ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Zytiga (abiraterone acetate) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Zytiga (abiraterone acetate)

Diagnosis (documentation supportive of diagnosis is required)

☐ Metastatic castration-resistant prostate cancer

☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

☐ Patient is taking Zytiga in combination with prednisone 5mg twice daily

Physician Specialty (diagnosis made by):

☐ Oncologist

☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

ZYTIGA® (abiraterone acetate)

CLASSIFICATION

- Antiandrogen

DESCRIPTION

- Abiraterone acetate is metabolized to abiraterone, an androgen biosynthesis inhibitor of CYP17. CYP17 is expressed in testicular, adrenal and prostatic tumor tissues and is required for androgen biosynthesis. Abiraterone decreases androgen levels and deprives androgen-sensitive prostatic carcinomas. It accomplishes this by interfering with the CYP17-catalyzed reactions involved in the production of dehydroepiandrosterone (DHEA) and androstenedione. DHEA and androstenedione are androgens and are precursors of testosterone. There is a decrease in serum testosterone and changes in serum PSA levels; however, this does not correlate with clinical benefit. Inhibition of CYP17 can result in increased mineralocorticoid production by the adrenals.
- Androgen sensitive prostatic carcinoma responds to treatment that decreases androgen levels. Androgen deprivation therapies, such as treatment with GnRH agonists or orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumor.
- Abiraterone acetate plus prednisone is indicated for the treatment of metastatic castration-resistant prostate cancer.
- Treatment with abiraterone plus prednisone compared with placebo plus prednisone demonstrated a statistically significant improvement in radiographic progression-free survival (not reached vs 8.28 months) but not overall survival in a randomized, multicenter, phase 3 trial (n=1088) in patients with metastatic castration-resistant prostate cancer who had not received prior chemotherapy. In a randomized, double-blind, multicenter, phase 3 trial (n=1195), treatment with abiraterone acetate plus prednisone demonstrated a significant improvement in overall survival in patients with metastatic castration-resistant prostate cancer who had received prior chemotherapy containing docetaxel compared with placebo plus prednisone (15.8 vs 11.2 months) and also resulted in statistically significantly improved pain control compared with prednisone alone.
- The most common adverse reactions (≥ 10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.
- The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.
- Laboratory parameters to monitor: liver function (ALT, AST, and bilirubin levels) and serum potassium.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Zytiga® (abiraterone) meets the definition of **medical necessity** for all FDA approved indications, not otherwise excluded from Part D, including the following:

- Metastatic castration-resistant prostate cancer (documentation supportive of diagnosis required)
    - Use of Zytiga must be in combination with prednisone

Zytiga® (abiraterone) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Oncology Specialists

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients):

METASTATIC PROSTATE CANCER, CASTRATION-RESISTANT, IN COMBINATION WITH PREDNISONE:

Normal Dosage:

- The recommended dosage is 1000 mg orally once daily plus prednisone 5 mg orally twice daily.
- Take on empty stomach with no food at least 2 hours before and 1 hour after administration.

Dosage in Renal Failure

- Dosage adjustment is not required in patients with renal impairment.

Dosage in Hepatic Insufficiency

- Preexisting Hepatic Impairment
    - Mild: Dosage adjustment is not required in patients with mild baseline hepatic impairment.
    - Moderate: In patients with moderate hepatic impairment (Child-Pugh class B), reduce the dose of abiraterone acetate to 250 mg orally once daily. If elevations in ALT and/or AST greater than 5 times ULN or total bilirubin greater than 3 times ULN occur despite the dose reduction, discontinue treatment and do not reinitiate therapy.
    - Severe: Do not use abiraterone acetate in patients with severe baseline hepatic impairment. Safety in this population has not been studied.
- Hepatotoxicity
    - In patients who develop ALT and/or AST > 5 times ULN or total bilirubin > 3 times ULN during treatment with abiraterone acetate, interrupt treatment until the liver function tests return to the patient's baseline value or to an AST and ALT 2.5 times ULN or less, and total bilirubin 1.5 times ULN or less. Then resume abiraterone acetate at 750 mg orally once daily. If hepatotoxicity recurs, interrupt treatment until the liver function tests return to the patient's baseline value or to an AST and ALT 2.5 times ULN or less, and total bilirubin 1.5 times ULN or less. Then resume abiraterone acetate at 500 mg orally once daily. If hepatotoxicity recurs, discontinue treatment. The safety of retreatment in patients who develop AST or ALT 20 times ULN or greater and/or bilirubin 10 times ULN or greater is unknown.

Dosage in Other Disease States

- Coadministration with Strong CYP3A4 Inducer: Not recommended. If concurrent use of abiraterone acetate and a strong CYP3A4 inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine) cannot be avoided, increase the dosing frequency of abiraterone acetate to twice daily (e.g., abiraterone acetate 1000 mg orally twice daily). Reduce abiraterone acetate to the previous dose and frequency when the strong CYP3A4 inducer is discontinued.

PRECAUTIONS

Contraindications:

- Pregnancy and women of childbearing potential (Category X - all trimesters); may cause fetal harm or loss of pregnancy; avoid becoming pregnant with effective contraception use during treatment and for at least 1 week following discontinuation.

Precautions:

- Adrenocortical insufficiency has been reported. Monitor for symptoms and signs of adrenocortical insufficiency. Perform appropriate tests to confirm diagnosis, and increased corticosteroid dose may be warranted before, during and after stressful situations. Risk for adrenocortical insufficiency is increased with prednisone dose reduction or withdrawal, concurrent infection, or unusual stress.
- An underlying cardiovascular condition (e.g., history of cardiovascular disease, heart failure, recent myocardial infarction, or ventricular arrhythmia) may be compromised by hypertension, hypokalemia, and fluid retention that can result from mineralocorticoid excess; monitoring recommended.
- Mineralocorticoid excess: Use Zytiga with caution in patients with a history of cardiovascular disease. The safety of Zytiga in patients with LVEF < 50% or NYHA Class III or IV heart failure in Study 1 or LVEF < 50% or NYHA Class II to IV heart failure in Study 2 was not established. Mineralocorticoid excess may cause hypertension, hypokalemia, and fluid retention. Control hypertension and correct hypokalemia before treatment. Monitor blood pressure, serum potassium and symptoms of fluid retention at least monthly. Concomitant use with a corticosteroid reduces incidence/severity of adverse reactions.
- Avoid concomitant use of CYP2D6 substrates with narrow therapeutic index (e.g., thioridazine). If unable to avoid use, exercise caution and consider CYP2D6 substrate dose reduction.
- Avoid use of concomitant strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital). Dose adjustment is required if coadministration is clinically indicated.
- Food effect: abiraterone Cmax and AUC increased significantly when taken with a meal; take on empty stomach with no food at least 2 hours before and 1 hour after administration.
- Severe hepatic impairment (Child-Pugh class C): avoid use.
- Moderate (Child-Pugh class B): initiate at reduced dose.
- Hepatotoxicity has been reported. Increases in liver enzymes have led to drug interruption, dose modification and/or discontinuation. Monitor liver function and modify, interrupt, or discontinue Zytiga dosing as recommended.

Billing/Coding information

HCPCS Coding:

C 9399	Unclassified drugs or biologicals (This code should only be used for drugs and biologicals that are approved by the FDA on or after January 1, 2004) (Hospital Outpatient Use ONLY)
J 8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

COST

- AWP (May 2011): Zytiga 250mg tablet (120): $6,000
- AWP (October 2013): Zytiga 250mg tablet (120): $8,204

COMMITTEE APPROVAL

- April 2011

GUIDELINE UPDATE INFORMATION

April 2011	Prior Authorization Criteria created
May 2014	Coverage Policy created

REFERENCES

- DRUGDEX®, accessed 05/05/2014.
- Product Information: Zytiga® (abiraterone), tablets for oral administration. Janssen Biotech, Inc., Horsham, PA. September 2013.