Report on New Patented Drugs – Torisel

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products conducted by Board Staff for purposes of applying the Board's pre-2010 Guidelines for all new active substances introduced in Canada after January 1, 2002.

Brand Name: Torisel

Generic Name: (*temsirolimus)*

DIN: 02304104 (25 mg/mL)

Patentee: Wyeth Pharmaceuticals

Indication – as per product monograph: Treatment of metastatic renal cell carcinoma

Date of Issuance of First Patent Pertaining to the Medicine: October 16, 2007

Notice of Compliance: December 21, 2007

Date of First Sale: February 20, 2008

ATC Class: L01XE09

Antineoplastic and Immunomodulating Agents; Antineoplastic Agents; Other Antineoplastic Agents; Protein kinase inhibitors

Application of the Guidelines

Summary

The introductory price of Torisel was found to be within the pre-2010 Guidelines because the cost of therapy did not exceed the cost of therapy of existing drug products in the Therapeutic Class Comparison and did not exceed the range of prices of the same drug product in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Torisel was sold.

Scientific Review

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

The Therapeutic Class Comparison (TCC) test of the pre-2010 Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drug products 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) classification system that are clinically equivalent in addressing the approved indication. See the PMPRB's *Compendium of Guidelines, Policies and Procedures "up to 2009"* for a more complete description of the pre-2010 Guidelines and the policies on TCCs.

The HDAP recommended Sutent (sunitinib), Nexavar (sorafenib) and Proleuken (aldesleukin) as appropriate comparators to Torisel. Sutent and Nexavar are approved for the same indication as Torisel and share the same 4th level ATC class. Proleukin is used as a first-line treatment option and is listed on BC Cancer Agency (BCCA) and Cancer Care Ontario (CCO) protocols for metastatic renal cell carcinoma (mRCC).

The pre-2010 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 Torisel and the comparable drug products were based on the respective product monographs and supported by clinical literature.

Price Review

Under the pre-2010 Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on the TCC test or if it exceeds the range of prices of the same drug product sold in the seven countries listed in the Regulations.

The introductory price of Torisel was within the pre-2010 Guidelines as the cost per treatment did not exceed the cost per treatment of the comparable drug products as shown in the following table.

Introductory Period (February to June 2008) — Torisel 25 mg/mL

Brand Name (generic Name)	Strength	Dosage Regimen (per 6 weeks)	Unit Price	Cost per Treatment (per 6 weeks)
Torisel (temsirolimus)	25 mg/mL	6 vials	$1,250.0000[1]	$7,500.0000[1]
Sutent (sunitinib)	50 mg	28 capsules	$248.1425[2]	$6,947.9900[2]
Nexavar (sorafenib)	200 mg	168 capsules	$43.7500[3]	$7,350.0000[3]
Proleuken (aldesleukin)	1.3 mg	56 vials	$488.0600[3]	$27,331.3600[3]

Sources:

1 Publicly available price as per the *Patented Medicines Regulations*
2 Régie de l'assurance maladie du Québec, 2008
3 Association québécoise des pharmaciens propriétaires, 2008

In 2008, Torisel was sold in two countries listed in the Regulations, namely, Germany and the United States. In compliance with the pre-2010 Guidelines, the price of Torisel in Canada did not exceed the prices of the same drug product in these countries. The Canadian price was the lowest of these countries.

The publication of Summary Reports is part of the PMPRB's commitment to make its price review process more transparent.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented drug products sold in Canada to ensure that such prices are not excessive.

The PMPRB reserves the right to exclude from the Therapeutic Class Comparison test any drug product it has reason to believe is being sold at an excessive price.

In Summary Reports under the pre-2010 Guidelines, the PMPRB refers to the publicly available prices of comparators, provided that such prices are not more than 10% above a non-excessive price, in which case no price will be made available. Publication of these prices is for information only and should not be construed as indicating that the public prices are considered to be within the pre-2010 Guidelines.

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

This report, including the references, is available on the PMPRB Web site at PMPRB/Regulatory/Patented Medicines/Reports on New Patented Drugs for Human Use/Torisel

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