SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: CRG (except those * which were made at GMMMG)	**9th May 2023**
Approved by: GMMMG	**8th June 2023**
Approved by: CEGC	**28th June 2023**
Approved by: Executive	**For noting by executive in June 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	Recommendation from GMMMG	Status
TA861: Upadacitinib for treating active non-radiographic axial spondyloarthritis 01/02/23 **Commissioning: ICS, tariff-excluded, 30 day TA**	Upadacitinib is recommended as an option for treating active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs) in adults. It is recommended only if: • tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough and the company provides upadacitinib according to the commercial arrangement.	On formulary in chapters 10 (rheumatoid arthritis and psoriatic arthritis) and 13 (atopic dermatitis). Add link to TA861 to chapter 10.1.3		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 for this patient group will be similar. Upadacitinib can be taken orally. Both clinical and patient experts highlighted the convenience of upadacitinib over comparators because of its oral administration.	Note the cost impact and approve the addition to formulary	Approved for publication and communication for implementation
TA863: Somatrogon for treating growth disturbance in children and young people aged 3 years and over 01/02/23 **Commissioning: ICS, tariff-excluded, 30 day TA**	Somatrogon is recommended, within its marketing authorisation, as an option for treating growth disturbance caused by growth hormone deficiency in children and young people aged 3 years and over.	Not on formulary Growth hormone for paediatric patients is AMBER in GM. Add to formulary in chapter 6.5.1 as a RED drug (pending the availability of a shared care protocol) in this indication, with a link to TA863.	Standard process for medicines which are suitable for shared care is to assign a RED status until an approved shared care protocol is approved to enable transfer of prescribing to primary care.	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 for this patient group will be similar.	Note the cost impact and approve the addition to formulary	Approved for publication and communication for implementation

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 from GMMMG	Status
*GMMMG May minutes	GMMMG Minutes May 23 fnl.pdf	Approved at June GMMMG meeting		Nil	CEGC to accept for publication to GMMMG website	Approved for publication
GMMMG CRG April minutes	CRG Minutes April 2023_FINAL.pdf	Accepted by GMMMG at June meeting		Nil	CEGC to accept for publication to GMMMG website	Approved for publication

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Status
Prescribing information for primary care – Drugs for dementia.	A technical update was made for 4 drugs for dementia, for which the primary care prescriber information leaflets produced by GMMMG which had expired.	All these medicines are on the GM formulary with a Green specialist advice status.	Technical update, approved by CRG for publication to the website.	None	Approved for publication
TA862: Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments 01/02/23 **Commissioning: NHSE**	Trastuzumab deruxtecan is recommended with managed access as an option for treating HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments in adults. It is only recommended if the conditions in the managed access agreement for trastuzumab deruxtecan are followed.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester.	For info, no action	It is estimated that around 600 people per year with HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments are eligible for treatment with trastuzumab deruxtecan. Trastuzumab deruxtecan will be available to the NHS in line with the managed access agreement with NHS England. As part of this, NHS England and Daiichi Sankyo have a commercial access agreement that makes trastuzumab deruxtecan available to the NHS at a reduced cost. The financial terms of the agreement are commercial in confidence.	Approved for publication and communication for implementation
TA864: Nintedanib for treating idiopathic pulmonary fibrosis when forced vital capacity is above 80% predicted 01/02/23 **Commissioning: NHSE**	Nintedanib is recommended as an option for treating idiopathic pulmonary fibrosis in adults, only if: • they have a forced vital capacity of above 80% predicted the company provides it according to the commercial arrangement.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester.	For info, no action	NICE estimate that: • The prevalent population is 5,300 people, and the annual incident population is 1,700 people. • 1,300 people will receive treatment with nintedanib from year 2027/28 onwards once market share has reached 63%. The average treatment period for people who continue treatment is 2 years. • Around 36% of people discontinue treatment in their first year, with an average treatment duration of 10 months. Around 5,400 additional monitoring appointments are needed in England from year 2027/28 onwards for people receiving nintedanib	Approved for publication and communication for implementation

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Status
TA865: Nivolumab with fluoropyrimidine- and platinum-based chemotherapy for untreated unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma 08/02/23 **Commissioning: NHSE**	Nivolumab with fluoropyrimidine-based and platinum-based combination chemotherapy is recommended as an option for untreated unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma in adults whose tumours express PD-L1 at a level of 1% or more. It is recommended only if: • pembrolizumab plus chemotherapy is not suitable the company provides nivolumab according to the commercial arrangement.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester.	For info, no action	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 population size is small.	Approved for publication and communication for implementation
TA866: Regorafenib for previously treated metastatic colorectal cancer 08/02/23 **Commissioning: NHSE**	Regorafenib is recommended, within its marketing authorisation, as an option for metastatic colorectal cancer in adults who have had previous treatment (including fluoropyrimidine-based chemotherapy, anti-VEGF therapy and anti-EGFR therapy) or when these treatments are unsuitable. Regorafenib is only recommended if the company provides it according to the commercial arrangement.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester.	For info, no action	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 for this patient group will be similar.	Approved for publication and communication for implementation
TA868: Vutrisiran for treating hereditary transthyretin-related amyloidosis 15/02/23 **Commissioning: NHSE, 30 day TA**	Vutrisiran is recommended, within its marketing authorisation, as an option for treating hereditary transthyretin-related amyloidosis in adults with stage 1 or stage 2 polyneuropathy. It is only recommended if the company provides vutrisiran according to the commercial arrangement.	Not on formulary. Add to RAG list as a RED drug in this indication, with a link to TA868		NICE estimate that: • 230 people with hereditary transthyretin-related amyloidosis (hATTR) are currently eligible to start treatment with vutrisiran after adjusting for population growth. • 210 people will receive treatment with vutrisiran from year 2027/28 onwards once market share has reached 91%. Around 3,500 fewer visits for IV infusion appointments would be needed from year 2027/28	Approved for publication and communication for implementation

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Status
TA870: Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma 22/02/23 **Commissioning: NHSE**	Ixazomib, with lenalidomide and dexamethasone, is recommended as an option for treating multiple myeloma in adults, only if: • they have had 2 or 3 lines of therapy and the company provides ixazomib according to the commercial arrangement.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester.	For info, no action	NICE estimate that: • Around 2,000 people are eligible for treatment each year. • Around 600 people are estimated to start treatment each year from 2023/24. This is 29.8% of the eligible population. This number is expected to remain constant over 5 years. • Around 1,800 people will receive ixazomib combination treatment from year 2025/26 including people continuing treatment from a previous year. • The average treatment period for ixazomib combination treatment is 25.7months. Around 16,000 oral chemotherapy administration appointments per year will be needed.	Approved for publication and communication for implementation
TA872: Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies 28/02/23 **Commissioning: NHSE**	Axicabtagene ciloleucel is recommended, within its marketing authorisation, as an option for treating relapsed or refractory diffuse large B-cell lymphoma or primary mediastinal large B-cell lymphoma in adults after 2 or more systemic therapies. It is recommended only if the company provides axicabtagene ciloleucel according to the commercial arrangement.	All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester.	For info, no action	NICE estimate that: • 470 people with large B-cell lymphoma are eligible for treatment with axicabtagene ciloleucel each year after adjusting for population growth. 180 people will receive axicabtagene ciloleucel each year - an uptake rate of 37% in line with data collected from the Cancer Drugs Fund after adjusting for population growth	Approved for publication and communication for implementation
HST22: Ataluren for treating Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene 22/02/23 **Commissioning: NHSE**	Ataluren is recommended, within its marketing authorisation, as an option for treating Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene in people 2 years and over who can walk. This is only if the company provides ataluren according to the commercial arrangement.	Not on formulary Add to RAG list as a RED drug in this indication, with a link to HST22.		This guidance updates and replaces NICE highly specialised technologies guidance HST3 on ataluren for treating Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene.	Approved for publication and communication for implementation

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	Status
CG181: Cardiovascular disease: risk assessment and reduction, including lipid modification (updated) 10/02/23 **Commissioning: ICS**	In February 2023, NICE added a new recommendation on aspirin for primary prevention of CVD. This is based on a 2023 surveillance decision: Do not routinely offer aspirin for primary prevention of CVD.	Links to CG181 are on formulary in chapter 2.12. Aspirin 75mg and 300mg are on formulary in chapter 2.9. Add note to chapter 2.9: "do not routinely offer aspirin for primary prevention of CVD", with link to CG181.		None expected. The NICE surveillance review notes that for most groups aspirin's harms are likely to outweigh benefit in the first 10 years of use, and that for those likely to receive a net benefit that the margin is likely to be small.	Approved for publication and communication for implementation AMDs requested to investigate any prescribing of aspirin for primary prevention of CVD through primary care audit, in each GM locality
*Fencino® (fentanyl transdermal patch) Rebate Scheme	There had been a transfer of the organisation managing the Fencino® rebate from Ethypharm to Luye Pharma. In order to satisfy GM ICB governance purposes, GMMMG approval was required to continue this rebate arrangement so there is a clear audit trail.	Fentanyl transdermal patches are listed on the formulary.	This decision was made at GMMMG, it was not considered by CRG who do not consider rebate schemes. It was accepted that the existing rebate arrangement in place for Fencino® could continue, as this was simply a transfer of the organisation managing the rebate, the scheme itself was the same as previously approved by GMMMG	Nil additional	Accepted

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