

Drug Name	Indication	Potential Plan Impact
Saizen 8.8mg injection	Growth hormone insufficiency or deficiency; Turner's syndrome	\$\$\$
Aptivus	To treat HIV infection in treatment experienced patients	\$\$
Wellbutrin XL	Extended release formulation of bupropion for the treatment of depression	\$
	\$ Little increase estimated in drug plan expenditure	
	\$\$ Drug plan expenditure estimated to be somewhat increased	
	\$\$\$ Potential for large increase in drug plan expenditure	

Somavert – To slow down growth hormone

Somavert is a new option in the treatment of acromegaly, a rare, chronic, debilitating and disfiguring disease, which is resistant to surgery, radiation therapy and conventional drug therapy. Acromegaly is caused by excess growth hormone due to a benign tumour of the pituitary gland. The excess levels of circulating growth hormone result in overgrowth of tissue and bone, especially in the hands, feet and face. One may remember Andre the giant, a wrestler turned actor who capitalized on his acromegaly.

Acromegaly is typically diagnosed in early middle age, with an incidence estimated at 3 to 6 new cases per million per year. Men and women are equally affected and without treatment, patients experience a 3.5-fold increase in mortality¹. The primary treatment for acromegaly is the surgical removal of the tumour. It is estimated that surgery is successful in 60% of patients². Patients who are not surgically cured or not surgical candidates may receive radiotherapy, drug therapy or both. Only about 5% of patients are cured with radiotherapy.

Drug therapy for acromegaly includes two classes of agents, namely somatostatin analogues (i.e. Sandostatin) and dopamine agonists. Somatostatin analogues, with or without dopamine agonists, are increasingly being used as first line therapy, especially if surgery is unavailable or undesirable³. Again, it is estimated that 40% of these patients will remain unresponsive. Somavert is prescribed for these unresponsive patients.

Somavert works by targeting growth hormone action in the target tissues rather than growth hormone secretion by the pituitary tumour, hence its effectiveness in non-responsive patients. Patients self administer the subcutaneous injection once daily. Dose adjustments are made every 4 to 6 weeks as needed. Somavert's cost per day is about \$113 to \$340 (10mg up to a maximum of 30mg/day). So, its monthly cost ranges from about \$3,174 up to \$9,513. Comparatively, Sandostatin costs about \$1,578 to \$2,058 per month.

Therefore, for clients who have adopted ClaimSecure's **Managed Formularies**, the drug will be placed under **Special Authorization**. The Special Authorization program provides plan sponsors with a tool to ensure that patients with acromegaly meet ClaimSecure's clinical guidelines for use. Approvals will be authorized for patients who have not responded to surgery, radiation therapy, and/or other drug therapies or for those patients for whom these therapies are inappropriate. However, for group plans with open formularies, Somavert will automatically be covered. *If you require additional information about Somavert, please contact Shellina Sevany in ClaimSecure's Clinical Services Department at (905) 949-3025 or 1-888-479-7587 ext.3025.*

Recommendation: Special Authorization

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

References:

1. Holdaway IM, Rajasoorya RC, Gamble GD. Factors influencing mortality in acromegaly. *J Clin Endocrinol Metab.* 2004;89: 667-674.
2. Trainer PJ, Drake WM, Katznelson L, et al. Treatment of acromegaly with the growth hormone-receptor antagonist pegvisomant. *New Engl J Med.* 2000;342:1171-1177.
3. Ayuk J, Sheppard MC. The role of growth-hormone receptor antagonism in relation to acromegaly. *Expert Opin Pharmacother* 2004;5(11):2279-2285.

