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# 5.21.108

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	February 23, 2018
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**Last Review Date:** March 8, 2024

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## Erleada

### Description

#### Erleada (apalutamide)

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#### Background

Erleada (apalutamide) is indicated for the treatment of patients with prostate cancer. Erleada is an androgen receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. Erleada inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription. Through this process, Erleada administration causes decreased tumor cell proliferation and increased apoptosis leading to a decrease in tumor volume (1).

#### Regulatory Status

FDA-approved indications: Erleada is an androgen receptor inhibitor indicated for the treatment of patients with: (1)

- Metastatic castration-sensitive prostate cancer (mCSPC)
- Non-metastatic castration-resistant prostate cancer (nmCRPC)

Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy (1).

Erleada can cause fetal harm and potential loss of pregnancy. Prescribers should advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of Erleada (1).

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Falls and fractures occurred in patients receiving Erleada. Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone targeted agents (1).

Seizure occurred in patients receiving Erleada. Permanently discontinue Erleada in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with Erleada. Advise patients of the risk of developing a seizure while receiving Erleada and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others (1).

Safety and effectiveness of Erleada in pediatric and female patients have not been established (1).

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## Related policies

Nilandron, Nubeqa, Orgovyx, Xtandi, Yonsa, Zytiga

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Erleada may be considered **medically necessary** if the conditions indicated below are met.

Erleada may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

**Gender** Male

### Diagnoses

Patient must have **ONE** of the following:

1. Metastatic Castration-Sensitive Prostate Cancer (mCSPC)
2. Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC)

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**AND ONE** of the following for **ALL** indications:

1. Patient is receiving gonadotropin-releasing hormone (GnRH) analog
2. Patient has had a bilateral orchiectomy

**AND ALL** of the following for **ALL** indications:

1. **NO** dual therapy with another androgen receptor inhibitor (see Appendix 1)
2. Prescriber agrees to advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of Erleada

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## Prior – Approval *Renewal* Requirements

Same as above

### Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Quantity** 240 mg per day

**Duration** 12 months

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## Prior – Approval *Renewal* Limits

Same as above

### Rationale

#### Summary

Erleada (apalutamide) is indicated for the treatment of patients with prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy (1).

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Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Erleada while maintaining optimal therapeutic outcomes.

## References

1. Erleada [package insert]. Thousand Oaks, CA: Janssen Products, LP; December 2023.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Apalutamide 2024. National Comprehensive Cancer Network, Inc. Accessed on January 18, 2024.

## Policy History

Date	Action
February 2018	Addition to PA
June 2018	Annual editorial review
September 2018	Annual editorial review
June 2019	Annual review
October 2019	Addition of indication: metastatic castration-sensitive prostate cancer
December 2019	Annual review
June 2020	Annual review
March 2021	Annual editorial review and reference update
June 2021	Annual review and reference update
March 2022	Annual review and reference update
December 2022	Annual review and reference update
March 2023	Annual review and reference update. Per PI update, changed quantity limit to 240 mg per day
June 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update

## Keywords

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**This policy was approved by the FEP<sup>®</sup> Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**

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## Appendix 1 - List of Androgen Receptor Inhibitors

Generic Name	Brand Name
abiraterone	Yonsa
abiraterone	Zytiga
abiraterone/niraparib	Akeega
apalutamide	Erleada
darolutamide	Nubeqa
enzalutamide	Xtandi
nilutamide	Nilandron