



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ENZALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENZALUTAMIDE	XTANDI	39580		GPI-10 (2140243000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)?

If yes, continue to #4.
If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer **AND** meet the following criterion?

- The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen levels)

If yes, continue to #4.
If no, continue to #3.

3. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer and meet **ONE** of the following criteria?

- The patient has contraindication or intolerance to prednisone
- The patient had a trial of or contraindication to Zytiga (abiraterone acetate)

If yes, continue to #4.
If no, do not approve.

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

4. Has the patient previously received a bilateral orchiectomy?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 capsules per day.**
If no, continue to #5.

5. Is the requested medication being used concurrently with a gonadotropin releasing hormone agonist or antagonist (e.g., leuprolide, goserelin, histrelin, degarelix)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 capsules per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL 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 **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
 2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)
- B. You meet ONE of the following:
1. The requested medication will be used at the same time with a gonadotropin releasing hormone agonist or antagonist (such as leuprolide, goserelin, histrelin, degarelix)
 2. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
- C. **If you have non-metastatic castration-resistant prostate cancer, approval also requires:**
1. You have a high-risk prostate cancer (rapidly increasing prostate specific antigen levels)
- D. **If you have metastatic castration-resistant prostate cancer, approval also requires ONE of the following:**
1. You have previously tried Zytiga (abiraterone acetate) unless there is a medical reason why you cannot take it (contraindication)
 2. You cannot tolerate prednisone or there is a medical reason why you cannot take it (contraindication)

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.

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
 - Metastatic or non-metastatic castration-resistant prostate cancer
 - Metastatic castration-sensitive prostate cancer (mCSPC)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 capsules per day.**

If no, do not approve.

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

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE

RENEWAL CRITERIA (CONTINUED)

RENEWAL 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 **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:

1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

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 Xtandi.

REFERENCES

- Xtandi [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/20

Created: 09/12

Client Approval: 02/20

P&T Approval: 01/20