SUMMARY OF DECISIONS FOR APPROVAL

Recommendations made by CRG or value subgroup	**Feb 2024**
Approved by: GMMMG	**14th March 2024**
Approved by: CEGC	**25th March 2024 (non-financial recommendations approved)**
Approved by: Executive	**10th April 2024**

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 90 days (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.

DECISIONS WITH A FINANCIAL OR COMMISSIONING IMPACT

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation and action
Cytisine 1.5mg tablets for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking.	A formulary application has been submitted to add the medicine to the GMMMG formulary for smoking cessation as a first line option alongside existing therapies. Varenicline has been unavailable after its withdrawal from the market due to concerns regarding nitrosamine impurities and this represents a licensed alternative for suitable groups of patients.	Green first line option	CRG heard that this product has been shown to be as effective as varenicline for supporting a quit attempt and is likely to be cost-effective based on price comparison vs existing therapies. Cytisine is contraindicated in pregnancy (Women of childbearing potential must use highly effective contraception while taking cytisine) and breastfeeding, unstable angina, recent history of MI or stroke and clinically significant arrhythmias which may limit its usefulness. It is understood that PGDs are in development for use by smoking cessation services	Cytisine is priced at £115 per 25 day course (100 tablets). Initial estimates are up to 1000 patients per year in GM, which would cost £115,000. However cytisine is likely to be cost-neutral because it is similarly priced to other therapies currently available; varenicline (unlicensed) £95, bupropion £125, NRT (patch only) £113.96. This estimate does not include potential benefits from reduced cardiovascular and respiratory diseases and cancers that are associated with smoking. A CURE Cost Benefit Analysis indicates that the return on investment from this intervention is £2.12 for every pound invested, with wider impacts on social care, businesses, poverty, and child poverty. The CBA also showed a current cost per Quality Adjusted Life Years (QALY) of £487	Approve the addition to formulary It is understood the regional tobacco control team (ICB population health team) have approved this agent. However because many localities in GM still recharge PH for prescribing of smoking cessation (and other treatments) GMMMG raise this issue to CEGC for consideration.
TA929: Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction **Commissioning: ICS** 01/11/2023	Empagliflozin is recommended, within its marketing authorisation, as an option for treating symptomatic chronic heart failure with preserved or mildly reduced ejection fraction in adults. On formulary as GREEN (following specialist advice) for treatment of chronic heart failure with reduced ejection fraction, as per NICE TA773. Dapagliflozin is on formulary as GREEN (following specialist advice) in this indication, as per NICE TA902.	Add to formulary as a GREEN (following specialist advice) drug in this indication, with link to TA929.		NICE expect the resource impact of implementing the recommendations in England will be less than £8,800 per 100,000 population. This is because the technology is a further treatment option, is available at the same price as dapagliflozin and clinical outcomes are expected to be similar. The list price of 10 mg empagliflozin is £36.59 per 28-tablet pack. The annual cost for either empagliflozin or dapagliflozin plus standard care is around £495, compared to £11 for standard care alone. This statement is supported by a resource impact template.	Approve the addition to formulary for this indication

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Riluzole Shared Care Protocol for amyotrophic lateral sclerosis (ALS)  5.1b Riluzole RDTC SCP adopted for GM ι	As one of the 18 NHSE-published SCPs this has been reviewed and updated by RDTC and developed for local implementation by GM ICB MO team	Amber shared care	This SCP has the addition of riluzole orodispersible tablets which is currently undergoing the GM ICB governance process for addition to the formulary. Due to supply problems with the 50mg standard tablets, the price of these has risen from £8.63 to £342.12 (Feb DT) for 56 and are frequently unavailable. The orodispersible are priced at £168 for 56 tablets (DM&D) In order to ease transfer of prescribing to primary care and enable access to the medicine, it is requested that the SCP is published with the orodispersible formulation despite this not yet being added to the formulary. The governance process will run as normal and any necessary changes to the SCP can be made at a later date	None for the shared care protocol For addition of orodispersible tablets: 50mg standard tablets currently cost £42.12 for 56 and 50mg orodispersible £168 for 56 tablets If prescribing of riluzole continues at current rates and product choice there will be a cost pressure to the GM ICB of around £300k per year. This can be mitigated to around £165k cost pressure with use of orodispersible tablets	Approve SCP and the inclusion of orodispersible tablets
Slenyto Rebate	Flynn Pharmaceuticals Ltd have suggested a rebate on their product Slenyto MR Tablets which would provide an annual rebate of £41,202.75 based on the last 12 months prescribing of branded Slenyto between Dec 2023 to November 2023.	AMBER status on paediatric RAG list and in SCP for paediatric Sleep disorders, ADHD.	The rebate was assessed against the existing rebate framework and found to meet all requirements. Therefore it was approved by medicines value subgroup for acceptance.	NHS GM spends over £150k annually on Slenyto 1mg and 5mg modified-release tablets. Annual rebate worth around £40k	Approve acceptance of this rebate for NHS GM.

DECISIONS WITHOUT A FINANCIAL OR COMMISSIONING IMPACT

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Recommendation
ADHD medicines shortage ICB comms  4.4b Addendum to GM pathway for prim	An update to the GM ICB response to shortage of ADHD medicines documentation and guidance was approved by CRG	Amber shared care	This request has been actioned as a technical update and the updated documentation published to GMMMG website. CRG recognised that it is not possible to stay up to date with this rapidly changing supply situation but the principles in the documents remain valid	None expected from this update	Note changes to published guidance documents
Gabapentinoid resource pack  Gabapentinoid-resou rce-pack-1-0.pdf	This documentation has expired and was removed from the GMMMG website Following requests to reinstate it has been checked and a further 2-year expiry granted	See individual products		None	Note the re-publication of this guidance
Guidance to support the implementation of NICE TA 924 (Tirzepatide)  Tirzepatide GM Guidance V1 FINAL.pc  GM GLP1 pathway v2.0 FINAL.pdf	This guidance has been updated to reflect recently published national guidance	Green	This guidance has been produced by clinicians on behalf of the GM Diabetes Board and reflect the GMMMG recommendation approved by CEGC on 5th March 2024. 1)Guidance produced by GM clinicians for the GM Diabetes board Guidance to support implementation Nice Technology Appraisal 924. It has been produced to provide primary care prescribers with information to support prescribing Tirzepatide for type 2 diabetes. 2)The updated version of previous guidance on GLP1 Receptor Agonists to account for changes in the supply situation. In particular, it reflects the fact that Rybelsus (oral Semaglutide tablets) are now more freely available.	As detailed to CEGC by GMMMG in March and reported as approved by executive on 13/3/2024.	Approve for publication

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
TA934: Foslevodopa–foscarbidopa for treating advanced Parkinson's with motor symptoms **Commissioning: NHSE** 29/11/2023	Foslevodopa–foscarbidopa is recommended as an option for treating advanced levodopa-responsive Parkinson's in adults whose symptoms include severe motor fluctuations and hyperkinesia or dyskinesia, when available medicines are not working well enough, only if: • they cannot have apomorphine or deep brain stimulation, or these treatments no longer control symptoms, and the company provides foslevodopa–foscarbidopa according to the commercial arrangement.	Add to formulary as a RED drug in this indication, with link to TA934.		No resource template or cost impact summary available. There is a simple discount patient access scheme for foslevodopa–foscarbidopa. The list price is not yet published. Foslevodopa-foscarbidopa is administered as a subcutaneous infusion. At the request of the company, foslevodopa–foscarbidopa was only considered by NICE as an alternative to standard care and levodopa–carbidopa intestinal gel. This does not include everyone who foslevodopa–foscarbidopa is licensed for.
CG164: Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer (updated) **Commissioning: ICS** 14/11/23	In November 2023, NICE removed the off-label warning for anastrozole in their recommendations on chemoprevention for women at moderate or high risk of breast cancer, in line with the MHRA licence variation. On formulary as GREEN (following specialist advice) for chemoprevention of breast cancer.	Add link to CG164 to formulary in chapter 8.3.4.1.		N/A
GMMMG minutes GMMMG Minutes Feb 24 fnl.pdf	-	-	-	-
GMMMG CRG minutes CRG Minutes Jan 2024_FINAL.pdf	-	-	-	-
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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