SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: CRG (except those * which were made at GMMMG)	**13th June 2023**
Approved by: GMMMG	**13th July 2023**
Approved by: CEGC	**26th July 2023**
Approved by: Executive	**2nd August 2023**

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
Efmody (modified release hydrocortisone) 5mg and 10mg capsules for congenital adrenal hyperplasia in adolescents and 12 years and over and adults. This is for second line use only for patients who are not well controlled on standard release hydrocortisone where there is: • Development of testicular cell rests • Excess glucocorticoid burden • Evidence of poor growth and/or poor pubertal development • Excess virilisation • Poor compliance	Efmody was requested for patients the second line treatment in patients who are not well controlled on standard release hydrocortisone, for example are developing testicular adrenal cell rests, or have an excess glucocorticoid burden. Efmody is requested for use in adolescents where there is concern about poor compliance, growth, pubertal development or excess virilisation. There is insufficient evidence to demonstrate superiority for the whole CAH population but analyses of existing data show there is likely to be a benefit for patients with the above clinical condition(s).	Add to formulary for the population proposed as Green Specialist initiation	It was noted that this medicine has been reviewed and is not recommended for this indication by SMC. However this looked at the whole CAH population, the AWMSG review looked at a similar population to that considered here and approved its use.	Efmody costs £2500 per patient per year at a dose of 15mg per day Estimated 10 patients per year across the North West region in year 1-2 with a maximum cost of £25,000 per year to the GM ICS. No significant service or commissioning impact is expected	Approve for addition to formulary
Dapagliflozin 5mg & 10mg tablets for CKD in children	Indication is as per NICE TA 775 to be used in children with CKD 2-3 aiming to preserve renal function and slow disease progression. This is considered unlicensed use in children	Add to paediatric RAG list as RED		Cost is £477.30 per patient per year and MFT have estimated a maximum of 80 patients per year. Maximum costs estimated to be £38k per year. Use in secondary care would be considered in tariff	Approve the RAG status recommendation

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Recommendation from GMMMG
Morphine sulphate orodispersible tablets (Actimorph) 1mg, 2.5mg, 5mg, 10mg, 20mg & 30mg for severe pain and breathlessness **in palliative care**	Actimorph should be available for prescribing in primary care for the management of acute pain and breathlessness in palliative care when morphine sulphate oral solution and tablets are unsuitable. The low strengths available may reduce the risk of overdose when small doses are required and support effective titration of opioid doses both up and down.	Add to formulary as a second line choice to morphine sulphate oral solution 10mg/5mL and morphine sulphate tablets, where these would be inappropriate where: • The small volumes required may prevent accurate dosing • There is a risk of unintentional overdose • The oral liquid and tablets are not tolerated • The patient/carer is physically unable to measure the required dose, with a RAG status of Grey & Green.	Following the May GMMMG where further information was requested about comparable pricing in secondary and primary care as well as feedback from palliative care further work has been undertaken to ascertain the ICS' inclination for its use. The feedback from palliative care teams is that Actimorph would be a valuable addition to the GMMMG formulary for use where patients struggle to manipulate small volumes of liquid dosage forms, to prevent inadvertent overdose or where other dosage forms are not tolerated, e.g. oral mucositis. The product is already on the NCA hospital formulary for these indications. Pricing of products in primary and secondary care is currently comparable.	Actimorph is comparable in price for 7 days treatment at most doses. e.g. at 100mg morphine per day Sevredol is £6.63 for 7 days treatment, Actimorph 20mg is £5.94 and oral solution 10mg/5mL is £5.73 At lower doses, where it is likely to have most benefit, there is an increase in cost. i.e. for one week's treatment totalling 10mg per day the cost is £2.50 for Actimorph 1mg tablets but £0.55 for oral solution 10mg/5mL Due to low numbers and comparable costs the impact is not likely to be significant. Estimates from NCA palliative care team suggest 30-50 patients per year. A concern regarding safe storage was identified particularly where morphine oral solution 10mg/5mL is the preferred choice and is not treated as a controlled drug. However Actimorph is not expected to replace oral solution 10mg/5mL as the preferred treatment option.	Approve addition to formulary only for use by palliative care teams (grey and green listing) as a second line choice where morphine sulphate oral solution and tablets are not appropriate.
TA871: Eptinezumab for preventing migraine 01/03/2023 **Commissioning: ICS, tariff-excluded, 30-day implementation**	Eptinezumab is recommended as an option for preventing migraine in adults, only if: • they have 4 or more migraine days a month, • at least 3 preventive drug treatments have failed, and • the company provides it according to the commercial arrangement.	Not on formulary. Erenumab, fremanezumab and galcanezumab are on formulary in chapter 4.7.4.2 as RED drugs and included in the headache pathway see page 2, box 8. Add to formulary as a RED drug in this indication, with link to TA871.	N/A	NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact in England will be less than approximately £9,000 per 100,000 population. This is because eptinezumab is another treatment option that works in a similar way to other CGRP inhibitors but is administered as an infusion into a vein. NICE do not think practice will change substantially as a result of this guidance. NICE estimates that 4% of people who take up a CGRP inhibitor will receive eptinezumab, or roughly 1 person per 100,000 population. Therefore, the overall incremental cost of treatment is low. A resource impact template is provided for completion at a local level. It covers all treatment options and updates and replaces the previous NICE resource impact templates that were published for these topics.	Approve addition to formulary as RED drug.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Recommendation from GMMMG

TA875: Semaglutide for managing overweight and obesity
08/03/2023
Commissioning: ICS
	Semaglutide is recommended as an option for weight management, including weight loss and weight maintenance, alongside a reduced-calorie diet and increased physical activity in adults, only if:
	• it is used for a maximum of 2 years, and within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4), and
	• they have at least 1 weight-related comorbidity and:
	  ○ a BMI of at least 35.0 kg/m^2, or
	  ○ a BMI of 30.0 kg/m^2 to 34.9 kg/m^2 and meet the criteria for referral to specialist weight management services in NICE's guideline on obesity: identification, assessment and management.
	Use lower BMI thresholds (usually reduced by 2.5 kg/m^2) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds.
		Not on formulary in this indication.
		Liraglutide is on formulary in this indication as a RED drug, in chapter 4.5.1
		Add semaglutide to formulary as a RED drug in this indication, for prescribing by specialist weight management services only, with link to TA875.
			CRG noted that although an initial RED status has been proposed, the NICE TA states that this should be available through any specialist weight management service (not limited to tiers 3 and 4) where there is MDT input and future commissioning arrangements may warrant a review of the RAG.
			CRG wished to highlight that there is likely to be a requirement of the ICB to commission further service capacity in order to meet the statutory obligations of this TA
				By 2027/28 NICE estimate that:
				• In a population of 100,000, around 7,500 people who meet the criteria for referral to specialist weight management services will be eligible for treatment with semaglutide each year after adjusting for predicted population growth.
				• Around 50 people per 100,000 will receive semaglutide each year after adjusting for predicted population growth, and 38 will continue with treatment in year 2.
				The estimated cost is not available, since semaglutide (Wegovy) is not yet launched in this indication.
				In GM this is about 1500 people per year starting Wegovy
				Specialist weight management services and capacity have recently been evaluated.
				CRG noted that a further review of GM weight management service commissioning arrangements is required alongside the implementation of this recommendation.
					Approve addition to formulary with the proposed RAG status of RED until such a time as community services are in place to provide access.
					GMMMG wishes to highlight that there is likely to be a requirement of the ICB to review and commission further service capacity in order to meet the statutory obligations of this TA.

TA877: Finerenone for treating chronic kidney disease in type 2 diabetes
23/03/2023
Commissioning: ICS
	Finerenone is recommended as an option for treating stage 3 and 4 chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults. It is recommended only if:
	• it is an add-on to optimised standard care; this should include, unless they are unsuitable, the highest tolerated licensed doses of:
	  ○ ACE inhibitors or ARBs and
	  ○ SGLT2 inhibitors and
	the person has an eGFR of 25 ml/min/1.73 m^2 or more.
		Add to formulary as suitable for prescribing in primary care, with links to TA877.
		Add to RAG as Green specialist advice
			CRG noted that in the TA NICE have stated that initially finerenone prescribing is likely to be retained by specialist services but in time is suitable for prescribing in primary care as experience in its use increases.
			There are requirements for the monitoring of potassium levels during the first 4 weeks of treatment and periodically thereafter
			Consultation feedback has changed the proposed RAG from Green specialist advice to better fit with current advice and guidance pathways and the eligible population
				NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than approximately £9,000 per 100,000 population.
				Part of the cost of treatment with finerenone is expected to be offset by savings and benefits. The clinical evidence suggests that finerenone plus standard care can improve kidney function and helps to slow the worsening of disease.
				Finerenone costs £36.68 per pack of 28 tablets.
					Approve the 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: Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 29/03/2023 **Commissioning: ICS**	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 the independent advisory group report commissioned by the Department of Health and Social Care. Sotrovimab is recommended as an option for treating COVID-19 in adults and young people aged 12 years and over and weighing at least 40 kg, only if: • they do not need supplemental oxygen for COVID-19 and • they have an increased risk for progression to severe COVID-19, as defined in the independent advisory group report commissioned by the Department of Health and Social Care and nirmatrelvir plus ritonavir is contraindicated or unsuitable. Sotrovimab is only recommended if the company provides it according to the commercial arrangement. Tocilizumab is recommended, within its marketing authorisation, as an option for treating COVID-19 in adults who: • are having systemic corticosteroids and • need supplemental oxygen or mechanical ventilation. Tocilizumab is only recommended if the company provides it according to the commercial arrangement. Casirivimab plus imdevimab is not recommended, within its marketing authorisation, for treating acute COVID-19 in adults.	Tocilizumab is not on formulary in this indication. All others are on formulary in chapter 5.3 as RED drugs. Add tocilizumab to formulary as a RED drug in this indication. Add links to TA878 to all relevant drugs.	This is the first of two TAs for medicines for this indication. The second is delayed as an appeal on NICE's decision is awaited. This includes molnupiravir, remdesivir and tixagevimab plus cilgavimab No comments were received through the consultation and the resource impact is too complex to be done at an ICS-level.	Local resource impact template available. This guidance will have resource implications at a local level which cannot be outlined due to commercial in confidence data and uncertainty around patient populations. Therefore, NICE encourage organisations to evaluate their own practices against the recommendations in the guidance and assess costs and impact on capacity by using the local resource impact template. This guidance does not cover molnupiravir, remdesivir or tixagevimab plus cilgavimab for treating COVID-19. NICE plans to publish technology appraisal guidance on these treatments in the future. An appeal has been lodged by AstraZeneca, Gilead Sciences and Merck Sharp & Dohme, and will be heard in May. For more information, see NICE's development page on molnupiravir, remdesivir and tixagevimab plus cilgavimab for treating COVID-19.	GMMMG noted the TA recommendations. CRG have been unable to obtain the information required to cost this TA, and raised this for GMMMG's attention. KL will take this to the CMDU for clarification of costs.

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
Long term azithromycin for chronic respiratory diseases	This is an established use of azithromycin which is supported by NICE and BTS guidance for COPD, bronchiectasis, and asthma. A review of prescribing in Bury identified a lack of regular review of efficacy and safety of the treatment, as well as the required monitoring not being consistently undertaken. CRG also considered a prescribing guidance document for primary care which will be published alongside this RAG status and is undergoing consultation separately	Add to RAG list as Green specialist advice	Supported by GMMMG guidance which is currently in development	It is estimated that prescribing of azithromycin for this indication costs the GM ICS £80k - £144k per year, the costs of which are already likely to be in the system. This recommendation and guidance is not expected to increase rates of prescribing. No significant service or commissioning impact is expected	Approve the RAG status recommendation
Chloral hydrate 143.3mg/5mL and 500mg/5mL oral solution and cloral betaine 707mg tablets all indications	A review of prescribing in GM has shown there may be inappropriate prescribing of these products for children. MHRA advice recommends limiting prescribing to no more than 2 weeks and that use is not generally recommended and should only be under the supervision of a specialist. There is evidence that long term prescribing is taking place in GM some of which may not have the necessary specialist follow-up	Currently these medicines are not on formulary and have no RAG status CRG recommend a RED status	First proposed in October 2022, feedback from clinicians running region-wide services for children from MFT stated that a RED status would disadvantage patients living a long distance from the service. The decision was paused to collect further information on the prescribing for GM patients. CRG reviewed their recommendation and the consultation comments at their June 2023 meeting. It was agreed that the medicine should be assigned a RED status based on its limited indications for use, the MHRA advice and the nature of the conditions being treated. The group believe that a service's inability to supply the medicine to patients living out of area was insufficient reason to override the safety issues highlighted by the MHRA. It was recommended that secondary care services explore alternative ways to supply these patients if long-term use is appropriate.	In the 12 months March 2023 there were 1006 items of chloral hydrate or cloral betaine issued by primary care in GM at a cost of £359k There are implications for services such as those at MFT which will need to review their prescribing practices to ensure continued supply to their patients. Trust pharmacy are aware and have agreed to support the affected services.	Approve the RED RAG status recommendation

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact	GMMMG decision
Tacalcitol (Curatoderm) 4 micrograms/g Lotion and ointment for use in psoriasis	A new vitamin D analogue for the treatment of psoriasis. The only available evidence compared tacalcitol to standard therapy of vitamin D analogue with/without steroid. Tacalcitol was demonstrated to be significantly less effective than standard therapy	Not to be added to the formulary	No formulary requests have been received CRG noted that existing vitamin D analogue treatments (without corticosteroid) for scalp psoriasis are very expensive and not recommended as first line treatment (NICE CG153) and should only be prescribed for those who cannot use steroids.	Tacalcitol ointment is available in 30g and 100g (£13.40/£30.86) pack sizes at a cost greater than that of generic calcipotriol ointment Tacalcitol lotion available as 30mL (£12.73) is cheaper than calcipotriol scalp solution.	Supported
GMMMG position statement regarding the use of edoxaban for NVAF  GMMMG DOAC Statement_ V1.1 Jun	This document is now due for review	N/A	CRG discussed all the factors affecting the choice of best value DOAC for AF and concluded that the statement remains a pragmatic position which is permissive enough to enable appropriate switching to take place if a locality wishes to do so for reasons of cost-saving, and also facilitates prescribing of alternative agents where there is a strong rationale to do so CRG approved the technical update to the document for publication to the website	None as part of this review GM spends a total of £34.1m on DOACs per year (Apr 22 – Mar 23) Edoxaban accounts for £3.1of this spend (9%) Apixaban accounts for £21.7m (64%)	Supported
Inclisiran primary care prescribers information leaflet  Inclisiran prescribers informat	Some changes to the reimbursement arrangements of this medicine are reflected in a technical update to the document	N/A	CRG approved the technical update to the document for publication to the website	None from this update	Supported

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact	GMMMG decision
GMMMG HCD rheumatology pathways  GMMMG HCD pathway for RA v6.1  GMMMG HCD pathway for PsA v1.2  GMMMG HCD pathway for AS v1.2	A technical update of the rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis pathways to include recent safety guidance on the use of Janus kinase (JAK) inhibitors and NICE TAs recently added to the formulary	N/A	CRG approved the technical update to the document for publication to the website	None from this update	Supported
TA873: Cannabidiol for treating seizures caused by tuberous sclerosis complex 01/03/2023 **Commissioning: NHSE**	Cannabidiol is recommended as an add-on treatment option for seizures caused by tuberous sclerosis complex in people aged 2 years and over, only if: • their seizures are not controlled well enough by 2 or more antiseizure medications (either used alone or in combination) or these treatments were not tolerated • seizure frequency is checked every 6 months, and cannabidiol is stopped if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment the company provides cannabidiol according to the commercial arrangement.	On formulary as a RED drug in line with NICE TAs 614 and 615 (Dravet syndrome and Lennox-Gastaut syndrome), and with a GREY status: "For children and adults with rare, severe forms of drug-resistant epilepsy, when used within its marketing authorisation." Add to formulary as a RED drug in this indication, with link to TA873.	N/A	NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than approximately £9,000 per 100,000 population. This is because the population size is small, and part of the cost of cannabidiol is likely to be offset by savings in management costs and delays to more expensive treatments. The use of cannabidiol plus usual care may reduce seizure frequency and increases the number of seizure-free days compared with usual care alone.	Supported

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact	GMMMG decision
NG122: Lung cancer: diagnosis and management (updated) 14/03/2023 **Commissioning: ICS, NHSE**	In March 2023 the NICE technology appraisal guidance on mobocertinib to the systemic anti-cancer therapy treatment pathways for advanced non-small-cell lung cancer was added.	For information.	N/A	NICE do not expect this update to the guideline to have a significant impact on resources; that is: • the resource impact of implementing any single guideline recommendation will be less than £1,800 per 100,000 population, and • the resource impact of implementing the whole guideline in England will be less £9,100 per 100,000 population. This is because most of the recommendations in the update to the previous NICE guideline reflect current practice. For those recommendations where clinical practice is likely to change as a result of this update, there will not be a significant change in resource use. This is because the populations the recommendations apply to are small and the unit costs for the interventions are small.	Supported

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact	GMMMG decision
NG191: COVID-19 rapid guideline: managing COVID-19 (updated) 29/03/2023 **Commissioning: ICS**	NICE updated the guideline to: • Reflect the recommendations in NICE TA878, as above. • Replace two recommendations on baricitinib with one updated recommendation to clarify how it should be used. • Update recommendations on remdesivir to account for an extension to the marketing authorisation to include the paediatric population. Removed the recommendation on sarilumab, which was for off-label use of sarilumab because it is not licensed for use in COVID-19. This recommendation has been superseded by TA878.	Link on formulary in chapter 5.3. For information no action		The cost of implementation of this new updated guidance can be calculated using the template for TA878	Supported

HST23: Asfotase alfa for treating paediatric-onset hypophosphatasia 01/03/2023 **Commissioning: NHSE**	This guidance updates and replaces HST6 (August 2017). Asfotase alfa is recommended as an option for treating paediatric-onset hypophosphatasia if the person's symptoms started before or at birth (perinatal onset) or between the ages of 0 and 6 months (infantile onset). It is also recommended for people whose symptoms started between the ages of 6 months and 17 years (juvenile onset) only if: • They are aged 1 year to 4 years and have: ○ not reached expected developmental gross motor milestones for their age, or ○ continuing or recurring significant musculoskeletal pain that affects daily activities and quality of life, and has not improved after 2 different types of painkiller recommended by a national pain specialist. • They are aged 5 years to 18 years and have: ○ limited mobility assessed by a specialist using the modified Bleck Ambulation Efficiency Score and a Bleck score between 1 and 6 or ○ continuing or recurring significant musculoskeletal pain that affects daily activities and quality of life, and has not improved after 2 different types of painkiller recommended by a national pain specialist or • They are over 18 years and have 2 or more of the following: ○ current fractures with a history of non-traumatic, recurring or non- or poorly healing fractures ○ limited mobility assessed by a specialist using the modified Bleck Ambulation Efficiency Score and a Bleck score between 1 and 6 or ○ continuing or recurring significant musculoskeletal pain that affects daily activities and quality of life, and has not improved after 2 different types of painkiller recommended by a national pain specialist.	Not on formulary or RAG list. Add to both adult and paediatric RAG list as a RED drug.		In perinatal- or infantile-onset hypophosphatasia, asfotase alfa is likely to increase how long people live before needing a ventilator and how long people live overall compared with best supportive care. In juvenile-onset hypophosphatasia, asfotase alfa is likely to improve outcomes including mobility, pain and health-related quality of life compared with best supportive care. In perinatal- and infantile-onset populations, the cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So asfotase alfa is recommended for all people in these groups. In juvenile-onset populations, the cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources when symptoms are more severe. So asfotase alfa is only recommended for juvenile-onset hypophosphatasia with severe symptoms.	Supported

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact	GMMMG decision
	Asfotase alfa is only recommended if the company provides it according to the commercial arrangement				
*GMMMG June minutes	GMMMG Minutes June 23 draft 3.pdf	Approved at July GMMMG meeting		Nil	CEGC to accept for publication to GMMMG website
*GMMMG medicines value subgroup ToR	GMMMG medicines vale ToR.docx	Approved (pending agreed amendment) at July GMMMG meeting		Nil	CEGC to note and accept for publication to GMMMG website pending amendment
*GMMMG July agenda	GMMMG July 2023 agenda .pdf	For information	GMMMG will verbally update CEGC of discussions at the July GMMMG meeting	Nil	For information

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