Recommendations from the September 2022 GMMMG meeting – for ICB 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 by GMMMG**
TA791: Romosozumab for treating severe osteoporosis Romosozumab is recommended as an option for treating severe osteoporosis in people after menopause who are at high risk of fracture, only if: • they have had a major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture) and • the company provides romosozumab according to the commercial arrangement.	**Red**	Add to formulary in chapter 6.6.2 **as equal first line treatment alongside teriparatide** with link to TA791 and The National Osteoporosis Guideline Group (NOGG) guidance	Current formulary options are alendronate (first choice), risedronate, and ibandronic acid tablets (all GREEN), sodum clodronate (specialist initiation), and ibandronic acid IV and zoledronic acid IV (both Red). Denosumab for osteoporosis in men and women is on formulary as AMBER; SCP includes monitoring of plasma calcium, 6 monthly renal function, and vitamin D testing if hypocalcaemia or low vitamin D suspected Some monitoring for hypocalcaemia is recommended: • all patients: signs & symptoms of hypocalcaemia • patients with severe renal impairment (eGFR 15-29 mL/ min/1.73m^2) or	NICE expects persistence on alendronic acid after romosozumab to be higher than alendronic acid alone. NICE expects providers to be hospital trusts and primary care providers. Based on the NICE resource impact template and the list price for romosozumab, the estimated cost impact for Greater Manchester is £700,000 in year 1, rising to £1.7 million in year 5. These figures do not include potential savings from fractures avoided or the confidential PAS price (simple discount). CRG heard this is likely to be an underestimate of potential patient numbers. Further information awaited.	Implications for rheumatology services and capacity to initiate.	**Approve formulary addition pending the pathway from GM rheumatology network**

			receiving dialysis: monitor calcium levels In line with the recent publication of updated NOGG guidance offer teriparatide or romosozumab as first line anabolic drug treatment options to postmenopausal women at high risk of fracture. **The GM rheumatology network have agreed to produce a pathway to support the implementation of this TA and NOGG guidance**			

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**
Green Inhalers Implementation Tools  Greener%20inhaler%20poster%20-%20Pat  Greener%20inhaler%20poster%20-%20Sta  PCN%20plan%20on%20a%20page%20FII	**N/A**	N/A	CRG approved these materials for immediate use as agreed by GMMMG at their July meeting. They have now been published to GMMMG website and shared with GMMMG stakeholders	None	None	**Approved**
Melatonin shared care protocol for children and adolescents (updated)	**Amber**	All products on formulary	After a number of revisions to include Adaflex as first choice melatonin products and the addition of information for primary care on stopping melatonin and drug	Cost-neutral or cost-saving through the use of lower cost Adaflex	None additional to those already noted	**Approved**

GMMMG SCP Melatonin for childrer			holidays, CRG approved the updated document for use. CRG did note that the situation whereby when children transition out of CAMHS services they are often discharged to the care of their GPand this can be is less than ideal. These medicines should be reviewed at this point and guidance provided by the discharging specialist rather than rely on the documentation provided by the SCP and continue under the care of a non-specialist .	products rather than Slenyto or Circadin.		
Epiduo gel (adapalene / benzoyl peroxide) for the treatment of acne	**Green**	For information Already in section 13.6	The GMMMG guidelines for management of acne in primary care include topical adapalene / benzoyl peroxide for management of mild inflammatory/papulopustular acne, or moderate acne with papules or pustules. There is one marketed product, Epiduo® gel. Chapter 13 of the GMMMG formulary currently includes Epiduo 0.1% / 2.5%, however a higher strength product is also available (0.3% / 0.25%). CRG agreed to remove the strength from the formulary entry	None expected. Both strengths of Epiduo cost £19.53 for 1 x 45g pump.	None expected	**Approved**
Topical vitamin D with steroid preparations for psoriasis	**Green**	For information Already in section 13.5	The GMMMG guidelines for the management of chronic plaque psoriasis in primary care include recommendations on topical vitamin D + steroid preparations for people with psoriasis, but do not specify a product. Chapter 13 of the GMMMG formulary includes Dovobet 50 microgram/g + 0.5 mg/g gel as the first choice. CRG agreed to remove the brand name and formulation from formulary entry for topical calcipotriol/ betamethasone, and add a	Expected to be cost saving. Dovobet gel is the most expensive of the currently available options. Cost per year: • Dovobet gel: £521 • Dovobet ointment: £278 • Enstilar foam: £278 • Wynzora cream: £250 • Calcipotriol /	None expected	**Approved**

			statement that prescribers should choose the most cost-effective option.	betamethasone ointment: £98 NB: licensed indications and treatment durations vary.		
Minoxidil foam	**DNP (Criterion 3)**	Not on formulary	GMMMG formulary currently states: "Androgenetic alopecia: Not prescribable on the NHS" An enquiry has highlighted that this is unclear, since minoxidil foam is included in part VIIIA of the Drug Tariff as a prescribable product. In contrast, minoxidil cream, lotion, ointment, and the brand name "Regaine" are included in Drug Tariff part XVIIIA (the "black list"). CRG agreed to amend the formulary to add minoxidil foam to the DNP list, and clarify that the following are included in part XVIIIA of the Drug Tariff and are not prescribable: • Minoxidil cream • Minoxidil lotion • Minoxidil ointment • Minoxidil solution (for external use)	Expected to be cost neutral. In the 12 months to March 2022, 181 primary care prescriptions were issued in Greater Manchester at a cost of £7,206.	None expected	**Approved**
Lixisenatide 10mcg & 20mcg injection	**Non-formulary**	Remove from section 6.1	In April 2022 Sanofi notified the MHRA of the discontinuation of lixisenatide 10mcg and lixisenatide treatment initiation pack (10mcg & 20mcg injection) effective from June 2022. This means no new patients can be initiated on lixisenatide. CRG recognised the impact on patients is limited but thought it likely that the 20mcg strength will subsequently be discontinued and requested both strengths are removed from formulary.	The alternative daily GLP-1 is liraglutide which is more costly than lixisenatide. Prescribing of lixisenatide represents about 3% of the patients currently receiving a daily injectable GLP-1 in GM. Therefore the impact is expected to be less than £30k per year.	New patients will require initiation with alternative agent. Switching to liraglutide is not currently recommended or required.	**Approved**

			No action to switch patients to an alternative GLP-1 receptor mimetic is currently recommended.			

DECISIONS FOR INFORMATION ONLY						
Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	**FINAL DECISION**
TA788: Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy Avelumab is recommended as an option for maintenance treatment of locally advanced or metastatic urothelial cancer that has not progressed after platinum-based chemotherapy in adults, only if: • avelumab is stopped at 5 years of uninterrupted treatment or earlier if the disease progresses and the company provides avelumab according to the commercial arrangement	**N/A**	For info, no action	Commissioning: NHSE	NICE estimate that: Around 1,040 people in England are eligible for treatment with avelumab each year 830 people will receive avelumab from year 2024/25 onwards once uptake has reached 80% There are potentially significant savings from reduced use of subsequent immunotherapy Around 19,800 additional appointments (35 per 100,000 population) are needed from year 2024/25 to administer the treatment which is delivered by IV infusion. These are partly offset by a reduction in the use of second-line immunotherapy treatments such as atezolizumab. A local resource impact template is available.	N/A	N/A
TA789: Tepotinib for treating advanced non-small-cell lung cancer with MET gene alterations Tepotinib is recommended, within its marketing authorisation, as an option for treating advanced non-small-cell lung cancer (NSCLC) with METex14 skipping alterations in adults, only if the company provides tepotinib according to the commercial arrangement.	**N/A**	For info, no action	**Commissioning: NHSE**	No significant resource impact is anticipated. 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 tepotinib is a further treatment option and the overall incremental cost of	N/A	N/A

				treatment is low. There are also resource benefits from the favourable side effect profile and reduced treatment administration burden offered by tepotinib, which is an oral therapy.		
HST20: Selumetinib for treating symptomatic and inoperable plexiform neurofibromas associated with type 1 neurofibromatosis in children aged 3 and over Selumetinib is recommended, within its marketing authorisation, for treating symptomatic and inoperable plexiform neurofibromas (PN) associated with type 1 neurofibromatosis (NF1) in children aged 3 and over, only if the company provides selumetinib according to the commercial arrangement.	RED	Add to RAG list as a red drug in this indication, with link to HST20.	**Commissioning: NHSE**	There is uncertainty in the economic modelling, but NICE considered selumetinib to be an effective treatment option for people with inoperable PN, and likely to provide value for money in the context of a highly specialised service.	N/A	N/A
NG191 COVID-19 rapid guideline: managing COVID-19 (updated) New recommendation: Offer baricitinib to adults in hospital with COVID-19 who: • need supplemental oxygen for COVID-19, and • are having or have completed a course of corticosteroids such as dexamethasone, unless they cannot have corticosteroids, and • have no evidence of infection (other than SARS-CoV-2) that might be worsened by	N/A	On formulary in chapters 10.1.3 & 13.5.3, in line with NICE TAs for rheumatoid arthritis and atopic dermatitis Add link to NG191 to formulary in chapters 10.1.3 & 13.5.3.	**Commissioning: NHSE**	None expected	None expected	Approved

baricitinib In addition: • two recommendations about advice to give to people with COVID-19 were replaced with a link to UKHSA guidance, which now provides this information. • A recommendation for people with pre-existing advanced comorbidities was deleted. A link to the UK Government's information on the COVID-19 vaccination programme was added.						
MTG70: Sleepio to treat insomnia and insomnia symptoms Sleepio is recommended as a cost saving option for treating insomnia and insomnia symptoms in primary care for people who would otherwise be offered sleep hygiene or sleeping pills. For people who may be at higher risk of other sleep disorder conditions, such as in pregnancy, or in people with comorbidities, a medical assessment should be done before referral to Sleepio.	**N/A**	N/A	**Commissioning: ICB** **Not added to formulary**. CRG accepted Sleepio has a role in supporting the use of non-pharmacological treatments but is outside the scope of the current formulary. Further discussion at GMMMG noted the uncertainties in funding and access mechanisms as well as ensuring equitable	Sleepio is a digital self-help programme that includes CBT for insomnia (CBT I). Clinical evidence shows that Sleepio reduces insomnia symptoms compared with sleep hygiene and sleeping pills. There is no direct evidence of its effectiveness compared with face-to-face CBT I. Based on a licence fee per year of £45 per user, the health economic assessment shows Sleepio as a cost saving option compared with sleep hygiene and sleeping pills. However, there are uncertainties in the cost modelling because of the limited data available. The economic evidence shows cash-releasing savings result from the reduced use of sleeping	None expected	Further information requested by GMMMG regarding the funding route for this intervention

				pills and other medications such as benzodiazepines and amitriptyline that can be inappropriately used to treat insomnia or insomnia symptoms. Capacity-releasing savings result from a reduced number of follow up equivalent appointment slots with GPs and other primary care healthcare professionals.		
Primary Care Prescribers information leaflet for inclisiran	**N/A**	Yes	This leaflet has been jointly produced by GMMMG and Health Innovation Manchester to support implementation of the NICE TA773 for inclisiran. GMMMG have requested some further amendments to the leaflet, but these will not fundamentally change the content. GMMMG will agree these virtually during September and then publish.	Inclisiran is already listed on the GM formulary as a green agent in line with NICE TA733. There is no financial impact associated with this leaflet which is an aid to support prescribers on a previously ratified decision.	Nil	Approved virtually following amendments as discussed
All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.						