# SUMMARY OF RECOMMENDATIONS FOR HNY-WIDE CONSULTATION

| **Recommendations made by the Medicines Formulary Group at their meeting on:** | 15 January 2025 |
|---|---|

## Local Recommendations

| Drug and indication | Rationale / criteria | Status and formulary position proposed* | Notes on decision | Cost impact | Commissioning / service implications |
|---|---|---|---|---|---|
| **Medicines for management actinic keratosis** | There is currently mismatch across the ICB in medicines for management of actinic keratosis, including traffic light classifications and which medicines are on formulary. It is proposed to add align the Humber and NY&Y formularies, to reduce variation across the system. | • 3% Diclofenac with HA (Solaraze) – GREEN, and annotate: less cost effective than topical fluorouracil<br>• 5% Fluorouracil (5-FU) (Efudix) - GREEN<br>• 5% Imiquimod (Aldara) – AMBER SPECIALIST RECOMMENDATION<br>• 0.5% 5-FU+10% salicylic acid (Actikerall) - green<br>• 3.75% Imiquimod (Zyclara) – AMBER SPECIALIST RECOMMENDATION<br>• Tirbanibulin 10mg/g (Klisyri) – GREEN | Formulary section to be annotated: All medications to be used in line with PCDS pathway - Actinic (Solar) Keratosis Primary Care Treatment Pathway<br>https://www.pcds.org.uk/files/general/AK-Pathway-2022-Update-web-1.pdf | None expected; medicines are already in use | None expected; existing group of patients. |
| **Sodium chloride 0.9% solution** for injection 2ml, 5ml, 10ml, 20ml ampoules for use as a diluent | Sodium Chloride 0.9% Injection is licensed for subcutaneous use and is widely used as a diluent for continuous subcutaneous infusion (CSCI) where indicated in the manufacturer's literature, particularly in palliative care. | GREEN when used for palliative care | Current RED status for intravenous sodium chloride is a barrier to care for patients receiving palliative care. | Acquisition cost may be slightly higher in primary care; however, a green status will simplify the treatment pathway and is likely to reduce demands on staff time and improve patient care. | None expected |
| **Sodium chloride 0.9% solution** for injection 2ml, 5ml, 10ml, 20ml ampoules for use as a flush | Sodium Chloride 0.9% Injection is widely used as a flush for maintenance of peripheral and central venous catheters | GREEN when used as a flush | Current RED status for intravenous sodium chloride is a barrier to care for patients receiving palliative care. | Acquisition cost may be slightly higher in primary care; however, a green status will simplify the treatment pathway and is likely to reduce demands on staff time and improve patient care. | None expected |

| Drug and indication | Rationale / criteria | Status and formulary position proposed* | Notes on decision | Cost impact | Commissioning / service implications |
|---|---|---|---|---|---|
| **Sodium chloride 0.9%** solution 500ml & 1000 ml bags for use in hypodermoclysis | Sodium Chloride 0.9% Injection for subcutaneous use in hypodermoclysis is supported by the Humber APC approved Guideline for Subcutaneous Fluid Administration Version 5.0 | AMBER Specialist Initiation (SI) (in line with Palliative Care or Virtual Ward MDT care plan) | Current RED status for intravenous sodium chloride is a barrier to care for patients receiving care in line with locally agreed guidelines. | Acquisition cost may be slightly higher in primary care; however, a AMBER SI status will simplify the treatment pathway and is likely to reduce demands on staff time and improve patient care. | None expected |

## NICE Technology Appraisals and Guidance

| NICE Technology appraisal or guidance | Status and formulary position assigned | Notes on decision | Cost impact | Commissioning / service implications |
|---|---|---|---|---|
| **TA1022: Bevacizumab gamma for treating wet age-related macular degeneration**<br>**04 December 2024**<br>**Commissioning: ICS, 30-day TA, tariff-excluded**<br>Bevacizumab gamma is recommended as an option for treating wet age-related macular degeneration in adults, only if:<br>• the eye has a best-corrected visual acuity between 6/12 and 6/96<br>• there is no permanent structural damage to the central fovea<br>• the lesion size is 12 disc areas or less in greatest linear dimension<br>• there are signs of recent disease progression (for example, blood vessel growth as shown by fluorescein angiography, or recent visual acuity changes)<br>• the company provides it according to the commercial arrangement. | Add to formulary as a RED drug, with links to TA1022. | Updated NHSE commissioning recommendations for wet AMD are expected in 2025. Place in therapy for this medicine will be influenced by those recommendations. | Low impact expected. Place in therapy will determine the exact impact, and will be reviewed once NHSE commissioning recommendations are available. | None expected; bevacizumab gamma is another treatment option for an existing population. |

| NICE Technology appraisal or guidance | Status and formulary position assigned | Notes on decision | Cost impact | Commissioning / service implications |
|---|---|---|---|---|
| **TA1026: Tirzepatide for managing overweight and obesity**<br>**23 December 2024**<br>**Commissioning: ICS**<br>Tirzepatide is recommended as an option for managing overweight and obesity, alongside a reduced-calorie diet and increased physical activity in adults, only if they have:<br>• an initial body mass index (BMI) of at least 35 kg/m$^2$ and<br>• at least 1 weight-related comorbidity.<br>Use a lower BMI threshold (usually reduced by 2.5 kg/m$^2$) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds.<br>Tirzepatide is a further treatment option and is the first GLP-1 receptor agonist to be recommended for use outside a specialist weight management setting. It is recommended for use in all settings. | Interim RED status to facilitate prescribing in specialist services during the initial implementation period.<br><br>Formulary entry to be annotated: "tirzepatide for management of overweight and obesity will be provided by specialists only during the initial implementation period from March 2025. Preparations for primary care implementation are underway." | The RAG and formulary status will be reviewed when NHSE commissioning recommendations are available; expected in February 2025. | Additional information is required to estimate the cost impact of tirzepatide, including the NHS England commissioning guidance, cost of commissioned services, and proportion of patients accessing services. The anticipated costs of implementing the recommendation exceed the budget impact test of £20 million in England in each of the first 3 years.<br>NHS England requested a delay of 6 months to the funding requirement for all eligible patients. Considering the responses from the consultation, NICE recommends mandated funding of tirzepatide:<br>• within 3 months from final guidance publication for all patients accessing specialist weight management services at that time and subsequently, since these services and the associated wraparound care is already established<br>• must be made available from 6 months of final guidance publication for a phased introduction of delivery to eligible cohorts, at a minimum, in line with NHS England's interim commissioning policy, since NICE accepts that it will take time for commissioners to establish effective services in primary care. | |
| 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<br>• TA1021: Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer<br>• TA1023: Elranatamab for treating relapsed and refractory multiple myeloma after 3 or more treatments<br>• TA1025: Ublituximab for treating relapsing multiple sclerosis | | | | |
| All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted. | | | | |

HNY APC Professional Secretariat Provided by:
Regional Drug and Therapeutics Centre
16/17 Framlington Place, Newcastle upon Tyne, NE2 4AB
Tel: **0191 213 7855** email: nuth.nyrdtc.rxsupp@nhs.net visit: https://humberandnorthyorkshire.org.uk/area-prescribing-committee-apc/
@RDTC_Rx

| RAG classifications for joint Humber and North Yorkshire ICB formulary | | | |
|---|---|---|---|
| **Red** | Specialist prescribing only<br>The specialist initiates, continues and completes all ongoing monitoring. | **Amber specialist recommendation (Amber SR)**<br><br>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.<br>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<br>Medicines that must be initiated by a specialist*, and which require significant monitoring on an ongoing basis.<br>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.<br>If a commissioned SCP is not available these must be treated as red. | **Green (with pathway/guideline)**<br><br>Formerly known as Amber 1 in Humber | Can be prescribed in primary care in line with a recommended approved pathway/guideline. |
| **Amber specialist initiation**<br>**(Amber SI)**<br><br>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.<br>Can be prescribed in primary care, as per the wording on the formulary and considering both the drug SPC and BNF. |