

Report on New Patented Drugs - Oencia

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

Brand Name: Oencia
Generic Name: (*abatacept*)
DIN: 02282097 (250 mg / 15 mL vial)
Patentee: Bristol-Myers Squibb Canada Inc.

Indication - as per product monograph:

For reducing signs and symptoms, including clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs and/or to TNF antagonists. Oencia may be used as a monotherapy or in combination with DMARD therapy.

Date of Issuance of First Patent(s) Pertaining to the Medicine: May 22, 2007

Notice of Compliance: June 29, 2006

Date of First Sale: August 6, 2006

ATC Class: L04AA
*Antineoplastic and Immunomodulating Agents;
Immunosuppressive Agents; Selective
immunosuppressive agents*

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Oencia was found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing comparable medicines in the therapeutic class comparison and the price did not exceed the range of the prices in other comparator countries where Oencia was sold.

Scientific Review

Orencia is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Orencia be classified as a category 3 new medicine (provides moderate, little or 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 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* for a more complete description of the selection of the Guidelines and the policies on TCCs.

The HDAP recommended Enbrel (*etanercept*), Humira (*adalimumab*), Kineret (*anakinra*), and Remicade (*infliximab*) as the most appropriate comparators for Orencia. These products are in the same 4th level as Orencia and are all biological agents that are indicated and used for the treatment of moderate to severe RA in patients who failed to respond to one or more synthetic disease modifying anti-rheumatic drugs.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. Comparative dosage regimens for Orencia and the comparators are based on product monographs, guidelines and published clinical trials.

As the treatment of RA is considered a chronic situation, the HDAP recommended that the maintenance dosage regimen of Enbrel, Humira, Kineret, and Remicade be compared to the maintenance dosage regimen of Orencia. Since the dosing frequency of the comparators varies so widely (i.e., from daily dosing to once every 8 weeks as in the case of Remicade), the amount of respective drugs that needs to be administered during one year was recommended for the purpose of establishing the TCC.

Price Review

Under the Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all of the comparable drug products, based in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations, 1994* (Regulations).

The price of Orenzia was within the Guidelines as the cost of treatment did not exceed the cost of treatment of the comparable medicines and did not exceed the range of the prices of the same medicine sold in the countries listed in the Regulations.

Introductory Period (August to December 2006)

Brand Name (Generic)	Strength	Dosage Regimen (per year)	Unit Price	Treatment Cost (per year)
Orenzia (abatacept)	250 mg/vial	39 vials	\$548.3300¹	\$21,384.8700
Enbrel (etanercept)	25 mg/vial	104 vials	\$165.0000 ³	\$17,160.0000
Humira (adalimumab)	40 mg/vial	26 vials	\$660.0000 ³	\$17,160.0000
Kineret (anakinra)	100 mg/syringe	365 syringes	\$43.3100 ²	\$15,808.1500
Remicade (infliximab)	100 mg/vial	22.75 vials	\$940.0000 ³	\$21,385.0000

Sources:

- (1) Publicly available price as per the *Regulations*.
- (2) Association québécoise des pharmaciens propriétaires, Février 2006.
- (3) Liste de médicaments du Québec, Régie de l'assurance médicaments du Québec, Février 2006.

In 2006, Orenzia was being sold in two countries listed in the Regulations, namely Sweden and the United States. The price of Orenzia in Canada was the lowest of those countries.

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 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 – Orenzia

- 1. Allison C. Abatacept as add-on therapy for rheumatoid arthritis [Issues in emerging health technologies issue 73]. Ottawa: Canadian Coordinating Office for Health Technology Assessment; 2005.

2. American College of Rheumatology Subcommittee on Rheumatoid Arthritis. Guidelines for the management of rheumatoid arthritis – 2002 update. *Arth Rheum* 2002;46(2):328-46.
3. Cron RQ. A signal achievement in the treatment of arthritis. *Arth Rheum* 2005;52(8):2229-32.
4. Genovese MC, Becker JC, Schiff M, *et al.* Abatacept for rheumatoid arthritis refractory to tumor necrosis factor alfa inhibition. *N Engl J Med* 2005;353:1114-23. Erratum in: *N Engl J Med* 2005;353:21;2311.
5. Kremer JM. Selective costimulation modulators: A novel approach for the treatment of rheumatoid arthritis. *J Clin Rheumatol* 2004;11:S55-62.
6. Kremer JM, Dougados M, Emery P, *et al.* Treatment of rheumatoid arthritis with the selective costimulation modulator abatacept. *Arth Rheum* 2005;52(8):2263-71. Erratum: *Arth Rheum* 2005;52:3321.
7. Kremer J, Shergy W, Tindall E, *et al.* Sustained clinical efficacy demonstrated by the selective co-stimulation modulator abatacept (CTLA4Ig) in combination with methotrexate at 1 year in rheumatoid arthritis patients with an inadequate response to methotrexate.
8. Kremer JM, Westhovens R, Leon M, *et al.* Treatment of rheumatoid arthritis by selective inhibition of T-cell activation with fusion protein CTLA4Ig. *N Engl J Med* 2003;349:1907-15.
9. Mariette X. Emerging biological therapies in rheumatoid arthritis. *Joint Bone Spine* 2004;71:470-4.
10. Moreland LW, Alten R, Filip Van den Bosch, *et al.* Costimulatory blockade in patients with rheumatoid arthritis. *Arth Rheum* 2002;46(6):1470-9.
11. National Institute for Health and Clinical Excellence. Proposed Health Technology Appraisal. Abatacept for the Treatment of Refractory Rheumatoid Arthritis. Provisional Matrix of consultees and commentators.
12. News Announcement. New 50 mg/mL Prefilled Syringe for Enbrel Now Available. Wyeth Canada. Montreal, Canada. 2006.
13. Olsen Nancy and Stein Michael. New drugs for rheumatoid arthritis. *N Engl J Med.* 350(21)2004; 2167-2179.

14. Pollard L, Choy E. Rheumatoid arthritis: non-tumor necrosis factor targets. *Curr Opin Rheumatol* 2005;17:242-6.
15. Prescribing Information of Rituxan (rituximab). Genetech/Biogen Idec. Available from: <http://www.rituxan.com/ra/prescribing-info.jsp> (accessed 6 April 2006).
16. Ruderman EM, Pope RM. The evolving clinical profile of abatacept (CTLA4-IG): a novel co-stimulatory modulator for the treatment of rheumatoid arthritis. *Arthritis Res Ther* 2004;7(suppl2):S21-5.
17. The Arthritis Society. Rheumatoid Arthritis. Available from: <http://www.arthritis.ca/types%20of%20arthritis/ra/default.asp?s=1> (accessed 30 Mar 2006).
18. WHO Collaborating Centre for Drug Statistics Methodology. New ATC codes, new DDD and ATC/DDD alterations. Available from: <http://www.whocc.no/filearchive/word/internet.doc> (Accessed 24 Mar 2006).