Recommendations from July 2022 GMMMG meeting – for approval

DECISIONS WITH SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

Status assigned define here

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 3 months (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.

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	**Recommendation from GMMMG**
Simple eye ointment	**Do not prescribe (DNP) (criterion 2)**	Not explicitly in formulary	Simple eye ointment is £53.28 per 4g tube Other products exist at less than £3 per pack GM spends in excess of £192k per year on a product for which alternatives exist at 96% less	If all simple eye ointment was switched to the cheapest alternative, GM could save £180k per year	None	**Approve DNP status for simple eye ointment**
TA775: Dapagliflozin for treating chronic kidney disease	**Green**	On formulary in chapter 2 as a GREEN (specialist advice) drug for chronic heart failure, in line with TA679. Add link to TA775	Dapagliflozin is recommended as an option for treating chronic kidney disease (CKD) in adults. It 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, and • people have an estimated glomerular filtration rate (eGFR) of 25 ml/min/1.73 m^2 to 75	NICE estimate that implementing the guidance will cost £158k in Greater Manchester in year 1, rising to £1.9 million in year 5. It is expected that resources will be released by reductions in eGFR ≥50% and acute kidney injury, and reduced requirement for dialysis, kidney transplant, and hospitalisation for heart failure. The net impact is therefore estimated at £136k in year 1, rising to £668k in year 5.	None anticipated	**Approve addition to the formulary and green RAG status**

			ml/min/1.73 m^2 at the start of treatment and: ○ have type 2 diabetes or have a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more			

DECISIONS WITHOUT SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	**FINAL DECISION**
Goserelin and Leuprorelin for male early/advanced breast cancer	**AMBER**	Add to chapter 6 Add link to Shared Care Protocol (SCP)	GM has a SCP for the treatment of breast cancer in females using these agents. This has now been updated and is approved by Clinical Reference subgroup CRG (see below). The previous SCP does not include the treatment of males with hormone dependent breast cancer, of which there are a small number each year who currently obtain treatment from the specialist and not via their GP. Monitoring requirements are the same for all patients regardless of gender, therefore it is more equitable to include males in the provision of shared care with these medicines for the stated indications. The use of these medicines for male patients is supported by guidance from the European Society for Medical Oncology (ESMO)	Anticipated 6 patients per year in GM Less than £7k per year.	Limited impact Shared care is not equitably available in GM and steps are being taken to manage this. It would appear to be an equality issue that has prevented male patients accessing treatment via their GP to date. This is now being addressed.	**Approved** **See SCP below**
Shared Care protocol for goserelin and	**N/A**	On formulary	CRG approved a copy of the shared care protocol which has been updated to include the treatment of male patients. This document supports the RAG change above	See above	See above	**Approved**

leuprorelin use for breast cancer GMMMG SCP GnRH analogues breast ca						
Micronised progesterone (Utrogestan®) vaginal 200mg capsules for prevention of miscarriage	**Green Specialist initiation**	Add to chapter 6	In line with the updated NG126: Ectopic pregnancy and miscarriage: diagnosis and initial management which recommends: "*Offer vaginal micronised progesterone 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding and have previously had a miscarriage. If a fetal heartbeat is confirmed, continue progesterone until 16 completed weeks of pregnancy*." This is an off-label use of vaginal micronised progesterone CRG believed this should be either RED or Green specialist initiation. However the group heard that follow-up for pregnant women in this group is inconsistent across GM and assigning a RED status may cause problems with access to the medicine.	NICE do not expect the recommendations in this update to have a significant impact on resources. The recommendations will increase the use of progestogens to prevent miscarriage but this is cost effective. Each pack of 21x200mg vaginal capsules has a price of £21.00	None expected	**Approved**
TA773: Empagliflozin for treating chronic heart failure with reduced ejection fraction	**Green Specialist Advice**	Already in chapter 6 Add to chapter 2 Add link to TA773	Empagliflozin is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction in adults, only if it is used as an add-on to optimised standard care with: • an angiotensin-converting enzyme (ACE) inhibitor or angiotensin 2 receptor blocker (ARB), with a beta blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA), or • sacubitril valsartan with a beta blocker and, if tolerated, an MRA.	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	None anticipated	**Approved**

			Start empagliflozin for treating symptomatic heart failure with reduced ejection fraction on the advice of a heart failure specialist. Monitoring should be done by the most appropriate healthcare professional.			
NG91: Otitis media (acute): antimicrobial prescribing (updated)	**Green**	Add phenazone + lidocaine eardrops to formulary, with link to NG91	Product is lidocaine hydrochloride 10 mg/g/ phenazone 40 mg/g ear drops (Otigo®) Currently, oral analgesia is routinely used to manage pain associated with acute otitis media (AOM) and there is minimal use of eardrops containing an anaesthetic and an analgesic. These eardrops may be used in addition to oral analgesics. The guideline covers patients under 18, however the highest number of cases are in the 0 to 5 years age range. There are around 896,000 episodes of AOM in children aged 0 to 5 years old in England each year, of which 524,000 are estimated to have AOM with no eardrum perforation or otorrhoea and are eligible for treatment with eardrops containing an anaesthetic and an analgesic. The use of eardrops containing an anaesthetic and an analgesic would be in children who do not receive an immediate oral antibiotic for their ear infection.	Cost for 1x 15mL bottle = £8.92 GM cost impact is up to £40,000 per year in GM (considered in May decision summary) This is likely to be antibiotic sparing and supports the current Antimicrobial stewardship (AMS) work on reducing the unnecessary prescribing of antibiotics.	None anticipated	**Approved**
TA776: Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea	**DNP**	Not on formulary On RAG list as RED for narcolepsy Add to DNP list with link to TA776	**Commissioner: ICB , nationally tariff-excluded** Pitolisant hydrochloride is not recommended, within its marketing authorisation, to improve wakefulness and reduce excessive daytime sleepiness in adults with obstructive sleep apnoea whose sleepiness has not been satisfactorily treated by primary obstructive sleep apnoea therapy such as continuous	None anticipated	None anticipated	**Approved**

			positive airway pressure (CPAP), or who cannot tolerate it.			
TA777: **Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea**	**DNP**	Not on formulary On RAG list as RED for narcolepsy Add to DNP list with link to TA777	**Commissioner: ICB , national tariff-excluded** Solriamfetol is not recommended, within its marketing authorisation, to improve wakefulness and reduce excessive daytime sleepiness in adults with obstructive sleep apnoea whose sleepiness has not been satisfactorily treated by primary obstructive sleep apnoea therapy, such as continuous positive airway pressure (CPAP).	None anticipated	None anticipated	**Approved**
GMMMG Charter Charter v5.pptx	**N/A**	N/A	GMMMG has developed and approved the attached charter to set out its priorities for the coming 18-24 months. Work plans to support the delivery of these priorities are being developed by the relevant subgroups.	None anticipated	None anticipated	**Approved**
DECISIONS FOR INFORMATION ONLY						
TA778: **Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria**	**RED**	Not on formulary Add to RAG list as a RED drug in this indication, with link to TA778.	**Commissioner: NHSE** Pegcetacoplan is recommended, within its marketing authorisation, as an option for treating paroxysmal nocturnal haemoglobinuria (PNH) in adults who have anaemia after at least 3 months of treatment with a C5 inhibitor. It is recommended only if the company provides pegcetacoplan according to the commercial arrangement.	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.	N/A	**N/A**
HST18: **Atidarsagene autotemcel for treating metachromatic leukodystrophy**	**RED**	Not on formulary Add to RAG list as a RED drug in this indication, with link to HST18.	**Commissioner: NHSE** Atidarsagene autotemcel is recommended, within its marketing authorisation, as an option for treating metachromatic leukodystrophy with mutations in the arylsulphatase A (ARSA) gene: • for children who have late infantile or early juvenile types, with no clinical signs or symptoms • for children who have the early juvenile type, with early clinical signs or symptoms, and who can still walk independently and	The cost-effectiveness estimates show that atidarsagene autotemcel provides substantial extra health and quality-of-life benefits. But how much is uncertain, and it varies for the different types of the condition. Taking into account the long-term uncertainty, for children with late infantile and early juvenile forms of the condition, the cost-	N/A	**N/A**

			have no cognitive decline It is recommended only if the company provides atidarsagene autotemcel according to the commercial arrangement.	effectiveness estimates are within what NICE normally considers an acceptable use of NHS resources for highly specialised technologies.		
All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.						