



5.21.109

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Antineoplastic Agents	Original Policy Date:	June 15, 2018
Subject:	Yonsa	Page:	1 of 5

Last Review Date: March 12, 2021

Yonsa

Description

Yonsa (abiraterone acetate)

Background

Yonsa (abiraterone acetate) is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC). Yonsa is converted in vivo to abiraterone, an androgen biosynthesis inhibitor, which inhibits the enzyme 17 α -hydroxylase/C17, 20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. By inhibiting this enzyme, androgen biosynthesis is diminished, thereby decreasing the androgen production of the adrenals and in the tumor, which androgen deprivation therapies such as GnRH agonists or orchiectomy, cannot impact (1).

Regulatory Status

FDA-approved indication: Yonsa is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC) (1).

Based on animal reproductive studies and mechanism of action, Yonsa can cause fetal harm and potential loss of pregnancy. Prescribers should advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 weeks after the last dose (1).

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Yonsa may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Yonsa should be used with caution in patients with a history of cardiovascular disease. Blood pressure, serum potassium, and symptoms of fluid retention should be monitored at least monthly. Adrenal cortical insufficiency may occur with the use of Yonsa. Caution should be used and monitor for symptoms and signs of adrenocortical insufficiency, particularly if patients are withdrawn from methylprednisolone, have methylprednisolone dose reductions, or experience unusual stress (1).

Yonsa may cause hepatotoxicity. Increases in liver enzymes have led to drug interruption, dose modification and/or discontinuation. Serum transaminases (ALT and AST) and bilirubin levels should be measured prior to initiation of therapy, every two weeks for the first three months of treatment, and monthly thereafter (1).

The safety and effectiveness of Yonsa in pediatric and female patients have not been established (1).

Related policies

Erleada, Nilandron, Nubeqa, Orgovyx, Xtandi, Zytiga

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Yonsa may be considered **medically necessary** for male patients 18 years and older for the treatment of metastatic castration resistant prostate cancer (CRPC) and if the conditions indicated below are met.

Yonsa may be considered **investigational** in patients who are female, in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

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Gender Male

Diagnosis

Patient must have the following:

Metastatic castration resistant prostate cancer (CRPC)

AND ALL of the following:

1. Used in combination with methylprednisolone
2. **NO** dual therapy with another androgen receptor inhibitor (see Appendix 1)
3. Prescriber agrees to advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 weeks after the last dose of Yonsa

Prior-Approval *Renewal* Requirements

Same as above

[Policy Guidelines](#)

Pre-PA Allowance

None

Prior-Approval Limits

Quantity

Strength	Quantity
125 mg	360 tablets per 90 days

Duration 12 months

Prior-Approval *Renewal* Limits

Same as above

[Rationale](#)

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Summary

Yonsa (abiraterone acetate) is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC). Yonsa may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Yonsa may cause hepatotoxicity. Increases in liver enzymes have led to drug interruption, dose modification and/or discontinuation. The safety and effectiveness of Yonsa in pediatric and female patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Yonsa while maintaining optimal therapeutic outcomes.

References

1. Yonsa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; August 2020.

Policy History

Date	Action
June 2018	Addition to PA
September 2018	Annual review
June 2019	Annual review
December 2019	Annual review
June 2020	Annual review
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

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Appendix 1 - List of Androgen Receptor Inhibitors

Generic Name	Brand Name
abiraterone	Yonsa
abiraterone	Zytiga
apalutamide	Erleada
darolutamide	Nubeqa
enzalutamide	Xtandi
nilutamide	Nilandron