



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACETATE	ZYTIGA, ABIRATERONE ACETATE	37571		GPI-10 (2140601020)	

**GUIDELINES FOR USE**

1. Does the patient have **ONE** of the following diagnoses?

- Metastatic castration-resistant prostate cancer (mCRPC)
- Metastatic high-risk castration-sensitive prostate cancer (mCSPC)

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of the guideline.

2. Will the requested medication be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)?

If yes, continue to #3.

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?

- The patient had a bilateral orchiectomy
- The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
- The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, continue to #4.

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of the guideline.

4. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit as follows:**

- **250mg: #8 per day.**
- **500mg: #4 per day.**

If no, **approve for 12 months by GPID or GPI-14 with a quantity limit as follows:**

- **250mg: #4 per day.**
- **500mg: #2 per day.**

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GUIDELINES FOR USE (CONTINUED)

**DENIAL TEXT:** \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE (Zytiga)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
  1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
  2. Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)
- B. The requested medication will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
- C. You meet ONE of the following:
  1. You had a bilateral orchiectomy (both testicles have been surgically removed)
  2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
  3. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zytiga.

**REFERENCES**

- Zytiga [Prescribing Information]. Horsham, PA: Janssen Biotech; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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