COVID-19 tixagevimab/cilgavimab (Evusheld) pre-exposure prophylaxis National Expert Group: Terms of Reference

Background

Tixagevimab/cilgavimab (Evusheld) has recently been has recently been issued a Conditional Marketing Authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) for COVID-19 prevention in people whose immune response is poor.

Tixagevimab/cilgavimab (Evusheld) is authorised to be used before being exposed to the risk of COVID-19 infection in order to prevent disease (known as 'pre-exposure prophylaxis'). Tixagevimab/cilgavimab (Evusheld) is a combination of two long-acting antibodies that works by binding to the spike protein on the outside of the SARS-CoV-2 virus. This in turn prevents the virus from attaching to and entering human cells.

A national expert group will be established to discuss the evidence and explore to the suitability of tixagevimab/cilgavimab (Evusheld) for an interim clinical commissioning policy. This interim clinical commissioning policy will be developed by the National Clinical Policy Team at NHS England and Improvement, with input from the national expert group, and updated as further guidance or evidence emerges.

This document sets out the terms of reference for the 'COVID-19 tixagevimab/cilgavimab (Evusheld) pre-exposure prophylaxis National Expert Group' in its role of reviewing the access criteria and in supporting the development of an interim clinical commissioning policy.

Role A: Review of access criteria for tixagevimab/cilgavimab (Evusheld) in the pre-exposure prophylaxis of COVID-19

A1. The group will review all available literature, alerts from the Food and Drug Administration (FDA) and European Medicines Agency or other international medicines regulatory bodies, and any other relevant emergent data (trial or otherwise), including data on activity and efficacy against new SARS-CoV-2 variants.

A2. The group will review and amend as necessary the clinical access criteria for tixagevimab/cilgavimab (Evusheld) in line with new findings and taking account of recommendations by the Department of Health and Social Care-commissioned Independent Advisory Group for pre-exposure prophylaxis.

Role B: Tixagevimab/cilgavimab (Evusheld) clinical policy development

B1. The interim clinical commissioning policy will be developed by the National Clinical Policy Team, in line with methods established for rapid clinical policy development.

B2. The 'COVID-19 tixagevimab/cilgavimab (Evusheld) pre-exposure prophylaxis National Expert Group' will support development of the policy statement, including: Population, Intervention, Comparator and Outcomes (PICO), access criteria, general policy text, equalities and health inequalities impact assessment, broader governance group input, and the four nations sign-off process.

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Role C: Tixagevimab/cilgavimab (Evusheld) research and real-world evidence collection

C1. The group will advise on further research data that may need to be collected to guide future policy and commissioning decisions.

Meeting schedule and governance

The group will meet once initially to support development of the Interim Clinical Commissioning Policy. The group will then be reconvened as necessary to review new evidence or changes to national or international consensus statements and guidelines. Notes will be taken of the meetings and shared with the group.

Where appropriate, a rapid policy statement (RPS) will be drafted based on best available clinical evidence and consensus from expert group members. Any draft RPS that have been agreed by the group will then be circulated to members of the UK Specialised Services Clinical Panel for further review and comments. Approved drafts will then be cascaded to the NHS England National Medical Director (and equivalent signatories for devolved administrations), following which they will be submitted to the UK Chief Medical Officer and Deputy Chief Medical Officer for final sign-off. The process may need to be amended depending on the context.

Confidentiality

Members are obliged to treat information shared and discussed within the group as clinically or commercially in confidence, as applicable. This may include, for example, commercially in confidence information on available medicines supply or pricing, or early research data prior to publication.

Membership

1) Professor Anthony Kessel – NHS England and Improvement, Clinical Director National Clinical Policy, Specialised Commissioning
2) [redacted]
NHS England
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Alder Hey Children's Hospital
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10) CRUK Barts Centre, [redacted]
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13) [redacted]
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21) [redacted] The University of Edinburgh
22) [redacted] UK Faculty of Public Health
23) [redacted] Welsh Government
24) [redacted], Llywodraeth Cymru/Welsh Government
25) [redacted] Llywodraeth Cymru/ Welsh Government
26) [redacted] The Scottish Government
27) [redacted] The Scottish Government
28) [redacted] Northern Ireland Department of Health
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31) Professor James Palmer- National Medical Director, Specialised Commissioning
32) [redacted] Specialised Commissioning
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Review

Given the evolving nature of the COVID-19 pandemic in the UK, the above terms of reference may be subject to review or change.

Date: 19/04/2022

Prepared by: [redacted]

Approved by: Anthony Kessel

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