



## **CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION**

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### **ABACAVIR/LAMIVUDINE (Kivexa™ - GlaxoSmithKline)**

#### **Description:**

Kivexa™ is a fixed dose combination of abacavir and lamivudine, two nucleoside reverse transcriptase inhibitors (NRTIs), that is indicated in antiretroviral therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults.

#### **Dosage Form:**

Tablet containing abacavir 600 mg and lamivudine 300 mg.

#### **Recommendation:**

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Kivexa™ be listed in a similar manner as drug plans list other NRTIs for treatment of HIV infected adults.

#### **Reasons for the recommendation:**

1. Two unpublished open label randomized controlled trials compared the fixed dose combination of abacavir/lamivudine (600mg/300mg) to either:
  - abacavir 300mg bid and lamivudine 300 mg once daily or
  - abacavir 300 mg bid and lamivudine 150 mg bid.These regimens were further combined with either a non-nucleoside reverse transcriptase inhibitor or a protease inhibitor with or without tenofovir. The trials found no statistically significant differences in the outcomes of viral load, CD4 cell counts, time to treatment failure, emergence of resistance or adverse events.
2. There was no significant difference in the overall frequency of hypersensitivity reactions or severe hypersensitivity reactions with the once daily versus twice daily dosing regimens of abacavir in either of the reported trials.
3. Once-daily dosing has the potential advantage of reducing pill burden in patients.
4. A bioequivalence trial demonstrated bioequivalence of the fixed dose combination of abacavir/lamivudine compared to the separately administered doses of abacavir and lamivudine, under fasting conditions.

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### **Common Drug Review**



5. Abacavir/lamivudine in fixed dose combination is comparable in price to the equivalent doses of abacavir and lamivudine when administered separately.

**Of Note:**

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.