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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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| **NICE Technology Appraisals** |

| **NICE Technology appraisal or guidance** | **Status and formulary position assigned** | **Notes on decision** | **Cost impact** | **Commissioning / service implications** |
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| [**TA1066: Somapacitan for treating growth hormone deficiency in people 3 to 17 years**](https://www.nice.org.uk/guidance/ta1066)  **3rd June 2025**  **Commissioning: ICB, tariff excluded, 30-day NICE TA**  Somapacitan can be used, within its marketing authorisation, as an option to treat growth failure caused by growth hormone deficiency in people 3 to 17 years. Somapacitan can be used if the company provides it at the same price or lower than that agreed with the Medicines Procurement and Supply Chain, where applicable.  Use the least expensive option of the available treatments (including somapacitan and any preparation of somatropin). Take account of administration costs, dosages, price per dose and commercial arrangements. If the least expensive option is unsuitable, people with the condition and their healthcare professional should discuss the advantages and disadvantages of other treatments. | Add somapacitan to formulary as a RED drug in this indication with a link to TA1066.  Somapacitan is subject to a commercial arrangement that is likely not accessible in primary care. To supply it in accordance with NICE it therefore likely requires a RED traffic light status.  NB: somapacitan is also licensed for use in adults, but NICE have not assessed this patient group and this indication is not in timetable. | The group acknowledged that there is currently variation across the ICB in traffic light status of growth hormone. | Somapacitan works in a similar way to somatrogon or somatropin, and would be offered to the same population. Clinical trial evidence shows that somapacitan works as well as somatropin. Both somapacitan and somatrogon are administered once per week whereas somatropin is administered daily.  NICE cost modelling used a range of dosages of somatropin that reflects the range used in the NHS. It also took into account the costs of somapacitan and somatropin in primary and secondary care. The cost comparison suggests that the cost of somapacitan is similar to or lower than the cost of somatropin. So somapacitan can be used.  The company has agreed a nationally available price reduction for somapacitan with the Medicines Procurement and Supply Chain. The prices agreed through the framework are commercial in confidence.  A NICE resource impact template is available, but requires local completion of drug prices and expected proportion of patients receiving each available treatment. | Some patients are referred to out of area services for care, and a RED traffic light status may have a particular impact on this group.  Feedback on impact on these patients is particularly sought at consultation. |
| [**TA1075: Dapagliflozin for treating chronic kidney disease**](https://www.nice.org.uk/guidance/ta1075)  **2nd July 2025**  **Commissioning: ICB, tariff included, 30-day NICE TA**  Dapagliflozin can be used as an option to treat chronic kidney disease (CKD) in adults, if:   * it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin‑2 receptor antagonists, unless these are contraindicated, and * people have an estimated glomerular filtration rate (eGFR) of:   + 20 ml/min/1.73 m2 to less than 45 ml/min/1.73 m2 or   + 45 ml/min/1.73 m2 to 90 ml/min/1.73 m2, and either:     - a urine albumin-to-creatinine ratio of 22.6 mg/mmol or more, or     - type 2 diabetes.   This guidance updates and replaces NICE TA775, dapagliflozin for CKD. It expands the eligible population to align with [NICE TA942 for empagliflozin](https://www.nice.org.uk/guidance/ta942/chapter/1-Recommendations). | Add links TA1075 to formulary.  Remove links to TA942. | Traffic light status is not harmonised across the ICB, and the same is true for empagliflozin. | The company has proposed that dapagliflozin should be available for the same population as empagliflozin. Empagliflozin is used in a similar but broader population to dapagliflozin, but this still does not include everyone who dapagliflozin is licensed for.  Dapagliflozin has not been directly compared with empagliflozin in a clinical trial, but an indirect treatment comparison considered in NICE's technology appraisal guidance on empagliflozin for treating CKD suggested that they have similar effectiveness and safety. Also, both treatments work in a similar way so are likely to have similar clinical effectiveness and safety for the population considered for this evaluation.  Both options have list prices of £36.59 for a pack of 28 tablets So, dapagliflozin can be used in the same population as empagliflozin. Dapagliflozin and empagliflozin are oral tablets, usually taken at a dose of 10 mg once daily. No additional capacity impacts are anticipated from implementing this guidance.  NICE expect that the resource impact of implementing the recommendations in England will be less than £8,800 per 100,000 population. This is because the technology is a further treatment option with the same list price as the other main option. So, the overall cost of treatment will be similar for this population.  Any resource increase in future years is likely to be because of population growth, not because of the cost of treatment or any change in market share between the 2 options. | None expected; existing patient cohort. |
| [**TA1080 Mirikizumab for treating moderately to severely active Crohn's disease**](https://www.nice.org.uk/guidance/ta1080)  **10th July 2025**  **Commissioning: ICB, tariff included, 30-day NICE TA**  Mirikizumab can be used as an option to treat moderately to severely active Crohn's disease in adults, only if:   * the disease has not responded well enough or stopped responding to a previous biological treatment, or * a previous biological treatment was not tolerated, or tumour necrosis factor (TNF)-alpha inhibitors are not suitable.   Mirikizumab can only be used if the company provides it according to the commercial arrangement.  If people with the condition and their healthcare professional consider mirikizumab to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. Take into account the administration costs, dosage, price per dose and commercial arrangements. | Add mirikizumab to formulary as a RED drug in this indication with a link to TA1080. |  | Usual treatment for moderately to severely active Crohn's disease includes biological treatments such as TNF-alpha inhibitors, risankizumab, ustekinumab and vedolizumab. Mirikizumab is another biological treatment.  Clinical trial evidence shows that mirikizumab works as well as ustekinumab in reducing symptoms and achieving disease remission. Indirect comparisons of mirikizumab with other biological treatments are uncertain. But, together with clinical expert opinion, there is enough evidence that mirikizumab is likely to work as well as risankizumab. Clinical expert opinion also suggests that mirikizumab would be used at the same point in the treatment pathway as risankizumab.  To be recommended as a treatment option, mirikizumab needs to cost less or have similar costs to 1 relevant comparator recommended in a published NICE technology appraisal guidance .A NICE cost comparison suggests the costs for mirikizumab are similar to or lower than risankizumab, which is recommended after biological treatment has not worked well enough, stopped working or was not tolerated, or when TNF-alpha inhibitors are unsuitable. So, mirikizumab can be used for this population.  The company has a commercial arrangement (simple discount patient access scheme). This makes mirikizumab available to the NHS with a discount. The size of the discount is commercial in confidence. | None expected. |

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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. |