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 Indication
Xtandi is indicated for the treatment of patients with metastatic castration-resistant prostate cancer.

B. Compendial Uses
Prostate cancer:
1. Used as a single agent as secondary hormone therapy for progression or metastases following medical or surgical androgen deprivation therapy (ADT)
2. In combination with ADT
   i. As part of neoadjuvant/concomitant/adjuvant ADT to enhance effectiveness of radiation therapy
   ii. In ADT-naïve patients for a minimum of 7 days in patients with overt metastases who are at risk of developing symptoms associated with androgen flare
   iii. Following inadequate testosterone suppression with ADT alone

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted to members for the treatment of prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; July 2017.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 26, 2017.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Prostate Cancer (Version 2.2017). http://www.nccn.org. Accessed July 17, 2017.