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, apalutamide administration causes decreased tumor cell proliferation and increased apoptosis leading to a decrease in tumor volume (1).

Regulatory Status
FDA approved indication: 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 is contraindicated for use in pregnant woman because the drug 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 in pediatric patients have not been established (1).

**Related policies**
Nilandron, Nubeqa, 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** for patients 18 years of age or older for the treatment of prostate cancer and if the conditions indicated below are met.

Erleada may be considered **investigational** in patients less than 18 years of age and 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

<table>
<thead>
<tr>
<th>Quantity</th>
<th>360 tablets per 90 days</th>
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<tr>
<td>Duration</td>
<td>12 months</td>
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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).
Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Erleada while maintaining optimal therapeutic outcomes.

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>February 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>October 2019</td>
<td>Addition of indication: metastatic castration-sensitive prostate cancer</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.
Appendix 1 - List of Androgen Receptor Inhibitors

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<tr>
<th>Generic Name</th>
<th>Brand Name</th>
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<tr>
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