



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

APALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APALUTAMIDE	ERLEADA	44773		GPI-10 (2140241000)	

**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 #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 [PSA] levels)

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 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 GPID or GPI-14 with the following quantity limits:**

- **60mg: #3 per day.**
- **240mg: #1 per day.**

If no, do not approve.

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

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APALUTAMIDE

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 **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:

- A. You have **ONE** of the following diagnoses:
1. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that does not respond to hormone reduction therapy and has not spread to other parts of the body)
  2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds 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 a non-metastatic castration-resistant prostate cancer, approval also requires:**
1. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA] 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 castration-sensitive prostate cancer (mCSPC)
  - Non-metastatic castration-resistant prostate cancer (nmCRPC)

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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APALUTAMIDE

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 GPID or GPI-14 with the following quantity limits:**

- **60mg: #3 per day.**
- **240mg: #1 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 **APALUTAMIDE (Erleada)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses:

1. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that does not respond to hormone reduction therapy but has not spread)
2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread and responds 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 Erleada.

**REFERENCES**

- Erleada [Prescribing Information]. Horsham, PA: Janssen; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/23

Created: 05/18

Client Approval: 05/23

P&T Approval: 04/23