction: for use in (1) patients without del (17p)/TP53 mutation who are not fit to receive FCR (fludarabine, cyclophosphamide and rituximab) chemo-immunotherapy and (2) patients with del (17p)/TP53 mutation. 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.			

JANUARY 2021				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Apalutamide Erleada SMC2323	ADVICE: in the absence of a submission from the holder of the marketing authorisation **apalutamide (Erleada®)** is not recommended for use within NHSScotland. Indication under review: in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy. 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.	18/01/2021	Not Recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/apalutamide-erleada-nonsub-smc2323/	24/02/2021
Brentuximab vedotin Adcetris SMC2310	ADVICE: following a full submission **brentuximab vedotin (Adcetris®)** is accepted for use within NHSScotland. Indication under review: in combination with cyclophosphamide, doxorubicin and prednisone (CHP) for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL). 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.	18/01/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/brentuximab-vedotin-adcetris-full-smc2310/	24/02/2021

Brigatinib Alunbrig SMC2314	ADVICE: following an abbreviated submission **brigatinib (Alunbrig®)** is accepted for use within NHSScotland. Indication under review: 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. 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.	18/01/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/brigatinib-alunbrig-abb-smc2314/	24/02/2021
Daratumumab Darzalex SMC2302	ADVICE: following a full submission assessed under the orphan medicine process **daratumumab (Darzalex®)** is accepted for use within NHSScotland. Indication under review: 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. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	18/01/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicine https://www.scottishmedicines.org.uk/medicines-advice/daratumumab-darzalex-full-smc2302/	24/02/2021
Daratumumab Darzalex SMC2326	ADVICE: following an abbreviated submission **daratumumab subcutaneous injection (Darzalex®)** is accepted for use within NHSScotland. Indication under review: 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. 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	18/01/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/daratumumab-darzalex-abb-smc2326/	24/02/2021

	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 SMC2324	ADVICE: in the absence of a submission from the holder of the marketing authorisation **dupilumab (Dupixent®)** is not recommended for use within NHSScotland. Indication under review: 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. 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.	18/01/2021	Not recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/dupilumab-dupixent-nonsub-smc2324/	24/02/2021
Entrectinib Rozlytrek SMC2294	ADVICE: following a full submission considered under the orphan equivalent process **entrectinib (Rozlytrek®)** is accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors. 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.	18/01/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/entrectinib-rozlytrek-full-smc2294/	24/02/2021
Fostamatinib Tavlesse SMC2300	ADVICE: following a full submission considered under the orphan equivalent process: **fostamatinib (Tavlesse®)** is accepted for restricted use within NHSScotland. Indication under review: treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. 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	18/01/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/fostamatinib-tavlesse-full-smc2300/	24/02/2021

	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 Slenyto SMC2306	ADVICE: following a resubmission **melatonin prolonged-release (Slenyto®)** is not recommended for use within NHSScotland. Indication under review: 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. 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.	18/01/2021	Not Recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/melatonin-slenyto-resubmission-smc2306/	24/02/2021
Secukinumab Cosentyx SMC2308	ADVICE: following a full submission **secukinumab (Cosentyx ®)** is accepted for use within NHSScotland. Indication under review: 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. 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.	18/01/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/secukinumab-cosentyx-full-smc2308/	24/02/2021
Talazoparib Talzenna	ADVICE: in the absence of a submission from the holder of the marketing authorisation **talazoparib (Talzenna®)** is not recommended for use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with germline BRCA1/2 mutations, who have	18/01/2021	Not Recommended for use in NHS Scotland – not routinely available for use https://www.scottishmedicines.org.uk/medicines-advice/talazoparib-talzenna-nonsub-smc2325/	24/02/2021

SMC2325	HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo) adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy. 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.			

FEBRUARY 2021				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Alpelisib Piqray SMC2339	ADVICE: in the absence of a submission from the holder of the marketing authorisation **aplelisib (Piqray®)** is not recommended for use within NHSScotland. Indication under review: in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine therapy as monotherapy. 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.	08/02/2021	Not Recommended for use in NHS Scotland – not routinely available for use https://www.scottishmedicines.org.uk/medicines-advice/alpelisib-piqray-nonsub-smc2339/	24/02/2021
Apremilast Otezla SMC2340	ADVICE: in the absence of a submission from the holder of the marketing authorisation **apremilast (Otezla®)** is not recommended for use within NHSScotland. Indication under review: Treatment of adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy. 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.	08/02/2021	Not Recommended for use in NHS Scotland – not routinely available for use https://www.scottishmedicines.org.uk/medicines-advice/apremilast-otezla-nonsub-smc2340/	24/02/2021
Buprenorphine/ naloxone	ADVICE: following an abbreviated submission **buprenorphine/naloxone sublingual film (Suboxone®)** is	08/02/2021	Not routinely available as local clinical experts do not wish to add the medicine to	24/02/2021

Suboxone SMC2316	accepted for restricted use within NHSScotland. Indication under review: substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Buprenorphine/ naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction. SMC restriction: to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate. Buprenorphine/naloxone sublingual film (Suboxone®) and buprenorphine/naloxone sublingual tablets (Suboxone®) deliver similar plasma concentrations of buprenorphine but are not bioequivalent. Please refer to the relevant Summary of Product Characteristics for further detail, including guidance on switching between formulations. Generic buprenorphine sublingual tablets are available at lower cost. 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.		the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/buprenorphinenaloxone-suboxone-abb-smc2316/	
Formoterol fumarate dihydrate / glycopyrronium bromide / budesonide Trixeo Aerosphere SMC2321	ADVICE: following an abbreviated submission **formoterol fumarate dihydrate / glycopyrronium bromide / budesonide (Trixeo® Aerosphere)** is accepted for restricted use within NHSScotland. Indication under review: maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. SMC restriction: in patients with severe COPD (forced expiratory volume in one second [FEV1] less than 50% predicted normal). Formoterol fumarate dihydrate / glycopyrronium bromide / budesonide (Trixeo® Aerosphere) offers an additional treatment choice of long-acting beta2-agonist (LABA), long-acting muscarinic antagonist (LAMA) and inhaled corticosteroid (ICS) in a single inhaler.	08/02/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/formoterol-fumarate-dihydrateglycopyrroniumbudesonide-trixeo-aerosphere-abb-smc2321/	24/02/2021
Glasdegib Daurismo	ADVICE: in the absence of a submission from the holder of the marketing authorisation **glasdegib (Daurismo®)** is not recommended for use within NHSScotland. Indication under review: In combination with low-dose cytarabine, for the treatment of newly diagnosed de novo or secondary acute myeloid leukaemia (AML) in adult patients who	08/02/2021	Not Recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/glasdegib-daurismo-nonsub-smc2341/	24/02/2021

SMC2341	are not candidates for standard induction chemotherapy. 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.			
Imipenem/cilastatin /relabactam Recarbrio SMC2342	ADVICE: in the absence of a submission from the holder of the marketing authorisation **imipenem/cilastatin/relabactam (Recarbrio®)** is not recommended for use within NHSScotland. Indication under review: Treatment of: • hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults. • bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults. 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.	08/02/2021	Not Recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/imipenemcilastatinrelabactam-recarbrio-nonsub-smc2342/	24/02/2021
Leuprorelin acetate Prostap DCS Early Breast Cancer SMC2319	ADVICE: following an abbreviated submission **leuprorelin acetate (Prostap®)** is accepted for use within NHSScotland. Indication under review: as adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in pre- and perimenopausal women at higher risk of disease recurrence (young age, high grade tumour, lymph node involvement). In women who have received chemotherapy, premenopausal status must be confirmed after completion of chemotherapy. Leuprorelin offers an additional treatment choice in the therapeutic class of gonadotropin-releasing hormone (GnRH) analogues for this indication.	08/02/2021	Routinely available in line with national guidance. https://www.scottishmedicines.org.uk/medicines-advice/leuprorelin-acetate-prostap-dcs-abb-smc2319/	24/02/2021
Leuprorelin acetate Prostap DCS Advanced Breast Cancer SMC2320	ADVICE: following an abbreviated submission **leuprorelin acetate (Prostap®)** is accepted for use within NHSScotland. Indication under review: as treatment in pre- and perimenopausal women with advanced breast cancer suitable for hormonal manipulation. Leuprorelin offers an additional treatment choice in the therapeutic class of gonadotropin-releasing hormone (GnRH) analogues for this indication.	08/02/2021	Routinely available in line with national guidance. https://www.scottishmedicines.org.uk/medicines-advice/leuprorelin-acetate-prostap-dcs-abb-smc2320/	24/02/2021
Mercaptamine Cystadrops SMC2343	ADVICE: in the absence of a submission from the holder of the marketing authorisation **mercaptamine (Cystadrops®)** is not recommended for use within NHSScotland. Indication under review: Treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this	08/02/2021	Not Recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/mercaptamine-cystadrops-nonsub-smc2343/	24/02/2021

	indication. As a result we cannot recommend its use within NHSScotland.			
Omalizumab syringe Xolair SMC2344	ADVICE: in the absence of a submission from the holder of the marketing authorisation **omalizumab (Xolair®)** is not recommended for use within NHSScotland. Indication under review: As add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control. 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.	08/02/2021	Not Recommended for use in NHS Scotland – not routinely available https://www.scottishmedicines.org.uk/medicines-advice/omalizumab-xolair-nonsub-smc2344/	24/02/2021
Ozanimod Zeposia SMC2309	ADVICE: following a full submission **ozanimod (Zeposia®)** is accepted for restricted use within NHSScotland. Indication under review: treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features. SMC restriction: suitable for or requesting an oral treatment. In two phase III studies, ozanimod demonstrated a significantly greater reduction in annualised relapse rate compared with another disease-modifying treatment in patients with relapsing forms of multiple sclerosis. 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.	08/02/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/ozanimod-zeposia-full-smc2309/ *Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia®), for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features. The DAD will published on Monday 8 February 2021.*	24/02/2021
Ravulizumab Ultomiris SMC2305	ADVICE: following a full submission under the orphan equivalent medicine process **ravulizumab (Ultomiris®)** is accepted for restricted use within NHSScotland. Indication under review: for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH):• In patients with haemolysis with clinical symptom(s) indicative of high disease activity; • In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months. SMC restriction: under the advice of the national PNH service. In two open-label, randomised, phase III studies, ravulizumab was non-inferior to another complement inhibitor across a range of relevant outcomes assessing the control of haemolysis. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-	08/02/2021	Awaiting decision from tertiary centre https://www.scottishmedicines.org.uk/medicines-advice/ravulizumab-ultomiris-full-smc2305/ *Due to comments from the company, minor amendments have been made to the Detailed Advice Document for ravulizumab (Ultomiris), for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH): • In patients with haemolysis with clinical symptom(s) indicative of high disease activity; • In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months. The DAD will published on Monday 08*	24/02/2021

	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.		*February 2021.*	
Upadacitinib Rinvoq SMC2315	ADVICE: following a full submission **upadacitinib (Rinvoq®)** is accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Upadacitinib may be used as monotherapy or in combination with methotrexate. SMC restriction: in patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF antagonist in whom rituximab is not appropriate. Upadacitinib (with or without methotrexate) compared with placebo, significantly improved signs and symptoms of RA in patients with an inadequate response to conventional DMARDs and in patients with an inadequate response to biological DMARDs. Upadacitinib was non-inferior to a biologic DMARD in patients who had an inadequate response to methotrexate. 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.	08/02/2021	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines https://www.scottishmedicines.org.uk/medicines-advice/upadacitinib-rinvoq-full-smc2315/	24/02/2021

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Medicine	Condition being treated	Date SMC Advice Published	NHS BORDERS decision	Date NHSB Decision
Beclometasone Trimbow SMC2335	ADVICE: following an abbreviated submission **beclometasone dipropionate, formoterol fumarate dihydrate, glycopyrronium (Trimbow®)** is accepted for use within NHSScotland. Indication under review: maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year. Beclometasone	08/03/2021	Available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/beclometasone-dipropionateformoterol-fumarate-dehydrateglycopyrronium-bromide-trimbow-abb-smc2335/	28/04/2021

	dipropionate / formoterol fumarate dihydrate / glycopyrronium (Trimbow®) offers an additional treatment choice of medium 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.			
Doravirine Pifeltro SMC2332	ADVICE: following an abbreviated submission **doravirine (Pifeltro®)** is accepted for use within NHSScotland. Indication under review: in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class. Doravirine offers an additional treatment choice in the therapeutic class of NNRTIs 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.	08/03/2021	No decision currently (May 2021) https://www.scottishmedicines.org.uk/medicines-advice/doravirine-pifeltro-abb-smc2332/	28/04/2021
Doravirine Delstrigo SMC2333	ADVICE: following an abbreviated submission **doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®)** is accepted for use within NHSScotland. Indication under review: for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir. Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) offers an additional treatment choice of NNRTI-based single-tablet regimen 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.	08/03/2021	No decision currently (May 2021) https://www.scottishmedicines.org.uk/medicines-advice/doravirinelamivudinetenofovir-disoproxil-fumarate-delstrigo-abb-smc2333/	28/04/2021
Entrectinib Rozlytrek SMC2295	ADVICE: following a full submission considered under the end of life and orphan equivalent process: **entrectinib (Rozlytrek ®)** is accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, • who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and • who have not received a prior NTRK inhibitor; • who have no satisfactory treatment options. In	08/03/2021	Not routinely available as local clinical experts do not wish to add to the formulary at this time or there is a local preference for alternative medicines. https://www.scottishmedicines.org.uk/medicines-advice/entrectinib-rozlytrek-full-smc2295/ *Note: The Scottish Genetic Laboratory Consortium (SGLC) laboratories are presently only able to deliver around 3% of the NTRK testing required for patients in*	28/04/2021

	a pooled analysis of three phase I/II studies in adults with metastatic or locally advanced NTRK fusion-positive solid tumours, 64% of patients achieved an objective response with entrectinib treatment. The median duration of response in these patients was 12.9 months. Positive objective response rate results were also reported in a phase I/Ib paediatric study. 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.		*Scotland. Without additional funding, the Consortium laboratories will not be able to increase capacity to deliver the level of NTRK testing required. On behalf of the SGLC, NSD service commissioners has submitted a case for funding for a cancer testing strategy as part of the New Action Plan for the recovery and redesign of cancer care (The Cancer Recovery Plan) which includes NTRK gene fusion testing.*	
Onasemnogene abeparvovec Zolgensma SMC2311	ADVICE: following a full submission assessed under the orphan medicine process **onasemnogene abeparvovec (Zolgensma®)** is accepted for restricted use within NHSScotland. Indication under review: treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene. SMC restriction: for the treatment of - patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or - pre-symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene, where patients are expected to develop SMA type 1. In a phase III study of patients with symptomatic SMA type 1 treated with onasemnogene abeparvovec, survival was significantly better than a historical control cohort. In addition, motor milestones achieved generally exceeded the natural history of SMA type 1. 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.	08/03/2021	Not routinely available as local clinical experts do not wish to add to the formulary at this time or there is a local preference for alternative medicines. https://www.scottishmedicines.org.uk/medicines-advice/onasemnogene-abeparvovec-zolgensma-full-smc2311/	28/04/2021
Trametinib Mekinist SMC2328	ADVICE: following an abbreviated submission **trametinib (Mekinist®)** is accepted for restricted use within NHSScotland. Indication under review: in combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. SMC restriction: after first line treatment. Trametinib in combination with dabrafenib	08/03/2021	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/trametinib-mekinist-abb-smc2328/	28/04/2021

	offers an additional treatment choice in the therapeutic class of BRAF/ mitogen-activated extracellular signal-regulated kinase (MEK) inhibitors. Another medicine combination within this therapeutic class has been accepted via the end of life and 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. SMC has previously accepted trametinib for restricted use in combination with dabrafenib for first-line treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation (SMC 1161/16). The current advice now extends use after first line treatment. Trametinib is also licensed as monotherapy. As the company submission related only to combination therapy, SMC cannot recommend use as monotherapy.			