**BENEFIT DESCRIPTION AND LIMITATIONS OF COVERAGE**

**ITEM:** Zytiga® (abiraterone acetate)

**PRODUCT LINES:** Commercial HMO/PPO/CDHP

**COVERED UNDER:** Rx (all product lines)

**DESCRIPTION:** Irreversible inhibitor of CYP17 which prevents downstream synthesis of the formation of the testosterone precursors dehydroepiandrosterone (DHEA) and androstenedione

**CPT/HCPCS CODE:** N/A

**COMPANY SUPPLYING:** Janssen Biotech, Inc.

**SETTING:** Self-administered oral tablets

**COVERAGE CRITERIA:** Medical literature

**APPROVAL PERIOD:** First fill limited to 14 day supply or quantity needed for one cycle, whichever is lesser

Subsequent fills could be up to 30 days at the discretion of the health plan pharmacist or medical director

**Recommended Authorization Criteria**

Coverage of abiraterone acetate is recommended for those who meet the following criteria:

Abiraterone acetate should be prescribed by, or in consultation with, an oncologist.

**FDA-Approved Indication**

1. **Metastatic castrate-resistant prostate cancer.** Approve if ALL of the following are met ():

   a. Diagnosis of metastatic hormone-refractory or castrate resistant prostate cancer\(^2-5\) as determined by the following:

      i. The patient has undergone castration surgically via bilateral orchiectomy and has documented progression of disease OR

      ii. The patient has undergone chemical castration via androgen-deprivation therapy with a luteinizing hormone-releasing hormone (LHRH) agonist or antagonist such as degarelix, leuprolide, goserelin, triptorelin, or histrelin and has documented progression of disease AND

      iii. Evidence of sufficient castration with serum testosterone level < 50 ng/dL\(^6\) AND

      iv. Progression of prostate cancer with castration is demonstrated by radiographic evidence of metastases to the soft tissue, lymph nodes, and/or bone or increases in serum prostate-specific antigen (PSA) levels\(^3-4,7\)

   b. Prescribed in combination with prednisone 5mg twice daily (PI)
Exclusions

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

References


APPROVAL:

<table>
<thead>
<tr>
<th>ENDORSED BY:</th>
<th>Pharmacy &amp; Therapeutics Committee</th>
<th>Original Date: 5/15/2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPROVED BY:</td>
<td>Medical Advisory Council</td>
<td>Date: 6/11/2013</td>
</tr>
</tbody>
</table>