



**NEW MEDICINE APPLICATIONS BROUGHT TO THE
BORDERS FORMULARY COMMITTEE (BFC)
AND AREA DRUG & THERAPEUTICS COMMITTEE (ADTC)
2014/15**

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 9TH APRIL 2014		
NMA	Indication	BFC Decision
Acetylcysteine	Indication for use is in patient preparation for upper GI endoscopy.(Off label)	Approved as Cat Red
Apixaban	Off label use in anticoagulation 5mg twice daily	Approved as Cat Amber for one patient only
Nicotine Mouth Spray (QuickMist)	Indication for use: it relieves and/ or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit.	Approved as Cat A: monitor usage and feedback in 6 months time.

Dimethyl fumarate 120mg, 240mg	Treatment of adult patients with relapsing remitting multiple sclerosis. Approved as per SMC approval	Approved as Cat B – specialist use only
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NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 14TH MAY 2014

NMA	Indication	ADTC Decision
Adapalene with benzoyl peroxide	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present. Approved as per SMC approval	Approved as Cat A: General use and hospital practice.
Dexmedetomidine	Sedation in adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3). Approved as per SMC approval.	Approved as Cat B: Development of a protocol for use and to be registered with clinical governance system.
Trehalose (Thealoz) eye drops	For treatment of severe dry eye syndrome	Approved as Cat B: Specialist use only and for supply through BGH only – not for GP prescription.
Apripiprazole depot injection	Maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.	Approved as Cat F: for shared care use and will need a protocol.
Denosumab	Treatment of osteoporosis - off label use in male patients with renal impairment.	Approved as Cat Red

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 11TH JUNE 2014

NMA	Indication	BFC Decision
Denosumab (Prolia) 60mg	Osteoporotic fractures, male patient requires bone protecting medication. Off label use.	Approved Category B – for specialist use only
NiQuitin Nicotine Strips	Provides quick release of cravings in smoking cessation.	Not Approved.
Ensure Compact 300kcal (125ml) bottles	Cost-effective replacement oral nutritional supplement.	Approved Category A – for general use.
Xeomin Botulinum Toxin A	For treatment of anal fissure. (off label use).	Approved for specialist use only, off label. Recommendation Red.
True You Mini testing strips	Cost effective blood glucose testing strips.	Approved Category A – for general use.
Exjade	For treatment of chronic overload associated with the treatment	Approved Category B – for specialist use only.

Deferasirox 125, 250, 500mg disp	of rare acquired or inherited anaemias requiring recurrent blood. Approved as per SMC approval.	
Metvix Methyl-5-aminolevulinate	Agent used in conjunction with Photodynamic therapy. Approved as per SMC approval.	Approved Category B – for specialist use only.
Ibuprofen Gel 5% Topical NSAID	Alternative product for formulary inclusion.	Not Approved.
Sovadi Sofosbuvir 400mg	Treatment of chronic Hepatitis C. High treatment success rate in combination with other products. Approved as per SMC approval.	Approved Category B – specialist use only.

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 9TH JULY 2014

NMA	Indication	ADTC Decision
Hyaluronic acid	This is for use in one patient only for osteoarthritic hips and knees.	This is only for one patient who had previously responded to this treatment. Category B - specialist use only. RED
Mepivacaine – Hydro – PG	Local anaesthetic for nail surgery. PGD application from Podiatry; unlicensed for use in podiatry. Committee asked to PGD update.	Not approved. Committee subsequently agreed to sign off (Meeting 10.12.14)

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 20TH AUGUST 2014

NMA	Indication	BFC Decision
dapagliflozin (Forxiga) 2nd Resub FINAL June 2014	Triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor.	Approved. Category F.
tocilizumab (RoActemra) FINAL July 2014	In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients.	Approved. Category B.
Vitaros	Treatment of men with erectile dysfunction.	Not approved. Committee subsequently approved (Meeting 08.10.14)
Relvar Ellipta (fluticasone)	Treatment of asthma in adults and adolescents aged 12 years and older where use of combination medicinal product is appropriate	Not approved. Committee subsequently approved for use (Meeting 10.12.14).

furoate/vilanterol)	in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta ₂ -agonists.	
Relvar Ellipta (fluticasone furoate/vilanterol 92/22 micrograms inhalation powder)	Symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD).	Not approved for local use. Committee subsequently approved for use (Meeting 10.12.14).
Fostair (beclometasone dipropionate and formoterol fumarate dehydrate metered dose inhaler 100 microgram / 6 microgram)	Symptomatic treatment of patients with severe COPD (FEV ₁ <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators	Approved. Category A
Co-enzyme Q10	Treatment of mitochondrial disorder/inherited metabolic disorder.	Approved Category Amber for one patient use only.
Colistimethate sodium (Colobreathe)	Treatment of chronic pulmonary infection in a cystic fibrosis.	

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 10TH SEPTEMBER 2014

NMA	Indication	ADTC Decision
Mirvaso Brimonidine Tartrate Gel	Symptomatic treatment of facial erythema of rosacea in adult patients	Approved for specialist use only for up to 10 patients and with feedback/data from Dr Laube.
Scandonest 3% Plain – Mepivacaine Hydrochloride	Local anaesthetic for nail surgery	To be brought to future meeting

Plain		
Olysio Simeprevir	Used in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adult patients.	Approved Specialist use only

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 8TH OCTOBER 2014

NMA	Indication	BFC Decision
Vitaros	Treatment of men with erectile dysfunction. Additional information brought to this meeting.	Approved – Category F specialist initiation and general use

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 12TH NOVEMBER 2014

NMA	Indication	ADTC Decision
NO MEETING	-	-
HELD 12.11.14	-	-

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 10TH DECEMBER 2014

NMA	Indication	BFC Decision
Relvar Ellipta (fluticasone furoate/vilanterol)	Treatment of asthma in adults and adolescents aged 12 years and older where use of combination medicinal product is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta ₂ -agonists. Additional information brought to this meeting.	Approved for asthma and COPD for specialist initiation only.
Relvar Ellipta (fluticasone furoate/vilanterol 92/22 micrograms inhalation powder)	Symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD). Additional information brought to this meeting.	Approved for asthma and COPD for specialist initiation only.
Aflibercept (Eylea)	Treatment of visual impairment due to diabetic macular oedema (DMO).	Approved Category B - in line with SMC approval; specialist use only
Brinzolamide-brimonidine (Simbrinza)	Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.	Approved category F - Consultant initiation and subsequent general use

Ustekinumab (Stelara)	Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate.	Approved Category B - Specialist Use only
Daclatasvir (Daklinza)	In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults	Additional information requested; no decision. - subsequently approved BFC 11.02.15
Posaconazole (Noxafil)	accepted for restricted use within NHS Scotland. In treatment of fungal infections in adults listed in SMC advice attached.	Additional information requested; no decision. - subsequently approved ADTC 11.03.15
Beclometasone dipropionate anhydrous (Fostair NEXhaler)	Regular treatment of asthma where a combination product is appropriate.	Approved Category A - for general use
Glucose for GTT (Rapilose OGTT oral solution)	Oral glucose tolerance tests.	Approved Category A -for general use
OM-89 (Uro-Vaxom)	UTI prophylaxis in female patients with recurrent multiple resistant, uncomplicated UTI.	Approved Category B -for one patient and ask for outcome information before approval of any more patients. Specialist use only

NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 14TH JANUARY 2015

NMA	Indication	ADTC Decision
Treclin (clindamycin 1% / tretinoin 0.025% gel)	Topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older.	Feedback from meeting to BFC and then letter to applicants, to be reviewed in 12 months. To be Approved Category F - for specialist initiation and general use.
Simponi (golimumab) 50mg	Alone or 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 drug therapy including methotrexate has been inadequate. Has been shown to reduce the rate of progression of joint damage as measured by x-ray and to improve physical function.	Approved Category B - for specialist use only.
Alendronic Acid 70mg/100ml liquid (Generic)	Prevention/ treatment of osteoporosis. Replaces zoledronic acid or denosumab – for some patients	Additional information requested; no decision. Subsequently approved
Xolair	Add-on therapy for the treatment of chronic spontaneous	Approved Category B - for specialist use only.

(Omalizumab 15mg solution for injection)	urticaria in adult and 12 years and above patients with inadequate response to H1 antihistamine treatment.	
InVita D3 (cholecalciferol)	Prevention and treatment of Vitamin D deficiency.	Additional information requested; no decision. Additional information received 11 02 15 see below.
Olodaterol (Striverdi Respimat)	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.	Not approved.
Indacaterol maleate 143 mgs with glycopyrronium bromide 63 mgs inhalation powder hard capsules (Ultibro Breezhaler 85mgs/43mgs)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Approved Category B - for specialist initiation with the recommendation - only for patients who are not on corticoids steroids.

NEW MEDICINE APPLICATIONS BROUGHT TO BFC MEETING OF 11TH FEBRUARY 2015

NMA	Indication	BFC Decision
Vital 1.5kcal (Abbott Nutrition)	Can be used as an oral sip feed (200ml bottles) or enteral feed (1000ml bottles) for dietary management of patients with malabsorption or poor feed intolerance.	Further evidence requested.
Fingolimod (Gilenya) (Novartis Pharmaceuticals UK)	A single disease modifying therapy in highly active relapsing remitting multiple sclerosis with patient groups outlined in application.	Approved Category B - for specialist use only.
Fultium D3 3200 iu	Vitamin D deficiency.	Approved Category B – for specialist use only for high dose and 3200 specialist initiation with GP continuation after that.
Sodium Hyaluronate 0.1% carmellose	Dry eyes.	Approved Category F – for specialist initiation and subsequent general use.

sodium 0.5% and glycerol 0.9% (Allergan) Optive fusion		
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NEW MEDICINE APPLICATIONS BROUGHT TO ADTC MEETING OF 11TH MARCH 2015

NMA	Indication	ADTC Decision
Posaconazole	For the use of antimicrobial prophylaxis in patients receiving treatment for haematological malignancies and undergoing haematopoietic transplants.	Approved Category B – for Haematology specialist use only.
Polymem	Chronic wounds such as leg ulcers, diabetic ulcers and pressure ulcers; infected wounds; prophylaxis of wound infection; post-surgical wound dressing; donor and graft sites; dehisced wounds; patients with Epidermolysis bullosa; superficial and partial thickness burns; traumatic wounds; skin tears; radiotherapy skin reactions.	Not approved. Application referred to the wound group. Further evidence required.
Tapentadol MR (Palexia)	Management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.	Approved for up to 10 patients for Specialist Initiation and Prescription only. Feedback on response required.
Ledipasvir/sofosbuvir (Harvoni)	Treatment of chronic hepatitis C (CHC) in adults	Approve for 3 patients – Category B – for specialist use only.