Reference number(s)
1933-A

SPECIALTY GUIDELINE MANAGEMENT

XTANDI (enzalutamide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Xtandi is indicated for the treatment of patients with:
1. Castration-resistant prostate cancer (CRPC)
2. Metastatic castration-sensitive prostate cancer (mCSPC)
3. Non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR)

B. Compendial Use
Prostate Cancer

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided if the requested medication is used in combination with a second-generation oral anti-androgen (e.g., apalutamide [Erleada]) or an oral androgen metabolism inhibitor (e.g., abiraterone acetate [Zytiga]).

III. CRITERIA FOR INITIAL APPROVAL

A. Castration-resistant prostate cancer (CRPC)
Authorization of 12 months may be granted for the treatment of castration-resistant prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (degarelix, relugolix).

B. Metastatic castration-sensitive prostate cancer (mCSPC)
Authorization of 12 months may be granted for the treatment of metastatic castration-sensitive prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).

C. Non-metastatic castration-sensitive prostate cancer (nmCSPC)
Authorization of 12 months may be granted for the treatment of non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; November 2023.
2. The NCCN Drugs & Biologics Compendium™ © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 2, 2024.