Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

Darolutamide (Nubeqa)

Notes:

- Quantity limits: Yes
- * If clinician determines that patient has a high risk of seizure, it is appropriate to use darolutamide in place of enzalutamide

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

- Patient is at least 18 years 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 more than 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
  2. Adequate trial of enzalutamide (Xtandi)* with documented toxicity AND no disease progression OR relative contraindication (i.e., history of seizure disorder, elderly and at risk of falls, cognitive impairment)
  3. Will be used concurrently with a gonadotropin releasing hormone (GNRH) analog (e.g., leuprolide, degarelix) AND docetaxel

-OR-

1. Patient has high-volume disease (defined as visceral met and/or 4 or more bone metastases, with at least one metastasis beyond the pelvis vertebral column) OR per oncologist's opinion patient has extremely high PSA or biologically aggressive disease.
2. Will be used concurrently with a gonadotropin releasing hormone (GNRH) analog (e.g., leuprolide, degarelix) AND docetaxel

Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Darolutamide (Nubeqa)

-OR-

- **Patient has diagnosis of non-metastatic, castrate-resistant prostate cancer AND meets the following:**
    1. Adequate trial of enzalutamide (Xtandi)* with documented toxicity AND no disease progression OR relative contraindication (i.e., history of seizure disorder, elderly and at risk of falls, cognitive impairment)
    2. Will be used concurrently with a gonadotropin releasing hormone (GNRH) analog (e.g., leuprolide, degarelix)
    3. Prostate Specific Antigen (PSA) doubling time is less than or equal to 10 months with GNRH analog

Criteria for new members or other members already on the medication who were not reviewed upon initiation: Non-formulary **darolutamide (Nubeqa)** will be covered on the prescription drug benefit when the following criteria are met:

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