SUMMARY OF SUBGROUP DECISIONS FOR GMMMG APPROVAL – 14th October 2021

SUBGROUP DECISIONS WITH SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

CRG DECISIONS June 2021

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	**GMMMG decision**
Cannabis extract (Sativex®) oromucosal spray for spasticity in adults with multiple sclerosis	RED	Y	The group agreed to add Sativex spray to formulary for treating moderate to severe spasticity in adults with multiple sclerosis in line with recommendations in NG144. A RED RAG status has been agreed at this time whilst operational implications are addressed.	The NICE resource impact predicts **a cost impact for GM of £232k per year in 2020/21 rising to £386k per year by 2023/24** but overall costs are likely to be lower initially whilst operational implications are addressed. A pay-for-responders scheme is in place.	Providers have confirmed that the specialist clinic services required to assess, prescribe for and monitor the eligible patients is not yet in place. Conversations are ongoing with commissioners.	**RAG Approved** **GMMMG noted that the service implications are currently under discussion.**
TA697: Andexanet alfa for reversing anticoagulation from apixaban or rivaroxaban	RED	Y	Andexanet alfa is recommended as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life-threatening or uncontrolled bleeding, only if: the bleed is in the gastrointestinal tract, and the company provides andexanet alfa according to the commercial arrangement. CCG commissioned PbRe.	**Significant cost impact expected**. Based on the NICE resource impact template, using the list price, cost impact in GM will be **£530k in year 1, increasing to £1.3m in year 5.** A confidential commercial access agreement is in place; this price is unknown.	None significant expected	**RAG approved**

SUBGROUP DECISIONS WITHOUT SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

MGSG Decisions Aug 2021

Product and indication	Notes on Decision	Cost impact	Commissioning/ Service implications	FINAL DECISION
GMMMG Shared Care protocol Updates: Mycophenolate for ILD & Oral methotrexate for pulmonary sarcoid  GMMMG-SCP-for-Mycophenolate-for-In  GMMMG-SCP-Methotrexate-oral-for-sar	MGSG were asked to approve these technical updates to existing GMMMG SCPs to align with current BSR/BHPR recommendations on routine monitoring for the drugs. MGSG agreed these were clinically relevant but noted the current commissioning issues with renewing SCPs	Nil	Nil	**Approved**
GMMMG Shared care information leaflet  GMMMG-Shared-care-information-for-p	This is designed as a patient information leaflet to provide patients with further details on the process of shared care. Credit was given to MFT rheumatology who developed the early drafts of the leaflet and thanks to MHCC communications team for providing guidance on use of plain language. MGSG wished the document to reflect current practice and requested some minor amendments to include details of the process where a “model B” shared care approach is used.	Nil	Nil	**Approved**
FreeStyle Libre and Libre 2 Primary care rebate scheme	The PCRS proposal was presented to MGSG as not being appropriate following assessment against the GMMMG ethical framework for rebate schemes due to not meeting the requirements for a simple scheme.	N/A – Potential savings unknown due to tiered nature of scheme	Nil	**Not appropriate**

CRG DECISIONS June 2021

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	FINAL DECISION
Ulipristal acetate (Esmya®) for uterine fibroids	RED	Y	Following a safety review of serious liver injury with Esmya, the product license which was suspended in March 2020 has been reinstated with restricted use as a result of cases of serious liver injury. Esmya can now only be used for intermittent treatment of moderate to severe uterine fibroids symptoms before menopause and	No significant cost impact anticipated. The restriction in the product license may result in some cost saving as a result of reduction in use.	There may be some impact on workload of specialist teams who will retain prescribing and monitoring responsibilities.	**RED RAG status approved by MGSG**

			when surgical procedures (including uterine fibroid embolisation) are not suitable or have failed. It must no longer be used for controlling symptoms of uterine fibroids while awaiting surgical treatment. The group felt that given the restricted use, the risk of serious liver injury and liver failure and the close monitoring required for this drug that it was safer that prescribing and monitoring of clinical and safety outcomes should remain the responsibility of the specialist team.			
Demeclocycline for hyponatraemia associated with syndrome of inappropriate antidiuretic home secretion.	RED	Y	CRG agreed a RED RAG status for demeclocycline for hyponatraemia associated with SIADH pending further information and guidance from specialists regarding place in therapy to inform a full RAG review.	Costly product; monthly cost of maintenance dose (600-900mg daily) of licensed product = £953 to £1,430. Total spend for demeclocycline in GM between Apr 20 and Mar 21 was around £178k.	There may be some impact on work load of specialist teams who will retain prescribing pending full RAG assessment.	**RED RAG status approved by MGSG** **GMMMG requested this is for new patients only**
TA694: Bempedoic acid with ezetimibe for treating primary hypercholesterola -emia or mixed dyslipidaemia **Bempedoic acid (Nilemdo®)** **Bempedoic acid-ezetimibe (Nustendi®)**	**GREEN following lipid specialist initiation as per NICE TA694.**	Y	Bempedoic acid with ezetimibe is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if: statins are contraindicated or not tolerated, ezetimibe alone does not control low-density lipoprotein cholesterol well enough, and the company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement. The group felt that appropriate patient selection for this treatment and initiation best sits with lipid specialists.	No significant impact on resources is expected (less than £9,000 per 100,000 population). Annual cost of bempedoic acid or bempedoic acid with ezetimibe using list price = £720. A Commercial discount is in place. This price is not known. NHSE have confirmed that there is a central rebate scheme which applies equally across primary and secondary care.	None expected.	**Green following specialist initiation RAG status approved by MGSG**
TA698: Ravulizumab for treating paroxysmal nocturnal haemoglobinuria	**RED**	N/A	NHSE commissioned PbRe.	NHSE		**RED RAG status approved by MGSG**
TA699: Ofatumumab for treating relapsing multiple sclerosis	**RED**	Y	NHSE commissioned PbRe.	NHSE		**RED RAG status approved by MGSG**

All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.