UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1244-9
Program	Prior Authorization/Notification
Medication	Erleada® (apalutamide)
P&T Approval Date	5/2018, 5/2019, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023, 11/2024, 11/2025
Effective Date	2/15/2026

1. Background:

Erleada (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. It is also indicated for the treatment of metastatic castration-sensitive prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Erleada or should have had bilateral orchiectomy.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Erleada** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Prostate Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Erleada** will be approved based on **<u>all</u>** of the following criteria:

   (1) Diagnosis of prostate cancer

   -AND-

   (2) **<u>One</u>** of the following:

   (a) **<u>Both</u>** of the following:

i. Disease is castration-resistant or recurrent

-AND-

ii. Disease is non-metastatic

-OR-

(b) **Both** of the following:

i. Disease is castration-sensitive or naive

-AND-

ii. Disease is metastatic

-AND-

(3) **One** of the following:

(a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

-OR-

(b) Patient has had bilateral orchiectomy

Authorization will be issued for 12 months.

2. **Reauthorization Criteria**

a. **Erleada** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Erleada therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Erleada [package insert]. Horsham, PA: Janssen Products LP; August 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at NCCN Drugs and Biologics Compendium®. Accessed September 26, 2025.

Program	Prior Authorization/Notification – Erleada (apalutamide)
Change Control	
5/2018	New program
5/2019	Annual review with no change to coverage criteria. Updated reference.
11/2019	Updated background and criteria to include new labeled indication in metastatic castration-sensitive prostate cancer. Added general NCCN recommendations for use statement. Updated references.
11/2020	Annual review. Minor formatting change. Updated references.
11/2021	Annual review with no change to coverage criteria. Updated references.
11/2022	Annual review with no changes to clinical coverage criteria. Updated reference and added state mandate footnote.
11/2023	Annual review with no change to coverage criteria. Updated references.
11/2024	Annual review with no change to coverage criteria. Updated references.
11/2025	Annual review with no change to coverage criteria. Updated references.