



## Prior Authorization Approval Criteria

### Zytiga (*abiraterone*)

<b>Generic name:</b>	Abiraterone
<b>Brand name:</b>	Zytiga
<b>Medication class:</b>	Antineoplastic; androgen biosynthesis inhibitor
<b>FDA-approved uses:</b>	In combination with prednisone for metastatic castration-resistant prostate cancer previously treated with chemotherapy containing docetaxel
<b>Available dosage forms:</b>	250mg tablet
<b>Usual dose:</b>	1,000mg daily in combination with prednisone 5mg twice daily
<b>Approximate monthly cost:</b> (based on AWP 2011)	\$6,000
<b>Duration of therapy:</b>	Until disease progression

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed metastatic castration-resistant prostate cancer
- Disease progression despite treatment with docetaxel (taxotere)
- Serum potassium level between 3.5-5mEq/L
- Baseline PSA level obtained
- ECOG status  $\leq 2$
- Approval will be for periods of 3 months

**Criteria for continuation of therapy:**

- Patient responding to treatment without disease progression
- Patient tolerating treatment
- Liver function, serum potassium, and blood pressure is being monitored
- <25% increase in baseline PSA level

**Caution:**

- Control hypertension and correct hypokalemia before treatment
- Increases in liver enzymes have led to drug interruption, dose modification, and/or drug discontinuation

**Monitoring:**

- Liver function
- Serum potassium level
- Blood pressure
- PSA level

**Contraindication:**

- None

**Not approved if:**

- Does not meet the above stated criteria

**Special considerations:**

- Do not use in patients with baseline severe hepatic impairment

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 09/07/2011