RECOMMENDATIONS FROM GMMMG to CEGC FOR APPROVAL - December 2022

Product and indication	Status Assigned Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	Recommendation for GMMMG
TA814: Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis **Commissioning: ICS (adults) and NHSE (young people), tariff-excluded** Abrocitinib and upadacitinib are recommended as options for treating moderate to severe atopic dermatitis that is suitable for systemic treatment in adults and young people 12 years and over, only if: • the disease has not responded to at least 1 systemic immunosuppressant, or these are not suitable • the companies provide abrocitinib and upadacitinib according to the commercial arrangement. Tralokinumab is recommended as an option for treating moderate to severe atopic dermatitis that is suitable for systemic treatment in adults, only if: • the disease has not responded to at least 1 systemic immunosuppressant, or these are not suitable • the company provides tralokinumab according to the commercial arrangement. Stop abrocitinib, upadacitinib or tralokinumab at 16 weeks if the atopic dermatitis has not responded adequately. Criteria for these drugs are similar to those for dupilumab (TA534, August 2018) and baricitinib (TA681, March 2021)	Add abrocitinib, tralokinumab and upadacitinib to formulary in chapter 13.5.3 (cytokine modulators) as RED drugs, with links to TA814.	There are now a number of NICE approved medicines for this condition. Abrocitinib, tralokinumab and upadacitinib are JAK inhibitors, and are an oral treatment option Specialist services have advised the GMMMG position on sequential use of biologics negates the need for a pathway. Assurance regarding the clinical and cost-effective use of medicines, and high cost drugs in particular, against NICE criteria is something the ICS could consider.	The JAK inhibitors included in the TA are lower cost than the injectable alternatives already in the pathway. Therefore over time the introduction of the medicines will reduce the cost of the atopic dermatitis pathway. Year 1 costs are estimated to be £250k, however as uptake rates of the JAK inhibitors increase the ICS can expect reductions in costs of up to £1.1m by year 5. A costing template is available for determining local impact if required	The new medicines are likely to be provided by homecare services.	**Approve addition to formulary**
GM HRT guidance for menopause management This clinical guideline seeks to provide clear prescribing guidance to primary care on the	All products to be included in GMMMG formulary	The significant formulary additions are Lenzetto spray and Bijuve capsules.	GMMMG spent over £2,000,000 on HRT from October 2020 – September 2021.	There is limited capacity for specialist services to make recommendation on use of testosterone.	**Approve guideline and formulary amendments**

management of menopause using hormone treatment. The guidance introduces a number of new products to the formulary to improve choice and rationalises the RAG status of testosterone for low sexual desire in women to Green (specialist advice). GM HRT Guidance for Menopause Mar		Discontinued and out of date products have been removed. First line treatment designation within the guidance and GM formulary to make all options available. This is to align with NICE and BMS on promoting individual approach to every patient and help manage stock shortages.	New products will replace existing and are therefore should not incur any additional prescribing costs. Switching from generic estriol cream to Ovestin® could save GM over £390k pa. Switching from Vagifem® to Vagirux® would save GM over £40,000 pa. Due to improved awareness of HRT and the menopause there is likely to be an overall increase in prescribing for this indication, however this cannot currently be estimated.	This is a national issue that is being addressed by the British Menopause Society which is aiming to deliver training for primary care from 2023 to help mitigate this.	
TA815: Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs **Commissioning: ICS, tariff-excluded** Guselkumab, 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 had 2 conventional DMARDs and: • have had at least 1 biological DMARD, or • tumour necrosis factor (TNF)-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis). Guselkumab is recommended only if the company provides it according to the commercial arrangement. Active psoriatic arthritis is defined as peripheral arthritis with 3 or more tender joints and 3 or more swollen joints. This guidance updates and replaces NICE TA711 on guselkumab for active psoriatic arthritis after inadequate response to DMARDs.	On formulary in chapter 10.1.3 RED drug	Remove links to TA711 and replace with links to TA815.	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 technology is a further treatment option and is available at a similar price to the current treatment options.	None significant expected	**Approve addition to formulary**
TA820: Brolucizumab for treating diabetic macular oedema **Commissioning: ICS, tariff-excluded** Brolucizumab is recommended as an option for treating visual impairment due to diabetic macular oedema in adults, only if: • the eye has a central retinal thickness of 400 micrometres or more at the start of treatment	On formulary in chapter 11.8.2.3 RED drug	Add brolucizumab to formulary as a RED drug. Add link to TA820.	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 technology is a further treatment option, and the overall cost of treatment will be similar.	None significant expected	**Approve addition to formulary**

the company provides brolucizumab according to the commercial arrangement.					
Quetiapine (oral) for psychotic symptoms in Parkinson's disease without cognitive impairment NICE NG71 recommends: 1.5.16: Consider quetiapine to treat hallucinations and delusions in people with Parkinson's disease who have no cognitive impairment. [2017]	Already in formulary as RED for this indication This will be an amber indication	There is no additional monitoring required above that required for quetiapine when used to treat mental health indications as detailed in the existing shared care protocol. An update to the SCP will include this indication.	Less than £2000 per year. Note this treatment is currently funded by secondary care. 50-60 patients per year are expected to receive the treatment.	A small impact on primary care services is expected due to transfer of monitoring from secondary to primary care,	**Approve amendment to formulary**
GM Hypersalivation Pathway Developed by MFT and adapted for GM use this guideline is intended to offer information on the management of hypersalivation and/or sialorrhoea in adults with neuromuscular disorders. Common conditions contributing to hypersalivation/sialorrhoea are Parkinson's disease, motor neurone disease, use of long-term ventilation, and brain injury.  MFT Hypersalivation patł	Green (specialist initiation) for this indication Glycopyrronium is currently listed on GMMMG RAG list. Add other medicines to formulary	CRG requested some minor amendments to take into account cost of products and first line choices, noting that atropine 1% pf Minims may be a cheaper option than a 10mL bottle.	Expected patient numbers are around 240 across GM. These are already being treated under the current pathway but more can now be done so in primary care. Impact is expected to be cost-neutral	None expected	**Approved**
Insuman® Comb 50 discontinued Insuman® Comb 50 cartridges (biphasic isophane insulin, 100 units/mL) were discontinued on 1st August 2022. This is currently one of the first-choice options for biphasic insulin on the GMMMG formulary, as follows: First choice: soluble/isophane mixtures • Humulin M3 • Insuman Comb 25 • Insuman Comb 50 Alternatives: intermediate acting analogue mixtures • Novomix 30 • Humalog Mix25 • Humalog Mix50 No change in availability of any other product is expected; manufacturers report they can support a full uplift in supply.	Sanofi reported on 8th August that they expected stock to be exhausted imminently. Remove Insuman Comb 50 from formulary.	Low impact. In the 12 months to June 2022, 45 items of Insuman Comb 50 were dispensed in Greater Manchester. Any patients stabilised on Insuman Comb 50 will require review and switch to a suitable alternative.	Neutral	None expected	**Approved**

MTG71: Faecal microbiota transplant for recurrent Clostridioides difficile infection **Commissioning: ICS** Faecal microbiota transplant (FMT) is recommended as an option to treat recurrent *Clostridioides difficile* infection in adults who have had 2 or more previous confirmed episodes. FMT treatment is cheaper than almost all treatment options with antibiotics. It is not cost saving compared with vancomycin taper pulse if it is administered via enema. However, FMT via enema would only be an option for the minority of people who cannot have FMT by another route.	Not on formulary; outside scope. In scope of GMMMG Antimicrobial Guidelines.	Flag guidance and any comments received to the GM Antimicrobial Group.	NICE estimates that around 20 people per year in Greater Manchester develop 2 or more recurrent *C. difficile* infections and are eligible for treatment. The cost impact depends on uptake, and route of FMT treatment. A local resource impact template is available to facilitate estimates. There is uncertainty in the uptake of FMT as well as the unit cost of the FMT material, therefore, any potential savings should be assessed at a local level. A local resource impact template is provided to help estimate the potential resource impact at a local level.	TBC by antimicrobial group	**N/A**
NG209: Tobacco: preventing uptake, promoting quitting and treating dependence (updated) **Commissioning: local authorities, ICS** In August 2022, NICE reviewed the evidence on Allen Carr's Easyway to stop smoking in-person seminar for people who smoke and updated recommendations on treating tobacco dependence in the section on stop-smoking interventions. In August 2022, varenicline was unavailable in the UK.	Link to guidance on formulary in chapter 4.10.2.	In scope of GMMMG tobacco dependency treatment guideline. The guideline recommends that patients should be offered brief advice on stopping smoking (step 1) and offered referral to a specialist stop smoking service (step 2).	Allen Carr's Easyway in-person group seminar has been recommended as an additional treatment option to the current treatment options. Making the intervention available through the NHS and local authorities alongside other interventions would broaden people's choice. It could also potentially increase the number of people attempting to quit by offering an alternative that does not include pharmacotherapy. Due to a lack of robust data on current practice and variation across organisations and services, the resource impact is also expected to vary locally depending on current and future commissioning arrangements.	TBC	**N/A**
Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists • use of nebuliser devices at home to deliver asthma rescue medication to children and adolescents, without adequate medical supervision, can mask a deterioration in the underlying disease, which could result in delays in seeking medical attention and have fatal or serious consequences • only specialists in asthma should initiate and clinically manage use of nebulisers and associated nebulised medicines at home for acute treatment of asthma in children and adolescents (see definition of specialists below) • independent purchase of nebuliser devices outside of medical advice for use at home to deliver rescue therapy for the acute	in chapter 3.1.1	GMMMG formulary and asthma guidance apply to adults only. Add link to MHRA advice to formulary in chapter 3.1.1, for information.	None expected.	None expected	**N/A**

treatment of asthma in children and adolescents is not recommended pharmacists are asked to advise people seeking to purchase a nebuliser for this purpose that such home use of nebulisers is not recommended without specialist clinical management continue to report suspected adverse reactions to nebulised medications and adverse incidents involving nebulisers on a Yellow Card					

Other items for consideration by CEGC

Item	Detail	Documents	Decision required
GMMMG and subgroups revised terms of reference	At its December meeting GMMMG accepted terms of reference from its subgroups; medicines safety subgroup, digital subgroup, population health management and health inequalities workstream subgroup , clinical reference subgroup. The pharmacy workforce transformation group recently met to consider their governance route, they are not currently reporting to GMMMG. Terms of reference are expected from the medicines value group in due course. GMMMG as the GM medicines optimisation committee has updated its terms of reference to reflect current governance arrangements, and the subgroups it governs. Clinical Effectiveness and Governance Committee is asked to approve these terms of reference, they will be updated as required as the system develops. Upon approval these terms of reference will replace those currently held on the GMMMG website.	GMMMG MOC TOR Dec 22.docx Medicines Safety TOR Dec 22.docx Digital TOR Dec 22.docx PHM and HI subgroup TOR Draft 3 Clinical Reference Subgroup Dec 22.doc	Approval
GMMMG minutes	GMMMG minutes November 2022 meeting are attached for ratification by CEGC. They will then be published on the GMMMG website	Minutes Nov 2022 GMMMG FNL.docx	Ratification
GMMMG Clinical reference subgroup	GMMMG CRG minutes October 2022 meeting are attached for ratification by CEGC. They will then be published on the GMMMG website	CRG Minutes October 2022_FINAL.p	Ratification