



## Recently Introduced Products

Drug Name	Indication	Potential Impact	Expected Avg. Annual Cost
Advagraf extended release capsules	Anti-rejection drug for organ transplant	\$\$	\$23,031
Stalevo tablet	Treatment of Parkinson's disease	\$	\$4,555

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

## Activelle™ - Low dose Hormone Replacement Therapy

Current Canadian guidelines recommend the use of the lowest effective dose for hormone replacement therapy ("HRT"). HRT is recommended for the short-term management (2 to 3 years and not more than 5 years) of moderate-to-severe hot flushes<sup>1</sup>. The gold standard for treatment of hot flushes is estrogen therapy, either in the form of conjugated estrogens 0.625mg or as estradiol 1mg. Progestin is added because it has been reported to be protective for endometrial cancer<sup>2</sup>.

The choice of HRT therapy depends on the estrogen dose needed to control postmenopausal symptoms in a woman. The dose of progestin needed, in turn, depends on the estrogen dose. Therefore, the choice of HRT therapy is dependent on the needs of the individual woman and on preference.

Activelle™ is a combination of 1mg estradiol with 0.5mg norethindrone acetate ("NETA"). Activelle LD™ is the low dose form and contains 0.5mg estradiol and 0.1mg NETA. Other treatment options available (either in oral or transdermal dosage forms) include estrogen alone, estrogen sequentially administered with a progestin and a continuous combination of estrogen/progestin.

Activelle provides another option in the current HRT armament, by providing a combination of low dose estradiol and NETA in one pill. In addition, clinical trials demonstrate that with Activelle™ there was a lower frequency of breakthrough bleeding in women than those taking traditional estrogen and progestin therapy<sup>3</sup>.

The annual cost of treatment with Activelle™ is approximately \$390. Since this is in line with other oral combinations, transdermal HRT preparations and estrogen gel (cost ranging from \$100 - \$442 annually); Activelle™ and Activelle LD will be fully covered under ALL ClaimSecure drug plans, including ClaimSecure Managed Formularies.

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

### Recommendation: Full Coverage

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

#### References:

- 1) Belisle S, Blake J *et al.* Canadian consensus conference on menopause, 2006 update. J Obstet Gynaecol Can. 2006; 28 (2 Suppl 1): S7-S94.
- 2) Archer, DF. Low-dose hormone therapy for postmenopausal women. Clin Obstet Gynecol. 2003;46(2): 317-24.
- 3) Activelle™ Private Payer Submission Binder. Novo Nordisk Canada, April, 2008.

