NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: November 2021

Intervention: Fostemsavir

Indication: multi-drug resistant HIV-1 infection (adult)

URN: 2018

Gateway: 2, Round 1

Programme: Blood and Infection

CRG: HIV

Information provided to the Panel

Evidence Review completed by Solutions for Public Health

Policy Proposition

Evidence to Decision Making Summary

Patient Impact Report

Equality and Health Inequalities Assessment (EHIA) Report

Clinical Priorities Advisory Group (CPAG) Summary report

Blueteq® Form

Policy Working Group Appendix

This Policy Proposition recommends the routine commissioning of a new licensed drug agent fostemsavir, a glycoprotein 120 attachment inhibitor, which is targeted against the HIV viral envelope. Fostemsavir is added to an optimised regimen of antiretroviral(s) in individuals with limited or no treatment options who have a diagnosis of multi-drug resistant HIV-1 (MDR HIV-1) infection. This is a licensed medicine.

The Clinical Panel were presented with the evidence review which consisted of a two-cohort, phase 3 multi-centre trial (presented across 3 publications) of 371 MDR HIV-1 patients, within the BRIGHTE trial with outcomes to 96 weeks. The evidence reported was very low certainty on GRADE assessment for critical and important clinical outcomes, including viral suppression, mortality, immune function (CD4 count) and safety. The Panel members debated at length the quality of evidence and if this supported a routine commissioning position, the main evidence demonstrating some response to reduction in viral load. The study design was discussed which Panel thought may be contributing to lack of clarity on some areas, such as patient outcomes.

No evidence was presented for cost-effectiveness.

The Panel members commented that the policy proposition was very well written and only had a couple of very minor comments for correction.

EHIA – no additional comments received.

Patient Impact Report – no additional comments received.

Recommendation

Clinical Panel recommends that this proposition progresses as proposed with minor amendments to the proposition and Blueteq® form.

Why the panel made these recommendations

The Panel debated the evidence at some length and concluded there was some evidence of effectiveness, albeit low, in this target population.

Documentation amendments required

Policy Proposition:

- Page 4, 3rd line last paragraph – typo needs correcting from 'Temsavir' to 'Fostemsavir'.
- the proposition needs to be checked against the People Charter for correctness in terminology – peoplefirstcharter.org

Blueteq® form:

- Q6 – mentions carer. This should be removed and included in Q5.

Declarations of Interest of Panel Members: One member with clinical expertise within this service area.

Panel Chair: James Palmer, National Director, Specialised Services

Post Panel Note

POC Note: The amendments as above have been undertaken and have been reflected in the documentation.

10 June 2022