SUMMARY OF DECISIONS FOR APPROVAL

Recommendations made by GMMMG subgroups	**July 2025**
Approved by: GMMMG	**By email w/c 11th August 2025**
Approved by: CEGC	**28th August 2025**
Approved by: Executive	**3rd September 2025**

The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals. When NICE recommends a treatment 'as an option', the NHS must make sure it is available within 90 days (unless otherwise specified) of its date of publication. This means that, if a patient has a disease or condition and the doctor responsible for their care thinks that the technology is the right treatment, it should be available for use, in line with NICE's recommendations.

DECISIONS WITH A FINANCIAL OR COMMISSIONING IMPACT

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Recommendation from GMMMG
Pregabalin prolonged-release tablets, 82.5mg, 165mg, 330mg (Misabri®) for all indications including but not limited to: neuropathic pain, epilepsy, generalised anxiety disorder, chronic cough and restless leg syndrome	No evidence of benefit over immediate release products was found and dosing is potentially confusing	Do Not Prescribe (DNP), criterion 2	CRG could not find a strong rationale for the use of M/R pregabalin and agreed the additional costs associated with its prescribing could not be justified.	Pregabalin MR tablets are priced 7-14x higher than immediate release capsules for an equivalent dose. GM ICB spent £2.0m on pregabalin (all products) in the 12 months to April 25. If 5% of this is prescribed as MR it could result in £1.4m of additional costs	Approve addition to DNP list

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Recommendation from GMMMG
Generic levetiracetam commissioning position	The Manchester Centre for Clinical Neurosciences (MCCN) at the Northern Care Alliance (NCA) has advised that it is not necessary to maintain a patient on specific manufacturer's product and that the switching of Keppra brand to generic Levetiracetam is acceptable and safe clinical practice for the following reasons: •Levetiracetam's therapeutic index is not narrow. •The dose-response curves for efficacy are not steep. •The potential for clinically relevant differences between different manufacturers' products is considered to be extremely low. •Therapeutic equivalence between branded and generic product (and between different generics) can be assumed.	Levetiracetam is GREEN (specialist advice) on the GMMMG formulary. This status will remain but the position statement and advice on generic prescribing will be annotated alongside this entry.	Levetiracetam is a Category 3 antiepileptic; for these drugs, the potential for clinically relevant differences to exist between different manufacturers' products is considered to be extremely low. There is a significant price difference between the Keppra brand of levetiracetam and the generic versions. A move to endorse the use of generic versions of levetiracetam as the first line in GM will bring significant savings into GM as a system. The NCA Medicines Optimisation Group has endorsed Manchester Centre for Clinical Neurosciences advice on the use of generic levetiracetam. NCA have agreed to stop using "Keppra" as a shorthand for levetiracetam in all of their correspondence Where the Keppra brand is required, there will be a clear rationale in correspondence of why this is necessary.	Based on prescribing data to August 2024 the savings to the GM system of a 100% change to generic levetiracetam is expected to be £1.23m per year	Approve for publication and the amendment of formulary Held pending review of updated national guidance.
TA1056: Molnupiravir for treating COVID-19 **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 only be prescribed in line with commissioned CMDU arrangements. Add to formulary with RED RAG status with links to TA1056.	An updated GM CMDU pathway is being prepared and is expected to be published in September	A resource impact template is available, but requires local completion of drug prices and expected proportion of patients receiving each available treatment. 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.	Approve addition to formulary

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Recommendation from GMMMG
TA878: Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 (update) **1st May 2025** **Commissioning: ICB**	Nirmatrelvir plus ritonavir is recommended as an option for treating COVID-19 in adults, only if they: • do not need supplemental oxygen for COVID-19 and • have an increased risk for progression to severe COVID-19, as defined in section 5.	Formulary will be aligned with updated recommendations	An updated GM CMDU pathway is being prepared and is expected to be published in September Nirmatrelvir plus ritonavir is no longer cost effective for the groups evaluated in the partial review (people with diabetes, obesity or heart failure, or aged 70 years or over). So, these groups were removed from the recommendation. Nirmatrelvir plus ritonavir remains cost effective for the highest-risk group, so this recommendation remains in place.	The recommendation for nirmatrelvir plus ritonavir was updated. The recommendation made in March 2024 after a partial review of the guidance was based on a confidential price offered by the company to the NHS. In May 2025, the company set a new list price of £829. This was because NICE was considering if the recommendation needed to be reviewed due to the evolving COVID-19 landscape and emerging data from NHS England.	Approve amendment to formulary

DECISIONS WITHOUT A FINANCIAL OR COMMISSIONING IMPACT

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Recommendation
Updated Grey list criteria	An additional criterion, criterion 4 has been added: Products which, due to funding or service capacity constraints, are approved only for a defined cohort as part of a phased implementation.	N/A	Identified during the work manage the introduction of tirzepatide for weight management into primary care, it was agree that an additional grey criterion was required to denote medicines which are subject to a controlled rollout to provide an extra check for prescribers who issue prescriptions. The Grey and DNP definitions have therefore been updated but the other RAG statuses remain the same and are likely to be subject to a review later in 2025-26 as part of the work to review shared care. The document has been split into two parts RAG and Grey/DNP to show that RAG is based on clinical criteria and Grey/DNP on affordability and cost.	None expected	Approve for publication
Proposed Interim Alignment of Eligibility Criteria for GLP-1 Receptor Agonists (GLP-1 RAs) in Weight Management in GM	Three glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are currently recommended by NICE NG246 for the overweight and obesity management: • Liraglutide (NICE TA664) • Semaglutide (NICE TA875) • Tirzepatide, a dual GIP/GLP-1 RA (NICE TA1026)	See embedded document Tirzepatide's RAG status is currently GREEN/GREY. Access will remain restricted to NHSE's Year 1 commissioning criteria (Cohort 1). In GM, local prioritisation has also been applied within that cohort, further dividing patients into three subgroups (Cohorts 1a–1c) based on BMI, with those in the highest BMI band prioritised for access. Semaglutide and liraglutide remain classified as RED drugs, restricted to use within specialist weight management services. (See Table 2 below for further details.)	This is an interim proposal, developed in response to current system challenges and intended to support a consistent, clinically prioritised approach during the phased implementation of GLP-1 RAs across Greater Manchester.	No financial impact from this amendment to formulary	Approve formulary amendment

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
GMMMG Minutes July 2025	Approved minutes of the GMMMG July 2025 meeting	N/A	None	None
TA1051: Efanesoctocog alfa for treating and preventing bleeding episodes in haemophilia A in people 2 years and over **2 April 2025** **Commissioning: NHSE**	Efanesoctocog alfa is recommended as an option for treating and preventing bleeding episodes in people 2 years and over with haemophilia A (congenital factor VIII deficiency), only if: • they have a factor VIII activity level of less than 1% (severe haemophilia A) • the company provides it according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to TA1051.		The list price of efanesoctocog alfa is commercial in confidence. A resource template is available and can be used to calculate the financial impact. Efanesoctocog alfa has a longer half-life than other factor VIII replacement therapies and can be used for both on-demand treatment and prophylaxis. The guidance committee concluded that a new treatment option with effective bleeding control and a less frequent dosing schedule would be welcomed by people with haemophilia A. NICE estimate that it will require an additional 440 specialist appointments in England in year 1, increasing to 860 in year 5.
TA1053: Cladribine for treating active relapsing forms of multiple sclerosis **15 April 2025** **Commissioning: NHSE**	Cladribine is recommended as an option for treating active relapsing forms of multiple sclerosis in adults, only: • if they have active relapsing–remitting multiple sclerosis, and • when high-efficacy disease-modifying therapies would be offered.	Add to formulary as a RED drug in this indication, with links to TA1053.		Costs may vary in different settings because of negotiated procurement discounts. Users can input the price of cladribine and amend other variables in the resource impact template. Cladribine is an oral treatment taken in 2 short courses over 2 years, and needs fewer administrations than comparators. The resource impact template includes all comparator options for treating RRMS in adults with active disease defined by clinical or imaging features.
TA1054: Ruxolitinib for treating acute graft versus host disease that responds inadequately to corticosteroids in people 12 years and over **15 April 2025** **Commissioning: NHSE**	Ruxolitinib is recommended, within its marketing authorisation, as an option for treating acute graft versus host disease (GvHD) that has an inadequate response to corticosteroids in people 12 years and over. Ruxolitinib is only recommended if the company provides it according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to TA1054.		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 population size is small and any cost is likely to be offset by displacement of more resource-intensive options that are part of established clinical management. For further analysis or to calculate the financial impact of cash items, see the resource impact template. There are potential capacity benefits from reduced use of ECP. The patient experts from the committee explained that some people commit significant time and money to travel for treatment, require invasive venous access, and may need to be hospitalised.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
HST33: Leniolisib for treating activated phosphoinositide 3-kinase delta syndrome in people 12 years and over **23 April 2025** **Commissioning: NHSE**	Leniolisib is recommended, within its marketing authorisation, for treating activated phosphoinositide 3-kinase delta syndrome (APDS) in people 12 years and over. Leniolisib is recommended only if the company provides it according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with links to HST33.		There are no licensed treatments for APDS. Standard care includes antimicrobial treatment, surgery, immunosuppressants, immunoglobulin (antibody) replacement therapy, and stem cell transplants. Clinical trial evidence shows that leniolisib, compared with placebo plus selected standard care treatments, reduces the size of people's lymph nodes and increases levels of immune cells called B cells. The cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, leniolisib is recommended. The list price of leniolisib is £29,000 per pack of 60 tablets (excluding VAT; company submission).
All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.				

Regional Drug and Therapeutics Centre
16/17 Framlington Place, Newcastle upon Tyne, NE2 4AB
Tel: **0191 213 7855** Fax: **0191 261 8839** email: nuth.nyrdtc.rxsupp@nhs.net visit: https://rdtc.nhs.uk

@RDTC_Rx

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