Drug recommendations from Area Prescribing Committee – 14th December 2017

APC recommendations

	Drug	Recommendation	Cumbria implications
The following RAG ratings have been allocated.	Insulin Degludec (Tresiba)	For use in patients with Type 1 Diabetes, for initiation by specialist only in line with the indications below: • Nocturnal / severe hypoglycaemia (with or without hypoglycaemic unawareness) in patients who would otherwise progress to insulin pump treatment as per NICE TA 151 • Recurrent DKA episodes despite good compliance and who would otherwise progress to insulin pump therapy.	AMBER
	FreeStyle Libre continuous blood glucose monitoring system	Indications for use: 1. Patients who undertake intensive monitoring >8 times daily 2. Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy. 3. Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does currently not have that function. 4. Frequent admissions (>2 per year) with DKA or hypoglycaemia. 5. Those who require third parties to carry out monitoring and where conventional blood testing is not possible.	RED In line with the NTAG decision and the prescribing criteria specified by the RMOC in their decision on the 26th October 2017.
	Insulin Aspart (Fiasp)	Treatment of Diabetes mellitus. At present this insulin has not shown any clinical benefit over other products that are available on formulary.	AMBER
	Rasagiline	Treatment of Parkinson's disease, as a single or add on therapy.	AMBER

	Influenza vaccine Trivalent	For prescribing in primary and secondary care.	GREEN
	Influenza vaccine Quadrivalent		BLACK
	Lercanidipine	Only be used as an alternative if Amlodipine is not tolerated.	GREEN

Lothian formulary decisions

October 2017

Drugs(s)	Formulation	Trade name	Indication	Date considered by Lothian	Decision	Current Cumbria RAG rating	NICE	Commission by	Cumbria APC decision
Golimumab		Simponi®	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. Golimumab, in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by x-ray and to improve physical function.	4th October 2017	**Included** on the Additional list, specialist use only. Routinely available in line with national guidance.	RED	TA375	CCG	Remains RED in line with TA375
Buprenorphine	Transdermal patch, 5, 10, 15 and 20 microgram/hr	Butec ®	In adults, for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia.	4th October 2017	**Not routinely available** as there is local preference for alternative medicine.	BLACK		CCG	BLACK
Baricitinib	2mg and 4mg film coated tablets	Olumiant ®	Treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Baricitinib may be used as monotherapy or in combination with methotrexate.	4th October 2017	**Included** in the LJF on the additional list, specialist use only. Routinely available in line with national guidance.	RED	TA466	CCG	Remains RED in line with TA466

Beclomethasone dipropioante / formoterol fumarate dehydrate / glycopyrronium	Metered dose inhaler 87 mcg / 5 mcg / 9 mcg	Trimbow ®	Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist.	4th October 2017	**Not routinely available** as local implementation plans are being developed.			CCG	GREY
Opicapone		Ongentys ®	For use within NHS Scotland as adjunctive therapy to preparations of levodopa / DOPA decarboxylase inhbitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.	4th October 2017	**Not Recommended** for use in NHS Scotland		NG71, ES9		AMBER
Maraviroc		Celsentri ®	In combination with other antiretroviral medicianl products for treatment experienced adolescents and children of 2 years and older and weighing at least 10kg infected with only CCR5-tropic HIV-1 detectable.	4th October 2017	**Not Recommended** for use in NHS Scotland			NHSE	RED
Desmopressin		Noqdirna ®	Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults.	4th October 2017	**Not routinely available** as there is local clinical experts do not wish to add the medicine to the formulary at this time or there is local preference for an alternative medicine.	GREY	ESUOM10, CG171, CG97		GREY

Rolapitant		Varuby®	Prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. Rolapitant is given as part of combination therapy.	4th October 2017	**Not routinely available** as there is local clinical experts do not wish to add the medicine to the formulary at this time or there is local preference for an alternative medicine.			NHSE	**RED**
Stiripentol		Diacomit®	In conjunction with clobazam and valproate as adjunctive therapy of refractory generalised tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI; Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate.	4th October 2017	**Not routinely available** as there is local clinical experts do not wish to add the medicine to the formulary at this time or there is local preference for an alternative medicine.	**BLACK** For the indication myoclonic epliepsy of infancy.	CG137 (Dravet syndrome in epilepsy)		**RED**
Ustekinumab		Stelara®	For the treatment of adult patients with moderately to severely active Crohn's disease 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 or have medical contraindications to such therapies.	4th October 2017	**Not routinely available** as local implementation plans are being developed or the ADTC is waiting further advice from local clinical experts, decision expected by the 8th Nov 17.	**RED**	TA456	NHSE	Remains **RED** in line with TA456

NTAG Treatment Appraisal recommendations

Drug/indication	NTAG recommendation	Cumbria APC decision
Nil this meeting		

NICE Technology assessments

	Drug	Condition	Summary	Comm-issioner	Cumbria APC Decisi-on
TA477	Autologous chondrocyte implantation	Treating symptomatic articular cartilage defects of the knee.	Autologous chondrocyte implantation (ACI) is recommended as an option for treating symptomatic articular cartilage defects of the knee, only if: the person has not had previous surgery to repair articular cartilage defects there is minimal osteoarthritic damage to the knee (as assessed by clinicians experienced in investigating knee cartilage damage using a validated measure for knee osteoarthritis) the defect is over 2 cm^2 and the procedure is done at a tertiary referral centre.	NHSE	RED
TA478	Brentuximab vedotin	Treating relapsed or refractory systemic anaplastic large cell lymphoma.	Brentuximab vedotin is recommended as an option for treating relapsed or refractory systemic anaplastic large cell lymphoma in adults, only if: they have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1	NHSE	RED
TA479	Reslizumab	Treating severe	Reslizumab, as an add-on therapy, is recommended as an option for the treatment of	NHSE	RED

		eosinophilic asthma.	severe eosinophilic asthma that is inadequately controlled in adults despite maintenance therapy with high-dose inhaled corticosteroids plus another drug, only if: the blood eosinophil count has been recorded as 400 cells per microlitre or more the person has had 3 or more severe asthma exacerbations needing systemic corticosteroids in the past 12 months . At 12 months: stop reslizumab if the asthma has not responded adequately or continue reslizumab if the asthma has responded adequately and assess response each year.		
TA480	Tofacitinib	For moderate to severe rheumatoid arthritis.	Tofacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying anti-rheumatic drugs (DMARDs), only if: disease is severe (a disease activity score [DAS28] of more than 5.1) and the company provides tofacitinib with the discount agreed in the patient access scheme. Tofacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot have, other DMARDs, including at least 1 biological DMARD, only if: disease is severe (a DAS28 of more than 5.1) and they cannot have rituximab and the company provides tofacitinib with the discount agreed in the patient access scheme. Tofacitinib can be used as monotherapy for adults who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in sections 1.1 and 1.2 are met.	CCG	RED

TA481	Immunosuppressive therapy	For kidney transplant in adults.	This guidance makes recommendations on using basiliximab, rabbit anti-human thymocyte immunoglobulin, tacrolimus (immediate-release and prolonged-release), mycophenolate mofetil, mycophenolate sodium, sirolimus, everolimus and belatacept after kidney transplant in adults. The recommendations apply only to the initial immunosuppressive therapy (induction and maintenance therapy) started around the time of kidney transplant. It was outside the scope of the appraisal to make recommendations on using the standard triple therapy regimen of ciclosporin, azathioprine and a corticosteroid after kidney transplant in adults	NHSE	RED
TA482	Immunosuppressive therapy	For kidney transplant in children and young people.	This guidance makes recommendations on using basiliximab, rabbit anti-human thymocyte immunoglobulin, tacrolimus (immediate-release and prolonged-release), mycophenolate mofetil, mycophenolate sodium, sirolimus, everolimus and belatacept after kidney transplant in children and young people. The recommendations apply only to the initial immunosuppressive therapy (induction and maintenance therapy) started around the time of kidney transplant. It was outside the scope of the appraisal to make recommendations on using azathioprine or corticosteroids after kidney transplant in children and young people.	NHSE	RED
TA483	Nivolumab	For previously treated squamous non-small-cell lung cancer	Nivolumab is recommended for use within the Cancer Drugs Fund as an option for treating locally advanced or metastatic squamous non-small-cell lung cancer in adults after chemotherapy, only if: nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression.	NHSE	RED
TA484	Nivolumab	For previously treated squamous non-small-cell lung cancer	Nivolumab is recommended for use within the Cancer Drugs Fund as an option for treating locally advanced or metastatic non-squamous non-small-cell lung cancer in adults after chemotherapy, only if: their tumours are PD-L1 positive and nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of	NHSE	RED

			disease progression.		
TA485	Sarilumab	Treating moderate to severe rheumatoid arthritis.	Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs), only if: disease is severe (a disease activity score [DAS28] of more than 5.1) and the company provides sarilumab with the discount agreed in the patient access scheme. Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if: disease is severe (a DAS28 of more than 5.1) and they cannot have rituximab and the company provides sarilumab with the discount agreed in the patient access scheme. Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to rituximab and at least 1 biological DMARD, only if: disease is severe (a DAS28 of more than 5.1) and the company provides sarilumab with the discount agreed in the patient access scheme. Sarilumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in sections 1.1 and 1.2 are met.	CCG	RED
TA486	Aflibercept	Treating choroidal neovascularisation.	Aflibercept is recommended, within its marketing authorisation, as an option for treating visual impairment because of myopic choroidal neovascularisation in adults, only if the company provides aflibercept with the discount agreed in the patient access scheme.	NHSE	RED

			If patients and their clinicians consider both aflibercept and ranibizumab to be suitable treatments, the least costly should be used, taking into account anticipated administration costs, dosage and price per dose.		
TA487	Venetoclax	Treating chronic lymphocytic leukaemia.	Venetoclax is recommended for use within the Cancer Drugs Fund, within its marketing authorisation, as an option for treating chronic lymphocytic leukaemia, that is, in adults: with a 17p deletion or TP53 mutation and when a B-cell receptor pathway inhibitor is unsuitable, or whose disease has progressed after a B-cell receptor pathway inhibitor **or** without a 17p deletion or TP53 mutation, and whose disease has progressed after both chemo-immunotherapy and a B-cell receptor pathway inhibitor.	NHSE	RED
TA488	Regorafenib	Previously treated unresectable or metastatic gastrointestinal stromal tumours.	Regorafenib is recommended as an option for treating unresectable or metastatic gastrointestinal stromal tumours in adults whose disease has progressed on, or who are intolerant to, prior treatment with imatinib and sunitinib, only if: their Eastern Cooperative Oncology Group (ECOG) performance status is 0 to 1 and the company provides regorafenib with the discount agreed in the patient access scheme.	NHSE	RED
TA489	Vismodegib	Treating basal cell carcinoma.	Vismodegib is **not recommended** within its marketing authorisation for treating symptomatic metastatic basal cell carcinoma, or locally advanced basal cell carcinoma that is inappropriate for surgery or radiotherapy, in adults.		
TA490	Nivolumab	For treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy.	Nivolumab is recommended for use within the Cancer Drugs Fund as an option for treating squamous cell carcinoma of the head and neck in adults whose disease has progressed on platinum-based chemotherapy, only if: the disease has progressed within 6 months of having chemotherapy nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression.	NHSE	RED

TA491	Ibrutinib	For treating Waldenstrom's macroglobulinaemia.	Ibrutinib is recommended for use in the Cancer Drugs Fund as an option for treating Waldenstrom's macroglobulinaemia in adults who have had at least 1 prior therapy, only if the conditions in the managed access agreement for ibrutinib are followed.	NHSE	RED

NICE Clinical guidelines

Clinical Guideline	Condition	Date of Publication	Summary of Guidance
NG76	Child abuse and neglect	October 17	This guideline provides recommendations based on evidence on how to recognise and respond to child abuse and neglect. It offers a robust and rigorous review of the literature, in addition to lessons from practice, and provides an overview of the research into best practice in child protection. As a result it provides a reliable guide to what works and what is cost effective, as indicated by the best available evidence. It offers practitioners and commissioners a clear guide to the interventions and approaches that are most appropriate, and represent best value for money. No specific prescribing implications.
NG77	Cataracts in adults: management	October 17	This guideline covers managing cataracts in adults aged 18 and over. It aims to improve care before, during and after cataract surgery by optimising service organisation, referral and surgical management, and reducing complications. It further aims to improve the availability of information for people with cataracts before, during and after cataract surgery. No specific prescribing implications.
NG78	Cystic fibrosis: diagnosis and management	October17	This guideline covers diagnosing and managing cystic fibrosis. It specifies how to monitor the condition and manage the symptoms to improve quality of life. There are also detailed recommendations on treating the most common infections in people with cystic fibrosis.
NG79	Sinusitus (acute): antimicrobial prescribing	October17	This guideline sets out an antimicrobial prescribing strategy for acute sinusitis. It aims to limit antibiotic use and reduce antimicrobial resistance. Acute sinusitis is usually caused by a virus, lasts for about 2 to 3 weeks, and most people get better without antibiotics. Withholding antibiotics rarely leads to complications.

NG80	Asthma: diagnosis, monitoring and chronic asthma management.	November 17	This guideline covers diagnosing, monitoring and managing asthma in adults, young people and children. It aims to improve the accuracy of diagnosis, help people to control their asthma and reduce the risk of asthma attacks. It does not cover managing severe asthma or acute asthma attacks. The investment and training required to implement the guideline will take time. In the meantime, primary care services should implement what they can of the recommendations, using currently available approaches to diagnosis until the infrastructure for objective testing is in place.
NG81	Glaucoma: diagnosis and management	November 17	This guideline covers diagnosing and managing glaucoma in people aged 18 and over. It includes recommendations on testing and referral (case-finding) for chronic open angle glaucoma and ocular hypertension, and on effective diagnosis, treatment and reassessment to stop these conditions progressing.