FORMULARY EXCEPTION POLICY

POLICY: Oncology – Zytiga® 250 mg tablets (abiraterone acetate tablets – Centocor 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**

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<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Date</th>
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<tr>
<td>New policy</td>
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