SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: CRG (except those * which were made at GMMMG)	**10th October 2023**
Approved by: GMMMG	**9th November 2023**
Approved by: CEGC	**29th November 2023**
Approved by: Executive	**13th December 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	GMMMG recommendation
*GM macular pathway 2 GM Wet AMD Treatment pathway in 1 GMMMG and subgroup wet AMD Tr	GMMMG accepted the proposed macular pathway which is aligned to the NHSE commissioning recommendations and supported by the wet AMD treatment pathway subgroup. It recommends the least expensive anti-VEGF agent that is clinically appropriate for the individual patient is the preferred option (i.e. currently ranibizumab biosimilar). The pathway recognises that the preferred first line agent is one of three first line treatment options that can be used according to their NICE TA and	Red	GMMMG approved the pathway but with a six month review date. It was requested that the proposed KPIs return to GMMMG in Dec, with an assurance report against these KPIs returning in May 24.	This commissioned pathway is expected to generate £3,675,340 in 2023/2024 and £3,575,461 in 2024/25 for MFT, with the potential for greater cost savings across GM. This will still allow clinicians and Trusts to have an element of choice in therapy, a key performance indicator is recommended based on the proposed % uptake of each of the first line treatments i.e. ranibizumab biosimilar (~ 30%), aflibercept + faricimab (~70%) and 100% target switch of Lucentis to ranibizumab	Approve under a 6 month period of review.

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3 GM wAMD Treatment Pathway Sc	allows clinical judgment to select the most clinically appropriate anti-VEGF. However, where there are a number of clinically suitable treatment options, clinicians are advised to select the treatment which is the least expensive to deliver.			biosimilar if this remains clinically suitable.	
Sodium Chloride 5% eye drops for corneal oedema	A request has been received to change the RAG status of these medicines to Green specialist advice. These were added to the formulary as RED due to there being no licensed product available at the time. There are now products available which are licensed as medical devices. Patients may receive NaCL 5% eye drops as short term treatment of transient corneal oedema post-operatively, or long term treatment of chronic corneal oedema due to Fuchs endothelial dystrophy / pseudophakic bullous keratopathy. Patients will remain under secondary care during the period they are prescribed the eye drops	GREEN (specialist advice)	CRG were informed that long-term prescribing is safe and patients will remain under the specialist during this time. These patients have struggled to obtain repeat supplies of the medicine due to its current RAG status of RED (implemented when there were no licensed products available)	In the 12 months to April 2023 there were 1,029 items prescribed by GM primary care organisations at a cost of £33k. • The majority of prescribing is undertaken in primary care (MREH issued 25 items during the 12 month period to April 23) so an increase in prescribing should be limited to an estimated extra 2.5% or £8250 per year.	Approve the RAG status
TA906: Rimegepant for preventing migraine **Commissioning:** ICS, tariff-excluded 5th July 2023	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%. NB: a second TA for rimegepant, for treating *acute* migraine, is expected in October 2023.	Add to formulary in chapter 4.7.4.2 as GREEN (specialist initiation) drug with link to TA906.	CRG were unsure how best to set the standards for transfer of prescribing to primary care. There are no reasons due to safety, efficacy or cost to maintain prescribing in secondary care long-term, however the requirement within NICE TA906 recommendations for a review of efficacy at 12 weeks suggests that this would be the logical point to transfer prescribing to primary care. Feedback from headache service providers suggests that this presents insurmountable logistical challenges and is not feasible. However a Green specialist initiation status was chosen as the most clinically appropriate status. CRG agreed that the 12 week review	NICE expect the resource impact of implementing the recommendations in England will be less approximately £8,800 per 100,000 population. This is because rimegepant is a further treatment option. Uptake of rimegepant would displace other calcitonin gene-related peptide (CGRP) receptor antagonists, and the overall cost to the ICS of treatment for this patient group will be similar, however this will now be split across primary and secondary care medicines budgets. As there are no commercial arrangements in place for rimegepant, this permits the medicine to be procured and dispensed in primary care and reimbursed at the Drug Tariff price of £25.80 per pack of 2 tablets,	Approve addition to formulary for this indication

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			should be undertaken by a specialist and that then would then be the most appropriate point in the pathway to transfer prescribing to primary care.	or £2,354 per year. This is comparable to other CGRP inhibitors (except Eptinezumab which is significantly more costly). Curent modelling (conducted by Pfizer) estimates around 200 patients per year to receive rimegepant.	

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
* Safe Management of Medicines within GP Practices  Front sheet management of medi  NHSGM Safe Management of Medi	The aim of this document is to provide guidance to GP Practices to support the safe management of prescribing and medicines use within the Practice leading to improved medicines optimisation for patients. The document provides Practices with a clear description of best practice in a wide range of areas related to prescribing and medicines use within the Practice to support:0 • Improved patient safety and high-quality prescribing • Improved patient experience • Reduced medicines wastage	N/A	Supported by GMMMG	Nil	Approve for publication
* ADHD medicines shortages: supporting information for the GM system ADHD medicines shortages - guidance and information - GMMMG  ADHD medicines shortages-supporting	In response to the National supply shortage of prescribed medication for ADHD, a GM task and finish group led the development of the following supporting guidance: • National Supply Shortage of prescribed medication for ADHD - A Guide for Secondary Care • GM Pathway for the management of patients prescribed medicines for ADHD during the national shortage – primary care guidance • Patient information – “National Supply Shortage of your prescribed medication for ADHD”	Amber	Supported by GMMMG	Nil	Approved by GMMMG on 9/11/23 and CEG Chair on 14/11/23

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG Recommendation
Bempedoic Acid 180mg tablets for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia (with ezetimibe) as an adjunct to diet in adults. NICE TA694	Bempedoic acid is currently GREEN (specialist advice) on the GMMMG formulary. A request from lipid clinic services has been received to change this to GREEN for indications in line with NICE TA694; It is recommended only if: • statins are contraindicated or not tolerated • ezetimibe alone does not control low-density lipoprotein cholesterol well enough and the company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement.	Change from GREEN (specialist advice) to GREEN	CRG heard that there is no consensus of opinion from lipid specialist regarding this change, but accepted that where current national guidance is followed the referral to a specialist is, in many cases, unnecessary for the initiation of the medicine. CRG believed the value of specialist input for this patient group is in optimising statin therapy prior to initiating bempedoic acid as this represents the more cost-effective treatment. An update to the GM secondary prevention lipid guidelines has been requested to support primary care prescribers.	The list price of bempedoic acid is £55.44 with or without ezetimibe. In GM there has been a total of £65k of bempedoic acid prescribing in the last 3 months, which is increasing. The NICE resource impact statement from April 2021 claimed there was no significant resource impact anticipated due to this being a further treatment option for which the overall cost of treatment is similar.	Approve the change in RAG status
Betamethasone 0.1% eye/ear/nose drops Dexamethasone 0.1% eye drops, preservative free (Minims) & unit dose vials Prednisolone 0.03%, 0.1%, 0.5% % 1% eye drops and preservative free eye drops Fluorometholone 0.1% eye drops **For ophthalmic indications only**	It is proposed these medicines have a change in RAG from RED (pending shared care) to Green specialist initiation. The Manchester Royal Eye Hospital has produced prescribing guidance for primary care to support this change. This guidance will be available separately for GM-wide consultation (see GMMMG consultations)	Amend formulary and RAG list to show these as GREEN (specialist initiation)	CRG queried if shared care was more appropriate for these medicines but decided that the required monitoring is not significant enough to warrant this and will be undertaken by secondary care.	This change is expected to be cost neutral to the GM system. Much of this prescribing already takes place in primary care. The GM ICB currently spends £160k per year on these preparations	Approve the change in RAG status

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TA910: Semaglutide for managing overweight and obesity in young people aged 12 to 17 years (terminated appraisal) **Commissioning: ICS** 13th July 2023	NICE is unable to make a recommendation on semaglutide (Wegovy) for managing overweight and obesity in young people aged 12 to 17. This is because Novo Nordisk has confirmed that it does not intend to make an evidence submission for the appraisal.	Add to paediatric DNP list. Liraglutide is DNP on the paediatric RAG list, in line with NICE TA749.		Novo Nordisk considers that, at this time, there is not enough evidence to support economic modelling for this population. In particular, there is not enough evidence for the risk equations that explore the link between weight loss and long-term outcomes in young people aged 12 to 17 years and utility estimates that adequately capture the full impact on their quality of life. Therefore, there is a high degree of uncertainty in the evidence base that would be used to support an economic model that meets the NICE reference case.	For information
GM ICS guidance and communication regarding the shortage of ADHD medicines	A collaboration between GM mental health service providers and ICB staff have produced a series of guidance and information leaflets aimed at primary and secondary care services and patients and carers to support this shortage.	N/A	The documents were approved by CRG for immediate discussion at GMMMG at their October meeting. GMMMG requested further work, therefore the documents are not included here because they are now out of date.	This documentation aims to mitigate the impact this supply problem is likely to have.	No recommendation

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
TA908: Olaparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube or peritoneal cancer after 2 or more courses of platinum-based chemotherapy **Commissioning: NHSE** 5th July 2023	Olaparib is recommended as an option for the maintenance treatment of relapsed, platinum-sensitive, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults whose cancer has responded to platinum-based chemotherapy, only if: • they have a BRCA1 or BRCA2 mutation • they have had 2 or more courses of platinum-based chemotherapy • the company provides olaparib according to the commercial arrangement. This guidance updates and replaces TA620. The committee discussion for TA620 is still available on the NICE website.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester. For info, no action	N/A	Olaparib is currently available for this population through the Cancer Drugs Fund. It is also recommended for people who have had 3 or more courses of platinum-based chemotherapy in routine commissioning. This partial review specifically updates and replaces the Cancer Drugs Fund recommendation for people who have had 2 courses of platinum-based chemotherapy in NICE's technology appraisal guidance on olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (TA620). NICE expect 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 (50 people per year in England).
TA909: Lorlatinib for untreated ALK-positive advanced non-small-cell lung cancer **Commissioning: NHSE** 12th July 2023	Lorlatinib is not recommended, within its marketing authorisation, for treating anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC) in adults who have not had an ALK inhibitor.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester. For info, no action	N/A	None
TA911: Selpercatinib for untreated RET fusion-positive advanced non-small-cell lung cancer **Commissioning: NHSE** 26th July 2023	Selpercatinib is recommended with managed access as an option for treating RET fusion-positive advanced non-small-cell lung cancer (NSCLC) in adults, only if: • it is untreated the conditions in the managed access agreement for selpercatinib are followed.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester. For info, no action		It is estimated that around 160 adults per year with untreated RET fusion-positive advanced NSCLC are eligible for treatment with selpercatinib. Since selpercatinib is administered orally, there will be a capacity benefit for providers if it is used instead of comparators that are administered by intravenous (IV) infusion. The resource impact of selpercatinib will be covered by the Cancer Drugs Fund budget. More evidence on selpercatinib is being collected until further data from LIBRETTO-001 and LIBRETTO-431 is available. After this, NICE will decide whether or not to recommend it for use on the NHS and update the guidance. It will be available through the Cancer Drugs Fund until then.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
NG83: Oesophago-gastric cancer: assessment and management in adults (update) **Commissioning: ICS/NHSE** 4th July 2023	In July 2023, NICE reviewed the evidence and made new recommendations on palliative management of luminal obstruction with no curative intent for adults with oesophageal or oesophago-gastric junctional cancer.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester. For info, no action		NICE expect that the resource impact of this update: • for any single guideline recommendation in England will be less than approximately £1,800 per 100,000 population and • for implementing the whole guideline in England will be less than approximately £8,800 per 100,000 population. This is because the population size is small and practice may not change substantially from these recommendations. However there may be a small cost saving from the recommendations if not currently implemented by reducing the number of external beam radiotherapy procedures after stenting and the number of different treatments that most people receive.
NG122: Lung cancer: diagnosis and management (update) **Commissioning: ICS/NHSE** 26th July 2023	In July 2023, NICE added to and updated the systemic anti-cancer therapy treatment pathways for advanced non-small-cell lung cancer: • added the NICE TA on dabrafenib and trametinib, for squamous and non-squamous non-small-cell lung cancer • added the NICE TA on mobocertinib, for non-squamous non-small-cell lung cancer • added the NICE TA on selpercatinib, for squamous and non-squamous non-small-cell lung cancer updated the treatment options in the pathways for EGFR-TK positive, KRAS G12C positive and METex14 skipping alteration non-small-cell lung cancer.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester. For info, no action		For information

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
CG189: Obesity: identification, assessment and management **(update)** **Commissioning: ICS** 26th July 2023	In July 2023, NICE reviewed the evidence on bariatric surgery for people living with overweight and obesity and updated the recommendations on surgical interventions. NICE has also produced guidelines on obesity prevention, maintaining a healthy weight, and managing overweight and obesity in adults and in children and young people.	For information.		Due to a lack of robust data on current practice and the variation across organisations and services, the size of the resource impact will need to be determined at a local level. A resource impact template is available. Depending on current local practice, recommendations/areas which may require additional resources and result in additional costs include: • Using lower BMI thresholds for overweight and obesity for people from a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background • Reducing barriers to access bariatric surgery Implementing the updated guideline may: • Reduce the incidence of type 2 diabetes, cardiovascular disease and other weight-related health conditions in these populations in the long term as they have earlier access to NHS weight management services. Reduce health-based inequalities for people from a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background.
GMMMG medicines safety subgroup report	GMMMG Medicines Safety Highlight Sumı	N/A	For info. The isotretinoin MHRA DSU will be captured by CRG in Nov meeting with likely action requested of medicines safety group.	-
GMMMG Pharmacy workforce subgroup report	GMMMG Pharmacy Workforce Highlight F	N/A	For info	-
GMMMG minutes Oct 23 and agenda Nov 23	GMMMG Minutes Oct 23 fnl.pdf GMMMG Nov 2023 agenda.pdf	-	approved	-

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