Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Yonsa (abiraterone acetate)

Policy Number: 5.01.667
Origination: 11/2018
Last Review: 11/2018
Next Review: 11/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Yonsa (abiraterone acetate)** when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Yonsa (abiraterone acetate) may be considered **medically necessary** when the following criteria are met:

FDA-Approved Indication

1. **Prostate Cancer – Metastatic, Castration-Resistant (mCRPC).** Approve for 1 year if Yonsa is used in combination with methylprednisolone.

When Policy Topic is not covered

Yonsa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions and may be considered **investigational**. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Considerations

Yonsa (abiraterone acetate) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service

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.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on prostate cancer (version 2.2018) have the following recommendations for drug therapies (primarily focusing on oral agents, Zytiga® [abiraterone acetate tablets] and Xtandi® [enzalutamide capsules]).[2] Yonsa has not yet been incorporated into the guidelines.

- 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 and prednisone is a recommended option. ADT (without EBRT) ± Zytiga and prednisone is a category 2A recommended option in this setting.
- 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.
- For patients who progress to CRPC and are positive for distant metastasis, M1 and there are no visceral metastases, Zytiga and prednisone, docetaxel, Xtandi, and Xofigo® (radium Ra 223 dichloride injection, for intravenous use) [for symptomatic bone metastases] are all category 1 recommended options.
  - If there are visceral metastases, biopsy should be considered to determine histopathology. If small cell, brain magnetic resonance imaging (MRI) should be considered and patients should be treated with chemotherapy (e.g., docetaxel/carboplatin, cisplatin/etoposide, carboplatin/etoposide) or enroll in clinical trial (both category 2A). If adenocarcinoma (majority), Xtandi and docetaxel are category 1 recommended options. Zytiga and prednisone, mitoxantrone with prednisone, or other secondary hormone therapies are other options (all category 2A).
  - For no visceral metastases, if patients had received prior therapy with Xtandi or Zytiga, then docetaxel and Xofigo are the category 1 options for subsequent therapy. If patients received prior docetaxel therapy, then Xtandi, Zytiga, Xofigo, and cabazitaxel are the category 1 options. For subsequent therapy with visceral metastases, docetaxel is the recommended category 1 option, if either Xtandi or Zytiga were used as prior therapies. For prior therapy with docetaxel, Xtandi, Zytiga, cabazitaxel are the recommended category 1 options.

Rationale

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Yonsa (abiraterone acetate) while maintaining optimal therapeutic outcomes.

References

1. Yonsa® tablets [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2018.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 2. 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 23, 2018.

Billing Coding/Physician Documentation Information

NA – Oral Yonsa is a pharmacy benefit

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/2018 New policy titled Yonsa (abiraterone acetate)