CRG SUMMARY OF DECISIONS FOR GMMMG APPROVAL – April 2022

SUBGROUP DECISIONS WITH SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

CRG DECISIONS March 2022

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	**FINAL DECISION**
None						

SUBGROUP DECISIONS WITHOUT SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT

CRG DECISIONS March 2022

Product and indication	Status Assigned	Include in formulary	Notes on Decision	Cost impact	Commissioning/ Service implications	**FINAL DECISION**
Dapagliflozin for T1DM	**Remove from formulary and RAG list for T1DM** Add note to formulary: "dapagliflozin 5mg is no longer authorised for the treatment of patients with T1DM and should no longer be used in this	No	AstraZeneca, in agreement with the European Medicines Agency and the MHRA have informed healthcare professionals that: • Effective 25th October 2021 dapagliflozin 5mg is no longer authorised for the treatment of patients with type 1 diabetes mellitus (T1DM) and should no longer be used in this population. This is based on AstraZeneca's decision to remove the T1DM indication for dapagliflozin 5mg. • Additional risk minimisation measures for healthcare professionals and patients, implemented to mitigate the risk of DKA with the use of dapagliflozin in T1DM, will no longer be available.	A reduction in overall spend on dapagliflozin may follow.	None expected	**Approved**

	population" with link to Healthcare Professional letter.		• Discontinuation of dapagliflozin in patients with T1DM must be made by or in consultation with a physician specialised in diabetes care and be conducted as soon as clinically practical. • After stopping dapagliflozin treatment, frequent blood glucose monitoring is recommended, and the insulin dose should be increased carefully to minimise the risk of hypoglycaemia. TA597 Dapagliflozin with insulin for treating T1DM has been withdrawn now that this indication has been removed.			
TA744: Upadacitinib for treating moderate rheumatoid arthritis	**RED**	Already on formulary. Add link to TA744	Upadacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs), only if disease is moderate (a disease activity score [DAS28] of 3.2 to 5.1) and the company provides upadacitinib according to the commercial arrangement. Upadacitinib can be used as monotherapy when methotrexate is contraindicated or if people cannot tolerate it, when the above criteria are met. Within the scope of moderate RA pathway in development.	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 £5 million per year in England (or approximately £9,000 per 100,000 population, based on a population for England of 56.3 million people). This is because the technology is a further treatment option and the overall cost of treatment will be similar.	TBC	**Approved**
NG191: COVID-19 rapid guideline: managing COVID-19 (updated)	Remove link to previous DHSC interim position statement on inhaled budesonide and replace	See status column	**Commissioning: NHSE** New recommendations on inhaled budesonide: only use budesonide to treat COVID-19 as part of a clinical trial. People already on budesonide for conditions other than COVID-19 should continue treatment if they test positive for COVID-19.	N/A	N/A	**Approved**

	with link to NG191 to chapter 3.2. Ronapreve® to be added as a RED drug to chapter 5 (see above also)		Updated recommendations on casirivimab and imdevimab (Ronapreve®): clarifying that these recommendations apply to people who are hospitalised because of COVID-19. New recommendation on ivermectin: do not use ivermectin to treat COVID-19 except as part of a clinical trial. Comments from the SCN were considered by CRG who noted the strength of the evidence and that prescribing would be contradictory to the CAS alert and declined to change the recommendation. Correspondence from the clinical director of the CMDU agreed with the decision to follow NICE guidance.			
GMMMG Neuropathic Pain Guidance and formulary update	**Update chapter 4**	Included in chapter 4	A review of the GMMMG guidance in line with CG173 was completed and approved by CRG and included an updated section 4.7.3 of the formulary. The addition of gabapentin and pregabalin to the DNP was not supported. CRG agreed this list is more medicines that should never be used rather than to reflect circumstances in which their use is not supported by NICE or subject to a NICE "Do Not Do".	None	None	**Approved**
Casirivimab and imdevimab (Ronapreve®) for COVID-19	**RED**	Add to chapter 5	**Commissioning: NHSE** In line with: • NHSE Interim Clinical Commissioning Policy: Neutralising monoclonal antibodies or antivirals for non-hospitalised patients with COVID-19. NHSE Interim Clinical Commissioning Policy on casirivimab and imdevimab for patients hospitalised due to COVID-19 (aged 12 years and above).	N/A	N/A	**Approved**
Molnupiravir for COVID-19	**RED**	Add to chapter 5	**Commissioning: NHSE**	N/A	N/A	**Approved**

			In line with DHSC Interim Clinical Commissioning Policy: Neutralising monoclonal antibodies or antivirals for non-hospitalised patients with COVID-19			
TA743: Crizanlizumab for preventing sickle cell crises in sickle cell disease	**RED**	Yes along with link to TA743	**Commissioning: NHSE** Crizanlizumab is recommended as an option for preventing recurrent sickle cell crises (vaso-occlusive crises) in people aged 16 or over with sickle cell disease only if the conditions in the managed access agreement are followed.	N/A	N/A	**Approved**
HST16: Givosiran for treating acute hepatic porphyria	**RED**	Add to RAG list along with link	**Commissioning: NHSE** Givosiran is recommended as an option for treating acute hepatic porphyria (AHP) in adults and young people aged 12 and older, only if they have clinically confirmed severe recurrent attacks (4 attacks or more within 12 months) and the company provides it according to the commercial arrangement.	N/A	N/A	**Approved**
NG208: Heart valve disease presenting in adults: investigation and management	**For info**	Link to be added to chapter 2.8 (anticoagulants) and 2.9 (antiplatelets).	This guideline covers investigation and management of heart valve disease presenting in adults. It aims to improve quality of life and survival for people with heart valve disease through timely diagnosis and appropriate intervention. This guideline includes recommendations on: • referral for echocardiography and specialist assessment • pharmacological management • indications for interventions • interventions monitoring after an intervention	The guideline is not anticipated to have a significant impact on resource because: The recommendations are broadly reflective of current practice. The recommendations on transcatheter mitral valve repair for primary mitral regurgitation represent a change in clinical practice, however NHS England has recently commissioned this intervention and it is not expected that the use of the intervention will be increased any further as a result of this guideline.	None expected	**Approved**

NG28: Type 2 diabetes in adults: management (updated)	**For info**	TBC	This is an update to NICE guideline NG28 Type 2 diabetes in adults: management (published December 2015). In November 2021, NICE reviewed the evidence on SGLT2 inhibitors for adults with type 2 diabetes and chronic kidney disease, and made new recommendations. Recommendation 1.7.13 For adults with type 2 diabetes and chronic kidney disease who are taking an ARB or an ACE inhibitor (titrated to the highest licensed dose that they can tolerate), offer an SGLT2 inhibitor (in addition to the ARB or ACE inhibitor) if: • ACR is over 30 mg/mmol and • they meet the criteria in the marketing authorisation (including relevant estimated glomerular filtration rate [eGFR] thresholds) Recommendation 1.7.14 For adults with type 2 diabetes and chronic kidney disease who are taking an ARB or an ACE inhibitor (titrated to the highest licensed dose that they can tolerate), consider an SGLT2 inhibitor (in addition to the ARB or ACE inhibitor) if: • ACR is between 3 and 30 mg/mmol and • they meet the criteria in the marketing authorisation (including relevant eGFR thresholds) A NICE TA for dapagliflozin for treating CKD is expected in March 2022.	The recommendations will lead to wider prescribing of SGLT2 inhibitors which will result in a substantial cost impact. However, there is likely to be a long-term cost saving from reduced downstream treatment costs, as SGLT2 inhibitors slow chronic kidney disease progression and reduce the number of cardiovascular and end-stage renal events. The cost at year 5 is equivalent to £14,000 per 100,000 population for recommendation 1.7.13, equating to £393,000 in Greater Manchester. This includes ~£700k in drug costs and ~£300k in savings associated with reductions in dialysis and progression to CKD4. The drug cost for every additional 1,000 people who were to receive an SGLT2 as a result of recommendation 1.7.14 would be an estimated £477,000. There may be savings associated with this but there are uncertainties surrounding these savings.	None expected	**Approved**
NG203: Chronic kidney disease: assessment and management	**For info**	Add link to NG203 against SGLT2 inhibitors	In November 2021, NICE updated their guidance on SGLT2 inhibitors for adults with type 2 diabetes and chronic kidney disease. For the new recommendations, see managing chronic kidney disease in the NICE guideline on type 2 diabetes in adults.	See above	None expected	**Approved**

NG143: Fever in under 5s: assessment and initial management (update	**For info**	For info	In November 2021, NICE added a definition of sepsis to recommendation 1.2.2. NICE also added a cross reference to table 2 to guide users to the risk stratification tool for children aged under 5 years with suspected sepsis (table 3 in the NICE guideline on sepsis).	None expected from update	None expected from update.	**Approved**
NG209: Tobacco: preventing uptake, promoting quitting and treating dependence	**For info**	Remove links to superseded guidance and add link to NG209 to chapter 4.10.2.	**Commissioning: ICS/CCG, NHSE, & local authorities** This guideline covers support to stop smoking for everyone aged 12 and over, and help to reduce people's harm from smoking if they are not ready to stop in one go. It also covers ways to prevent children, young people and young adults aged 24 and under from taking up smoking. The guideline brings together and updates all NICE's previous guidelines on using tobacco, including smokeless tobacco. It covers nicotine replacement therapy and e-cigarettes to help people stop smoking or reduce their harm from smoking. It does not cover using tobacco products such as 'heat not burn' tobacco. This guideline updates and replaces all of NICE's previous guidelines on using tobacco, including PH45 and NG92.	Most of the recommendations have remained unchanged. However, the following new recommendations on offering voucher incentives in addition to behavioural support and nicotine replacement therapy to stop smoking during pregnancy may have potential resource implications regarding the cost of voucher incentives. They are: • Offering voucher incentives [recommendation 1.20.12] • Consider providing voucher incentives jointly o the pregnant woman and to a friend or family member that she has chosen to support her during her quit attempt [recommendation 1.20.13] • Ensuring staff training [recommendation 1.20.14]. A resource impact template is provided to reflect local practice and help with assessing the resource impact at a local level.	Incentive schemes are already used in some areas. Areas that do not already use them will need staff time to run them, and financial resources to award the vouchers. Training for people promoting and delivering the incentive schemes may need resources. Information on rationale and impact of the guidance can be found here.	**Approved**
All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.						