



## Recently Introduced Products

Drug Name	Indication	Potential Impact	Expected Avg. Annual Cost
Clindoxy ADV	For the treatment of moderate acne vulgaris characterized by the presence of comedones (blackheads/whiteheads), papules and pustules	\$	\$495

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

## Xtandi® – A New Oral treatment for Prostate Cancer

Xtandi® is a new oral treatment option for individuals with prostate cancer that has spread to other parts of the body (i.e. metastatic) and is resistant to conventional anti-androgen therapies (i.e. drugs that block the effects of testosterone) and chemotherapy. Prostate cancer is relatively prevalent in Canada. It accounts for 27% of all new cancer cases and is estimated to have affected approximately 26,500 men in year 2012. 10-20% of these cases will have cancers that develop resistance to anti-androgen therapies and 90% of them will evolve to become metastatic, known as metastatic castration-resistant prostate cancer (i.e. mCRPC). Xtandi is indicated to treat mCRPC in individuals with previous exposure to chemotherapy with docetaxel.

Treatment for prostate cancer is dependent on the stage of the disease. Initial diagnosis with early stages of prostate cancer is often treated with anti-androgen therapies. For individuals with mCRPC, chemotherapy with docetaxel, an IV hospital medication, given every three weeks with a daily prednisone regimen is the first line of therapy. Progression post-docetaxel is not uncommon and a number of new treatment options have been developed for this purpose. These include Jevtana® and Zytiga®, which were marketed in 2011, as well as Xtandi®, the most recently introduced alternative.

Xtandi® has a novel mechanism of action that is different from those that are currently available. It interferes with the androgen signaling pathway at multiple points to ensure growth inhibition of tumor cells, thus potentially delaying the progress of mCRPC. The recommended dose for Xtandi® is 4 capsules (160mg) taken orally once daily. Xtandi® does not need to be taken with prednisone. The annual cost of Xtandi is approximately \$41,000 (\$28 per capsule).

Due to the significant cost associated with this medication and to ensure this medication is used for the appropriate patient, it is recommended that Xtandi® be placed under Special Authorization for ClaimSecure groups that subscribe to the Managed Formulary, Specialty Drug, and Stop Loss Programs. The Special Authorization process seeks to ensure that: 1) the member has a confirmed diagnosis of mCRPC and 2) has been previously treated with chemotherapy with docetaxel and 3) to coordinate benefits with available provincial public programs. For Open Drug Formularies, Xtandi® will be fully covered.

**If you require additional information about Xtandi®, please contact the 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. Xtandi® Product Monograph. Bayer Inc. June 2013
2. Treatment Options available at <http://www.prostatecancer.ca/>

