NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: October 2019

Intervention: Dolutegravir/lamivudine fixed dose combination

Indication: Human Immunodeficiency Virus (HIV) infected adults and adolescents aged over 12 years

ID: 1920

Gateway: 2 Round 1

Programme: Blood and Infection

CRG: HIV

Information provided to the panel

Preliminary Policy Proposal

Three evidence papers submitted with the Preliminary Policy Proposition

Clinical Priorities Advisory Group Summary Report

Policy Proposition

Key elements discussed

This proposition is proposed as for routine commissioning. Dolutegravir/Lamivudine (DTG/3TC) is recommended as an alternative first-line treatment option in people for whom other recommended nucleoside analogues are not suitable or not optimal. This is licensed in children and adults over 12 years and for HIV-1 and not HIV-2. Usually three drugs are given at time of diagnosis to stop progression.

The policy proposition is based on three evidence papers considered previously by Clinical Panel, submitted with the original PPP. The evidence base was considered which demonstrated effectiveness, achieving viral load targets, reduced toxicity and reported adverse events.

The Clinical Panel questioned whether this proposition relates to single products or a fixed dose combination? This needs clarification in the proposition.

Some amendments to various sections of the proposition are required.

Panel did not consider this an independent evidence review as currently written and all subjectivity in the commentary in the evidence review section should be removed, and only the evidence without interpretation should be included.

A description regarding the multidisciplinary team involvement needs to be included.

Recommendation

Clinical Panel recommended that this proposition progress as recommended with the revisions undertaken. The Clinical Effectiveness Team (CET) will sign off the changes to the evidence review, the Pharmacy Lead sign off changes to the pharmacy clarifications, CET will then assure the final documents for Chair's action.

Why the panel made these recommendations

The Clinical Panel considered that the evidence base presented demonstrates effectiveness and safety within the licensed indication.

Documentation amendments required

Policy Proposition:

- Page 4 – proposed treatment section – abbreviations are mixed up and inaccurate. Need to be revised.
- Page 4 – typo to be corrected as number missing in the last sentence on that page – 3500.
- Page 6 – review 2nd paragraph bullets regarding whether response rates as stated are correct
- Page 9 and 10 – review and amend the wording regarding cost
- Page 10 criteria no. 5 – should state not be used, remove 'with caution' language
- Remove the subjectivity in the evidence review section.

Declarations of Interest of Panel Members: A member of the Panel has previously worked within this specialty area, although was not present at Panel for any previous discussion relating to this specific proposition.

Panel Chair: James Palmer, Medical Director

Post meeting note:

The Policy working group made amendments to the policy as per panels request:

- Page 4 - abbreviations amended to improve accuracy and numbers reviewed and added.
- Page 6- Bullet points were reviewed as part of the review of evidence
- Page 9 and 10 wording amended regarding cost to reflect use of cheapest clinically appropriate version.
- Page 10 criteria 5 amended.
- Sentence added to define role of MDT in prescribing.

Evidence sections reviewed by PH lead and CET and revisions made to wording.