I. Medication Description

Enzalutamide is an androgen receptor inhibitor. It works by competitively inhibiting androgen binding to androgen receptors and by inhibiting androgen receptor nuclear translocation and DNA interaction. Enzalutamide caused decreased proliferation and prostate cancer cell death in vitro and decreased tumor volume in a mouse xenograft model. The androgen-AR signaling pathway is important in castration-resistant prostate cancer (CRPC). Enzalutamide differs from other agents that are indicated for the treatment of metastatic prostate cancer that also target the androgen-AR pathway. Enzalutamide is a pure AR antagonist, whereas bicalutamide is an AR antagonist that exhibits some degree of AR agonist activity. Enzalutamide inhibits the androgen-AR pathway at the receptor and post-receptor ligand binding level, whereas abiraterone is a CYP17 inhibitor that works at the pre-receptor ligand binding level via extragonadal androgen synthesis inhibition. Unlike CYP17 inhibitors, enzalutamide does not require the concomitant use of corticosteroids.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Xtandi is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is limited to 120 capsules per each 30 days.

V. Coverage Duration

Coverage is granted for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Xtandi is available as 40mg oral capsules.

VIII. Summary of Policy Changes

- 3/15/13: new policy
- 3/15/14: Policy updated to include second line and concurrent use with ADT
- 3/15/15: Policy updated to include NCCN guideline update: diagnosis of metastatic castration resistant prostate cancer and use with or previous ADT
- 7/1/15: formulary distinctions made
- 3/15/16: Updated coverage to coincide with current NCCN treatment guidelines
- 1/1/17: no policy updates
- 1/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines
- 1/15/19: no policy changes
- 1/30/20: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.