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)	
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946			

**** 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. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)
   - The patient has a serum testosterone level < 50 ng/dL

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ABIRATERONE

GUIDELINES FOR USE - ZYTIGA (CONTINUED)

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

   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **Zytiga 250mg: #4 per day.**
   - **Zytiga 500mg: #2 per day.**

   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 prednisone
   C. You meet ONE of the following:
      1. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      2. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)
      3. Your blood testosterone levels are less than 50 ng/dL

   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.

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ABIRATERONE

GUIDELINES FOR USE - YONSA

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 had a trial of or contraindication to Zytiga (abiraterone acetate)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)
   - The patient has a serum testosterone level < 50 ng/dL

   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 or GPI-14 with a quantity limit of #8 per day.**
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**

   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 (Yonsa)** requires the following rule(s) be met for approval:
   A. You have 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)
   B. The requested medication will be used in combination with methylprednisolone
   C. You have previously tried or have a contraindication to (medical reason why you cannot use) Zytiga (abiraterone acetate)

   (Denial text continued on next page)

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ABIRATERONE

GUIDELINES FOR USE - YONSA (CONTINUED)

D. You meet ONE of the following:
   1. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

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 Yonsa and Zytiga.

REFERENCES

- Yonsa [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; June 2018.
- Zytiga [Prescribing Information]. Horsham, PA: Janssen Biotech; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/25/20
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Client Approval: 08/20
P&T Approval: 07/20