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Clinical Expert Summary Darunavir/cobicistat/emtricitabine/tenofovir (Symtuza®) 800 mg/150 mg/200 mg/10 mg film-coated tablet

Darunavir/cobicistat/emtricitabine/tenofovir (Symtuza®) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40 kg).

1. Existing guidelines

Clinical experts listed the following available guidelines:

- British HIV association (BHIVA) guidelines
- Children's HIV association (CHIVA) guidelines
- Local health board guidelines

2. Disease prevalence/incidence

There is not a database of HIV patients in Wales, so it is not possible to estimate the number of patients across Wales who would be eligible for this treatment. One clinical expert reported approximately 800–1,000 patients with HIV accessing treatment in Cardiff, and estimated that 200 of these patients are using a protease inhibitor and would be eligible to switch to Symtuza®, if appropriate. Another clinical expert reported a cohort of 300 HIV patient with approximately 100 patients receiving a boosted protease inhibitor within the Aneurin Bevan University Health Board. A clinical expert stated that, if the price is competitive, switching to Symtuza® would be more likely and it might be a preferred option for patients starting therapy. They expect that uptake of Symtuza® would be reasonably high and estimate that 50–100 patients in the Cardiff area would take up Symtuza® in the first year (including newly diagnosed patients and patients switching from other medications).

3. Current treatment options

Atripla® is the predominant treatment, followed by Truvada® plus darunavir/ritonavir. Triumeq® and other integrase inhibitors are now frequently preferred for patients starting therapy, or patients who require switching therapy due to toxicity or intolerability. One clinical expert reported that integrase inhibitor combinations are generally replacing Atripla®.

4. Unmet needs

Clinical experts reported that as a single, once-daily tablet, Symtuza® would be an attractive option for patients. One expert noted that protease inhibitors are a preferred treatment choice for patients who may struggle with compliance, therefore a reasonable proportion of patients may choose to switch therapy to Symtuza® as a result. Symtuza® would be used in patients who have drug resistance, who are intolerant of other treatments or in patients where adherence is a concern, as per the BHIVA and CHIVA guidelines. It was noted by a clinical expert that all treatment options have side effects, and 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

Symtuza® contains a newer formulation of tenofovir: tenofovir alafenamide fumarate. Tenofovir alafenamide fumarate can be prescribed to a wider range of patients compared to tenofovir disoproxil fumarate, including those with moderate renal dysfunction. Tenofovir alafenamide fumarate requires no additional renal monitoring, whereas tenofovir disoproxil fumarate has specific requirements for renal monitoring. It was noted that Symtuza® would therefore be an attractive option for patients starting therapy, particularly if they cannot tolerate an integrase inhibitor.

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