



## **Thelin™ - New Treatment Option for a Rare Pulmonary Disease**

Pulmonary Arterial Hypertension (PAH) is a rare disease that affects approximately 480 to 640 Canadians at any one given time.<sup>1</sup> PAH is a condition, of unknown origin, caused by an increase in blood pressure of the pulmonary artery. There is currently no cure for this life threatening disease, however, there are drug treatments to help alleviate the symptoms associated with PAH, such as, shortness of breath, fatigue, dizziness, chest pain, and swollen ankles or legs and prolong the survival rate for the patients.<sup>2</sup> Long and short term clinical studies have shown that Thelin™ has a good safety profile and it significantly improves patient exercise capacity (as determined by the 6-minute walk distance test – 6MWD). The long term studies specifically identified sustained improvements with single Thelin™ therapy.<sup>1</sup>

Thelin™ (sitaxsentan) is a once daily drug therapy for patients with PAH who have not responded to conventional drug therapies. Other treatment options for patients with PAH include parenteral drugs (i.e. drugs administered by injection) such as Remodulin™ and Flolan® (that has specialized administration requirements often administered in a hospital setting). Oral treatments options for PAH include Revatio™ and Tracleer®. Often, these alternative therapies require additional drug therapies and frequent dose adjustments in order to achieve sustainable and effective clinical benefits.

Conventional drug therapies for the treatment of PAH have an annual cost is between \$26,000 and \$46,000. Thelin™ (100mg once a day) is priced at an estimated annual cost of \$24,000.

Thelin™ is covered under existing open drug formularies. For clients that subscribe to ClaimSecure Managed Formularies, Thelin™, similarly to Remodulin®, Revatio™, and Tracleer®, will be placed under Special Authorization. The Special Authorization status for Thelin™ will ensure that drug plan members first try and fail or are intolerant to other optional drug therapies and allow for any possible provincial formulary benefit coordination, if applicable and where possible.

*If you require additional information about Thelin™, please contact Shellina Sevany, Manager, Clinical Services Department, at (905) 949-3025 or 1-888-479-7587 ext.3025.*

### **Recommendation: Full Coverage / Special Authorization**

*ClaimSecure reserves the right to amend in part or in its entirety stated special authorization clinical guidelines*

Flolan® is registered trademark of GlaxoSmithKline Inc.  
Remodulin™ is a trademark of United Therapeutics Corporation  
Revatio™ is a trademark of Pfizer Canada Inc  
Tracleer® is a registered trademark of Actelion Pharmaceuticals Inc.

#### References:

- 1) Encysive Canada Inc., Product Monograph for Thelin™, June 22, 2007.
- 2) Wikipedia, the free encyclopedia. *Pulmonary hypertension*. Retrieved August 26, 2007, from the Wikipedia Web site [http://en.wikipedia.org/wiki/Pulmonary\\_hypertension](http://en.wikipedia.org/wiki/Pulmonary_hypertension)

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