



Health Newsflash

New Drugs and Indications Reviewed at the December 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 Drug

Xolair [*Zole-air*] (125 mg/ml of omalizumab) is available from Novartis Pharmaceuticals Canada as an injection under the skin. It is the first biologic agent to treat asthma by blocking immunoglobulin E (IgE), an underlying cause of allergic asthma symptoms. Asthma is a lung disease which affects approximately 1 in 10 Canadian adults. Approximately 70% of moderate to severe asthma cases have an allergic component. Xolair is used in patients older than 12 years of age with moderate to severe allergic asthma who also are uncontrolled with inhaled steroids. To start therapy with Xolair, a patient must have positive skin and blood IgE allergy tests. One injection of 150 to 375 mg is given every 2 or 4 weeks, depending on body weight and IgE blood level. Anaphylaxis (severe allergic reaction which can result in death), although rare, has been reported and, as a result, Xolair must be given in a physician's office. The manufacturer has established a program where physicians can enroll patients and designated pharmacies dispense the drug directly to physicians' offices for injection. In clinical trials, Xolair was associated with two times the risk of cancer in general (increase from 0.2% to 0.5%). This potential association will be examined in future studies to determine if the risk of cancer outweighs the benefits of using Xolair. Xolair is priced at \$600 per 150 mg vial. Annual cost will vary by patient, due to dosing regimens, and will range between \$8,000 and \$31,000. Since its approval in the United States in June 2003, Xolair has been prescribed to 20,000 patients (approximately 0.2% of asthmatics). Because of the potential clinical value and cost of this new drug, it is anticipated that Xolair will have an intermediate impact on employer drug plans.

New Indications

Seroquel [*Sir-oh-kwell*] (25, 100, 150, 200 and 300 mg of quetiapine) is available as oral tablets from AstraZeneca Canada Inc. Seroquel was previously indicated for treating schizophrenia. It is now approved to treat acute manic episodes (exaggerated excitement) associated with bipolar disorder, a mood disorder characterized by alternating states of depressed and excited behaviour. Zyprexa (olanzapine) is another antipsychotic drug recently approved for this condition. Mood stabilizers such as lithium, carbamazepine and valproic acid have been the standard for bipolar disorder. For the dosage required, Seroquel would cost \$2,000 to \$3,750 per year, similar to Zyprexa at \$2,500 to \$4,000 per year. In comparison, the older mood stabilizers cost between \$150 and \$500 per year. As Seroquel is the second antipsychotic drug for this indication, it is anticipated that Seroquel will have minimal impact to employer drug plans.

Saizen [*Sigh-zen*] (3.33 and 5 mg per vial powder for solution of somatropin) is available as injections into muscle or under the skin from Serono Canada Inc. Saizen is one of several brands containing the human growth hormone, somatropin. It is now approved to treat adult growth hormone deficiency (GHD). Previously, Saizen was approved to treat GHD in children with growth failure. It is also used to treat two specific diseases that also cause growth failure in children (Turner's syndrome and chronic renal failure). The

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adult dose is 0.005 mg/kg daily for the first 4 weeks and then 0.01 mg/kg daily, if required. For example, a 70 kg person using 0.01 mg/kg/day maintenance therapy would cost about \$13,000 per year. Most patients will require daily injections indefinitely to maintain the benefits. Humatrope is another brand of somatropin approved for the treatment of GHD syndrome in adults. The prevalence of GHD in adults is rare at approximately 0.01% (1 in 10,000). As GHD is rare in adults and Humatrope already has the same indication, it is anticipated that this new indication for Saizen will have minimal impact to employer drug plans using these drugs. Provincial drug programs may cover these drugs based on specific conditions (e.g., income-based, disease criteria) and patients will have to contact their respective provinces to determine coverage options.

Optimizing the Value of Drug and Dental Benefits

New Generic

Novo-levofloxacin [*No-vo-leave-oh-flocks-ah-sin*] (250 and 500 mg of levofloxacin) is available from Novopharm as oral tablets. Novo-levofloxacin is the generic equivalent of Levaquin, an antibiotic used to treat bacterial infections in the lungs, such as pneumonia. Avelox and Tequin are other antibiotics in this therapy class. This class represented 0.36% of ESI Canada drug expenditure, with Levaquin having a 37% market share in the class, for the 12-month period ending November 2004. As generic Novo-levofloxacin is 30% less expensive than Levaquin, savings to employer drug plans will eventually result when interchangeability on provincial drug plans for these two products are approved.

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