

Clinical Expert Summary
Dolutegravir (Tivicay[®]) 10 mg and 25 mg film-coated tablets

Dolutegravir (Tivicay[®]) in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected children aged 6–12 years

1. Existing guidelines

Clinical experts highlighted guidelines from their health board and the British HIV Association (BHIVA).

2. Disease prevalence/incidence

Experts stated that there are very few children in Wales (14 in total) with HIV; four are younger than 12 and ten are older than 12. There are 2 children who have drug resistance; one is 11 years old and the other is 13. It was stated that dolutegravir could be used in patients who have drug resistance or are intolerant of their current regime. The number of patients that this medicine would be appropriate for is negligible.

3. Current treatment options

Experts highlighted atripla, truvada + darunavir/ritonavir, and truvada + atazanavir/ritonavir. Other antiretrovirals are given as appropriate on an individual patient basis.

4. Unmet needs

Experts highlighted that HIV is a chronic condition that is controllable with medication; however all of the currently available medications have side effects. Experts stated that there is not one treatment option that is suitable for all patients. Having access to a variety of medicines is important as it enables the clinician to construct a treatment regime that is suitable for the vast majority of patients.

5. Knowledge of product in given indication

Experts stated that dolutegravir is used in patients who have drug resistance or are intolerant of other treatment options as part of an antiretroviral regime. It is considered for first line as per BHIVA guidelines where appropriate.

One expert expressed their support for the extension of use of dolutegravir in the 6–12 year age group. Their support is based on their extensive experience of its use in adults. They added that it is currently the most commonly prescribed “third agent” in their catchment area and many other adult HIV clinics.

It should be noted that one expert involved in compiling this response declared a personal specific interest in relation to dolutegravir for the indication under consideration.

Appendix: Previous AWMSG clinical expert summary (published September 2014)

This report was published as part of a previous AWMSG appraisal of dolutegravir (Tivicay[®]) (Advice number 2314). The advice from this appraisal has been superseded by advice number 2017. The original appraisal documentation is included here for completeness.

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Clinical Expert Summary Dolutegravir (Tivicay[®]▼) 50 mg film-coated tablets

Dolutegravir (Tivicay[®]▼) in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age

1. Existing guidelines

The following guideline was highlighted:

- British HIV Association (BHIVA) guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy 2012 (Updated November 2013)¹.

Experts also referred to local health board guidelines.

2. Disease prevalence/incidence

Clinical expert opinion estimated that approximately 700 patients would be potentially eligible for treatment with dolutegravir in their catchment area. It was stated that, in the first year, up to 100 patients may be suitable for treatment with uptake expected to grow in subsequent years.

3. Current treatment options

Experts suggested the following treatment options:

- Atripla[®]
- Stribild[®]
- Eviplera[®]
- Truvada[®] + darunavir/ritonavir
- Truvada[®] + atazanavir/ritonavir
- Truvada[®] + raltegravir
- Abacavir + efavirenz
- Abacavir + darunavir/ritonavir

4. Unmet needs

Expert opinion suggested that, as all of the currently available medications have side effects, there is not one treatment option that is suitable for all patients. It was stated that having access to a variety of medicines is important, as it enables clinicians to construct a treatment regime that is suitable for the vast majority of patients. Experts noted that dolutegravir is a new integrase inhibitor that can be taken once daily. It has a higher barrier to resistance than the currently available integrase inhibitors and this is important in preserving therapeutic options for patients.

5. Knowledge of product in given indication

The clinical experts noted that dolutegravir may be an option as first line therapy in all patients or, an alternative therapy in patients unable to tolerate or ineligible for Atripla[®]/truvada + efavirenz or truvada + darunavir/ritonavir (decision partly influenced by cost). Expert opinion suggested that it may also be a suitable option in patients switching therapy because of resistance or intolerability of their current regime. Experts felt that dolutegravir may be a suitable option in all lines of treatment.

REFERENCES

- 1 British HIV Association. Treatment of HIV-1 positive adults with antiretroviral therapy 2012 (updated November 2013). 2013. Available at: http://www.bhiva.org/TreatmentofHIV1_2012.aspx. Accessed May 2014.