



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 **ONE** of the following diagnoses?

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

If yes, continue to #3.

If no, continue to #2.

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

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

If yes, continue to #3.

If no, do not approve.

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

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

- The patient previously received 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., leuprolide, goserelin, histrelin, degarelix)

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

If no, do not approve.

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

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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 castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
 2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
 3. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
- B. You meet ONE of the following:
1. You previously received 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 analog (such as leuprolide, goserelin, histrelin, degarelix)
- 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)

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 (CRPC)
 - Metastatic castration-sensitive prostate cancer (mCSPC)

If yes, continue to #2.

If no, do not approve.

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

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RENEWAL CRITERIA (CONTINUED)

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

- The patient previously received 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., leuprolide, goserelin, histrelin, degarelix)

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

If no, do not approve.

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 castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
3. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)

B. You meet **ONE** of the following:

1. You previously received 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 analog (such as leuprolide, goserelin, histrelin, 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.

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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.; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/23

Created: 09/12

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P&T Approval: 10/22