



## Recently Introduced Products

Drug Name	Indication	Potential Impact	Expected Avg. Annual Cost
Angeliq	Treatment of the climacteric syndrome (hot flashes) in menopausal and post-menopausal women	\$	\$269
Cyestra-35	Treatment of women with severe acne, unresponsive to oral antibiotic and other available treatments, with associated symptoms of androgenization, including seborrhea and mild hirsutism.	\$	\$296

\$: Est. drug plan expenditure increase of <1%\* \$\$: Est. drug plan expenditure increase of 1-5%\* \$\$\$: Est. drug plan expenditure increase of >5%\*

## Catena® - A New Prescription Drug for Friedreich's Ataxia

Friedreich's Ataxia (FA) is a genetic, neuromuscular degenerative disorder that results in the progressive breakdown of nervous tissue in the spinal cord. Patients experience a range of neurological and non-neurological symptoms including loss of coordination (ataxia), muscle weakness in the limbs, speech disability, vision and hearing loss, diabetes and heart disease. Typically, symptoms of FA appear anywhere between 5 to 20 years of age. Individuals with late onset FA may develop symptoms in the late 20s or 30s. The severely debilitating disease most often results in the inability to walk 8-10 years following the onset of symptoms and death by mid-life<sup>1</sup>. Although FA is the most common hereditary ataxia, affecting approximately 1 in 50,000 individuals in North America, it is considered a very rare disease<sup>2</sup>.

Catena is the first drug approved for treatment of Friedreich's Ataxia. Catena's exact mechanism of action is unknown; however, it is believed that Catena may slow down the progression of the disease and improve symptoms by reducing oxidative stress and damage on the nervous system<sup>3</sup>. Its active ingredient, idebenone, is a synthetic variant of coenzyme Q10, a potent antioxidant and vitamin sold over-the-counter. Although comparative studies are lacking between coenzyme Q10 and Catena, they are thought to share similar therapeutic properties<sup>2,3</sup>. Catena is administered at significantly higher doses than over-the-counter coenzyme Q10, therefore, requiring a prescription and monitoring from a physician.

Health Canada has granted conditional approval based on the results of one clinical trial. However, the study's small sample size is of concern. Final approval is contingent on results of clinical trials currently underway in the United States and in Europe.

The annual cost of treatment with Catena® can range from \$20,969 to \$62,907 in pediatric patients and \$41,939 to \$104,846 for adult patients. Due to the lack of rigorous, solid evidence of its benefits in patients with FA and pending provincial coverage, Catena will be excluded from all ClaimSecure drug plans and Managed Formularies. Catena's coverage status will be re-evaluated once results of ongoing clinical trials and provincial coverage information become available.

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

### Recommendation: Exclude

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

- References:
- 1) Friedreich's Ataxia. Muscular Dystrophy Canada. Sept. 2007: p.1-3. [http://www.muscle.ca/fileadmin/National/Muscular\\_Dystrophy/Disorders/42\\_7E\\_Friedreichs\\_Ataxia\\_2007.pdf](http://www.muscle.ca/fileadmin/National/Muscular_Dystrophy/Disorders/42_7E_Friedreichs_Ataxia_2007.pdf) Accessed December 5, 2008.
  - 2) Friedreich's ataxia. Wikipedia. [http://en.wikipedia.org/wiki/Friedreich's\\_ataxia](http://en.wikipedia.org/wiki/Friedreich's_ataxia) Accessed October 5, 2008.
  - 3) Catena® Private Payer Submission Binder. Santhera Pharmaceuticals, Inc. October, 2008.

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\* Based on the Financial Impact Analysis per 100 000 lives covered  
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