Reference number(s)
2498-A

Specialty Guideline Management
Erleada

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Erleada	apalutamide

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 Indications[1]

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

Compendial Uses[2]

Prostate Cancer

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

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]).

Coverage Criteria

Non-metastatic castration-resistant prostate cancer[1,2]

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 luteinizing hormone-release hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).

Metastatic castration-sensitive prostate cancer[1,2]

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 luteinizing hormone-release hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).

Continuation of Therapy

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

References

1. Erleada [package insert]. Horsham, PA: Janssen Products, LP; August 2024.
2. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed May 12, 2025.