Drug recommendations from Area Prescribing Committee – 13th October 2016

APC recommendations

	Drug	Recommendation	Cumbria implications
The following drugs have been recommended for use in Cumbria under the stated rating.	Nefopam	Black for new patients, all current patients to be reviewed in practice.	BLACK
	Ascorbic Acid	Green for scurvy licensed indication	GREEN
		Black for all other indications.	BLACK
	IM Ergocalciferol		RED
	Treatment of vitamin D deficiency in children		AMBER

Lothian formulary recommendations

	Drug	Licensed indication	Recommendation
The following drugs have been recommended as suitable for use:	Bevacizumab 25mg/ml concentrate for solution for infusion Avastin®	In combination with paclitaxel and cisplatin or, alternatively paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adults with persistent, recurrent, or metastatic carcinoma of the cervix.	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.	RED **in line with NICE TA349**
	Zoledronic acid	Treatment of patients with osteogenesis imperfecta, juvenile idiopathic osteoporosis, recurrent fractures due to osteopaenia. Zoledronic acid will be used first-line in preference to pamidronate, however some patients will be treated with pamidronate first.	RED

	Drug	Licensed indication	Recommendation
	Thrombin injection Floseal®	Bleeding gastric and ectopic varices. It was noted that Floseal® is a medical device which will be used off-label.	RED
	Diamorphine 720 microgram / actuation and 1600 microgram / actuation nasal spray Ayendi®	Treatment of acute sever nociceptive pain in children and adolescents in a hospital setting. Diamorphine hydrochloride nasal spray (Ayendi®) should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with the appropriate monitoring.	RED
	Emtricitabine / tenofovir alafenamide 200mg/25mg, 200mg/10mg film coated tablets Descovy®	In combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) injected with human immunodeficiency virus type 1.	RED NHS England Commissioned
	Rilpivirine 25mg film coated tablet Edurant®	In combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients aged 12 to 18 years of age and older with a viral load (VL) <100,000 HIV-1 RNA copies/ml.	RED NHS England Commissioned
	Tisseel Ready to use (RTU) fibrin glue Tisseel®	Opthalmic surgery involving conjunctiva and cornea as tissue adhesive. This product will replace the Tisseel kit which has been discontinued.	RED
	Prednisolone 10mg/ml oral solution and prednisolone 5mg tablets	For steroid responsive inflammatory conditions in children. This product will replace prednisolone soluble tablets, the new product is more palatable and cost efficient. Plain 5mg tablets can also be used in older patients.	RED
	Prednisolone 1mg/ml oral solution and prednisolone 5mg tablets	Joint first choice preparation for the acute wheeze in children. This product will replace prednisolone soluble tablets, the new product is more palatable and cost efficient. Plain 5mg tablets can also be used in older patients.	RED

	Drug	Licensed indication	Recommendation
	Hypertonic sodium chloride - 7% nebuliser solution Resp-Ease®	First choice for mobilise lower respiratory tract secretions in mucous consolidation. This product will replace Nebusal hypertonic saline 7% nebuliser solution.	AMBER
	Human alpha1-proteinase inhibitor Respreeza®	Maintenance treatment to slow the progression of emphysema in adults with documented severe alpha1-proteinase inhibitor (A1-PI) deficiency.	BLACK
	Elotuzumab Empliciti®	Treatment of multiple myeloma in combination with lenalidomide and dexamethasone in adult patients who have received at least one prior therapy.	BLACK
	Brivaracetam Briviact®	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.	BLACK
	Nivolumab Opdivo®	Treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. Remains Red in line with NICE TA 384	RED
	Vortioxetine Brintellix®	The treatment of major depressive episodes in adults. Remains GREEN in line with NICE TA367	GREEN

NTAG Treatment Appraisal recommendations

Drug/indication	NTAG recommendation	Cumbria APC decision
FreeStyle Libre Flash (Abbott)	RECOMMENDED as an option for continuous glucose monitoring (CGM) only and for patients who fulfil the NICE criteria for CGM and as per the North East and Cumbria CGM guidelines.	RED
Eluxadoline(Truberizi®, Allergan)	NOT RECOMMENDED as an option for the treatment of diarrhoea dominant irritable bowel syndrome (IBS-D).	BLACK
Ferric Maltol (Ferracrru®, Shield TX, UK)	RECOMMENDED as an option for the treatment if iron deficiency anaemia (IDA) in adults with inflammatory bowel disease (IBD).	RED

NICE Technology assessments

	Drug	Condition	Summary	Cumbria APC Decision
TA401	**Bosutinib**	For previously treated chronic myeloid leukaemia in adults	Bosutinib is recommended as an option, within its marketing authorisation, for chronic, accelerated and blast phase Philadelphia chromosome positive chronic myeloid leukaemia in adults, when: they have previously had 1 or more tyrosine kinase inhibitor and imatinib, nilotinib and dasatinib are not appropriate and the company provides bosutinib with the discount agreed in the patient access scheme	RED

TA402	**Pemetrexed**	Maintenance treatment for non-squamous non- small cell lung cancer after pemetrexed and cisplatin	Pemetrexed is recommended as an option for the maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer in adults when: their disease has not progressed immediately after 4 cycles of pemetrexed and cisplatin induction therapy their Eastern Cooperative Oncology Group (ECOG) performance status is 0 or 1 at the start of maintenance treatment and the company provides the drug according to the terms of the commercial access agreement as agreed with NHS England.	RED
TA403	**Ramicirumab**	For previously treated locally advanced or metastatic non-small cell lung cancer	Ramucirumab, in combination with docetaxel, is not recommended within its marketing authorisation for treating locally advanced or metastatic non-small-cell lung cancer in adults whose disease has progressed after platinum-based chemotherapy.	BLACK
TA404	**Degarelix**	Treating advanced hormone dependent prostate cancer	Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer in people with spinal metastases, only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016.	AMBER
TA405	**Trifluridine - tipiracil**	Previously treated metastatic colorectal cancer	Trifluridine–tipiracil is recommended, within its marketing authorisation, as an option for treating metastatic colorectal cancer, that is: in adults who have had previous treatment with available therapies including fluoropyrimidine-, oxaliplatin- or irinotecan-based chemotherapies, anti-	RED

			vascular endothelial growth factor (VEGF) agents and anti-epidermal growth factor receptor (EGFR) agents, or when these therapies are not suitable, and only when the company provides trifluridine–tipiracil with the discount agreed in the patient access scheme.	
TA406	**Crizotinib**	For untreated anaplastic lymphoma kinase-positive advanced non-small cell lung cancer	Crizotinib is recommended, within its marketing authorisation, as an option for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer in adults. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.	RED
TA407	**Secikinumab**	For active ankylosing spondylitis after treatment with non-steroidal anti- inflammatory drugs or TNF- alpha inhibitors	Secukinumab is recommended, within its marketing authorisation, as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors). The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.	RED
TA408	**Pegaspargase**	For treating acute lymphoblastic leukaemia	Pegaspargase, as part of antineoplastic combination therapy, is recommended as an option for treating acute lymphoblastic leukaemia in children, young people and adults only when they have untreated newly diagnosed disease.	RED
TA409	**Aflibercept**	For treating visual impairment caused by macular oedema after branch retinal vein occlusion.	Aflibercept is recommended as an option within its marketing authorisation for treating visual impairment in adults caused by macular oedema after branch retinal vein occlusion, only if the company provides aflibercept with the discount agreed in the patient access scheme.	RED

TA410	**Talimogene laherparepvec**	For treating unresectable metastatic melanoma	Talimogene laherparepvec is recommended, in adults, as an option for treating unresectable, regionally or distantly metastatic (Stage IIIB, IIIC or IVM1a) melanoma that has not spread to bone, brain, lung or other internal organs, only if: treatment with systemically administered immunotherapies is not suitable and the company provides talimogene laherparepvec with the discount agreed in the patient access scheme.	RED
TA411	**Necitumumab**	For treating advanced or metastatic squamous non-small cell lung cancer	Necitumumab, in combination with gemcitabine and cisplatin, is not recommended within its marketing authorisation for adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-expressing squamous non-small-cell lung cancer that has not been treated with chemotherapy.	RED
TA412	**Radium-223 dichloride**	For treating hormone-relapsed prostate cancer with bone metastases	Radium-223 dichloride is recommended as an option for treating hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases in adults, only if: they have already had docetaxel or docetaxel is contraindicated or is not suitable for them. The drug is only recommended if the company provides radium-223 dichloride with the discount agreed in the patient access scheme.	RED

NICE clinical guidelines

Clinical Guideline	Condition	Date of Publication	Summary of Guidance
NG53	Transition between inpatient mental health settings and community or care home settings	August 16	This guideline covers the period before, during and after a person is admitted to, and discharged from, a mental health hospital. It aims to help people who use mental health services, and their families and carers, to have a better experience of transition by improving the way it's planned and carried out This guideline includes recommendations on: • overarching principles for good transition • planning for admission and discharge • out-of-area admissions • support for families and carers There are no specific prescribing recommendations
NG54	Mental health problems in people with learning disabilities: prevention, assessment and management	September 16	This guideline covers preventing, assessing and managing mental health problems in people with learning disabilities in all settings (including health, social care, education, and forensic and criminal justice). It aims to improve assessment and support for mental health conditions, and help people with learning disabilities and their families and carers to be involved in their care. This guideline includes recommendations on: • organising and delivering care

			• involving people in their care • prevention, including social, physical environment and occupational interventions • annual GP health checks • assessment • psychological interventions, and how to adapt these for people with learning disabilities • prescribing, monitoring and reviewing pharmacological interventions **1.10 Pharmacological interventions** 1.10.1 For pharmacological interventions for mental health problems in people with learning disabilities, refer to the NICE guidelines on specific mental health problems and take into account the principles for delivering pharmacological interventions (see recommendations 1.10.2–1.10.9). 1.10.2 For guidance on adherence and the safe and effective use of medicines, see the NICE guidelines on medicines adherence and optimisation. 1.10.3 Only specialists with expertise in treating mental health problems in people with learning disabilities should start medication to treat a mental health problem in: • adults with more severe learning disabilities (unless there are locally agreed protocols for shared care) • children and young people with any learning disabilities. 1.10.4 Before starting medication for a mental health problem in children, young people or adults with learning disabilities: • take account of:

			○ potential medication interactions ○ the potential impact of medication on other health conditions ○ the potential impact of other health conditions on the medication • when necessary consult with specialists (for example, neurologists providing epilepsy care when prescribing antipsychotic medication that may lower the seizure threshold), to minimise possible interactions • assess the risk of non-adherence to the medication regimen or any necessary monitoring tests (for example, blood tests), and the implications for treatment • establish a review schedule to reduce polypharmacy • provide support to improve adherence (see the NICE guideline on medicines adherence) • assess whether support from community and learning disabilities nurses is needed for physical investigations (such as blood tests) • agree monitoring responsibilities, including who will carry out blood tests and other investigations, between primary and secondary care. 1.10.5 Monitor and review the benefits and possible harms or side effects, using agreed outcome measures and taking into account communication needs. If stated in the relevant NICE guideline, use the timescales given for the specific disorder to inform the review, and adjust it to the person's needs. 1.10.6 When deciding the initial dose and subsequent increases, aim for the lowest effective dose. Take account of both potential side effects and difficulties the person may have in reporting them,

			and the need to avoid sub-therapeutic doses that may not treat the mental health problem effectively. 1.10.7 Prescribers should record: • a summary of what information was provided about the medication prescribed, including side effects, to the person and their family members, carers or care workers (as appropriate) and any discussions about this • when the medication will be reviewed • plans for reducing or discontinuing the medication, if appropriate • full details of all medication the person is taking, including the doses, frequency and purpose. 1.10.8 For people with learning disabilities who are taking antipsychotic drugs and not experiencing psychotic symptoms: • consider reducing or discontinuing long-term prescriptions of antipsychotic drugs, • review the person's condition after reducing or discontinuing a prescription • consider referral to a psychiatrist experienced in working with people with learning disabilities and mental health problems • annually document the reasons for continuing the prescription if it is not reduced or discontinued. 1.10.9 When switching medication, pay particular attention to discontinuation or interaction effects that may occur during titration. Only change one drug at a time, to make it easier to identify these

			effects.
NG55	Harmful sexual behaviour among children and young people	September 16	This guideline covers children and young people who display harmful sexual behaviour, including those on remand or serving community or custodial sentences. It aims to ensure these problems don't escalate and possibly lead to them being charged with a sexual offence. It also aims to ensure no-one is unnecessarily referred to specialist services. 'Young people' refers mainly to those aged 10 to 18 but also includes people up to 25 with special educational needs or a disability. This guideline includes recommendations on: • multi-agency approach and universal services • early help assessment • risk assessment for children and young people referred to harmful sexual behaviour services • engaging with families and carers before an intervention begins • developing and managing a care plan for children and young people displaying harmful sexual behaviour • developing interventions for children and young people displaying harmful sexual behaviour • supporting a return to the community for 'accommodated' children and young people • There are no specific prescribing recommendations
NG56	Multimorbidity:	September	This guideline covers optimising care for adults with multimorbidity (multiple long-term conditions)

	clinical assessment and management	16	by reducing treatment burden (polypharmacy and multiple appointments) and unplanned care. It aims to improve quality of life by promoting shared decisions based on what is important to each person in terms of treatments, health priorities, lifestyle and goals. The guideline sets out which people are most likely to benefit from an approach to care that takes account of multimorbidity, how they can be identified and what the care involves. This guideline includes recommendations on: • taking account of multimorbidity in tailoring an approach to care • how to identify people who may benefit • how to assess frailty • principles of an approach to care that takes account of multimorbidity • delivering the approach to care 1.3.4 Use an approach to care that takes account of multimorbidity for adults of any age who are prescribed 15 or more regular medicines, because they are likely to be at higher risk of adverse events and drug interactions. 1.3.5 Consider an approach to care that takes account of multimorbidity for adults of any age who: • are prescribed 10 to 14 regular medicines • are prescribed fewer than 10 regular medicines but are at particular risk of adverse events. 1.5.2 Follow these steps when delivering an approach to care that takes account of multimorbidity: • Discuss the purpose of an approach to care that takes account of multimorbidity (see

			recommendation 1.6.2). • Establish disease and treatment burden (see recommendations 1.6.3 to 1.6.5). • Establish patient goals, values and priorities (see recommendations 1.6.6 to 1.6.8). • Review medicines and other treatments taking into account evidence of likely benefits and harms for the individual patient and outcomes important to the person (see recommendations 1.6.9 to 1.6.16). • Agree an individualised management plan with the person (see recommendation 1.6.17) 1.6.2 Discuss with the person the purpose of the approach to care, that is, to improve quality of life. This might include reducing treatment burden and optimising care and support by identifying: • ways of maximising benefit from existing treatments • treatments that could be stopped because of limited benefit • treatments and follow-up arrangements with a high burden • medicines with a higher risk of adverse events (for example, falls, gastrointestinal bleeding, acute kidney injury) • non-pharmacological treatments as possible alternatives to some medicines • alternative arrangements for follow-up to coordinate or optimise the number of appointments .6.3 Establish disease burden by talking to people about how their health problems affect their day-to-day life. Include a discussion of:

			• mental health • how disease burden affects their wellbeing • how their health problems interact and how this affects quality of life. 1.6.4 Establish treatment burden by talking to people about how treatments for their health problems affect their day-to-day life. Include in the discussion: • the number and type of healthcare appointments a person has and where these take place • the number and type of medicines a person is taking and how often • any harms from medicines • non-pharmacological treatments such as diets, exercise programmes and psychological treatments • any effects of treatment on their mental health or wellbeing. 1.6.5 Be alert to the possibility of: • depression and anxiety (consider identifying, assessing and managing these conditions in line with the NICE guideline on common mental health problems) • chronic pain and the need to assess this and the adequacy of pain management. 1.6.9 When reviewing medicines and other treatments, use the database of treatment effects to find information on: • the effectiveness of treatments

			• the duration of treatment trials • the populations included in treatment trials. 1.6.10 Consider using a screening tool (for example, the STOPP/START tool in older people) to identify medicine-related safety concerns and medicines the person might benefit from but is not currently taking. [This recommendation is adapted from the NICE guideline on medicines optimisation.] 1.6.11 When optimising treatment, think about any medicines or non-pharmacological treatments that might be started as well as those that might be stopped. 1.6.12 Ask the person if treatments intended to relieve symptoms are providing benefits or causing harms. If the person is unsure of benefit or is experiencing harms from a treatment: • discuss reducing or stopping the treatment • plan a review to monitor effects of any changes made and decide whether any further changes to treatments are needed (including restarting a treatment). 1.6.13 Take into account the possibility of lower overall benefit of continuing treatments that aim to offer prognostic benefit, particularly in people with limited life expectancy or frailty. 1.6.14 Discuss with people who have multimorbidity and limited life expectancy or frailty whether they wish to continue treatments recommended in guidance on single health conditions which may offer them limited overall benefit. 1.6.15 Discuss any changes to treatments that aim to offer prognostic benefit with the person, taking into account:

			• their views on the likely benefits and harms from individual treatments • what is important to them in terms of personal goals, values and priorities (see recommendation 1.6.7). 1.6.16 Tell a person who has been taking bisphosphonate for osteoporosis for at least 3 years that there is no consistent evidence of: • further benefit from continuing bisphosphonate for another 3 years harms from stopping bisphosphonate after 3 years of treatment. Discuss stopping bisphosphonate after 3 years and include patient choice, fracture risk and life expectancy in the discussion.