Zytiga® (abiraterone acetate) and generic abiraterone acetate

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2020
Revision Date: March 23, 2022
Review Date: March 16, 2022
Line of Business: Medicare, Commercial, HUM Medicaid
Policy Type: Prior Authorization

For the Humana Medicaid line of business, the following state applies: South Carolina. For other state-managed Medicaid plans, please refer to the state's Medicaid pharmacy site for pharmacy coverage policies.

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

Abiraterone acetate is an androgen biosynthesis inhibitor that inhibits 17 α-hydroxylase/C17, 20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. Inhibition of CYP17 by abiraterone acetate can also result in increased mineralocorticoid production by the adrenals. Androgen sensitive prostatic carcinoma responds to treatment that decreases androgen levels. Androgen deprivation therapies, such as treatment with GnRH agonists or orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumor.

Abiraterone acetate in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer and metastatic high-risk castration-sensitive prostate cancer.

Abiraterone acetate is available as Zytiga in 250mg and 500 mg tablets and as generic abiraterone acetate in 250 mg and 500 mg tablets.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Zytiga (abiraterone acetate) and generic abiraterone acetate will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

For brand Zytiga: Member must have an intolerance or contraindication to generic abiraterone acetate **AND** member must meet clinical criteria below.

Prostate Cancer (mCRPC)

- The member has metastatic (stage IV) castration-resistant prostate cancer (CRPC) **AND**

- The member will be using abiraterone acetate in combination with prednisone

Prostate Cancer (mCSPC)

- The member has a diagnosis of castration-sensitive prostate cancer plus one of the following scenarios:
  - Metastatic (stage IV) disease **AND**
    - Is high risk (e.g. Gleason score of 8 or more, at least three bone lesions, or presence of measurable visceral metastases) **OR**
  - Node-positive (any T, N1) disease **OR**
  - Localized disease with high risk features (e.g. a PSA level >4 ng per milliliter with a doubling time of <6 months, a PSA level >20 ng per milliliter, nodal or metastatic relapse, or adjuvant or neoadjuvant therapy lasting less than 12 months of total ADT and completed at least 12 months previously) that is persistent or recurrent after prior radical prostatectomy and/or radiation therapy **AND**
- The member will be using abiraterone acetate in combination with prednisone and one of the following applies:
  - in combination with LHRH analog (e.g. Lupron, Trelstar, etc.) **OR**
  - had previous bilateral orchiectomy

Zytiga (abiraterone acetate) and generic abiraterone acetate will be approved in six month durations or as determined through clinical review.

Coverage Limitations

Zytiga (abiraterone acetate) and generic abiraterone acetate therapy is not considered medically necessary for members with the following concomitant conditions:

- Members with severe hepatic impairment (Child-Pugh Class C)

- Members that have experienced disease progression while on abiraterone acetate

- Concomitant use with Erleada (apalutamide), Xtandi (enzalutamide), Provenge (sipuleucel-T), Taxotere (docetaxel), or Jevtana (cabazitaxel) is not recommended at this time due to lack of evidence supporting safety and efficacy

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Zytiga (abiraterone acetate) and generic abiraterone acetate.

Please refer to the Prescribing Information for further detail on dose modifications.

The Child-Pugh score is a measure of hepatic impairment severity. The components of this score are: Hepatic encephalopathy, ascites, INR, serum albumin and total bilirubin. A calculator can be found at the following website link – http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp.

Abiraterone acetate is a substrate of CYP3A4. Avoid or use with caution, strong inhibitors and inducers of CYP3A4 during abiraterone acetate treatment.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Zytiga; abiraterone acetate; prostate cancer; pharmacy

References

Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL: http://www.clinicalpharmacology.com. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

Zytiga (abiraterone acetate) package insert. Horsham, PA: Janssen Biotech; August 2021.