NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Cabotegravir and rilpivirine for treating HIV-1

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of cabotegravir and rilpivirine within its proposed marketing authorisation for treating virologically suppressed adults with HIV-1.

Background

HIV is a virus that causes AIDS. HIV attacks the immune system destroying CD4 positive (CD4+) T cells, a type of white blood cell that is vital for fighting infections. The destruction of these cells leaves people living with HIV with a suppressed immune system and vulnerable to infections and some other diseases.

There are two main types of HIV. Most cases within the UK are from the HIV-1 type and it is considered more transmissible than HIV-2. An estimated 103,800 people live with HIV in the UK in 2018, of which 93% were diagnosed (95,500 diagnosed cases). Of these patients, 97% were receiving treatment (estimated 92,600) and 97% of these patients were virally suppressed (estimated 90,000).[1]

Current clinical management involves life-long antiretroviral treatment (ART), which stops the virus replicating in the body and destroying CD4+ T cells. There is no cure for HIV, but ART enables most people to live a long and healthy life with an undetectable viral load, which eliminates the risk of passing on the infection. ARTs are usually used as triple- or dual-combination to avoid the disease adapting and becoming resistant. Choice of ART combinations is complex and individualised, often including consideration of contraindications, drug-drug interactions, tolerability, treatment history, drug resistance profile, adherence and future salvage regimens.[2] People seek to change their ART regimen mainly for reasons unrelated to virologic suppression. These reasons could include difficulties with adhering to the dose schedule (pill burden), psychological or physiological issues with swallowing pills, individual preference and concerns with having HIV treatment in their house.

The technology

Cabotegravir (Vocabria, ViiV Healthcare) is a HIV-1 integrase strand transfer inhibitor (INSTI) which prevents viral DNA integration and inhibits HIV replication. Rilpivirine (Rekambys, ViiV Healthcare) is a diarylpyrimidine non-nucleoside reverse-transcriptase inhibitor (NNRTI) of HIV-1. Cabotegravir and rilpivirine are administered as an oral lead-in therapy for 4 weeks followed by separate intramuscular injections once every month until the fifth month and then once every 2 months.

Cabotegravir in combination with rilpivirine do not currently have a marketing authorisation for treating HIV-1; this regimen has been studied in clinical trials compared with various ART regimens. This drug combination received a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) in October 2020.

Intervention	Cabotegravir and rilpivirine long acting injections with oral lead-in therapy
Population	Adults with HIV-1 infection who are virologically suppressed on a stable regimen and who have not shown prior virological failure due to drug resistance to INTI/INIs.
Comparator	• Antiretroviral treatment (established clinical management such as an integrase inhibitor-based regimen)
Outcomes	The outcome measures to be considered include: • maintenance of virological suppression • CD4+ T-cell levels • treatment-emergent resistance • adherence to treatment regimen • AIDS-defining events • mortality • comorbidities • adverse events (including inflammation) • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account.
Other considerations	The availability and cost of biosimilar and generic products should be taken into account. Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	Related Guidelines: 'HIV testing: increasing uptake among people who may have

and NICE Pathways	undiagnosed HIV' (2016). NICE guideline 60 Related Quality Standards: 'HIV testing: encouraging uptake' (2017). NICE quality standard 157. Related NICE Pathways: 'HIV testing and prevention' (2019) NICE pathway
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019), Chapter 16: adult specialist services for patients infected with HIV Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1-5. NHS England (2019) Best Practice in HIV Prescribing and Multidisciplinary Teams BHIVA (2016) BHIVA guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy 2015 (2016 interim update) BHIVA (2019) BHIVA treatment guidelines: 2019 interim statement on two-drug regimens

References

1. Public Health England (2019) HIV in the United Kingdom: Towards Zero HIV transmissions by 2030. Accessed January 2020

2. British HIV Association (BHIVA) (2016) British HIV Association guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy. Accessed January 2020