



## Health Newsflash

### New Drugs and Indications Reviewed at the August 2005 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.*

#### **New Drugs:**

**Luveris** [*Loo-ver-riz*] (75unit/vial lutropin alpha) is available from Serono Canada Inc. as an injection under the skin. It is given with another drug (Gonal-f) for treating infertility in women. Luveris is the only one in this class of fertility drugs that is derived from a pure source (not from urine). It costs about \$67.50 per vial. Luveris will have a minimal impact on drug plans having dollar or number of cycle limits on fertility treatment.

**Tarceva** [*Tar-see-vah*] (25mg, 100mg, and 150mg erlotinib) is available from Hoffmann-La Roche Limited as oral tablets. Tarceva is used to treat patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after treatment with other cancer therapies have failed. The dose is 150 mg/day. There have been infrequent reports of serious lung disease, including fatalities. The incidence of lung cancer in Canada (1995) was 60 per 100,000 (0.06%), with approximately 56% having advanced NSCLC. The overall incidence has declined since the 1990s.

Tarceva will replace some chemotherapy regimens that would normally be paid by hospitals. Iressa is another oral drug with the same indication as Tarceva currently on the market; therefore there will be minimal cost shifting from hospital to private payers. Iressa and Tarceva have similar daily costs with \$75 for Iressa and \$80 for Tarceva. Since Iressa incurred 0.04% of ESI Canada's drug expenditures from July 2004 to July 2005, we anticipate Tarceva to have minimal impact on private plans.

**Tramacet** [*Tram-mah-set*] (37.5mg/325mg tramadol hydrochloride, acetaminophen) is available as oral tablets by Janssen-Ortho Inc. It is a new combination product containing two drugs: tramadol (an opioid) and generic acetaminophen (Tylenol). Tramacet is used to treat acute pain for up to 5 days. Tramadol has been on the market in other countries since 1977 and has less abuse potential than other opioids. Several pain medications are currently available for treating acute pain and Tramacet is more expensive at \$0.62 per tablet, compared to generic Percocet (oxycodone and acetaminophen) at \$0.29. Tramacet is another option for patients, and is anticipated to have minimal impact on private plans.

**Angeliq** [*An-jel-leak*] (1mg/1mg, estradiol, drospirenone) is available as oral tablets by Berlex Canada Inc. as a new combination hormone replacement therapy (HRT). It reduces typical menopausal symptoms and prevents the development of osteoporosis. Due to its lower dose, it has less potential for causing blood clots compared to the standard 2mg dose. Angeliq is similar to existing HRT therapies, although it has a different progestin component (drospirenone). We anticipate that Angeliq will have minimal impact to employer plans as the HRT class accounted for approximately 0.31% of all ESI Canada drug expenditures in 2004.

**Aclasta** [*A-class-tah*] (5mg/100ml zoledronic acid) is available as an intravenous infusion (slow injection into the vein) by Novartis Pharmaceuticals Canada Inc. to treat Paget's disease, a bone disease in men and women. Zometa and Aredia are other drugs to treat cancer patients with bone involvement or increased blood calcium levels. Its cost for 1 course of treatment is about \$650 which is similar to oral drugs currently used for

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page 2



#### Optimizing the Value of Drug and Dental Benefits

this condition (e.g., Fosamax and generics, Actonel - from \$450 to \$680 and Aredia from \$560 to \$1,230). Aclasta can be administered in the community setting. Since it is similarly priced to existing drug treatments, it is expected to have minimal impact on private plans.

#### **New Indications:**

For the drugs listed below, we anticipate that their new indications will have minimal impact on employer drug plans, unless otherwise stated.

**Remicade** [*Rem-mah-cayd*] (100mg/vial infliximab) is available as an intravenous infusion (slow injection into the vein) by Centocor Inc. It is now indicated for ankylosing spondylitis (AS), a disease that causes inflammation of the spine and large joints, and affects 0.05 to 1.8% of the population. Previously, Remicade was only indicated for rheumatoid arthritis (RA) and Crohn's disease. Dosing for AS is based on weight at 5mg/kg and given at 0, 2, and 6-week intervals, then every 6 to 8 weeks thereafter. Currently accepted treatment for AS is exercise and NSAIDs (ibuprofen), with 75% of patients adequately responding. Remicade will be reserved for non-responders to these therapies. The costs of treatment is approximately \$24,000 to \$33,000 per year, which is \$6,000 to \$14,000 more than RA treatment. Although most patients with AS won't require Remicade, we anticipate that this new indication will have an intermediate impact to private plans.

#### **New Dosage Forms:**

For the drugs listed below, we anticipate that their new dosage forms will have minimal impact on employer drug plans, unless otherwise stated.

**Lipidil EZ** [*Lip-eh-dill Ee-Zee*] (48mg, 145mg fenofibrate) is available as oral tablets by Fournier Pharma Inc. Lipidil EZ is a new formulation of Lipidil Supra. With Lipidil EZ, lower doses of the active ingredient have similar efficacy to higher doses of the Supra formulation (e.g., 145mg vs. 160mg). Studies have shown the Supra 160mg to have similar efficacy/tolerability for lowering cholesterol as 200mg of the older "Micro" formulation. With each new formulation, the effective doses are lowered, but there is no evidence that the actual clinical outcomes are superior. It is expected that Lipidil EZ will have minimal impact on private plans since the tablet price is similar to the Supra formulation (48mg at \$0.54, 145mg at \$1.24).

#### **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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