SUMMARY OF DECISIONS FOR APPROVAL

Decisions made by: CRG (except those * which were made at GMMMG)	**9th January 2024**
Approved by: GMMMG	**8th February 2024**
Approved by: CEGC	**5th March 2024**
Approved by: Executive	**March 2024**

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
Carbimazole 10mg and 15mg tablets For all indications	Carbimazole is available as a 5mg, 10mg, 15mg and 20mg tablet. The 5mg and 20mg tablets are of low cost and are on the GMMMG formulary. The 10mg and 15mg are not listed on the formulary and have been of extremely high cost for several years.	Add to DNP list with criterion 2 (Products which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation)		During the period Sep 22 – Aug 23 there was 4404 items prescribed in the GM ICB for the 10mg and 15mg tablets at a cost of £154k It is estimated a complete switch to 5mg tablets would save £149k per year in prescribing costs	Approve the amendment to the DNP list and recommends localities review usage

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Acetylcysteine 600mg effervescent tablets and Carbocisteine 375mg capsules For COPD	The oral mucolytic of choice for reducing sputum viscosity in respiratory tract disorders is carbocisteine. During 2022-23 97% of prescribing was of carbocisteine. Acetylcysteine 600mg effervescent tablets are a cost-effective alternative when taken once daily, and do not require a dose reduction It is recommended that reviews are undertaken for patients who have been prescribed a mucolytic for longer than 4-12 weeks to assess benefit. Treatment should be stopped where no benefit is apparent.	Assign a Green status to both acetylcysteine 600mg eff tablets carbocisteine 375mg capsules Amend formulary to place acetylcysteine 600mg eff tablets as first choice mucolytics and carbocisteine 375mg capsules as an alternative choice	The effervescent tablets are not suitable for patients who require a low sodium diet. This will be reflected in the formulary. Carbocisteine capsules (or oral solution) would remain a treatment option for these patients. Blanket switching is not recommended but use of mucolytics in COPD should be regularly reviewed and only continued if there is symptomatic improvement.	The GM ICB spends £1.8m on mucolytics each year. Exact cost savings are not possible due to the variation in dose of carbocisteine currently being prescribed. However where 750mg tds dosing is being used there is a 32% saving by using acetylcysteine 600mg eff tablets.	Approve the amendment to formulary

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TA916: Bimekizumab for treating active psoriatic arthritis **Commissioning: ICS, tariff-excluded, 30-day implementation** 4th October 2023	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..	On formulary in chapter 13 as a RED drug for treatment of plaque psoriasis Add to formulary in chapter 10.1.3 as a RED drug in this indication, with links to TA916.		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 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.	Approve addition to formulary

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TA918: Bimekizumab for treating axial spondyloarthritis **Commissioning: ICS, tariff-excluded, 30-day implementation** 11th October 2023	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.	On formulary in chapter 13 as a RED drug for treatment of plaque psoriasis. Add to formulary in chapter 10.1.3 as a RED drug in this indication, with links to TA918.		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 technology is a further treatment option and the overall cost of treatment will be similar.	Approve addition to formulary

TA919: Rimegepant for treating migraine **Commissioning: ICS, tariff-excluded** 18th October 2023	Rimegepant is recommended as an option for the acute treatment of migraine with or without aura in adults, only if for previous migraines: • at least 2 triptans were tried and they did not work well enough or triptans were contraindicated or not tolerated, and nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol were tried but did not work well enough.	Add to formulary as a Green medicine drug in this indication, with link to TA919. Rimegepant is already on formulary as Green (specialist initiation) for the prevention of episodic migraine (TA906). A further consultation has opened to amend this to Green (specialist advice)	CRG did not agree with the NICE assessment of resource impact and felt that this is likely to be significantly higher due to it offering an alternative treatment option prior to specialist referral. CRG heard that this is a condition principally managed in primary care and as such patients would not routinely be referred to a specialist at the point in the pathway that NICE have placed this agent. Following the consultation where it was proposed this should be Green (specialist advice, CRG heard from the headache service lead clinician who successfully reasoned that this medicine and indication is amendable to management in primary care and should have a Green RAG status. An update to the headache pathway is underway to support primary care prescribing of this agent	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 rimegepant is a further treatment option and is for use after other options have been tried or are contraindicated or not tolerated. In the preventing migraine setting, rimegepant and other treatments (such as galcanezumab [TA659], erenumab [TA682] and fremanezumab [TA764]) are also recommended. In clinical practice, when a person is having migraines sufficiently often to benefit from a preventative effect, there is a reasonable likelihood that they will be having 1 of the approved preventative treatments which have the same mechanism of action to rimegepant for preventing migraine. Given there is current use of rimegepant and its position in the pathway, it is not anticipated there will be a significant resource impact as a result of this guidance.	Decision pending GMMMG request that a decision on this agent is paused so that both licensed indications (treatment (TA919) and prophylaxis TA906) can be managed simultaneously, with the required supporting information to ensure safe and effective use in line with the license and TA recommendations. Supporting information for TA906 is currently being consulted on by the GM system N.B this action will delay the NICE timeframes for implementation of TA919

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			for this indication.		
TA920: Tofacitinib for treating active ankylosing spondylitis **Commissioning: ICS, tariff-excluded, 30-day implementation** 18th October 2023	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.	On formulary in chapter 10 as a RED drug for treatment of RA and PsA. Add to formulary in chapter 10.1.3 as a RED drug in this indication, with links to TA920.		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. 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.	Approve addition to formulary for this indication

TA922: Daridorexant for treating long-term insomnia **Commissioning: ICS** 18th October 2023	Daridorexant is recommended for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if: • cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or • CBTi is not available or is unsuitable. The length of treatment should be as short as possible. Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, assess whether it is still working at regular intervals.	Not on formulary. Formulary recommendation pending pathway development	CRG noted that current provision of CBTi is not equitable with it commissioned in 3 GM localities only. and cannot support the population who are eligible to receive this. Further information on an NHSE procurement process for CBTi for all ICBs is awaited. It is understood that this will involve a digital offer accessible without referral via a web link and will be free of charge for up to 12 months for each patient who requires it. The license is for treatment of long-term insomnia but data for use longer than 3 months is poor, as is information regarding dependence and efficacy versus existing treatments, therefore a pathway is required. Training is recommended prior to clinicians prescribing the medicine, this is provided by the manufacturer of daridorexant which CRG thought was a conflict of interest. Clinical trials excluded	NICE estimate that around 1,760 adults with insomnia per 100,000 population are expected to be eligible for treatment each year. NICE expect providers to mainly be GPs. The cost impact is estimated to be up to £350k in year 1 and £2m by year 5 which does not include the displacement of existing therapeutic options. NICE estimate that 2 hours of training time will be required for each GP prior to prescribing daridorexant which will have a resource cost to the ICS.	GMMMG request the development of a GM wide primary care sleep pathway to support the equitable introduction of this agent into the GM system, detailing availability of CBTi across GM. GMMMG noted that approval without a supporting pathway posed a significant financial risk and requests additional resource from the ICB (via CEGC) to develop this pathway GMMMG recommend that this agent be added to the GM formulary upon approval of the GM sleep pathway and wish to make CEGC aware that NICE timeframes will not be met whilst this pathway is pending.

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			any patients taking psychotropic medicines despite this group comprising a large proportion of those treated with BDZs and Z-drugs. Therefore its use in patients with mental health conditions required treatment with prescribed psychotropic medicines is not recommended		

TA924: Tirzepatide for treating type 2 diabetes **Commissioning: ICS** 25th October 2023	Tirzepatide is recommended for treating type 2 diabetes alongside diet and exercise in adults when it is insufficiently controlled only if: • triple therapy with metformin and 2 other oral antidiabetic drugs is ineffective, not tolerated or contraindicated, and • they have a body mass index (BMI) of 35 kg/m^2 or more, and specific psychological or other medical problems associated with obesity, or • they have a BMI of less than 35 kg/m^2, and: ○ insulin therapy would have significant occupational implications, or weight loss would benefit other significant obesity-related complications.	Not on formulary. Add to formulary in chapter 6.1.2.3 as an alternative to GLP-1 inhibitors where these are ineffective, not tolerated or contraindicated with a GREEN RAG status. Include links to TA924.	There is as yet no stock available of this medicine in the UK, despite it being licensed as a vial and pre-filled syringe. A further product license is pending for a pre-filled pen and the granting of this marketing authorisation by the MHRA is the current limiting factor to UK availability. CRG heard that it is positioned in the same place as GLP-1 inhibitors within the T2DM treatment pathway but has yet to gain any evidence for CVD benefits unlike the majority of GLP-1s. Historically choice of GLP-1 has been based on the availability and quality of CVD outcome data, but with the stock issues affecting GLP-1 products likely to continue into mid 2024, tirzepatide is likely to be selected because of its availability rather than proven CVD benefits. Confirmation of the suitability of this position and place in therapy is being sought from the GM Diabetes	NICE estimate that around 320 people per 100,000 population are eligible for treatment with tirzepatide. However, depending on the local prevalence of type 2 diabetes and current prescribing patterns for GLP-1 RAs, this could be an underestimate. Adjusting for the known prevalence of T2DM and current GLP-1 prescribing patterns, there may be around 13,000 people eligible for either tirzepatide or a GLP-1 RA in GM. Depending on market share, the cost impact of tirzepatide may be around £76,000 in year 1, rising to £1m per year from year 3 onwards. This includes anticipated reductions in use of GLP-1 RAs, but not any reduction in adverse outcomes associated with T2DM. These figures are highly dependent on future prescribing patterns of tirzepatide and the GLP-1 RAs, and should be interpreted cautiously. The ongoing GLP-1 RA shortages are expected to have a significant impact.	Approve addition to formulary

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact and commissioning / service implications	GMMMG recommendation
			Strategy Board, but there has been no engagement from the group with this process.		
TA925: Mirikizumab for treating moderately to severely active ulcerative colitis **Commissioning: ICS, tariff-excluded, 30-day implementation** 25th October 2023	Mirikizumab is recommended as an option for treating moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or lost response to treatment, only if: • a tumour necrosis factor (TNF)-alpha inhibitor has not worked (that is the condition has not responded well enough or has lost response to treatment) or • a TNF-alpha inhibitor cannot be tolerated or is not suitable and the company provides it according to the commercial arrangement.	Not on formulary. Add to formulary in chapter 1.5.3 as a RED drug in this indication, with links to TA95.		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 mirikizumab is a further treatment option and the overall cost of treatment for this patient group will be similar.	Approve addition to formulary GM pathways require update to ensure the most cost effective agents are utilised accordingly

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TA943: Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes **19/12/2023** **Commissioning: NHSE** .	Hybrid closed loop (HCL) systems are recommended as an option for managing blood glucose levels in type 1 diabetes for adults who have an HbA1c of 58 mmol/mol (7.5%) or more, or have disabling hypoglycaemia, despite best possible management with at least 1 of the following: • continuous subcutaneous insulin infusion (CSII) • real-time continuous glucose monitoring • intermittently scanned continuous glucose monitoring. HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England, and implemented following NHS England's and NHS Wales' implementation plans.	Begin planning for implementation. Consider whether links to the guidance or a holding statement should be added to formulary in the meantime. The formulary position should reflect the NICE TA as well as any associated NHSE SSCs.	There has been no consultation yet on this guidance as a recommendation is yet to be made. CRG believe that this planning should sit with the Diabetes Strategy Board and ICB commissioners. An implementation plan has been made available from NHSE to support ICB planning for the introduction of this technology.  PRN01097_Hybrid closed loop technol	Access to hybrid closed loop systems will therefore be through a 5-year phased roll out in line with NHS England's and NHS Wales' implementation plans. Hybrid closed loop systems will be commissioned via NHS England or NHS providers in line with the 5-year strategy. The normal period of compliance has been extended to 5 years for this technology because NHS England submitted a funding variation request, which was accepted by NICE after a period of public consultation. A resource impact template is available, as well as a guide to using the template. The template requires local completion with information including annual number of clinic appointments, time per clinic appointment, staff mix and device costs for each relevant technology.	Note the content of the recommendations from NICE and request that the ICB diabetes strategy board undertake the planning 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	GMMMG Recommendation
Nil in Jan 2024					

DECISIONS FOR INFORMATION ONLY

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
Blueteq forms to support the use of omalizumab for chronic inducible urticaria (CindU)  Blueteq forms for unlicensed use of o	Use of omalizumab for this indication should be in line with the GMMMG commissioning statement	N/A	The forms have been developed in conjunction with the 2 services looking to use the medicine for this indication based at Salford and Wythenshawe. CRG approved for use noting that because of a lack of expertise on CRG, the best governance route for future decisions similar to this would be via a HCDs subgroup to GMMMG.	None
TA926: Baricitinib for treating severe alopecia areata **Commissioning: ICS, tariff-excluded** 25th October 2023	Baricitinib is not recommended, within its marketing authorisation, for treating severe alopecia areata in adults. .	On formulary in chapter 10 for rheumatology indications Add to DNP list with criterion 1 (Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns)		Hair loss can cause severe psychological distress, but baricitinib did not show a meaningful improvement in most of the health-related quality-of-life assessments done in the trials compared with placebo. The cost-effectiveness estimates for baricitinib are uncertain and are higher than what NICE normally considers an acceptable use of NHS resources. So, baricitinib is not recommended.

Drug and indication	Rationale / criteria	Status and formulary position assigned	Notes on decision	Cost impact
TA921: Ruxolitinib for treating polycythaemia vera **Commissioning: NHSE** 18th October 2023	Ruxolitinib is recommended, within its marketing authorisation, for treating polycythaemia vera in adults who cannot tolerate hydroxycarbamide (also called hydroxyurea) or when the condition is resistant to it. It is only recommended if the company provides it according to the commercial arrangement.	For info, no action.	N/A	Resource impact template available NICE estimate that: • Around 660 people with polycythaemia vera are eligible for treatment with ruxolitinib each year from 2027/28 after adjusting for population growth. • Around 330 people will receive ruxolitinib from year 2027/28 onwards once uptake has reached 48% If the number of appointments follows the number of cycles, there may be around 700 additional appointments needed each year from 2027/28 after adjusting for population growth. This is because of shorter treatment cycles (28 days) compared with some comparator options.
GM Non-medical prescribing best practice guide  	This document is intended to detail the essential governance standards that NHS GM expect providers to have in place with regards to non-medical prescribing (NMP).	GMMMG support approval	This guidance was developed by Jude Owens (NMP Lead Salford Locality) and Stephanie Pacey (NMP Lead Manchester Locality) and has been considered and supported by the GM NMP leads group, the GMMMG workforce subgroup and GMMMG.	N/A

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GMMMG Jan 24 minutes  GMMMG Minutes Jan 24 fnl.pdf	-	-	-	-
CRG Dec 23 minutes  CRG Minutes Dec 2023 FINAL.pdf				
Medicines safety, value, digital and population health subgroup updates  Medicines Value update.docx  Jan 24_Medicines Safety Update.docx  HI Highlight Report Nov and Dec 2023.do  Digital Highlight Report 2023.docx				

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All links to MHRA drug safety updates added to formulary as published. Significant alerts where further action is required are highlighted.				

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