SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: GMMMG	**At their meeting on: 10th November 2022**
For approval by: CEGC	**At their meeting on: 15th December 2022**

DECISIONS EXPECTED TO HAVE A FINANCIAL IMPACT

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

TA805: Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides
Commissioning: ICS
July 2022
	Icosapent ethyl is recommended as an option for reducing the risk of cardiovascular events in adults. It is recommended if they have a high risk of cardiovascular events and raised fasting triglycerides (1.7 mmol/litre or above) and are taking statins, but only if they have:
	• established cardiovascular disease (secondary prevention), defined as a history of any of the following:
	  ○ acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation)
	  ○ coronary or other arterial revascularisation procedures
	  ○ coronary heart disease
	  ○ ischaemic stroke
	  ○ peripheral arterial disease, and
	low-density lipoprotein cholesterol (LDL-C) levels above 1.04 mmol/litre and below or equal to 2.60 mmol/litre.
		Add icosapent ethyl to formulary as a GREEN (specialist advice) drug, as per local specialist opinion, with link to TA805, pending pathway position.		Icosapent ethyl costs £144.21 per pack (120 capsules/30 days), and £1,750 per patient per year.
				NICE estimate that:
				• 20,603 people in GM with an established cardiovascular disease are eligible for treatment with icosapent ethyl from year 5 after adjusting for population growth.
				• 1,030 people will have started icosapent ethyl by year 5 once uptake has reached 5% after adjusting for population growth.
				The estimated annual cost of implementing the guidance in GM is £342k in year 1, rising to £1.5m in year 5.
				A resource impact template is available.
					The route by which primary care can obtain specialist advice before initiation is TBC	Approve the addition to the formulary

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TA807: Roxadustat for treating symptomatic anaemia in chronic kidney disease **Commissioning: ICS, tariff-excluded** July 2022	Roxadustat is recommended as an option for treating symptomatic anaemia associated with chronic kidney disease (CKD) in adults only if: • they have stage 3 to 5 CKD with no iron deficiency and • they are not on dialysis at the start of treatment and the company provides roxadustat according to the commercial arrangement.	Add to formulary in chapter 9.1.3 as a RED drug, with link to TA807.		By 2026/27 NICE estimate that around 2,241 people with symptomatic anaemia associated with CKD will be eligible for treatment with roxadustat in GM each year, and 22% (493 people) will choose roxadustat. Using the NICE resource impact template and default rate of uptake for each medicine and list prices, it is estimated that the financial impact is £55k in year 1 up to £149k by year 5. NB: roxadustat is NHSE-commissioned for dialysis-induced anaemia, but is not routinely commissioned.	None identified	Approve the addition to the formulary
Potassium binders shared care protocols Sodium zirconium cyclosilicate and patiromer acetate for people with persistent hyperkalaemia and stages 3b to 5 chronic kidney disease or heart failure Patiromer SCP Oct 22 final for GMMMC SZC Lokelma SCP Oct 22 final for GMM	Shared care protocols have been produced to enable transfer of prescribing into primary care to facilitate patients to obtain the medicine. The SCPs stipulate that specialist review and oversight should continue and set out the requirements prior to transfer of prescribing to primary care, what monitoring must be undertaken and by whom and when to seek specialist advice. See NICE TA623 & TA599	Amber shared care protocol		NICE costing template is available as part of TA623. It estimates additional resource impact of £445k per year by year 5 (2023-24) However spend in primary care is already at £80k per year on both agents by July 2022. Therefore an additional £365k spend per year is expected across both primary and secondary care by end of 2023-24.	All new shared care protocols have commissioning implications. There is ongoing work in GM to manage shared care.	Publish SCP on GMMMG website and communicate to commissioners

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TA803: Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs **Commissioning: ICS, tariff-excluded** July 2022	Risankizumab, alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. It is recommended only if they have: peripheral arthritis with 3 or more tender joints and 3 or more swollen joints moderate to severe psoriasis (a body surface area of at least 3% affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10) had 2 conventional DMARDs and at least 1 biological DMARD. Risankizumab is recommended only if the company provides it according to the commercial arrangement.	Add to formulary in chapter 10.1.3 as a RED drug, with link to TA803.	On formulary in chapter 13 for moderate to severe plaque psoriasis, as per NICE TA596.	A resource impact template is provided for completion at a local level. 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 £9,000 per 100,000 population. This is because the technology is a further treatment option and is available at a similar price to the current treatment options. Risankizumab has a commercial arrangement which makes it available to the NHS with a discount.	None significant expected	Add to formulary
TA808: Fenfluramine for treating seizures associated with Dravet syndrome **Commissioning: NHSE, tariff-excluded** July 2022	Fenfluramine is recommended as an add-on to other antiseizure medicines for treating seizures associated with Dravet syndrome in people aged 2 years and older, only if: seizures have not been controlled after trying 2 or more antiseizure medicines the frequency of convulsive seizures is checked every 6 months, and fenfluramine is stopped if it has not fallen by at least 30% compared with the 6 months before starting treatment the company provides fenfluramine according to the commercial arrangement.	Add to formulary in chapter 4.8.1 as a RED drug, with link to TA808.	Fenfluramine was previously not routinely commissioned, with IFR approval required.	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 £9,000 per 100,000 population. This is because the technology is a further treatment option and the population size is small. The use of fenfluramine added to standard care drugs may reduce the number of convulsive seizures. However, any savings as a result are not expected to be significant at a national level.	N/A	Add to formulary

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TA809: Imlifidase for desensitisation treatment before kidney transplant in people with chronic kidney disease **Commissioning: NHSE, tariff-excluded** July 2022	Imlifidase is recommended as a desensitisation treatment option for adults who: are waiting for a kidney transplant from a deceased donor are highly sensitised to human leukocyte antigens (HLA) have a positive crossmatch with the donor and are unlikely to have a transplant under the available kidney allocation system (including prioritisation programmes for highly sensitised people). It is recommended only if: a maximum of 1 dose is given it is given in a specialist centre with experience of treating high sensitisation to HLA the company provides imlifidase according to the commercial arrangement.	Add to formulary as a RED drug in chapter 8.2, with link to TA809.	Imlifidase was previously not routinely commissioned, with IFR approval required.	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. The conditional marketing authorisation states the use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system (including prioritisation programmes for highly sensitised patients).	N/A	Add to formulary
NG224: Urinary tract infection in under 16s: diagnosis and management **Commissioning: ICS** July 2022	This guideline covers diagnosing and managing first or recurrent upper or lower urinary tract infection (UTI) in babies, children and young people under 16. It aims to achieve more consistent clinical practice, based on accurate diagnosis and effective management. It does not cover babies, children and young people with urinary catheters in situ, neurogenic bladders, significant pre-existing urinary tract disorders (uropathies), underlying renal disease or immunosuppression, or recurrent UTI in sexually active girls and young women under 16. It also does not cover babies, children and young people in intensive care units. This guideline updates and replaces NICE guideline CG54 (August 2007).	Update antimicrobial guidelines to replace links to CG54 with links to NG224	In scope of antimicrobial guidelines The updated recommendations relate to diagnosis and identifying the signs and symptoms of a UTI. These are unlikely to substantially change practice because although some of the symptoms and signs suggesting a UTI have changed, the diagnostic pathway remains the same. There may be resource benefits from aligning practice on testing, and not routinely testing the urine of babies, children, and young people over 3 months who have symptoms and signs that suggest an infection other than a UTI.	NICE do not expect this update to have a significant impact on resources; that is: the impact of implementing any single guideline recommendation in England will be less than ~£1,800 per 100,000 population, and the resource impact of implementing the whole guideline will be less than ~£9,000 per 100,000 population.	None expected	Add to formulary

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HST21: Setmelanotide for treating obesity caused by LEPR or POMC deficiency **Commissioning: NHSE** July 2022	Setmelanotide is recommended, within its marketing authorisation, as an option for treating obesity and controlling hunger caused by pro-opiomelanocortin (POMC) deficiency, including proprotein convertase subtilisin/kexin type 1 or leptin receptor (LEPR) deficiency in people 6 years and over. It is only recommended if the company provides setmelanotide according to the commercial arrangement.	Add to RAG list as a RED drug, with link to HST21.		There are uncertainties around the ongoing treatment effect with setmelanotide, and the quality-of-life decrement value associated with severe hyperphagia. Despite the uncertainties, setmelanotide is likely to provide important clinical and psychological benefits for people with the condition and their carers, and value for money within the context of a highly specialised service.	N/A	Add to formulary
Oral atypical antipsychotics shared care protocol	Revisions made to this outdated SCP include: •Additional of lurasidone and paliperidone •The addition of an indication of psychotic symptoms in Parkinson's disease (NICE approved indication and recently consulted on as a RAG change) •Updates to reflect current guidance on contraindications and cautions, pregnancy and breastfeeding •Recommendations on actions for primary care following any adverse findings as part of routine monitoring.	Amber All agents as detailed in SCP to be added to the formulary	A rapid review and update to this shared care protocol has been undertaken by GM mental health and medicines optimisation teams, as it became apparent that patients are unable to have their care transferred from their specialist to their GP for two oral antipsychotics because the current oral atypical antipsychotic SCP is out of date and does not include the medicines lurasidone and paliperidone. GMMMG pre-approved this SCP for publication pending approval of its clinical content by CRG.	Up to 20 new patients per year for lurasidone and 10 paliperidone patients is estimated to cost: Total extra cost £24,740 per year Paliperidone 6mg OD = £1264 per year Lurasidone 18.5mg – 74mg OD = £605 per year	Shared care is not consistently commissioned across GM. There is ongoing work in GM to manage shared care, this SCP like all GMMMG SCPs will be considered as part of the commissioning review.	Approve for publication pending approval by the GMMMG Clinical reference Subgroup

DECISIONS NOT EXPECTED TO HAVE A FINANCIAL IMPACT

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Apomorphine Injection shared care protocol For Parkinson's disease under the supervision of a specialist GMMMG SCP - Apomorphine 2022_	This updated shared care protocol, now includes the new product Dacepton® and has been transferred into the new template.	Amber Shared Care	This was initially approved at September CRG but was delayed pending the addition of a new product Apo-Go POD. This is yet to be launched and no price is currently available, so has not been included in this update.	Already considered at May GMMMG as part of the April CRG decisions. Overall cost saving is expected due to similar product costs but longer Dacepton shelf-life	None expected	Publish SCP on GMMMG website and communicate to commissioners N.B CEGC approved this by email on 18/11/2022
Famotidine 20mg & 40mg tablets For the treatment and maintenance of duodenal ulceration and reflux oesophagitis where a PPI is not appropriate or tolerated	Adults only Paediatric use will be considered separately	Add to formulary as Green drug as first line H2-receptor antagonist to replace ranitidine for adults		Expected to be cost- neutral This agent is currently the H2 receptor antagonist of choice in GM. GM currently spends £1.9m per year on famotine	None expected	Add to formulary
Asthma Inhaler Guide	This pictorial guide supports the implementation of the GMMMG asthma management plan and promotes the use of cost-effective and lower carbon inhaler device options	N/A	Some minor revisions to the links to inhaler technique videos may be required as currently links to Asthma UK demonstrations.	None	None	Approved by GMMMG CRG and uploaded to GMMMG website
Modafinil Patient information leaflet	This prescribing information guide aims to support primary care prescribers to manage the provision of modafinil within its licensed indications to patients in primary care. It supports the change of RAG status from RED (pending shared care) to Green (Specialist initiation) as approved by GMMMG in May 2022	Modafinil will be amended to Green (Specialist initiation)		None	None for the information leaflet The implications of the RAG change have already been considered by GMMMG	Approved by GMMMG CRG and uploaded to GMMMG website

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Metolazone (Xaqua®)	A new licensed formulation of metolazone has been marketed and effectively replaces the unlicensed version which should only be available on a named patient basis. It has up to twice the bioavailability of the unlicensed product.	To remain Green (Specialist initiation)	CRG considered the management of patients prescribed metolazone and agreed that review and substitution should be on an individual patient basis with specialist input, plus: • Prescribing and dispensing must be done by brand name • Primary care should seek to identify patients and invite for review	Potential saving of £9000 per year in GM on medicines spend if prescribing patterns remain the same. Any switch to alternative agents would create further savings	Impact on primary care for the necessary reviews. Up to 90 patients have been identified in GM so impact per practice should be small. There is likely to be a transient increase in demand for specialist advice on the management of patients currently prescribed metolazone	For information GMMMG RAG list amended following GMMMG CRG recommendation.
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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