Pharmacy Policy Bulletin: J-0726 Zytiga and Yonsa (abiraterone acetate) - Commercial and Healthcare Reform	
Number: J-0726	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Rx Mgmt Quantity Limits = Safety/ Specialty **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **3.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Quantity Limit = QPC = Yes **Healthcare Reform:** Not applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0726-013	**Original Date:** 05/08/2001
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Abirtega (abiraterone acetate) • Zytiga (abiraterone acetate) • Yonsa (abiraterone acetate micronized)

FDA-Approved Indication(s):	• Abirtega, Zytiga
	  ○ In combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).
	  ○ In combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer.
	• Yonsa
	  ○ In combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Background:	• Abiraterone 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. In clinical trials, abiraterone acetate decreased serum testosterone and other androgens. Androgen-sensitive prostatic carcinoma responds to treatment that decreases androgen levels. Androgen deprivation therapies, such as treatment with gonadotropin-releasing hormone (GnRH)

	agonists or orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumor. • Abirtega is a generic formulation of Zytiga and is only available in a 250 mg strength. • Patients should receive a GnRH analog (for example, Zoladex [goserelin acetate], Lupron [leuprolide acetate], Vantas [histrelin], etc.) concurrently with Abirtega, Zytiga, or Yonsa, or should have had a bilateral orchiectomy • Prescribing Considerations: ○ Yonsa tablets (a micronized dosage form of abiraterone) may have different dosing and food effects than other abiraterone acetate products. ○ Abirtega and Zytiga (abiraterone acetate) must be taken as a single dose once daily on an empty stomach. Do not eat food 2 hours before and one hour after taking Abirtega or Zytiga (abiraterone acetate). ○ Yonsa (abiraterone acetate micronized) must be taken as a single dose once daily with or without food. ○ It is recommended to avoid use of concomitant CYP3A4 inducers, such as rifampin, rifabutin, rifapentine, phenytoin, carbamazepine, phenobarbital, or St. John's Wort with Abirtega, Zytiga, and Yonsa. ▪ If concomitant use cannot be avoided, the dose of Abirtega or Zytiga should be increased during the co-administration period. ▪ If concomitant use cannot be avoided, the dosing frequency of Yonsa should be increased to twice a day during the co-administration period. If the CYP3A4 inducer is discontinued, the dose of Yonsa should be reduced back to the previous dose and frequency. ○ Safety and effectiveness of abiraterone acetate in pediatric patients have not been established.

Approval Criteria

I. Initial Authorization

A. Abirtega, Zytiga (abiraterone acetate)

When a benefit, coverage of Abirtega or Zytiga (abiraterone acetate) may be approved when all of the following criteria are met **(1. through 6.):**

1. The member is 18 years of age or older.

2. The member has a diagnosis of one (1) of the following **(a. or b.)**:

a. The member has a diagnosis of prostate cancer (ICD-10: C61), classified as metastatic castration-resistant.

b. The member has a diagnosis of prostate cancer (ICD-10: C61), classified as metastatic high-risk castration-sensitive.

3. The member is using Abirtega or Zytiga (abiraterone acetate) in combination with prednisone.

4. The member meets one (1) of the following **(a. or b.)**:

a. Abiraterone or Zytiga (abiraterone acetate) is being used in combination with a GnRH analog.

b. The member has had a bilateral orchiectomy.

5. If the request is for brand Zytiga 500 mg tablets or generic abiraterone acetate 500 mg tablets, the member has experienced therapeutic failure or intolerance to one (1) of the following plan-preferred, generic products **(a. or b.)**:

a. abiraterone acetate 250 mg tablets

b. Abirtega

6. If the request is for brand Zytiga 250 mg tablets, the member has experienced therapeutic failure or intolerance to one (1) of the following generic products **(a. or b.)**:

a. abiraterone acetate 250 mg tablets

b. Abirtega

Quantity Limits
When a benefit, additional quantities of Zytiga (abiraterone acetate) 500 mg, up to 4 tablets per day; or Abirtega or Zytiga (abiraterone acetate) 250 mg, up to 8 tablets per day, may be approved when the following criterion is met **(1.)**:
1. The member is taking a strong CYP3A4 inducer.

B. Yonsa
When a benefit, coverage of Yonsa may be approved when all of the following criteria are met **(1. through 5.):**
1. The member is 18 years of age or older.
2. The member has a diagnosis of prostate cancer (ICD-10: C61), classified as metastatic castration-resistant.
3. The member is using Yonsa in combination with methylprednisolone.
4. The member meets one (1) of the following **(a. or b)**:
  a. Yonsa is being used in combination with a GnRH analog.
  b. The member has had a bilateral orchiectomy.
5. The member has experienced therapeutic failure or intolerance to one (1) of the following plan-preferred, generic products **(a. or b.)**:
  a. abiraterone acetate 250 mg tablets
  b. Abirtega

Quantity Limits
When a benefit, additional quantities of Yonsa 125 mg, up to 8 tablets per day, may be approved when the following criterion is met **(1.)**:
1. The member is taking a strong CYP3A4 inducer.

II. Reauthorization
When a benefit, reauthorization of an abiraterone product may be approved when all of the following criteria are met **(A., B., and C.):**
A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following criteria **(1. or 2.):**
  1. Disease improvement
  2. Delayed disease progression
B. If the request is for Yonsa, brand Zytiga 500 mg tablets, or generic abiraterone acetate 500 mg tablets, the member has experienced therapeutic failure or intolerance to one (1) of the following plan-preferred, generic products **(1. or 2.)**:
  1. abiraterone acetate 250 mg tablets
  2. Abirtega
C. If the request is for brand Zytiga 250 mg, the member has experienced therapeutic failure or intolerance to one (1) of the following generic products **(1. or 2.)**:
  1. abiraterone acetate 250 mg tablets
  2. Abirtega

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology medications listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will be approved only if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Abirtega [package insert]. Lehi, UT: CivicaScript, LLC; October 2024.
2. Yonsa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; March 2022.
3. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2021.
4. Abiraterone acetate. Clinical Pharmacology On-Line, Tampa, FL: Elsevier 2024. Accessed March 26, 2025.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com. Accessed March 26, 2025.
6. Gerald K. McEvoy, ed. 2015. AHFS Drug Information® - 56th Ed. Bethesda, MD. American Society of Health-System Pharmacists. STAT!Ref Online Electronic Medical Library.
7. Fizazi K, Tran N, Fein L, et al. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *NEJM*. 2017. Doi: 10.1056/NEJMoa1704174.