



Clinical Commissioning Policy: Dolutegravir for treatment of HIV- 1 infection (all ages)

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Clinical Commissioning

Policy: Dolutegravir for treatment of HIV-1 infection (all ages)

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Description	NHS England will routinely commission dolutegravir as a second-line treatment choice where the HIV multidisciplinary team (MDT) assesses the patient as unable to tolerate first line therapy or experiencing treatment failure or resistance. Those starting or stable on treatment or not discussed in the MDT are exclusions to the policy.
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Document Status

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Policy Statement

NHS England will commission dolutegravir for treatment of HIV-1 infection (all ages) in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Throughout the production of this document, due regard has been given 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 in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Dolutegravir (trade name Tivicay®) is an HIV drug that was first approved in Europe in January 2014. This is a type of HIV drug called an integrase inhibitor (INI). It is the third drug in this class. In September 2014, a fixed dose combination drug combining dolutegravir, abacavir and lamivudine (trade name Triumeq®) also received approval.

HIV treatment usually involves taking three or more drugs in a combination. However, sometimes two, three or four of these drugs are combined in a single pill.

Dolutegravir has the potential to improve care because:

- a) It reduces levels of HIV virus in the body quickly. This is the main aim of HIV treatment.
- b) It causes fewer side effects than some other HIV drugs. This includes a much lower risk of common side effects such as mood changes, depression, anxiety, disrupted sleep and suicidal thoughts. Overall, this means the treatment is better tolerated and improves patient safety.

The evidence for these benefits came from large randomised studies.

1. Introduction

HIV treatment has improved greatly over the last two decades and standard of care now involves triple therapy, typically with two nucleos(t)ide reverse transcriptase inhibitors (NRTIs) plus one of the following: a ritonavir-boosted protease inhibitor (PI/r), a non nucleoside reverse transcriptase inhibitor (NNRTI) or an integrase inhibitor (INI) [1].

Effective antiretroviral treatment (ART) requires 95% adherence to drug regimes. Development of new ARV medicines often focuses on improvements in tolerability, reductions in toxicity and drug to drug interactions.

Effectiveness of ART is measured by an undetectable viral load. In 2015, the proportion of patients on treatment with an undetectable viral load was very high: 94% had less than 50 copies [2]. Current standard treatment is therefore effective for many people. The availability of generic anti-retroviral treatments has reduced the cost of standard treatment considerably. New drug treatments need to demonstrate both clinical and cost effectiveness over current standard treatments.

Despite the success of current standard treatment in terms of clinical outcomes, neuropsychiatric side effects have commonly been reported with efavirenz which is currently the most widely prescribed drug. People with a history of psychiatric disorders appear to be at greater risk of serious psychiatric side effects. These may include suicidal ideation and possible increased risk of suicide [3, 4].

Dolutegravir (Tivicay ®) is produced by ViiV Healthcare UK Ltd and is the third HIV integrase strand transferase inhibitor (INI) to be approved. It is the first INI that can be taken as once daily dosing without boosting with a pharmacokinetic enhancer. Dolutegravir received an EU license for treatment in HIV-1 infected adults and adolescents in January 2014. A fixed dose combination tablet combining dolutegravir, abacavir and lamivudine (trade name Triumeq®) received approval in September 2014. A license indication extension to cover children diagnosed with HIV-1 infection aged 6-12 years old was granted in March 2017.

HIV drugs are not currently reviewed by NICE to determine their clinical and cost effectiveness.

2. Definitions

The key terms used in this policy and their definitions are:

Antiretroviral therapy (ART): This usually consists of a combination of 3 antiretroviral drugs. A backbone of 2 nucleoside reverse transcriptase inhibitors (NRTI) and a 3rd agent from one of the following classes of drugs: non-nucleoside reverse transcriptase inhibitors (NNRTI), ritonavir boosted protease inhibitors (PI/r) and integrase inhibitors (INI).

Fixed dose combination (FDC): Single tablets which combine a number of agents

First line therapy: Efavirenz is one of the recommended first line 3rd agent, given in combination with either tenofovir and emtricitabine or lamivudine and abacavir, and for reasons of clinical effectiveness and cost is a preferred first line option.

NRTI / NNRTI backbone and 3rd Agent: These include individual agents often used in fixed dose combinations including: abacavir and lamivudine; tenofovir and emtricitabine; tenofovir with efavirenz and emtricitabine; tenofovir, rilpivirine and emtricitabine; and tenofovir, elvitegravir, cobicistat and emtricitabine.

Second line therapy: The use of alternative 3rd agents where efavirenz cannot be used for reasons of potential or actual intolerance or transmitted HIV drug resistance. Alternative 3rd agents include: the NNRTIs rilpivirine and nevirapine, the INIs raltegravir, elvitegravir/cobicistat and dolutegravir, and the PI/rs darunavir/ritonavir and atazanavir/ritonavir. Drug selection depends on side effects profile, tolerability, resistance profile, drug-drug interactions and cost.

Viral load: plasma HIV RNA levels are used to monitor response to antiretroviral therapy. Patients on effective therapy sustain a plasma HIV RNA level of <50 copies/ml (undetectable). Patients who fail to achieve an undetectable viral load or experience a confirmed viral load rebound above 50 copies/ml are deemed to be experiencing virological failure.

Intolerance: patients who are either assessed to be at high risk of adverse effects or experience adverse effects that will or have led to drug discontinuation are deemed to be intolerant.

Stable patients: patients who continue to experience an undetectable viral load and who are not experiencing any intolerance to their medication are deemed to be stable.

3. Aim and objectives

This policy aims to identify the evidence and cost implications of routine commissioning of dolutegravir for specific patient groups.

The objectives are to enable access to dolutegravir where its use is supported by clinical evidence and where it is demonstrated to represent good value.

Dolutegravir is price comparative to second line therapies. This policy aims to identify those patients that would benefit from dolutegravir as a second line therapy choice where first line treatment is not clinically indicated, or where patients are experiencing treatment failure or are experiencing intolerance.

4. Epidemiology and needs assessment

The HIV epidemic continues to pose a public health risk in England. By the end of 2015, an estimated 101,500 (CI 97,500) people were living with HIV in the UK; approximately 13% (13,500, CI 10,200 – 17,800) of whom were undiagnosed and unaware of their infection [5]. Whilst untreated HIV-1 remains a life-threatening disease, effective antiretroviral (ARV) medicines mean that it can be managed as a chronic long term condition. In 2015 there were 88,769 HIV positive patients in the UK in HIV services (81,062 in the UK), of whom 96% were receiving ART [2]. This is a rise from 90% on treatment in 2014.

British HIV Association Treatment guidelines currently recommend as a first-line therapy[1]:

- NRTI backbone: tenofovir and emtricitabine
- Third agent: EITHER atazanavir/ritonavir, OR darunavir /ritonavir, OR efavirenz, OR raltegravir OR elvitegravir/cobicistat

These guidelines remain under review in view of new outcome data, the expiry of patents for standard of care drugs and the availability of new agents.

Up to 30% of patients requiring ART will be unable to take first line therapies or will require treatment choices to manage demonstrated toxicity, intolerance, adherence, treatment failure or resistance. These patients require alternative regimens. Dolutegravir offers an additional option to all recognised second line therapies.

5. Evidence base

Dolutegravir is the third HIV integrase strand transferase inhibitor (INI) to be made available and has advantages over the other two. In randomised studies it has shown superiority over two other commonly used third agents, efavirenz and boosted darunavir [6, 7]. It has also shown activity against integrase resistant strains of HIV [8]. In summary:

- In antiretroviral naïve patients, dolutegravir has been shown to be non-inferior to raltegravir (Spring 2 study) and superior to tenofovir with efavirenz and emtricitabine, when combined with abacavir and lamivudine (Single study).
- In treatment experienced but integrase naïve patients, dolutegravir has been shown to be superior to raltegravir (Sailing study).
- Dolutegravir has been shown to be superior to boosted darunavir irrespective of the nucleoside backbone that it is combined with (Flamingo study).
- Dolutegravir has been shown to be an effective treatment option in patients with integrase resistant virus (Viking 3 study). The dolutegravir dose in integrase resistance is 50mg twice daily.
- In a number of trials, dolutegravir was combined with abacavir/lamivudine including at high viral loads, which was previously a restriction when using abacavir/lamivudine with other drugs.
- Trials have shown that dolutegravir has reduced side effects and improved tolerability compared with some current alternatives.

Dolutegravir is a once-daily drug that can be taken with or without food. Treatment adherence is considered to be an important factor in achieving good clinical outcomes and preventing drug-resistance within drug classes. Issues such as tolerability, pill burden, dose frequency, side effects, safety concerns and access to adherence support may impact on a patient's ability to adhere to their treatment regimen.

Several studies have shown higher adherence rates with once daily dosing of ART compared with twice daily [9,10].

Dolutegravir has a good tolerability profile. In phase III studies, approximately 2% of patients stopped the drug due to adverse events compared with 10% taking tenofovir with efavirenz and emtricitabine[6] and 4% taking darunavir/ritonavir [7]. Discontinuation rates were similar compared to raltegravir.

Although the most common first line regimens used in the UK contain efavirenz[9], a proportion of patients are unable to tolerate it due to severe psychiatric side effects that include mood changes, anxiety, depression, sleep disturbance, suicidal ideation and possible increased risk of suicide [3,4].

Dolutegravir has a lower propensity for the development of resistant mutations during treatment compared with raltegravir [11,12].

Dolutegravir does not require pharmacokinetic boosting which may result in complex drug-drug interactions and it does not need to be taken with food [13].

In the UK, the virological failure rate on current first-line regimens in 2008–2009 was approximately 10% at one year [14]. Around 3% of patients have evidence of triple-class resistance [15]. BHIVA recommend that patients with triple-class resistance switch to a new ART regimen containing at least two, and preferably, three fully active agents; an integrase inhibitor is normally required as part of this [1]. Relatively little is known about transmitted integrase resistance as it is not routinely screened for in the treatment naïve population [16], and may only be tested in those failing integrase inhibitor-based therapy.

The proportion of patients who may require a switch from efavirenz ranges from 11% to up to 30% at four years [17,18].

A fixed dose combination tablet combining dolutegravir, abacavir and lamivudine (trade name Triumeq®) received approval in September 2014. The approval was based on bioequivalence data for dolutegravir in a combined product compared to its co.

6. Rationale behind the policy statement

Up to 30% of patients requiring ART will be unable to take first line therapies or will require treatment choices to manage demonstrated toxicity, intolerance, adherence, treatment failure or resistance. These patients require alternative regimens.

Dolutegravir offers an additional option to all recognised second line therapies.

This commissioning policy proposes routine commissioning of dolutegravir for specific patient groups based on evidence that exists to demonstrate superiority and non-inferiority compared with some existing therapies and where this would be cost effective to do so.

NHS England has been offered a commercial in confidence discount for dolutegravir. The cost of the drug is comparable to a second line treatment. Component agents [19].

7. Criteria for commissioning

Dolutegravir (single agent and FDC) will be routinely commissioned for the treatment of HIV-1 infection in the following clinical scenarios:

Patients unable to tolerate first line therapy

Patients who are not suitable for or who do not tolerate efavirenz based first line therapy due to demonstrated toxicity, intolerance, adherence, treatment failure or resistance. MDT agreement for Dolutegravir use is not required where Dolutegravir is clinically appropriate, the rationale for choice is clearly documented in the clinical notes, and is compliant with regional cost-based ART prescribing algorithms (which will outline MDT requirements across all ARTs).

This policy recommends that where dolutegravir is used, it should be combined with the lowest cost, clinically indicated backbone.

Patients failing treatment and those with resistance

Dolutegravir is approved for use in these patients requiring an integrase inhibitor due to recorded treatment failure or resistance:

- In treatment experienced and integrase inhibitor naïve patients at a dose of 50mg daily.
- In treatment experienced and integrase resistant patients at a dose of 50mg twice daily.

All patients with resistance should be discussed at an MDT.

Dolutegravir should be combined with at least two other anti-viral drugs to which the virus is sensitive.

All patients for whom dolutegravir is considered a treatment option (including those with toxicity, intolerance, adherence, treatment failure and resistance) **must be considered in an HIV specialist treatment multidisciplinary** (MDT) meeting and the decision of the MDT recorded.

Children aged 6-12 years

In March 2017, Dolutegravir received a license extension to include treatment of children aged 6-12 years with diagnosed HIV-1.

Prescribing of Dolutegravir in this cohort of patients should be in line with local prescribing guidelines and PENTA prescribing guidance.

Dolutegravir is not licensed for the treatment of children under 6 years of age. Where there is felt to be a clinical indication for use should be discussed and agreed with paediatric clinical network lead MDTs prior to prescribing.

Exclusions

- Patients starting therapy for the first time who are able to tolerate efavirenz based regimens.
- Patients prescribed or switching to dolutegravir where the decision about their treatment is not recorded to demonstrate compliance with the criteria.
- Use of dolutegravir by providers who are not commissioned by NHS England to provide HIV care and treatment services.
- An increase in the price of dolutegravir would require a review of this policy.

8. Patient pathway

Commissioned HIV care and treatment providers who meet the service specification initiate and monitor HIV drug treatment. Prescription and monitoring of dolutegravir is in line with the existing patient pathway.

9. Governance arrangements

All patients identified who might benefit from dolutegravir must be referred to and discussed at a specialist HIV MDT and the recommendation recorded. This includes the cohorts identified for routine commissioning as well as any exceptional cases.

10. Mechanism for funding

NHS England is responsible for funding the use of all antiretroviral medicines. Funding for ART is currently on a pass through basis reported to Area Teams. Trusts will be required to separately identify spend on dolutegravir.

11. Audit requirements

Regional prescribing algorithms should be agreed between regional commissioners, clinical leads and the HIV CRG Drugs Subgroup. All ART decisions, including rationale for drug choice, should be documented in the clinical notes.

Regular audit of prescribing against regional algorithms is expected.

12. Documents which have informed this policy

B06/S/a Specialised Human Immunodeficiency Virus (HIV) Services (Adult) – service specification

B06/S/b Specialised Human Immunodeficiency Virus (HIV) Services (Children) - service specification

B06/PS/a Clinical commissioning policy statement: Stribild for the treatment of HIV-1 infection in adults.

13. Links to other policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

14. Date of review

This policy will be reviewed when required as further information is received that indicates a review is needed.

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Change Notice for Published Specifications and Products developed by Clinical Reference Groups (CRG)

Product Name

Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents

Ref No

B06/P/a

CRG Lead

Laura Waters

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents	Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 infection (all ages)	Title (and throughout the document where referenced)	Policy now covers children as well as adults and adolescents in line with license extension and agreed routine commissioning.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Referred to this treatment as a “relatively new type of drug”.	Removes reference to this treatment being relatively new.	Plain Language Summary	No longer a new treatment, as reflected by the reduction in the cost.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Studies looking at switching people on stable therapy are still ongoing.	Removed.	Plain Language Summary	Removed this reference as studies have now been completed.	Janette Harper, Lead Commissioner HIV CRG	August 2018

Reference to viral load suppression levels in 2012 and to availability of generic efavirenz.	Updated to reference to reflect 2015 data and availability of generic ART.	Introduction	Updated information available.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Policy restricted to adults and adolescents infected with HIV-1.	Included details of license extension to cover children aged 6-12 years.	Introduction	Licence extension to include treatment in children aged 6-12 years granted in March 2017 and commissioned as an in-year service development in July 2017.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Efavirenz being the recommended first line 3rd agent due to clinical effectiveness and cost.	Efavirenz being one of the recommended first line 3 rd agents due to clinical effectiveness and cost.	Definitions	Updated to reflect range of first line therapies available.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Epidemiology references 2012 data.	Update to 2015 epidemiology.	Epidemiology and Needs Assessment	Updated to reflect latest epidemiology information.	Janette Harper, Lead Commissioner HIV CRG	August 2018
British HIV Association Treatment guidelines currently recommend:	British HIV Association Treatment guidelines currently recommend as a first-line treatment:	Epidemiology and Needs Assessment	Updated to more accurately reflect BHIVA (British HIV Association) treatment guidelines.	Janette Harper, Lead Commissioner HIV CRG	August 2018
BHIVA recommend that patients with triple-class resistance switch to a new anti-viral drug regimen	BHIVA recommend that patients with triple-class resistance switch to a new ART regimen	Evidence Base	Correction of typographical error.	Janette Harper, Lead Commissioner HIV CRG	August 2018
No trial data is currently available on switching to dolutegravir in patients who are currently on stable treatment.	Removed.	Evidence Base	Switching trials have now been completed.	Janette Harper, Lead Commissioner HIV CRG	August 2018

A dolutegravir named patient programme has been available since 2011 for patients with integrase resistant mutations, and has been accessed by a small number of patients to date.	Removed.	Evidence Base	Names patient programme ceased.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Requirement for MDT where use of Dolutegravir indicated in all cases.	MDT agreement for Dolutegravir use is not required where Dolutegravir is clinically appropriate, the rationale for choice is clearly documented in the clinical notes, and is compliant with regional cost-based ART prescribing algorithms (which will outline MDT requirements across all ARTs).	Criteria for commissioning	Updated to reflect change in national requirement for MDT given cost reduction and alignment with regional prescribing guidelines.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Dolutegravir is one potential treatment option for the group of patients unable to tolerate first line therapy as set out above. The cohort of patients required alternative to first line therapy is expected to be no more than 30% of the total treatment patient cohort.	All patients with resistance should be discussed at an MDT.	Criteria for commissioning	Updated to reflect requirement for MDT discussion on all patients with resistance, and removal of anticipated level of patients accessing Dolutegravir for this indication.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Policy covered adults and adolescents diagnosed with HIV-1 infection.	License indication now extended to include 6-12 year olds. Prescribing should be in	Criteria for Commissioning	NHS England agreed routine commissioning of Dolutegravir in children aged 6-12 years as an in-	Janette Harper, Lead Commissioner	August 2018

	line with local prescribing guidelines and PENTA guidance.		year service development in July 2017. Addition to policy delayed until policy revision.	HIV CRG	
Exclusion of switching patients who are stable or not discussed at MDT. Direction to IFR process where clinician wants to use Dolutegravir outside of policy.	Removed exclusions linked to nationally mandated MDT requirements and reference to not switching stable patients. Removed IFR requirement as consideration outside of policy should be discussed and agreed at MDT.	Exclusions	Removed exclusions linked to nationally mandated MDT requirements and updated evidence around switching patients.	Janette Harper, Lead Commissioner HIV CRG	August 2018
All patients considered for treatment with dolutegravir must be referred to and discussed in an HIV MDT. Recommendations for treatment must be recorded. Commissioners will review the audits. This policy will be reviewed by the CRG annually.	Regional prescribing algorithms should be agreed between regional commissioners, clinical leads and the HIV CRG Drugs Subgroup. All ART decisions, including rationale for drug choice, should be documented in the clinical notes. Regular audit of prescribing against regional algorithms is expected.	Audit Requirements	Updated to reflect the removal of mandatory MDT discussion requirement, and reflect general requirement for audit against regional prescribing algorithms.	Janette Harper, Lead Commissioner HIV CRG	August 2018
This policy will be reviewed in April 2016 unless information is received which indicates that the proposed review date should be brought forward or delayed.	This policy will be reviewed when required as further information is received that indicates a review is needed.	Date of Review	Remove fixed timescale for review to enable flexibility to review and revise the document when required.	Janette Harper, Lead Commissioner HIV CRG	August 2018
Public Health England Personal	Public Health England (2016)	References	Updated reference to latest	Janette	

Communication (SOPHID 2012).	HIV in the UK report.		available published data on HIV epidemiology.	Harper, Lead Commissioner HIV CRG	August 2018
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