NHS
North East and North Cumbria

SUMMARY OF MEDICINES SUBCOMMITTEE DECISIONS

Decisions made by: NTAG	**December 2023**	
Approved by: Medicines Subcommittee	**4th December 2023**	
For consideration by: NENC executive	**No submission to executive required, medicines subcommittee decisions carried on director authority. Decision status as per this document.**	

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 SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT (decisions approved by NENC ICB executive committee)

NICE Technology Appraisal/Guidance/Drug	Date published	Current formulary status or pathway/ guidance relevance	Recommendation	Commissioning & financial implications	Status
None					

Key for Recommended RAG status: Not Approved (DNP), Green – suitable for prescribing in primary care; Green+ Specialist Initiation/Recommendation – should be started or recommended by a specialist but suitable for ongoing prescribing in primary care; Shared Care – suitable for prescribing under an agreed shared care protocol; or Red – not suitable for prescribing in primary care.

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DECISIONS WITHOUT A SIGNIFICANT FINANCIAL/COMMISSONING IMPACT (decisions approved on medicines committee ICB directors' authority)					
NICE Technology Appraisal/Guidance/Drug	**Date published**	**Current formulary status or pathway/ guidance relevance**	**Decision**	**Commissioning & financial implications**	**Decision taken by medicines subcommittee**
TA912: Cipaglucosidase alfa with miglustat for treating late-onset Pompe disease **Commissioning: NHSE** Cipaglucosidase alfa (CIPA) plus miglustat is recommended, within its marketing authorisation, as an option for treating late-onset Pompe disease in adults. It is recommended only if the company provides it according to the commercial arrangement.	15/08/2023	Not on formulary.	Add to formulary as a RED drug in this indication. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved
NG233: Otitis media with effusion in under 12s **Commissioning: ICS** This guideline covers identifying and managing otitis media with effusion (OME), also known as 'glue ear', in children younger than 12 years. It aims to improve hearing and quality of life in children with OME. This guideline updates and replaces the former NICE guideline on otitis media with effusion in under 12s: surgery (CG60, February 2008). It does not update or replace NG91: Otitis media (acute): antimicrobial prescribing (Last updated March 2022). The updated guidance adds 'Do Not Do' recommendations on antibiotics, oral and nasal corticosteroids, antihistamines, leukotriene receptor antagonists, mucolytics, PPIs, anti-reflux medicines, and decongestants for OME-related hearing loss.	30/08/2023	Not on formulary	Add link to formulary in chapter 12.1.2.	Most of the recommendations in the updated guideline are consistent with current clinical practice and will not represent any change locally. However, some of the recommendations may represent a change to current local practice and require additional resources to implement. The size of the resource impact will need to be determined at a local level and will depend on service configurations and future uptake of the recommendations. Benefits derived from the change in practice may help offset some of the additional costs.	Approved

TA913: Mavacamten for treating symptomatic obstructive hypertrophic cardiomyopathy **Commissioning: NHSE** Mavacamten is recommended as an option for treating symptomatic obstructive hypertrophic cardiomyopathy in adults who have a New York Heart Association class of 2 to 3. It is recommended only if: • it is an add-on to individually optimised standard care that includes beta-blockers, non-dihydropyridine calcium-channel blockers or disopyramide, unless these are contraindicated, and the company provides it according to the commercial arrangement.	06/09/23	Not on formulary	Add to formulary as RED, with a link to TA913.	None for ICB as NHSE commissioned.	Approved

TA914: Pembrolizumab for previously treated endometrial, biliary, colorectal, gastric or small intestine cancer with high microsatellite instability or mismatch repair deficiency **Commissioning: NHSE** Pembrolizumab is recommended as an option for treating tumours with high microsatellite instability (MSI) or mismatch repair (MMR) deficiency in adults with: • advanced or recurrent endometrial cancer that has progressed during or after a platinum-based therapy, who cannot have curative surgery or radiotherapy • unresectable or metastatic gastric, small intestine or biliary cancer that has progressed during or after 1 therapy • colorectal cancer after fluoropyrimidine combination therapy, only if they cannot have nivolumab with ipilimumab. It is only recommended if: • pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if the cancer progresses, and the company provides it according to the commercial arrangement.	20/09/23	On formulary in chapter 8.1.5 as a RED drug, for other NICE-approved indications.	Add link to TA914 to formulary.	None for ICB as NHSE commissioned.	Approved

TA916: Bimekizumab for treating active psoriatic arthritis **Commissioning: ICS - 30 day implementation** Bimekizumab alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis (defined as peripheral arthritis with 3 or more tender joints and 3 or more swollen joints) in adults whose condition has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. It is recommended only if they have had 2 conventional DMARDs and: • at least 1 biological DMARD or • tumour necrosis factor (TNF)-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis). Bimekizumab is recommended only if the company provides it according to the commercial arrangement.	04/10/2023	*Not listed.*	Add to formulary as RED, with a link to TA916. Approved by NENC ICB Chief Pharmacist 19.10.23. as 30 day TA and within their level of delegated authority.	NICE expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 56.6 million people). This is because the technology is a further treatment option and is available at a similar price to the current treatment options. Bimekizumab works in a similar way to ixekizumab and secukinumab, and would be offered to the same population. Bimekizumab and the other treatment options have discounts that are commercial in confidence.	Approved

TA918: Bimekizumab for treating axial spondyloarthritis **Commissioning: ICS - 30 day implementation** Bimekizumab is recommended as an option in adults for treating active ankylosing spondylitis (AS) when conventional therapy has not worked well enough or is not tolerated, or active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation (shown by elevated C-reactive protein or MRI) when non-steroidal anti-inflammatory drugs (NSAIDs), have not worked well enough or are not tolerated. 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 it according to the commercial arrangement.	11/10/2023	*Not listed.*	Add to formulary as RED, with a link to TA918. Approved by NENC ICB Chief Pharmacist 15.11.23. as 30 day TA and within their level of delegated authority.	Resource impact template available. NICE expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 56.6 million people). This is because the technology is a further treatment option and the overall cost of treatment will be similar. The company has a commercial arrangement. This makes bimekizumab available to the NHS with a discount.	Approved

TA920: Tofacitinib for treating active ankylosing spondylitis **Commissioning: ICS 30 day implementation** Tofacitinib 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 tofacitinib according to the commercial arrangement.	18/10/2023	*RED drug for other NICE TA approved indications.*	Add to formulary as RED, with a link to TA920. Approved by NENC ICB Chief Pharmacist 15.11.23. as 30 day TA and within their level of delegated authority.	NICE expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 56.6 million people). This is because the technology is a further treatment option and the overall cost of treatment will be similar. Tofacitinib represents an additional treatment option for those patients with active ankylosing spondylitis, where tumour necrosis factor alpha inhibitors are not suitable or do not control the condition well enough and who would benefit from or prefer an oral treatment, as opposed to injectable treatments. Tofacitinib and some of the other treatment options have discounts that are commercial in confidence.	Approved
TA927: Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments **Commissioning: NHSE - 30 day implementation** Glofitamab is recommended, within its marketing authorisation, as an option for treating relapsed or refractory diffuse large B-cell lymphoma in adults after 2 or more systemic treatments. Glofitamab is only recommended if the company provides it according to the commercial arrangement.	17/10/2023	*Not listed*	Add to formulary as RED, with a link to TA927. Formulary updated approved by NENC ICB Chief Pharmacist 15.11.23. .	None for ICB as NHSE commissioned.	Approved

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NENC MEDICINES APPLICATIONS (decisions approved on medicines committee ICB directors' authority)				
Title	**Date recommended by NTAG**	**Summary of NTAG decision**	**Commissioning or financial implications**	**Decision taken by medicines subcommittee**
Riluzole Orodispersible Tablets (Emylif®). Treatment of MND	21/11/2023	For patients with swallowing difficulties where crushing tablets is not appropriate. Add to formulary as an AMBER Shared Care drug.	Modest cost savings. Bioequivalent to Riluzole 50mg tablets Cheaper than the Riluzole suspension.	Approved
Quinine Sulfate 300mg tablets-leg cramps	21/11/2023	Add to formulary as a GREEN drug. To be used for nocturnal leg cramps in accordance with MHRA advice. Inadvertently missed off during the formulary merger.	Likely to be cost neutral 300mg tablets cheaper than the 200mg tablets.	Approved
Adcal-D3 effervescent tablets and Cacit D3 sachets	21/11/2023	Add to formulary as GREEN drugs. Adcal-D3 effervescent tablets to be added to formulary along with Cacit D3 sachets (as a sodium free alternative). Calfovit D3 effervescent granules discontinuation	Likely to be cost neutral.	Approved
AquaGel (oil free) lubricating jelly	21/11/2023	Add to formulary as a GREEN drug. AquaGel (oil free) lubricating jelly to be added to the formulary, to relieve dryness of the nose, lips and the face when the patient is using oxygen via nasal prongs, CPAP masks etc. Oil free preparations should be used where there will be direct contact with oxygen on the face such as nasal prongs and CPAP masks.	Unknown - likely to be minimal.	Approved
Tadalafil 5mg daily - Erectile dysfunction (ED)	21/11/2023	Add to formulary as a GREEN drug. Tadalafil 5mg daily to be added to the formulary for general ED (in accordance with SLS criteria).	Likely to be minimal. Once daily tadalafil 5mg has been removed from the "Items which should not routinely be prescribed in primary care: policy guidance" due to its price now being comparable with the "as required" treatment.	Approved
Sodium Chloride 5mmol/ml oral solution	21/11/2023	Add to formulary as a GREEN+ drug.	Likely to be cost neutral.	Approved

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		Sodium Chloride 5mmol/ml to be added to the formulary in addition to the 1mmol/ml solution. This is to allow secondary care organisations to switch over. NPPG/RCPCH Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children recommends using the 5mmol/ml strength solution. Both the 5mmol/ml and 1mmol/ml solutions are now licensed; however, these are currently unavailable.		
Ciprofloxacin ear drops 0.2% - otitis externa	21/11/2023	Requested to change to GREEN from GREEN+ to allow prescribing in resistant cases in accordance with C&S results. Included in the NICE CKS guidelines. Not included in the NICE primary care antibiotic guidelines.	Unknown - likely to be minimal.	Approved
Midazolam 10mg/2ml - palliative care	21/11/2023	Requested to change to GREEN as first line for agitation, restlessness, and delirium in palliative care but is currently GREEN+ on formulary which prohibits GP prescription. First line in NENC palliative care guidelines for agitation, restlessness, and delirium.	Nil expected.	Approved
Immunosuppressants - solid organ transplants	21/11/2023	Recommended that the formulary status of solid organ transplant immunosuppressants to be RED until EPS is in place. This reflects what currently happens. Exception: Shared care guidelines need to remain in place for transplant patients in the community who require MDS boxes as NUTH currently does not have access to EPS to facilitate the required weekly scripts AND for those adult liver transplant patients who have not been repatriated.	Nil expected. NHSE commissioned when provided by Trusts. Repatriation of immunosuppressants for solid organ transplants started almost 10 years ago, but there is variable uptake across England. In NUTH - adult renal and adult cardiothoracic transplants have been repatriated. Adult liver transplant patients haven't been repatriated - to do so would require restructuring of the OPD clinics.	Approved
Anthelios Sunscreen Lotion SPF50+	21/11/2023	Recommended as replacement for Sunsense on formulary which has been discontinued.	Nil expected.	Approved

		To be used as AVBS criteria when prescribed for skin protection against ultraviolet radiation and/or visible light in abnormal cutaneous photosensitivity causing severe cutaneous reactions in genetic disorders (including xeroderma pigmentosum and porphyrias), severe photodermatoses (both idiopathic and acquired) and in those with increased risk of ultraviolet radiation causing adverse effects due to chronic disease (such as haematological malignancies), medical therapies and/or procedures	Anthelios lotion SPF 50+ (£12.50 for 250ml) Sunsense ultra lotion SPF 50+ (Ego Pharmaceuticals) £8.26 for 125ml)	
Teriparatide biosimilar Indication for which product is requested: (Biosimilar teriparatide only): Treatment of osteoporosis in postmenopausal women and in men who: • Are at very high risk and imminent risk of fracture as per NOGG (2021) guidelines • For first line use for secondary prevention in this specific group • Where romosozumab (NICE TA791) is either not indicated (all men) or contraindicated (women with significant CV disease)	21/11/2023	Recommend not to add to formulary for these indications but to await updated NICE guidance expected in January 2025. NTAG March 2023: NTAG agreed to recommend approval as a RED drug and to flag the cost/service implications to the Medicines Committee and ICB Executive for consideration. NENC Medicines Subcommittee April 2023: The committee was unable to support the recommendation made by NTAG concerning the use of teriparatide outside NICE guidance as per NOGG 2021 guidelines. It asked that further information pertaining to the cost impact and benefit of this use be returned to this committee if this application is to be pursued. Based on the information available and that provided in application not possible for NTAG/RDTC to produce a cost impact assessment that meets the ask of the NENC Medicines Subcommittee concerning the use of teriparatide outside NICE guidance as per NOGG 2021 guidelines. Note that no cost impact assessment provided by NOGG itself.	Nil expected as application rejected by NTAG.	Approved
North of Tyne, Gateshead and North Cumbria Urinary Catheter Care Product Formulary 2023	21/11/2023	Recommend approve the updated NoTGNC Catheter formulary. Similar formularies exist elsewhere in NENC. All four Trusts in NoTGNC involved in review and updating of this formulary.  NoTGNC Catheter Formulary 2023 V6.d	Nil expected. All products either in Drug Tariff, NHS Supply Chain approved or both	Approved

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NENC AHSN/Renal Network project proposal - Facts CKD Gateshead	21/11/2023	NTAG is minded to recommend approval on the clinical & operational aspects of the project because this is a pilot project to enable information gathering to support possible wider NENC rollout in the future. NTAG minded to support the overall aim of the project. NTAG noted the project hopes to address the following: • Concept of case finding via CDRC tools • CKD treatment optimisation – how this works in practice • Potential cost to roll out the project across the ICB and how this could be funded. • If a front-loaded approach to NICE TA implementation with funded pharmacist time could be used as a model across ICB. Following points raised during NTAG discussions: • ICB need a plan to minimise inequalities in future if this pilot project proves to be successful. Inequality is inevitable across a range of issues not just CKD Ideally would use PCN/practice pharmacists but they have competing work priorities which would hinder the delivery of this project. Every practice has the offer of pharmacist roles via ARRS funding for PCNs. • Decision to do pilot project in a single locality should be based on CKD risk factors not just because a pharmacy provider is linked in that particular area. There may be other providers that could do this work. • Discussed how Gateshead has been chosen for project due to: ○ High levels of health inequality/deprivation across ICB. ○ Population representative of other areas across ICB with high levels of deprivation. ○ Availability of Pharmacius to deliver pilot project in practices they are already familiar with. ○ The percentage change in proportion of people receiving Renal Replacement Therapy (RRT) in Gateshead is the second highest in ICB when benchmarked against other CCG boundaries in NENC	No ICB funding required for this pilot project in Gateshead. Drug costs expected by project team to be no greater than those already approve for the associated NICE TA (Dapagliflozin for treating chronic kidney disease TA775, March 2022). Project does not take into account cost of other therapies for CKD being maximized (e.g. ACEi/ARBs). Cost modelling based on SGLT2i only. This pilot project designed to collect data on potential savings that could be achieved due to improved patient outcomes which could offset any increases in drug costs, and costs associated with staff resource to deliver the project. Some concerns expressed that majority of funding for project comes from Astra Zeneca.	Medicines Subcommittee acknowledged this pilot project and wished to receive regular project updates.

		region. • Empagliflozin is also licensed for CKD and NICE TA expected in December 2023. Project claims no preferred choice of SGLT2i (dapagliflozin or empagliflozin) should be prescribed. Local guidelines should be followed and this will be highlighted to project pharmacists. • Project has exit strategy and following completion of project will use outcomes including cost/cost savings identified to seek ICB approval for roll out across NENC.		

APPLICATIONS SUBMITTED DIRECTLY TO MEDICINES SUBCOMMITTEE FOR CONSIDERATION			
Title	**Summary of request**	**Commissioning or financial implications**	**Decision from medicines subcommittee**
None			

MEDICINES SUBCOMMITTEE MINUTES (for publication to the NTAG website)	
Medicines Subcommittee minutes October 2023	