



Prior Authorization Approval Criteria

Zytiga (*abiraterone*)

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

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