Reference number(s)
2498-A

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

1. Erleada is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.
2. Erleada is indicated for the treatment of patients with metastatic castration-sensitive 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., enzalutamide [Xtandi]) or an oral androgen metabolism inhibitor (e.g., abiraterone acetate [Zytiga]).

III. CRITERIA FOR INITIAL APPROVAL

1. Non-metastatic castration-resistant prostate cancer

Authorization of 12 months may be granted for treatment of non-metastatic castration-resistant prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a gonadotropin-releasing hormone (GnRH) analog.

2. Metastatic castration-sensitive prostate cancer

Authorization of 12 months may be granted for 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 gonadotropin-releasing hormone (GnRH) analog.

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. Erleada [package insert]. Horsham, PA: Janssen Products, LP; July 2020.

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