SUMMARY OF DECISIONS FOR APPROVAL

Recommendations made GMMMG subgroups	**March 2024**
Approved by: GMMMG	**11th April 2024**
Approved by: CEGC	**24th April 2024 – those decisions without financial impact**
Approved by: Executive	**Confirmed 24th May 2024**

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
Melatonin 1mg/mL SF oral solution (Consilient and Ceyesto brands) for children and adolescents in line with the indications listed as part of the GM shared care protocol only where crushed Adaflex tablets are not appropriate.	A request from the Oldham MO team to rationalise the use of melatonin liquid products has been received. Analysis of GM prescribing data shows a significant proportion of generic prescribing which can result in the dispensing of Colonis 1mg/mL Melatonin oral solution S/F which is on the DNP list due to safety concerns regarding propylene glycol content. This presents a safety issue which should be addressed. Much of the use of these products is off-label but both Consilient and Ceyesto products have a license for use in children aged 6-17 years old for varying conditions – see SPC Prescribers will be asked to review melatonin prescribing for their patients and ensure they are using the most appropriate formulation and brand.	Add Consilient melatonin 1mg/mL S/F oral solution as the preferred liquid product for children aged 5 years or younger Add Ceyesto 1mg/mL S/F oral solution as the preferred liquid product for children aged 6 years and over. **The use of these products should be limited to where crushed Adaflex tablets are not suitable.**	CRG noted that melatonin liquids should be initiated on an exceptional basis only. This is usually in patients with severe sensory sensitivity in autism spectrum disorder and learning disability where switching to crushed melatonin may be significantly distressing to the patient. Therefore use of liquid products should be minimised as a key action from the analysis. An action to update the SCP is required if the formulary is amended Due to small amounts of propylene glycol and benzyl alcohol, Ceyesto is not suitable for use in patients under 6 years of age	GM spends £1.9m per year on melatonin, of which £708k is for the liquid products (all strengths Nov – Oct 23) Melatonin 1mg/mL oral solution S/F is in the drug tariff as Cat M at a price of £129.18 per 150mL. This equates to £86.12 per 100mg. Consilient is £86.67 and Ceyesto £17.10 per 100mg respectively. If prescribed by brand for reasons of safety then Consilient melatonin would be the preferred liquid product for children aged 5 years or younger and Ceyesto 1 would be the preferred liquid product for children aged 6 years and over. A change to the Consilient brand is cost neutral however if prescribing of existing melatonin 1mg/mL oral solution S/F is changed to Ceyesto as appropriate (aged 6 years and over) this could save up to £347k per year in GM Branded prescribing is required to but CRG thought this was justified for reasons of safety. Work will be required with specialist services to rationalise prescribing of melatonin liquid products and ensure prescribing of appropriate products is clearly communicated to primary care.	Approve additions to formulary and support the implementation of the decision through engagement with mental health and specialist services

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.	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.	Approve the change in RAG status

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TA937: Targeted-release budesonide for treating primary IgA nephropathy **20/12/2023** **Commissioning: ICB for all patients**	Targeted-release budesonide is recommended as an option for treating primary immunoglobulin A nephropathy (IgAN) when there is a risk of rapid disease progression in adults with a urine protein-to-creatinine ratio of 1.5 g/g or more. Targeted-release budesonide is recommended only if: • it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs), unless these are contraindicated • the company provides it according to the commercial arrangement.	Add to formulary in chapter 1.5.2 as a RED drug in this indication, with link to TA937.	When presented to CRG the commissioner was thought to be NHSE for patients with AKI or those undergoing dialysis. Communication has been received to clarify that ICBs will be the responsible commissioner for all patients.	Kinpeygo® (Britannia) costs around £6,500 per pack of 120 modified-release capsules (30 day supply at full dose). The licensed dose is 16mg (4 capsules) once daily for 9 months. At the end of therapy the dose should be reduced to 8mg daily for 2 weeks then 4 mg daily for 2 weeks. There is a commercial arrangement which is confidential. Kinpeygo is included as a HCD in the proposed list for 2024/25. NICE expect the resource impact of implementing the recommendations will be less than £8,800 per 100,000 population. At the time of writing there is no cost impact template available for local use.	Approve addition to formulary

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
TA942: Empagliflozin for treating chronic kidney disease **20/12/2023** **Commissioning: ICS**	Empagliflozin is recommended as an option for treating chronic kidney disease (CKD) in adults, only if: • it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs), unless these are contraindicated, and • people have an estimated glomerular filtration rate (eGFR) of: ○ 20 ml/min/1.73 m^2 to less than 45 ml/min/1.73 m^2 or ○ 45 ml/min/1.73 m^2 to 90 ml/min/1.73 m^2 and either: ▪ a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or type 2 diabetes (T2D)	On formulary in chapter 2 as a GREEN (following specialist advice) drug for management of chronic heart failure and chapter 6 for diabetes Add to formulary in chapter 2.5.5.1 as a GREEN drug in this indication, with link to TA942.	Dapagliflozin is on formulary in chapter 2 as a GREEN drug for management of CKD.	NICE estimate that: • Around 23,000 people in GM are eligible for treatment (811 per 100,000 population) • Around 2,514 people (89 per 100,000 population) will receive empagliflozin from 2026/27 onwards once market share has reached 12% of people with CKD and T2D and 10% of people with CKD without T2D. • Empagliflozin is a further SGLT2 inhibitor treatment option for most of the population covered by the recommendation. • The additional drug cost is expected to be no cost in year 1, £136k in year 2 and rising to £740k by year 5 • The total resource impact, including the cost of uACR testing, is estimated at no cost in year 1, increasing to £6k in year 2 and £32k in year 5. This estimate does not include the resource impact of any differences in clinical outcomes as a result of implementation of the guidance. No service impact is expected as this represents an additional option within an existing pathway	Approve addition to formulary

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
Discontinuation of non GM-wide rebates	Some localities had rebates with Kyowa Kirin and Fontus for some branded generic products which were continued from agreements with CCGs. However, neither company was prepared to widen the scope of the rebate to all of NHS GM. As localities are not statutory bodies, it is inappropriate to have rebates in some localities and not others.	n/a.	Medicines Value Subgroup agreed with a proposal that these rebates should be terminated. Cheaper brands are available for the products for which there was a rebate agreement with Fontus e.g. the rebates are worth approximately £10k per annum. Switching to cheaper alternatives would save over £33k annually. The Kyowa Kirin rebate is worth approximately £2k per year.	Annual rebate worth around £12k would no longer be available but this can be more than compensated for by switching away from these products. Some reduction in administration will also result.	Approve discontinuation of these rebates for NHS GM.

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
FreeStyle Libre 3 real-time Continuous Glucose Monitor (rtCGM) for use with compatible insulin pumps systems	From January 2024 FSL3 has been added to the Drug Tariff alongside FSL2. Its use at present should be limited to patients with a compatible insulin pump system and should be prescribed by a specialist diabetes team. NHS GM will also work to implement TA943: Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes	Add to RAG list with a RED status	It should be noted that NHS GM is working on identifying data to allow assessment of the clinical capacity required and the financial impact of adoption of the NICE guidance on access to CGM for Type 1 and Type 2 diabetes patients in line with the recommendations from , NG17, NG18, NG28 and NG3	FLS3 is priced at £42 per sensor compared to £35 for FSL2 This recommendation is expected to be cost neutral and ensure prescribing of FSL3 remains with the specialist service Specialist diabetes services can continue to supply FSL3 via the Abbott portal system or other established routes.	Approve addition to RAG list
Levonorgestrel 20 micrograms/24 hours Intrauterine Delivery System (Benilexa® One Handed) for its licensed indications of contraception for 6 years, the treatment of heavy menstrual bleeding and also as endometrial protection as part of HRT (off-label)	A request to add this product to the formulary has been received.	Add as a Green drug first line option alongside existing products on the formulary	CRG were unable to rationalise the formulary choices in this therapeutic area as this product has advantages over some existing choices but is also unlikely to be suitable as a first line for all patients The off-label use is supported by FSRH guidance	The cost of Benilexa is £71 or £11.83 per year compared with £17.60 for Mirena, £15.20 for Kyleena and £11 for Levosert. After the application was received the license for Mirena has been extended to 8 years which reduced its cost to £11 per year and negates the 20% saving vs this product, it remains cheaper than Kyleena, however its larger insertion tube means it is not suitable for all patients. Overall cost impact expected to be neutral No service impact expected	Approve addition to formulary

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Amiodarone and dronedarone shared care protocols  Amiodarone SCP adopted for GM ver  Dronedarone SCP adopted for GM v1.(	These shared care protocols have been developed to support the change in RAG status following the adoption of the recommendations made by NHSE in the guidance on items which should not be routinely prescribed in primary care Since the RAG status was amended specialist services have met resistance from primary care when attempting to transfer prescribing due in the absence of a SCP. The SCPs are intended to support this transition to primary care prescribing.	Current RAG status: Amiodarone: Amber – shared care protocol in development Dronedarone: Green (specialist initiation) Both to be Amber	The SCPs have been adapted from the national versions produced by RMOC and NHSE, and updated by RDTC in 2023-24. Cardiology services have been consulted and have agreed with the RAG status and the content of the SCP. A further consultation was thought unnecessary due to the urgent requirement to introduce a SCP to support patients to receive the right medicine in the right place and because these have already undergone a national and local consultation but have now been updated to meet the GM ICS requirements	In the 12 months to December 2023 there were 15,900 items of amiodarone and 1579 of dronedarone prescribed by GM ICB. This equates to a cost of £25k and £116k respectively. It is therefore estimated that around 1200 patients are receiving amiodarone and about 120 patients being prescribed dronedarone each year. Therefore there are considerations on how to manage these patients. New patients should have a SCP on transfer of prescribing to primary care. Existing patients should be monitored as per the SCP however GMMMG are asked to consider how the documents should be applied to existing patients both for long and short-term treatment.	Approve shared care protocols for GM use Approve the amendment of the dronedarone RAG status to Amber GMMMG have requested a T&F group is formed to consider the most appropriate way to manage the introduction of shared care to patients historically receiving these medicines, but not under a shared care arrangement.

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
TA935: Secukinumab for treating moderate to severe hidradenitis suppurativa **6/12/2023** **Commissioning: NHSE, tariff-excluded**	Secukinumab is recommended as an option for treating active moderate to severe hidradenitis suppurativa (acne inversa) in adults when it has not responded well enough to conventional systemic treatment, only if: • adalimumab is not suitable, did not work or has stopped working • the company provides secukinumab according to the commercial arrangements.	On formulary in chapters 10 and 13 as a RED drug. Add to formulary in chapter 13.5.3 as a RED drug in this indication, with link to TA935.	N/A	NICE expect the resource impact of implementing the recommendations in England will be less than approximately £8,800 per 100,000 population.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
NG238: Cardiovascular disease: risk assessment and reduction, including lipid modification **14/12/2023** **Commissioning: ICS**	This guideline updates and replaces NICE guideline CG181 (July 2014). NICE reviewed the evidence and made a new recommendation: • For secondary prevention of CVD, aim for low-density lipoprotein (LDL) cholesterol levels of 2.0 mmol per litre or less, or non-HDL cholesterol levels of 2.6 mmol per litre or less. The guidance was also restructured to improve navigation. Some existing recommendations have been amended to be consistent with the new recommendations or for clarification because of the restructure.	Links to CG181 on formulary in chapter 2. Remove links to CG181 and replace with links to NG238.		A resource impact template is available. A significant proportion of adults in England do not achieve the current QOF treatment target for lipid levels for secondary prevention of CVD and are therefore eligible for treatment escalation in line with the NICE guideline. The recommendations for a specific lipid target for secondary prevention of CVD may increase the use of lipid-lowering treatments, resulting in higher treatment costs. Potential costs would depend on the size of the eligible population, the escalation regimen used and the associated primary care capacity implications (GP appointments for reviews, treatment escalation and reviews following treatment escalation, pharmacies, and blood culture tests). However, any additional costs would be partly offset by savings from reduced CVD events and post-event health and social care associated costs.
HST29: Velmanase alfa for treating alpha-mannosidosis **13/12/2023** **Commissioning: NHSE**	Velmanase alfa is recommended as an option for treating the non-neurological signs and symptoms of mild to moderate alpha-mannosidosis, only if: • treatment is started in people under 18 years (it can be continued in people who turn 18 while on treatment) the company provides it according to the commercial arrangement	Add to RAG list as a RED drug with link to HST29.	N/A	The most likely cost-effectiveness estimate for velmanase alfa is around what is considered value for money in the context of a highly specialised service. Although there are some uncertainties in the economic model, when taking into account all the evidence and the factors affecting the decision, velmanase alfa is recommended.
GMMMG minutes March 2024	 GMMMG Minutes Mar 24 fnl.pdf	-	Publish to GMMMG website	-
GMMMG Clinical Reference Group Minutes February 2024	 CRG Minutes Feb 2024_FINAL.pdf	-	Publish to GMMMG website	-
Medicines safety subgroup report	 GMMMG medicines safety subgroup repo	-	No action – information only	-
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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