SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: CRG	**By December and January 2023**	
Approved by: GMMMG	**9th February 2023**	
Approved by: CEGC	**16 February 2023**	
For approval by: GM executive (decisions with a financial impact only are submitted on this summary)	Approved as detailed below (email confirmation 15/3/23)	
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	Executive decision
TA824: Dexamethasone intravitreal implant for treating diabetic macular oedema **Commissioning: ICS** 14th September 2022	Dexamethasone intravitreal implant is recommended as an option for treating visual impairment caused by diabetic macular oedema in adults only if their condition has not responded well enough to, or if they cannot have non-corticosteroid therapy. This guidance updates and replaces TA349 (July 2015).	Add to formulary as a RED drug in this indication	Remove links to TA349 and replace with link to TA824.	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. There is no resource impact template available. This is because the technology is a further treatment option and the overall cost of treatment will be similar.	Approve addition to formulary	Approved
TA825: Avacopan for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis **Commissioning: NHSE** 21st September 2022	Avacopan with a cyclophosphamide (CYC) or rituximab (RTX) regimen is recommended, within its marketing authorisation, as an option for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis in adults. It is recommended only if the company provides it according to the commercial arrangement.	Add avacopan to formulary as a RED drug in this indication, with link to TA825.		NICE estimate that: • 490 newly diagnosed people with GPA or MPA are eligible for treatment with avacopan plus CYC or RTX each year after adjusting for population growth • 740 people with GPA or MPA from the prevalent population will relapse and become eligible for avacopan plus CYC or RTX each year, along with newly diagnosed cases, this is 1,230 people in total • 885 people will receive avacopan from year 2026/27 onwards once uptake has reached 72% Resources may be released from a reduction in end stage renal disease (ESRD).	Approve addition to formulary (note NHSE commissioned)	Approved

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation	Executive decision
TA828: Ozanimod for treating moderately to severely active ulcerative colitis **Commissioning: ICS** 5th October 2022	Ozanimod is recommended as an option for treating moderately to severely active ulcerative colitis in adults, only if: • conventional treatment cannot be tolerated or is not working well enough and infliximab is not suitable, or • biological treatment cannot be tolerated or is not working well enough, and the company provides it according to the commercial arrangement.	Not on formulary.	Add to formulary as a RED drug in chapter 1.5.3, with links to TA828. The current work being undertaken to update the GMMMG IBD HCDs pathway will include ozanimod.	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. The previously published template for this patient group has been updated and replaced to include ozanimod and all other treatment options for moderately to severely active ulcerative colitis. The price is considered commercial in confidence.	Approve addition to formulary	Approved

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TA829: Upadacitinib for treating active ankylosing spondylitis **Commissioning: ICS** 30th September 2022	Upadacitinib is recommended as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy in adults, 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. If patients and their clinicians consider upadacitinib to be one of a range of suitable treatments (including secukinumab and ixekizumab), choose the least expensive treatment, taking into account administration costs, dosage, price per dose and commercial arrangements.	Add upadacitinib to formulary as a RED drug in this indication, with link to TA829.	Upadacitinib represents an additional treatment option for those patients with active ankylosing spondylitis who would benefit from or prefer an oral treatment, as opposed to the currently available injectable treatments. Upadacitinib and some of the other treatment options have discounts that are commercial in confidence. Other treatment options include upadacitinib, ixekizumab, secukinumab, adalimumab (Humira & biosimilar), certolizumab, etanercept (Enbrel & biosimilar), and golimumab.	NICE estimates that there are around 3,500 people with ankylosing spondylitis in GM, of whom around 1,400 are eligible for treatment with a biologic. 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. A resource impact template is available.	Approve addition to formulary	Approved

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TA832: Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids **Commissioning: ICS** 19th October 2022	Relugolix–estradiol–norethisterone acetate is recommended, within its marketing authorisation, as an option for treating moderate to severe symptoms of uterine fibroids in adults of reproductive age.	Not on formulary.	Add to formulary as a Green (Specialist Advice) drug in this indication, with links to TA832.	Relugolix–estradiol–norethisterone acetate is an oral pharmacological treatment that can be used on a long-term basis. The comparator treatment, injectable gonadotrophin-releasing hormone agonists requires clinic visits. 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 approximately £9,000 per 100,000 population. This is because the technology is a further treatment option and is available at a similar price to the current treatment options. Since the technology is taken orally and does not require clinic visits there is expected to be a capacity benefit as a result. However, this is not expected to be significant at a national level. Relugolix with estradiol and norethisterone acetate is priced at £72 per month of treatment, which is similar to the alternative treatment options.	Approve addition to formulary	Approved

Implementation of NICE guidance on Continuous Blood Glucose Monitoring (CGM)	Criteria for use of Continuous Glucose Monitoring (CGM) as stated in NICE NGs 17,18 and 28 i.e. to adopt the following policy statements: • CGM is commissioned for adults with type 1 diabetes in line with NICE NG17 issued August 2015 as per the 2022 revision of the section regarding Continuous Glucose Monitoring • CGM is commissioned for Children and Young People with type 1 diabetes in line with NICE NG18 issued August 2015 as per the 2022 revision of the section regarding Continuous Glucose Monitoring • CGM is commissioned for adults with type 2 diabetes in line with NICE NG28 issued December 2015 as per the 2022 revision of the section regarding Continuous Glucose Monitoring • As per the previous GM EUR policy, pregnant Type 1 diabetics should continue to be offered CGM in line with the letter from NHS England and NHS improvement dated 29 September 2020 headed "Type 2 Diabetes prevention Programme and Type 1 diabetes monitoring". NHS England Type 2 DPP and Type 1 CGM letter.pdf • As per the previous GMMMG policy on the use of Freestyle Libre, use of intermittently scanned CGM (isCGM) is recommended for pregnant Type 2 persons on a basal bolus insulin regime. (NICE NG3 Diabetes in pregnancy only includes Type 1s)	Add to formulary as per criteria specified	At their December meeting GMMMG requested further information, to enable a more detailed local cost and commissioning impact to be considered. Some additional information was returned to GMMMG, and finance colleagues agreed to continue efforts to improve the accuracies of localised costing methodologies beyond that provided by NICE. It was agreed at the January GMMMG meeting that the recommendation to provide CGM in line with NICE as detailed here, be submitted to CEGC for approval based on the NICE costing template information.	The NICE costing template estimates a financial impact to GM of £1,725,998 by year 5 Greater capacity may be needed in specialist clinics (primary and / or secondary care) to deal with increasing numbers of diabetics and to implement NICE's recommendation that CGM should be provided by a team with expertise in its use, as part of supporting people to self-manage their diabetes (NG17 recommendation 1.6.12, NG18 recommendation 1.2.64 and NG28 recommendation 1.6.20.	GMMMG approve (it should be noted that efforts to undertake a local cost impact are underway by finance teams) CEGC noted that finance teams will need to take this item through executive	NOT approved yet. The case for Continuous Glucose monitoring will be brought back to executive after discussion with finance, as a business case

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Dexcom One rtCGM device.	To be first choice CGM device alongside FreeStyle Libre 2 for eligible patients as defined by the proposed GM commissioning statement on CGM. • CGM is commissioned for adults with type 1 diabetes in line with NICE NG17 as per the 2022 revision of the section regarding Continuous Glucose Monitoring. • CGM is commissioned for Children and Young People with type 1 diabetes in line with NICE NG18 as per the 2022 revision of the section regarding Continuous Glucose Monitoring. • CGM is commissioned for adults with type 2 diabetes in line with NICE NG28 as per the 2022 revision of the section regarding Continuous Glucose Monitoring	First choice CGM alongside FSL NICE recommend that all CGM should be provided by a team with expertise in its use, as part of supporting people to self-manage their diabetes. Formulary does not currently include devices	This recommendation has been pending the approval of the updated GM position statement on the use of CGM. CRG heard that the cost impact is likely to be neutral because the cohort of patients for who this is recommended is the same as that for FSL which is already in use but provides an alternative option for these patients. It was highlighted that guidance for primary care is required to facilitate cost-effective use.	Expected to be cost neutral. Potential workload implications for community pharmacy due to need to supply transmitters every 3 months. A comprehensive education & training package for clinicians and patients is available from the manufacturer. This is comparable to that produced for FSL	Approve addition to formulary	NOT approved yet, awaiting the CGM decision (The case for Continuous Glucose monitoring will be brought back to executive after discussion with finance, as a business case).
GMMMG antimicrobial guidance	Green	Already on formulary	Updates to this guidance include: • A statement that local resistance to COPD treatments warrants a local response • Updates to the scarlet fever section which has been moved to URTI section from skin	The Antimicrobial guidelines working group have identified that FMT not available across the whole GM system. NICE MTG71 recommends this treatment as an option.	Accepted by GMMMG CEGC noted commissioning implications regarding MTG71.	Approved – awaiting updated version to publish from authors

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