Reference number: 2344
Publication date: 16 July 2026

Clinical Commissioning Policy:

Lenacapavir for multi-drug resistant Human Immunodeficiency Virus 1 infection (adults) [URN: 2344]

Summary

Lenacapavir for mult-drug resistant human immunodeficiency virus 1 will be routinely commissioned and made by NHS England following a recommendation from the Clinical Priorities Advisory Group.

Committee discussion

Clinical Panel agreed with the policy proposition and recommended that it progresses as a routine commissioning policy. Please see Clinical Panel reports for full details of Clinical Panel's discussion.

The Clinical Priorities Advisory Group are asked to consider the evidence and the policy. The Clinical Priorities Advisory Group committee papers can be accessed here: Clinical commissioning policy: Lenacapavir for multi-drug resistant human immunodeficiency virus 1 infection (adults)

What we have decided

NHS England has carefully reviewed the evidence to treat MDR HIV-1 infection with lenacapavir. We have concluded that there is enough evidence to make the treatment available at this time.

The evidence review which informs this commissioning position can be accessed here: Clinical commissioning policy: Lenacapavir for multi-drug resistant human immunodeficiency virus 1 infection (adults)

Links and updates to other policies

NHS England has no other policies relating to the use of lenacapavir in MDR HIV-1. However, this policy is linked to:

- Best Practice in HIV Prescribing and Multidisciplinary Teams (NHS England, 2019)
- Service Specifications B06/S/a Adult specialised services for people living with HIV-1 (NHS England, 2024).
- Clinical Commissioning Policy 170028P: Immediate antiretroviral therapy for treatment of HIV 1 in adults and adolescents (NHS England, 2018).
- Clinical Commissioning Policy 200301P: Dolutegravir/lamivudine for the treatment of Human Immunodeficiency Virus (HIV-1) infected adults and adolescents over 12 years of age (NHS England. 2020).

- Clinical Commissioning Policy 200210P: Dolutegravir/rilpivirine for treating HIV-1 in adults (NHS England. 2020).
- Clinical Commissioning Policy 190137P: Doravirine for the treatment of HIV-1 in adults (NHS England. 2019).
- Clinical Commissioning Policy F03/P/a: Elvitegravir/cobicistat/emtricitabine/tenofovir for treatment of HIV-1 in adults (NHS England. 2015).
- Clinical Commissioning Policy B06/P/a: Dolutegravir for treatment of HIV-1 infection (all ages) (NHS England. 2019)
- Clinical Commissioning Policy 16043/P: Tenofovir Alafenamide for treatment of HIV 1 in adults and adolescents (NHS England. 2016).
- Clinical Commissioning Policy 170131P: Bictegravir-emtricitabine-tenofovir alafenamide for the treatment of HIV-1 in adults (NHS England. 2019).
- Clinical Commissioning Policy 201008P: Fostemsavir in multi-drug resistant HIV-1 infection (adults) (NHS England, 2022)

Plain language summary

Human immunodeficiency virus type 1 (HIV-1) attacks the immune system destroying CD4 positive (CD4+) T cells, a type of white blood cell that is vital for fighting infection. The reduction of these cells leaves people living with HIV less able to fight off infections (also known as being immunosuppressed), making them susceptible to other diseases including cancers. If HIV is untreated, a high viral load (high level of virus) can be observed, meaning the HIV is not suppressed (under control). This can increase the chance of HIV being transmitted, as well as cause significant morbidity and mortality for the person living with HIV. There are two main types of HIV: HIV-1 and HIV-2. Most cases in the UK are caused by HIV-1, which is considered more transmissible than HIV-2.

Multi-drug resistant HIV-1 infection

Treatment for HIV-1 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. An undetectable viral load eliminates the risk of transmitting infection. Combination antiretroviral therapy has transformed HIV-1 infection into a manageable chronic condition for many people living with HIV. However, for some individuals, finding effective ART is not always possible. A suitable regimen may no longer exist because of multidrug resistance (MDR), meaning that the virus does not respond or only partially responds to the drugs. Contraindications, previous intolerances, treatment history, adherence issues, drug-to-drug interactions, or drug resistance patterns are other reasons why an individual might have MDR HIV-1 infection.

About current treatment

The standard of care is treatment with a drug regimen comprising at least two agents offered immediately after a diagnosis to limit viral replication. People typically start on a two or three drug regimen and only move to another if there is lack of virological response, treatment failure, or tolerability issues. Additional issues include pill burden and dose frequency, which may affect adherence. Considerations related to potential for drug-drug interactions are particularly relevant as people living with HIV now have a near-normal life expectancy, which means they may take other medication for age-related comorbidities.

Effective treatment is one that suppresses viral replication and maintains an undetectable viral load. In addition to preventing progression of HIV infection to immunosuppression and life-threatening illness, effective treatment also prevents HIV transmission.

The current British HIV Association (BHIVA) guidelines recommend that individuals with limited or no therapeutic options (i.e. for whom a fully viral suppressive regimen cannot be constructed) should either:

- access new agents though research trials, expanded access or on named patient basis supply, or
- attempt to construct a regimen that is least likely to cause rapid development of resistance, while awaiting newer drugs.

About lenacapavir treatment

Lenacapavir is the first of a new class of drugs called capsid inhibitors for the treatment of HIV. Lenacapavir works by blocking the HIV-1 viral capsid, interfering with essential steps of the virus's lifecycle. It is licensed in combination with other ARTs, for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen. It is taken as an oral tablet initially, before switching to a maintenance 6 monthly subcutaneous injection.

Epidemiology and needs assessment

UKHSA data suggest that in 2022 there were 92,557 people living with HIV in England receiving ART. 98% of these individuals have a viral load of 200 c/ml and below. The aim of treatment is for viral suppression, defined as an undetectable viral load of <50c/ml. A viral load of between 50c/ml and 200c/ml is considered a low-level viraemia and is not necessarily indicative of virological failure. A viral load persistently greater than 200c/ml is suggestive of virological failure. Therefore, it is estimated that the number of individuals on treatment, engaged with care and a reported viral load of >200c/ml is 1851. A proportion of these individuals will have MDR HIV-1. Clinical experience estimates that approximately 1 in 20 of these individuals will have MDR HIV-1, meaning that the estimated eligible population is 92 individuals per year.

This estimate needs to be interpreted with caution, as the approach to HIV care is very individual, and those with low level viraemia (between 50-200c/ml) may also meet criteria for MDR HIV-1, and therefore be included in this policy.

Implementation

NHS England will routinely commission lenacapavir in accordance with the patient pathway for individuals meeting all of the following inclusion criteria, and none of the exclusion criteria. Please note that the use of lenacapavir as outlined in this policy is within the product's marketing authorisation.

The population included in this policy are also eligible to be considered for fostemsavir as per NHS England Clinical Commissioning Policy 201008P: Fostemsavir in multi-drug resistant HIV-1 infection (adults).

Inclusion criteria

- Individuals aged 18 years and over have MDR HIV-1[1] infection and are either:
    - not virally suppressed with existing ART regimen [2] **OR**
    - are virally suppressed but on a highly complex regimen with concerns of tolerance, resistance or safety where the addition of lenacapavir could simplify the regimen and optimise individuals' outcome and experience.

AND must meet all the following criteria:

- Individuals have limited or no therapeutic options remaining [3] **AND**
- The use of lenacapavir has been discussed and agreed with the individual or individual's representative and the HIV specialist MDT **AND**
- The individual or individual's representative is able to agree to the required injection schedule **AND**
- Lenacapavir is to be added to an optimised background ART regimen[4]

Exclusion criteria

Individuals who meet the following criteria are not eligible for treatment with lenacapavir under this policy:

- Contraindications to lenacapavir, as described in the Summary of Product Characteristics (SmPC)
- Weight <35kg
- Previously received a trial of lenacapavir with no clinical response [5]
- The HIV specialist MDT has determined that the individual is not suitable
- The HIV specialist MDT considers there are contraindications to subcutaneous injections

The prescribing clinician should be aware of the special warnings and precautions, including pregnancy and breast-feeding, for use of lenacapavir as detailed in the Summary of Product Characteristics.

Starting criteria

At the time of starting or switching ART regimens, it is recommended that a baseline viral load is done.

Stopping criteria

Lenacapavir should be stopped in the following individuals:

- Those who develop significant toxicity or contraindications

[1] MDR HIV-1 can be defined by intrinsic multi-drug resistance, where the virus has certain genetic mutations that render ART infective, or functional multi-drug resistance with impacts the ability to use certain ART due to concerns about tolerability, availability, safety concerns or contraindications.
[2] Virological suppression: achieving and maintaining a HIV-1 RNA of <50 copies per mL
[3] Limited treatment or no therapeutic options defined as either: no fully active ARV remaining OR one or two fully or partially active ARV remaining
[4] The optimised background regimen needs to be robust, and should ideally include a number of partially active and/or fully active medications
[5] If no clinical response was determined to be the result of factors which have now been addressed such as adherence or drug-drug reactions, a re-trial could be considered

- Individual's decision to stop

Consideration of lenacapavir cessation should be reviewed in the HIV specialist MDT in the following two scenarios:

1. No treatment response:

Individuals with no treatment response (defined as no change or an increase in the HIV-1 RNA level compared to baseline) assessed at 6 months.

2. Limited treatment response:

Defined as individuals with a decline in HIV-1 RNA level but are still not virally suppressed after 6 months of treatment. The decision to continue lenacapavir should be reached jointly between the HIV specialist MDT and the individual, with other alternatives considered and background ART regimen optimised.

Dosing

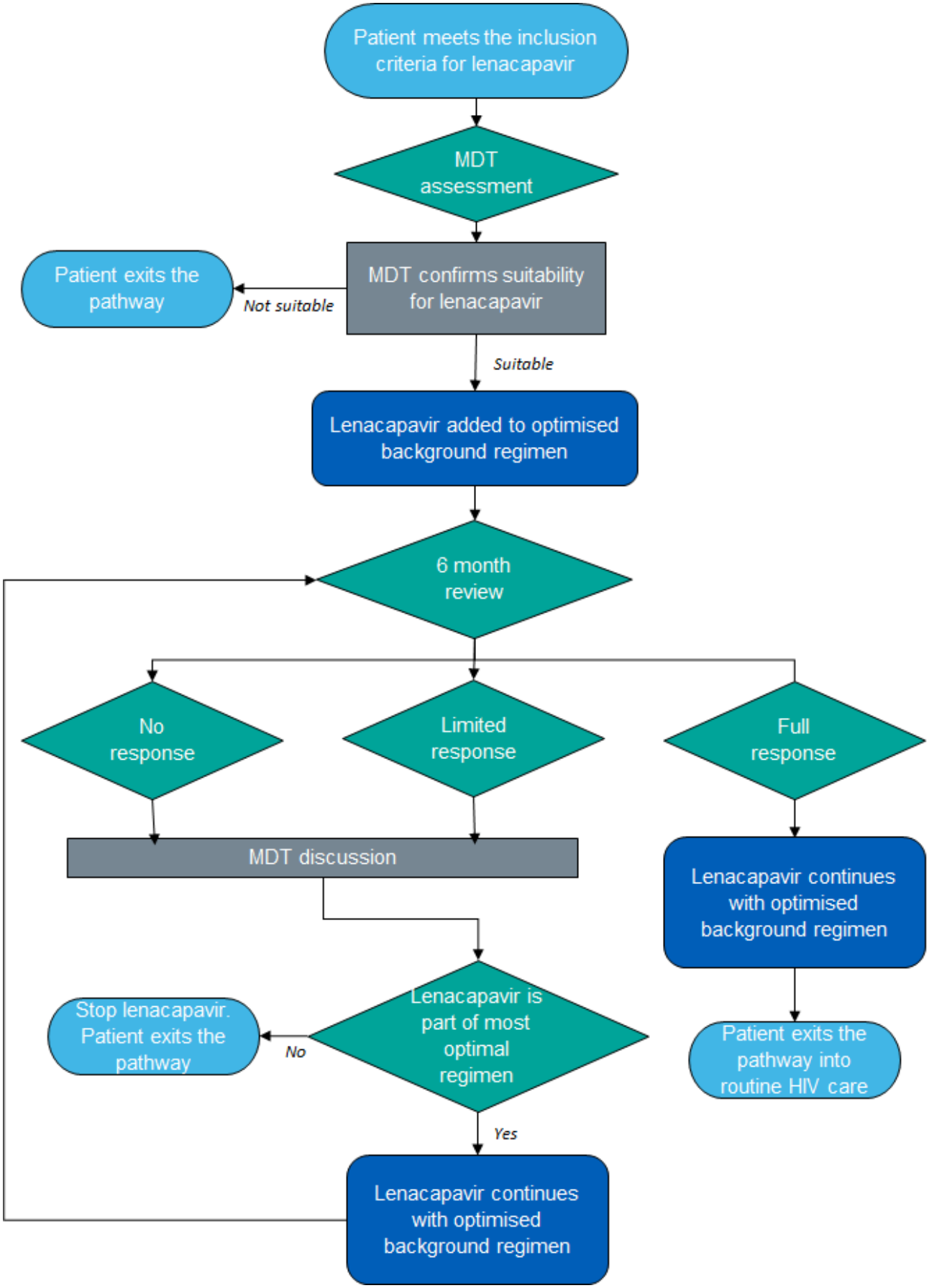
Initiation followed by maintenance dosing once every 6 months. Tablets may be taken with or without food. The dosing regimen is described fully in the SmPC.

Please note that drug-drug interactions need to be considered when the drug is initiated and for 9 months after stopping.

Monitoring

It is recommended that individuals receiving lenacapavir should have a repeat viral load blood test every 6 months.

Patient pathway



Governance arrangements:

This policy should be used in conjunction with the following service specifications:

- Adult specialised services for people living with HIV-1 B06/S/a
- Specialised human immunodeficiency virus services (children) B06/S/b

Any provider organisation treating individuals with this intervention will be required to assure itself that the internal governance arrangements have been completed before the medicine is prescribed. These arrangements may be through the Trust's Drug and Therapeutics committee (or similar) and NHS England may ask for assurance of this process.

Mechanism for funding

Lenacapavir within the criteria set out in this document will be commissioned and funded by NHS England under existing arrangements for the provision of specialised services.

Audit requirements

Provider organisations must register all individuals receiving lenacapavir using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined. This information is collected to inform future clinical policy revisions.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment, and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Antiretroviral therapy (ART)	ART is a combination of drugs used in HIV treatment. ART drugs are divided into different groups depending on where they act on the HIV virus enzymes.
Human immunodeficiency virus	Is a virus which attacks the immune system destroying CD4 positive T cells, a type of white blood cell that is vital for fighting infections. The reduction of these cells leaves people living with HIV less able to fight off infections (immunosuppressed). There is currently no cure for HIV, but more people living with HIV can lead a normal life, as ART medication can control the virus.
Multi-drug resistant HIV-1 infection (MDR HIV-1).	The HIV-1 virus does not respond or only partially responds to the ART drugs. An individual may also have other medical problems, or reasons why certain types of ART cannot be used.

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