PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Yonsa Prior Authorization Policy
- Yonsa® (abiraterone acetate tablets – Sun Pharmaceutical)

REVIEW DATE: 08/07/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

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

Guidelines

The National Comprehensive Cancer Network guidelines on prostate cancer (version 4.2024 – May 17, 2024) recommend Yonsa for the following uses:[2]

- At initial diagnosis, for patients classified in the regional risk group (metastases in regional nodes [N1] with no distant metastases [M0]) and with a > 5 year expected patient survival, external beam radiation therapy (EBRT) + androgen deprivation therapy (ADT) [category 1] + Zytiga® (abiraterone acetate tablets) and prednisone (category 2A) or Yonsa and methylprednisolone (category 2B) are recommended options. ADT (without EBRT) ± Zytiga and prednisone is a category 2A recommended option in this setting; ADT + Yonsa and methylprednisolone is a category 2B recommendation.
- If patients are positive for distant metastasis (M1) and have castration-naïve disease, ADT + Zytiga and prednisone and ADT + docetaxel are both category 1 recommended options. ADT + Yonsa and methylprednisolone is a category 2B recommendation in this setting.
- For patients with metastatic CRPC and who have not received prior docetaxel or prior novel hormone therapy, Zytiga + prednisone (category 1 without visceral metastases and category 2A with visceral metastases) and Yonsa + methylprednisolone (category 2A) is recommended.

- For patients with metastatic CRPC who have received prior novel hormone therapy but no prior docetaxel, Zytiga + prednisone or Yonsa + methylprednisolone is recommended (category 2A); Zytiga + dexamethasone or Yonsa + dexamethasone is recommended in this setting if patients have had disease progression on either formulation of abiraterone (category 2A). If docetaxel was used previously but no prior hormone therapy, Zytiga + prednisone (category 1) or Yonsa + methylprednisolone (category 2A) is recommended. If docetaxel and prior novel hormone therapy were used, Zytiga + prednisone or Yonsa + methylprednisolone are recommended (category 2A without visceral metastases; category 2B with visceral metastases).
- In metastatic CRPC with *BRCA* mutation positive tumors, Yonsa can be used in combination with Lynparza® (olaparib tablets) [category 2A] or Zejula® (niraparib tablets) [category 2B].

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Yonsa. All approvals are provided for the duration noted below.

- **Yonsa® (abiraterone acetate tablets (Sun Pharmaceutical)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Prostate Cancer – Metastatic, Castration-Resistant.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** The medication is used in combination with methylprednisolone or dexamethasone; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog; OR
       Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
     - **ii.** Patient has had a bilateral orchiectomy.

CONDITIONS NOT COVERED

- **Yonsa® (abiraterone acetate tablets (Sun Pharmaceutical)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Yonsa® tablets [prescribing information]. Cranbury, NJ: Sun Pharmaceutical; March 2022.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 5, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	07/12/2023
Annual Revision	**Prostate Cancer – Metastatic, Castration-Resistant:** The criterion requiring the trial of gonadotropin-releasing hormone "agonist" was changed to "analog," which allows use of both agonists and antagonists. Firmagon and Orgovyx were added as examples in the Note. The separate criterion previously asking for concurrent use of medication with Firmagon was deleted.	08/07/2024