Yonsa

Description

Yonsa (abiraterone acetate)

Background

Yonsa 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 17α-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 orchietomy, 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).

Yonsa is contraindicated for use in pregnant woman because the drug 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).
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Caution should be used and monitor for symptoms and signs of adrenocortical insufficiency, particularly if patients are withdrawn from methylprednisolone, have methylprednisolone dose reductions, or experience unusual stress (1).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 patients have not been established (1).

**Related policies**
Erleada, Nilandron, Nubeqa, 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 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 investigative in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age or older

**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

<table>
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<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>125 mg</td>
<td>360 tablets per 90 days</td>
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Duration 12 months

Prior–Approval Renewal Limits
Same as above

Rationale
Summary
Yonsa 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 (1).

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

References

Policy History

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<thead>
<tr>
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<tbody>
<tr>
<td>June 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2019</td>
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</tr>
<tr>
<td>December 2019</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.
### Appendix 1 - List of Androgen Receptor Inhibitors

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<tr>
<th>Generic Name</th>
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<td>Yonsa</td>
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<tr>
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<tr>
<td>apalutamide</td>
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