



**NEW MEDICINE APPLICATIONS BROUGHT TO THE
BORDERS FORMULARY COMMITTEE (BFC)
AND AREA DRUG & THERAPEUTICS COMMITTEE (ADTC)
2016/17**

New Medicine Product/Device Endorsement Categories

A	Approved for general use - hospital and general practice	Green	Unrestricted General Use Used widely and in accordance with a respectable, responsible body of clinical opinion (e.g. BNF for children; SIGN/NICE recommendation; royal college guidelines)
B	Approved for specialist use only	Amber	General Use With Restrictions (Prescribers to be outlined) Supporting clinical evidence has been evaluated by NHS Borders ADTC/Formulary committee. Local use has peer group support and reflects practice in other NHS Board areas. May require "shared care protocol". (include information here) Specific patient consent not normally required.
C	Approved for consultant initiation, with ongoing prescribing in general practice		
D	Approved for shared care between hospital and general practice. Shared care protocol to be developed. (Information included here)	Red	Specialist Use Only Supporting clinical evidence has been evaluated by NHS Borders ADTC/Formulary committee. Limited evidence of efficacy available. Rarely used or may have serious potential side effects requiring close supervision of treatment Specific patient consent indicated.
E	Not approved (reason given)		
F	No decision – further information required (listed here)	Black	Not Approved for use

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 13th APRIL 2016		
NMA	Indication	BFC Decision
Alendronate (Binosto)	Treatment of Osteoporosis – fracture prevention	Approved Category C – limited numbers - feedback/additional info required
Certolizumab pegol (Cimzia)	In combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drugs, including methotrexate has been inadequate. As monotherapy in	Approved Category B

	case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.	
Tolvaptan (Jinarc)	To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.	Approved Category B
Sacubitril/valsartan (Entresto)	Treatment of symptomatic chronic heart failure with reduced ejection fraction.	Approved Category C

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 11th MAY 2016

NMA	Indication	ADTC Decision
Tropicamide & Phenylephrine (Mydriaser)	To obtain pre-operative mydriasis or for diagnostic purposes when monotherapy is known to be insufficient.	Approved Category B once evidence and info provided
Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide film coated tablet (Genvoya)	Treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.	Approved Category B
Adalimumab (Humira)	Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.	Approved Category B

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 8th JUNE 2016

NMA	Indication	BFC Decision
Camellia sinensis green tea leaf extract (Catephen)	Cutaneous treatment of external genital and perianal warts (<i>condylomata acuminata</i>) in immunocompetent patients from the age of 18 years.	Approved Category B
Febuxostat (Adenuric)	Prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS).	Approved Category B

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 13th JULY 2016

NMA	Indication	ADTC Decision
Sugammadex (Bridion)	Reversal of neuromuscular blockade induced by Rocuronium or Vecuronium.	Approved Category B
Secukinumab (Cosentyx)	Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy.	Approved Category B

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 10th AUGUST 2016

NMA	Indication	BFC Decision
Secukinumab (Cosentyx)	Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.	Approved – Category B
AquaMax Emollient Cream	Emollient, for dry and itchy skin conditions such as Eczema and Psoriasis.	Approved – Category A
Guanfacine prolonged-release (Intuniv)	Treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.	Not Approved – Category E
Certolizumab pegol (Cimzia)	Treatment of adult patients with severe active axial spondyloarthritis, comprising: Ankylosing spondylitis (AS) Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs); Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA). Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and /or MRI, who have had an inadequate response to, or are intolerant to NSAIDs	Approved – Category B
Certolizumab pegol (Cimzia)	In combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate	Approved – Category B
Adalimumab (unlicensed indication)	Pyoderma gangrenosum	Approved – Category B for 1 patient

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 14th SEPTEMBER 2016

NMA	Indication	ADTC Decision
Calcipotriol + Betamethasone (Enstilar)	Topical treatment of psoriasis vulgaris in adults.	Approved Category F
Paliperidone palmitate (Trevicta)	A three-monthly injection is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically unstable on one-monthly paliperidone palmitate injectable product.	Approved Category B
Idarucizumab (Praxbind)	Reversal of dabigatran etexilate	Approved Category B
OM-89 (UroVaxam)	UTI Prophylaxis in female patients with recurrent multiple resistant, uncomplicated UTI	Approved Amber up to 5 patients
Vortioxetine (Brintellix)	Treatment of major depressive episodes in adults.	Approved Category F

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 12th OCTOBER 2016

NMA	Indication	BFC Decision
Budesonide 9mg prolonged release tablet (Cortiment)	Induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient.	Category F
Aflibercept 40mg/ml (Eylea)	Treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV)	Category B
Alirocumab (Praluent®)	Primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: - in combination with a statin or 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 contraindicated.	Category B

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 9th NOVEMBER 2016

NMA	Indication	ADTC Decision
No applications		

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 14th DECEMBER 2016

NMA	Indication	BFC Decision
Aclidinium/Formoterol (Duaklin Genuair)	COPD	Category A
Insulin Degludec (Tresiba)	Treatment of diabetes mellitus in adults.	Category F
Dulaglutide (Trulicity)	Type 2 diabetes mellitus to improve glycaemic control as add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.	Category C
Melatonin MR	Acute insomnia in Critical Care.	Category B/Amber
Alemtuzumab (Lemtrada)	Adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.	Category B
Sofosbuvir-Velpatasvir (Epclusa)	Treatment of chronic hepatitis C virus (HCV) infection in adults.	Category B
Tapentadol SR	Management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.	Category F

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 11th JANUARY 2017

NMA	Indication	ADTC Decision
No applications		

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 8th FEBRUARY 2017

NMA	Indication	BFC Decision
Lurasidone (Latuda)	Treatment of schizophrenia in adults aged 18 years and over	Category C
Elbasvir 50mg, Grazoprevir 100mg film-coated tablet (Zepatier)	Treatment of chronic hepatitis C (CHC) in adults. (The efficacy of elbasvir-grazoprevir has not been demonstrated in genotypes 2, 3, 5 and 6. Elbasvir-grazoprevir is not recommended in patients infected with these genotypes).	Category B

Evolocumab 140mg (Repatha)	Primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or, • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. See SMC Advice for restrictions	Category B
5-Fluorouracil for injection	Extensive Keloid Scarring	Category B – non formulary off label request

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 8th MARCH 2017

NMA	Indication	ADTC Decision
Tocilizumab (RocActemra)	In combination with methotrexate is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with methotrexate.	Category B – 1 patient
Aztreonam (Azactam)	Alternative to carbapenems in treatment of severe infection caused by susceptible gram negative bacteria on the advice of Consultant Microbiologist	Category B