

## SPECIALTY GUIDELINE MANAGEMENT

### ERLEADA (apalutamide)

#### 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.

##### FDA-Approved Indication

Erleada is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.

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

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Non-metastatic castration-resistant prostate cancer**

Authorization of 24 months may be granted for treatment of non-metastatic castration-resistant prostate cancer when Erleada will be administered with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.

##### III. CONTINUATION OF THERAPY

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

##### IV. REFERENCES

1. Erleada [package insert]. Horsham, PA: Janssen Products, LP; February 2018.