NHS
Vale of York
Clinical Commissioning Group

Recommendations from York and Scarborough Medicines Commissioning Committee May 2017

Drug name	Indication	Recommendation, rationale and place in therapy	RAG status	Potential full year cost impact
TA440 Pegylated liposomal irinotecan for treating pancreatic cancer after gemcitabine		Pegylated liposomal irinotecan, in combination with 5-fluorouracil and leucovorin, is **not recommended**, within its marketing authorisation, for treating metastatic adenocarcinoma of the pancreas in adults whose disease has progressed after gemcitabine-based therapy.	Already assigned Black and link added to formulary	None as not recommended.
TA441 Daclizumab for treating relapsing-remitting multiple sclerosis		**NHS England commissioned** Daclizumab is recommended as an option for treating multiple sclerosis in adults, only if: • the person has active relapsing–remitting multiple sclerosis previously treated with disease-modifying therapy, or rapidly evolving severe relapsing–remitting multiple sclerosis (that is, at least 2 relapses in the previous year and at least 1 gadolinium-enhancing lesion at baseline MRI) and • alemtuzumab is contraindicated or otherwise unsuitable and • the company provides the drug with the discount agreed in the patient access scheme.	Red	No cost impact to CCGs as NHS England commissioned.
TA443 Obeticholic acid for treating primary biliary cholangitis		**NHS England commissioned** Obeticholic acid is recommended, within its marketing authorisation, as an option for treating primary biliary cholangitis in combination with ursodeoxycholic acid for people whose disease has responded inadequately to ursodeoxycholic acid or as monotherapy for people who cannot tolerate ursodeoxycholic acid. Obeticholic acid is recommended 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.
York and Scarborough merged COPD Pathway		The pathway was approved following some minor formatting adjustments.	N/A	There were no significant differences in agent choice or pathway between the two separate pathways previously in use.

Removal of Grey and non-formulary categories from the formulary	The group considered that the Grey category (no formal commissioning position) particularly used for new NICE TAs may not always be helpful given the well-established RAG system which prescribers are familiar with and there is a risk of appearing non-compliant with NICE TAs if this status is not amended within 3 months. It was also considered that having a designated non-formulary section would require that all drugs are covered by the formulary which was deemed impractical and defeats the purpose of the formulary. It was agreed that instead of having the Grey category, the inclusion of new NICE TAs to the formulary should be delayed until they have been considered and a RAG status agreed by MCC. Also, any drugs that are not a formulary choice or unsuitable for Black list inclusion would simply not be included in the formulary. If the MMT notice an increased frequency of requests for drugs not included in the formulary, this should be highlighted to MCC for review.	N/A	N/A
Paroxetine for depression – review of formulary status following removal of non-formulary category. Currently non-formulary Green for continuation only.	Following removal of the non-formulary category, the group approved paroxetine to be included as a formulary drug, annotated with "continuation only", and retaining its Green status.	Green	None expected as continuation only restriction still applies.
Desmopressin 25/50 mcg oral lyophilisate (Noqdirna®) for symptomatic treatment of nocturia due to idiopathic nocturnal polyuria	This product was approved for addition to the formulary with an Amber Specialist Recommendation status. It is the first licensed treatment for this indication. A higher strength desmopressin preparation (100 mcg) has been used but is off-label for this indication. As a licensed product Noqdirna would be preferable to off-label use of other medicines. NICE guideline on management of LUTS in men (updated June 2015) states *"Consider offering oral desmopressin to men with nocturnal polyuria if other medical causes have been excluded and they have not benefited from other treatments."* This refers to off-label use of desmopressin as the guideline predates the launch of the licensed product. The urology team confirmed low dose desmopressin would be included as a treatment option for nocturnal polyuria in the RSS pathway for LUTS in men, alongside late afternoon loop diuretic.	Amber Specialist Recommendation	YFT urology directorate estimate a maximum of 20 patients per year to be treated in primary care. Other directorates may rarely prescribe for inpatients. Comparative annual drug costs: Noqdirna 25 to 50 mcg daily costs £181.92 per year per patient. Total cost per year for 20 patients = £3638.40 A 50 mcg dose using off-

			label desmopressin 100 mcg tablets which are scored would cost £126.18 per year per patient. Total cost per year for 20 patients = £2523.60
Fast-acting insulin aspart (Fiasp®) for treatment of diabetes mellitus in adults.	Fiasp was not approved for addition to the formulary at this time and a Black status was assigned on the basis that: • There is a lack of clear evidence of significant benefit from Fiasp over NovoRapid • Fiasp has Black Triangle status and more established treatments with greater clinical experience are generally preferred • Considering the approaching patent expiry of NovoRapid in June 2017, there could potentially be missed opportunities for efficiency savings if a biosimilar becomes available in the near future and patients have already been transferred to, or started on Fiasp, and without any added clinical benefit.	Black	No cost impact as not approved.
Febuxostat for treatment of chronic gout - The group received a request to review the RAG status. Currently rrestricted for initiation by consultant rheumatologists and renal physicians only but a Green status was proposed.	The group approved the Green RAG status for febuxostat with the inclusion of links to the relevant RSS guidance and the CKS guideline on gout to the formulary. No safety concerns were identified compared to allopurinol to warrant a restricted status and place in therapy is clearly defined in the NICE CKS topic on gout as per the NICE TA. The higher cost of febuxostat compared to allopurinol was noted (£24.36 vs £0.75 to £0.85 per month), but was not considered to pose an issue if used in line with guidance.	Green	Low/no cost impact expected.
Diltiazem 2% ointment for anal fissures	The group approved the addition of diltiazem 2% ointment to the formulary with a Green status to replace diltiazem 2% cream. Both preparations are unlicensed but the ointment costs significantly less than the cream (£35.52 vs £60.50 for 30g). There appeared to be no particular reasons to choose one preparation over the other.	Green	Cost saving.
Novorapid FlexTouch device for patients with dexterity problems	The group had the opportunity to compare placebo devices of the FlexTouch and the FlexPen pre-filled pens. There was doubt that the FlexTouch device offered significant advantages over the FlexPen and concerns were raised around who would be responsible for deciding whether patients had dexterity problems. The FlexTouch device is slightly more expensive than the	N/A (not for inclusion in formulary)	No cost impact as not approved.

	FlexPen (£32.13 vs £30.60 for 5x3mL pre-filled pens). Given the considerable financial pressures being faced by the CCG and the lack of a proven benefit of the FlexTouch device over the FlexPen, the group did not approve the FlexTouch device.		
New RAG status for Grey listed items	Following a review of all Grey listed drugs, the group approved the following RAG ratings/ formulary status: **Black**: • Fosavance® • Actonel Combi® (risedronate + calcium and vitamin D) • Olanzapine embonate (ZypAdhera®) • Paliperidone (oral) – as per TEWV **Red:** • Apremilast for indications in TA433 & TA419 • Daclizumab for indications in TA441 & TA99 (both NHSE commissioned) • Ivermectin (oral); for specialist dermatologist use • Mepolizumab (TA431); specialist centre (NHSE commissioned) • Obeticholic acid (NHSE commissioned) **Amber:** • Flupentixol decanoate (Depixol®); specialist initiation – as per TEWV • Fluphenazine decanoate; specialist initiation – as per TEWV • Haloperidol decanoate; specialist initiation – as per TEWV • Paliperidone (injection); shared care – as per TEWV • Risperidone LA injection (Risperdal Consta®); specialist initiation – as per TEWV • Zulcopenthixol Decanoate (Clopixol®); specialist initiation – as per TEWV **Removal from formulary (not used):** • Cangrelor • Histerelin • Pipotiazine palmitate depot (Piportil® Depot) - discontinued	As stated	No cost impact expected; apremilast TAs have previously been approved.
Public Health Formularies	The group approved the following RAG ratings for drugs included in the NY Public Health Formularies for the Shared Care Drug Misuse Treatment and Recovery Service, Pharmacological	As stated	None as public health commissioned.

	abstinence supervision service for alcohol misuse, and Targeted Primary Care Sexual Health Service. **Alcohol dependence** **RAG: Amber Specialist Initiation by North Yorkshire Horizons** Duration: NYH prescribe for initial 12 weeks. GP then prescribes for up to (further) 12 weeks. May be prescribed by GP for longer if structured medicine review at 12 weeks determines this to be clinically appropriate. Structured medicines reviewed required 6 monthly thereafter, if prescribing to continue**.** • Acamprosate • Disulfiram • Naltrexone **Substance misuse** **RAG: Green but in conjunction with NYH Recovery co-ordinator** Duration: No fixed duration • Buprenorphine S/L tabs S/F 2mg, 4mg & 8mg • Buprenorph/Naloxone S/L tabs S/F 8mg/2mg • Buprenorphine_Tab Subling 4mg S/F • Methadone HCl_Mix 1mg/1ml, 1mg/1ml C/F, 1mg/1ml S/F **Sexual health** **RAG: Green** Duration: No fixed duration • Mirena • Jaydess • Nexplanon • Ancora 375 Cu • Copper T380 A • Flexi-T 300 & Flexi-T+380 • GyneFix intrauterine contraceptive implant • Load 375 • Mini TT380 Slimline • Multiload CU 375 • Multi-Safe 375 • Neo-Safe T380		

	• Nova-T 380 • Novaplus T 380 Ag (Normal, Mini) & Novaplus T 380 Cu (Normal, Mini) • Optima TCu380A • Steriload • T-Safe 380A QL • TT380 Slimline • UT380 Short & UT380 Standard		