Report on New Patented Drugs - Prezista

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's *Excessive Price Guidelines* (Guidelines) for all new active substances introduced after January 1, 2002.

Brand Name: Prezista

Generic Name: (*darunavir*)

DIN: 02284057 (300 mg tablet)

Patentee: Janssen-Ortho Inc.

Indication - as per product monograph:

Co-administered with 100 mg ritonavir, and with other antiretroviral agents, is indicated for the treatment of HIV infection in treatment-experienced adult patients who have failed prior antiretroviral therapy.

Date of Issuance of First Patent(s) Pertaining to the Medicine: August 27, 2002

Notice of Compliance with Conditions: July 28, 2006

Date of First Sale: August 14, 2006

ATC Class: J05AE10
Antiinfectives for Systemic Use; Antivirals for Systemic Use; Direct Acting Antivirals; Protease inhibitors

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Prezista was found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and did not exceed the range of prices of the same medicine in the comparator countries listed in the *Patented Medicines Regulations, 1994* (Regulations) where Prezista was sold.

Scientific Review

Prezista is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Prezista be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) System that are clinically equivalent in addressing the approved indication. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP identified Aptivus (*tipranavir*) as a comparator to Prezista as it is clinically equivalent to Aptivus. Aptivus shares the same 4th level ATC class and is indicated and used in combination antiretroviral treatment of HIV-1 infected adult patients with evidence of viral replication who are treatment-experienced.

Other boosted Protease inhibitors (PIs) were not recommended for inclusion in the TCC as they are not indicated nor used for treatment-experienced HIV-1 patients who have multiple PIs resistant strains.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Prezista and the comparator Aptivus are based on respective product monographs and supported by clinical literature.

Price Review

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the price of all of the comparable drug products in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the Regulations.

The price of Prezista 300 mg tablet was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicine.

Introductory Period (August to December 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost per Treatment (per day)
Prezista (*darunavir*) + Norvir SEC (*ritonavir*)	300 mg tablet + 100 mg capsule	4 tablets + 2 capsules	$6.9000[(1)] $1.4169[(2)]	$27.8400 + $2.8338 $30.6738
Aptivus (*tipranavir*) + Norvir SEC (*ritonavir*)	250 mg capsule + 100 mg capsule	4 capsules + 4 capsules	$8.2500[(3)] $1.4169[(2)]	$33.0000 + $5.6676 $38.6676

Sources:
(1) Publicly available price as per the Regulations
(2) Ontario Drug Benefit Formulary, June 2006
(3) Liste des médicaments, Régie de l'assurance maladie du Québec, Février 2007

In 2006, Prezista was being sold in one of the seven countries listed in the Regulations, namely the United States. In compliance with the Guidelines, the price in Canada did not exceed the price in the United States.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the PMPRB Staff and the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.

References - Prezista

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