Mass General Brigham
Health Plan

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

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Jevtana is only available through the medical benefit.		

Overview

No PA	Drugs that require PA
Casodex # (bicalutamide)	Erleada® (apalutamide)
flutamide	Jevtana® (cabazitaxel) [MB]
nilutamide	Nubeqa® (darolutamide)
Docefrez (docetaxel)	Xtandi® (enzalutamide)
docetaxel	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.
MB 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.
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