UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1244-1
Program	Prior Authorization/Notification
Medication	Erleada™ (apalutamide)
P&T Approval Date	5/2018
Effective Date	8/1/2018; Oxford only: 8/1/2018

1. Background:

Erleada™ (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Erleada or should have had bilateral orchiectomy.[1]

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. Patients less than 19 years of age

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. Prostate Cancer

1. Initial Authorization

a. **Erleada** will be approved based on **all** of the following criteria:

(1) Diagnosis of prostate cancer

-AND-

(2) Disease is castration-resistant or recurrent

-AND-

(3) Disease is non-metastatic

-AND-

(4) **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.

3. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

1. Erleada [package insert]. Horsham, PA: Janssen Products LP. February 2018
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 21, 2018.

Program	Prior Authorization/Notification – Erleada (apalutamide)
Change Control	
5/2018	New program