



EXPRESS SCRIPTS®

FORMULARY EXCEPTION POLICY

POLICY: Oncology – Zytiga® 250 mg tablets (abiraterone acetate tablets – Centcor Ortho Biotech/Patheon)

DATE EFFECTIVE: 7/1/2019

Documentation: Documentation is required for use of generic abiraterone acetate tablets 250 mg as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or other information.

Approval Duration: All approvals are provided for 1 year.

CRITERIA

Coverage of brand Zytiga 250 mg tablets are recommended in those who meet the following criteria:

FDA-Approved Indications

1. Prostate Cancer – Metastatic, Castration-Resistant (mCRPC).

Approve if the patient has tried generic abiraterone acetate tablets AND cannot take generic abiraterone acetate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction **[documentation required]**.

2. Prostate Cancer – Metastatic, Castration-Sensitive (mCSPC).

The patient has tried generic abiraterone acetate tablets AND cannot take generic abiraterone acetate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction **[documentation required]**.

Other Uses with Supportive Evidence

3. Prostate Cancer – Regional Risk Group or Locally Advanced.

The patient has tried generic abiraterone acetate tablets AND cannot take generic abiraterone acetate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction **[documentation required]**.

4. Prostate Cancer – Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT).

The patient has tried generic abiraterone acetate tablets AND cannot take generic abiraterone acetate tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per

the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required].

HISTORY

Type of Revision	Summary of Changes	Date
New policy	--	7/1/2019