NHS
North East and
North Cumbria

SUMMARY OF MEDICINES SUBCOMMITTEE DECISIONS

Decisions made by: NTAG	**May 2024**	
Approved by: Medicines Subcommittee	**10th June 2024**	
For consideration by: NENC executive	**See highlighted items** **For all other items 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.

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 WITH A SIGNIFICANT FINANCIAL OR COMMISSIONING IMPACT					
NICE Technology Appraisal/Guidance/Drug	**Date published**	**Current formulary status or pathway/ guidance relevance**	**Recommendation**	**Commissioning & financial implications**	**Status**
TA958: Ritlecitinib for treating severe alopecia areata in people 12 years and over **Commissioning: ICS, tariff excluded** Ritlecitinib is recommended, within its marketing authorisation, as an option for treating severe alopecia areata in people 12 years and over. Ritlecitinib is only recommended if the company provides it according to the commercial arrangement.	27/3/2024	*Not listed.*	Add to formulary as a RED drug in this indication, with links to TA958.	Ritlecitinib is expected to be a long-term treatment for a chronic condition. It is anticipated prescribing will be from dermatology services. Use of ritlecitinib may lead to a reduction in non-pharmacological interventions such as wigs from dermatology or NHS services and psychological support. NICE expect around 25 adults and adolescents per 100,000 population to be eligible each year. At list price, the estimated cost is around £55,000 to £65,000 per year per 100,000 population. However a PAS is available with a confidential discount. A resource impact template is available. The number of patients eligible for this could be quite high and have already seen a lot of old AA patients being referred back for consideration of treatment etc. In addition, there is no real cost saving either as rarely use anything to treat it otherwise, and if we do it is usually a very cheap drug such as methotrexate. It will also place a much larger burden on overstretched specialist nurses for follow up appointments. In addition to cost of drug need to factor in capacity due to regular blood tests every 3months, follow up appointments with specialist nurses and manpower to deal with prescribing and management of prescriptions will raise a number of commissioning issues.	Formulary decision deferred.

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DECISIONS WITHOUT A SIGNIFICANT FINANCIAL OR COMMISSIONING 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**
TA949: Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over **Commissioning: NHSE** Belumosudil is recommended, within its marketing authorisation, for treating chronic graft-versus-host disease in people 12 years and over after 2 or more systemic treatments. It is recommended only if the company provides it according to the commercial arrangement.	7/2/2024	*Not currently listed.*	Add to formulary as a RED drug in this indication, with link to TA949. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved
TA950: Nivolumab–relatlimab for untreated unresectable or metastatic melanoma in people 12 years and over **Commissioning: NHSE** Nivolumab–relatlimab is recommended as an option for untreated advanced (unresectable or metastatic) melanoma in people 12 years and over, only if: • nivolumab–relatlimab is stopped after 2 years of treatment, or earlier if the cancer progresses, and • the company provides it according to the commercial arrangement.	7/2/2024	*Not currently listed.*	Add to formulary as a RED drug in this indication, with link to TA950. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved

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TA951: Olaparib with abiraterone for untreated hormone-relapsed metastatic prostate cancer **Commissioning: NHSE** Olaparib with abiraterone and prednisone or prednisolone is recommended, within its marketing authorisation, as an option for untreated hormone-relapsed metastatic prostate cancer in adults who cannot have or do not want chemotherapy. It is only recommended if the company provides it according to the commercial arrangements.	7/2/2024	*Listed as RED drug as per other NICE TAs.*	Add to formulary as a RED drug in this indication, with link to TA951. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved
TA952: Talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations **Commissioning: NHSE** Talazoparib is recommended, within its marketing authorisation, for treating HER2-negative, locally advanced or metastatic breast cancer with germline BRCA1 or BRCA2 mutations in adults who have had: • an anthracycline or a taxane, or both, unless these treatments are not suitable, and • endocrine therapy if they have hormone receptor (HR)-positive breast cancer, unless this is not suitable. Talazoparib is only recommended if the company provides it according to the commercial arrangement.	21/2/2024	*Not currently listed.*	Add to formulary as a RED drug in this indication, with link to TA952. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved

TA954: Epcoritamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments **Commissioning: NHSE** Epcoritamab is recommended as an option for treating relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in adults after 2 or more systemic treatments, only if: • they have had polatuzumab vedotin, or if polatuzumab vedotin is contraindicated or not tolerated, and • the company provides epcoritamab according to the commercial arrangement.	6/3/2024	*Not listed.*	Add to formulary as a RED drug in this indication, with links to TA954. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved
TA955: Dupilumab for treating moderate to severe prurigo nodularis **Commissioning: ICS, tariff excluded** Dupilumab is not recommended, within its marketing authorisation, for treating moderate to severe prurigo nodularis in adults when systemic treatment is suitable.	13/3/2024	*RED drug as per other NICE TA approved indications.*	Consider adding to Not Recommended / Do Not Prescribe lists in this indication.	No cost impacted expected as not recommended by NICE.	Approved
TA957: Momelotinib for treating myelofibrosis-related splenomegaly or symptoms **Commissioning: NHSE** Momelotinib is recommended as an option for treating myelofibrosis-related splenomegaly or symptoms in adults with moderate to severe anaemia who have not had a JAK inhibitor or have had ruxolitinib, only if: • they have intermediate-2 or high-risk myelofibrosis, and • the company provides momelotinib according to the commercial arrangement.		*Not listed.*	Add to formulary as a RED drug in this indication, with links to TA957. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved

TA959: Daratumumab in combination for treating newly diagnosed systemic amyloid light-chain amyloidosis **Commissioning: NHSE** Daratumumab plus bortezomib, cyclophosphamide and dexamethasone is recommended as an option for treating newly diagnosed systemic amyloid light-chain (AL) amyloidosis in adults. It is recommended only if: • daratumumab is stopped after 24 cycles of treatment, or earlier if the condition progresses, and • the company provides daratumumab according to the commercial arrangement.	27/3/2024	*RED drug as per other NICE TA approved indications.*	Add to formulary as a RED drug in this indication, with links to TA959. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved
TA960: Satralizumab for preventing relapses in neuromyelitis optica spectrum disorders (terminated appraisal) **Commissioning: NHSE** NICE is unable to make a recommendation about the use in the NHS of satralizumab for preventing relapses in neuromyelitis optica spectrum disorders. This is because Roche Products has confirmed that it does not intend to make an evidence submission for the appraisal. Roche Products considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources for this population.	27/3/2024	*Not listed.*	Add to Not Approved list in this indication.	None for ICB as NHSE commissioned.	Approved

TA961: Sebelipase alfa for treating lysosomal acid lipase deficiency that is not Wolman disease (terminated appraisal) **Commissioning: NHSE** NICE is unable to make a recommendation about the use in the NHS of sebelipase alfa for treating lysosomal lipase deficiency that is not Wolman disease. The Wolman disease population was evaluated separately in NICE highly specialised technology guidance on sebelipase alfa (HST30). The cost effectiveness of the remaining non-Wolman population has not been demonstrated at this stage.	28/3/2024	*Not listed*	Consider adding to Not Approved list in this indication.	None for ICB as NHSE commissioned.	Approved
TA962: Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy **Commissioning: NHSE** Olaparib is recommended, within its marketing authorisation, as an option for maintenance treatment of BRCA mutation-positive, advanced (FIGO stages 3 and 4), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to first-line platinum-based chemotherapy in adults. It is only recommended if the company provides it according to the commercial arrangement.	28/3/2024	*RED drug as per other NICE TA approved indications.*	Add to formulary as a RED drug in this indication, with links to TA962. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	None for ICB as NHSE commissioned.	Approved

TA965: Human alpha1-proteinase inhibitor for treating emphysema (terminated appraisal) **Commissioning: NHSE** After ongoing discussions between NICE and CSL Behring UK, NICE is unable to make a recommendation about the use of human alpa1-proteinase inhibitor for treating emphysema in the NHS. CSL Behring UK has confirmed that it does not intend to launch the product in England and Wales. The reasons for this decision are primarily related to the company's inability to offer the product at a price to meet the current threshold of cost effectiveness.	28/3/2024	*Not listed.*	For information.	For information. Product not expected to launch in England and Wales.	Approved
TA878: Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 (update) **Commissioning: ICS, tariff excluded** In March 2024: • after a partial review of this guidance, NICE updated the recommendation on nirmatrelvir plus ritonavir to include additional groups eligible for treatment NICE removed the recommendation on casirivimab plus imdevimab because the conditional marketing authorisation for casirivimab plus imdevimab was withdrawn.	13/3/2024	*Listed as RED drugs.*	For information.	In 2023, around 570,000 new cases of people with COVID-19 were recorded in England (Gov.uk). It's important to note that this data only extends until December 13, 2023, and the actual number of cases may be higher due to changes in recording practices. For people who are aged 70 years and over, or who have a body mass index (BMI) of 35 kg/m^2 or more, diabetes or heart failure, the normal period of compliance has been extended to 15 months to 1st June 2025. This is because NHS England, on behalf of ICBs, submitted a funding variation request for this expanded population, which was accepted by NICE after a period of public consultation.	Noted separate paper with ICB re future NENC service provision and expansion of eligible cohort of patients.

NG239: Vitamin B12 deficiency in over 16s: diagnosis and management **Commissioning: ICS, local authorities** This guideline covers recognising, diagnosing and managing vitamin B12 deficiency in people aged 16 and over, including deficiency caused by autoimmune gastritis. It also covers monitoring for gastric cancer in people with autoimmune gastritis. Includes recommendations on use of oral vitamin B12 for some groups (e.g. deficiency that is not caused by autoimmune gastritis, or a total gastrectomy or complete terminal ileal resection, deficiency that is a side effect of taking a medicine, recreational use of nitrous oxide, or dietary deficiency).	6/3/2024	*Link already including in the formulary.*	Add links to NG239 to formulary. Noted that update NENC ICB guideline in development.	NICE expect that the resource impact of this guideline: • for any single guideline recommendation in England will be less than approximately £1,800 per 100,000 population, and • for implementing the whole guideline in England will be less than approximately £8,800 per 100,000 population,. This is because any cost from an increase in testing and treatment is likely to be offset by savings and benefits from referrals to secondary care and investigations avoided, and the unit cost for the interventions are small. Commissioners and providers should consider that the increase in testing and diagnosis will happen in primary care while the savings from reduced referrals and earlier treatment and diagnosis will happen in secondary care when implementing this guideline. This statement is supported by a local resource impact template.	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**
Bupropion – Resistant Depression	21.5.2024	To add this indication to the formulary as GREEN Plus - subject to an information sheet being produced and the patients staying under regular review. Request from TEWV / CNTW to change the RAG status from RED to GREEN Plus for resistant depression. It was GREEN+ previously before recent supply issues with Zyban® which have now been resolved. Off label use. Patients had been repatriated during the supply issue with Zyban® in order to allow continued treatment (with an unlicensed preparation).	Overall usage small low so cost impact likely to be small	Approved
Aflibercept 8mg intravitreal injection (Eyelea®) – wAMD & DMO	21.5.2024	To add this additional formulation of aflibercept to the formulary as a RED drug. Longer interval between injections compared to the 2mg preparation.	Some cost savings expected. The 8mg preparation costs the same as the 2mg preparation. It is up to individual Trusts to balance the potential interim savings / benefits to capacity against the larger potential savings that may result from the 2mg biosimilar preparations (anticipated in 2025).	Approved
Phenobarbital liquid preparations	21.5.2024	Formulary to specify that the 50mg / 5ml alcohol free oral solution (unlicensed) (e.g. Rosemont) should be used in all children (<18yrs) who require a liquid preparation. Classed as GREEN Plus on the formulary already. Licensed 15mg/5ml product contains 38% alcohol so is not suitable for use in children.	Minimal cost impact expected.	Approved
Codeine Linctus 15mg/5ml	21.5.2024	GREEN - cough suppression in palliative care patients unable to take tablets.	Minimal cost impact expected.	Approved

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		Request from Sunderland MO team to add to formulary for cough suppression in palliative care patients unable to take tablets.		
Dapsone - dermatology	21.5.2024	To change from GREEN+ to AMBER shared care. No change to formulary status to be made a shared care guideline is approved. Request to review the RAG status of dapsone for dermatology indications such as dermatitis herpetiformis and bullous pemphigoid. Was AMBER shared care on the Durham and Tees Valley formulary and GREEN Plus on the North of Tyne, Gateshead and North Cumbria Formulary. Given a GREEN Plus status during the merge. Requires monitoring similar to DMARDs so therefore more suitable to shared care status.	Nil expected in terms of drug costs. To ensure included in ongoing discussions around shared care drugs within ICB, and costs associated with it becoming a shared care drug considered as part of this. No change to formulary status to be made until these discussions conclude, and a shared care guideline is approved.	Approved
Liothyronine formulations	21.5.2024	Remove strengths / formulations from formulary and add statement that the most cost effective strength / formulation should be used.	Some cost savings	Approved
Levetiracetam injection	21.5.2024	GREEN Plus for palliative care Levetiracetam injection currently has a RED status however it is included in the regional palliative care guidelines.	Minimal cost impact expected.	Approved
Colesevelam – bile acid malabsorption	21.5.2024	GREEN Plus and for second line use after cholestyramine. Colesevelam had a GREEN Plus status but was changed to GREEN as a result of the supply issues with cholestyramine. Patients are presumed to have bile acid malabsorption on the basis of history, pending confirmatory tests and are often recommended to start a trial of treatment in the interim. Colesevelam is often started in preference to cholestyramine in secondary care as it is better tolerated. The ICS is an outlier for both colesevelam and cholestyramine use.	No cost impacted as reflects current prescribing practice.	Approved
Testosterone 20 mg/g Transdermal gel (Testavan®)	21.5.2024	GREEN Plus - Not for low libido in menopausal / post-menopausal women due to the testosterone dose contained in each actuation being too high. Topical testosterone preparation that is the cheapest of the available options. Hands free applicator. Testim® has been discontinued.	Some cost savings	Approved
Mitomycin eye drops	21.5.2024	To change from GREEN+ to RED.	Nil	Approved

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		Currently listed as a GREEN+ medicine. As an unlicensed, cytotoxic, treatment the group agreed this should be supplied solely by secondary care.		
Lactulose preparations	21.5.2024	Formulary to specify the liquid formulation only. Request to specify that the lactulose sachets shouldn't be used as these are significantly more expensive than the liquid.	No cost impact expected.	Approved
Aripiprazole and paliperidone long acting injections (LAI)	21.5.2024	The NTAG guidelines for aripiprazole and paliperidone should be stood down and these treatments should be used in accordance with NICE CG178. On formulary as per NTAG guidance i.e. only to be used in patients who have failed to respond to first generation antipsychotic depots or for whom these treatments are unsuitable. Paliperidone is off patent and aripiprazole is due to go off patent soon. NICE CG178 does not differentiate between first and second generation antipsychotic treatments.	No cost impact expected.	Approved
NENC Adult headache guideline	21.5.2024	Recommend approval of this new NENC ICB wide guideline that existed previously in parts of the NENC.	Access to CGRP Mab/ antagonist / Botox treatments for headache may differ between Trusts within the ICB. No significant cost impact expected as reflects current prescribing practice and relevant NICE TAs which have previously been approved by the ICB.	Approved
NENC Type 2 diabetes guideline in adults	21.5.2024	Recommend approve use of this updated guideline. The following technical updates are presented for approval to reflect the latest relevant NICE TAs; • Update with addition of new section for newly licensed medication Tirzepatide in line with new NICE TA. • Update to SGLT2 section to reflect new licensed indications and NICE TA's for Empagliflozin in preserved ejection fraction heart failure and CKD, which includes simplification of the licensed indication table. • Addition of link to a new SGLT2 decision recently published. • Update to links to include updated advice on GLP-1 shortage.	No cost impact expected as reflects current prescribing practice and relevant NICE TAs which have previously been approved by the ICB.	Approved

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		• Removal of SGLT2 and metformin combination section to reflect formulary advice. Updates have been fully consulted on across NENC Diabetes Network and have their approval. This included input from GPs in primary care. It has been agreed that full NTAG consultation is not required as this is technical update to reflect latest NICE TAs previously approved by the ICB.		
NENC Hydroxychloroquine shared care guideline	21.5.2024	Recommend approval of this shared care guideline across the NENC which is based on the recently reviewed/updated RDTC SCG template for hydroxychloroquine. To replace the following current documents across the NENC: • North of Tyne, Gateshead and North Cumbria Area Prescribing Committee • Hydroxychloroquine Shared Care Guidance for patients within adult services Approved Sep 2022. Expires Sep 2025 • County Durham & Darlington Hydroxychloroquine SCG May 2028. Expired Nov 2020 • South Tyneside & Sunderland SCG Hydroxychloroquine sulfate for use in Rheumatology. Dec 2019. Expired Dec 2022.	No cost impact expected as reflects current prescribing practice and ophthalmological montoring services that are commissioned across the NENC.	Approved
NTAG CGM Recommendation – update re Dexcom ONE+ and Freestyle Libre 2+	21.5.2024	Recommend approval of this updated NTAG recommendation on continuous glucose monitoring (CGM) to include the latest versions of Freestyle Libre 2 and Dexcom One. To also approve the addition of sentence that Freestyle Libre 3 should not be prescribed by primary care as approved at the March 2024 of NTAG.	No cost impact expected as updated versions cost the same per year per patient as current versions. Await further information from both companies on how current patients will be switched to updated versions. Until then patients should remain on the version they were initiated on.	Approved

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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 April 2024	