DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology (Oral - Androgen Receptor Inhibitor) – Xtandi Drug Quantity Management Policy – Per Rx
- Xtandi® (enzalutamide capsules and tablets – Astellas/Pfizer)

REVIEW DATE: 05/02/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with **castration-resistant prostate cancer (CRPC), metastatic castration-sensitive prostate cancer (mCSPC)**, and **non-metastatic castration-sensitive prostate cancer (nmCSPC)**, with biochemical recurrence at high risk for metastasis (high-risk biochemical recurrence [high-risk BCR]).[1] For CRPC and MCSPC, patients should receive Xtandi with a concurrent gonadotropin-releasing hormone (GnRH) analog or should have had a bilateral orchiectomy. Patients with nmCSPC with high-risk BCR may be treated with or without a GnRH analog.

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] To manage adverse events

(AEs) ≥ Grade 3 or an intolerable AEs, stop Xtandi for 1 week or until symptoms improve to ≤ Grade 2, then resume at the same or a reduced dose (120 mg or 80 mg QD). Concomitant use of Xtandi with strong cytochrome P450 (CYP)2C8 inhibitors or strong CYP3A4 inducers should be avoided if possible. If Xtandi is co-administered with a strong CYP2C8 inhibitor, the dose of Xtandi should be reduced to 80 mg QD. If Xtandi is co-administered with a CYP3A4 inducer, the dose of Xtandi should be 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 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Xtandi® (enzalutamide capsules and tablets)	40 mg tablets	120 tablets	360 tablets
	80 mg tablets	60 tablets	180 tablets
	40 mg capsules	120 capsules	360 tablets

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Xtandi 80 mg tablets

1. If the patient is taking the medication with cytochrome P450 (CYP)3A inducers, approve to the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.
   Note: Examples of 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; March 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. Approval duration was changed from 3 years to 1 year.	05/10/2023
Annual Revision	No criteria changes.	05/15/2024
Annual Revision	The policy name was changed from "Oncology – Xtandi DQM Policy – Per Rx" to "Oncology (Oral - Androgen Receptor Inhibitor) – Xtandi DQM Policy – Per Rx". No criteria changes.	05/02/2025