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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 23, 2018
Subject:	Erleada	**Page:**	1 of 5

Last Review Date: December 13, 2024

Erleada

Description

Erleada (apalutamide)

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).

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).

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)

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

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 240 mg per day

Duration 12 months

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).

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; September 2024.
2. NCCN Drugs & Biologics Compendium® Apalutamide 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 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
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

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