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**SUMMARY OF RECOMMENDATIONS FOR HNY-WIDE CONSULTATION**

| **Recommendations made by the Medicines, Formulary, and Guidelines Group at their meeting on:** | 21 May 2025 |
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| **Local Recommendations** |

| **Drug and indication** | **Rationale / criteria** | **Status and formulary position proposed\*** | **Notes on decision** | **Cost impact** | **Commissioning / service implications** |
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| **Paravit Mod® oral drops and oral capsuiles**  **Fat soluble multi-vitamin for Cystic Fibrosis (CF) patients** | CFTR modulator therapy has changed the management of CF and patients on CFTR modulator therapy have lower vitamin A requirements. | Amber Specialist Initiation | In place of Abidec/Dalivit and Vitamin E liquid for under 3s. As an alternative to DEKAs and Paravit-CF for over 3s. | Paravit Mod is comparable in price to Paravit CF and DEKAs that are already in use. Paravit Mod® is less expensive than vitamin regimens containing Vitamin E (Alpha Tocopheryl Acetate) Oral Suspension and has a longer in use shelf life. | None – existing patient group |
| **Pylera® tablets**  **Bismuth/ metronidazole/ tetracycline**  **For treating Helicobacter Pylori** | Pylera as a 10 day course (to be used with omeprazole 20mg BD as per its license) as an alternative to the off-label bismuth / tetracycline / metronidazole regimens in the BNF.  Individual components are hard to source, bismuth has been unavailable for some time. | In penicillin allergy - Green   * Pylera 10 day course (with omeprazole 20mg BD) as alternative first line for patients previously treated with clarithromycin * Pylera 10 day course (with omeprazole 20mg BD) as alternative second line in patients who have received previous treatment with a fluoroquinolone   Amber SR in those without penicillin allergy   * Pylera 10 day course (with omeprazole 20mg BD) - Third line on specialist (microbiology or gastroenterology) advice only | Place in therapy is same as the off-label bismuth / tetracycline / metronidazole regimens in the BNF. | Cost saving over individual components. | None – existing patient group |

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| **NICE Technology Appraisals and Guidance** |

| **NICE Technology appraisal or guidance** | **Status and formulary position assigned** | **Notes on decision** | **Cost impact** | **Commissioning / service implications** |
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| [**TA1056: Molnupiravir for treating COVID-19**](https://www.nice.org.uk/guidance/ta1056)  **16 April 2025**  **Commissioning: ICB**  Molnupiravir is recommended as an option for treating mild to moderate COVID‑19 in adults who have a positive SARS‑CoV‑2 test, only if:   * they have 1 or more risk factors for progression to severe COVID‑19 (as defined in section 5 of NICE's technology appraisal guidance on nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19) and * both nirmatrelvir plus ritonavir and sotrovimab are contraindicated or unsuitable. | Should be prescribed in line with CMDU. Add to formulary with RED RAG status aligned with CMDU delivery model, with links to TA1056.    Remove links to NHSE interim commissioning policy. |  | NICE expects the resource impact of implementing the recommendations in England will be less than approximately £8,800 per 100,000 population. This is because the technology is a further treatment option and the overall cost of treatment will be similar for this population, and NICE do not think practice will change substantially as a result of this guidance. | None – would use existing CMDU delivery model |
| [**TA1057: Relugolix–estradiol–norethisterone for treating symptoms of endometriosis**](https://www.nice.org.uk/guidance/ta1057)  **16 April 2025**  **Commissioning: ICB**  Relugolix–estradiol–norethisterone (relugolix combination therapy [CT]) can be used, within its marketing authorisation, as an option for treating symptoms of endometriosis in adults of reproductive age who have had medical or surgical treatment for endometriosis. | Add to formulary as an amber (specialist initiation) drug in this indication, with links to TA1057 |  | Costs may vary in different settings because of negotiated procurement discounts. Comparator options have commercial medicines unit (CMU) discounted prices that are confidential. The net cash impact of this topic therefore cannot be reported.  There will be potential savings from the reduced cost of hormone add-back treatments which are given with GnRH agonists | Treatment with relugolix is initiated in secondary care where an appointment every 6 months is needed in the first year of treatment. It is expected that further prescriptions of relugolix are given at the same time as monitoring attendances after the first year of treatment. After the first year, 4 monitoring attendances per year with a GP nurse are required. |
| The following NHSE-commissioned medicines received positive NICE appraisals. They will be assessed by provider trusts once all necessary information is available, and if added to the HNY formulary they will have a status of RED  [**TA1051: Efanesoctocog alfa for treating and preventing bleeding episodes in haemophilia A in people 2 years and over**](https://www.nice.org.uk/guidance/ta1051)  [**TA1053: Cladribine for treating active relapsing forms of multiple sclerosis**](https://www.nice.org.uk/guidance/ta1053)  [**TA1054: Ruxolitinib for treating acute graft versus host disease that responds inadequately to corticosteroids in people 12 years and over**](https://www.nice.org.uk/guidance/ta1054)  [**TA1055: Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy**](https://www.nice.org.uk/guidance/ta1055)  [**HST33: Leniolisib for treating activated phosphoinositide 3-kinase delta syndrome in people 12 years and over**](https://www.nice.org.uk/guidance/hst33) | | | | |
| All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted. | | | | |

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| **RAG classifications for joint Humber and North Yorkshire ICB formulary** | | | |
| **Red** | Specialist prescribing only  The specialist initiates, continues and completes all ongoing monitoring. | **Amber specialist recommendation (Amber SR)**  Formerly known as Amber 1 in Humber | Does not need to be initiated by a specialist but can be recommended by a specialist to general practice.  No ongoing arrangements between specialist and general practice. General practice can refer back to specialist at any time in relation to medication query, if required. |
| **Amber shared care (Amber SCP)** | Specialist initiation with ongoing monitoring  Medicines that must be initiated by a specialist\*, and which require significant monitoring on an ongoing basis.  Full agreement to share the care of each specific patient must be reached under the shared care protocol (SCP) which must be provided to the primary care provider.  If a commissioned SCP is not available these must be treated as red. | **Green (with pathway/guideline)**  Formerly known as Amber 1 in Humber | Can be prescribed in primary care in line with a recommended approved pathway/guideline. |
| **Amber specialist initiation**  **(Amber SI)**  Formerly known as Amber 2 in Humber | Must be started by a specialist and remain with specialist until the patient is stable on the new medicine but can then be transferred to primary care (general practice) to continue prescribing without ongoing arrangements between specialist and general practice. General practice can refer back to specialist at any time in relation to medication query, if required. | **Green (no pathway/guideline)** | Medicines suitable for routine use within primary care and secondary care.  Can be prescribed in primary care, as per the wording on the formulary and considering both the drug SPC and BNF. |