DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology (Oral - Androgen Biosynthesis Inhibitor) – Abiraterone Acetate Drug Quantity Management Policy - Per Rx
- Yonsa® (abiraterone acetate tablets – Sun)
- Zytiga® (abiraterone acetate tablets – Janssen, generic)

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

The abiraterone acetate products are 17 α-hydroxylase/C17, 20-lyase (CYP17) inhibitors.[1,2]

Yonsa is indicated in combination with methylprednisolone for the treatment of patients with **metastatic castration-resistant prostate cancer** (CRPC).[1]

Abiraterone acetate (Zytiga, generic) is indicated for the treatment of patients with:[2]
- **Metastatic CRPC**
- **Metastatic high-risk castration-sensitive prostate cancer** (CSPC).

Dosing

Yonsa

The recommended dose of Yonsa is 500 mg (four 125 mg tablets) administered orally once daily (QD) in combination with methylprednisolone 4 mg administered orally twice daily (BID).[1] Yonsa can be taken with or without food. Tablets should not be crushed or chewed.

The Yonsa dose should be reduced in patients with hepatic impairment (Child-Pugh Class B) or hepatotoxicity.[1] Use of Yonsa with strong cytochrome P450 (CYP)3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital) should be avoided. However, if a strong CYP3A4 inducer must be co-administered, increase the dosing frequency of Yonsa to BID (e.g., from 500 mg QD to 500 mg BID). Once the concomitant strong CYP3A4 inducer is discontinued, reduce the dose back to the previous frequency.

Abiraterone Acetate (Zytiga, generic)

For metastatic CRPC, the recommended dose of abiraterone acetate is 1,000 mg QD with prednisone 5 mg BID.[2] The recommended dose is also 1,000 mg QD for metastatic CSPC, but in this setting it is given with 5 mg of prednisone QD. Patients who are taking abiraterone acetate should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. Abiraterone acetate is given as a single dose QD on an empty stomach. Tablets should not be chewed or crushed.

For patients with baseline moderate hepatic impairment, the recommended starting dose of abiraterone acetate is 250 mg QD.[2] If a patient develops hepatotoxicity during treatment, hold abiraterone acetate until recovery and then resume at a reduced dose. If severe hepatotoxicity develops, discontinue abiraterone acetate. Use of abiraterone acetate with strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital) should be avoided. However, if a strong CYP3A4 inducer must be co-administered, increase the dosing frequency of abiraterone acetate to BID (e.g., from 1,000 mg QD to 1,000 mg BID). Once the concomitant strong CYP3A4 inducer is discontinued, reduce the dose back to the previous frequency.

Availability

Yonsa is available as 125 mg tablets in bottles containing 120 tablets each.[1]

Abiraterone acetate (Zytiga, generic) is available as 250 mg (120 tablets per bottle) and 500 mg tablets (60 tablets per bottle).[2]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Yonsa and abiraterone acetate (Zytiga, generic). 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	Package Size	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Yonsa® (abiraterone acetate tablets)	125 mg tablets	120 tablets	360 tablets
Zytiga® (abiraterone acetate tablets, generic)	250 mg tablets	120 tablets	360 tablets
	500 mg tablets	60 tablets	180 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

Yonsa 125 mg tablets

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve 240 tablets per dispensing at retail or 720 tablets per dispensing at home delivery.
Note: Strong CYP3A4 inducers include, but are not limited to, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital.

Abiraterone acetate 250 mg tablets (Zytiga, generic)

No overrides recommended.

Abiraterone acetate 500 mg tablets (Zytiga, generic)

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.
Note: Strong CYP3A4 inducers include, but are not limited to, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital.

REFERENCES

1. Yonsa® tablets [prescribing information]. Cranbury, NJ: Sun; July 2022 2022.
2. Zytiga® tablets [prescribing information]. Horsham, PA: Janssen; November 2024.

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. No criteria changes.	05/25/2023
Annual Revision	No criteria changes.	05/29/2024
Annual Revision	The name of the policy was updated to "Oncology (Oral - Androgen Biosynthesis Inhibitor) – Abiraterone Acetate Drug Quantity Management Policy - Per Rx". Previously, the policy was named "Oncology – Abiraterone Acetate Drug Quantity Management Policy – Per Rx". There were no other changes to criteria.	05/02/2025