NHS
Vale of York
Clinical Commissioning Group

Recommendations from York and Scarborough Medicines Commissioning Committee September 2020

	Drug name	Indication	Recommendation, rationale and place in therapy	RAG status	Potential full year cost impact
CCG commissioned Technology Appraisals					
1.	**TA631: Fremanezumab for preventing migraine**		Fremanezumab is recommended as an option for preventing migraine in adults, only if: • the migraine is chronic, that is, 15 or more headache days a month for more than 3 months with at least 8 of those having features of migraine • at least 3 preventive drug treatments have failed and • the company provides it according to the commercial arrangement. Stop fremanezumab if the migraine frequency does not reduce by at least 30% after 12 weeks of treatment. Locally agreed that ideally after 3 oral preventative drug treatments botulinum toxin should be tried before Fremanezumab – seeking legal advice if this is in keeping with NICE TA.	RED	In England NICE expect: 58,900 people with chronic migraine are eligible for treatment with fremanezumab each year. This is from prevalent cases. By the end of year 2024/25, 20% of people eligible will have commenced treatment with fremanezumab. 45% of people's chronic migraine responds to treatment at 12 weeks – based on trial data for migraine frequency reduction of 30%. 55% of people stop treatment after 12 weeks of treatment. 5,300 people will have fremanezumab from year 2024/25 onwards once market share has reached 20% Cost impact from NICE costing template: o VoY = £138,745 net impact by year 5 o Scarborough & Ryedale = £43,251 net impact by year 5 NICE estimate that: o VoY = 16 new patients per year, of this 7 respond to treatment o Scarborough & Ryedale = 5 new patients per year, of this 2 respond to treatment. In reality within YFT there are currently 50 patients that have not responded to botulinum toxin therapy. The costings are based on the fact that these patients will start fremanezumab in year one. From the trial data on average 45% of patients get a 30% or greater reduction in migraine free days after 12 weeks. The costings assume only 45% of patients will continue treatment after 12 weeks. Have built in a 10% increase in patients that receive fremanezumab on a year by year basis. The 22 patients currently on Aimovig will transition to fremanezumab in year 3 if it does not get approved by NICE. Year one costs = £111,000 Year two costs £94,380 Year three costs = £156,300

NHSE commissioned Technology Appraisals – for noting				
2.	**TA638: Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer**	Atezolizumab with carboplatin and etoposide is recommended as an option for untreated extensive-stage small-cell lung cancer in adults, only if they have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, and the company provides atezolizumab according to the commercial arrangement.	RED	No cost impact to CCGs as NHS England commissioned.
3.	**TA639: Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer**	Atezolizumab with nab‑paclitaxel is recommended, within its marketing authorisation, for treating triple-negative, unresectable, locally advanced or metastatic breast cancer in adults whose tumours express PD‑L1 at a level of 1% or more and who have not had previous chemotherapy for metastatic disease. It is recommended only if the company provides atezolizumab according to the commercial arrangement.	RED	No cost impact to CCGs as NHS England commissioned.
4.	**TA640: Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant**	Treosulfan with fludarabine is recommended as an option for conditioning treatment before allogeneic haematopoietic stem cell transplant (allo-HSCT) for people with malignant diseases for whom a reduced intensity regimen, such as low-dose busulfan with fludarabine, would be suitable.	RED	No cost impact to CCGs as NHS England commissioned.
5.	**TA641: Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma**	Brentuximab vedotin with cyclophosphamide, doxorubicin and prednisone (CHP) is recommended, within its marketing authorisation, as an option for untreated systemic anaplastic large cell lymphoma in adults. It is only recommended if the company provides brentuximab vedotin according to the commercial arrangement.	RED	No cost impact to CCGs as NHS England commissioned.
6.	**TA642: Gilteritinib for treating relapsed or refractory acute myeloid leukaemia**	Gilteritinib monotherapy is recommended as an option for treating relapsed or refractory FLT3‑mutation-positive acute myeloid leukaemia (AML) in adults only if the company provides gilteritinib according to the commercial arrangement. Gilteritinib should not be given as maintenance therapy after a haematopoietic stem cell transplant	RED	No cost impact to CCGs as NHS England commissioned.
7.	**TA643: Entrectinib for treating ROS1-positive advanced non-small-cell lung cancer**	Entrectinib is recommended, within its marketing authorisation, as an option for treating ROS1-positive advanced non-small-cell lung cancer (NSCLC) in adults who have not had ROS1 inhibitors. It is recommended only if the company provides entrectinib according to the	RED	No cost impact to CCGs as NHS England commissioned.

		commercial arrangement.		
8.	**TA644: Entrectinib for treating NTRK fusion-positive solid tumours**	Entrectinib is recommended for use within the Cancer Drugs Fund as an option for treating neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours in adults and children 12 years and older if: • the disease is locally advanced or metastatic or surgery could cause severe health problems and • they have not had an NTRK inhibitor before and • they have no satisfactory treatment options. It is recommended only if the conditions in the managed access agreement for entrectinib are followed.	RED	No cost impact to CCGs as NHS England commissioned.
Formulary applications or amendments/pathways/guidelines				
9.	Clonidine:for the treatment of dystonia in children	Y&S Formulary to mirror Leeds APC decision from June 2020 as tertiary centre treatment	AMBER SI	No cost impact to CCGs as position reflects current prescribing practice for this indication.
10.	Co-enzyme Q10 (Ubidecarenone/Ubiquinone) capsules and liquid (unlicensed) for treatment of Inborn errors of CoQ10 synthesis & mitochondrial disorders/cytopathies	Y&S Formulary to mirror Leeds APC decision from June 2020 as tertiary centre treatment	AMBER SI	No cost impact to CCGs as position reflects current prescribing practice for this indication.
11.	Diazoxide - 50mg/mL (30mL) Proglycem brand (unlicensed) and 50mg tablets for treatment of Hyperinsulinism Hyperammoniaemia Syndrome (HIHA)	Y&S Formulary to mirror Leeds APC decision from June 2020 as tertiary centre treatment	AMBER SI	No cost impact to CCGs as position reflects current prescribing practice for this indication.
12.	Oestrogel : for the treatment of Gender Dysphoria in Adults	Y&S Formulary to mirror Leeds APC decision from June 2020 as tertiary centre treatment	AMBER SI	No significant cost impact to CCGs expected as one of several similarly priced treatment options.
13.	ACARIZAX® sublingual tablets 12 SQ-HDM for house dust mite allergy	Y&S Formulary to mirror Leeds APC decision from June 2020 as tertiary centre treatment	RED	No cost impact to CCGs as RED drug.

<table>
<tr>
<td>14.</td>
<td>Enalapril</td>
<td>Request for addition of enalapril onto formulary as 1st line for any new patients diagnosed with HF as a long-term treatment until able / suitable for switch to sacubitril/valsartan (Entresto) was not approved.

Currently ramipril is used. National/NICE guidance does not specify which ace inhibitor should be used.

No justification for change as no clear evidence of benefit of enalapril over Ramipril.</td>
<td>NOT APPROVED</td>
<td>No cost impact to CCGs as formulary application not approved.
<table>
<tr><th>Product</th><th>Monthly secondary care cost (£)</th><th>Monthly primary care cost (£)</th></tr>
<tr><td>Ramipril (max 10mg daily; capsules)</td><td>0.36</td><td>1.20</td></tr>
<tr><td>Lisinopril (max 35mg daily)</td><td>0.36 (20mg) + 0.24 (20mg) + 0.18 (5mg)

= 0.78</td><td>1.06 (20mg) + 1.01 (10mg) + 0.87 (5mg)

= 2.94</td></tr>
<tr><td>Enalapril (max 20mg twice daily)</td><td>2.28</td><td>4.24</td></tr>
</table>
</td>
</tr>
<tr>
<td>15.</td>
<td>Dailiport®</td>
<td>Dailiport® is a once a day tacrolimus prolonged release branded generic, which has demonstrated bioequivalence to Advagraf® (tacrolimus prolonged release). It has been approved by Leeds to be added to formulary
The only people they will be starting this in for now are new patients that we are considering for a once a day preparation due to:
• Neurological side-effects e.g. difficulties sleeping at night
• Very small total dose
• Concerns about compliance e.g. Younger or transition patients, variable trough
levels
• Patient choice’</td>
<td>AMBER Shared care</td>
<td>No cost impact to CCGs as NHS England commissioned.
Nil expected as cheaper than equivalent dose of Advagraf®</td>
</tr>
<tr>
<td>16.</td>
<td>Melatonin (Slenyto®) 1mg and 5mg modified release tablets for treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.</td>
<td>Approved Slenyto® melatonin 1mg and 5mg modified release tablets in line with licensed indications only once guidance from TEWV in place and supported by Acute Trust Paediatricians.
• 1st line remains: melatonin 2mg modified release tablets (Circadin®), crushing if needed
• Rosemont melatonin 5mg/5ml oral solution (alcohol-free and propylene glycol free) - for patients only unable to use crushed tablets.
• May reduce prescribing of the more costly unlicensed Melatonin liquid preparations in this patient population.
• TEWV to produce guideline on use of Slenyto® highlightling cost differential and emphasing to use Circardin where possible and only use oral solution if absolutely necessary. This guidance will also be</td>
<td>AMBER Shared care</td>
<td>ASD = 1.5% of the population. 80% have sleep difficulties = 1.25% of the population. . However most will manage with immediate release tablets, liquids or circadin. Smith magenis syndrome has a melatonin night time deficit with melatonin produced in the day as part of the genetic condition. It affects 1 in 15000 to 25000 so very rare.

Slenyto 2 mg daily x 30 days = £41.20
Circadin 2 mg daily x 30 days = £15.39
Slenyto 5 mg daily x 30 days = £103.00
Circadin 4 – 6 mg daily x 30 days = £30.78 - £46.17

Risk of creep in use if used outsider limited licensed indication. This creep in use could have significant</td>
</tr>
</table>

		shared with paediatric teams in Acute Trusts for them to follow. • Existing patients with ASD and and / or Smith-Magenis requiring melatonin should not be switched to Slenyto®. This approval is for new patients only with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome.		cost impact of approx. £200,000 per CCG (£100,000 for Vale of York) if even just 50% of patients on Circadin switch to Slenyto.
17.	Methotrexate Shared Care Guideline – addition of Sarcoidosis	Approved addition of Sarcoidosis as an indication.		None as no change in practice.
18.	Modafinil for excessive daytime sleepiness in Parkinson's disease Shared Care Guideline	Approved addition of excessive daytime sleepiness in Parkinson's disease as an indication following recent formulary approval. Recommended treatment option in NICE guidance.	AMBER Shared Care	Up to 5 patients per year £204.60 -£772.80 for 5 patients per year.
19.	Guidance on the Self-Monitoring of Blood Glucose for Adults with Diabetes for Primary Care in North Yorkshire and York	Approved	n/a	Nil expected
20.	Asthma & COPD Pathways - updated	Approved.	n/a	No significant cost impact expected.