Clinical Policy: Abiraterone (Zytiga)

Reference Number: CP.PHAR.84
Effective Date: 10.01.11
Last Review Date: 05.18
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Abiraterone (Zytiga®) 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.

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® 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 prostate cancer;
2. Prescribed by or in consultation with an oncologist;
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 C*);
   c. Will use ADT concurrently with Zytiga;
5. Zytiga is prescribed in combination with prednisone;
6. Dose does not exceed 1,000 mg once daily, or 1,000 mg twice daily if prescribed concomitantly with a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, and phenobarbital).

Approval duration:
Medicaid/HIM - 6 months
Commercial - Length of Benefit

B. Other diagnoses/indications

1. Refer to CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 Centene benefit, or documentation supports that member is currently receiving Zytiga for 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 1,000 mg once daily or 1,000 mg twice daily if prescribed concomitantly with a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital).

Approval duration:
Medicaid/HIM - 12 months
Commercial - Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADT: androgen deprivation therapy
CYP17: 17 α‑hydroxylase/C17,20-lyase

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: 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)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Metastatic castration-resistant prostate cancer	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 daily PO; 1,000 mg PO twice daily if taking a strong CYP3A4 inducer
Metastatic high-risk castration-sensitive prostate cancer	1,000 mg (four 250 mg tablets or two 500 mg tablets) PO QD in combination with prednisone 5 mg PO QD	1,000 mg daily PO; 1,000 mg PO twice daily if taking a strong CYP3A4 inducer

VI. Product Availability

Tablet: 250 mg, 500 mg

VII. References

1. Zytiga Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; May 2016. Available at: https://www.zytiga.com/. Accessed February 13, 2018.
2. Abiraterone acetate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed February 19, 2018.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 5, 2018.
4. National Comprehensive Cancer Network. Prostate Cancer Version 02.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 19, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added hepatic impairment dosing to algorithm and Safety section Removed requirement for prior chemo treatment to algorithm	12.13	01.14
Updated background information Removed dose verification for hepatic toxicity from algorithm	12.14	12.14
Converted policy to bullet format Limited references to PI (updated) and NCCN guidelines (updated); edited narrative accordingly Added abbreviation key, safety appendix; deleted appendix about disease progression (criteria not clearly defined in guidelines) Deleted dose adjustment table and instructions on how to take Zytiga with food In criteria section, eliminated documentation requests, added age requirement, added question about Zytiga contraindications per PI, kept disease progression question but deleted reference to appendix, removed question about whether would be used with additional	09.15	11.15

Reviews, Revisions, and Approvals	Date	P&T Approval Date
treatment, added initial approval period of 3 months and kept 6 months for continuation approval period		
Policy converted to new template. Removed age and prescriber specialty requirements. Added max dose requirement. Updated reasons to discontinue. Approval duration changed to 6 months for initial and 12 months for renewal.	10.16	11.16
Added max dose for concomitant use with a strong CYP3A4 inducer.	01.17	
Converted to new template. Initial: clarified CRPC. Re-auth: added clarification that Zytiga must be used in combination with; added efficacy requirement of positive response. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	09.17	11.17
Criteria added for new FDA indication: castration-sensitive prostate cancer.	03.06.18	05.18

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.