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Cheshire and Merseyside Area Prescribing Group

New Medicine Assessment Summary

# Drug name

# Indication or proposed use

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| **Recommendation:** [Only complete recommendation after discussion and agreement at NMSG]**Proposed RAG rating**: **[RAG]****Rationale:** [Brief paragraph summarising basis of decision] |
| **Summary of supporting evidence**Effectiveness[Complete to assist discussions at NMSG]Safety[complete to assist discussions at NMSG]Cost[complete to assist discussions at NMSG]Implementation considerationsBullet key points from the body of the assessment that support the recommendation. The summary should accurately reflect the text and not introduce any new information. Structure the points in a logical way Highlight strengths and weaknesses of the supporting evidence.Indicate advantages or disadvantages, clinical or practical, compared to existing therapies. Include potential benefits for the patient such as convenience e.g. route, administration schedule, monitoring requirements.Highlight cost implications. |

### **Author details**

### Current review

|  |  |
| --- | --- |
| Author |  |
| Email address |  |
| Organisation |  |
| NMSG discussion date |  |
| NMSG recommended position |  |

Previous review [delete if not applicable]

|  |  |
| --- | --- |
| Author |  |
| Email address |  |
| Organisation |  |
| NMSG discussion date |  |
| NMSG recommended position |  |

## Background and context

### What is the purpose of the application?

Summarise what change is required and why. What is the reason for this application?

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| Briefly describe what the medicine is and its indication. Outline existing treatment options. Briefly outline NICE guidance recommendations relevant to the therapeutic area, or in the absence of NICE, other national, international or best practice guidance.Summarise reason for application and why has this been identified as a priority.  |

## Medicine

### Generic name, brand name (if applicable) and manufacturer

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| Click or tap here to enter text. |

###  Formulation, strength and presentation

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| Click or tap here to enter text. |

### Dose, frequency, course length and administration route

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| Click or tap here to enter text. |

### BNF therapeutic class / mode of action

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| Use BNF wording and section number or SmPC description. |

### Licensed indication(s)

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| Click or tap here to enter text. |

## Place in therapy

### Will the proposed drug replace an existing drug on the formulary?

If YES, please say which drug it is replacing and describe why this new product should be used in preference. Consider patent expiry dates of the products being replaced by this proposed medicinal product.

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| Click or tap here to enter text. |

### Will the proposed drug be an additional option to an existing drug on the formulary?

If YES, please say which drug it is in addition to and describe why this new product should also be available as an option.

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| Click or tap here to enter text. |

### Is this drug routinely used as an add-on therapy (at an additional cost) to an existing treatment?

If YES, what are the other treatment options? Please indicate clearly, where within the current drug pathway the product should be used.

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| Click or tap here to enter text. |

### What is the applicant’s proposed position RAG status in the formulary?

Refer to the [RAG definitions and criteria](https://www.cheshireandmerseyside.nhs.uk/media/5yzo3tzp/definitions-and-criteria-for-categorisation-of-medicines-in-the-cheshire-and-merseyside-formulary.pdf). Please note that RAG status refers to the drug not the condition being treated.

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## Relevant guidance

###  Relevant NICE guidance

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| List relevant NICE guidance including NG, CG, TAs and MTAs. |

### Other relevant national or local guidance

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| Click or tap here to enter text. |

## Application

### Which local groups, networks and provider trusts has this application been discussed with and supported by?

Applications should not be made by an individual or organisation in isolation without involving other groups, networks and local provider trusts as appropriate. Please state the details of the discussion and the outcome.

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| Has this application been approved by a Clinical Group across the Cheshire and Merseyside system? If so, state the details of the group and of the outcome.Has this application been approved by the directorate finance manager? Has this application been discussed with and supported by local networks and other provider trusts? Please add details. |

## Appropriateness

### Is there a potential alignment with a local or national strategic commissioning goal?

If so, please state the details.

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### What impacts will this treatment have on the environment?

For example, does it help optimise prescribing by reducing the demand for other medicines? Is this a lower carbon alternative to an existing medicine, for example, dry powder inhaler? Would approving this application help the ICS to deliver on its NHS Green agenda objectives? Does this medicine have a positive impact on global warming potential?

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## Prescribing

### What setting is this drug proposed to be prescribed?

Consider initiation and continuation prescribing. For example, out-patient clinics, primary care, general practice.

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### Is this medicine excluded from the NHS Payment Scheme?

Previously known as the Payment by Results tariff (PbR)

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| Click or tap here to enter text. |

### Have prescribing guidelines been produced?

If YES, please attach or provide a hyperlink.

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### Will this medication have any prescribing or commissioning restrictions?

For example, microbiological advice or consultant use only, requires completion of a Blueteq form.
If YES, what are the restrictions?

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| Click or tap here to enter text. |

Are there any prescribing or risk management issues?
These include but are not limited to contraindications, cautions, interactions, monitoring, patient support materials required, administration / storage / disposal requirements, toxicity / harm in overdose, prescribing restrictions

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| ContraindicationsCautionsInteractionsMonitoringPatient support materials required Administration / storage / disposal requirementsToxicity / harm in overdosePrescribing restrictions |

## Patient factors

### Specify any relevant patient factors.

These include but are not limited to renal impairment, hepatic impairment, elderly, pregnancy and breast feeding, other

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| Renal impairment Hepatic impairment ElderlyPregnancy and breast feedingOther |

## Clinical effectiveness

### Summarise the evidence for efficacy of the product in proposed use

Summary points should include clinical outcomes; numbers needed to treat (NNT’s); quality-of-life measures; how the outcomes might extrapolate on the system population level. Discuss evidence versus placebo and versus current therapies where possible.

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| *Include in this section*A brief description of the trials and the primary results. Use the table (at the end of this document) to present more details of the trials. It can be helpful to complete the table early in the drafting process; this will identify key elements of a study and determine whether it is relevant to the review. * Indicate the source of the information (e.g. published PIII RCT, conference abstracts/posters).
* Quote outcomes as absolute risks and/or numbers needed to treat (NNTs) if appropriate, rather than relative risks. Do not rely on published NNTs - re-calculate.
* Include details of any patient impact assessments if possible e.g. quality of life studies.

*Source of evidence*Use a reliable secondary source as basis for the review, if available (e.g. NICE evidence summary, SMC or AWMSG guidance). Ensure it is current (i.e. no new data have been published since it was produced) and relevant. Acknowledge the origin of the evidence assessment e.g.“This evidence review draws largely on that produced by the Scottish Medicines Consortium (SMC) in December 2013 [4].”Use systematic reviews/meta-analyses if available. Ensure they have identified all relevant trials and the included trials are of good quality, or as a minimum, a quality assessment of included trials has been done and the influence of low quality trials on the results has been assessed.Use the EPAR if available. This describes trials used to support licensing and highlights limitations and safety issues. Use in combination with any published reports of included and additional studies. Use fully published PIII randomised controlled trials (RCTs) where available.*What to describe*Read papers thoroughly and conduct a fair, independent critical evaluation of the data and representation of the results. Think PICO (Population, Interventions, Comparators and Outcomes).**P**opulation - Consider inclusion criteria AND exclusion criteria. Has the trial excluded important patient groups? Do included patients reflect those likely to be treated in local practices e.g. same age, similar risks, and similar treatment histories? **I**nterventions & **C**omparators - Is the intervention used in the same dose, formulation etc as the licensed medicine? Is the comparator the most relevant comparator in practice? Is it a placebo or active comparator? Is the comparator used in a way that reflects clinical practice e.g. dose, administration schedule – under-dosing reduces efficacy, overdosing increases adverse events **O**utcomes – Focus particularly on primary outcomes. Are they patient- or disease (surrogate)-oriented outcomes? Are they relevant outcomes? Do they match the outcomes preferred by the EMA (or FDA) for the particular disease or condition? Were the scoring systems validated? Were the reported outcomes pre-specified or have analyses been done ad-hoc? Strengths and limitations of the evidence:Highlight issues identified from your appraisal of the evidence. This may include size (population) and duration of studies; comment of the choice of outcome and comparator; how the results were presented; the face validity of studies and the relevance to your local population.State what evidence is not available that would have been relevant to clinical practice and to the decision problem.Think about trial design and analysis of results:*Assessing the evidence*Trial design - What type of study was it? Was it adequately controlled? Was the study randomised - was the randomisation method described and appropriate? Was there a pre-randomisation study phase and what was the purpose of it? Were all potential subjects exposed to the study drug and only those who tolerated it then randomised? How was the study ‘blinded’? Were there any factors that might have jeopardised blinding e.g. was the active drug associated with a high frequency of a particular adverse effect?If the study is a systematic review/meta-analysis, is it from a credible source, e.g. Cochrane, or critiqued on the DARE / CRD database? Is the protocol specified; literature search thorough; inclusion/exclusion criteria relevant and explicit; quality of included studies assessed; clinical or statistical heterogeneity present; is it reasonable to combine data? Analysis of results - Were patients in study groups comparable? Were sufficient numbers recruited (is there a power calculation)? What was the drop-out rate and were all drop-outs accounted for? How are the results reported – intention to treat or per protocol? Is the study credible? What is the quality of the results? How relevant are they to clinical practice? Are confidence intervals quoted (or other means of describing precision of a measurement)? For non-inferiority studies, is the non-inferiority margin reasonable and explained? |

### Strengths and limitations of the evidence for efficacy of the product in proposed use

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| Click or tap here to enter text. |

### Could the product improve overall effectiveness of the pathway?

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| Click or tap here to enter text. |

## Cost-effectiveness

### Summarise the evidence for cost effectiveness of the product in proposed use

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| Do not attempt a *de novo* cost effectiveness analysis! Identify UK independent cost effectiveness analyses from a reputable HTA organisation e.g. NICE, SMC, AWMSG. If available, report their recommendations and check for stated reasons for the recommendations. Was the estimate of cost effectiveness considered to be reliable? To what assumptions was the estimate most sensitive? In the absence of the above, consider other published reports, but note that these may have been conducted in different countries, operating different health care systems, and may not be relevant to the UK.Manufacturers’ estimates presented in marketing materials rarely provide enough information to conduct a proper critique and may not have been independently peer reviewed. Use as a last resort and highlight uncertainties.  |

### Strengths and limitations of the evidence for cost effectiveness of the product in proposed use

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| Click or tap here to enter text. |

### Could the product improve overall cost-effectiveness of the pathway?

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| Click or tap here to enter text. |

## Other evidence

### Summarise the evidence for efficacy of the product and safety data in other use

If relevant, include brief details of other efficacy and safety data with some relevance to the decision problem. For example, use of lixisenatide in dual therapy when the focus of the review is use in triple therapy. Include strengths and limitations of the evidence.

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## Affordability

### Cost of the product (excluding VAT)

Include primary care cost and secondary care costs. Specify if listed prices are branded or generic. Specify pack sizes.

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| Click or tap here to enter text. |

### Comparative cost of existing alternative treatments

Please state comparative costs for each existing treatment option. Use most cost-effective comparator which may be branded or generic. Include primary care cost and secondary care costs. Specify if listed prices are branded or generic. Specify pack sizes

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| Briefly comment on the acquisition costs of the medicine and relevant comparators.• Tabulate actual costs. • Add footnote to table of where costs obtained from and date of the source. |

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| **Drug**  | **Example regimen** | **Pack cost** | **Cost per patient per course/ per year (ex VAT)** |
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| Costs based on NHSBSA dm+d list prices DATE. \*add dm+ d infoThis table does not imply therapeutic equivalence of drugs or doses. |

### Associated additional costs or available discounts

For example, monitoring costs or patient access schemes.

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### Estimated number of patients to be treated per annum and net budget impact

Based on Cheshire and Merseyside population of approx. 2.7M

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| Outline estimates of the incidence and/or prevalence of the disease/condition per 100,000 population. Useful sources include local public health observatories, patient registries, NICE costing templates. Use information above to assess net budget impact. Quote cost per 100,000 population as a minimum.Local data can added by individual Places. For example, this may include likely uptake figures derived from ePACT data. |

### What is the financial cost or saving resulting from the introduction of the product?

Please include drug costs and other relevant costs / savings (e.g. capacity saving)

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### If there is a cost pressure, can this be offset by a reduction in expenditure on anything else?

Please specify, for example, could the use of this medicine improve secondary care capacity?

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## Implementation

### Briefly outline impact on service delivery

For example, are there any productivity gains or losses, will use of this medicine free up nursing time, can it be delivered in primary rather than secondary care, will implementation of the proposal require significant effort and resource? If wide-scale switching and monitoring is required, would the benefits of the proposal offset these?

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| To include:Implementation requirementsImplementation monitoringImpact on systemImpact on existing workload, pathways or expertiseWorkforce capacity |

## Access to treatment

### Will access for the whole of Cheshire and Merseyside be equitable?

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| Click or tap here to enter text. |

### Are there any cross-border issues?

For example, RAG status in neighbouring areas.

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## Innovation and need

### Highlight issues relating to innovation, special needs of the population, wider benefits

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| Focus on additional or mitigating circumstances that are not captured in the efficacy, safety or cost effectiveness estimates.An innovative medicine will have demonstrated a step change in treatment, or significantly improved patient experience, productivity, etc. |

## Ethics

### Are there any ethical considerations?

For example, will this treatment have an impact on health inequalities or protected groups, or could the treatment improve productivity in the population or help maintain independence?

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| Click or tap here to enter text. |

## Supplementary information

### Any additional background information relevant to application (optional)

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| Click or tap here to enter text. |

## References

### Any additional background information relevant to application (optional)

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| Reference all sources cited. Number the references in the order they appear in the text. Place the citation number in the text at the end of the appropriate sentence in [brackets], before the full stop. For studies, list the first three authors, followed by ‘et al’ if there are more than three. Give the full title of the article, using US spelling if in the original. This is followed by the title of the journal, year of publication, volume number and first and last page numbers. References to books should include names of the authors, any editors, the title, edition, place of publication and year. For references accessible via the web include a web address together with the date accessed.Examples of format for common types of references using human readable hyperlink:1. Sanofi. Summary of Product Characteristics; [Lyxumia 20 micrograms solution for injection](https://www.medicines.org.uk/emc/product/2966/smpc), 05 May 2021. Accessed online 06 September 2022. National Institute for Health and Care Excellence.
2. NICE Guideline [NG] 87; [Type 2 diabetes in adults: management](https://www.nice.org.uk/guidance/ng28), 29 June 2022. Accessed online 06 September 2022.
3. Scottish Medicines Consortium. [Dapagliflozin (Forxiga) for the treatment in adults of chronic kidney disease (AstraZeneca UK Ltd)](https://www.scottishmedicines.org.uk/medicines-advice/dapagliflozin-forxiga-full-smc2428/), 09 May 2022. Accessed online 06 September 2022.
4. European Medicines Agency. [European Public Assessment Report; Lyxumia](https://www.ema.europa.eu/en/documents/assessment-report/lyxumia-epar-public-assessment-report_en.pdf), 28 November 2012. Accessed online 06 September 2022
 |

Table: Summary of key drug RCTs relevant to use in xxxxxxxxxxxxx

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| --- | --- | --- | --- | --- | --- |
| **Ref** | **Trial design**  | **Trial population and treatment** | **Primary outcome**  | **Key secondary / exploratory outcomes** | **Grading of evidence\* / risk of bias** |
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| Footnotes |

The aim of the table is to present details of the trials in a concise manner. Some information may need repeating in the text. The table should be fully explanatory so that it can be understood without reference to the text. If necessary a key should be included. The table may be adapted as necessary but should include the following data as a minimum: ref no, trial design, trial population, treatment regimen, primary outcomes. Additional headings which may be required include: inclusion/exclusion criteria, secondary outcomes, comments.

Use the Strength of Recommendation Taxonomy (SORT) criteria below to grade each included study in terms of strength of evidence it provides and add the grading level (1, 2 or 3) to the right-hand column of the table above. Also include what the risks of bias are (e.g. Patient oriented outcome? No. Blinded? Yes, but single-blind.)

**Grading of evidence (based on SORT criteria):**

See [Strength of Recommendation Taxonomy (SORT): A Patient-Centered Approach to Grading Evidence in the Medical Literature](https://www.aafp.org/pubs/afp/issues/2004/0201/p548.html#:~:text=An%20A%2Dlevel%20recommendation%20is,or%20case%20series%20for%20studies) for more information regarding grading evidence according to SORT.

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| **Level 1** | Patient-oriented evidence from:* high quality randomised controlled trials (RCTs) with low risk of bias
* systematic reviews or meta-analyses of RCTs with consistent findings
 | **Patient-oriented (PO) evidence** includes: cardiovascular events, mortality, hospitalisation rate, quality of life, symptoms. But note, some PO outcomes may depend on local practice (eg rates of revascularisation) or on criteria for assessing the outcome eg symptomatic fracture vs radiograph fracture. Appraise how outcomes are assessed. **Duration**: Is the trial long-enough to assess the outcome? **Bias**: Assess following factors when considering bias: * Blinding/masking: double blind (low risk of bias but are there any specific characteristics eg side effects, that might help identify treatment arm to assessor/patient); single-blind (observer blind – potential risk of bias, but have steps been taken to minimise bias eg central adjudication of endpoints?); open-label = high risk of bias (but sometimes unavoidable. Extension studies to assess safety are often open-label).
* Method of allocation. Is it described? If not then there is a risk of bias. Most studies these days have reasonable methods of allocation ie random allocation using computer generated sequences vs patients seen on a Tuesday will get….
* Power: always check if there is a power calculation. Trials that are too small increase bias.
* Analysis: Intention to treat (ITT) or modified ITT (is modification reasonable?) are best (except for non-inferiority trials where Per Protocol analysis is less likely to over-estimate treatment effect and both ITT and PP analysis should be presented and be in agreement).
* Follow-up: Are over 80% of patients accounted for at the end of the trial? If not bias may be an issue.
 |
| **Level 2** | Patient-oriented evidence from:* clinical trials at moderate or high risk of bias
* systematic reviews or meta-analyses of such clinical trials or with inconsistent findings
* cohort studies
* case-control studies
 |
| **Level 3** | Disease-oriented evidence or evidence from:* consensus guidelines
* expert opinion
* case series
 | Disease-oriented (DO) evidence eg blood pressure, HB1Ac levels. But note that these are widely accepted outcomes and may be required by regulatory authorities. |

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