NHS
Vale of York
Clinical Commissioning Group

Recommendations from York and Scarborough Medicines Commissioning Committee October 2017

	Drug name	Indication	Recommendation, rationale and place in therapy	RAG status	Potential full year cost impact
1	TA471: Eluxadoline for treating irritable bowel syndrome with diarrhoea		Eluxadoline is recommended as an option for treating irritable bowel syndrome with diarrhoea in adults, only if: • the condition has not responded to other pharmacological treatments (for example, antimotility agents, antispasmodics, tricyclic antidepressants) or • pharmacological treatments are contraindicated or not tolerated, and • it is started in secondary care. Stop eluxadoline at 4 weeks if there is inadequate relief of the symptoms of irritable bowel syndrome with diarrhoea. Specialists have indicated that only patients refractory to diet measures, loperamide and a TCA would be considered which is said to be uncommon. The pathway for review of treatment benefit at 4 weeks and further supply in a timely manner (if needed) requires clarification from specialists. In the meantime, the group agreed that eluxadoline should be added to the formulary as an Amber Specialist Initiation drug in line with TA471.	Amber Specialist initiation	Annual cost per patient = £1,146.60 Estimated patient numbers from YFT specialists is less than 10 patients per year.
2	TA474: Sorafenib for treating advanced hepatocellular carcinoma		Sorafenib is recommended as an option for treating advanced hepatocellular carcinoma only for people with Child-Pugh grade A liver impairment, only if the company provides sorafenib within the agreed commercial access arrangement.	Red	No cost impact to CCGs as NHS England commissioned.
3	TA475: Dimethyl fumarate for treating moderate to severe plaque psoriasis		Dimethyl fumarate (Skilarence®) is recommended as an option for treating plaque psoriasis in adults, only if the disease: • is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and • has not responded to other systemic therapies, including, ciclosporin, methotrexate and PUVA	Red	Cost saving compared to use of unlicensed Fumaderm® and biologics. Annual cost of Skilarence® 120 mg to 720 mg per day = £771.68 to £4,630.08 Current patient numbers: Vale of York – 4 patients; dose range

		(psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated. Stop dimethyl fumarate treatment at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as: • a 75% reduction in the PASI score from when treatment started or • a 50% reduction in the PASI score and a 5-point reduction in DLQI from when treatment started. The proposed place in therapy by YFT dermatology specialists is as a further option to be used in a similar way to the agreed use of apremilast i.e. those with a contraindication/intolerance to biologics, in exceptional cases for those who have a significant psychological problem with injections, or if biologics had failed. A cohort of patients were on treatment with Fumaderm® - an unlicensed product containing dimethyl fumarate as the main active ingredient; these patients have been switched to Skilarence® - 4 patients each in York and Scarborough. Fumaderm was on the formulary as a Red drug for specialist use only but the Trust has proposed that patients who have been successfully switched to Skilarence be transferred to the GP for ongoing prescribing. The suitability of primary care prescribing of Skilarence requires further assessment. In the meantime, the group agreed that it should be added to the formulary as a Red drug.		120 mg to 360 mg daily Scarborough – 4 patients; dose range 120 mg to 720 mg daily As a NICE approved licensed drug, there may be slightly more use than unlicensed Fumaderm, however specialists do not expect the numbers to change greatly, and it may delay or avoid the need for biologics in some patients.
4	TA476: Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer	Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) with gemcitabine is recommended as an option for untreated metastatic adenocarcinoma of the pancreas in adults, only if: • other combination chemotherapies are unsuitable and they would otherwise have gemcitabine monotherapy and • the company provides nab-paclitaxel with the discount agreed in the patient access scheme.	Red	No cost impact to CCGs as NHS England commissioned.
5	RAG status for Spiolto Respimat®	It had been identified that Spiolto Respimat® (tiotropium and olodaterol) is currently on the formulary as an amber drug for COPD. However this is not in line	Green	Confirmation of RAG status

		with the COPD pathway as other LABA/LAMA combinations for COPD are on the formulary as green drugs. Therefore a green status was agreed for Spiolto Respimat®.		
6	Non-transplant indications for mycophenolate	A shared care guideline for mycophenolate use for non-transplant indications is currently in development. Non-transplant indications are unlicensed and have not previously been formally approved by the committee. The group approved the inclusion of the following indications on the basis that there is information available supporting the use of mycophenolate for these indications and they are recognised uses of mycophenolate. In addition, these indications were found in mycophenolate shared care guidelines from other areas. The Trust has historically used mycophenolate for these indications. • connective tissue disease • vasculitis • systemic lupus erythematosus • dermatomyositis • polymyositis • severe psoriasis • severe atopic dermatitis • blistering conditions • pyoderma gangrenosum • autoimmune bullous dermatoses (e.g. pemphigus) • uveitis • scleritis	Amber Shared Care	No significant cost impact expected as use for these indications is current practice.