SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: CRG	**At their meeting on: 12.09.23**
For approval by: GMMMG	**At their meeting on: 12.10.23**

Decisions made by: CRG (except those * which were made at GMMMG)	**12th September 2023**
Approved by: GMMMG	**12th October 2023**
Approved by: CEGC	**19th October 2023**
Approved by: Executive	**8th November 2023**

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
TA902: Dapagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction **Commissioning: ICS** 21/06/23	Dapagliflozin is recommended, within its marketing authorisation, as an option for treating symptomatic chronic heart failure with preserved or mildly reduced ejection fraction in adults. NB: NICE TA679 recommended dapagliflozin as an option for treating chronic heart failure with reduced ejection	Add to formulary in chapter 2.5.5.1 as GREEN (specialist advice), with link to TA902. On formulary in chapter 2.5.5.1 as a GREEN (specialist advice) drug for	The SCN has been approached and agreed to write to colleagues once the formulary amendment has been made in order to speed up implementation.	NICE estimate that: • Around 326 people per 100,000 population are eligible, or 9,240 in Greater Manchester • Around 100 people per 100,000 will receive dapagliflozin from year 3 onwards once uptake has reached 30%, or 2,740 in Greater Manchester • The estimated medicine cost impact is £437,000 in GM in year 1, rising to £1.3 million	Approve addition to formulary for this indication. T&F group to be convened with SCN for pathway development

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
	fraction.	chronic heart failure with reduced ejection fraction, in line with TA679.		in year 3 onwards. • The total net impact of introducing dapagliflozin is therefore expected to be around £900,000 of additional spend per year from year 3 onwards, assuming that NICE's assumptions are correct and that uptake reaches 30%. • This does not include costs or savings associated with adverse events (e.g. AKI, UTI, fracture, volume depletion). • There is expected to be some release in capacity due to reduced hospitalisation for heart failure and mortality rates. Using outcome data from a pooled meta-analysis of dapagliflozin outcomes this is estimated at £130,000 in year 1, rising to £400,000 in year 3 onwards. This estimate is sensitive to local patterns of use and event rates; a resource impact template is available for local completion.	
TA905: Upadacitinib for previously treated moderately to severely active Crohn's disease **Commissioning: ICS, tariff-excluded, 30 day TA** 21/06/23	Upadacitinib is recommended as an option for treating moderately to severely active Crohn's disease in adults, only if: • the disease has not responded well enough or lost response to a previous biological treatment or • a previous biological treatment was not tolerated or • tumour necrosis factor (TNF)-alpha inhibitors are contraindicated. Upadacitinib is only recommended if the company provides it according to the commercial arrangement.	Add to formulary in chapter 1.5.3 as a RED drug in this indication, with link to TA905. On formulary in chapter 1 for ulcerative colitis, in line with NICE TA 856. On formulary in chapter 10 for rheumatology indications. On formulary in chapter 13 for dermatology indications.	The updated GM HCDs pathway for IBD includes upadacitinib for both ulcerative colitis and Crohn's disease	NICE estimate that 47 people per 100,000 population are eligible for treatment, and that 7 people per 100,000 population will receive upadacitinib from year 3 onwards once uptake has reached 15%. Upadacitinib is the first oral treatment for this population and will release capacity when used instead of IV alternatives. NICE estimate that around 30% of patients currently choose vedolizumab IV and around 5% of these may choose upadacitinib in future. This equates to 2 people per 100,000 population choosing upadacitinib instead of vedolizumab IV in year 3 onwards. At list price upadacitinib has a similar or lower cost than vedolizumab and ustekinumab and the guidance is expected to be cost saving. However, the technology and comparators have prices which are commercial in confidence. A resource impact template is available for local completion.	Approve addition to formulary for this indication
TA907: Deucravacitinib for treating moderate to severe plaque	Deucravacitinib is recommended as an option for treating moderate to severe plaque psoriasis in adults, only if: • the Psoriasis Area and Severity Index	Add to formulary in chapter 13.5.3 as a RED drug in this indication, with link to		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 and the	Approve the addition to formulary

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
psoriasis **Commissioning: ICS, tariff-excluded** 21/06/23	(PASI) score is 10 or more and the Dermatology Life Quality Index (DLQI) score is more than 10 • the condition has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated • the company provides deucravacitinib according to the commercial arrangement.	TA907.		overall cost of treatment for this patient group will be similar. NICE estimate that 51 people per 100,000 population have plaque psoriasis and are eligible for treatment with a biologic. A resource impact template is provided for completion at a local level. This is because there are now several treatment options (biological and non-biological therapies) including deucravacitinib that are recommended by NICE for plaque psoriasis. Organisations should complete both current and future uptake based on local practice.	
GM ICB Commissioning statement: Omalizumab for Chronic Inducible Urticaria (CIndU)  Omalizumab for CindU - commisisonir	Following the changes to the GM ICB IFR process, a cohort of patients for this medicine and condition has been identified and a position statement requested to facilitate treatment. CIndU is a chronic condition which usually lasts several years, and often poses a great treatment challenge due to poor or no response to first-line therapy with 2nd generation of H1-antihistamines. CIndU can be debilitating and severely impacting patients' quality of life as avoidance of the offending trigger is often not feasible and requires major changes to everyday life. Therefore, there is high unmet need for an effective treatment" Omalizumab should be stopped at the end of a course of treatment (6 doses) if the condition has responded, to establish whether the condition has gone into spontaneous remission and is restarted only if the condition relapses. Relapse is defined as UAS7 score of 16 or more, a DLQI score of 6 or more, a UCT score of 11 or less or an AECT score of 9 or less.	On formulary in chapter 3 for chronic spontaneous urticaria (NICE TA339) and severe persistent allergic asthma (NICE TA278) as RED	CRG considered the initial request from NCA and identified a further dermatology service operating out of MFT that wished to use the medicine. The alternative is ciclosporin which specialists have advised is usually less efficacious, requires frequent monitoring and can cause severe adverse effects. 9 IFRs for this medicine and condition have been submitted since 2017, all of which were approved and feedback from the services showed the treatments were well tolerated and objectively effective. Consideration should be given to monitoring the uptake and the efficacy of the	It is estimated that there may be up to 30 patients per year treated by GM dermatology services at NCA and MFT Based on a list price of £256.15 per 150mg prefilled syringe and consequently £512.3 for a single 300mg dose (excluding VAT). The total cost for 24-week therapy (6 doses) equals £3,073.80 (excluding VAT). The maximum cost per year is £92,214 (exc VAT) Omalizumab should be stopped at the end of a course of treatment (6 doses) if the condition has responded, to establish whether the condition has gone into spontaneous remission and is restarted only if the condition relapses. Relapse is defined as UAS7 score of 16 or more, a DLQI score of 6 or more, a UCT score of 11 or less or an AECT score of 9 or less. Having these patients' disease under control will lead to fewer appointments requested by the patient to seek for urgent medical attention for symptom relief. It will also reduce the days these patients have to be off sick due to the same. Mental health issues are also prevalent when the disease is not under control. At secondary care it would reduce the number of required appointments in the clinic as well as the need for blood tests.	Approve addition to formulary and publication of the commissioning statement. Request 6-12 monthly assurance report on the use for this indication.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
			treatment		

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	GMMMG Recommendation
Long-Term Azithromycin in Adults with Chronic Respiratory Disease: Guidance for Primary Care  GM Azithromycin guidance V1.8.docx	Developed by Bury MO team and finalised for the GM ICB this guidance document seeks to standardise the management of azithromycin when prescribed for the treatment of long-term respiratory conditions	On RAG list as Green (specialist advice) for this indication		This is not expected to increase prescribing but should improve the management of patients in primary care	Approve the guidance for publication
GMMMG High cost drugs pathways for inflammatory bowel disease  GMMMG HCD Pathway - IBD - FINAL	Current review was undertaken to incorporate up to date national clinical guidance and bring the document in line with the recently updated HCD rheumatology pathways. On this occasion, the main changes include: • The incorporation of NICE TA recommendations • The addition of subcutaneous infliximab and vedolizumab • A Review of all relevant chapters and tables of the pathways to include evidence published since previous pathway review including NICE, BSG,, ECCO guidance on management CD and UC, changes to summaries of product characteristics, safety alerts (notably alert on JAK inhibitors) • An update of section on fertility, pregnancy, and lactation as per recently published ECCO guidance to support prescribing of high cost drugs, particularly where there is data available from observational trials. • Incorporation of MHRA and NHSE's guidance on biosimilars • A simplification of treatment algorithms • The incorporation of the GMMMG sequential HCD statement and update of the IFR section to align with current arrangements • An update of the templates for pre-treatment checklists and drug-specific monitoring forms	All medicines on formulary in chapter 1 as RED drugs		There are no financial and commissioning implications arising as a result of this pathway update. This version incorporates the latest positive NICE technology appraisals which provide additional treatment options. All of which have been incorporated into the GMMMG formulary following the usual CRG and GMMMG process	Approve the updated pathway for publication

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG Recommendation
CG57: Atopic eczema in under 12s: diagnosis and management (updated) **Commissioning: ICS** 07/06/23	In June 2023, NICE reviewed the evidence on emollients: • added a "do not do" recommendation for emollient bath additives for children with atopic eczema	Emollient bath additives have been on the DNP list in GM since 2018 Update DNP entry to add link to NICE 'do not do' recommendation.	CRG have referred a query that arose through the consultation on the use of emollients with antimicrobials to the GM AMS steering group	The 'do not do' recommendation reflects current evidence and is expected to further reduce the prescribing of emollient bath additives. Prescribing of these products has declined since 2019 as a result of evidence from the BATHE trial, which informed NHS England guidance on their use. However, there is still some prescribing, so a reduction would result in savings for the NHS. A local resource impact template has not been produced for this topic because of challenges in estimating current use of emollient bath additives, which has wide geographical variation.	Approve update to the DNP list
TA896: Bulevirtide for treating chronic hepatitis D **Commissioning: NHSE** 07/06/23	Bulevirtide is recommended as an option for treating chronic hepatitis D in adults with compensated liver disease only if: • there is evidence of significant fibrosis (METAVIR stage F2 or above or Ishak stage 3 or above) and • their hepatitis has not responded to peginterferon alfa-2a (PEG-IFN) or they cannot have interferon-based therapy. Bulevirtide is only recommended if the company provides it according to the commercial arrangement.	Add to formulary in chapter 5.3.3 as a RED drug in this indication, with link to TA896. Formulary position should reflect the NICE TA as well as any associated NHSE SSCs.		Resource impact template available. NICE estimate that around: • 80 adults with chronic hepatitis D are eligible for treatment with bulevirtide based on expected population growth. • 64 adults will start treatment with bulevirtide each year by 2027/28 adjusted for expected population growth.	Approve addition to formulary
TA899: Esketamine for treating major depressive disorder in adults at imminent risk of suicide (terminated appraisal) **Commissioning: ICS** 14/06/23	NICE is unable to make a recommendation about the use in the NHS of esketamine for treating major depressive disorder in adults at imminent risk of suicide. This is because Janssen has confirmed that it does not intend to make an evidence submission for the appraisal at this time. Janssen considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources for this population.	Update DNP listing to list the indication as depression, and add link to TA899. Included in DNP list for treatment-resistant depression, with link to prior NICE TA854.		None	Approve addition to DNP list

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG Recommendation
*GMMMG Sept minutes	GMMMG Minutes Sept 23.pdf	N/A	N/A	N/A	Approve for publication

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
TA893: Brexucabtagene autoleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over **Commissioning: NHSE** 07/06/23	Brexucabtagene autoleucel is recommended for use within the Cancer Drugs Fund as an option for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over. It is recommended only if the conditions in the managed access agreement for brexucabtagene autoleucel are followed.	For info, no action.		It is estimated that around 90 people per year, with relapsed or refractory B-cell acute lymphoblastic leukaemia who are 26 years and over are eligible for treatment with brexucabtagene autoleucel. The resource impact of brexucabtagene autoleucel will be covered by the Cancer Drugs Fund budget.
TA895: Axicabtagene ciloleucel for treating relapsed or refractory diffuse large B-cell lymphoma after first-line chemoimmunotherapy **Commissioning: NHSE** 07/06/23	Axicabtagene ciloleucel is recommended for use within the Cancer Drugs Fund as an option for treating diffuse large B-cell lymphoma in adults when an autologous stem cell transplant is suitable if it: • has relapsed within 12 months after first-line chemoimmunotherapy or • is refractory to first-line chemoimmunotherapy. It is recommended only if the conditions in the managed access agreement for axicabtagene ciloleucel are followed.	For info, no action		It is estimated that around 540 people per year with diffuse large B-cell lymphoma are eligible for treatment with axicabtagene ciloleucel. The resource impact of axicabtagene ciloleucel will be covered by the Cancer Drugs Fund budget.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
TA897: Daratumumab with bortezomib and dexamethasone for previously treated multiple myeloma **Commissioning: NHSE** 06/06/23	Daratumumab with bortezomib and dexamethasone is recommended as an option for treating multiple myeloma in adults, only if they have had just 1 previous line of treatment and: • it included lenalidomide or • lenalidomide is unsuitable as a second-line treatment and the company provides it according to the commercial arrangement.	For info, no action		Resource impact template available. NICE estimate that around: • 3,360 adults with multiple myeloma are eligible for treatment with daratumumab with bortezomib and dexamethasone based on expected population growth. 2,020 adults will start treatment with daratumumab with bortezomib and dexamethasone by 2027/28 adjusted for expected population growth. This is based on an estimate of the current number of people receiving treatment in the cancer drugs fund (CDF); 60% of the eligible population. This uptake is expected to remain constant over 5 years
TA898: Dabrafenib plus trametinib for treating BRAF V600 mutation-positive advanced non-small-cell lung cancer **Commissioning: NHSE** 14/06/23	Dabrafenib plus trametinib is recommended as an option for treating BRAF V600 mutation-positive advanced non-small-cell lung cancer (NSCLC) in adults, only if: • it is used as first-line treatment of advanced stage cancer, and the company provides it according to the commercial arrangement.	For info, no action		NICE expect the resource impact of implementing the recommendations in England will be less than approximately £8,800 per 100,000 population. This is because the number of eligible people is estimated to be around 400 people per year. Some of this population will have other treatments first line, because delays in receipt of genetic tests mean dabrafenib plus trametinib cannot always be used. These are oral treatments which have been available in the NHS since 2020, as a COVID-19 interim treatment. For every 10 people receiving dabrafenib plus trametinib, around 110 attendances at intravenous chemotherapy day units may be avoided, which would release around 110 hours of chemotherapy chair time. There are also wider benefits to people and environmental benefits associated with reduced need to travel to chemotherapy day centres.
TA903: Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer **Commissioning: NHSE** 21/06/23	Darolutamide with docetaxel is recommended, within its marketing authorisation, as an option for treating hormone-sensitive metastatic prostate cancer in adults. Darolutamide is only recommended if the company provides it according to the commercial arrangement.	For info, no action		NICE estimate that around: • 6,040 adults with hormone-sensitive metastatic prostate cancer are eligible for treatment with darolutamide plus androgen deprivation therapy (ADT) and docetaxel each year based on expected population growth. around 1,510 adults will start treatment with darolutamide plus ADT and docetaxel each year by 2027/28 after adjusting for expected population growth.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
TA904: Pembrolizumab with lenvatinib for previously treated advanced or recurrent endometrial cancer **Commissioning: NHSE** 21/06/23	Pembrolizumab plus lenvatinib is recommended, within its marketing authorisation, for treating advanced or recurrent endometrial cancer in adults: • whose cancer has progressed on or after platinum-based chemotherapy and • who cannot have curative surgery or radiotherapy. Pembrolizumab plus lenvatinib is recommended only if the companies provide them according to the commercial arrangements.	For info, no action.		By 2027/28 NICE estimate that: • 880 people with advanced or recurrent endometrial cancer are eligible for treatment with pembrolizumab plus lenvatinib after adjusting for expected population growth • 660 people will receive pembrolizumab plus lenvatinib from year 3 onwards once uptake has reached 75% adjusted for expected population growth. A resource impact template is available.
*GMMMG October agenda PDF GMMMG Oct 2023 agenda.pdf	To highlight to CEGC the items considered by GMMG in October	N/A	Items 6-10 were deferred to November as item 4 required urgent detailed discussion.	N/A

Regional Drug and Therapeutics Centre
16/17 Framlington Place, Newcastle upon Tyne, NE2 4AB
Tel: **0191 213 7855** Fax: **0191 261 8839** email: nuth.nyrdtc.rxsupp@nhs.net visit: https://rdtc.nhs.uk

@RDTC_Rx