NHS Borders: New Medicines Decisions APRIL 2017 – MARCH 2018

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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 2017				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Daclizumab Zinbryta 1216/17	Advice following a full submission, **Daclizumab (Zinbryta®)** is accepted for restricted use within NHS Scotland. Indication under review: In adult patients for the treatment of relapsing forms of multiple sclerosis. Restriction: for use : • in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or • in patients with RRMS with an inadequate response to disease modifying therapy. In a phase III study, the adjusted annualised relapse rate (over a period of 144 weeks) was statistically significantly lower for daclizumab than for an interferon beta treatment in patients with RRMS. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of daclizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	10.04.2017	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 *(October2017)* http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1216_17_daclizumab_Zinbryta/daclizumab_Zinbryta	12.04.2017
Emtricitabine/ Tenofovir disoproxil Truvada 1225/17	Advice following a full submission **Emtricitabine/Tenofovir disoproxil (Truvada®)** is accepted for use within NHS Scotland. Indication under review: In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. In the pivotal studies conducted in men who have sex with men (iPrEx) and heterosexual couples, one of whom was HIV negative (Partners PrEP), there were statistically significant relative reductions in incidence of HIV for emtricitabine/tenofovir disoproxil compared with placebo.	10.04.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1225_17_emtricitabine_tenofovir_disoproxil_Truvada/emtricitabine_tenofovir_disoproxil_Truvada	12.04.2017
Ibrutinib Imbruvica 1151/16	Advice following a resubmission assessed under the end of life and orphan medicine process **Ibrutinib (Imbruvica®)** is accepted for restricted use within NHS Scotland. Indication under review: the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. SMC restriction: patients with relapsed/refractory CLL and for whom fludarabine-based regimens are inappropriate. In an open-label, phase III study, ibrutinib significantly increased progression-free survival compared with an anti-CD20 antibody in patients with relapsed or refractory CLL. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib. This advice is contingent upon the	10.04.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1151_16_ibrutinib_Imbruvica_CLL/ibrutinib_Imbruvica_CLL_Resub	12.04.2017

	continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. This resubmission relates to use as a single agent for the treatment of adult patients with CLL who have received at least one prior therapy. SMC published advice in August 2016 that ibrutinib was accepted for restricted use as a single agent for patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy (SMC 1151/16).			
Insulin aspart Fiasp 1227/17	Advice following an abbreviated submission **Insulin aspart (Fiasp®)** is accepted for use within NHS Scotland. Indication under review: treatment of diabetes mellitus in adults. Insulin aspart (Fiasp®) is a new formulation with a faster onset of action than another formulation of insulin aspart and is available at an equivalent cost.	10.04.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1227_17_insulin_aspart_Fiasp/insulin_aspart_Fiasp	12.04.2017
Ixekizumab Taltz 1223/17	Advice following a full submission **Ixekizumab (Taltz®)** is accepted for restricted use within NHS Scotland. Indication under review: moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: patients who have failed to respond to standard systemic therapies, are intolerant to, or have a contra-indication to these treatments and including patients who have failed on one or more tumour necrosis factor (TNF) antagonists. Ixekizumab was superior to placebo and to a TNF antagonist for improving symptoms of adults with moderate to severe plaque psoriasis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ixekizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	10.04.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1223_17_ixekizumab_Taltz/ixekizumab_Taltz	12.04.2017
Nepafenac Nevanac 1228/17	Advice following an abbreviated submission **Nepafenac (Nevanac®)** 3mg/mL eye drops are accepted for use within NHS Scotland. Indication under review: reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. Nepafenac 3mg/mL eye drops provide a once daily alternative to nepafenac 1mg/mL eye drops (administered three times daily). The cost of a course of treatment is the same for both formulations. Nepafenac 3mg/mL is also licensed for the prevention and treatment of postoperative pain and inflammation associated with cataract surgery. The company submission related only to reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. SMC cannot recommend the use of nepafenac eye drops for	10.04.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1228_17_nepafenac_Nevanac/nepafenac_Nevenac_Abbreviated	12.04.2017

	postoperative pain and inflammation associated with cataract surgery.			
Ofatumumab Arzerra® 1237/17	Advice in the absence of a submission from the holder of the marketing authorisation **Ofatumumab 100mg & 1000mg concentrate for solution for infusion (Arzerra®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of adult patients with relapsed CLL in combination with fludarabine and cyclosphosphamide. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.	10.04.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1237_17_ofatumumab_Arzerra/ofatumumab_Arzerra	12.04.2017
Tenofovir alafenamide Vemlidy® 1238/17	Advice in the absence of a submission from the holder of the marketing authorisation **Tenofovir alafenamide 25mg film-coated tablets (Vemlidy)®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg). 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.	10.04.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1238_tenofovir_alafenamide_Vemlidy/tenofovir_alafenamide_Vemlidy	12.04.2017
Ticagrelor Brilique 1224/17	Advice following a full submission **Ticagrelor 60mg film-coated tablets (Brilique®)** is not recommended for use within NHS Scotland. Indication under review: co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with a history of myocardial infarction and a high risk of developing an atherothrombotic event. A large, phase 3, randomised, double-blind study in a high risk population who had suffered a myocardial infarction in the previous one to three years demonstrated that the addition of ticagrelor to aspirin significantly reduced the risk of ischaemic events (a composite of cardiovascular death, myocardial infarction and stroke). The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	10.04.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1224_17_ticagrelor_Brilique/ticagrelor_Brilique	12.04.2017
Trastuzumab emtansine Kadcyla 990/14	Advice following a resubmission assessed under the orphan equivalent and end of life process **Trastuzumab emtansine (Kadcyla ®)** is accepted for use within NHS Scotland. Indication under review: as a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic	10.04.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/990_14_trastuzumab_emtansine_Kadcyla/trastuzuma	12.04.2017

	breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for locally advanced or metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy. In a randomised phase III open-label study, trastuzumab emtansine (Kadcyla®) conferred a significant survival benefit compared with an active comparator. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of trastuzumab emtansine (Kadcyla®). This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.		b_emtansine_Kadcyla_Re-sub	

MAY 2017				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Alectinib hydrochloride Alecensa® 1223/17	Advice in the absence of a submission from the holder of the marketing authorisation **alectinib hydrochloride (Alecensa®)** is not recommended for use within NHS Scotland. Indication under review: As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib. 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.	08.05.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1223_17_ixekizumab_Taltz/ixekizumab_Taltz	10.05.2017
Belimumab Benlysta 775/12	Advice following a resubmission **belimumab (Benlysta®)** is accepted for restricted use within NHS Scotland. Indication under review: Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. SMC restriction: patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10. Belimumab, in addition to standard of care, modestly improved disease control in patients with SLE in two phase III studies. This SMC advice takes	08.05.2017	May be routinely available from a specialist centre in another NHS board http://www.scottishmedicines.org.uk/SMC_Advice/Advice/775_12_belimumab_Benlysta/belimumab_Benlysta_Resub	10.05.2017

	account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of belimumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
Idebenone Raxone 1226/17	Advice following a full submission assessed under the ultra-orphan medicine process **idebenone (Raxone®)** is accepted for restricted use within NHS Scotland. Indication under review: Treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). SMC restriction: to patients with LHON who are not yet blind i.e. they do not meet the UK criteria to be registered as severely sight impaired. In a 24-week double-masked randomised placebo-controlled study, patients who received idebenone had numerical improvements in visual acuity over placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idebenone. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	08.05.2017	Local specialists advise that it is unlikely that this product would be prescribed in NHS Borders, but it would then be available in line with national guidance (link to SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1226_17_idebenone_Raxone/idebenone_Raxone	10.05.2017
Liraglutide 6mg/mL solution for injection in pre-filled pen Saxenda® 1247/17	Advice in the absence of a submission from the holder of the marketing authorisation **liraglutide (Saxenda®)** is not recommended for use within NHS Scotland. Indication under review: as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index of • ≥ 30kg/m² (obese), or • ≥ 27kg/m² to < 30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. 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.	08.05.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1247_17_liraglutide_Saxenda/liraglutide_Saxenda_Non_Sub	10.05.2017
Mircronised progesterone Utrogestan 935/13	Advice following a full submission **micronised progesterone (Utrogestan®)** is accepted for use within NHS Scotland. Indication under review: in women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles. In women receiving luteal support during ART cycles, micronised progesterone 200mg vaginal capsules administered three times daily were non-inferior to another progesterone preparation administered vaginally with respect to ongoing pregnancy rate at the end of the 12th week of gestation.	08.05.2017	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/935_13_micronized_progesterone_Utrogestan/micronised_progesterone_Utrogestan_Vaginal_Full	10.05.2017

	This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of progesterone (Utrogestan®) 200mg vaginal tablets. This advice is contingent on the continuing availability of the PAS in Scotland or a list price that is equivalent or lower.			
Nepafenac Nevanac 1228/17	Advice following an abbreviated submission **Nepafenac (Nevanac®)** 3mg/mL eye drops are accepted for use within NHS Scotland. Indication under review: reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. Nepafenac 3mg/mL eye drops provide a once daily alternative to nepafenac 1mg/mL eye drops (administered three times daily). The cost of a course of treatment is the same for both formulations. Nepafenac 3mg/mL is also licensed for the prevention and treatment of postoperative pain and inflammation associated with cataract surgery. The company submission related only to reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. SMC cannot recommend the use of nepafenac eye drops for postoperative pain and inflammation associated with cataract surgery.	08.05.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1228_17_nepafenac_Nevanac/nepafenac_Nevenac_Abbreviated	10.05.2017
Talimogene laherparepvec 106 and 108 plaque forming units (PFU)/mL solution for injection Imlygic® 1248/17	Advice in the absence of a submission from the holder of the marketing authorisation **talimogene laherparepvec (Imlygic®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease. 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.	08.05.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1248_17_talimogene_laherparepvec_Imlygic/talimogene_laherparepvec_Imlygic_Non_Sub	10.05.2017

JUNE 2017				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Adalimumab Humira 1243/17	Advice following an abbreviated submission **Adalimumab (Humira®)** is accepted for use within NHS Scotland. Indication under review: treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy. SMC has previously accepted adalimumab	12.06.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1243_17_adalimumab_Humira/adalimumab_Humira_	14.06.2017

	for the treatment of active moderate to severe HS (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.		Abbreviated	
Aprepitant Emend 1241/17	Advice following a full submission **Aprepitant (Emend®)** is accepted for use within NHS Scotland. Indication under review: As part of combination therapy, for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in infants, toddlers and children from the age of six months to less than 12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules). Aprepitant is given as part of combination therapy. A randomised, double-blind, placebo-controlled study demonstrated that the addition of aprepitant to a 5HT3 receptor antagonist (+/- steroid) in children and adolescents receiving chemotherapy with a moderate to very high emetogenic risk produced a significant anti-emetic benefit.	12.06.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1241_17_aprepitant_Emend/aprepitant_Emend	14.06.2017
Budesonide-formoterol Symbicort SMART 1244/17	Advice following an abbreviated submission **Budesonide/ formoterol (Symbicort® SMART®)** is accepted for use within NHS Scotland. Indication under review: the regular treatment of asthma where use of a combination (inhaled corticosteroid and a long-acting β2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" short-acting β2 adrenoceptor agonists, or patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists. This advice relates to the extension of the license for Symbicort maintenance and reliever therapy (SMART®) to adolescents aged 12 to <18 years. SMC has previously accepted Symbicort maintenance and reliever therapy (SMART®) in adults.	12.06.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1244_17_budesonide_formoterol_Symbicort_SMART/budesonide_formoterol_Symbicort_SMART	14.06.2017
Buprenorphine oral lyophilisate Espranor 1245/17	Advice following an abbreviated submission **Buprenorphine oral lyophilisate (Espranor®)** is accepted for restricted use within NHS Scotland. Indication under review: Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction. SMC restriction: to patients in whom methadone is not suitable. Buprenorphine oral lyophilisate provides an alternative to buprenorphine/naloxone sublingual (SL) tablets at reduced cost. The oral lyophilisate formulation has the advantage of a faster dissolution time. Prescribers should be aware that available buprenorphine preparations are not interchangeable. Generic	12.06.2017	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1245_17_buprenorphine_oral_lyophilisate_Espranor_Abbreviated/buprenorphine_oral_lyophilisate_Espranor_Abbreviated	14.06.2017

	buprenorphine SL tablets are available at lower cost. This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improves the cost effectiveness of buprenorphine oral lyophilisate. This advice is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower.			
Cabozantinib Cabometyx 1234/17	Advice following a full submission assessed under the end of life process **Cabozantinib (Cabometyx®)** is accepted for use within NHS Scotland. Indication under review: For the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy. Cabozantinib, compared with a mammalian target of rapamycin (mTOR) inhibitor, significantly increased progression-free survival in patients with advanced or metastatic RCC who had received at least one previous regimen of VEGF receptor tyrosine kinase inhibitor. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cabozantinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	12.06.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1234_17_cabozantinib_Cabometyx/cabozantinib_Cabometyx	14.06.2017
Deferasirox Exjade 1246/17	Advice following an abbreviated submission **Deferasirox film-coated tablets (Exjade®)** is accepted for restricted use within NHS Scotland. Indication under review: • Treatment of chronic iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. • Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups: o in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) aged 2 to 5 years, o in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7mL/kg/month of packed red blood cells) aged 2 years and older, o in adult and paediatric patients with other anaemias aged 2 years and older. SMC restriction: deferasirox film-coated tablets are restricted to	12.06.2017	Routinely available in line with national guidance *Following a comment from the service, a minor amendment has been made to the advice document for **deferasirox (Exjade)** for the treatment of chronic iron overload due to frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older and the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate. The DAD will be published on the SMC website on Monday 12 June.* *http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1246_17_deferasirox_Exjade/deferasirox_Exjade_Abbreviated*	14.06.2017

	use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07). Deferasirox film-coated tablets will replace deferasirox dispersible tablets which are to be discontinued. Deferasirox film-coated tablets demonstrated higher bioavailability compared to the deferasirox dispersible tablet formulation and therefore a dose adjustment is required when switching from dispersible tablets to film-coated tablets. Deferasirox film-coated tablets cannot be accepted for use in treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older as a full submission has not been received by SMC for this indication.			
Ibrutinib Imbruvica® 140mg hard capsules 1258/17	Advice in the absence of a submission from the holder of the marketing authorisation **Ibrutinib (Imbruvica®)** is not recommended for use within NHS Scotland. Indication under review: In combination with bendamustine and rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.	12.06.2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1258_17_ibrutinib_Imbruvica/ibrutinib_Imbruvica_Non-submission	14.06.2017
Nivolumab Opdivo 1188/16	Advice following a resubmission assessed under the end of life and orphan medicine process **Nivolumab (Opdivo®)** is accepted for use within NHS Scotland. Indication under review: As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults. Nivolumab, compared with a mammalian target of rapamycin (mTOR) inhibitor, significantly increased overall survival in patients with advanced or metastatic renal cell carcinoma who had received one or two previous regimens of anti-angiogenic therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	12.06.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1188_16_nivolumab_Opdivo_for_renal_cell_carcinoma/nivolumab_Opdivo_Resubmission	14.06.2017
Obeticholic acid Ocaliva 1232/17	Advice following a full submission assessed under the orphan medicine process **Obeticholic acid (Ocaliva®)** is accepted for use within NHS Scotland. Indication under review: primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate	12.06.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1232_17_obeticholic_acid_Ocaliva/obeticholic_acid_Ocaliva	14.06.2017

	ursodeoxycholic acid. In a randomised, double-blind, phase III study of patients with early stage primary biliary cholangitis and poor response or intolerance to ursodeoxycholic acid, treatment with obeticholic acid (+/- concomitant ursodeoxycholic acid) was associated with a greater biochemical response rate at 12 months when compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of obeticholic acid. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.			
Pertuzumab Perjeta 897/13	Advice following a second resubmission assessed under the orphan medicine process **Pertuzumab (Perjeta®)** is not recommended for use within NHS Scotland. Indication under review: for use in combination with trastuzumab and 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. Addition of pertuzumab to current first-line treatment, trastuzumab plus docetaxel, significantly increased progression-free and overall survival for women with HER2-positive metastatic breast cancer. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	12.06.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/897_13_pertuzumab_Perjeta/pertuzumab_Perjeta_2nd_Resubmission	14.06.2017
Safinamide Xadago® 50mg/100mg film-coated tablets 1259/17	Advice in the absence of a submission from the holder of the marketing authorisation **Safinamide (Xadago®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients. 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.	12.06.2017	Not routinely available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1259_17_safinamide_Xadago/safinamide_Xadago_Non-submission	14.06.2017

JULY 2017				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Aprepitant Emend 1252/17	Advice following an abbreviated submission **Aprepitant (Emend®)** is accepted for use within NHS Scotland. Indication under review: As part of combination therapy, for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy in children, toddlers and infants from the age of six months to <12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules). SMC has previously accepted aprepitant for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy in adults. The marketing authorisation has since been extended to cover prevention of nausea and vomiting in adults associated with highly emetogenic non-cisplatin based chemotherapy. SMC does not plan to assess this minor licence extension.	10/07/2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1252_17_aprepitant_Emend_Abbreviated/aprepitant_Emend	12.07.2017
Ciprofloxacin 3mg/mL/ dexamethasone 1mg/mL ear drops Cilodex 1256/17	Advice following an abbreviated submission **ciprofloxacin +dexamethasone (Cilodex®)** is accepted for restricted use within NHS Scotland. Indication under review: Treatment of the following infections in adults and children: Acute otitis media in patients with tympanostomy tubes (AOMT) ; Acute otitis externa SMC restriction: Treatment of acute otitis media in patients with tympanostomy tubes (AOMT). Cilodex® provides a licensed alternative to "off-label" use of ciprofloxacin and dexamethasone eye drops in the treatment of AOMT and is available at an equivalent cost.	10/07/2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1256_17ciprofloxacin_3mg_mL_dexamethasone_1mg_mL_ear_drops_Cilodex/ciprofloxacin_3mg_mL_dexamethasone_1mg_mL_ear_drops_Cilodex	12.07.2017
Dolutegravir Tivicay® 1253/17	Advice following an abbreviated submission **Dolutegravir (Tivicay®)** is accepted for use within NHS Scotland. Indication under review: in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected children aged >6 to 12 years of age. SMC has previously accepted dolutegravir 50mg film-coated tablets for use in combination with other anti-retroviral medicinal products for the treatment of HIV infected adults and adolescents above 12 years of age. This SMC advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of dolutegravir. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is	10/07/2017	Routinely available in line with national guidance (link to SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1253_17_dolutegravir_Tivicay/dolutegravir_Tivicay	12.07.2017

	equivalent or lower.			
Emtricitabine / tenofovir disoproxil 200mg/245mg film-coated tablets Truvada® 1263/17	Advice in the absence of a submission from the holder of the marketing authorisation **Emtricitabine / tenofovir disoproxil (Truvada®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of HIV-1 infected adolescents aged 12 to <18 years with nucleoside reverse transcriptase inhibitor resistance or toxicities precluding the use of first line agents. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.	10/07/2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1263_17_emtricitabine_tenofovir_disoproxil_200mg_245mg_film_coated_tablets_Truvada/emtricitabine_tenofovir_disoproxil_200mg_245mg_film_coated_tablets_Truvada	12.07.2017
Glycopyrronium bromide Sialanar 1254/17	Advice following an abbreviated submission **Glycopyrronium (Sialanar®)** is accepted for use within NHS Scotland. Indication under review: symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. The availability of glycopyrronium (Sialanar®) provides a licensed alternative to an existing generic preparation used outwith the terms of its marketing authorisation, at a small additional cost.	10/07/2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1254_17_glycopyrronium_bromide_Sialanar/glycopyrronium_bromide_Sialanar	12.07.2017
Nivolumab Opdivo 1240/17	Advice following a full submission assessed under the end of life and ultra-orphan process **Nivolumab (Opdivo®)** is accepted for use within NHS Scotland. Indication under review: the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin. In an open-label, single-arm study, a clinically meaningful objective response rate was achieved in patients with relapsed or refractory cHL treated with nivolumab. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of nivolumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	10/07/2017	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 *Nov 17* http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1240_17_nivolumab_Opdivo_for_cHL/nivolumab_Opdivo_for_cHL	12.07.2017
Pembrolizumab Keytruda 1239/17	Advice following a full submission assessed under the end of life and orphan equivalent process **Pembrolizumab (Keytruda®)** is accepted for restricted use within NHS Scotland. Indication under review: As monotherapy for the first-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) with a ≥50% tumour proportion score (TPS) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) positive tumour mutations. SMC	10/07/2017 Amended Advice 07/08/2017 published 10/07/2017	Routinely available in line with national guidance *Please Note: The Scottish Pathology Network has facilitated PD-L1 testing in NHS Scotland. Requests should be directed to labs in Glasgow, Edinburgh or Aberdeen.* http://www.scottishmedicines.org.uk/SMC_Advice/Advic	12.07.2017

	restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a randomised, open-label, phase III study, treatment with pembrolizumab provided an additional 4.3 months of progression free survival compared to standard of care. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.		e/1239_17_pembrolizumab_Keytruda/pembrolizumab_Keytruda	
Saxagliptin/ dapagliflozin fixed dose combination Qtern 1255/17	Advice following an abbreviated submission **Saxagliptin/ dapagliflozin 5mg/10mg (Qtern®)** is accepted for restricted use within NHS Scotland. Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus: • to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of Qtern® do not provide adequate glycaemic control, • when already being treated with the free combination of dapagliflozin and saxagliptin. SMC restriction: for use in combination with metformin when the use of a sulphonylurea is inappropriate. In patients for whom this combination is appropriate, saxagliptin/dapagliflozin (Qtern [offers a single tablet at a lower cost per dose compared with the individual components. The marketing authorisation for saxagliptin currently specifies the medicines that may be given concomitantly but is to be amended to 'use in combination with other diabetes medicines'. It is anticipated that this licence change will be outwith SMC remit.	10/07/2017	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) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1255_17_saxagliptin_dapagliflozin_fixed_dose_combination_Qtern/saxagliptin_dapagliflozin_fixed_dose_combination_Qtern	12.07.2017
Selexipag Uptravi 1235/17	Advice following a full submission assessed under the orphan equivalent process **Selexipag (Uptravi®)** is not recommended for use within NHS Scotland. Indication under review: For the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II to III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. In a phase III study of patients with PAH, selexipag was statistically significantly better than placebo as measured by a composite primary outcome of death or a complication related to PAH. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. This advice takes account of the	10/07/2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1235_17_selexipag_Uptravi/selexipag_Uptravi	12.07.2017

	views from a Patient and Clinician Engagement (PACE) meeting.			
Trametinib 0.5mg, 2mg film-coated tablets Mekinist® 1264/17	Advice in the absence of a submission from the holder of the marketing authorisation **Trametinib (Mekinist®)** is not recommended for use within NHS Scotland. Indication under review: in combination with dabrafenib for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation. 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.	10/07/2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1264_17_trametinib_0.5mg_2mg_film_coated_tablets_Mekinist/trametinib_0.5mg_2mg_film_coated_tablets_Mekinist	12.07.2017
Ustekinumab Stelara 1250/17	Advice following a full submission **Ustekinumab (Stelara®)** is accepted for use within NHS Scotland. 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 or have medical contraindications to such therapies. Ustekinumab was associated with improved clinical response and remission versus placebo during induction and maintenance treatment in patients with moderately to severely active Crohn's disease who had failed to respond to or not tolerated conventional therapy or TNFα antagonists. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ustekinumab. The advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	10/07/2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1250_17_ustekinumab_Stelara/ustekinumab_Stelara	12.07.2017

AUGUST 2017

Medicine	Condition being treated	Date SMC Advice Published	NHS BORDERS decision	Date NHSB Decision
5-aminolevulinic acid hydrochloride Ameluz 1260/17	Advice following a full submission **5 aminolaevulinic acid (as hydrochloride) (Ameluz®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of superficial and / or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment-related morbidity and / or poor cosmetic outcome in adults. In a phase III study of patients with BCC, up to two cycles of photodynamic therapy (PDT) with 5 aminolaevulinic acid gel was non-inferior to PDT with an alternative photosensitising agent for the primary endpoint, complete clearance, defined as clearance of all treated lesions,	07/08/2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1260_17_aminolaevulinic_acid_Ameluz/5_aminolaevulinic_acid_Ameluz	09/08/2017

	assessed visually at 12 weeks after the last PDT. The submitting company did not present a sufficiently robust economic case to gain acceptance by SMC.			
Canakinumab Ilaris 1268/17	Advice in the absence of a submission from the holder of the marketing authorisation **Canakinumab (Ilaris ®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older: • tumour necrosis factor receptor associated periodic syndrome •hyperimmunoglobulin D syndrome / mevalonate kinase deficiency • Familial Mediterranean Fever 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.	07/08/2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1268_17_canakinumab_Ilaris/canakinumab_Ilaris	09/08/2017
Carfilzomib Kyprolis 1242/17	Advice following a full submission assessed under the orphan process **Carfilzomib (Kyprolis®)** is accepted for use within NHS Scotland. Indication under review: In combination with dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Carfilzomib in combination with dexamethasone, compared with another proteasome inhibitor in combination with dexamethasone, increased progression free survival in adults with relapsed or refractory multiple myeloma who had received between one and three previous lines of treatment. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of carfilzomib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	07/08/2017	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 *Nov 17* http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1242_17_carfilzomib_Kyprolis/carfilzomib_Kyprolis	09/08/2017
Desmopressin oral lyophilisate Noqdirna 1218/17	Advice following a resubmission **Desmopressin oral lyophilisate (Noqdirna®)** is accepted for restricted use within NHS Scotland. Indication under review: Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. SMC restriction: For use in patients aged 65 years and over. Two phase III, placebo-controlled studies demonstrated that desmopressin, at licensed doses over three months, significantly reduced the mean number of nocturnal voids and resulted in higher proportions of responders compared with placebo, in patients with nocturia.	07/08/2017	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 *Nov 17* http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1218_17_desmopressin_Noqdirna/desmopressin_Noqdirna_Resubmission	09/08/2017

Follitropin delta Rekovelle 1269/17	Advice in the absence of a submission from the holder of the marketing authorisation **Follitropin delta (Rekovelle®)** is not recommended for use within NHS Scotland. Indication under review: Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies such as an in vitro fertilisation or intracytoplasmic sperm injection cycle. 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.	07/08/2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1269_17_follitropin_delta_Rekovelle/follitropin_delta_Rekovelle	09/08/2017
Sufentanil citrate Zalviso 1270/17	Advice in the absence of a submission from the holder of the marketing authorisation **Sufentanil citrate (Zalviso ®)** is not recommended for use within NHS Scotland. Indication under review: Management of acute moderate to severe post-operative pain in adult patients. 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.	07/08/2017	Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1270_17_sufentanil_citrate_Zalviso/sufentanil_citrate_Zalviso	09/08/2017
Venetoclax Venclyxto 1249/17	Advice following a full submission assessed under the end of life and orphan medicine process **Venetoclax (Venclyxto®)** is accepted for use within NHS Scotland. Indication under review: as monotherapy for the treatment of chronic lymphocytic leukaemia (CLL): • in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor. • in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor. In phase II, non-comparative studies of patients with relapsed / refractory CLL, treatment with venetoclax was associated with clinically meaningful overall response rates.This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of venetoclax. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	07/08/2017	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 *Nov 17* http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1249_17_venetoclax_Venclyxto/venetoclax_Venclyxto	09/08/2017