CRG SUMMARY OF DECISIONS FOR GMMMG APPROVAL – 12th May 2022

SUBGROUP DECISIONS WITH SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

CRG DECISIONS April 2022

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	FINAL DECISION
Modafinil 100mg and 200mg tablets for excessive sleepiness associated with narcolepsy with or without cataplexy and Parkinson's disease	**GREEN following Specialist Initiation**	In chapter 4	This is a proposed change from the current RAG status of modafinil on the formulary – RED pending shared care development (AMBER). The development of a shared care protocol (SCP) had been in progress for some time. However, SCP development is currently paused in GM while issues with commissioning of SCPs cross GM CCGs are being addressed. The following were taken into consideration to support the proposed change: There are limited ongoing monitoring requirements for modafinil. Blood pressure and heart rate monitoring is considered to be mainly indicated in hypertensive patients as per the BNF and these patients will already have blood pressure monitoring in place. These patients will remain under the overall supervision of the specialist service and will be followed on an annual basis. An information leaflet can be developed to support primary care prescribers.	None significant expected. A total of 2865 items were issued in GM in the 12 months to Nov 21, costing £33,289. It was estimated that around 230 patients are currently prescribed modafinil in primary care in GM. There may be some increase to this number if more patients are initiated on modafinil by the specialist service. However, modafinil is relatively inexpensive; annual cost for a dose of 200mg to 400mg daily is ~£63 to £126 respectively.	There may be some increase in requests to primary care as a result of the change.	**Approved**

			It was also considered that the change would help to increase access to this treatment for patients. Comments from the consultation were considered by the GPs present at the meeting who believed this medicine is not suitable for shared care.			

SUBGROUP DECISIONS WITHOUT SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

CRG DECISIONS April 2022

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	FINAL DECISION
Dacepton® (apomorphine): 10mg/mL [30mg/3mL] solution for injection and 5mg/mL [100mg/20mL] solution for infusion for motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease	**AMBER (to be added to current GMMMG apomorphine SCP)**	Yes	Dacepton® is another brand of apomorphine in addition to Apo-go® which is already on the GM formulary as an AMBER drug. However the devices for administration of Dacepton are different to that for Apo-go and are not interchangeable. Dacepton was noted to have a number of advantages including: • Longer in-use shelf-life of both the solution for injection and solution for infusion. This will help to minimise waste and offers the potential for cost savings. • A simple pump set up process with the pump reservoir filled via an automated process which is helpful for patients with dexterity issues. • Mg based flow rate for the pump rather than mL removing the need for calculation of flow rate and associated error.	Overall cost saving Volume for volume, the costs of Dacepton and Apo-go are quite similar: Pens/cartridges: Apo-go vs Dacepton 30mg/3mL solution for injection £123.91 vs £123 for 5 pens Solution for infusion: Apo-go 50mg/10mL vs Dacepton 100mg/20ml £73.11 vs £145 for 5 syringes/vials However, the longer in-use shelf-life for Dacepton will result in some cost savings, the magnitude of which is dependent on the dose.	None expected	**Approved. Awaiting updated shared care protocol.**

			• Availability of downloadable usage history data that can be used to inform the management of the patient. Both Dacepton and Apo-go are to be included in the formulary to allow continuation of Apo-go in stable patients but Dacepton will be the preferred option for new initiations. The existing GMMMG apomorphine SCP will undergo a technical update to reflect the Dacepton product.			
Bempedoic acid used as per NICE TA694	**GREEN following specialist advice**	In chapter 2	A request to amend the status from GREEN following specialist initiation to GREEN following specialist advice was approved recognising that while agreed there should be specialist input for appropriate patient selection, there are no reasons to warrant initiation by the specialist specifically.	None	None	**Approved**
TA753: Cenobamate for treating focal onset seizures in epilepsy	**GREEN following specialist initiation (by a tertiary epilepsy service)**	Yes with link to TA753.	**Commissioning: ICS/CCG, tariff included** Cenobamate is recommended as an option for treating focal onset seizures with or without secondary generalised seizures in adults with drug-resistant epilepsy that has not been adequately controlled with at least 2 antiseizure medicines. It is recommended only if it is used as an add-on treatment, after at least 1 other add-on treatment has not controlled seizures, and treatment is started in a tertiary epilepsy service.	No significant resource impact is anticipated 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 cenobamate is a further treatment option, the overall cost of treatment will be similar.	NICE do not think practice will change substantially as a result of this guidance. Short-term clinical evidence shows that cenobamate reduced the number of seizures and also increases how many people stop having any seizures. These benefits may result in capacity benefits from a reduction in administration and management costs.	**Approved**

TA758: Solriamfetol for treating excessive daytime sleepiness caused by narcolepsy	**RED**	Yes with link to TA758	**Commissioner: ICS/CCG, tariff-excluded** Solriamfetol is recommended as an option for treating excessive daytime sleepiness in adults with narcolepsy with or without cataplexy. This is only if modafinil and either dexamfetamine or methylphenidate have not worked well enough or are not suitable.	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.	TBC	**Approved**
TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update)	**RAG being reviewed, TBC**	Already on	**Commissioning: ICS/CCG** Guidance updated because sodium zirconium cyclosilicate is now available in both primary and secondary care; references to outpatient care removed.	A local resource impact template is available from NICE as costs may vary in different settings because of negotiated procurement discounts. Prices from BNF: 30 x 5g sachets - £213.60 30 x 10g sachets = £427.20	There may be an impact for services and patients if a portion of prescribing is transferred from secondary to primary care.	**Approved. Awaiting updated shared care protocol.**
GMMMG asthma and COPD formulary sections	**Green**	Yes in chapter 2	Following the update to **the GM asthma pathway**, the corresponding formulary section has been updated to reflect the changes. A draft of the updated formulary section was approved by CRG. The pathway now has final approval by the DoCs/CFOs and has been uploaded on the website with the updated formulary section	Cost impact difficult to estimate as communicated to Docs and CFOs. GMMMG to monitor prescribing costs and carbon impact.	None	**Approved**
Sotrovimab for COVID-19 as per NG191	**RED**	Yes	**Commissioning: NHSE** New recommendation: Offer a neutralising monoclonal antibody (sotrovimab, or combination casirivimab plus imdevimab) for people aged 12 and over with COVID-19 who: • are not in hospital, and • are thought to be at high risk of progression to severe COVID-19, as per NHSE interim clinical commissioning policy	N/A	N/A	**Approved**

			Be aware that the choice of neutralising monoclonal antibody may depend on availability as well as contextual factors Casirivimab/imdevimab already on formulary as a RED drug.			
TA749: Liraglutide for managing obesity in people aged 12 to 17 years (terminated appraisal)	**Add to paediatric DNP list for this indication with link to TA749.**	No	**Commissioning: NHSE** NICE is unable to make a recommendation about the use in the NHS of liraglutide for managing obesity in people aged 12 to 17 years. This is because Novo Nordisk does not intend to provide an evidence submission for the appraisal. Novo Nordisk considers that there is not enough evidence to provide an evidence submission for this appraisal.	N/A	N/A	**Approved**
TA751: Dupilumab for treating severe asthma with type 2 inflammation	**RED**	Yes with link to TA751.	**Commissioning: NHSE, tariff excluded** Dupilumab as add-on maintenance therapy is recommended as an option for treating severe asthma with type 2 inflammation that is inadequately controlled in people 12 years and over, despite maintenance therapy with high-dose inhaled corticosteroids and another maintenance treatment, only if: • the dosage used is 400 mg initially and then 200 mg subcutaneously every other week • the person has agreed to and follows an optimised standard treatment plan • the person has a blood eosinophil count of 150 cells per microlitre or more and fractional exhaled nitric oxide of 25 parts per billion or more, and has had at least 4 or more exacerbations in the previous 12 months • the person is not eligible for mepolizumab, reslizumab or benralizumab, or has asthma that has	N/A	N/A	**Approved**

			not responded adequately to these biological therapies • the company provides dupilumab according to the commercial arrangement. Stop dupilumab if the rate of severe asthma exacerbations has not been reduced by at least a 50% after 12 months.			
TA752: Belimumab for treating active autoantibody-positive systemic lupus erythematosus	**RED**	Already on; replace TA397 with TA752.	**Commissioning: NHSE, tariff excluded** Belimumab is recommended as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in people with high disease activity despite standard treatment, only if: • high disease activity is defined as at least 1 serological biomarker (positive anti-double-stranded DNA or low complement) and a SELENA-SLEDAI score of greater than or equal to 10 • treatment is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more • the company provides belimumab according to the commercial arrangement. This guidance updates and replaces TA397.	N/A	N/A	**Approved**
TA755: Risdiplam for treating spinal muscular atrophy	**RED**	Yes with link to TA755.	**Commissioning: NHSE, tariff excluded** Risdiplam is recommended as an option for treating 5q spinal muscular atrophy (SMA) in people 2 months and older with a clinical diagnosis of SMA types 1, 2 or 3 or with pre-symptomatic SMA and 1 to 4 SMN2 copies. It is recommended only if the conditions of the managed access agreement are followed.	N/A	N/A	**Approved**
TA759: Fostamatinib for treating refractory	**Add to DNP list, with link to TA759**	No	**Commissioner: NHSE**	N/A	N/A	**Approved**

chronic immune thrombocytopenia			Fostamatinib is not recommended, within its marketing authorisation, for treating refractory chronic immune thrombocytopenia in adults. This recommendation is not intended to affect treatment with fostamatinib that was started in the NHS before this guidance was published. The cost-effectiveness estimates for fostamatinib compared with rituximab are higher than what NICE normally considers cost effective. So, fostamatinib is not recommended.			
All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.						