UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Erleada

Program	Prior Authorization
Medication	Erleada™ (apalutamide)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2018
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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.[1]

2. Coverage Criteria:

A. Prostate Cancer

1. Initial Authorization

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

(1) Diagnosis of prostate cancer

-AND-

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

(a) **Both** 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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Erleada** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Erleada therapy

Authorization will be issued for 12 months.

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. September 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 5, 2020.

Program	Prior Authorization
Change Control	
Date	Change
5/2018	New program
5/2019	Annual review with no change to coverage criteria. Updated references.
11/2019	Updated background and criteria to reflect new indication in metastatic castration sensitive disease. Updated references.
11/2020	Annual review. Updated references. Added Additional Clinical Rules section.