# FINAL RECOMMENDATION and REASONS for RECOMMENDATION

## ATAZANAVIR SULFATE capsules (Reyataz<sup>TM</sup>—Bristol-Myers Squibb)

### **Description**:

Atazanavir is an azapeptide HIV-1 protease inhibitor (PI) which is indicated in combination with other antiretroviral agents for the treatment of patients with HIV-1 infection.

#### **Recommendation:**

CEDAC recommended that atazanavir be listed in a similar manner as drug plans list other protease inhibitors as part of HIV treatment regimens.

#### **Rationale for the recommendation:**

- 1. In randomized controlled trials (RCTs), atazanavir had a similar effect on viral load and CD4+ cell counts as other protease inhibitors.
- 2. Atazanavir is similar in cost to the current preferred protease inhibitor comparator, lopinavir/ritonavir (Kaletra).

#### Other considerations:

- 1. The frequency of statistically significant LDL and triglyceride elevations with atazanavir is less, compared to other protease inhibitors. Although the clinical relevance of these observations in patients with HIV is uncertain, this represents a potential therapeutic advantage. Elevated lipids in these patients are currently treated as part of clinical practice.
- 2. Atazanavir is associated with hyperbilirubinemia in 20-45% of patients and clinically evident jaundice in 2-11% of patients. Experience to date suggests that this is not associated with important liver toxicity; however, liver tests need to be monitored during treatment.