

# **Prostate Cancer - Pharmacological Treatment**

**Adjudication Guideline** 

**Rule Category:** Pharmaceutical

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**Related Adjudication** 

Governance



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### 1. Abstract

#### 1.1 For Members

Prostate cancer, one of the most common type of cancer in men, occurs when normal cells of prostate gland begins to grow faster or die slower. Prostate gland - a small gland that produces the seminal fluid that nourishes and transports sperm. Prostate cancer drugs are covered by Daman as per policy terms and conditions, if medically indicated.

#### 1.2 For Medical Professionals

The goal of pharmacotherapy to induce remission, reduce morbidity and prevent complication. Prostate cancer treatment includes hormones, chemotherapy.

# 2. Scope

This adjudication rule defines the medical necessity of prescribing prostate cancer drugs.

The scope of this AR is only limited to the pharmacological treatment of prostate cancer; any other procedure used to treat prostate cancer or drugs used to alleviate complications of chemotherapy are out of the scope of this AR.

# 3. Adjudication Policy

# 3.1 Eligibility / Coverage Criteria

Daman covers prostate drugs when medically necessary and prescribed by specialized clinician as policy terms and conditions.

#### 1. Hormonal therapy

Androgens (testosterone and Dihydrotestosterone) causes the prostate cancer to grow. Hormonal therapy also known ADT androgen deprivation therapy/androgen suppression therapy, remove or block Androgen action and stop cancer cell from growing.

#### a) Primary ADT

LHRH agonist /LHRH antagonists/

Luteinizing hormones releasing hormone (LHRH) or Gonadotropin releasing hormone (GnRH) agonists are drugs that lower Testosterone in men. Anti-androgens block the action of testosterone and stop prostate cancer from growing. These drugs (in table below) are used as neo-adjuvant or adjuvant therapy for clinically localized with intermediate, locally advance and metastatic disease state.

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| Primary ADT                  | Medical necessity   |
|------------------------------|---|
| Leuprolide (LHRH agonists)   | <ul> <li>Anti-Androgens therapy ADT are used in all stages of<br/>prostate cancer till disease state stops response.</li> </ul> |
| Goserelin (LHRH agonists)    | <ul> <li>ADT used in locally advance prostate cancer,<br/>adjuvant treatment for lymph node metastasis.</li> </ul>              |
|                              | <ul> <li>Neo-adjuvant, concurrent or adjuvant to radiation<br/>therapy for clinically localized cancer.</li> </ul>              |
| Triptorelin (LHRH agonists)  | ADT used for M0 or M1 castration naive disease.   |
| Degarelix (LHRH Antagonist)  | ADT is gold standard for metastatic prostate cancer   |
| Flutamide (Anti-androgen)    | castration sensitive patients.  |
| Bicalutamide (Anti-androgen) |   |

#### b) Secondary ADT

Drugs which block synthesis of androgen at different sites and use in advanced prostate cancer.

Androgens receipt activation and paracrine androgen synthesis are potential mechanism leads to recurrence prostate cancer (CRPC) during primary ADT usage. In resistant tumour status other option of hormone therapies depends on whether patient has metastasis by imaging; M0 CRPC vs M1 CRPC.

| Secondary ADT                    | Medical Necessity   |
|----------------------------------|---|
| Abiraterone (CYP17 inhibitor)    | M1 CRPC      Used in advanced stage castration resistant prostate cancer (CRPC)).   |
|                                  | ❖ FDA revised in February 2018, the use of Abiraterone in<br>metastatic high-risk castration naïve prostate cancer (CSPC) |
|                                  | In combination with prednisolone metastatic prostate cancer<br>who is has already used chemotherapy such as Docetaxel     |
|                                  | M1 CRPC   |
| Enzalutamide (Anti-<br>androgen) | Used in patient who has develop resistant to ADT (CRPC) and<br>have previously received Docetaxel                         |
| Apalutamide                      | MO CRPC   |

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#### 2. Chemotherapy

Chemotherapy-Chemotherapy are systemically given to kill or stop cell from growing, mainly useful when cancer have spreads to distant organs.

| Chemotherapy Drugs | Medical Necessity  |
|--------------------|--|
| Docetaxel          | M1 CRPC  |
|                    | Used in androgen independent hormone refractory metastatic prostate cancer.  |
|                    | ❖ Docetaxel is an upfront treatment option in castration-naïve prostate cancer and distant metastases. (ECO/CHAARTED).   |
| Cabazitaxel        | M1 CRPC  ❖ Used in metastatic CRPC previously treated with Docetaxel  ❖ Used when Docetaxel fails to work in hormone refractory prostate cancer.  ❖ Additional code Encounter for chemotherapy Z51.11 is needed to validate the chemotherapy administration. |
|                    | Used as initial chemotherapy for advances hormone refractory<br>prostate cancer.   |
| Mitoxantrone       | Additional code Encounter for chemotherapy Z51.11 is needed<br>to validate the chemotherapy administration.  |

#### 3. Steroid

Prednisolone or dexamethasone in combination with Abiraterone, Docetaxel, Cabazitaxel and Mitoxantrone in metastatic prostate cancer.

# 3.2 Requirements for Coverage

ICD-10, CPT and drug codes must be coded to the highest level of specificity.

# 3.3 Non-Coverage

- Pharmacological treatment of prostate cancer is not covered when it does not meet medical necessity.
- Daman does not cover prostate cancer treatment for investigational and clinical trial purposes.
- Pharmacological treatment for prostate cancer is not covered for visitor plan.

# 3.4 Payment and Coding Rules

Please apply HAAD payment rules and regulations and relevant coding manuals for ICD and DOH drug codes.

**Note:** ICD codes for code Encounter for chemotherapy Z51.11 should only be used as principal diagnosis, followed by the reason of chemotherapy therapy as a secondary diagnosis.

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### 4. Denial Codes

| Code     | Code Description  |
|----------|---|
| CODE-014 | Activity/diagnosis is inconsistent with the patient's age/gender  |
| MNEC-005 | Service/supply may be appropriate, but too frequent   |
| CODE-010 | Activity/diagnosis inconsistent with clinician specialty  |
| MNEC-004 | Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities |
| AUTH-001 | Prior approval is required and was not obtained   |

# 5. Appendices

### 5.1 References

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https://www.accessdata.fda.gov/drugsatfda\_docs/label/2011/074728s011lbl.pdf

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# 5.2 Revision History

| Date       | Version No. | Change(s)  |
|------------|-------------|--|
| 01/11/13   | V1.0        | V1.0 Release                                       |
| 15/07/14   | V1.1        | V1.1 Disclaimer updated as per system requirements |
| 01/08/18   | V2.0        | V2.0 Content update                                |
| 29/10/2024 | V3.0        | No change/ Release of V3.0                         |

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