envolve Pharmacy Solutions

Clinical Policy: Abiraterone (Zytiga)
Reference Number: ERX.SPA.143
Effective Date: 03.01.14
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Abiraterone (Zytiga®) is a CYP17 inhibitor.

FDA approved indication
Zytiga is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Zytiga is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of metastatic castration resistant prostate cancer as evidenced by disease progression despite androgen deprivation therapy (ADT);
2. Age ≥ 18 years;
3. Zytiga will be used in combination with prednisone;
4. Dose does not exceed 1,000 mg per day;
   If used concomitantly with a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital), dose does not exceed 1,000 mg twice daily.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no disease progression);
3. Zytiga is used in combination with prednisone as evidenced by pharmacy claims history;
4. If request is for a dose increase, new dose does not exceed 1,000 mg per day;
   If used concomitantly with a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital), new dose does not exceed 1,000 mg twice daily.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADT: androgen deprivation therapy
FDA: Food and Drug Administration

Appendix B: Androgen Deprivation Therapy
ADT can be accomplished using bilateral orchiectomy (surgical castration) or a luteinizing hormone-releasing hormone (also known as gonadotropin-releasing hormone) agonist or antagonist (medical castration).

Appendix C: Therapeutic Alternatives
N/A

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Castration-resistant prostate cancer	The recommended dose of Zytiga is 1,000 mg (two 500 mg tablets or four 250 mg tablets) orally once daily in combination with prednisone 5 mg administered orally twice daily	1,000 mg daily PO; 1,000 mg PO twice daily if taking a strong CYP3A4 inducer

VI. Product Availability

- Tablets (film-coated): 250 mg, 500 mg
- Tablets (uncoated): 250 mg

VII. References

1. Zytiga Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; April 2017. Available at: https://www.zytiga.com/. Accessed June 23, 2017.
2. National Comprehensive Cancer Network. Prostate Cancer Version 02.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed June 23, 2017.
3. Abiraterone acetate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed June 23, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	02/14	03/14
Updated background information. Removed dose verification for hepatic toxicity from algorithm. References updated.	02/15	03/15
Policy converted to new template. Limited references to PI and NCCN guidelines; edited narrative accordingly. Added abbreviation key; deleted appendix about disease progression (criteria not clearly defined in guidelines). Deleted dose adjustment table and instructions on how to take Zytiga with food. Added max dose criteria. Removed PSA documentation request. Added age requirement. Added initial approval period of 3 months and kept 6 months for continued approval period.	08/16	09/16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Clarified that castration resistant prostate cancer is evidenced by disease progression despite ADT; Updated max dose requirement to allow doses up to 1000 mg twice daily if used concomitantly wih strong CYP3A4 inducers; Modified initial/continued approval duration from 3/6 months to 6/12 months, respectively. On re-auth, added clarification that Zytiga must be used in combination with prednisone as evidenced by pharmacy claims history; Added Appendix B; Updated references.	06/17	08/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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