RXADVANCE
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|---|---|
| **Clinical Policy Title:** | abiraterone |
| **Policy Number:** | RxA.325 |
| **Drug(s) Applied:** | Zytiga®, Yonsa® |
| **Original Policy Date:** | 02/07/2020 |
| **Last Review Date:** | 09/14/2020 |
| **Line of Business Policy Applies to:** | All lines of business |

## Background

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

Zytiga® is indicated in combination with prednisone for the treatment of patients with
- metastatic castration-resistant prostate cancer (CRPC).
- metastatic high-risk castration-sensitive prostate cancer (CSPC).

Yonsa® is indicated in combination with methylprednisolone for the treatment of patients with
- metastatic castration resistant prostate cancer (CRPC).

## Dosing Information

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Abiraterone (Zytiga®) | 1,000 mg (four 250 mg tablets or two 500 mg tablets) PO once daily in combination with prednisone 5 mg PO BID | 1,000 mg once daily; 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 |

## Dosage Forms

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

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

**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**
**Commercial:** 6 months
**Medicaid/HIM:** 6 months

## II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by Rxadvance or the member has met initial approval criteria for indication of metastatic prostate cancer and has received this medication for at least 30 days;
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, <u>any</u> of the following: phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, and phenobarbital.*

**Approval duration**
**Commercial:** 12 months
**Medicaid/HIM:** 12 months

## III. Appendices

**APPENDIX A: Abbreviation/Acronym Key**
ADT: androgen deprivation therapy
CYP17: cytochrome $_{17\,\alpha}$-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 once daily in combination with prednisone 5 mg PO BID (CRPC) or prednisone 5mg PO once daily (CSPC) | 1,000 mg once daily; 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 (Yonsa® only)

- Boxed warning(s):
  - None.

**APPENDIX D: General Information**

- Examples of ADT include:
  - Bilateral orchiectomy (surgical castration)
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an antiandrogen:
    - 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)
- Per the NCCN Prostate cancer guidelines version 02.2020:
  - For castration-naïve metastatic (M1) prostate cancer: Zytiga® + prednisone + ADT is a category 1 recommendation, while Yonsa® + methylprednisolone +ADT is a category 2B recommendation.
  - For castration-resistant metastatic (M1) prostate cancer without visceral metastases: Zytiga® + prednisone + ADT is a category 1 recommendation, while Yonsa® + methylprednisolone +ADT is a category 2A recommendation.
  - For castration-resistant metastatic (M1) prostate cancer with visceral metastases: Both Zytiga® + prednisone + ADT and Yonsa® + methylprednisolone +ADT is a category 2A recommendation.

**References**

1. Zytiga Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; June 2019. Available at: https://www.zytiga.com/. Accessed July 28, 2020.
2. Abiraterone acetate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed July 28, 2020.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 28, 2020.
4. National Comprehensive Cancer Network. Prostate Cancer Version 02.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 28, 2020.
5. Yonsa Prescribing Information. Cranbury, NU: Sun Pharmaceutical Industries, Inc.; May 2018. Available at: www.yonsarx.com. Accessed July 28, 2020.

| Review/Revision History | Review/Revised Date | P&T Approval Date |
|---|---|---|
| Policy established. | 01/2020 | 02/07/2020 |
| Policy was reviewed:<br>1) Policy title was updated.<br>2) Indications were updated.<br>3) Initial Approval criteria updated.<br>4) Continued Therapy Approval criteria II.A.1 was rephrased.<br>5) Appendices updated.<br>6) References were updated. | 07/28/2020 | 09/14/2020 |