SUMMARY OF DECISIONS FOR APPROVAL

Recommendations made by GMMMG sub-groups	**April 2024**
Approved by: GMMMG	**9Th May 2024**
Approved by: CEGC	**23rd May 2024** *(decisions without a financial or commissioning impact)*
Approved by: Executive	**12th June 2024** *(those with a financial or commissioning impact)*

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	GMMMG recommendation
Riluzole 50mg orodispersible tablets for treatment of amyotrophic lateral sclerosis (ALS) in line with the GMMMG shared care protocol for this indication	Due to supply problems caused at least in part by manufacturer withdrawal of the 50mg standard tablets from the UK market, the price of these has risen from £8.63 to £300.23 for 56 and are frequently unavailable	Add 50mg orodispersible tablets as AMBER shared care to GM formulary as an alternative to standard tablets	CRG heard that the supply problems necessitate an alternative product be added to the shared care protocol, a review of which is currently also undergoing the GM ICB governance process. This addition would be required even if there were no cost pressures to mitigate.	50mg standard tablets currently cost £300.23 for 56 and 50mg orodispersible £168 for 56 tablets If prescribing of riluzole continues at current rates and product choice there will be a cost pressure to the GM ICB of around £270k per year. This can be mitigated to around £165k pressure with use of orodispersible tablets.	Approved

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
TA919: Rimegepant for treating migraine **Commissioning: ICS, tariff-excluded** 18th October 2023	Rimegepant is recommended as an option for the acute treatment of migraine with or without aura in adults, only if for previous migraines: • at least 2 triptans were tried and they did not work well enough or • triptans were contraindicated or not tolerated, and nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol were tried but did not work well enough.	Add to formulary as a Green medicine drug in this indication, with link to TA919. Rimegepant is already on formulary as Green (specialist initiation) for the prevention of episodic migraine (TA906). A further consultation has opened to amend this to Green (specialist advice)	CRG did not agree with the NICE assessment of resource impact and felt that this is likely to be significantly higher due to it offering an alternative treatment option prior to specialist referral. CRG heard that this is a condition principally managed in primary care and as such patients would not routinely be referred to a specialist at the point in the pathway that NICE have placed this agent. Following the consultation where it was proposed this should be Green (specialist advice, CRG heard from the headache service lead clinician who successfully reasoned that this medicine and indication is amendable to management in primary care and should have a Green RAG status. An update to the headache pathway is underway to support primary care prescribing of this agent for this indication. In February GMMMG requested that a decision on this agent is paused so that both licensed indications (treatment (TA919) and prophylaxis TA906) can be managed simultaneously, with the required supporting information to ensure safe and effective use in line with the license and TA recommendations.	NICE estimated the cost impact to be less than 8,800 per 100,000 population. Further modelling estimates that around 200 patients per year in GM may receive rimegepant for this indication and RDTC cost impact estimates range from £10,000 to £38,000 per 100,000 population by year 5, which equates to between £300k to £1.3m per year for GM depending on % uptake within the eligible population. In the preventing migraine setting, rimegepant and other treatments (such as galcanezumab [TA659], erenumab [TA682] and fremanezumab [TA764]) are also recommended. In clinical practice, when a person is having migraines sufficiently often to benefit from a preventative effect, there is a reasonable likelihood that they will be having 1 of the approved preventative treatments which have the same mechanism of action to rimegepant for preventing migraine.	Approved

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
Rimegepant 75mg oral lyophilisate for the prevention of episodic migraine in line with NICE TA906:	• Rimegepant is recommended as an option for preventing episodic migraine in adults who have at least 4 and fewer than 15 migraine attacks per month, only if at least 3 preventative treatments have not worked. • Stop rimegepant after 12 weeks of treatment if the frequency of migraine attacks does not reduce by at least 50%. A previous consultation sought to apply a Green (specialist initiation) status to this product and indication and this is how it is currently listed on the formulary and RAG. (Please note the alternative indication of treatment of acute migraine will have a different RAG status when added to the formulary) A request has been received to amend this status to Green (specialist advice)	Amend the current status of Green (specialist initiation) to Green (specialist advice)	Feedback from the specialist service shows that a specialist initiation status is impractical because this cohort of patients is managed predominantly in primary care. It is reasoned that the medicine is safe and effective and the 12 week review can be reasonably undertaken by primary care. A supporting guidance document for primary care has been produced and is also undergoing consultation Advice and guidance requests will be accepted by the GM headache service prior to initiating rimegepant for this indication. An update to the headache pathway is underway to support primary care prescribing of this agent for this indication. GMMMG approved this recommendation at their April meeting. It is submitted again for information on the decision regarding TA919 above.	The cost impact of this recommendation has previously been considered and approved by GM ICB. At the time this was estimated by NICE to be less than 8,800 per 100,000 population. Further modelling estimates that around 200 patients per year in GM may receive rimegepant for this indication. Rimegepant is priced at £25.80 for 2 tablets. This recommendation is expected to streamline patient access to the medicine for those who are eligible, whilst maintaining a degree of specialist involvement. It is recognised that the review of efficacy at 12 weeks will now be undertaken by primary care. The accompanying guidance recommends this review may be undertaken by a nurse practitioner or pharmacist and not necessarily by a GP.	Approved
Updated PCRS Ethical Framework	NHS GM has received some rebate applications which have had to be rejected as they failed to meet the requirements of the current Ethical Framework. It is pertinent to review guidance from time to time and this review, carried out in conjunction with a legal director at Hill Dickinson LLP, enables a more risk-based approach to rebate applications.	n/a.	The proposed updated EF has been out for consultation in the usual way. One response was received which was positive. Medicines Value group supported GM adoption of the updated EF.	Adoption of this new Ethical Framework will enable NHS GM to take a more risk-based approach to rebate submissions and perhaps enter into rebates which would have been rejected under the previous EF, thereby enabling NHS GM to receive greater sums of money.	Approved

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
Revised Adcal D3 rebate agreement	The manufacturer of Adcal D3 was not prepared to extend a rebate for some localities to all of NHS GM. Notice of termination was therefore given. The manufacturer came back with a revised offer for all of NHS GM which Medicines Value subgroup accepted.	No brand stated in Formulary	Discussed at Medicines value meetings and it was agreed to accept the revised rebate agreement which was worth the same but across all of NHS GM. Localities are recommended to switch away from Adcal D3 as other preparations are better value even after accounting for the rebate.	Savings of £12.4k per quarter but value of the rebate likely to decline as we move away from this preparation.	Approved
GM Prescribing Budget proposals 2024/25 GM prescribing budget proposals 242	GMMMG considered the attached paper detailing potential impacts to the primary and secondary care budgets for 24/25. They were asked to note the risks associated with primary care and secondary care budget setting in 2024/25. The group was also asked to escalate the requirement to consider the practicalities surrounding the possible introduction of drugs for the treatment of Alzheimer's Disease with Mental Health Trusts and their commissioners	N/A	GMMMG heard from ICB finance representative that the budgets had required early communication through the system given the current financial position of NHSGM. Whilst budgetary targets had been set these would be constantly reviewed throughout the year to react to the pressures as they arise. GMMMG members expressed concern around some of the assumptions in the paper, particularly around the proposed biosimilar savings, and stressed the need for regular review of the prescribing budgets. This will be tabled quarterly at GMMMG.	GMMMG were asked to approve the proposed uplift of 6.35% for primary care prescribing budgets and 7.5% for high cost drugs in GM in 2024/25.	Supported but as an iterative process with quarterly review by GMMMG

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	GMMMG Recommendation
Diclofenac 50mg tablets for the treatment of musculoskeletal conditions	Currently on formulary in chapter 10 as alternative NSAID after Ibuprofen (musculoskeletal and joint diseases) with no RAG status	Position diclofenac as 3rd line NSAID after ibuprofen and naproxen	The request to clarify status was received after a clinical incident at a GM trust and there followed a request to clarify the formulary and status of diclofenac	None, this is not expected to change the usage of this medicine	Approved
Updated levonorgestrel-containing intrauterine devices comparison table IUS-comparison-table-Apr 2024 _FINAL.dc	Due to the recent approval of Benilexa IUD which has been added to formulary and significant changes in the licensing of Mirena and other products an update was required for this table	All products are Green	N/A	None	Approved
Hydroxycarbamide shared care protocol Hydroxycarbamide RDTC SCP adapted f	This is an updated SCP, based on the NHSE document, updated by RDTC and prepared for GM use.	Hydroxycarbamide is Amber		None expected. This supersedes existing out of date SCPs on the GMMMG website	Approved

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG Recommendation
“Seven minute safety briefings”	The medicines safety group of GMMMG has started to share learning from incidents involving medicines that have cross sector implications. The shared learning can arise following a trust, locality or community pharmacy incident or from a coroner issued regulation 28 as well as feedback from professional networks e.g. MSOs network. The briefings will be published to a dedicated area on the GMMMG, they will be cascaded through the usual GMMMG channels which includes all AMDs, but also to NW MSOs group, NHS GM Primary Care communication channels and LPCs for dissemination throughout their respective organisations. The medicines safety group would consider on a case-by-case basis whether assurance is required from the system that learning and implementation of actions has been undertaken.	N/A	GMMMG requested minor amendments to the briefings, and as these have not undergone the usual six week consultation period to ensure that all sectors representation had the opportunity to comment. The need for timely publication was accepted and it was agreed that Chairs approval would then be sufficient for publication, with pre-approval be sought from CEGC.	Nil	To return for chairs approval, submit for CEGC pre-approval

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact	GMMMG recommendation
HST30: Sebelipase alfa for treating Wolman disease **10/1/2024** **Commissioning: NHSE** Sebelipase alfa is recommended as an option for long-term enzyme replacement therapy in Wolman disease (rapidly progressive lysosomal acid lipase deficiency [LAL-D]), only if people are 2 years or under when treatment starts. It is recommended only if the company provides sebelipase alfa according to the commercial arrangement.	Not on formulary	Add to formulary as a RED drug in this indication, with link to HST30	Wolman disease is a rare genetic condition that presents in babies and children under 2 years old. It causes a build-up of fat in cells in the liver, heart, blood vessels, and digestive system. Without treatment, the baby or child will not survive. There are no treatments for Wolman disease available in the NHS. Standard care without sebelipase alfa is palliative. Sebelipase alfa is used as an enzyme replacement therapy alongside a restricted diet, and can allow a haematopoietic stem cell transplant to be done, if appropriate.	Because of the clinical uncertainties, including those related to how sebelipase alfa is used in the treatment pathway for people with Wolman disease, the cost-effectiveness estimates are also uncertain. When considering the condition's severity, and the effect of sebelipase alfa on quality and length of life, the most likely cost-effectiveness estimates are within the range NICE considers an acceptable use of NHS resources. So, sebelipase alfa is recommended.	Approved
CRG minutes March 2024 CRG Minutes Mar 2024_FINAL.pdf	-	-	Approved for website publication	-	Approved
GMMMG minutes April 2024 GMMMG minutes Apr 24 FNL.pdf	-	-	Approved for website publication	-	Approved
Medicines value subgroup summary report Medicines value minutes_summary Re	-	-	For information It was noted that the promethazine workstream is being supported by CRG rather than medicines value due to the clinical focus required.	-	Noted
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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