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

| **Recommendations made by the Medicines, Formulary, and Guidelines Group at their meeting on:** | 16 July 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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| **Rufinamide (Eisai Ltd)**  Rufinamide tablets in strengths 100mg, 200mg and 400mg  Rufinamide 40mg/ml oral suspension sugar free | Formulary alignment:  Currently rufinamide is on NY&Y formulary as Amber – Specialist Initiation and Amber 2 in Hull/ERY and Red in NEL/NL. | **Amber – Specialist Initiation** for adults and children with link to NICE NG 217 <https://www.nice.org.uk/guidance/ng217>  Additional Notes: Category 2 Antiepileptic  Base the need for continued supply of a particular manufacturer’s product on clinical judgement and consultation with patient and/or carer. See;  [Antiepileptic drugs: updated advice on switching between different manufacturers’ products - GOV.UK](https://www.gov.uk/drug-safety-update/antiepileptic-drugs-updated-advice-on-switching-between-different-manufacturers-products) | Currently in Northern Lincolnshire patients have to get prescriptions for their prescriptions from their tertiary specialist which for paediatrics is Sheffield Children’s Hospital and adults could be either HUTH or Sheffield Teaching Hospitals. | No change in Hull, East Riding of Yorkshire, Vale of York and North Yorkshire from current primary care spend. Potential for small increase in NEL and NL. However, Lennox Gaustaut syndrome (LGS) is a rare epilepsy syndrome so unlikely to have huge effect. Also, likely that they are already receiving via secondary or tertiary care  No cost difference between primary and secondary care | There is also a cost to the trusts supplying for deliveries to patient's home (which is likely to be quite significant for out of area deliveries). |
| **Phosphate Binders for renal patients**  **Calcium acetate**  **Sevelamer carbonate/ hydrochloride**  **Calcium carbonate**  **Sucroferric oxyhydroxide**  **Lanthanum** | Formulary alignment:  Adding these phosphate binders to the formulary NL/NEL and aligning RAG rating across the ICB will make access more equitable. | **Amber – Specialist Recommendation** with link to NG203 <https://www.nice.org.uk/guidance/ng203> for the following drugs when used as phosphate binders in renal patients   * Calcium acetate * Sevelamer carbonate/ hydrochloride * Calcium carbonate * Sucroferric oxyhydroxide * Lanthanum   **Monitoring and dose adjustment remains the responsibility of the specialist** | In adults NG203 <https://www.nice.org.uk/guidance/ng203> recommends calcium acetate as first line phosphate binder, or sevelamer carbonate if calcium acetate is not indicated. If neither calcium acetate or sevelamer carbonate can be used then either sucroferric oxyhydroxide (for dialysis patients if calcium-based phosphate binder is not needed) or calcium carbonate (if a calcium based phosphate binder is needed). As a fourth choice i.e. if no other phosphate binders can be used lanthanum is recommended. | No overall change of expenditure. However, switch of expenditure from secondary care (HUTH) to primary care in NEL/NL expected. Expected that expenditure in Hull/ERY/YoY and NY will remain the same. | Northern Lincolnshire does not currently list phosphate binders within their formulary, and this causes issues when renal patients are admitted within NLAG and require phosphate binders as in patients.  Patient experience – patients within NEL/NL with CKD 4-5 including dialysis currently receive their phosphate binders via HUTH outsourced outpatient dispensaries. Deliveries can be offered; with a potential cost impact to HUTH. Deliveries cannot be offered in Y&S and wide geography can lead to patients travelling significant distances to collect medicines. |
| **Ospemifene (Senshio®)**  **60mg oral tablet**  **Ospemifene is indicated for the treatment of moderate to severe symptomatic vulvar and vaginal atrophy (VVA) in post-menopausal women.**  **Restricted to pateints who are not candidates for local vaginal oestrogen therapy (unable to administer)** | New Line Request:  Ospemifene as an oral treatment for genitourinary symptoms, ONLY if the use of locally applied treatments is impractical, for example, because of disability. | **Green**  **Restricted to post-menopausal women who are not candidates for local vaginal oestrogen therapy (unable to administer)** | Menopause: identification and management (Last updated: 07 November 2024) <https://www.nice.org.uk/guidance/ng23>  Evidence showed that ospemifene was not cost-effective and could therefore not be recommended as a first-line treatment option for all people with genitourinary symptoms associated with menopause. However, the committee noted that, for some people, local application of vaginal oestrogen may be impractical. For example, people with physical or intellectual disabilities may find it difficult to use local vaginal oestrogen. Ospemifene is an oral tablet and should therefore be considered as an option in such specific circumstances | £39.50 per pack of 28 tablets  Comparator products (all applied vaginally).  Imvaggis (Estriol)  30 microgram pessaries £13.38 (24)  Estriol 500 microgram pessaries £5.45 (15)  Estriol 0.01% cream £5.45 (15g)  Estriol 50 microgram /g cream £18.90 (30g) | None |
| **Sumatriptan / naproxen**  85 mg/457 mg film-coated tablets  (Suvexx®, Orion Pharma) | This a new product | **Not Routinely Commissioned** | Use of the single ingredients is a more cost-effective option than the combination product.  Both ingredients are on formulary and available. | Suvexx® 9 tablets = £36.00  Drug tariff price for components:  28 x naproxen 500mg = £1.37  6 x sumatriptan 100mg = £1.17  Total cost for 9 doses = £2.20 | None |

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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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| [**TA1067: Linzagolix for treating symptoms of endometriosis**](https://www.nice.org.uk/guidance/ta1067)  **4 June 2025**  **Commissioning: ICB**  Linzagolix with hormonal add-back therapy can be used within its marketing authorisation as an option to treat symptoms of endometriosis in adults of reproductive age who have had medical or surgical treatment for their endometriosis. | Add to formulary as an Amber - Specialist Initiation drug in this indication, with links to TA1067.  Patient is to remain under the care of a specialist at least until the 1 year DXA scan is reviewed.  On formulary for fibroids as per NICE TA996  NY&Y:  Amber (specialist initiation or recommendation)  Humber:  Amber (as per HNY classification) | Relugolix combination therapy (CT) was recommended as an option for treatment in [NICE TA1057](https://www.nice.org.uk/guidance/ta1057).  Relugolix CT and linzagolix are both oral treatments, while GnRH agonists are mostly subcutaneous injections. Intranasal options are available but not generally used in the NHS  Relugolix CT (estradiol hemihydrate, norethisterone acetate, relugolix) includes fixed dose hormonal add back therapy. Additional add back therapy is required alongside Linzagolix for treating symptoms of endometriosis.  Hormonal add back therapy reduces the menopausal symptoms associated with relugolix and linzagolix, including decreases in bone mineral density (BMD). | The list price of linzagolix is £80 for 28 tablets. Add-back therapy with estradiol + norethisterone is needed alongside this (£13.20 for 84 tablets) for a total cost of £93.20 excl. VAT per 28 days (£1,211.60 per year). Relugolix CT has a list price of £72 excl. VAT per 28 tablets (£936 per year).  Because linzagolix is more expensive than relugolix CT and needs additional add-back therapy, NICE assumed relugolix CT to have a higher market share. Increased use of relugolix CT may reduce the number of GP attendances needed for administering GnRH agonists, depending on whether the new drugs displace GnRH agonists or best supportive care. | Both relugolix CT and linzagolix require monitoring for bone loss. SmPC recommendations are:  Relugolix CT:   * In patients with risk factors for osteoporosis or bone loss, a DXA scan is recommended prior to starting Ryeqo treatment. * Decreases of >3% were seen in 21% of the patients. Therefore, a DXA scan is recommended after the first 52 weeks of treatment and as considered appropriate thereafter.   Linzagolix:   * In patients with risk factors for osteoporosis or bone loss, a dual X-ray absorptiometry DXA scan is recommended prior to starting treatment. * A DXA scan is recommended after 1 year of treatment for all women, and there is a need for continued BMD monitoring thereafter |
| [**TA1070: Spesolimab for treating generalised pustular psoriasis flares**](https://www.nice.org.uk/guidance/ta1070)  **18 June 2025**  **Commissioning: ICB, tariff-excluded**  Spesolimab is recommended as an option for treating generalised pustular psoriasis (GPP) flares in adults, only if it is used to treat:   * initial moderate to severe flares when:   + the Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score is 3 or more (at least moderate), and   + there are fresh pustules (new appearance or worsening of existing pustules), and   + the GPPGA pustulation subscore is at least 2 (at least mild), and   + at least 5% of the body's surface area is covered with erythema (abnormal redness of the skin or mucous membranes) and has pustules * subsequent flares with a GPPGA pustulation subscore of 2 or more (at least mild), if the last flare was treated with spesolimab and resolved to a GPPGA pustulation subscore of 0 or 1 (clear or almost clear skin). * Spesolimab can only be used if the company provides it according to the commercial arrangement.   A second dose of spesolimab can be used after 8 days if a flare has not resolved to a GPPGA pustulation subscore of 0 or 1. | Add to formulary as a RED drug in this indication, with links to TA1070. | There is no licensed standard care for GPP flares. Usual treatment includes ciclosporin, acitretin and biological treatments used to treat other forms of psoriasis | A resource impact template is available, but requires input of the confidential prices for spesolimab and comparators and local input of capacity impacts.  NICE expect 268 people in England to receive spesolimab in year 1, rising to 927 in year 5. They reported that a consultant in dermatology stated that all GPP flares will have responded by week 12 and patients have on average 1 flare per year.  The Effisayil 1 trial reported 7.14% of people in the spesolimab and BAC arm had treatment for a subsequent flare after the initial flare resolved to a GPPGA pustulation subscore of 0 or 1.  NICE assumed there will be a faster flare resolution with spesolimab, with lower hospitalisation rates and shorter lengths of hospital stay. Using Wolf et al. (2024) it is assumed 77.6% of people who had BAC were hospitalised for treatment of GPP flares. The committee stated the proportion of people with GPP who would be admitted to hospital after having spesolimab is highly uncertain, but the company assumed that spesolimab reduced hospital rates by 50%. | Spesolimab is administered as a single dose intravenous infusion in a secondary or tertiary care setting. A second dose may be given after 8 days if a flare has not resolved. Based on the Effisayil 1 trial, 34% of people did not achieve a GPPGA pustulation subscore of 0 or 1 and received a second dose.  Treatment would not require any additional services not already in place for the administration of best available care. |
| [**TA1069: Efgartigimod for treating antibody-positive generalised myasthenia gravis**](https://www.nice.org.uk/guidance/ta1069)  **4 June 2025**  **Commissioning: ICB**  Efgartigimod is not recommended, within its marketing authorisation, as an add-on to standard treatment for generalised myasthenia gravis in adults who test positive for anti-acetylcholine receptor antibodies. | Add to not routinely commissioned list in this indication, with links to TA1069. | NY&Y: Red, as per [EAMS decision](https://www.gov.uk/government/publications/efgartigimod-alfa-in-the-treatment-of-myasthenia-gravis-gmg?UNLID=6410529172025714115831) which has now been withdrawn.  . | The economic model does not accurately capture how efgartigimod would be used in the NHS; that is, as an additional treatment in the treatment pathway. The most likely cost-effectiveness estimates are substantially above what NICE considers an acceptable use of NHS resources |  |
| [**TA1074: Sparsentan for treating primary IgA nephropathy**](https://www.nice.org.uk/guidance/ta1074)  **25 June 2025**  **Commissioning: ICB, tariff excluded**  Sparsentan can be used as option to treat primary immunoglobulin A nephropathy (IgAN) in adults with a:   * urine protein excretion of 1.0 g/day or more, or * urine protein-to-creatinine ratio (UPCR) of 0.75 g/g or more.   It can only be used if the company provides it according to the commercial arrangement. | Add to formulary as a RED drug in this indication, with links to TA1074.  Sparsentan is a tariff-excluded drug and a commercial arrangement is in place. Supply is therefore likely to be via secondary care unless mechanisms are put in place for primary care to access the discounted price. |  | A resource template is available but requires input of the confidential price.  NICE estimates that primary IgAN affects roughly 565 people in HNY, of whom around 130 may be eligible for treatment with sparsentan. The comparator treatment for the eligible population is irbesartan. NICE expect 2 people to take up sparsentan in year 1, increasing to a total of 22 people treated by year 5. | IgAN is a progressive kidney disease which can result in end stage renal disease. Patient experts highlighted that delaying the need for kidney transplant has health benefits. Clinical and patient experts also highlighted that the demand for renal services is increasingly impacting the availability of dialysis and waiting times for transplants. The committee recognised these issues and concluded that there were uncaptured benefits of sparsentan to consider in its decision making. |
| 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  [**TA1071: Atezolizumab for adjuvant treatment of resected non-small-cell lung cancer**](https://www.nice.org.uk/guidance/ta1071)  [**TA1073: Marstacimab for treating severe haemophilia A or B in people 12 years and over without anti-factor antibodies**](https://www.nice.org.uk/guidance/ta1073) | | | | |
| The following NHSE-commissioned medicines have NOT received positive NICE appraisals. They will be added to the not routinely commissioned list for the listed indication with link to the terminated TA,  [**TA1072: Tislelizumab for treating advanced non-small-cell lung cancer after platinum-based chemotherapy (terminated appraisal)**](https://www.nice.org.uk/guidance/ta1072) | | | | |
| 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. |