



Health Newsflash - a Quarterly Publication

New Drugs and Pipeline Drugs Reviewed at the April to June 2007 DEC Meeting



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

New Drugs

Optimizing the Value of Health Benefits

Sprycel (20 mg, 50 mg, 70 mg dasatinib monohydrate) is a new oral tablet available from Bristol-Myers Squibb Canada indicated for the treatment of adult patients with chronic myeloid leukemia (CML) who are resistant or intolerant to prior therapy including imatinib mesylate (Gleevec). The recommended adult dosage for Sprycel is 70 mg twice daily (140 mg/day). However, recent data has shown that a 100 mg daily dose provides a more favorable side effect profile while maintaining comparable efficacy. Generally, treatment is continued long-term unless there is evidence of disease progression or the drug becomes no longer tolerated by the patient. Currently, it is estimated that about 3,000 Canadians are living with CML and that 30% of patients are over 60 years of age. Possible treatment options include conventional chemotherapy, interferons, bone marrow transplant, Gleevec, and now Sprycel. One-quarter to one-third of patients will undergo bone marrow transplants (only definitive CML cure) while those ineligible will typically begin Gleevec therapy. If patients develop resistance to Gleevec, its dose may be increased up to a maximum of 800 mg/day, or the drug can be discontinued and another treatment modality chosen, such as Sprycel. For a standard daily dose of 140 mg/day and the lower dose of 100 mg/day, Sprycel is priced at \$150.94 and \$136.86 per day, respectively. The daily cost for Gleevec ranges from \$107.96 to \$215.92 based on a dosage range of 400-800 mg/day. Sprycel, therefore, offers a cost saving advantage over high-dose Gleevec. Due to this price difference, the low number of patients being treated, and the fact that Sprycel is considered a second line therapy, this drug should have minimal impact to private payers.

Somatuline Autogel (60 mg/0.3 mL, 90 mg/0.3 mL, and 120 mg/0.3 mL lanreotide acetate) is a long acting formulation of lanreotide, a somatostatin analogue, used for the treatment of acromegaly (excessive growth hormone secretion). Somatuline Autogel is available as an injection from Ipsen Limited and is administered under the skin every 28 days at doses of 60 mg, 90 mg and 120 mg. Acromegaly is a chronic condition that affects approximately 3-4 people per million. Treatment strategies include surgery, medications, or radiation. Recommended first line agents are the somatostatin analogues octreotide (Sandostatin, Sandostatin LAR and generics) and lanreotide (Somatuline Autogel). Dopamine agonists are considered second line or are used as adjunctive therapy, and pegvisomant (Somavert) is recommended for those patients who have failed therapy with the other agents mentioned. Pricing has now become available for Somatuline Autogel and ranges from \$1,102 for 60 mg to \$1,840 for 120 mg. Based on a 28 day dosing schedule, the annual cost will be approximately \$15,000 to \$25,000 per patient. Somatuline Autogel's main comparator, octreotide LAR (Sandostatin LAR), is also administered once a month and has an annual cost of \$16,000 to \$27,000 per patient. Somatuline Autogel, therefore, is within the price range for other comparators within the somatostatin analogues class. Both agents are equally effective at treating acromegaly and Somatuline Autogel should have a minimal impact on private plans.

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Optimizing the Value of Health Benefits

Xyrem (500 mg/mL, sodium oxybate) is an oral solution from Valeant Canada indicated for the treatment of cataplexy (abrupt episodes of weak or paralyzed muscles) in adult patients with narcolepsy (involuntary daytime sleepiness). The recommended starting dose is 4.5 g/night where the first dose is taken at bedtime and the second dose is taken 2.5 - 4 hours later. The maximum recommended dose is 9 g/night. Narcolepsy is a debilitating neurologic sleep disorder that affects approximately 9600 Canadians. It is often diagnosed when patients are in their 20s and progresses in severity over time. The classic symptoms include sudden sleep onset/offset, cataplexy, hallucinations, and unexpected sleep paralysis. Traditional therapy options for cataplexy include tricyclic antidepressants (TCAs - e.g. nortriptyline), and selective serotonin reuptake inhibitors (SSRIs - e.g. fluoxetine). Fluoxetine costs between \$1.01 and \$4.03 per day and nortriptyline has a daily cost varying from \$0.50 to \$2.02. On the other hand, each 180 mL bottle of Xyrem costs approximately \$450.00 (\$2.50 per 500 mg). Since the average daily dose is about 7 g/night, the daily cost would be approximately \$35.00. Clinical trial data indicate that 80% of patients have their symptoms controlled by either TCAs or SSRIs. This, in addition to the large price differential, will cause Xyrem to be reserved for patients unresponsive or resistant to TCAs and SSRIs. It is also important to note that Xyrem is a known drug of abuse. Due to this fact, the manufacturer has designed a risk management program known as the Xyrem Success Program to facilitate the safe and effective use of the drug while limiting its abuse potential. Physicians, pharmacists and patients are required to complete special training before the drug can be prescribed, dispensed and used. Furthermore, Xyrem will only be available from a single wholesaler who will only ship the product to pharmacies when a prescription is presented (i.e., on an as-needed basis). In light of Xyrem's place in therapy and the safeguards for its use, its introduction will have a minimal impact on private coverage.

Pipeline News

This section highlights newsworthy drugs that are expected to come to market in the near future and that are anticipated to be highly utilized, or priced at a premium in Canada.

The U.S. Food and Drug Administration (FDA) recently approved a novel vaccine for humans against the H5N1 influenza virus, commonly known as the avian or bird flu. The vaccine, developed by Sanofi Pasteur Inc, could be used in the event the current H5N1 avian influenza virus was to develop the capability to effectively spread between humans. In such an instance, the vaccine may provide early, limited protection in the months before a vaccine specifically adapted to a pandemic strain of the virus could be developed and manufactured. Currently, there have been no human cases of H5N1 virus infection in the United States or Canada, however, nearly 300 people worldwide have been infected with this virus since 2003 and more than 150 have died. The new H5N1 influenza virus vaccine was developed from a human strain of the virus and is intended for immunizing adults between the ages of 18 and 64, who are at risk of exposure. Immunization consists of two intramuscular injections given one month apart. It is important to note that the vaccine will not be available commercially but only through the U.S. government which has purchased it for inclusion in their National Stockpile. To date there have been no reports of an avian flu vaccine being available in Canada.

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