



Health Newsflash - a Quarterly Publication

New Drugs and Indications Reviewed at the July to September 2006 DEC Meetings



*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, 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.*

Optimizing the Value of Drug and Dental Benefits

New Drugs

Gardasil (recombinant human papillomavirus) is a new vaccine produced by Merck Frosst that is indicated for women aged 9-26 years to prevent against infection caused by human papillomavirus (HPV) strains 6, 11, 16, and 18. HPV strains 6 and 11 are implicated in up to 90% of genital wart cases, and types 16 and 18 are responsible for up to 70% of cervical cancers. Gardasil will not protect against diseases due to non-vaccine HPV types and will not protect against types the patient has already been exposed to (i.e. the vaccine is only for prevention, not treatment). Gardasil is dosed as 3 separate injections – one at a specified date, then 2 months after the first dose, and the last at 6 months after the first dose. Each dose costs approximately \$145, which makes the total treatment course \$435/patient. This product has been assessed to have an intermediate impact on plans because of the high number of females that potentially may be treated, and this number could increase should the vaccine be granted approval in the male population as well. Merck Frosst is currently conducting research on male patients.

Myozyme (50 mg/vial alglucosidase alfa) is a new biologic drug for injection into the vein from Genzyme Corporation. Myozyme is indicated for the treatment of glycogen storage disease (type II), or more commonly known as Pompe disease. This drug is a welcome addition as it is the first treatment that specifically targets the disease process by replacing the enzyme that patients are lacking. Previously, drugs were only available to treat the symptoms of this disease. Because this disease is rare (estimated incidence of 1 per every 40,000 births) and this drug is a revolution for patients, it comes at a substantial cost. Pricing is currently unknown in Canada, but reports from the US indicate that it will cost a single patient in excess of \$200,000 per year. Life-threatening allergic reactions have been observed during administration, thus it is likely that this drug will be given primarily in a hospital setting. It is currently considered a hospital drug by ESI Canada; as a result, impact to private payers applying the ESI Canada Hospital Drug Program should be minimal.

Orencia (250 mg/vial abatacept) is a new biologic drug available as an injection into the vein from Bristol-Myers Squibb. Orencia is indicated for the treatment of rheumatoid arthritis (RA) in patients who have not responded adequately to one or more disease modifying anti-rheumatic drugs (DMARDs) (e.g. methotrexate, sulfasalazine) and/or TNF antagonists (e.g. Remicade and Enbrel). Orencia is given as a weight-based injection at 0, 2 and 4 weeks, and then every 4 weeks thereafter. Pricing for Orencia is on average \$23,000 per patient per year (based on a 75 kg patient), which puts it in the same price range as the other biologics for RA – approximately \$20,000-\$30,000. Orencia will provide patients with another treatment option as it has a unique mechanism of action. Impact to plans should be minimal as Orencia is not expected to expand the market.

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Baraclude (0.5 mg and 0.05 mg/mL entecavir) is a new drug available as an oral tablet or oral solution from Bristol-Myers Squibb which is indicated for the treatment of chronic hepatitis B. Dosing for Baraclude is 0.5 mg to 1 mg daily. This drug has been studied in both treatment-naïve patients as well as in patients who have developed lamivudine (available as oral tablets and solution) resistance, one of the first-line agents typically given to hepatitis B patients. Concern with lamivudine therapy is that resistance develops over a short period of time; there is thus the need for additional therapies. Baraclude has demonstrated little to no resistance emergence in studies up to 48 weeks in duration. Daily cost of Baraclude is \$22/day which is higher than lamivudine (\$5/day) but equivalent to Hepsera (also \$22/day), which is another treatment option. Baraclude is not expected to expand the market for hepatitis B and because it is priced on par with other agents, it will likely have minimal impact to private plans.

Nexavar (200 mg sorafenib) is a new drug available as an oral tablet indicated for the treatment of metastatic (advanced) renal (kidney) cell carcinoma (RCC). This product by Bayer is dosed as 800 mg daily (4 tablets total) and is typically given in 6-week cycles. First-line therapy for advanced RCC is cytokine-based treatment – i.e. interferon alpha and/or interleukin-2. Nexavar is meant to be used in patients who fail cytokine-based therapy or for patients who are not deemed candidates for this type of therapy. Cost of Nexavar per 6-week treatment course is \$7,350 per patient. As this type of cancer is somewhat rare and cost is not substantially greater than existing treatments, Nexavar should have minimal impact to private plans. However, one thing to note is that Nexavar is just one example of how there is increasing cost-shifting between public and private payers. As more and more oncology drugs are being manufactured as oral preparations, more patients will have the ability to be treated at home as opposed to solely in a hospital setting.

Azilect (0.5 mg and 1 mg rasagiline mesylate) is a new drug available as oral tablets from Teva Neuroscience. Azilect is indicated for the treatment of Parkinson's disease, either in early disease as monotherapy (on its own) or in late disease in combination with Sinemet (levodopa/carbidopa). Recommended and maximum daily dose is 1 mg. Clinical trials have demonstrated that Azilect is comparable in efficacy to entacapone (Comtan), another agent for Parkinson's and has a safety profile similar to placebo. Azilect is in the same therapy class as selegiline (MAO-B inhibitor), an older agent that has been plagued by cardiovascular (heart) and psychiatric side effects. Azilect apparently is devoid of these effects but how this translates into patient compliance and improved symptom control is still unclear. Azilect cost per day is \$7.00 compared to a maximum of \$2.54 and \$12.64 for selegiline and entacapone, respectively. Because pricing is within the current treatment range, impact to private plans is expected to be minimal.

New Indications

For the following new indications, the impact is considered to be minimal unless otherwise noted.

Remicade (100 mg/vial infliximab) is available as an injection into the vein from Centocor Inc., and is now indicated for the treatment of both psoriatic arthritis and chronic plaque psoriasis. The dosing for both these new indications is 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter. The annual cost per patient is approximately \$28,000 - \$36,000 based on a 75 kg (165 lbs.) person. Other biologics used to treat psoriasis include Amevive, Raptiva and Enbrel. Annual per patient costs for these therapies are \$16,000 - \$32,000, \$22,600, and \$22,400 - \$36,000, respectively. Enbrel and Humira are used for the treatment of psoriatic arthritis and cost on average \$18,000 per patient per year. As other biologics are already approved to treat the above diseases, impact to private plans should be minimal. However, it is important to note that existing biologics continue to receive approval for expanded indications, potentially increasing the number of patients that can be treated with these costly, yet valuable, agents.

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Rituxan (10 mg/mL rituximab) is a biologic drug available as an injection into the vein from Hoffman-La Roche and has received a new indication for the treatment of moderate to severe rheumatoid arthritis (RA) in patients who have had an inadequate or intolerance to one or more TNF inhibitors (e.g. Remicade and Enbrel). Rituxan is also indicated for the treatment of non-Hodgkin's lymphoma (NHL). Dosing for RA is two infusions of 1000 mg IV, given two-weeks apart. In clinical studies, re-treatment was given on average 24 weeks later (no earlier than 16 weeks). Pricing for Rituxan is at the lower end of the biologic range, as annual cost per patient is roughly \$20,000. Rituxan will likely be reserved as a last line option for patients initially, until there is more experience with this drug in RA.

Humira (40 mg/0.8 mL adalimumab) is a biologic drug available from Abbott Laboratories which is given as an injection under the skin. Humira is now indicated for patients with moderate to severe rheumatoid arthritis (RA) who have not been previously treated with methotrexate (i.e. early RA), and for active arthritis in adult patients with psoriatic arthritis (PsA). The former indication is simply an extension of Humira's indication for RA in that it is now approved for earlier use in the disease. Enbrel and Remicade also may be used in early RA. The approval for use in psoriatic arthritis is a new indication for Humira. Dosing of Humira for PsA is 40 mg injection under the skin every other week. Annual cost is on par with Enbrel at ~\$20,000 per patient. Humira will now compete with Remicade and Enbrel in the treatment of psoriatic arthritis.

Sutent (12.5 mg, 25 mg, and 50 mg sunitinib malate) is available as oral tablets from Pfizer Canada Inc., and is currently indicated for the treatment of gastrointestinal stromal tumors (GIST). Sutent has now received a new indication for the treatment of metastatic (advanced) renal (kidney) cell carcinoma after failure of cytokine-based therapy (interferon alfa and/or interleukin-2) or in patients likely to be intolerant to this therapy. Sutent is given in 6-week cycles, where it is dosed once daily for 4 weeks, followed by 2 weeks off. Interferon alfa and interleukin-2 are recommended treatment options for renal cell carcinoma, and Sutent (and Nexavar) would be considered second line options for patients. Like Nexavar, Sutent is priced at approximately \$7,330 for 6 weeks of therapy. Although it is anticipated that this product will have minimal impact to private plans, once again we see the introduction of oral dosage forms for diseases that were historically treated in a hospital setting. While this does improve patient compliance, it will increase cost-shifting to private payers.

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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