Lopinavir/Ritonavir

Product:
LOPINAVIR/RITONAVIR (Kaletra®)
200/50mg tablet

Class of drugs:
Antiretroviral agent; protease inhibitor

Indication:
Treatment of HIV infection

Manufacturer:
Abbott Laboratories Ltd.

CED Recommendation

The CED recommended that lopinavir/ritonavir (Kaletra) 200mg/50mg tablet be listed on the Ontario Drug Benefit (ODB) Formulary as a General Benefit via the Facilitated Access Mechanism. The CED’s recommendation was made on the basis that this new formulation of lopinavir/ritonavir (Kaletra) appears to be comparable in efficacy, safety and cost to the currently funded 133/33mg soft gel capsule.

Executive Officer Decision

Based on the CED’s recommendation and a negotiated pricing agreement with the manufacturer, the Executive Officer decided to list lopinavir/ritonavir (Kaletra) 200/50mg tablet on the ODB Formulary as a General Benefit via the Facilitated Access Mechanism.

Status

Funding available through the Ontario Public Drug Programs.

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**Detailed Discussion:**

- The Committee reviewed this drug on two occasions, initially in February 2007 and again in July 2007. Both published and unpublished data were considered as a part of this review.
- Evidence supporting lopinavir/ritonavir (Kaletra) 200mg/50mg tablet comes from clinical trial data as well as bioequivalence data.
- Results from the submitted bioequivalence study comparing lopinavir/ritonavir (Kaletra) 200mg/50mg tablet to the 133mg/33mg soft gel capsule demonstrated that the two formulations are not bioequivalent. In particular, the peak concentration (Cmax) of ritonavir was higher in the tablet formulation.
- Evidence from clinical trials indicated that the difference in bioavailability between the 200mg/50mg tablet and the 133mg/33mg soft gel capsule did not result in any clinically important differences in safety or tolerability.
- There is no evidence that lopinavir/ritonavir (Kaletra) 200mg/50mg tablet offers any therapeutic advantages (e.g. improved tolerability, improved adherence) over the soft gel capsule.
- The most common adverse events reported with lopinavir/ritonavir were gastrointestinal symptoms, fatigue, and headache.
- The Ministry negotiated a pricing agreement with the manufacturer.
- Overall, the Committee noted that lopinavir/ritonavir (Kaletra) 200mg/50mg tablet is comparable to the currently listed Kaletra 133mg/33mg soft gel capsule with respect to efficacy, safety, tolerability, and cost.

**CEDAC Recommendation:**

(http://www.cadth.ca/index.php/en/cdr/recommendations)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review lopinavir/ritonavir (Kaletra) 200mg/50mg tablet.

**For more information, please contact:**

Ministry of Health and Long-Term Care
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