Specialised Services Circular

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

Circulation

For action	**For information**
Local Team Assistant Directors of Specialised Commissioning Regional Team IFR Leads Finance Leads Local Team Pharmacists Local Teams to circulate to: Acute Trust Chief Executives; Acute Trust Medical Directors Acute Trust Chief Pharmacists Clinical Reference Group Chairs: onward circulation relevant CRG members.	Regional Directors of Specialised Commissioning Regional Medical Directors Regional Clinical Directors of Specialised Commissioning

Background

The *Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents* has been approved.

In phase III studies, dolutegravir has been shown to be non-inferior or superior to a number of other antiretroviral medicines. The manufacturer has offered a commercial in confidence price to NHS England.

Market authorisation was received on 3rd September 2014 for a fixed dose combination (FDC) product combining dolutegravir with abacavir and lamivudine. A commercially confidential price has been offered for the FDC which will permit use of the FDC in line with the criteria of this policy. Bio equivalence of the component drugs has been demonstrated in the FDC.

Summary

The *Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents* sets out the following commissioning criteria.

Patients unable to tolerate first line therapy

Patients who are not suitable for or who do not tolerate efavirenz based first line therapy as agreed in the HIV Specialist Multi-Disciplinary Team MDT to ensure peer review of treatment decisions in line with the criteria.

The policy recommends use of dolutegravir with the lowest cost, clinically indicated 'backbone' drug.

Patients failing treatment and those with resistance

Dolutegravir is approved for use in those 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.

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

It is anticipated that around 30% of patients on HIV treatment may require an alternative to first line therapy and dolutegravir is one choice for such patients.

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

The manufacturer provides dolutegravir to NHS organisations according to the price agreed in confidence with the Department of Health Commercial Medicines Unit and NHS England.

Exclusions

- Patients switching to dolutegravir who have not been referred to and discussed in the HIV specialist treatment MDT meeting or where the decision about their treatment is not recorded.

- Patients stable on treatment **should not be** switched to dolutegravir. There are no published trial data for switching stable patients on to dolutegravir.
- 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.

Where clinicians consider switching to dolutegravir for patients not covered in the circumstances above, an Individual Funding Request may be considered where the patient's case in exceptional. The MDT discussion should be included in the IFR.

Action

Local Teams are asked to:

- Note the *Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents* has been approved and published.
- Confirm with providers that dolutegravir may be used in line with the commissioning criteria. This should not result in a cost pressure as use in line with the commissioning criteria will mean use of dolutegravir in place of other similarly priced or more expensive drugs.
- Ensure providers have arrangements in place to prospectively audit use of dolutegravir against commissioning criteria. Local Teams should make arrangements to assure themselves that criteria have been met, in particular MDT approval of patients.

Note that the Fixed Dose Combination of dolutegravir with abacavir and lamivudine (Triumeq®) received market authorisation in September. This is bio-equivalent to the component drugs and so will not be subject to a further policy. Local Team Pharmacists should ensure they are aware of the pricing for these drugs and support use of the most appropriate, lowest cost agents.

Further Information

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