NHS
Vale of York
Clinical Commissioning Group

Recommendations from York and Scarborough Medicines Commissioning Committee February 2018

	Drug name	Indication	Recommendation, rationale and place in therapy	RAG status	Potential full year cost impact
CCG commissioned Technology Appraisals					
1.	TA497: Golimumab for treating non-radiographic axial spondyloarthritis.		Golimumab is recommended, within its marketing authorisation, as an option for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, nonsteroidal anti-inflammatory drugs. If patients and their clinicians consider golimumab to be one of a range of suitable treatments, including adalimumab, etanercept and certolizumab pegol, the least expensive (taking into account administration costs and patient access schemes) should be chosen. Assess the response to golimumab 12 weeks after the start of treatment. Continue treatment only if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and • a reduction in the spinal pain visual analogue scale (VAS) score by 2 cm or more.	Red	The list price of golimumab is £762.97 for a 50 mg pre-filled syringe/pen and £1,525.94 for a 100 mg pre-filled pen. Merck Sharp & Dohme has agreed a PAS with the Department of Health. This will make the 100 mg dose of golimumab available to the NHS at the same cost as the 50 mg dose. Therefore annual cost (50 – 100 mg SC once a month) = £9,156. NICE do not expect this guidance to have a significant impact on resources; that is, it will be less than £5 million per year in England (or £9,100 per 100,000 population). This is because the technology is an option alongside current standard treatment options and the drugs are similarly priced. YFT estimate use in 1-2 patients per year.
2.	TA503: Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer.		Fulvestrant is not recommended, within its marketing authorisation, for treating locally advanced or metastatic oestrogen-receptor positive breast cancer in postmenopausal women who have not had endocrine therapy before.	Black	No cost impact as not recommended.
NHSE commissioned Technology Appraisals – for noting					
3.	TA498: Lenvatinib with everolimus for previously treated advanced renal cell carcinoma.		Lenvatinib plus everolimus is recommended as an option for treating advanced renal cell carcinoma in adults who have had 1 previous vascular endothelial growth factor (VEGF)-	Red	No cost impact to CCGs as NHS England commissioned.

		targeted therapy, only if: • their Eastern Cooperative Oncology Group (ECOG) performance status score is 0 or 1 and • the company provides lenvatinib with the discount agreed in the patient access scheme.		
4.	TA499: Glecaprevir–pibrentasvir for treating chronic hepatitis C.	Glecaprevir–pibrentasvir is recommended, within its marketing authorisation, as an option for treating 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	No cost impact to CCGs as NHS England commissioned.
5.	TA500: Ceritinib for untreated ALK-positive non-small-cell lung cancer.	Ceritinib is recommended, within its marketing authorisation, as an option for untreated anaplastic lymphoma kinase (ALK) −positive advanced non-small-cell lung cancer in adults, only if the company provides it with the discount agreed in the patient access scheme.	Red	No cost impact to CCGs as NHS England commissioned.
6.	TA501: Intrabeam radiotherapy system for adjuvant treatment of early breast cancer.	The Intrabeam radiotherapy system is not recommended for routine commissioning for adjuvant treatment of early invasive breast cancer during breast-conserving surgical removal of the tumour. Use of the Intrabeam radiotherapy system is recommended only using machines that are already available and in conjunction with NHS England specified clinical governance, data collection and submission arrangements.	N/A	No cost impact to CCGs as NHS England commissioned.
7.	TA502: Ibrutinib for treating relapsed or refractory mantle cell lymphoma.	Ibrutinib is recommended as an option for treating relapsed or refractory mantle cell lymphoma in adults, only if: • they have had only 1 previous line of therapy and • the company provides ibrutinib with the discount agreed in the commercial access agreement with NHS England.	Red	No cost impact to CCGs as NHS England commissioned.

<table>
<tr><th colspan="5">Formulary applications or amendments/pathways/guidelines</th></tr>
<tr><td>8.</td><td>RAG status for Spiriva Respimat® for COPD</td><td>It had been identified that Spiriva Respimat® (tiotropium) is currently on the formulary as amber specialist recommendation for COPD. However this status is not consistent with the primary care COPD pathway. Also other LAMA inhalers for COPD are on the formulary as green drugs. The group was agreed that Spiriva Respimat® should be changed to green for COPD.</td><td>Green</td><td>Confirmation of RAG status.</td></tr>
<tr><td>9.</td><td>Triple combination inhalers for COPD: Trelegy® and Trimbow® and updated COPD pathway.</td><td>The group reviewed two new triple combination inhalers containing LABA/ICS/LAMA for the management of COPD for addition to the formulary:
Trimbow® MDI - Formoterol 5mcg/beclomethasone 87mcg/glycopyrronium 9mcg per inhalation
Trelegy® Ellipta (DPI) – Vilanterol 22mcg/fluticasone 92mcg/umeclidinium 55mcg
The group noted evidence from clinical trials demonstrating that open or closed triple therapy with LABA/ICS/LAMA improved lung function (FEV1) and the rate of moderate to severe exacerbations to a greater degree than dual therapy with LABA/ICS, though there were some caveats to the evidence. It was also noted that the triple therapy inhalers were less costly than various combinations using two separate inhalers on the formulary to achieve triple therapy i.e. LABA/ICS + LAMA.
The group approved the addition of both products to the formulary as green drugs on the basis of cost effectiveness as well as practical benefits to patients – simplification of treatment regimens and potentially improved adherence. The COPD pathway has been updated to reflect the new products.</td><td>Green</td><td>The triple therapy inhalers are cost saving as they are cheaper than using two separate inhalers on formulary to achieve triple therapy.

Comparative costs:<table><tr><th>Product/Device</th><th>Annual cost</th></tr><tr><td colspan="2">MDI options</td></tr><tr><td>Trimbow® (beclometasone/ formoterol/glycopyrronium)</td><td>£539.93</td></tr><tr><td>Fostair (beclometasone/formoterol) plus Spiriva Respimat (tiotropium)</td><td>£634.82</td></tr><tr><td colspan="2">DPI options</td></tr><tr><td>Trelegy® Ellipta (fluticasone/vilanterol/umeclidinium)</td><td>£539.93</td></tr><tr><td>Relvar Ellipta (fluticasone/vilanterol) plus Incruse Ellipta (umeclidinium)</td><td>£600.60</td></tr><tr><td>Duoresp Spiromax (budesonide/formoterol) plus Seebri Breezhaler (glycopyrronium)</td><td>£673.04</td></tr><tr><td>Fostair Nexthaler (beclometasone/formoterol) plus Eklira Genuair (aclidinium)</td><td>£702.76</td></tr><tr><td>Symbicort Turbohaler (budesonide/formoterol) plus Eklira Genuair (aclidinium)</td><td>£808.08</td></tr></table>Note: DPI combinations above are examples, other combinations possible.</td></tr>
<tr><td>10.</td><td>Fiasp® (10 mL vial and cartridges only) for management of T1DM</td><td>The group reviewed an appeal against the current position of Fiasp® i.e. black issued in May 2017.
It was agreed that Fiasp cartridges and 10 mL</td><td>Amber specialist recomme</td><td>No significant cost impact expected. The cost of Fiasp is comparable to that of other short-acting insulins. Estimated number of eligible</td></tr>
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		vials only would be added to the formulary as an amber specialist recommendation drug for use in the following patient cohorts: • Patients with T1DM on a basal bolus regimen or insulin pump therapy who have failed to achieve their individualised HbA1c target AND have a post prandial glucose (PPG) level >9 mmol/l at 2 hours post meal. • Pregnant women with diabetes with a PPG level >7.8 mmol/l at 1 hour post meal. After giving birth, women will be expected to transfer back to their original short acting insulin unless they continue to meet other criteria above to continue Fiasp. The ONSET 1 & 2 trials evaluating Fiasp in T1DM & T2DM patients respectively demonstrated a significant improvement in PPG at 1 hour post meal compared to Novorapid (secondary outcome measure). The appeal included information suggesting that although there is a lack of direct evidence that correcting post prandial hyperglycaemia improves clinical outcomes, treatments aimed at reducing PPG levels may be beneficial and help to lower HbA1c. In addition for pregnant women, NICE recommend stringent post prandial glucose targets which some may not achieve due to insulin resistance.	ndation	patients per year are: 120 T1DM patients (80 patients from York and up to 40 from Scarborough) 5-10 pregnant women with diabetes across both York and Scarborough.
11.	Nebivolol for heart failure and hypertension – **for patients unable to tolerate other beta blockers**.	The group reviewed an appeal against a previous MCC decision not to commission nebivolol for heart failure and hypertension on the basis of lack of cost-effectiveness compared to other beta-blockers. The appeal outlined that nebivolol had an odd pricing structure whereby the 5 mg tablets are much cheaper than the other strengths; 28x5 mg tablets cost £1.00, compared to £18.17 for 2.5 mg and £6.31 for 10 mg tablets. The 5 mg tablets are quadrisected and licensed to be divided into 4 equal doses if necessary. Therefore this strength can be used to achieve a range of doses from 1.25 mg to 10 mg. In addition some data were provided	5 mg tablets – Green 2.5 & 10 mg tablets - Black	Low/ no significant cost impact expected. Annual cost of nebivolol per patient using 5 mg tablets only: £6.50 to £26 for dose range 2.5 to 10 mg daily. In comparison, annual costs of other beta-blockers on formulary range between £7.67 to up to £77 depending on dose.

		suggesting greater cardioselectivity of nebivolol over other beta-blockers and demonstrating efficacy for heart failure and hypertension. The group agreed to add nebivolol 5 mg tablets to the formulary as a green drug for patients unable to tolerate other beta-blockers; the other strengths (i.e. 2.5 mg and 10 mg) will remain black. The formulary will be annotated to state that the 5 mg tablets are cross-scored and can be divided into 4 equal doses.		
13:	Darbepoetin alfa for use in chronic renal disease – guideline for use	Darbepoetin alfa is currently amber shared care on the Y&S formulary. However the Trust will now be doing all of the prescribing and not transferring to primary care therefore a red RAG status was agreed. The information contained in the shared care guideline was however thought to be useful as it included instructions and advice for primary care on management of these patients. Therefore this document has been retitled as a guideline for use with a different appearance to SCGs but with the same format.	Red	None expected as use is current practice.