

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Xtandi Drug Quantity Management Policy – Per Rx

- Xtandi® (enzalutamide capsules and tablets – Astellas/Pfizer)

REVIEW DATE: 05/04/2022

OVERVIEW

Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with **castration-resistant prostate cancer (CRPC)** and **metastatic castration-sensitive prostate cancer (mCSPC)**.¹ Patients should receive Xtandi with a concurrent gonadotropin-releasing hormone (GnRH) analog or should have had a bilateral orchiectomy.

Dosing

The recommended dose of Xtandi is 160 mg orally once daily (QD) [either as two 80 mg tablets or four 40 mg tablets or capsules].¹

Concomitant use of Xtandi with strong cytochrome P450 (CYP)2C8 inhibitors or strong CYP3A4 inducers should be avoided if possible.¹ If Xtandi is co-administered with a strong CYP2C8 inhibitor, the dose of Xtandi is reduced to 80 mg QD. If Xtandi is co-administered with a CYP3A4 inducer, the dose of Xtandi is increased to 240 mg QD.

Availability

Xtandi is available in 40 mg tablets and capsules and 80 mg tablets in bottles of 120 (tablets or capsules) and 60 tablets, respectively.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Xtandi. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 3 years in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Xtandi® (enzalutamide capsules and tablets)	40 mg tablets	120 tablets
	80 mg tablets	60 tablets
	40 mg capsules	120 capsules

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CRITERIA

Xtandi 80 mg tablets

1. If the patient is taking the medication with cytochrome P450 (CYP)3A inducers, approve up to 90 tablets per dispensing.

Note: CYP3A inducers include, but are not limited to, carbamazepine, rifampin, rifabutin, ritonavir, and St. John's wort.

Xtandi 40 mg tablets

No overrides recommended.

Xtandi 40 mg capsules

No overrides recommended.

REFERENCES

1. Xtandi[®] capsules and tablets [prescribing information]. Northbrook, IL: Astellas/Pfizer; January 2022.