**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.**

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### 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