



Health Newsflash

New Drugs and Indications Reviewed at the October to December 2006 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.

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New Drugs:

Tysabri (300 mg/15 mL natalizumab) is a new biologic drug available from Biogen Idec Canada Inc., indicated as monotherapy (i.e. to be used alone) for the treatment of relapsing-remitting multiple sclerosis (MS) in patients intolerable or unresponsive to conventional therapies (e.g. interferons and Copaxone). Tysabri is administered as a 300 mg injection into the vein every 4 weeks. While Tysabri is significantly more expensive than other treatments for MS (approx. \$36,000 vs. \$13,000-\$21,000 for interferons and Copaxone), it has been shown to significantly reduce the number of patients who experience relapses when compared to conventional treatment. The other concern with Tysabri use is its association with progressive multifocal leukoencephalopathy (PML), a rare viral brain infection that can cause severe disability or even death. Due to the need for close monitoring and administration via injection, Tysabri will only be available at private infusion clinics across the country. These will be operated in conjunction with the manufacturer providing support for administration costs, nursing and physician services, and patient enrollment into a safety program. Tysabri is expected to have an intermediate impact to plans because of its increased cost over other therapies, however prior authorization can help to ensure conventional treatments are attempted first and that safety risks are acknowledged by prescribers.

Prexige (100 mg lumiracoxib) is a new COX-2 inhibitor from Novartis Pharmaceuticals Canada Inc. It is available as an oral tablet and is indicated for the acute and chronic management of osteoarthritis of the knee. Prexige is dosed 100 mg once daily; increasing the dose does not provide any additional benefit. This product will directly compete with Celebrex, the only other COX-2 remaining on the market, as well as other anti-inflammatory products. Following the withdrawal of both Vioxx (rofecoxib) and Bextra (valdecoxib), COX-2 utilization has markedly decreased in favor of older, non-steroidal anti-inflammatories (e.g. ibuprofen and naproxen). Prexige has been studied in patients with preexisting stomach and cardiovascular conditions with no increased incidence of adverse outcomes. However, there will likely still be some hesitation in using this product until long-term safety and efficacy is established. To this point, Novartis will be conducting extensive post-marketing research to monitor these effects. Prexige is priced lower than Celebrex (\$1.23/day vs. \$1.37/day) and is anticipated to have minimal impact to private payers.

Alvesco (50, 100, and 200 mcg/actuation ciclesonide) is a new corticosteroid for oral inhalation available from Altana Pharma Inc. Alvesco is indicated for the prophylactic management of steroid-responsive bronchial asthma in patients 18 years and older. The recommended starting dose is 400 mcg once daily, with a maintenance dosing range between 100 – 800 mcg daily. Alvesco will compete with other inhaled corticosteroids on the market, including Flovent (fluticasone), QVAR (beclomethasone), and Pulmicort (budesonide). Clinical trials in patients with asthma have demonstrated that Alvesco provides similar benefits as other inhaled corticosteroids with an improved safety profile. The cost of Alvesco is similar to other agents, and at standard treatment doses, it is priced lower than the market leader Flovent (\$1.14/day vs. \$1.20/day, respectively). Impact to private plans is anticipated to be minimal as Alvesco is not expected to expand the market for asthma and its cost is on par with other agents.

Volume 9
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2007



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Health Newsflash

New Drugs and Indications Reviewed at the October to December 2006 DEC Meeting

page 2



Exjade (125, 250, and 500 mg deferasirox) is available as a tablet for oral suspension from Novartis Pharmaceuticals Canada Inc. Exjade is the first oral therapy for treating chronic iron overload (too much iron in the blood) in patients receiving frequent blood transfusions for anemia. Previously patients had to resort to 8-12 hour injections 5-7 times per week with Desferal (deferoxamine). Because most patients have this condition beginning in the early years of life, compliance is limited due to the age of the patient and daily injection requirements. In addition, use of injection equipment to administer Desferal is costly and inconvenient, and injection site reactions are common. Exjade is similar in efficacy to Desferal at standard doses and offers the advantage of a once daily tablet. However, Exjade is more expensive (~\$7,000 per patient per year) than Desferal when all costs are taken into account. Despite this cost increase, the patient population with this condition is extremely small in Canada (~800 patients), and therefore Exjade should have minimal impact to private plan sponsors.

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Tygcil (50 mg/vial tigecycline) is a new IV antibiotic available from Wyeth Canada indicated for the treatment of complicated intra-abdominal and skin infections. The initial dose for both indications is 100 mg given as injection into the vein followed by 50 mg every 12 hours for a duration of 5 to 14 days depending on disease severity and patient response. Tygcil belongs to a family of antibiotics called tetracyclines, which includes other drugs like minocycline, doxycycline, and tetracycline. Tygcil has demonstrated equivalent cure rates in clinical trials as other common treatments for severe abdominal and skin infections with comparable safety. Because of the severity of conditions treated with this agent, Tygcil has been coded as a hospital drug and will not impact those plans using ESI's Hospital Drug Program. Price is currently unknown.

Norlevo (0.75 mg levonorgestrel) is a new emergency contraceptive tablet available from Laboratoire HRA Pharma. This product is the same as Plan B and patients are to take one tablet as soon as possible (i.e. within 72 hours following intercourse), followed by another tablet 12 hours later. Common side effects include nausea and vomiting. If vomiting occurs within 1-2 hours after the first tablet is taken, the first tablet must be repeated. Norlevo is considered a non-prescription requiring product that will be kept behind the pharmacist's counter. This product will only impact those plans that cover Plan B and similar non-prescription products. Price and availability of Norlevo are currently unknown.

Fosrenol (250, 500, 750 and 1000 mg lanthanum carbonate hydrate) is available as an oral tablet from Shire BioChem Inc. This new drug is used in patients with end-stage kidney disease who have high levels of phosphate in the blood (hyperphosphatemia). Fosrenol is typically dosed three times daily with most patients requiring between 1500 and 3000 mg/day. Other oral phosphate binders already on the market include calcium carbonate products (Os-Cal and others), calcium acetate (PhosLo), and Renagel (sevelamer). Calcium-based drugs are often used first but may lead to high blood levels of calcium. If this occurs, Fosrenol or Renagel are suitable alternatives. The majority of calcium-based products are available without a prescription and are relatively inexpensive. Based on the maintenance dosage range above, Fosrenol costs between \$6.50 and \$13.00 per day. This is similar to the daily cost of Renagel which ranges from \$4.65 to \$13.95 per day. As cost is on par with Renagel and because the patient population is relatively small, impact is expected to be minimal.

New Indications

The following drugs have had new indications for use approved. Impact is considered to be minimal unless otherwise noted.

Humira (40 mg/0.8 mL adalimumab) is a biologic drug for injection under the skin from Abbott Laboratories Ltd. Humira has recently received a new indication for reducing the signs and symptoms in patients with active

Volume 9
Issue 1

Feb. 9,
2007





Health Newsflash

New Drugs and Indications Reviewed at the October to December 2006 DEC Meeting

page 3



Optimizing the Value of Drug and Dental Benefits

ankylosing spondylitis (AS) who have had an inadequate response to conventional therapy (e.g. NSAIDs such as naproxen). Humira is already approved for the treatment of rheumatoid arthritis and psoriatic arthritis. Dosing for AS is the same as for rheumatoid arthritis – 40 mg every other week. AS affects approximately 0.05-1.8% of the national population and most patients (~75%) will respond to NSAID therapy. Humira will join Enbrel and Remicade as biologics approved for the treatment of AS. Humira and Enbrel are priced lower than Remicade on a per patient per year basis - ~\$20,000 vs. ~\$25,000-\$33,000, respectively.

Comment on Patent/Product Life Extensions

Pharmaceutical manufacturers are continually devising new ways to prolong patent life in hope of delaying the introduction of generics to market or retain the brand's market share. Often they look for ways to directly compete with new generics coming to the marketplace. Recent examples of such strategies include new formulations (Wellbutrin XL, Flomax CR and other sustained release products) and combination products (e.g. Altace-HCT, Fosavance, Actonel Sachet Kit). While some of these products improve patient quality of life through increased adherence with once daily dosing and possibly fewer side effects, others have only theoretical advantages over the parent drug. Another benefit includes the possibility of saving a dispensing fee on combination products by packaging drugs for the same condition together. However when tailored treatment and dose individualization is needed these products have limited usefulness. It is critical to weigh the benefits against the risks to determine if the new product has a true advantage for patients and subsequently an advantage for plan sponsors. This is especially true when the cost of the new product is significantly higher, yet lacks evidence of clinical outcomes. A more recent strategy has been to price new versions of products at the same price of the parent drug or at the price at which a generic would enter the market. The intent is to get the new drug covered because it is priced on par or lower than the current brand drug. It then will compete for market share when the generic is approved for sale. In summary, these newer versions of older drugs may provide benefits to patients but should be investigated closely as to what value they provide to patients – theoretical vs. actual.

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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