ABIRATERONE

Generic	Brand	HICL	GCN	Exception/Other
ABIRATERONE ACETATE	ZYTIGA	37571		
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946		

This drug requires a written request for prior authorization.

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

ZYTIGA

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. Is the requested medication being used in combination with prednisone?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. 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 with a quantity limit as follows:**
   - **Zytiga 250mg (GPID 29886): #8 tablets per day.**
   - **Zytiga 500mg (GPID 43205): #4 tablets per day.**

   If no, **approve for 12 months by GPID with a quantity limit as follows:**
   - **Zytiga 250mg (GPID 29886): #4 tablets per day.**
   - **Zytiga 500mg (GPID 43205): #2 tablets per day.**

ZYTIGA DENIAL TEXT: The guideline named **ABIRATERONE (Zytiga)** requires a diagnosis of metastatic castration-resistant prostate cancer or metastatic high-risk castration-sensitive prostate cancer. In addition, the requested medication must be used in combination with prednisone.

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ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

YONSA

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The requested medication is being used in combination with methylprednisolone
   - The patient has had a trial of or has a contraindication to Zytiga (abiraterone acetate) or prednisone therapy

   If yes, continue to #2.
   If no, do not approve.
   YONSA DENIAL TEXT: The guideline named **ABIRATERONE (Yonsa)** requires that the patient have a diagnosis of metastatic castration-resistant prostate cancer. In addition, the following criteria must also be met:
   - The requested medication must be used in combination with methylprednisolone
   - The patient has had a trial of or has a contraindication to Zytiga (abiraterone acetate) or prednisone therapy

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

   If yes, **approve for 12 months by HICL with a quantity limit of #8 tablets per day.**
   If no, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**

RATIONALE

To ensure appropriate use of abiraterone products consistent with FDA approved indications.

FDA APPROVED INDICATIONS

Zytiga is indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and metastatic high-risk castration-sensitive prostate cancer.

Yonsa is indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer.

DOSAGE AND ADMINISTRATION

Metastatic castration-resistant prostate cancer: The recommended dose of Zytiga is 1,000 mg (two 500 mg tablets or four 250 mg tablets) administered orally once daily in combination with prednisone 5 mg administered orally twice daily.

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ABIRATERONE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dose of Yonsa is 500 mg (four 125 mg tablets) administered orally once daily in combination with methylprednisolone 4 mg administered orally twice daily. Yonsa tablets can be taken with or without food. The tablets should be swallowed whole with water. Do not crush or chew tablets.

If a strong CYP3A4 inducer must be co-administered, increase the Yonsa dosing frequency to twice a day only during the co-administration period (e.g., from 500 mg once daily to 500 mg twice a day). Reduce the dose back to the previous dose and frequency, if the concomitant strong CYP3A4 inducer is discontinued.

Metastatic high-risk castration-sensitive prostate cancer: The recommended dose of Zytiga is 1,000 mg (two 500 mg tablets or four 250 mg tablets) administered orally once daily in combination with prednisone 5 mg administered orally once daily.

Patients receiving Zytiga or Yonsa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. Zytiga must be taken on an empty stomach, either one hour before or two hours after a meal. The tablets should be swallowed whole with water. Do not crush or chew tab.

If a strong CYP3A4 inducer must be co-administered, increase the Zytiga dosing frequency to twice a day only during the co-administration period (e.g., from 1,000 mg once daily to 1,000 mg twice a day).

REFERENCES

- Yonsa [Prescribing Information]. Sun Pharma. Cranbury, NJ. May 2018.
- Zytiga [Prescribing Information]. Horsham, PA. Janssen Biotech; February 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/18
Created: 06/11
Client Approval: 09/18
P&T Approval: 07/18