# Clinical Policy: Abiraterone (Zytiga, Yonsa)

Reference Number: PA.CP.PHAR.84
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

**Description**
Abiraterone (Zytiga®, Yonsa®) is a selective and irreversible inhibitor of enzyme CYP17.

**FDA Approved Indication(s)**
Zytiga is indicated in combination with prednisone for the treatment of metastatic castration-resistant prostate cancer and metastatic high-risk castration-sensitive prostate cancer.

Yonsa is indicated in combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer.

**Policy/Criteria**
It is the policy of Pennsylvania Health and Wellness that Zytiga is **medically necessary** when one of the following criteria are met:

**I. Initial Approval Criteria**

**A. Prostate Cancer** (must meet all)**:**

1. Diagnosis of metastatic prostate cancer;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Member meets one of the following ( a, b or c):
   a. History of bilateral orchiectomy;
   b. Previously failed androgen deprivation therapy (ADT) (*see Appendix D*);
   c. Will use ADT concurrently;
5. For Zytiga requests: prescribed in combination with prednisone;
6. For Yonsa requests, both of the following (a and b):
   a. Prescribed in combination with methylprednisolone;
   b. Medical justification supports inability to use generic abiraterone (e.g., contraindications to the excipients of generic products);
7. Dose does not exceed one of the following (a, b, or c):
   a. Zytiga: 1,000 mg once daily, or 1,000 mg twice daily if prescribed concomitantly with a strong CYP3A4 inducer*;
   b. Yonsa: 500 mg per day, or 500 mg twice daily if prescribed concomitantly with a strong CYP3A4 inducer*;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

** Examples of strong CYP3A4 inducers include, but are not limited to, <u>any</u> of the following: phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, and phenobarbital.*

**Approval duration: 6 months**

**B. Other diagnoses/indications:** Refer to PA.CP.PMN.53

**II. Continued Approval**

**A. Prostate Cancer** (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
    a. Zytiga: 1,000 mg once daily, or 1,000 mg twice daily if prescribed concomitantly with a strong CYP3A4 inducer*;
    b. Yonsa: 500 mg per day, or 500 mg twice daily if prescribed concomitantly with a strong CYP3A4 inducer*;
    c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

** Examples of strong CYP3A4 inducers include, but are not limited to, any of the following: phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, and phenobarbital.*

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

## III. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

ADT: androgen deprivation therapy

CYP17: cytochrome 17 α-hydroxylase/C17,20-lyase

FDA: Food and Drug Administration

LHRH: luteinizing hormone-releasing hormone

*Appendix B: Therapeutic Alternatives*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| abiraterone (Zytiga) | 1,000 mg (four 250 mg tablets) PO QD in combination with prednisone 5 mg PO BID | 1,000 mg QD; 1,000 mg BID if taking a strong CYP3A4 inducer |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): pregnancy
- Boxed warning(s): none reported

*Appendix D: General Information*

- Examples of ADT include:

- Bilateral orchiectomy (surgical castration)
- Luteinizing hormone-releasing hormone (LHRH) given with or without an anti-androgen:
  - LHRH agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)
  - Anti-androgens: bicalutamide (Casodex®), flutamide, nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide)
- LHRH antagonist: Firmagon® (degarelix)

- Zytiga + prednisone + ADT for castration-naïve metastatic (M1) prostate cancer is a category 1 recommendation supported by the NCCN Compendium.

## IV. Dosage and Administration

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Abiraterone (Zytiga) | 1,000 mg (four 250 mg tablets or two 500 mg tablets) PO QD in combination with prednisone 5 mg PO BID | 1,000 mg QD; 1,000 mg BID if taking a strong CYP3A4 inducer |
| Abiraterone (Yonsa) | 500 mg (four 125 mg tablets) PO QD in combination with methylprednisolone 4 mg PO BID | 500 mg QD; 500 mg BID if taking a strong CYP3A4 inducer |

## V. Product Availability

| Drug Name | Availability |
|---|---|
| Abiraterone (Zytiga) | Tablets: 250 mg, 500 mg |
| Abiraterone (Yonsa) | Tablets: 125 mg |

## VI. References

1. Zytiga Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; April 2018. Available at: https://www.zytiga.com/. Accessed February 26, 2019.
2. Abiraterone acetate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed February 26, 2019.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 26, 2019.
4. National Comprehensive Cancer Network. Prostate Cancer Version 01.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 26, 2019.
5. Yonsa Prescribing Information. Cranbury, NU: Sun Pharmaceutical Industries, Inc.; May 2018. Available at: www.yonsarx.com. Accessed January 7, 2019

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Converted to new template. added clarification that Zytiga must be used in combination with; added efficacy requirement of positive response; references reviewed and updated. | | |
| 2Q 2019 annual review: Added approval criteria for requests for Yonsa; references reviewed and updated. | 04/19 | |