Clinical Policy Title:	abiraterone
Policy Number:	RxA.325
Drug(s) Applied:	Zytiga®, Yonsa®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2021
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	Indication	Dosing Regimen	Maximum Dose
abiraterone (Zytiga®)	Prostate cancer	CRPC: 1,000 mg orally once daily in combination with prednisone 5 mg orally twice daily CSPC: 1,000 mg orally once daily in combination with prednisone 5 mg orally daily	1,000 mg once daily; 1,000 mg twice daily if taking a strong CYP3A4 inducer
abiraterone (Yonsa®)	Prostate cancer	CRPC: 500 mg orally daily in combination with methylprednisolone 4 mg orally twice daily Hepatic impairment: (Child-Pugh Class B), reduce the YONSA starting dose to 125 mg once daily	500 mg daily; 500 mg twice daily if taking a strong CYP3A4 inducer

Dosage Forms

- 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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
   a. Can use dexamethasone 1 mg/day in place of prednisone;
6. For Yonsa® requests, both of the following (a and b):
   a. Prescribed in combination with methylprednisolone;
      i Can use dexamethasone 1 mg/day in place of 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: 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, any of the following: phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, and phenobarbital.

Approval duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- 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 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 02.2021:
  - 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.; October 2020. Available at: https://www.zytiga.com/. Accessed June 4, 2021.
2. Abiraterone acetate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed June 4, 2021.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 4, 2021.
4. National Comprehensive Cancer Network. Prostate Cancer Version 02.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed June 4, 2021.

5. Yonsa Prescribing Information. Cranbury, NU: Sun Pharmaceutical Industries, Inc.; August 2020. Available at: www.yonsarx.com. Accessed June 4, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title was updated. 2. Indications were updated. 3. Initial Approval criteria updated. 4. Continued Therapy Approval criteria II.A.1 was rephrased. 5. Appendices updated. 6. References were updated.	07/28/2020	09/14/2020
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial and Continued therapy criteria approval duration was updated to remove HIM approval duration. 3. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. Therapeutic alternative verbiage was updated to “Below are suggested therapeutic alternatives based on clinical guidance..”. 5. References were reviewed and updated.	05/31/2021	09/14/2021
Policy was reviewed: 1. Dosing Information was updated to include indication, “Prostate cancer”. 2. Dosing Information dosing regimen was updated to include indications “CRPC” and “CSPC”. 3. Dosing Information dosing regimen was updated to include hepatic impairment dosing, “Hepatic impairment: (Child-Pugh Class B), reduce the YONSA starting dose to 125 mg once daily”. 4. Dosage Forms was updated from table format to bullet-list format.	6/4/2021	09/14/2021

5. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 6. Initial Approval Criteria I.A.5.a was updated to include “Can use dexamethasone 1 mg/day in place of prednisone”. 7. Initial Approval Criteria I.A.6.a.i was updated to include “Can use dexamethasone 1 mg/day in place of methylprednisolone”. 8. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 9. Appendix C contraindications was updated to remove “Pregnancy (Yonsa® only)”. 10. References were reviewed and updated.		