Consultation Report

Topic details

Title of policy or policy statement:	Dolutegravir-rilpivirine for treating HIV-1 in adults
Programme of Care:	Blood and Infection
Clinical Reference Group:	F03 HIV
URN:	1806

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition.

2. Background

Human immunodeficiency virus, or HIV, is the virus that causes acquired immunodeficiency syndrome (AIDS). HIV attacks the immune system and leaves people living with HIV vulnerable to other infections, diseases and other complications. HIV treatment with antiretroviral therapy (ART) has transformed the outlook for people living with HIV from that of a significantly shortened lifespan to a manageable long term chronic condition. Consequently, people living with HIV are more likely to develop age-related medical conditions. Careful management of those conditions alongside their HIV infection is important. HIV management involves life-long treatment with ART. As a result, HIV clinicians should aim to maximise tolerability and quality of life while minimising harm.

Typically, HIV treatment includes three different drugs. The three-drug regimen will include two drugs known as nucleoside reverse transcriptase inhibitors (NRTIs), plus one of the following: a non-nucleoside reverse transcriptase inhibitor (NNRTI), a protease inhibitor (PI), or an integrase inhibitor (INI). Dolutegravir-rilpivirine provides an alternative treatment with similar effectiveness in people whose HIV is already virologically suppressed (that is, where levels of the virus are too low to be detected) but using two drugs instead of three. Dolutegravir is an INI. It sticks to HIV integrase and prevents HIV DNA being inserted into uninfected CD4 cells. Rilpivirine is an NNRTI. It sticks to HIV reverse transcriptase to prevent HIV DNA replicating.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 23rd Sept to 23rd Oct. 2019. Consultation comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to be made to this document, and why?

4. Results of consultation

The consultation received twelve responses from patients, clinicians, patient groups and a pharmaceutical company. Responses supported the policy and potential to decreased side effects from ART.

The pharmaceutical company highlighted some concerns about the commissioning criteria not being equitable to previous policies, however they are consistent with current multi-disciplinary team (MDT) and prescribing guidance for HIV.

Most patient, groups and clinicians welcomed it as an addition to treatment for HIV , increasing the range of options available to clinicians, help to maintain the current success in combating HIV in England.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

6. Has anything been changed in the policy as a result of the consultation?

As a result of the consultation, the eligible population numbers have been adjusted to reflect feedback and new data. Changes have been made to the commissioning criteria to improve accuracy, clarity and maintain consistency across policies.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?

No.