

## Drug recommendations from Area Prescribing Committee – 15<sup>th</sup> December 2016

### APC recommendations

	Drug	Recommendation	Cumbria implications
<i>The following drugs have not been recommended for use in Cumbria under the stated rating.</i>	Armour Thyroid	Black for new patients, all current patients to be reviewed	<b>BLACK</b>

### Lothian formulary decisions

Drug	Licensed indication	APC Recommendation
Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen Cosentyx <sup>®</sup>	Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy. Remains RED in line with NICE TA407	<b>RED</b>
Fulvestrant 250mg solution for injection Faslodex <sup>®</sup>	Treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen. Remains BLACK in line with TA239	<b>BLACK</b>
Nivolumab 40mg/4ml and 100mg/10ml vials of concentrate for solution for infusion Opdivo <sup>®</sup>	Treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. NHSE commissioned. Remains RED	<b>RED</b>
10mg/ml vials for infusion	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. RED in line with NICE TA384.	<b>RED</b>

Blinatumomab 38.5 micrograms powder for concentrate and solution for solution for infusion Blincyto®	The treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). NHSE commissioned. Remains RED	RED
Crizotinib 200mg and 250mg hard capsule Xalkori®	First line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). NHSE commissioned. Remains RED in line with NICE TA406	RED
Insulin Degludec 100units/ml solution for injection in pre-filled pen or cartridge and 200 units/ml solution for injection in pre-filled pen Tresiba®	Treatment of diabetes mellitus in adults. Remains RED in line with NG17. BLACK for children 1yr+.	RED BLACK
Zoledronic acid Zerlinda®	Off-label use of zoledronic acid for the adjuvant use in women at high risk of recurrence to reduce the rate of breast cancer recurrence in bone.	RED
Paliperidone 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection. Trevicta®	Three monthly injection, indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product.	RED
Calcipotriol + betamethasone 50 micrograms/g and 0.5g/g cutaneous foam Enstilar®	Topical treatment of psoriasis vulgaris in adults.	GREEN
Fosfomycin trometamol Granules for oral solution (equivalent to 3g fosfomycin) Monuril®	Treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females. AMBER in line with previous decision.	AMBER

Rilpivirine / emtricitabine / tenofovir alafenamide 200mg/25mg/25mg film coated tablets Odefsey®	Treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg), infected with HIV-1 without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load HIV-1 RNA < 100,000 copies/ml. NHS England commissioned	<b>RED</b>
Vitamin A Oral solution 10,000 units/ml	Treatment of low vitamin A levels in children. This product would replace vitamin A 150,000 units/ml preparation which has been discontinued.	<b>GREEN</b>
Carfilzomib Kyprolis®	In combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Not recommended –noted. NHSE commissioned. GREY until NICE TA published	GREY
Iron isomaltoside 1000 Diafer®	Treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral preparations are ineffective or cannot be used.	<b>BLACK</b>
Bevacizumab Avastin®	In combination with erlotinib for first line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. Not recommended –noted. NHSE commissioned. GREY until NICE TA published	GREY
Liraglutide Victoza®	Monotherapy for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance or contraindications. Not recommended –noted- remains GREEN in line with NICE NG28.	<b>GREEN</b>
Budesonide / formoterol Symbicort Turbohaler® and Sumbicort®	Treatment of patients with COPD with forced expiratory volume in 1 second (FEV1) 50% to 70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.	<b>BLACK</b>

Golimumab Simponi®	In combination with methotrexate for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40kg, who have responded inadequately to previous therapy with methotrexate. Not recommended – noted- NHSE commissioned GREY until NICE TA published	GREY
Perampanel Fycompa®	Adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy. Not recommended.	BLACK
Tocilizumab RoActemra®	Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Not recommended – noted -remains RED in line with TA247	RED
Ibrutinib Imbruvica®	Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). Not recommended – noted- NHSE commissioned GREY until NICE TA published  Treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. Not recommended – noted- NHSE commissioned GREY until NICE TA published	GREY  GREY
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. GREY until NICE TA published	GREY

Alirocumab Praluent®	Adults with 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. Not recommended- remains RED in line with NICE TA 393	RED
Levofloxacin Quinsair®	The management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis. Not recommended- noted - NHS England commissioned	GREY
Trametinib Mekinsit®	In combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Not recommended – noted- remains RED in line with NICE TA 396.	RED
Dasatinib Sprycel®	For the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase. RAG status remains BLACK in line with NICE TA251.	BLACK
Idarucizumab Praxbind®	Idarucizumab is a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding. Not recommended -Noted	RED
Dexamethasone 700 micrograms intravitreal implant in applicator Ozurdex®	Treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy. Remains RED in line with NICE TA 349	RED
Levofloxacin 240mg nebuliser solution Quinsair®	Management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis. Recommended noted - NHS England commissioned	GREY

<b>Brivaracetam 10mg, 25mg, 75mg, 100mg film coated tablets; 10mg/ml oral solution; 10mg/ml solution for injection / infusion Briviact®</b>	Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy.	<b>AMBER</b> Injection - <b>RED</b>
<b>Lenvatinib 4mg and 10mg hard capsules Lenvima®</b>	Treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hurthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).Recommended. noted- NHSE commissioned -GREY until NICE TA published.	<b>GREY</b>
<b>Pegaspargase 750U/ml solution for injection/infusion Oncaspar®</b>	As a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients. Recommended – noted- remains RED in line with NICE TA 408.	<b>RED</b>
<b>Ulipristal acetate 5mg tablet Esmya®</b>	Intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Not recommended – noted- RAG status remains AMBER in line with previous decision.	<b>AMBER</b>
<b>Nexobrid®</b>	Removal of eschar in adults with deep partial and full thickness thermal burns up to a maximum of 15% total body surface area (TBSA)Not recommended. Noted.	<b>BLACK</b>

<p><b>Adalimumab Humira®</b></p>	<p>Treatment of moderately active Crohn’s disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or immunomodulator, or who are intolerant to or have contraindications for such therapies. – Not recommended. Noted – NHSE commissioned-remains RED</p> <p>Treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. Not recommended - Noted – GREY until NICE TA published</p>	<p><b>RED</b></p> <p><b>GREY</b></p>
<p><b>Canakinumab Ilaris®</b></p>	<p>Treatment of active Still’s disease including Adult-Onset Still’s Disease who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate. Not recommended - Noted GREY until NICE TA published</p>	<p><b>GREY</b></p>
<p><b>Fampridine Fampyra®</b></p>	<p>Improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4 to 7).Not recommended-noted – remains BLACK in line with NICE CG186.</p>	<p><b>BLACK</b></p>
<p><b>Lenalidomide Revlimid®</b></p>	<p>Treatment of adults with relapsed or refractory mantle cell lymphoma. Not recommended – noted - GREY until NICE TA published</p>	<p><b>GREY</b></p>
<p><b>Aflibercept Eyelea®</b></p>	<p>For adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV). GREY until NICE TA published</p>	<p><b>GREY</b></p>

<b>Budesonide Cortiment®</b>	In adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient. Not included –noted- GREY until NICE TA published	GREY
<b>Dasatanib Sprycel®</b>	For the treatment of adult patients with chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate. Not recommended-noted-Remains RED in line with relevant NICE TA	RED
<b>Nivolumab Opdivo®</b>	Treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. Not recommended-noted GREY until NICE TA published	GREY
<b>Progesterone Lutigest®</b>	Luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women. Not recommended -noted	BLACK

#### NTAG Treatment Appraisal recommendations

Drug/indication	NTAG recommendation	Cumbria APC decision
<b>Alfapump device</b>	RECOMMENDED for refractory ascites caused by advanced liver disease as recommended by specialists for patients that fulfil the specified criteria.	Noted for information (device)

## NICE Technology assessments

	Drug	Condition	Summary	Cumbria APC Decision
TA413	Elbasvir - grazoprevir	Treating chronic hepatitis C	Elbasvir–grazoprevir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.	RED
TA414	Cobimetinib in combination with vemafurenib	Treating unresectable or metastatic BRAF V600 mutation -positive melanoma	Cobimetinib in combination with vemurafenib is not recommended within its marketing authorisation for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation.	BLACK
TA415	Certolixumab pegol	Treating rheumatoid arthritis after inadequate response to a TNF- alpha inhibitor	<p>Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other disease-modifying antirheumatic drugs (DMARDs) including at least 1 tumour necrosis factor-alpha (TNF-alpha) inhibitor, only if:</p> <ul style="list-style-type: none"> <li>• disease activity is severe and</li> <li>• rituximab is contraindicated or not tolerated</li> </ul> <p>Certolizumab pegol, as monotherapy, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other DMARDs including at least 1 TNF-alpha inhibitor, only if:</p> <ul style="list-style-type: none"> <li>• disease activity is severe and</li> </ul>	RED

			rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated	
<b>TA416</b>	<b>Osimertinib</b>	Treating locally advanced or metastatic EGFR T790M mutation – positive non small cell lung cancer	<p>Osimertinib is recommended as an option for use within the Cancer Drugs Fund for treating locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer in adults whose disease has progressed only:</p> <ul style="list-style-type: none"> <li>• after first-line treatment with an EGFR tyrosine kinase inhibitor and</li> </ul> <p>if the conditions in the <a href="#">managed access agreement</a> for osimertinib are followed.</p>	<b>RED</b>
<b>TA417</b>	<b>Nivolumab</b>	Previously treated advanced renal cell carcinoma	Nivolumab is recommended, within its marketing authorisation, as an option for previously treated advanced renal cell carcinoma in adults, when the company provides nivolumab with the discount agreed in the patient access scheme.	<b>RED</b>
<b>TA418</b>	<b>Dapagliflozin</b>	In triple therapy for treating type 2 diabetes	Dapagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in adults, only in combination with metformin and a sulfonyleurea.	<b>GREEN</b>
<b>TA419</b>	<b>Apremilast</b>	Treating moderate to severe plaque psoriasis	<p>Apremilast is recommended as an option for treating chronic plaque psoriasis in adults whose disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and ultraviolet-A light), or when these treatments are contraindicated or not tolerated, only if:</p> <p>the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10</p>	<b>RED</b>

			treatment is stopped if the psoriasis has not responded adequately at 16 weeks	
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### NICE clinical guidelines

Clinical Guideline	Condition	Date of Publication	Summary of Guidance
NG57	Physical health of people in prison	November 16	<p>This guideline covers assessing, diagnosing and managing physical health problems of people in prison. It aims to improve health and wellbeing in the prison population by promoting more coordinated care and more effective approaches to prescribing, dispensing and supervising medicines.</p> <p>This guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• <a href="#">assessing a person’s health when they come into prison</a></li> <li>• <a href="#">managing and supervising medicines</a></li> <li>• <a href="#">promoting health and wellbeing in prison</a></li> <li>• <a href="#">how to manage health emergencies and support people with rapidly deteriorating health</a></li> </ul> <p>There are no specific prescribing recommendations</p>
NG58	Coexisting severe mental illness and substance misuse: community health and social care	November 16	<p>This guideline covers how to improve services for people aged 14 and above who have been diagnosed as having coexisting severe mental illness and substance misuse. The aim is to provide a range of coordinated services that address people’s wider health and social care</p>

	services.		<p>needs, as well as other issues such as employment and housing.</p> <p>This guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• <a href="#">first contact with services</a></li> <li>• <a href="#">referral to secondary care mental health services</a></li> <li>• <a href="#">the care plan: multi-agency approach to address physical health, social care, housing and other support needs</a></li> <li>• <a href="#">partnership working between specialist services, health, social care and other support services and commissioners</a></li> <li>• <a href="#">improving service delivery</a></li> <li>• <a href="#">maintaining contact between services and people with coexisting severe mental illness and substance misuse who use them</a></li> </ul> <p>There are no specific prescribing recommendations.</p>
NG59	Low back pain and sciatica in over 16s: assessment and management.	November 16	<p>This guideline covers assessing and managing low back pain and sciatica in people aged 16 and over. It outlines physical, psychological, pharmacological and surgical treatments to help people manage their low back pain and sciatica in their daily life. The guideline aims to improve people's quality of life by promoting the most effective forms of care for low back pain and sciatica.</p> <p>This guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• <a href="#">assessment of low back pain and sciatica</a></li> </ul>

		<ul style="list-style-type: none"> <li>• <a href="#">non-invasive treatments for low back pain and sciatica</a></li> <li>• <a href="#">invasive treatments for low back pain and sciatica</a></li> </ul> <p><b>Pharmacological interventions</b></p> <p>1.2.16 For recommendations on pharmacological management of sciatica, see NICE's guideline on <a href="#">neuropathic pain in adults</a>.</p> <p>1.2.17 Consider oral non-steroidal anti-inflammatory drugs (NSAIDs) for managing low back pain, taking into account potential differences in gastrointestinal, liver and cardio-renal toxicity, and the person's risk factors, including age.</p> <p>1.2.18 When prescribing oral NSAIDs for low back pain, think about appropriate clinical assessment, ongoing monitoring of risk factors, and the use of gastroprotective treatment.</p> <p>1.2.19 Prescribe oral NSAIDs for low back pain at the lowest effective dose for the shortest possible period of time.</p> <p>1.2.20 Consider weak opioids (with or without paracetamol) for managing acute low back pain only if an NSAID is contraindicated, not tolerated or has been ineffective.</p> <p>1.2.21 Do not offer paracetamol alone for managing low back pain.</p> <p>1.2.22 Do not routinely offer opioids for managing acute low back pain (see recommendation 1.2.20).</p> <p>1.2.23 Do not offer opioids for managing chronic low back pain.</p> <p>1.2.24 Do not offer selective serotonin reuptake inhibitors, serotonin–norepinephrine reuptake inhibitors or tricyclic antidepressants for managing low back pain.</p>
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			1.2.25 Do not offer anticonvulsants for managing low back pain.
NG60	HIV testing: increasing uptake among people who may have undiagnosed HIV  (Joint NICE and PHE guideline)	December 16	<p>This guideline covers how to increase the uptake of HIV testing in primary and secondary care, specialist sexual health services and the community. It describes how to plan and deliver services that are tailored to the local prevalence of HIV, promote awareness of HIV testing and increase opportunities to offer testing to people who may have undiagnosed HIV.</p> <p>This guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• offering and recommending HIV testing in different settings</li> <li>• increasing opportunities for HIV testing</li> <li>• promoting awareness and uptake of HIV testing</li> <li>• reducing barriers to HIV testing</li> </ul> <p>There are no specific prescribing recommendations.</p>