

**Prostate Cancer Agents:**  
**Erleada (apalutamide)**  
**Jevtana (cabazitaxel)**  
**Nubeqa (darolutamide)**  
**Xtandi (enzalutamide)**  
**Yonsa (abiraterone 125 mg)**  
**Zytiga (abiraterone 250 mg, 500 mg)**  
**Effective 12/04/2023**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	Jevtana is only available through the medical benefit.		

### Overview

No PA	Drugs that require PA
Casodex # (bicalutamide) flutamide nilutamide Docefrez (docetaxel) docetaxel	Erleada® (apalutamide) Jevtana® (cabazitaxel) <sup>MB</sup> Nubeqa® (darolutamide) Xtandi® (enzalutamide) Yonsa® (abiraterone 125 mg) Zytiga® (abiraterone 250 mg, 500 mg)*

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

<sup>MB</sup> This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.

\* A-rated generic available, both brand and A-rated generic require a PA.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted for members when all the following criteria are met:

#### Erleada® (apalutamide)

**ONE** of the following:

1. Diagnosis of Nonmetastatic Castration Resistant Prostate Cancer (NM-CRPC)
  - a. Prescriber is an oncologist or urologist
  - b. Appropriate dosing
  - c. **ONE** of the following:
    - i. Requested agent will be used in combination with a gonadotropin-releasing hormone (GnRH) analog
    - ii. Member had a bilateral orchiectomy
  - d. Physician attestation of inadequate response (i.e., progression of cancer), adverse reaction, or contraindication to the use of Xtandi (enzalutamide) for NM-CRPC
2. Diagnosis of Metastatic Castration-Sensitive Prostate Cancer (mCSPC)
  - a. Prescriber is an oncologist
  - b. Appropriate dosing
  - c. **ONE** of the following:
    - i. Requested agent will be used in combination with a GnRH analog
    - ii. Member had a bilateral orchiectomy
  - d. Physician attestation of inadequate response (i.e., progression of cancer), adverse reaction, or contraindication to the use of abiraterone for the treatment of mCSPC

**Jevtana®** (cabazitaxel)

1. Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Requested agent will be used in combination with prednisone
5. Physician attestation of inadequate response (i.e., progression of cancer) or adverse reaction to one docetaxel containing regimen

**Nubeqa®** (darolutamide)

**ONE** of the following:

1. Diagnosis of Non-Metastatic Castration Resistant Prostate Cancer (NM-CRPC)
  - a. Prescriber is an oncologist or urologist
  - b. Appropriate dosing
  - c. **ONE** of the following:
    - i. Requested agent will be used in combination with a GnRH analog
    - ii. Member had a bilateral orchiectomy
  - d. Physician attestation of inadequate response (i.e., progression of cancer), adverse reaction, or contraindication to the use of Xtandi (enzalutamide) for NM-CRPC
2. Diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC, mCSPC)
  - a. Prescriber is an oncologist or urologist
  - b. Appropriate dosing
  - c. **ONE** of the following:
    - i. Requested agent will be used in combination with a GnRH analog
    - ii. Member had a bilateral orchiectomy
  - d. Requested agent will be used in combination with docetaxel
3. Diagnosis of M1 Metastatic Castration-Resistant Prostate Cancer (mCRPC) – off label
  - a. Appropriate dosing (600 mg twice daily)
  - b. **ONE** of the following:



- i. If no prior docetaxel or no novel hormone therapy, inadequate response, adverse reaction, or contraindication\* to **ALL** of the following:
  1. abiraterone
  2. docetaxel
  3. enzalutamide
- ii. If prior docetaxel but no prior novel hormone therapy, inadequate response, adverse reaction, or contraindication\* to **BOTH** of the following:
  1. abiraterone
  2. enzalutamide
- iii. If prior novel hormone therapy but no prior docetaxel, inadequate response, adverse reaction, or contraindication\* to docetaxel
- iv. If prior docetaxel and prior novel hormone therapy, inadequate response, adverse reaction, or contraindication\* to cabazitaxel

\* Documentation of **ONE** of the following is sufficient clinical rationale for contraindication:

- Any drug-drug interaction listed as contraindicated or major severity
- Xtandi® (enzalutamide): history of falls/fractures, seizures, severe hypertension, dyslipidemia despite adequate treatment
- Abiraterone: hepatic impairment, individuals with history of hypoglycemia or currently on a thiazolidinedione (e.g., pioglitazone, rosiglitazone), adrenocortical insufficiency, heart failure, recent myocardial infarction, or ventricular arrhythmia
- Docetaxel: hepatic impairment, neutropenia

**Xtandi®** (enzalutamide)

**ONE** of the following:

1. Diagnosis of Metastatic castration-sensitive prostate cancer (mCSPC) or metastatic castration-resistant prostate cancer (mCRPC)
  - a. Prescriber is an oncologist
  - b. Appropriate dosing
  - c. **ONE** of the following:
    - i. Requested agent will be used in combination with a GnRH analog
    - ii. Member had a bilateral orchiectomy
  - d. Physician attestation of inadequate response (i.e., progression of cancer), adverse reaction, or contraindication to the use of abiraterone for the treatment of mCSPC or mCRPC
2. Diagnosis of Non-metastatic castration resistant prostate cancer (NM-CRPC)
  - a. Prescriber is an oncologist or urologist
  - b. Appropriate dosing
  - c. **ONE** of the following:
    - i. Requested agent will be used in combination with a GnRH analog
    - ii. Member had a bilateral orchiectomy

**Yonsa®** (abiraterone 125 mg)

1. Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Requested agent will be used in combination with methylprednisolone
5. **ONE** of the following:



- a. Requested agent will be used in combination with a GnRH analog
- b. Member had a bilateral orchiectomy

**Zytiga®** (abiraterone 250 mg, 500 mg)

1. Diagnosis of mCSPC or mCRPC
2. Prescriber is an oncologist
3. Appropriate dosing
3. **ONE** of the following:
  - a. Requested agent will be used in combination with a GnRH analog
  - b. Member had a bilateral orchiectomy
4. Requested agent will be used in combination with prednisone
5. For the 500 mg tablet, medical necessity for use instead of the 250 mg tablet

**Continuation of Therapy**

Resubmission by prescriber will infer a positive response to therapy

**Limitations**

1. Initial approvals will be granted for the following:
  - a. abiraterone 250 mg, 500 mg, Erleada®, Nubeqa® (FDA-approved indications), Xtandi®, Yonsa®: 1 year
  - b. Nubeqa® (off-label): 3 months
  - c. Jevtana®: 8 months
2. Reauthorizations will be granted for the following:
  - a. abiraterone 250 mg, 500 mg, Erleada®, Nubeqa®, Xtandi®, Yonsa®: 1 year
  - b. Jevtana®: 8 months

**References**

1. NCCN Practice Guidelines in Oncology. Prostate Cancer [guideline on the Internet]. Version 1.2023. 2022 Sep 16 [cited 2022 Sep 27]. Available from: [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf).
2. ERLEADA™ (apalutamide), a Next-Generation Androgen Receptor Inhibitor, Granted U.S. FDA Approval for the Treatment of Patients with Non-Metastatic Castration-Resistant Prostate Cancer [news blast on the internet]. Pipeline Review; 2018 Feb 15 [cited 2019 Oct 15]. Available from: <http://pipelinereview.com/index.php/2018021567391/Small-Molecules/ERLEADA-apalutamide-a-Next-Generation-Androgen-Receptor-Inhibitor-Granted-U.S.-FDA-Approval-for-the-Treatment-of-Patients-with- Non-Metastatic-Castration-Resistant-Prostat.html>.
3. Erleada® (apalutamide) [prescribing information]. Horsham (PA): Janssen Products, LP; 2022 Jun.
4. Jevtana® [package insert]. Bridgewater (NJ): Sanofi-Aventis US LLC; 2021 Feb.
5. Zytiga® [package insert]. Horsham (PA): Centocor Ortho Biotech Inc; 2021 Oct.
6. Provenge® [package insert on the internet]. Seattle (WA): Dendreon Corporation; 2021 Dec.
7. Kantoff P, Higano C, Shore N, Berger E, Small E, Penson D. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. *N Engl J Med* 363(5):411-22.
8. Xtandi® [package insert]. Northbrook (IL): Astellas Pharma US, Inc; 2022 Apr.
9. Yonsa® (abiraterone acetate) [prescribing information]. Cranbury (NJ): Sun Pharmaceuticals; 2022 Mar.
10. Nubeqa® (darolutamide) [prescribing information]. Whippany (NJ): Bayer Healthcare Pharmaceuticals, Inc.; 2022 Aug.
11. ClinicalTrials.gov Internet]. Bethesda (MD): National Library of Medicine (US). 2021- [cited 2022 Sep 26]. Available from: <http://clinicaltrials.gov>



**Review History**

Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

11/15/23 – Reviewed and updated for P&T. Updated to remove Zytiga 500 mg tablet from BOGL (no longer brand preferred). No clinical changes. Effective 12/4/23

