MEDICAL MUTUAL®

Drug Policy

Policy:	Yonsa (abiraterone) Prior Approval Criteria	Annual Review Date: 06/16/2022 Last Revised Date: 06/16/2022

OVERVIEW

Yonsa is an androgen biosynthesis inhibitor that inhibits the enzyme 17 α-hydroxylase/C17,20-lyase (CYP17).[1] This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. Yonsa, in combination with methylprednisolone, is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). Inhibition of CYP17 by Yonsa can also result in increased mineralocorticoid production by the adrenal glands; the use of methylprednisolone with Yonsa is to counteract this mineralocorticoid excess.

POLICY STATEMENT

This policy involves the use of Yonsa. Prior authorization is recommended for pharmacy benefit coverage of Yonsa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Yonsa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Yonsa be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist, urologist, or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Yonsa is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

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

1. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.** Prescriber will provide specific diagnosis for documentation. Approve.

2. **Patient has been started on YONSA.** Approve for an indication or condition addressed as an approval in this document.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- YONSA [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc; May 2018.
- The NCCN Clinical Practice Guidelines in Prostate Cancer (Version 2.2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 14, 2019.