



Commercial/Healthcare Exchange PA Criteria

Effective: May 1, 2018

Prior Authorization: Erleada

Products Affected: Erleada (apalutamide) tablet

Medication Description:

Erleada (apalutamide) is indicated to treat non-metastatic, castration-resistant prostate cancer (NM- CRPC).

Erleada is an androgen receptor (AR) inhibitor which directly binds to the AR. In doing so, it slows transcription mediated by AR while inhibiting nuclear translocation and DNA binding.

Covered Uses:

1. Treatment of non-metastatic, castration-resistant prostate cancer
2. Treatment of metastatic castration-sensitive prostate cancer

Exclusion Criteria:

1. Pediatric patients

Required Medical Information:

1. Diagnosis
2. Confirmation of surgical or medical castration

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by or in consultation with an oncologist.

Coverage Duration: 12 months

Other Criteria:

Approve if the patient meets the following criteria (A or B):

- A. Patient has a diagnosis of non-metastatic, castration-resistant prostate cancer (NM-CRPC); **OR**
- B. Patient has a diagnosis of metastatic castration-sensitive prostate cancer

References:

1. Erleada [package insert]. Horsham, PA; Janssen; September 2019.
2. Seigel RL, Miller KD, Jemal A, et al. Cancer Statistics, 2017. CA Cancer J Clin 2017;67:7-30. DOI: 10.3322/caac.21387.
3. Mohler JL, Antonarakis ES, Armstrong AJ, et al. National Comprehensive Cancer Center Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer. V2.2018. Available a http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 13, 2018.

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Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	04/16/2018
2	Policy Update	CCI Adopted EH Template and policy; CCI P&T Review History: 5/18, 5/19; CCI Revision Record: 5/19; Added new indication to match FDA Label; Removed Dose and Frequency from Required information	Covered Uses Required Information Other Criteria	11/8/2019