



## Drug Quantity Management – Per Rx Oncology – Xtandi® (enzalutamide capsules and tablets)

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### Product Identifier(s)

93246

#### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### National Formulary Medical Necessity

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.

#### 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

**Cigna covers quantities as medically necessary when the following criteria are met:**

#### Xtandi 80 mg tablets

- If the individual 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.

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

### 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)**.<sup>1</sup> 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].<sup>1</sup>

Concomitant use of Xtandi with strong cytochrome P450 (CYP)2C8 inhibitors or strong CYP3A4 inducers should be avoided if possible.<sup>1</sup> 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.<sup>1</sup>

## References

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

## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	<b>Xtandi 80 mg tablets.</b> Override criteria for co-administration of Xtandi with strong CYP3A4 inducers updated to 90 tablets per dispensing (previously, 120 tablets).	05/04/2022

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