SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: CRG (except those * which were made at GMMMG)	**12th December 2023**
Approved by: GMMMG	**12th January 2024**
Approved by: CEGC	**25th January 2024**
Approved by: Executive	*Pending, expected Jan 24*

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
Micronized progesterone 100mg capsules (Gepretix®) for adjunctive use with oestrogen in postmenopausal women with an intact uterus, as HRT.	Micronized progesterone 100mg capsules (Utrogestan®) capsules are on formulary for adjunctive use with oestrogen in postmenopausal women with an intact uterus, as HRT. Utrogestan capsules have recently been subject to a serious shortage protocol The shortage is now resolving, but to increase resilience in case of future supply issues the authors of the GMMMG HRT guidance have requested that an additional brand, Gepretix®, be added to formulary. Gepretix 100mg capsules have the same licensed indication as Utrogestan, and are marketed at a slightly lower price (£4.62 for 30 capsules vs. £6.60 for Utrogestan).	Add Gepretix 100mg capsules to formulary as a first choice option when micronized progesterone 100mg capsules are required for HRT.	The request was as an alternative to Utrogestan but the lower price for Gepretix means there are cost savings associated with its use over Utrogestan and CRG therefore wished to place this as the preferred formulation.	Gepretix 100mg capsules have the same licensed indication as Utrogestan, and are marketed at a lower price (£4.62 for 30 capsules vs. £6.60 for Utrogestan). Around 5000 items of micronized progesterone 100mg capsules were dispensed in Greater Manchester in September 2023 at a cost of £72k. If prescribing were to remain at this level and be split between the two brands, a saving of £129k per year may be realised for the ICB.	Approve addition to formulary

Temporary suspension of certain conditions from GM Commissioning Statement: *Conditions for which over the counter items should not routinely be prescribed in primary care* *AND* Permanent amendments to the policy to reflect the national Pharmacy First scheme	NHS GM has commissioned a Minor Ailments Service for the Winter period from 5th December 2023 until 31st March 2024 which goes against the principles regarding commissioning of medicines for the treatment of conditions which may be self-limiting or are suitable for self-care, previously approved by all GM CCGs during 2019. Therefore, the statement is required to be temporarily amended for the duration of the Minor Ailments Service. A cross check of the conditions covered by the commissioning statement with those of the MAS shows that the principles which apply to 15 conditions in the commissioning statement require to be suspended for the duration of the MAS. These are: athletes foot, constipation, contact dermatitis, diarrhoea, dry eyes, ear wax, fever, head lice, indigestion and heartburn, insect bites and stings, mouth ulcers, nappy rash, oral thrush, pain including teething, threadworm Pharmacy First will be a new advanced service starting on 31st January 2024 that includes seven new clinical pathways and will replace the Community Pharmacist Consultation Service (CPCS). As Pharmacy First includes treatment of infected insect bites and (bacterial) sore throats, the following changes are proposed: Acute Sore Throat – insert Specific Exception: Bacterial Sore Throat requiring provision of antibiotics after working through Acute Sore Throat Clinical Pathway (persons 5 years and over) Insect bites and stings – insert Specific Exception: Infected Insect Bites requiring provision of antibiotics after working through the Infected Insect Bites clinical pathway (persons 1 year and over) Full details of Pharmacy First may be found at the Community Pharmacy England website.	Green	It is proposed that the amendments detailed be made and that following statement be appended to the commissioning statement on the GMMMG website: *For the period 5th December 2023 until 31st March 2024, this commissioning statement is not applicable to the following conditions* <list of 15 conditions as above> *as they are included in a Minor Ailments Service. Details of the GM Minor Ailments Service may be found here.* The changes are required to ensure the commissioning statement is not at variance with the new Pharmacy First service	The action proposed by GMMMG in relation to the temporary amendment to this commissioning statement does not in itself pose a financial impact. There will be a financial impact to NHS GM through the commissioned minor ailments scheme which will already have been accepted by the ICB executive in order for the scheme to be live at this time. Additional costs will be picked up within Pharmacy First service but as these conditions would be treated with antibiotics prescribed by a GP or a non-medical prescriber, there is no net increase in overall cost.	GMMMG support the amendments to this commissioning statement until the end of the GM MAS scheme 31/3/24.  Commissioning Statement for NHS GM GMMMG ask CEGC to ensure that post March 24 arrangements are made to ensure all GM residents have equitable access to a longer-term MAS scheme.

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
Prednisolone enteric coated 2.5 and 5mg tablets All indications	Prednisolone enteric coated tablets are included on the GMMMG DNP list as criterion 2: "Products which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation." The price of some strengths of prednisolone EC and prednisolone plain tablets is now similar	Remove 2.5mg and 5mg tablets from the DNP list 1mg tablets should remain on the DNP list	Prednisolone EC tablets are not suitable for everyone, since they appear to be associated with less predictable absorption of prednisolone. There are case reports of loss of disease control in patients with inflammatory bowel disease. The enteric coating does not reduce the risk of peptic ulceration, since this is a systemic effect. However, there are no compelling reasons that prednisolone EC tablets should not be available for patients for whom it is clinically appropriate.	In the 12 months to July 2023 GM has spent £63,599 on 2.5mg and 5mg EC tablets. During the same period the spend on the 2.5mg and 5mg plain tablets was £404k	Approve amendment to DNP list
Lixisenatide 20 micrograms solution for injection for the treatment of T2DM	In April 2022 Sanofi notified the MHRA of the discontinuation of lixisenatide 10 microgram and lixisenatide treatment initiation packs. As a result CRG agreed that lixisenatide should be removed from formulary, and this was actioned in September 2022. In August 2023, Sanofi wrote to HCPs to notify that lixisenatide will be entirely discontinued from the UK market when current stock is exhausted, which is expected in December 2023.	No longer on formulary	CRG wish to ensure that locality teams are aware of the product discontinuation, and recommend MO teams communicate with practices to support review of treatment for affected patients.	Around 600 items of lixisenatide were dispensed in Greater Manchester in the 12 months to July 2023 at a cost of £37,380, with prescribing consistently around 40-50 items per month over that period. Patients will need to be identified and reviewed, and selecting alternative treatments may be challenging given the ongoing supply problems with the other marketed GLP-1 agonists.	Approve removal from formulary

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG Recommendation
TA913: Mavacamten for treating symptomatic obstructive hypertrophic cardiomyopathy **Commissioning: NHSE** 06/09/23	Mavacamten is recommended as an option for treating symptomatic obstructive hypertrophic cardiomyopathy in adults who have a New York Heart Association class of 2 to 3. It is recommended only if: • it is an add-on to individually optimised standard care that includes beta-blockers, non-dihydropyridine calcium-channel blockers or disopyramide, unless these are contraindicated, and the company provides it according to the commercial arrangement	Not on formulary. Add to formulary in chapter 2 as RED, with a link to TA913.		Resource impact template available. NICE estimate that around: • 6,300 people with NYHA class 2 to 3, obstructive hypertrophic cardiomyopathy are eligible for treatment with mavacamten and beta blockers or calcium channel blockers from year 5, after adjusting for population growth • 650 people will start treatment with mavacamten and beta blockers or calcium channel blockers in year 5 once cumulative uptake has reached 70%, after adjusting for population growth by year 5, 1,200 people will be continuing treatment with mavacamten and beta blockers or calcium channel blockers from previous years. People receiving mavacamten will require additional monitoring during their first and subsequent years of treatment, this will include outpatient appointments and an echocardiogram at each outpatient appointment. This will have a capacity impact on outpatient appointments and for echocardiographic services during people's treatment.	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
Update to chapter 5.3 COVID Medicines	NICE TA878 originally aimed to assess all treatments for Covid, however it currently includes positive recommendations for nirmatrelvir plus ritonavir, sotrovimab and tocilizumab and negative recommendation for casirivimab plus imdevimab. NHSE's interim policy: Remdesivir and molnupiravir for non-hospitalised patients with COVID-19 is still in place. This policy stipulates remdesivir as third line and molnupiravir as fourth line treatments. Future access to these medicines is subject to final recommendations by NICE. It also needs to be noted that NICE TA878 underwent a partial rapid review [ID6262] and the outcome is to recommend use of nirmatrelvir plus ritonavir in much wider population. NHSE responded to consultation on funding variation suggesting as staggered approach. Further details are not available at the moment.	Casirivimab / imdevimab - remove – negative recommendation by NICE TA878 Nirmatrelvir / ritonavir (Paxlovid) – keep as red – NICE TA878 Sotrovimab (Xevudy) – keep as red – NICE TA878 Molnupiravir (Lagevrio) – keep as red – NHSE interim policy Remdesivir (Veklury) – keep as red – NHSE interim policy Tocilizumab (RoActemra) – add as red - NICE TA 878 (only for hospitalised patients, and so by definition red)	It was noted that TA878 was taken away for an assessment of the financial impact from July's GMMMG meeting but has not returned to GMMMG	From the updates proposed here: none GMMMG has yet to receive a financial impact estimate for NICE TA878, it is understood that this has been assessed by the ICB executive as part of the commissioning proposal.	Approve amendment to formulary

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GM Antimicrobial guidance updated October 2023  GM Antimicrobial guidelines October	This update includes: • Correction of a brand name error in Acne section. • Lower UTI in pregnant women section: addition of which trusts microbiology labs test for which antibiotic sensitivity to aid clinicians during drug selection. • ***Removed statement ' CHECK AVAILABILITY AS NOT ALL PHARMACIES HOLD STOCK.' as this is no longer the case for fosfomycin.*** • Switch of 1st line and alternative antifungal to use for vulvovaginal candidiasis. This aligns the antimicrobial guideline with GMMG formulary and other national documents (PGDs, CKS and BASSH guidelines).	N/A	None	Some small savings if fluconazole capsules are used in preference to clotrimazole pessaries	Approve for publication

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
NG234: Spinal metastases and metastatic spinal cord compression **Commissioning: ICS, NHSE**	This guideline covers recognition, referral, investigation and management of spinal metastases and metastatic spinal cord compression (MSCC). It is also relevant for direct malignant infiltration of the spine and associated cord compression. It aims to improve early diagnosis and treatment to prevent neurological injury and improve prognosis. This guidance updates and replaces CG75 (November 2008).	N/A		Resource impact template available. Implementing the guideline may result in the following additional costs: • More people being referred to MSCC services each year. • More muti-professional assessments being carried out each year. • More people having systemic anti-cancer therapy each year. Implementing NICE's guideline may result in the following benefits and savings: • Fewer people having surgery each year. • Fewer people having radiotherapy each year.

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NG235: Intrapartum care **Commissioning: ICBs**	This guideline covers the care of women and their babies during labour and immediately after birth. It focuses on women who give birth between 37 and 42 weeks of pregnancy ('term'). The guideline helps women to make informed choices about where to have their baby and about their care in labour. It also aims to reduce variation in aspects of care. This guidance updates and replaces CG190 (December 2014).	N/A		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 £8,800 per 100,000 population. This is because the overall incremental cost of treatment is low and any cost is likely to be offset by savings and benefits. However, some of the guideline areas and recommendations may represent a change to current local practice. These are: **Remifentanil patient-controlled analgesia (recommendations 1.6.20 to 1.6.23)** The recommendations to consider remifentanil may increase the use of intravenous remifentanil patient-controlled analgesia, and this will have resource implications such as increased monitoring, which will require the presence of a qualified midwife or other suitably qualified person to be available at all times. But this is likely to be offset by reduced use of rescue analgesia (including epidurals). **Management of the third stage of labour (recommendations 1.10.11 to 1.10.13)** The recommendation will increase the administration of oxytocin by intravenous bolus injection for women in the third stage of labour who have already had oxytocin during labour, and this may have resource implications if an additional midwife is needed to assist with the intravenous administration.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
NG192: Caesarean birth (update) **Commissioning: ICS**	In September 2023, NICE updated the recommendations on the use of neuraxial opioids for postoperative pain relief, and monitoring for women and pregnant people who have had neuraxial opioids.	N/A		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. The guideline recommends morphine as the preferred alternative when diamorphine is not available. Compared to neuraxial diamorphine, neuraxial morphine may be associated with an increased risk of respiratory depression over a longer period. Additional monitoring may therefore be required when morphine is used, and this should be determined by clinical assessment of individual cases. The impact of the requirement for any increased monitoring will be dependent on the setting in which any additional monitoring takes place and the resources used to do this.
NG50: Cirrhosis in over 16s: assessment and management (update) **Commissioning: ICS**	In September 2023, NICE reviewed the evidence and made new or updated recommendations on safe prescribing and use of carvedilol and propranolol in people with cirrhosis, detecting and preventing bleeding from medium or large varices, preventing spontaneous bacterial peritonitis, and primary prevention of decompensation. NICE have also changed recommendations 1.2.7 and 1.2.8 without an evidence review. These changes have been made to clarify that people with cirrhosis who are planning to take carvedilol or propranolol to prevent decompensation do not need an upper gastrointestinal endoscopy.	N/A		A local resource impact template is available. Implementing the guideline may: • increase the uptake of non-selective beta blockers • reduce the number of monitoring endoscopies for people receiving non-selective beta blockers • reduce the use of endoscopic variceal band ligation which will result in a reduction of costs and create a capacity benefit • delay decompensation and reduce associated treatments costs • reduce costs of prescribing antibiotics • lead to improved consistency of best practice across the country • lead to better health outcomes and care experience. For every 100 patients who switch to non-selective beta blockers for prevention of variceal bleeding, an estimated 200 endoscopic variceal band ligation procedures and 830 endoscopic surveillance procedures, and their associated costs, are avoided over a 5-year period. These benefits may also provide some savings to offset some of the potential costs identified above and the updated recommendations are expected to be cost saving overall.

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GMMMG Dec 23 minutes  GMMMG Minutes Dec 23 fnl.pdf	-	-	-	-
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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