

Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Apalutamide (Erleada)

Initiation (new start) criteria: Non-formulary **apalutamide (Erleada)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient is at least 18 year of age **AND**
- Medication is prescribed by hematology/oncology **AND**
- **Patient has diagnosis of metastatic hormone-sensitive prostate cancer AND meets the following:**
 1. Adequate trial of abiraterone (Zytiga) with either documented disease progression or toxicity OR relative contraindication as defined as:
 - Type 2 diabetes mellitus with an A1C > 7% OR patient is on insulin
 - Severe liver disease (Child-Pugh Class C)
 - Other cardiovascular risk clearly documented by oncologist (e.g., heart failure with left-ventricular ejection fraction <50%; recent myocardial infarction, or ventricular arrhythmia)
 2. Adequate trial of enzalutamide (Xtandi) with documented toxicity AND no disease progression
 3. Adequate trial of darolutamide (Nubeqa) with docetaxel with intolerable side effects AND no disease progression or relative contraindication to docetaxel per oncologist's opinion (i.e. poor performance status, preexisting chemotherapy-induced peripheral neuropathy) -AND-
 4. Will be used concurrently with a gonadotropin releasing hormone (GNRH) analog (e.g. leuprolide, degarelix)

-OR-

- **Patient has diagnosis of non-metastatic castrate resistant prostate cancer and meets the following criteria:**
 1. Adequate trial of enzalutamide (Xtandi) with documented toxicity AND no disease progression **-AND-**
 2. Adequate trial of darolutamide (Nubeqa) with documented toxicity AND no disease progression **-AND-**
 3. Will be used concurrently with a gonadotropin releasing hormone (GNRH) analog (e.g. leuprolide, degarelix) **-AND-**

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4. Prostate Specific Antigen (PSA) doubling time is less than or equal to 10 months with GNRH analog

Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): non-formulary **apalutamide (Erleada)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has diagnosis of prostate cancer **-AND-**
- Patient is stable on medication