Cymbalta™ and Abilify™ were originally reviewed by the Medication Advisory Panel in 2008 and 2010, respectively. Cymbalta is an antidepressant agent that has indications that includes: the treatment of neuropathic (nerve) pain due to diabetes, fibromyalgia, and spinal cord injury. Abilify is an antipsychotic agent used for the treatment of schizophrenia and other mood disorders.

Upon reviewing the clinical data for Cymbalta and Abilify, the Medication Advisory Panel concluded that these medications were cost effective treatment options for select indications. In order to limit utilization of these drugs to these indications, a decision was made to add Cymbalta and Abilify as Special Authorization benefits to our managed formularies only (i.e., HealthWise) and not to our less restrictive formularies.

A review of this listing decision was recently conducted. As the Medication Advisory Panel believes that there is clinical value in reimbursement of these medications, both Cymbalta and Abilify will be added as regular benefits on our open formularies, and they will be listed on the second tier of our tiered formulary product, Rx Choices™. Both Cymbalta and Abilify will continue to require Special Authorization on our managed formularies, and reimbursement will be limited to those previously approved indications (diabetic peripheral neuropathic pain for Cymbalta; and Abilify for the indication of schizophrenia). Upon analysis of our book of business, our Actuarial team has estimated that the addition of Cymbalta and Abilify would result in a 0.2% increase to overall health costs.
Product Indications

**Aczone®**  A topical agent for the treatment of acne.

**Benlysta®**  A biologic drug for the treatment of systemic lupus erythematosus.

**Rapaflo®**  Indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia.

**Restoran®**  Indicated for the treatment of chronic idiopathic constipation in adult female patients in whom laxatives fail to provide adequate relief.

**Visanne®**  A new agent for the management of pelvic pain associated with endometriosis.

### Pharmaceutical Decisions

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*Special Authorization where applicable.
*This decision only applies to those groups that follow the Medication Advisory Panel recommendations.

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Detailed Pharmaceutical Decisions

**Aczone**

Aczone (dapsone) is a topical agent for the treatment of acne vulgaris. Treatment options for acne range from topical treatments, such as benzoyl peroxide, topical antibiotics and topical retinoids, to systemic therapy with antibiotics, retinoids and hormonal therapy.

Aczone is supplied as a 5 per cent gel and is available in a 60g tube at a manufactureres list price of $60 per tube. The recommended dose is a small amount, applied to the affected areas twice daily.

The MAP agrees that results of the clinical studies demonstrate the safety and efficacy of Aczone. The addition of Aczone will allow physicians and patients another choice for the treatment of acne.

**Decision:** Aczone has been listed as a regular benefit  
**RX Choices:** Tier 2  
**RAMQ:** Under review

**Benlysta**

Benlysta (belimumab) is a biologic drug for the treatment of systemic lupus erythematosus (SLE). It is the first new agent to be approved for treatment of SLE in Canada in the past 50 years. SLE is an autoimmune disorder, which affects multiple organ systems within the body. Goals of treatment include controlling disease activity, preventing organ damage and improving quality of life.

Benlysta is supplied as powder for intravenous infusion. It is available in two sizes. The 120mg/5mL single-use vial is priced at a cost of $277.20 and the 400mg/20mL vial is priced at $924.

Based on clinical evidence and the lack of alternative treatments the MAP agrees that treatment with Benlysta offers benefits for patients with SLE.

**Decision:** Benlysta has been listed with Special Authorization.  
**RX Choices:** Tier 1  
**RAMQ:** Under review

**Rapaflo**

Rapaflo (silodosin) is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). BPH is a non-cancerous enlargement of the prostate, which can lead to difficulty urinating and increased frequency of urination. BPH is one of the most commonly diagnosed conditions in men over the age of 50.

Rapaflo is supplied in 4mg and 8mg capsules at costs of $1.77 per capsule. The recommended dose is 8mg once daily. For patients with moderate kidney impairment the recommended dose is 4mg once daily.

The MAP agrees that there is no clinical data to demonstrate any advantages of treatment with Rapaflo over existing medications, such as Flomax® and Xatral®, which are available as generics and at a lower cost.

**Decision:** Rapaflo has been declined  
**RX Choices:** N/A  
**RAMQ:** Under review
Detailed pharmaceutical decisions ...continued from page 2.

**Restoran®**

Restoran (prucalopride) is indicated for the treatment of chronic idiopathic constipation in adult female patients for whom laxatives fail to provide adequate relief. Resotran is the only agent available that is indicated for patients with chronic constipation who are unable to find relief with traditional treatments.

Restoran is available in strengths of 1mg and 2 mg tablets at costs of $2.15 and $3.30 respectively. The recommended dose in adults is 2mg once daily. For those over the age of 65 or those who have kidney/liver impairment the dose should be decreased to 1mg once daily. If Restoran is not effective during the first four weeks of treatment, therapy should be stopped.

The MAP agrees that results of clinical trials demonstrate Restoran to be a safe and effective treatment for chronic constipation.

**Decision**: Restoran has been listed as a regular benefit for female patients.

**RX Choices**: Tier 2

**RAMQ**: Under review

**Visanne®**

Visanne (dienogest) is an agent for the management of pelvic pain associated with endometriosis.

Endometriosis occurs when tissue from the lining of the womb grows in other areas of the body, leading to pain, irregular menstrual bleeding and problems getting pregnant. The prevalence of endometriosis is estimated to be about 5 to 10 per cent among women of reproductive age. There is no cure, instead, treatment is focused on managing symptoms. The most commonly used treatment is oral contraceptives.

Visanne helps relieve some of the pain associated with endometriosis. It is supplied as a blister back containing 28 2mg tablets at a cost of $1.96 per tablet. The recommended dose is one tablet per day.

The MAP agrees that results of clinical trials demonstrate Visanne to be a safe and cost-effective treatment.

**Decision**: Visanne has been listed as a regular benefit.

**Rx Choices**: Tier 2

**RAMQ**: Under review