



**NEW MEDICINE APPLICATIONS BROUGHT TO THE
BORDERS FORMULARY COMMITTEE (BFC)
AND AREA DRUG & THERAPEUTICS COMMITTEE (ADTC)
2015/16**

New Medicine Product/Device Endorsement Categories

A	recommended for general use - hospital and general practice	<p>Green - Unrestricted General Use Used widely and in accordance with a respectable, responsible body of professional opinion (e.g. Medicines for Children; SIGN/NICE recommendation)</p> <p>Amber - General Use With Restrictions Use has been evaluated by the ADTC and has been authorised as being "acceptable". May require "shared care protocol". Local use has peer group support. Specific consent not normally required.</p> <p>Red - Specialist Use Only Limited evidence of efficacy available. Rarely used or may have serious potential side effects requiring close supervision. Specific consent may be advisable.</p>
B	recommended for specialist use only	
C	recommended for shared care between hospital and general practice	
D	not recommended (reason given)	
E	no decision - need more details	
F	recommended for consultant initiation and subsequent general use – hospital and general practice	

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 8TH APRIL 2015		
NMA	Indication	BFC Decision
Bevacizumab (Avastin)	Radionecrosis in brain stem and cerebellum, secondary to previous radiotherapy for posterior fossa ependymoma.	Approved Category B for specialist use only for this single patient
Omnican Fine Screw on Needles for Insulin Pens	Needs for pre-filled and reusable pen injectors	Approved Category A for general use.

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 13TH MAY 2015

NMA	Indication	ADTC Decision
Peginterferon-beta-1a 63, 94 and 125 microgram solution for injection in pre-filled syringe (Plegridy)	Treatment of relapsing remitting multiple sclerosis.	Approved Category B specialist use only.
Levonorgestrel 13.5mg (Jaydess) Bayer	Contraception for up to 3 years.	Approved for Category C Shared Care between hospital and general practice.

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 10TH JUNE 2015

NMA	Indication	BFC Decision
Gabup Buprenorphine 0.4mg, 1mg, 2mg, 4mg, 6mg, 8mg sublingual tablets (Martindale Pharma)	Substitution therapy for opioid drug dependence, within a framework of medical, social and psychological administration.	Approved Category B for Specialist Use only and prescription generically.
Ombitasvir 12.5mg / paritaprevir 75mg / ritonavir 50mg (Viekirax) and dasabuvir 250mg (Exviera) – AbbVie	For use in combination with dasabuvir with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults.	Approved Category B Specialist Use only.

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 8TH JULY 2015

NMA	Indication	ADTC Decision
fosfomycin 40mg/ml powder for solution for intravenous infusion (Fomicyt®)	Acute osteomyelitis ; Complicated urinary tract infections ; Nosocomial lower respiratory tract infections ; Bacterial meningitis ; Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above	Approved Category B -Specialist Use only

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 12TH AUGUST 2015

NMA	Indication	BFC Decision
theiCal-D3 1000mg/880 IU chewable tablets	Calcium Vitamin D3 1000 mg / 880 IU chewable tablets is indicated: - for the prevention and treatment of vitamin D and calcium deficiency in the elderly ; - as vitamin D and calcium supplement as an adjunct to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency.	Approved for a trial of 50 patients over 1 year with feedback required to BFC. Category F - Specialist Initiation followed by General Use
Golimumab 50mg, 100mg (prefilled device) (MSD)	Ulcerative colitis	Category E – no decision need more details.
Secukinumab 150mg prefilled, prefilled syringe (Novartis)	In treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy) are intolerant to, or have a contra-indication to, these treatments.	Approved Category B – Specialist Use Only
Vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio)	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 (TNF α) antagonist.	Approved for 1 patient – request for further details to discuss

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 9TH SEPTEMBER 2015

NMA	Indication	ADTC
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		Decision
aflibercept 40mg/mL solution for injection (Eylea)	Treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion.	Approved Category B – Specialist Use only

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 14TH OCTOBER 2015

NMA	Indication	BFC Decision
Ciclosporin eye drops 0.1% (Ikervis)	Treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.	Further information requested
Apremilast (Otezla) psoriatic arthritis	Alone or in combination with disease modifying anti-rheumatic drugs (DMARDS) for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. SMC restriction: for use in adult patients with active PsA who have had an inadequate response with at least two prior DMARD therapies or who are intolerant to such therapies.	Approved Category B _ Specialist Use only with subsequent Shared Care Protocol for Primary Care use.
Adrenaline injector pen (Emerade)	Acute anaphylaxis	Approved Category A but further information required requested.
Vedolizumab 300mg powder for concentrate for solution for infusion	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.	Approved Category B _ Specialist Use only. Review at 10 weeks.
Rituximab NMA	Intralesional for follicular lymphoma	Approved RED off label use for 1 patient with response to treatment at 6 months.

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 11TH NOVEMBER 2015

NMA	Indication	ADTC Decision
Denosumab 60mg (Prolia)	Osteoporotic fractures, needs bone protecting medication.	Approved RED Off label use.

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 9TH DECEMBER 2015

NMA	Indication	BFC Decision
Insulin degludec/liraglutide 100 units/mL / 3.6mg/mL solution for injection (Novo nordisk)	Treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with a GLP-1 receptor agonist or with basal insulin do not provide adequate glycaemic control.	Approved Category F - for Consultant initiation and subsequent general use – hospital and general practice.
Insulin Glargine (Eli Lilly)	Diabetes mellitus.	Approved Category F – for Consultant initiation and subsequent general use – hospital and general practice.
Ulipristal acetate (Esmya)	Pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The duration of the treatment is limited to three months.	Approved Category B - for specialist use only.
Methylphenidate XL (Sandoz)	ADHD	Approved Category C - for Shared Care between hospital and general practice.
Denosumab	Osteoporotic fractures, needs bone protecting medication, High fracture Risk	Approved Category C - for shared care between hospital and general practice for this patient. (Approval is specialist off label)
Medroxyprogesterone acetate (Pfizer)	Contraception.	Approved Category A - for general use – hospital and general practice.
Ivermectin (Galderma)	Treatment of moderate to severe inflammatory lesions of rosacea where a topical treatment is considered appropriate	More information requested.
Apixaban (Bristol, Myers, Squibb)	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults	Approved Category A - for general use – hospital and general practice with clarity on dosage requested.
Rituximab off label use	Systemic follicular lymphoma. Treatment of symptomatic cutaneous lesions on back with intralesional Rituximab	Approved Category B – for specialist use only for one patient.

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 13TH JANUARY 2016

NMA	Indication	ADTC Decision
Ciprofloxacin tablet 500mg	Antibiotic prophylaxis for Spontaneous Bacterial Peritonitis (SBP)	Approved as AMBER - General Use With Restrictions
Co-trimoxazole tablet 960mg	Second line alternative antibiotic prophylaxis for Spontaneous Bacterial Peritonitis (SBP)	Approved as AMBER - General Use With Restrictions
Naloxegol (Moventig)	Treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s)	Approved Category B for Specialist Use Only

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 10TH FEBRUARY 2016

NMA	Indication	BFC Decision
Artificial saliva spray (Saliveze)	Dry mouth	Approved Category A for General Use – Hospital and General Practice
Liquid paraffin/white soft paraffin eye ointment (Xailin night)	Dry Eye Conditions	Approved Category A for General Use – Hospital and General Practice
Ulipristal (Esmya)	The intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	Response to questions required before approval

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 9TH MARCH 2016

NMA	Indication	ADTC Decision
Uro-Vaxom (OM-89)	UTI prophylaxis in female patients with recurrent multiple resistant, uncomplicated UTI	Approved Category B for Specialist Use Only
Dymista nasal spray	Relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient	Category F – for Consultant initiation and subsequent general use – hospital and general practice.
Phenol	Local anaesthetic for grommet insertion	Approved Category B for Specialist Use Only