



Health Newsflash

New Drugs and Indications Reviewed at the October 2004 DEC Meeting



The Drug Evaluation Committee (DEC) of ESI Canada conducts a monthly review of all new drugs receiving their Notices of Compliance from Health Canada, to ascertain their places in therapy and their possible impacts on the private payer sector. Pricing information is included when the drug is available for sale. However, availability of a drug does not immediately follow its approval by Health Canada. This issue is provided to our insurance customers as a value-added service. We hope you will find this Health Newsflash informative, timely, and useful.

Optimizing the Value of Drug and Dental Benefits

New Brand Drugs:

Frova [*Froe-vah*] (2.5 mg of frovatriptan) is available as an oral tablet from Vernalis Development Limited. It is used for treating migraine headaches and belongs to the triptan drug class (e.g., Imitrex, Relpax, Zomig). It is reported that 8% of the population suffers from migraines and two-thirds of those are women. The recommended dose is one tablet as soon as possible at onset of headache. Frova stays longer in the blood compared to other triptans (26 hours vs. 6 hours) and therefore, may provide longer relief from migraines and reduce the need for a second dose. ESI Canada will monitor this drug class as Frova may effect utilization. Pricing information is currently not available, but it is anticipated to be priced similarly to other drugs in its class at about \$13 to \$15 per tablet. Since the triptan drug class currently includes a number of similar drugs, it is anticipated that Frova will have minimal impact to employer drug plans.

Humira [*You-meer-rah*] (40 mg/0.8 ml of adalimumab) is available as an injection under the skin from Abbott Laboratories Limited. Since it is given under the skin, Humira can be administered in the home or home-care setting by any trained individual (e.g., like insulin). It is used to reduce the signs and symptoms of moderate to severe rheumatoid arthritis, as well as slow the progression of the disease. This is the first fully human monoclonal antibody (helps the body fight certain foreign substances) that targets tumor necrosis factor alpha (TNF- α), a substance in the body that causes swelling and joint damage in rheumatoid arthritis. Other drugs in this therapy class include Enbrel and Remicade. Humira is available in pre-filled syringes and the recommended dosage is 40 mg under the skin every other week. It can be used alone or in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs). Annual cost of therapy for any of these drugs is approximately \$17,000-\$20,000 per patient. Due to its convenience, some patients may be switched from current therapy to Humira. This drug class has been designated as intermediate impact and it is anticipated that Humira will compete for marketshare with the other drugs in the class. Employer plans using a prior authorization program for Enbrel or Remicade may want to include Humira as well.

Zymar [*Zeye-mar*] (3 mg/ml of gatifloxacin) is available as eye drops from Allergan Inc. It is an antibiotic used for treating bacterial eye infections such as conjunctivitis. Bacterial conjunctivitis (pink eye) is the most common eye infection, especially among children. Zymar is similar to Vigamox, another recently approved drug. Both drugs have a broad range of activity against bacteria and can be used when current therapy does not work. While pricing is currently unavailable, it is anticipated to be priced similarly to Vigamox (\$12.00/bottle). Other eye drops used for treating pink eye vary in cost (e.g., Ocuflax \$7.08, Apo-ofloxacin \$4.96, Ciloxan \$9.70). It is anticipated that Zymar will have minimal impact to employer drug plans.

New Indications

Celebrex [*Sell-leh-brecks*] (100 mg and 200 mg of celecoxib) is available as oral capsules from Pfizer Canada Inc. It can now be used in the short term (seven-day) treatment for moderate to severe acute pain (e.g., pain after surgery) in adults. The recommended dose is 200 mg to 400 mg daily. Celebrex, a COX-2 inhibitor is comparable in efficacy to other non-steroidal anti-inflammatory agents (NSAIDs-e.g., Motrin, Naprosyn).

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page 2



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Celebrex was previously indicated for relieving pain, swelling and stiffness caused by rheumatoid or osteoarthritis. This new indication is anticipated to have minimal impact to employer drug plans.

Arixtra [*Ah-ricks-trah*] (12.5 mg/ml of fondaparinux) is available as an injection under the skin co-marketed by Organon and Sanofi-Aventis. Since it is given under the skin, Arixtra can be administered in the home or home-care setting by any trained individual. Arixtra is available in this new strength for treating venous thromboembolism (blood clots). Arixtra is a low molecular weight heparin also used for preventing blood clots in patients undergoing surgery of the lower limbs (e.g., knee or hip surgery). Dosing is based on patient weight and administered for 5 to 9 days. Pricing information is not yet available, but it is anticipated that the new strength will be priced similarly to its comparator drugs (e.g., Lovenox, Fragmin) at approximately \$20 per injection.

New Generic Drug

Apo-Leflunomide [*Ah-po Le-flewn-no-mide*] (10 mg, 20 mg of leflunomide) was approved by Health Canada on September 8, 2004 and is available as an oral tablet by Apotex Inc. This drug is a generic form of Arava by Aventis Pharma Canada. It is used for treating active rheumatoid arthritis in adults. When compared to other drugs in this therapy class (e.g., Enbrel, Remicade, methotrexate), Arava accounts for 3.3% of the total claims volume and 7.7% of the total claims paid (September 2003 to August 2004) Apo-Leflunomide is approximately 34% less expensive than Arava and will eventually save on employer drug plans costs when interchangeability on provincial drug plans, which would allow substitution for Arava with Apo-Leflunomide, has been established.

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