# SUMMARY OF DECISIONS FOR APPROVAL

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| **Decisions made by: CRG (except those * which were made at GMMMG)** | **8th August 2023** |
| **Approved by: GMMMG** | **14th September 2023** |
| **Approved by: CEGC** | **27th September 2023** |
| **Approved by: Executive** | **4th October 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 |
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| ***GM GLP1 Clinical Model Pathway – amendments to the GMMMG formulary**<br><br>GM GLP1 Pathway FINAL 18-Sep-23.pdf | A GLP1 oversight group as part of the GM diabetes strategy board has developed the attached temporary pathway in response to the shortage of GLP1 agents. GMMMG has accepted the temporary changes proposed and agreed to reflect these in the formulary. | Changes have been approved to the GMMMG formulary (through CRG and GMMMG Chairs action) to reflect this pathway. These will be reviewed in due course when supply issues are resolved. | GMMMG support the temporary clinical positioning of these agents in response to the current shortage of GLP1 agents. | To be provided to CEGC by the GLP1 oversight group. GMMMG has not been provided as it was only asked to support the revisions to the formulary as per the temporary pathway. | GMMMG support the publication of this pathway and have made temporary revisions to the GMMMG formulary to reflect the pathway.<br><br>It is understood that representation from the GM diabetes strategy board will simultaneously seek approval for this pathway from CEGC and the diabetes strategy board who meet at the same time. |

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| ***Semaglutide for use in overweight or obesity** | On 20th March 2023, NICE issued a positive Technology Appraisal for the use of semaglutide for managing overweight and obesity. (TA875). However, at that time, no stock nor exact pricing information was available.<br>On 4th September and without any prior notice, the NHS was informed by Novo Nordisk®, the manufacturer of semaglutide (brand name Wegovy®), that limited stock would be available to the NHS in a "controlled and limited launch". Information from the Press indicates there will be sufficient stock to treat 50,000 people nationally so that would mean about 3,000 in Greater Manchester. Note: at the time of writing there have been no official communications from NHS England. | On formulary as a RED drug | The drug was added to the GMMMG Formulary as 'Red' i.e. only for prescribing within secondary care or specialist services following the usual CRG / GMMMG processes.<br><br>At its August meeting, GMMMG noted that is likely to be a requirement of the ICB to review and commission further service capacity in order to meet the statutory obligations of this TA. | While the price of semaglutide for weight loss is subject to a commercial arrangement, it is estimated that treating 3,000 people will cost just under xxxx per annum (N.B this figure is commercially sensitive and not for wider sharing or publication). This is a locality financial pressure as weight management services are commissioned locally. Weight management service capacity is likely to be the limiting factor in permitting patient access.<br>Novo Nordisk has committed to providing stock for this number of NHS patients.<br>Health Innovation Manchester recently undertook a survey of capacity within weight management services and we hope to obtain information regarding their findings shortly.<br>Applying NICE's Resource Impact Report to the GM population estimates that 1236 people will receive semaglutide in 2022/23 (sic), rising to 2958 by 2027/28. Note however that the total population eligible to receive semaglutide is 200,000-250,000 although NICE believes the vast majority will choose to treat their obesity through diet and exercise.<br>As service capacity is likely to be limited, GMMMG / GM ICB may wish to consider prioritising certain groups for treatment first e.g. those with a BMI over 40 + / - co-morbidities.<br>A condition of the NICE TA is that treatment is continued for a maximum of 2 years. However, it appears that after stopping treatment people put back on some | GM ICB should review and may need to commission further service capacity in order to meet the statutory obligations of this TA.<br><br>GMMMG understand there are a number of different weight management service providers currently commissioned across GM, and that an assessment of service capacity may have been started by the ICB, but GMMMG are not linked into this assessment. |

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| | | | | or all of the weight lost. | |
| **Hydrocortisone 0.5 ointment, 2.5% cream and 2.5% ointment** 15g pack for all indications | A review by Oldham locality MO team has demonstrated that there is a large amount of prescribing of these products which have a limited place in therapy and are significantly more expensive than alternative low potency topical steroid products. Their use is not in line with current best practice recommendations in BNF/BNFc and are not on the GMMMG formulary. More cost-effective products exist both as mild or moderately potent steroids if a step up is required.<br>The recommendation has received local dermatology support and the consultation seeks to expand this to GM support for the proposal. | It is proposed that 0.5% ointment, 2.5% cream and 2.5% ointment are assigned a DNP status (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) | CRG recognised that there are more cost-effective products available such as 1% cream and ointment and recommend that any switches of the 0.5% are to one of these products. Where the 2.5% is being used the patient should be stepped down if their condition is under control or if a more potent steroid is required an alternative formulary product would be clobetasone 0.05% (Eumovate) or betamethasone 0.025% (Betnovate RD) | 0.5% and 2.5% ointment is priced at £44 per 15g, 2.5% cream £52.97.<br>In comparison 1% cream and 1% ointment is £0.99 and £2.51 per 15g pack.<br>GM spent £240k over the last 12 months on the 3 products listed. A 100% switch to the alternatives listed would release savings of up to £230k per year. | Approve addition to DNP list |
| **Infliximab (Remsima) 120mg solution for injection in pre-filled syringe/pen** for Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis in line with the NICE TA for IV infliximab and the GMMMG HCDs pathways | The subcutaneous version of this NICE approved drug offers increased patient choice and may provide some savings by releasing day case and aseptics capacity.<br>The relevant NICE TAs are: TA187, TA199, TA329, TA375, TA383, TA715 | Add to chapters 1 & 10 as a RED drug | An audit of use in GM has identified that a number of trusts are already using this product despite it having no formulary position. A retrospective formulary request seeks to address this.<br>The majority of use is for the gastroenterology indications<br><br>CRG acknowledged the increased homecare service burden but were informed that the nursing (training and ad hoc visits where needed) and delivery bundle are funded by the manufacturer. | Infliximab IV 100mg powder for concentrate for solution for infusion vial = £377.66<br>Infliximab SC 120mg per 1ml solution for injection pre-filled pen/syringe = £755.32 (pack of 2)<br>Due IV dosing being weight based, and the existence of local contract prices, the cost comparison is complex. Calculations provided by one of the GM trusts show savings of £1-2k per patient per year, depending on patient weight, assuming standard 8-weekly dosing, use of outsourced infusion bags and when factoring in the cost of day case attendances.<br>There may also be resource implications for providers to consider if a switch programme is implemented | Approve addition to formulary |

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| **Vedolizumab (Entyvio) 108mg solution for injection in pre-filled syringe/pen** for Crohn's disease and ulcerative colitis in line with relevant NICE TAs and the GMMMG HCDs pathways | The subcutaneous version of this NICE approved drug offers increased patient choice and may provide savings by releasing day case capacity.<br>The relevant NICE TAs are: TA342 and TA352. | Add to chapter 1 as a RED drug | An audit of use in GM has identified that a number of trusts are already using this product despite it having no formulary position. A retrospective formulary request seeks to address this.<br><br>CRG acknowledged the increased homecare service burden but were informed that that the nursing (training and ad hoc visits where needed) and delivery bundle are funded by the manufacturer. | Drug only costs for the sc preparation are the same as the IV version and any change is therefore expected to be cost neutral. There are likely to be opportunities for service efficiencies on reduced day case attendances and clinical resource.<br>Day case costs have been estimated as £400-450 per infusion.<br>There may also be resource implications for providers to consider if a switch programme is implemented | Approve addition to formulary |
| **TA888: Risankizumab for previously treated moderately to severely active Crohn's disease**<br>**Commissioning: ICS, tariff-excluded, 30 day TA**<br>17/05/23 | Risankizumab is recommended as an option for treating moderately to severely active Crohn's disease in people 16 years and over, only if:<br>• the disease has not responded well enough or lost response to a previous biological treatment, or<br>• a previous biological treatment was not tolerated, or<br>• tumour necrosis factor (TNF)-alpha inhibitors are not suitable.<br>Risankizumab is only recommended if the company provides it according to the commercial arrangement. | On formulary in chapter 13 for moderate to severe plaque psoriasis and chapter 10 for psoriatic arthritis as RED drugs<br>Add to formulary in chapter 1 as a RED drug in this indication, with link to TA888 | | Because risankizumab has been available through the early access to medicines scheme, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication or the date that the on-body device receives CE marking (if this is later).<br>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.<br>The first 3 doses of risankizumab are administered by IV in a secondary care setting, thereafter it is administered by subcutaneous injection by people themselves in their home. Where risankizumab displaces the use of intravenous (IV) vedolizumab there will be capacity savings in the maintenance phase. | Approve addition to formulary and RAG status |

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| **CG181: Cardiovascular disease: risk assessment and reduction, including lipid modification** (update)<br>**Commissioning: ICS**<br>24/05/23 | In May 2023, NICE reviewed the evidence and made new/updated recommendations on risk assessment tools for primary prevention of CVD, cardioprotective diets, and statin treatment for primary and secondary prevention of CVD. | Atorvastatin is listed on formulary as a Green drug<br>Add links to CG191 on formulary | CRG noted the uptake of these recommendations are likely to be slow as acknowledged by NICE, so the impact is likely to be smaller than anticipated.<br>This is partly because primary care advised that there is no capacity for case finding and anecdotally patients at this CVD risk threshold are less likely to agree to be treated with lipid lowering therapy. | The estimated cost per 100,000 population is £5,000 in year one, increasing to £10,000 in year 5. Of these, £1,000 per 100, population in year 1 and £7,000 in year 5 are cash impacts, and the remainder are non-cash.<br>The resource impact estimate does not include NHS and social care post event savings, but the resource template allows users to model these savings at a local level.<br>Resource impacts are expected from:<br>• an increase in primary care prescribing budgets for statins<br>• an increase in GP consultations for statin therapy<br>• an increase in follow-up appointments for people receiving statins (at 3 months of starting treatment and annual reviews)<br>• a decrease in CVD events and the associated secondary and primary care costs | Note the resource impact and the capacity of primary care to implement the recommendations. |
| **NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)**<br>**Commissioning: NHSE, ICS**<br>11/05/23 | In May 2023, NICE reviewed the evidence on glucose-lowering agents for managing blood glucose levels in children and young people with type 2 diabetes. Updates include new or amended recommendations on:<br>• education and information at diagnosis<br>• monitoring blood glucose levels (including real-time and intermittently-scanned continuous blood glucose monitoring) and reviewing treatment<br>• when to reduce insulin for people who have been on it | All medicines recommended are currently on formulary for adults for this indication as Green drugs. CGM provision is currently being reviewed by the GM ICB executive<br>Add links to NG18 to formulary alongside liraglutide, dulaglutide, and empagliflozin.<br><br>The new recommendations on the use of CGM for children and young adults with T2DM will be | | NICE expects that the resource impact of this update:<br>• for any single guideline recommendation in England will be less than approximately £1,800 per 100,000 population, and<br>• for implementing the whole guideline in England will be less than approximately £8,800 per 100,000 population.<br>This is because the prevalence of type 2 diabetes in the paediatric population identified in this review is relatively low.<br>Increased support from a | Note the resource impact of the guidance |

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| | from diagnosis<br>• adding liraglutide, dulaglutide, or empagliflozin<br>• insulin therapy<br>changing treatments and updating healthcare plans. | considered for GM adoption as part of the existing work. | | paediatric diabetic nurse and consultant may be needed when a child or young person starts glucose-lowering agents or a CGM device for managing blood glucose levels. | |

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| * An easy read leaflet Valproate; A guide for people who can become pregnant<br>Easy Read Valproate version 6.pdf | National valproate patient resources are not available in alternative languages to English or easy read format. The Medicines safety subgroup acknowledged this gap as part of its valproate safety improvement work.<br>Bury locality has produced an easy read leaflet Valproate; A guide for people who can become pregnant that can be adopted across the Integrated Care System (ICS). | N/A | GMMMG asked that the leaflet be refined with support and approval from the GM ICB comms team, this has been undertaken. Chairs approval has been granted following this action. | Nil | Approve for publication to GMMMG website and onward dissemination. |
| Hypertension Pathway supporting documentation<br>HTN supporting table V3 FINAL.docx<br>HYP Medication Pathway Supporting | Approved via chairs action on 01.09.23<br><br>These contain factual information to support prescribers using the hypertension pathway with their choice of antihypertensive medicines and to reiterate NICE guidance recommendations. | N/A | | None | Accepted |
| **NG198: Acne vulgaris: management (update)** | In May 2023, NICE clarified their recommendations on oral isotretinoin treatment in line with the 2020 MHRA reminder of important risks and precautions, and the 2023 | Isotretinoin is on formulary in chapter 13 as a RED drug due to | | None expected; update reflects current practice. There may be implications when the new MHRA safety measures are introduced. | Accepted |

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| **Commissioning: ICS**<br>17/05/23 | MHRA advice on new safety measures to be introduced in the coming months following the April 2023 report of the Commission on Human Medicines Isotretinoin Expert Working Group.<br>NICE will further update their guidance when the recommendations on new safety measures for isotretinoin come into effect across the healthcare system. | safety concerns in pregnancyn. | | | |
| **NG232: Head injury: assessment and early management**<br>**Commissioning: ICS, NHSE**<br>18/05/23 | This guideline covers assessment and early management of head injury in babies, children, young people and adults. It aims to ensure that people have the right care for the severity of their head injury, including direct referral to specialist care if needed.<br>This guideline updates and replaces NICE guideline CG176 (January 2014).<br>• NICE have reviewed the evidence on pre-hospital interventions, assessment and management in the emergency department, and discharge and follow up, including follow up of people with a head injury and normal scans for deterioration. | Add tranexamic acid injection to the formulary as a RED drug for this indication | | Depending on current local practice, recommendations/areas which may require additional resources and result in additional costs include:<br>• Using tranexamic acid for isolated head injuries (recommendation 1.3.17). This is expected to increase tranexamic acid use by paramedics. The cost of using tranexamic acid as a result of this recommendation is not expected to be significant at a national level, but more resources might be needed for treatment, rehabilitation and care for the people who would not have survived without tranexamic acid. The committee identified there was a benefit with tranexamic acid in terms of reducing all-cause mortality and mortality from traumatic brain injury.<br>• CT head scan for people who have sustained a head injury and are on anticoagulant or antiplatelet treatment but have no other indications for a CT head scan (recommendation 1.5.13). Clinical opinion indicates there may be an overall increase in the number of scans. The recommendation wording has changed in this update from 'offer' to 'consider' for people with a head injury who are on anticoagulants and have no other indication for imaging but has been expanded to include people with a head injury who are on antiplatelet treatment.<br>Implementing the guideline may lead to the following benefits:<br>• A reduction in the number of people with an isolated skull fracture who are admitted for observation. It is expected that many of these people could be discharged from the | Accepted |

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| | | | | emergency department without admission to hospital unless there are other indications for admission (recommendation 1.9.1).<br>Better health outcomes and care experience. | |
| *Primary care rebate schemes | 1. Rebate for Vizidor & Vizidor Duo Glaucoma PCRS<br>2. Rebate for Viscotears 0.1% drops and Viscotears Treha Duo | N/A | These savings do not meet the rebate ethical framework threshold of £50,000 savings across GM.<br>It is proposed that this rebate is rejected on this basis | Below financial threshold for consideration | GMMMG support rejection of this PCRS |
| *GMMMG August minutes | PDF<br>GMMMG Minutes August 23 fnl.pdf | N/A | N/A | N/A | GMMMG request permission to publish to GMMMG website |

## DECISIONS FOR INFORMATION ONLY

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| **TA882: Voclosporin with mycophenolate mofetil for treating lupus nephritis**<br>**Commissioning: NHSE**<br>03/05/23 | Voclosporin with mycophenolate mofetil is recommended, within its marketing authorisation, as an option for treating active class 3 to 5 (including mixed class 3 and 5, and 4 and 5) lupus nephritis in adults. It is only recommended if the company provides voclosporin according to the commercial arrangement. | Add to formulary as a RED drug in this indication, with link to TA882. | | A resource template is available. NICE estimate that:<br>• 12,800 people with lupus nephritis are eligible for treatment with voclosporin with mycophenolate mofetil (MMF)<br>• In year 2027/28, once the market share of voclosporin with MMF has reached 10%, around 520 people will start treatment and around 760 people will continue treatment from previous years.<br>• From the trial data, the average time people receive treatment is 36 months.<br>Where uptake of voclosporin with MMF displaces treatments delivered by intravenous infusion there are potential cost savings and capacity benefits |
| **TA885: Pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer**<br>**Commissioning: NHSE**<br>03/05/23 | Pembrolizumab plus chemotherapy with or without bevacizumab is recommended for use within the Cancer Drugs Fund as an option for treating persistent, recurrent or metastatic cervical cancer in adults whose tumours express PD-L1 with a combined positive score (CPS) of at least 1. It is recommended only if:<br>• pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if disease progresses, and<br>the conditions in the managed access agreement for pembrolizumab are followed. | All anti-cancer drugs with a positive NICE Health Technology Appraisal are approved for use in Greater Manchester. | | The resource impact of pembrolizumab plus chemotherapy with or without bevacizumab will be covered by the Cancer Drugs Fund budget. More evidence on pembrolizumab plus chemotherapy with or without bevacizumab is being collected until the final results of the KEYNOTE-826 trial are available. After this, NICE will decide whether or not to recommend it for use on the NHS and update the guidance. It will be available through the Cancer Drugs Fund until then. |
| **TA886: Olaparib for adjuvant treatment of BRCA mutation-positive HER2-negative high-risk early breast cancer after chemotherapy**<br>**Commissioning: NHSE**<br>10/05/23 | Olaparib (alone or with endocrine therapy) is recommended, within its marketing authorisation, as an option for the adjuvant treatment of HER2-negative high-risk early breast cancer that has been treated with neoadjuvant or adjuvant chemotherapy in adults with germline BRCA1 or 2 mutations. It 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. | | Resource template available. By 2027/28 NICE estimate that:<br>• 300 people with HER2-negative high-risk early breast cancer with germline BRCA 1 or 2 mutations are eligible for treatment with olaparib based on expected population growth<br>290 people will receive olaparib from year 3 onwards once uptake has reached 95% |

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| **TA887: Olaparib for previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer**<br>**Commissioning: NHSE**<br>10/05/23 | Olaparib is recommended, within its marketing authorisation, as an option for treating hormone-relapsed metastatic prostate cancer with BRCA1 or BRCA2 mutations that has progressed after a newer hormonal treatment (such as abiraterone or enzalutamide) in adults. Olaparib 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. . | | 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 overall incremental cost of treatment is low.<br>Olaparib is an oral treatment and therefore where it replaces the use of intravenous comparator treatments, such as cabazitaxel, there will be a capacity benefit from a reduced number of chemotherapy administration appointments required. The average treatment duration for olaparib is slightly longer than comparator treatments, and therefore there may be additional outpatient oncology appointments for monitoring patients receiving treatment. |
| **TA890: Difelikefalin for treating pruritus in people having haemodialysis**<br>**Commissioning: NHSE**<br>17/05/23 | Difelikefalin is recommended, within its marketing authorisation, for treating moderate to severe pruritus in adults with chronic kidney disease (CKD) having in-centre haemodialysis. Difelikefalin is only recommended if the company provides it according to the commercial arrangement. | Add to formulary as a RED drug in this indication, with link to TA890 | | 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 cost of treatment is relatively low.<br>There are no capacity concerns expected as a result of treatment with difelikefalin as it is administered at the same time as having dialysis. |
| *GM Antimicrobial stewardship highlight report | GM AMS Priorities<br>1. To optimise prescribing of antimicrobials for children in primary care, focussing on what activities will have the biggest impact across the GM population<br>2. To optimise the prescribing of antimicrobials in urinary tract infections (UTIs) in adults and children focussing on what activities will have the biggest impact across the GM population.<br>3. To optimise the prescribing of IV antibiotics in secondary care | Identified Issues and/or Risks:<br>1. Lack of infrastructure and support<br>2. Capacity of attendees in all task and finish group<br>3. High prescribing across primary care | | GMMMG wish to highlight to CEGC that this group requires support if it is to make any progress in delivering its work plan. |

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