Drug recommendations from Area Prescribing Committee – 11th August 2016

APC recommendations

	Drug	Recommendation	Cumbria implications
The following drugs have been recommended for use in Cumbria under the stated rating.	Lidocaine patches (Versatis)	All unlicensed indications re-categorise to red.	RED
	Dipipanone & cyclizine tablets	Re-categorise to black.	BLACK

Lothian formulary recommendations

	Drug	Licensed indication	Recommendation
The following drugs have been recommended as suitable for use:	Adapalene/benzoyl peroxide (Epiduo®)	Cutaneous treatment of acne vulgaris when comedones papules and pustules are present.	GREEN
	Panobinostat 10mg, 15mg and 20mg hard capsules (Farydak®)	In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and /or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent	RED
	Secukinumab 150mg pre-filled syringe, 150ng pre-filled pen (Cosentyx®)	Treatment of moderate to severe plaque psoriasis in adults whom are candidates for systemic therapy.	RED
	Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg Film coated tablets (Genvoya®)	The treatment of adults and adolescents (aged 12 yrs and older with body weight at least 35kg) infected with HIV-1 without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.	RED
	Eribulin 0.44mg/ml solution for injection (Halaven®)	Treatment of adults with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease.	BLACK

	Drug	Licensed indication	Recommendation
	Everolimus 2.5mg,5mg and 10mg tablets (Afinitor®)	For the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women with symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.	RED
	Methotrexate Pre-filled syringe (Zlatal®)	Second choice preparation for the treatment of rheumatoid arthritis, psoriatic arthritis and juvenile idiopathic arthritis.	AMBER
	Fluorescein 10% injection (Anatera®)	Treatment of fluorescein angiography of the ocular fundus. This will replace fluorescein injection 20% which is an unlicensed product.	RED
	Tobramycin Nebuliser solution (Tymbrineb®)	Treatment of chronic pulmonary Pseudomonas aeruginosa infection in children and adults (6 years and older) This will replace Bramitop® and TOBI®nebuliser solution.	RED
	Naproxen 250mg effervescent tablets	Treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in adults. Use in patients unable to swallow naproxen tablets.	GREEN
	Bevacizumab	In combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.	RED
	Blinatumomab	The treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia	RED
	Co-careldopa Intestinal gel (Duodopa®)	Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.	RED
	Cabazitaxel (Jevtana®)	In combination with prednisone or prednisolone for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel containing regimen.	RED

	Drug	Licensed indication	Recommendation
	Eltrombopag olamine (Revolade®)	Treatment in adults with acquired severe aplastic anaemia (SAA)who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.	BLACK
	Ramucirumab (Cyramza®)	In combination with docetaxel for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum based chemotherapy. In combination with paclitaxel for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progession after prior platinum and fluoropyrimidine chemotherapy. As monotherapy for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate.	BLACK
	Ruxolitinib (Jakavi®)	Treatment of adults with polycythaemia vera who are resistant to or intolerant of hydroxyurea.	BLACK
	Afatanib (Giotrif®)	Monotherapy for the treatment of locally advanced or metastatic non-small cell lung cancer of squamous histology progressing on or after platinum based chemotherapy.	RED

NTAG Treatment Appraisal recommendations

Drug/indication	NTAG recommendation	Cumbria APC decision
None this meeting		

NICE Technology assessments

	Drug	Condition	Summary	Cumbria APC Decision
TA392	**Adalimumab**	Recommended for treating moderate to severe hidradenitis suppurativa.	Adalimumab is recommended, within its marketing authorisation, as an option for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic therapy. The drug is recommended only if the company provides it at the price agreed in the patient access scheme. Assess the response to adalimumab after 12 weeks of treatment, and only continue if there is clear evidence of response, defined as: a reduction of 25% or more in the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas.	RED
TA393	**Alirocumab**	Recommended for treating primary hypercholesterolaemia and mixed dyslipidaemia.	Alirocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if: Low-density lipoprotein concentrations are persistently above the thresholds specified despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia: identification and management). The company provides alirocumab with the discount agreed in the patient	RED

			access scheme.	
TA394	**Evolocumab**	Recommended for Treating primary hypercholesterolaemia and mixed dyslipidaemia .	Evolocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if: Low-density lipoprotein concentrations are persistently above the thresholds specified despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached, or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia). The company provides evolocumab with the discount agreed in the patient access scheme.	RED
TA395	**Ceritinib**	Recommended for treating previously treated anaplastic lymphoma kinase positive non-small cell lung cancer .	Ceritinib is recommended, within its marketing authorisation, as an option for treating advanced anaplastic lymphoma kinase positive non-small-cell lung cancer in adults who have previously had crizotinib. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.	RED
TA396	**Trametinib**	Recommended in combination with dabrafenib for treating unresectable or metastatic melanoma.	Trametinib in combination with dabrafenib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation only when the company provides trametinib and dabrafenib with the discounts agreed in the patient access schemes.	RED
TA397	**Belimumab**	Recommended for treating active autoantibody-positive systemic lupus	Belimumab is recommended as an option as add-on treatment for active	RED

		erythematosus.	autoantibody-positive systemic lupus erythematosus in adults only if all of the following apply: There is evidence for serological disease activity (defined as positive anti-double-stranded DNA and low complement) and a Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of greater than or equal to 10 despite standard treatment. Treatment with belimumab is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more. The company provides belimumab with the discount agreed in the patient access scheme.	
TA398	**Lumacaftor – ivacaftor**	Not recommended for treating cystic fibrosis homozygous for the F508del mutation.	Lumacaftor–ivacaftor is not recommended, within its marketing authorisation, for treating cystic fibrosis in people 12 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	**BLACK**
TA399	**Azacitidine**	Not recommended for treating acute myeloid leukaemia with more than 30% bone marrow blasts.	Azacitidine is not recommended, within its marketing authorisation, for treating acute myeloid leukaemia with more than 30% bone marrow blasts in people of 65 years or older who are not eligible for haematopoietic stem cell transplant.	**BLACK**
TA400	**Nivolumab**	Recommended In combination with ipilimumab for treating advanced melanoma.	Nivolumab in combination with ipilimumab is recommended, within its marketing authorisation, as an option for treating advanced	RED

			(unresectable or metastatic) melanoma in adults, only when the company provides ipilimumab with the discount agreed in the patient access scheme.	

NICE clinical guidelines

Clinical Guideline	Condition	Date of Publication	Summary of Guidance
NG48	Oral health for adults in care homes	July 16	This guideline covers oral health, including dental health and daily mouth care, for adults in care homes. The aim is to maintain and improve their oral health and ensure timely access to dental treatment. **Recommendations** This guideline includes recommendations on: • care home policies on oral health and providing residents with support to access dental services • oral health assessment and mouth care plans • daily mouth care • care staff knowledge and skills • availability of local oral health services • oral health promotion services • general dental practices and community dental services

			No specific prescribing implications.
NG49	Non-alcoholic fatty liver disease (NAFLD): assessment and management	July 16	This guideline covers how to identify the adults, young people and children with non-alcoholic fatty liver disease (NAFLD) who have advanced liver fibrosis and are most at risk of further complications. It outlines the lifestyle changes and pharmacological treatments that can manage NAFLD and advanced liver fibrosis. **Recommendations** The guideline includes recommendations on: • identifying groups at higher risk of NAFLD • diagnosing NAFLD in children and young people, and referring them to tertiary care • identifying adults, young people and children with advanced liver fibrosis • lifestyle modifications for NAFLD • pharmacological treatment for advanced liver fibrosis 1.2.15 Do not offer omega-3 fatty acids to adults with NAFLD because there is not enough evidence to recommend their use 1.3.1 Be aware that people with NAFLD who are taking statins should keep taking them. 1.3.2 Only consider stopping statins if liver enzyme levels double within 3 months of starting statins, including in people with abnormal baseline liver blood results. **1.4 Pharmacological treatment**

			1.4.1 In secondary or tertiary care settings only, consider pioglitazone[1] or vitamin E[2] for adults with advanced liver fibrosis, whether they have diabetes or not. 1.4.2 Before prescribing pioglitazoneor vitamin E to adults, take into account any comorbidities that they have and the risk of adverse events associated with these conditions. 1.4.3 In tertiary care settings only, consider vitamin E for children with advanced liver fibrosis, whether they have diabetes or not. 1.4.4 In secondary or tertiary care settings only, consider vitamin E for young people with advanced liver fibrosis, whether they have diabetes or not. 1.4.5 Offer to retest people with advanced liver fibrosis 2 years after they start a new pharmacological therapy to assess whether treatment is effective. 1.4.6 Consider using the ELF test to assess whether pharmacological therapy is effective. 1.4.7 If an adult's ELF test score has risen, stop either vitamin E or pioglitazone and consider switching to the other pharmacological therapy. 1.4.8 If a child or young person's ELF test score has risen, stop vitamin E. **Areas with a potential resource impact** **Testing everyone with NAFLD for advanced liver fibrosis** 3.1 Implementing the guideline may result in a change in practice in the following areas: • Testing everyone diagnosed with NAFLD for advanced liver fibrosis, to identify those who are most likely to progress to cirrhosis (recommendation 1.2.1). • Retesting adults with NAFLD and an enhanced liver fibrosis (ELF) score below 10.51 for advanced liver fibrosis every 3 years (recommendation 1.2.7).

			• Potentially using the ELF test in primary care to identify people with advanced liver fibrosis (recommendations 1.2.2 and 1.2.8). • Referring those with NAFLD and advanced liver fibrosis to secondary care (recommendation 1.2.5). • Considering pioglitazone or vitamin E for adults with advanced liver fibrosis who have been referred to secondary care (recommendation 1.4.1). 3.2 Current practice varies, with some people with NAFLD monitored in primary care and others referred to secondary care for testing and follow-up. Referral may not currently be based on the risk of progression to cirrhosis. Therefore some people at low risk of progressing may be referred inappropriately, while some people at high risk may not be referred until they are symptomatic and have advanced disease. Testing all people with NAFLD for advanced liver fibrosis will identify those who are at higher risk of progressing to cirrhosis so that their treatment can be managed in secondary care. 3.3 Currently people with advanced fibrosis are not routinely offered a pharmacological treatment. Pioglitazone or vitamin E may now be considered for adults with advanced liver fibrosis who have been referred to secondary care 3.4 The ELF test can be used in primary care to identify people with advanced liver fibrosis before they are referred to secondary care. This would be a change in practice in areas where testing is currently done in secondary care. 3.5 Users can input estimates into the local resource impact template to reflect local practice and estimate the impact of implementing the guideline locally. The template has been pre-populated with unit costs and other estimates where available. **4 Other considerations** 4.1 There is a lack of robust data on the incidence and prevalence of people diagnosed with NAFLD. In practice the number of people diagnosed with NAFLD is likely to be fewer than the prevalence reported in studies due to the asymptomatic nature of early stage disease. Based on an assumption that 20% of the adult population are diagnosed with NAFLD, the estimates

			impact of implementing this guidance could be £11m over the next five years, half of this would be the use of ELF to test for advanced fibrosis, £5m for referrals to liver specialists and £734K medication costs.
NG50	Cirrhosis in over 16s: assessment and management	July 16	This guideline covers assessing and managing suspected or confirmed cirrhosis in people who are 16 years or older. It aims to improve how cirrhosis is identified and diagnosed. It recommends tools to assess the severity of cirrhosis and gives advice on monitoring people with cirrhosis to detect and manage complications early, and referral criteria for tertiary care. **Recommendations** The guideline includes recommendations on: • Diagnosing cirrhosis • Monitoring cirrhosis • Managing the complications of cirrhosis The Resource Impact Report that accompanies NG 50 notes that the following recommendations may result in changes in practice and have the greatest resource implications: • 1.1.11 Offer retesting for cirrhosis every 2 years (for identified at-risk groups). • 1.2.4 Offer ultrasound (with or without measurement of serum alpha fetoprotein) every 6 months as surveillance for hepatocellular carcinoma (HCC) for people with cirrhosis who do not have hepatitis B virus infection. • 1.3.1 Offer endoscopic variceal band ligation for the primary prevention of bleeding for people with cirrhosis who have medium to large oesophageal varices.

			The Resource Impact Report also estimates that implementation of NG 50 could reduce gastrointestinal bleeds due to oesophageal varices, limit disease progression (via earlier diagnosis and behavioural intervention), improve response to treatment for hepatocellular carcinoma (via earlier detection) and reduce the number of liver transplants needed. These potential benefits are likely to take time to accrue and the financial impact of some may only be apparent after ten years or more. Using an assumption that 1% of the population drink at harmful levels and discuss this with their GP, the cost of implementing this guidance could be £50,000 over the next five years, with half of that being in 19/20 and 20/21, mainly due to the increased number of test carried out.
NG51	Sepsis: recognition, diagnosis and early management	July 16	This guideline covers the recognition, diagnosis and early management of sepsis for all populations. The guideline committee identified that the key issues to be included were: recognition and early assessment, diagnostic and prognostic value of blood markers for sepsis, initial treatment, escalating care, identifying the source of infection, early monitoring, information and support for patients and carers, and training and education. In July 2016, the accompanying algorithms and risk tables had some minor typographical errors corrected. Also, references to systolic blood pressure levels wrongly included in some algorithms for children were removed. **Recommendations**

			The guideline includes recommendations on: • Identifying and assessing people with suspected sepsis • Risk factors and risk stratification for sepsis • Managing suspected sepsis in acute hospital settings and out of hospital Cost impact is mainly within secondary care, although there may be increased demand for GP and Out of Hours services for assessment and screening. Cost savings can be achieved better treatment in secondary care and associated reduction in morbidity and mortality. There is a baseline assessment tool for use by provider trusts.
NG52	Non-Hodgkin's lymphoma: diagnosis and management	July 16	This guideline covers diagnosing and managing non-Hodgkin's lymphoma in people aged 16 years and over. It aims to improve care for people with non-Hodgkin's lymphoma by promoting the best tests for diagnosis and staging and the most effective treatments for 6 of the subtypes. Tests and treatments covered include excision biopsy, radiotherapy, immunochemotherapy and stem cell transplantation. This guideline includes recommendations on: • diagnosis • staging and end-of-treatment assessment using fluorodeoxyglucose-positron emission tomography-CT • managing:

			- follicular lymphoma - MALT lymphoma - mantle cell lymphoma - diffuse large B-cell lymphoma - Burkitt lymphoma - peripheral T-cell lymphoma • information and support • survivorship NICE has not published a resource impact report for this guidance because NICE do not expect the guideline on non-Hodgkin's lymphoma to have a significant1 resource impact. There may be an increase in costs due to changes in prescribing practices. However, these are for small populations so any associated costs are not expected to be significant NICE have produced a baseline assessment tool for use by provider trusts.