Reference number(s)
1934-A

Specialty Guideline Management abiraterone products

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
Zytiga	abiraterone
Abirtega	abiraterone

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[1-3]

- Indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC)
- Indicated in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer (CSPC)

Compendial Uses[4-6]

- Node-positive (N_1), non-metastatic (M_0) prostate cancer
- High-risk, non-metastatic prostate cancer
- Very-high-risk prostate cancer
- Salivary gland tumor

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

Exclusions

Coverage will not be provided if the requested medication is being used in combination with a second-generation oral anti-androgen (e.g., apalutamide [Erleada]) or an oral androgen metabolism inhibitor (e.g., fine-particle abiraterone acetate [Yonsa]).

Coverage Criteria

Prostate Cancer[1-6]

Authorization of 12 months may be granted for the treatment of prostate cancer when both of the following criteria are met:

- The member has had a bilateral orchiectomy or will be using the requested medication with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).
- The member meets either of the following criteria:
    - The disease is non-metastatic and the disease is node positive, high-risk, or very-high-risk.
    - The disease is metastatic.

Salivary Gland Tumor[4,7]

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumor in combination with prednisone and a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) when the tumor is androgen receptor positive.

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. Zytiga [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
2. Abiraterone [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; March 2025.
3. Abirtega [package insert]. Lehi, UT: CivicaScript, LLC.; February 2025.

4. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 14, 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at https://www.micromedexsolutions.com. Accessed August 14, 2025.
6. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 14, 2025.
7. NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed August 14, 2025.