



Health Newsflash - a Quarterly Publication

New Drugs and Pipeline Drugs Reviewed at the January to March 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 Drug and Dental Benefits

Champix (0.5 mg and 1 mg varenicline) is a new oral tablet available from Pfizer Canada indicated for smoking cessation. Champix is dosed on a titration schedule – 0.5 mg once daily on days 1-3, 0.5 mg twice daily on days 4-7, and 1 mg twice daily for the remaining period. Total treatment duration is typically 12 weeks; however, treating for an additional 12 weeks may lead to a significantly higher abstinent rate at one-year follow-up. The only other oral prescription requiring agent currently on the market for smoking cessation is Zyban (bupropion SR). In clinical trials, Champix was almost twice as effective as Zyban at 12 weeks in achieving abstinence from smoking. Follow-up at one year (52 weeks) demonstrated that more patients treated with Champix remained smoke-free compared to those receiving Zyban. Champix is priced at an average of \$3.37/day whereas Zyban costs \$1.84/day. Despite this cost difference, Champix is expected to have minimal impact on plans that have dollar or quantity maximums on smoking cessation products. In addition, for plans covering transdermal nicotine patches (non-prescription requiring), the daily cost differential is minimal or neutral.

Sebivo (600 mg telbivudine) is available from Novartis Pharmaceuticals Canada Inc. as an oral tablet indicated for the treatment of chronic infection with hepatitis B virus (HBV) in adults 16 years and older. Sebivo is dosed 600 mg once daily and will compete with other oral agents for chronic HBV, including lamivudine, and newer agents Hepsera (adefovir) and Baraclude (entecavir). Chronic HBV is also treated with weekly injections of interferon alfa (e.g. Pegasys), but it is not as well tolerated as the oral agents. Sebivo has been demonstrated to be as effective as lamivudine, but how it compares to the newer agents is unknown at this time. Further study is needed on its long-term efficacy and safety. The daily cost of Sebivo is approximately \$18/day, which is considerably lower than Hepsera and Baraclude (both \$23.21/day); however, it is still significantly more expensive than lamivudine at \$4.64/day. Sebivo is expected to have minimal impact on private plans because of the small population of patients with HBV (less than 5% of patients with acute hepatitis B develop chronic HBV) and its lower cost compared to Hepsera and Baraclude. It will be interesting to monitor which agent becomes the market leader in this category over the next several years.

Pipeline News

The following section is intended to highlight any noteworthy drugs that we expect will come to market this year and that are anticipated to be highly utilized or priced at a premium in Canada.

Tekturna (aliskiren) is an oral tablet manufactured by Novartis Pharmaceuticals which was recently approved by the FDA (Food and Drug Administration) in the US for the treatment of high blood pressure. Tekturna belongs to a new class of agents called renin inhibitors, the first new therapy class for high blood pressure in almost 10 years. Renin is a key enzyme that helps regulate blood pressure in the kidneys. Tekturna will likely

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compete with the ACE inhibitors (Angiotensin Converting Enzyme) and ARBs (Angiotensin Receptor Blockers) classes of drugs as they work on similar mechanisms in the body. Common examples of drugs from these classes are Altace and Diovan, respectively. Tekturna is dosed once daily and is available as 150 and 300 mg tablets. It has been approved for use alone or in combination with other high blood pressure medications, but until long-term data on efficacy and safety is available, Tekturna will likely be reserved as add-on therapy to other agents. US pricing is approximately \$2/day and it is anticipated to be priced similarly in Canada. Tekturna will be called Rasilez in Canada and has been submitted to Health Canada for approval with NOC expected by the end of 2007. Of note, high blood pressure medications are ranked #1 among the Top 5 Health Conditions in ESI Canada's book of business (BOB) by ingredient cost for 2006.

Impact Statements

Minimal Impact

1. The estimated cost of the new drug is similar to existing drugs and the new drug is likely to become one of a number of existing drugs used for the medical condition (shifting of market share) or,
2. The estimated cost of the new drug is similar to existing drugs and the new drug has low utilization due to either its place in therapy, its relation to other drugs or the prevalence of the medical condition

Intermediate Impact

1. New drug has an estimated higher than average cost compared to drugs used for the medical condition or,
2. New drug has an anticipated higher than average utilization due to either its place in therapy, its relation to other drugs or the prevalence of medical condition

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