NHS
Vale of York
Clinical Commissioning Group

Recommendations from York and Scarborough Medicines Commissioning Committee January 2019

	Drug name	Indication	Recommendation, rationale and place in therapy	RAG status	Potential full year cost impact
CCG commissioned Technology Appraisals					
1.	Nil				
NHSE commissioned Technology Appraisals – for noting					
2.	TA548: Decitabine for untreated acute myeloid leukaemia (terminated appraisal)		NICE is unable to make a recommendation about the use in the NHS of decitabine for untreated acute myeloid leukaemia because no evidence submission was received from Janssen. The company has confirmed that it does not intend to make a submission because there is unlikely to be sufficient evidence that decitabine is cost-effective use of NHS resources in this population.	BLACK	No cost impact to CCGs as NHS England commissioned and NICE did not recommend.
3.	TA549: Denosumab for preventing skeletal-related events in multiple myeloma (terminated appraisal)		NICE is unable to make a recommendation about the use in the NHS of denosumab for preventing skeletal-related events in multiple myeloma because no evidence submission was received from Amgen. The company has confirmed that it does not intend to make a submission because there is unlikely to be sufficient evidence that denosumab is cost-effective use of NHS resources in this population.	BLACK	No cost impact to CCGs as NHS England commissioned and NICE did not recommend.
4.	TA550: Vandetanib for treating medullary thyroid cancer		Vandetanib is not recommended, within its marketing authorisation, for treating aggressive and symptomatic medullary thyroid cancer in adults with unresectable, locally advanced or metastatic disease.	BLACK	No cost impact to CCGs as NHS England commissioned and NICE did not recommend.
5.	TA551: Lenvatinib for untreated advanced hepatocellular carcinoma		Lenvatinib is recommended as an option for untreated, advanced, unresectable hepatocellular carcinoma in adults, only if: • they have Child–Pugh grade A liver impairment and an ECOG performance status of 0 or 1 and • the company provides it according to the commercial arrangement.	RED	No cost impact to CCGs as NHS England commissioned.

6.	TA552: Liposomal cytarabine–daunorubicin for untreated acute myeloid leukaemia	Liposomal cytarabine–daunorubicin is recommended, within its marketing authorisation, as an option for untreated therapy-related acute myeloid leukaemia or acute myeloid leukaemia with myelodysplasia-related changes in adults. It is recommended only if the company provides it according to the commercial arrangement.	RED	No cost impact to CCGs as NHS England commissioned.
7.	TA553: Pembrolizumab for adjuvant treatment of resected melanoma with high risk of recurrence	Pembrolizumab is recommended for use within the Cancer Drugs Fund as an option for the adjuvant treatment of stage III melanoma with lymph node involvement in adults who have had complete resection. It is recommended only if the conditions in the managed access agreement for pembrolizumab are followed.	RED	No cost impact to CCGs as NHS England commissioned.
8.	TA554: Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years	Tisagenlecleucel therapy is recommended for use within the Cancer Drugs Fund as an option for treating relapsed or refractory B‑cell acute lymphoblastic leukaemia in people aged up to 25 years, only if the conditions in the managed access agreement are followed.	RED	No cost impact to CCGs as NHS England commissioned.
Formulary applications or amendments/pathways/guidelines				
4.	Tinidazole (amoebicide)	Agree a RAG status for this formulary drug which currently has no status.	AMBER Specialist Recommendation	No significant cost to CCGs expected as all the proposals are current practice.
5.	Diloxanide	Agree a RAG status for this formulary drug which currently has no status. Currently no licensed product available in UK.	RED	No significant cost to CCGs expected as all the proposals are current practice.
6.	Pyrimethamine (Toxoplasmosis)	Agree a RAG status for this formulary drug which currently has no status. Currently no licensed product available in UK.	RED	No significant cost to CCGs expected as all the proposals are current practice.
7.	Spiramycin (Toxoplasmosis)	Agree a RAG status for this formulary drug which currently has no status.	RED	No significant cost to CCGs expected as all the proposals are current practice.
8.	Actipatch®	Agreed to not recommend the use of Actipatch® for management of localised musculoskeletal pain on the NHS. Should patients wish to use the device it can be purchased over the counter.	BLACK	No cost impact as not recommended.

		The group was concerned that the published clinical evidence was not sufficient to demonstrate the product's efficacy, and evidence from high quality randomised controlled trials was lacking. There are no RCTs comparing the efficacy of Actipatch® with other pharmacological or non-pharmacological interventions for localised musculoskeletal pain.		
9.	Erenumab Free of Charge Medicines Scheme	The MCC agreed to recommend that CCGs support the Free of Charge Scheme use of Erenumab in this patient cohort and the CCG will review the commissioning position when a NICE TA is issued. Erenumab would be used in patients with chronic migraine only who have not responded adequately or tolerated at least 3 different preventors, including botulinum toxin. Tight inclusion criteria will include : • Diagnosis of chronic migraine and experiencing 15 or more headache days/month, 8 of which must be migraine. • Age 18 to 65 years old • Medication Overuse Headache will be managed or excluded. • Response will be assessed after 12 weeks These are patients in whom botulinum toxin has not been tolerated or effective and there are currently no further treatment options available to them. The frequency of their headache is debilitating and has a significant detrimental effect on quality of life and ability to work. Exclusion criteria: • Under 18 and over 65 • Pregnant or breastfeeding • Episodic Migraine Erenumab is licensed for the prevention of migraine in in adults who have at least 4 migraine days per month. Therefore the above	RED	No cost impact or financial risk to CCGs at this stage other than political pressure from patients should Erenumab not receive positive NICE TA approval in the future. CCG is making no financial commitment to fund this drug in the future unless positive recommendation NICE TA issued. <u>Positive recommendation NICE TA issued</u> FOC supply will continue until funding arrangements are in place OR 90 days from published NICE TA, whichever is sooner. <u>No NICE TA issued</u> The FOC scheme for existing patients will continue for up to 36 months after 30th Sept 2019 if no NICE guidance has been issued by that date OR when positive guidance is issued, whichever is sooner. No new patients will be permitted to enter the scheme after 30th Sept 2019. <u>Negative NICE TA recommendation</u> Existing patients will continue for up to 36 months from the date of guidance OR if the patient falls outside the final criteria approved by NICE. Approximately 5 new patients per month across both hospital sites until publication of NICE TA or commissioning agreed. At this stage, before the NICE Technology Appraisal (TA) has been issued, the intention

		inclusion criteria are much more restrictive than the licence, pending publication of NICE guidance. NICE TA for botulinum toxin in headache supports the use of botulinum in chronic migraine, defined as headaches on at least 15 days per month of which at least 8 days are with migraine. Eligible patients must sign a form as part of informed consent process acknowledging the provision of drug is via a free of charge access scheme, and future provision of the drug is not guaranteed depending on NICE guidance. The CCG as the responsible commissioner will review the commissioning position when NICE TA is issued. If NICE do not mandate the provision of the drug through a TA the CCGs will consider the appropriateness of continuing to support its provision free of charge or otherwise. As the product is new and not established the MCC expects secondary care clinicians to formally audit the benefits of the drug in patients in whom it is tried to establish greater understanding of its place in therapy and help inform future decisions. (N.B this recommendation is specific to this free of charge scheme only and it should not be expected that all free of charge schemes will be supported). *Post MMC: NICE published on 10.1.2019 its Appraisal consultation document: Erenumab for preventing migraine. In it Erenumab is not recommended for use in the NHS. This appraisal is out for consultation until 31.1.2019 and NICE meets again on 14th Feb 2019.*		would be to limit treatment to the most severely affected until NICE guidance is issued and commissioning agreed. The Specialist Nurse at York has kept a register of all patients receiving botulinum toxin for migraine prophylaxis since the service was established in March 2014. • 309 patients in total included on the register from March 2014 to Dec 2018. • 228 patients have been discharged of which 70 patients were Non-Responders. Reasons for "Non Responders" included a) Pregnancy b) refused further cycles c) DNA 2nd cycle d) less than 30% improvement. • 81 patients currently active having Botox of these 18 have only had 1 cycle

		There is still no expected publication date for the NICE TA. It is important to note that is may not be final NICE guidance. *For people who have had at least 3 previous treatments, the clinical trial evidence shows that erenumab 140 mg works better than best supportive care for preventing chronic migraine. Erenumab 70 mg also works better than best supportive care, but not as well as erenumab 140 mg. For preventing episodic migraine, the 140 mg dosage may work better than best supportive care, but the 70 mg dosage does not. There is no evidence directly comparing erenumab with botulinum toxin type A in chronic migraine or another oral preventive treatment in chronic or episodic migraine. Also, there is uncertainty about whether erenumab works in the long term.* *For chronic migraine, the cost-effectiveness estimates for erenumab are higher than what NICE normally considers acceptable when there is substantial uncertainty. For episodic migraine the estimates are much higher than what NICE considers a cost-effective use of resources. So erenumab is not recommended for preventing chronic or episodic migraine.*		