Yonsa®
(abiraterone acetate)
125 mg tablets

COMPREHENSIVE PATIENT SUPPORT SERVICES

YONSA SUPPORT™ Starter Kit

INDICATION

YONSA® (abiraterone acetate) in combination with methylprednisolone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Important Administration Instructions
YONSA® may not be interchangeable with other abiraterone acetate products. To avoid substitution errors and overdose, be aware that YONSA® tablets may have different dosing and food effects than other abiraterone acetate products. Patients receiving YONSA® should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

YONSA® can cause fetal harm and potential loss of pregnancy.

WARNINGS AND PRECAUTIONS

Hypertension, Hypokalemia, and Fluid Retention Due to Mineralocorticoid Excess: YONSA® may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Monitor patients for hypertension, hypokalemia, and fluid retention at least once a month. Control hypertension and correct hypokalemia before and during treatment with YONSA®.

Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia or fluid retention, such as those with heart failure, recent myocardial infarction, cardiovascular disease, or ventricular arrhythmia. The safety of YONSA® in patients with left ventricular ejection fraction < 50% or New York Heart Association (NYHA) Class III or IV heart failure (in Study 1) or NYHA Class II to IV heart failure (in Study 2) was not established because these patients were excluded from these randomized clinical trials.

Please see additional Important Safety Information throughout this document and full Prescribing Information at www.YonsaRX.com/Yonsa-PI.

Welcome to YONSA SUPPORT™

A simple path to Savings and Support services

EASY YONSA® ACCESS

To get your patients started:

Enroll them in YONSA SUPPORT™

or

send their prescription directly to any Specialty Pharmacy Provider (SPP)

Benefits of starting with YONSA SUPPORT™

- Personalized assistance for your patients
- Enrollment in Early Access Program
- Support in understanding insurance coverage
- Financial assistance information
- Co-pay Program

HOW TO ENROLL?

- Simply fill in a single patient enrollment form available at www.YonsaRx.com
- If you have questions, please contact YONSA SUPPORT™ at 1-855-44YONSA (1-855-449-6672)

IF YOU HAVE QUESTIONS, PLEASE CONTACT YONSA SUPPORT™

IMPORTANT SAFETY INFORMATION, WARNINGS AND PRECAUTIONS

Adrenocortical Insufficiency (AI): AI was reported in patients receiving abiraterone acetate in combination with corticosteroid, following an interruption of daily steroids and/or with concurrent infection or stress. Monitor patients for symptoms and signs of AI, particularly if patients are withdrawn from corticosteroids, have corticosteroid dose reductions, or experience unusual stress. Symptoms and signs of AI may be masked by adverse reactions associated with mineralocorticoid excess seen in patients treated with YONSA®. Perform appropriate tests, if indicated, to confirm AI. Increased dosages of corticosteroids may be used before, during, and after stressful situations.

Please see additional Important Safety Information throughout this document and full Prescribing Information at www.YonsaRX.com/Yonsa-PI.

Commonly Asked Questions About YONSA SUPPORT™

What if my patient has questions about YONSA SUPPORT™ services?

YONSA SUPPORT™ Case Managers are available to help patients address questions about financial assistance options and support services. Patients (including those not enrolled in YONSA SUPPORT™) can speak with a Case Manager at 1-855-44YONSA (1-855-449-6672) Monday through Friday, 8AM to 8PM ET.

What if my patient needs help paying for YONSA®?*

YONSA SUPPORT™ may help your eligible patients find the right financial option that fits their needs. YONSA SUPPORT™ offers a Co-pay Program, Patient Assistance Program, and referrals to independent third-party foundations. Contact a YONSA SUPPORT™ Case Manager to learn more.

How can I get my patient started on YONSA® right away?*

YONSA® patients who experience a delay in coverage may be eligible for the Early Access Program. Eligible patients can receive YONSA® free of charge while the YONSA SUPPORT™ service team works with their insurance company to gain approval for YONSA®.

Who can my office staff speak with about YONSA SUPPORT™?

For more information about YONSA SUPPORT™ services, your office staff can speak with a YONSA SUPPORT™ Case Manager at 1-855-44YONSA (1-855-449-6672), Monday through Friday, 8AM to 8PM ET.

Support Programs*

- **Benefits investigations (BI) and PA assistance**

  YONSA SUPPORT™ will initiate a BI of the patient's insurance coverage for YONSA® and/or obtain information on any associated PA requests/appeals and/or route patient information to a specialty pharmacy.

- **Co-pay Program (eligible commercially insured patients)†**

  YONSA SUPPORT™ will determine a patient's eligibility and enroll him/her into the Co-pay Program for YONSA®.

- **Early Access Program (EAP)**

  YONSA SUPPORT™ will enroll patients who experience a delay in coverage into EAP. EAP will provide free product for up to 30 days.

- **Patient Assistance Program (PAP)‡**

  Noncommercial: If applicable, YONSA SUPPORT™ will research alternate forms of funding (including PAP) and, if the patient is eligible, will help with enrollment.

- **Claim denial assistance**

  YONSA SUPPORT™ will, if applicable, initiate review and research of a patient's denied claim.

Please see additional Important Safety Information throughout this document and full Prescribing Information at www.YonsaRX.com/Yonsa-PI.

*Subject to terms and conditions. Must be enrolled in YONSA SUPPORT™ to qualify. †$5,000 maximum program benefit per fill and $12,000 maximum program benefit per calendar year. Not valid for patients without commercial insurance coverage or if prescription is paid for by any state or federally funded healthcare program, including but not limited to Medicare, Medicaid, VA, DOD, or TRICARE. Available to US, Guam, Virgin Islands, or Puerto Rico residents only. ‡Income documentation is required. See www.YonsaRx.com.

Sample Letter of Medical Necessity and Letter of Appeal

You may need to draft a letter of medical necessity or letter of appeal for YONSA® for submission to your patient's health plan. The following sample letters are based on the information that a payer may request.

- You may draft your letter of medical necessity or letter of appeal based on the sample letters shown or download the editable versions at www.YonsaRx.com
- Make sure to replace all content shown in brackets with appropriate information, check the letter for accuracy, and then print it on your letterhead

[Date]
[Appeals department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Treatment requested: YONSA™ (abiraterone acetate)

Dear [Medical director],

This letter is sent on behalf of [patient's name] to request an appeal of a denied prior authorization for YONSA™. According to the denial letter, [name of health plan] denied this prior authorization because [reason from denial letter]. I am asking that you reconsider your denial of coverage for YONSA™ for the treatment of metastatic CRPC [ICD-10 code] for [patient's name].

Treatment with YONSA™ [dose, frequency] is medically appropriate and necessary for this patient.

[Patent's name] is a [age]-year-old male who was diagnosed with metastatic CRPC on [date]. [Patient's name] has been in my care since [date]

[List any previous therapies/ procedures, response to those interventions, description of the patient's recent symptoms. Use medical judgement and discretion when providing a description of the patient's medical condition.]

Enclosed you will find additional documentation with relevant clinical history for [patient's name], including diagnosis, current condition, and symptoms. Using YONSA™ for my patient is based on [provide a clinical rationale for the use of YONSA™ in this clinical case].

Please contact my office by calling [phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,
[Physician signature]
[Insert name]

Suggested enclosures:
Copy of denial letter
Package insert for YONSA™
Medication records
Clinical records that support the need for YONSA™
Other supporting documentation

PM-US-YON-0018

Letter of Appeal

IMPORTANT SAFETY INFORMATION, WARNINGS AND PRECAUTIONS

Hepatotoxicity: In postmarketing experience, there have been abiraterone acetate-associated severe hepatic toxicity, including fulminant hepatitis, acute liver failure and deaths. Measure serum transaminases (ALT and AST) and bilirubin levels prior to starting treatment with YONSA®, every two weeks for the first three months of treatment and monthly thereafter. In patients with baseline moderate hepatic impairment receiving a reduced YONSA® dose of 125 mg, measure ALT, AST, and bilirubin prior to the start of treatment, every week for the first month, every two weeks for the following two months of treatment and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the ULN, or the bilirubin rises above three times the ULN, interrupt YONSA® treatment and closely monitor liver function.

Please see additional Important Safety Information throughout this document and full Prescribing Information at www.YonsaRX.com/Yonsa-PI.

[Date]
[Appeals department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]
Subject: Supporting Coverage of YONSA™ (abiraterone acetate)

Dear [Medical director],

This letter is sent on behalf of [patient's name] to document that [he/she] has been diagnosed with metastatic CRPC and requires treatment with YONSA™. I am writing to document my patient's medical history and diagnosis and summarize my treatment rationale. Treatment with YONSA™ [dose, frequency] is medically appropriate and necessary for this patient.

[Patent's name] is a [age]-year-old male who was diagnosed with metastatic CRPC on [date]. [Patient's name] has been in my care since [date]

[List any previous therapies/ procedures, response to those interventions, description of the patient's recent symptoms. Use medical judgement and discretion when providing a description of the patient's medical condition.]

Considering my patient's history, condition, and the full Prescribing Information supporting the use of YONSA™ I believe treatment with YONSA™ is appropriate, medically necessary, and should be covered and reimbursed. Enclosed you will find other relevant supporting documentation.

Please contact my office by calling [phone number] for any additional information you may require. Given the urgency of [patient's name]'s metastatic CRPC, I look forward to your timely approval.

Sincerely,
[Physician signature]
[Insert name]

Suggested enclosures:
Package insert for YONSA™
Copy of patient medical records
Other supporting documentation

PM-US-YON-0017

Letter of Medical Necessity

IMPORTANT SAFETY INFORMATION, WARNINGS AND PRECAUTIONS

Re-treatment with YONSA® at a reduced dose level may take place only after return of liver function tests to the patient's baseline or to AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN.

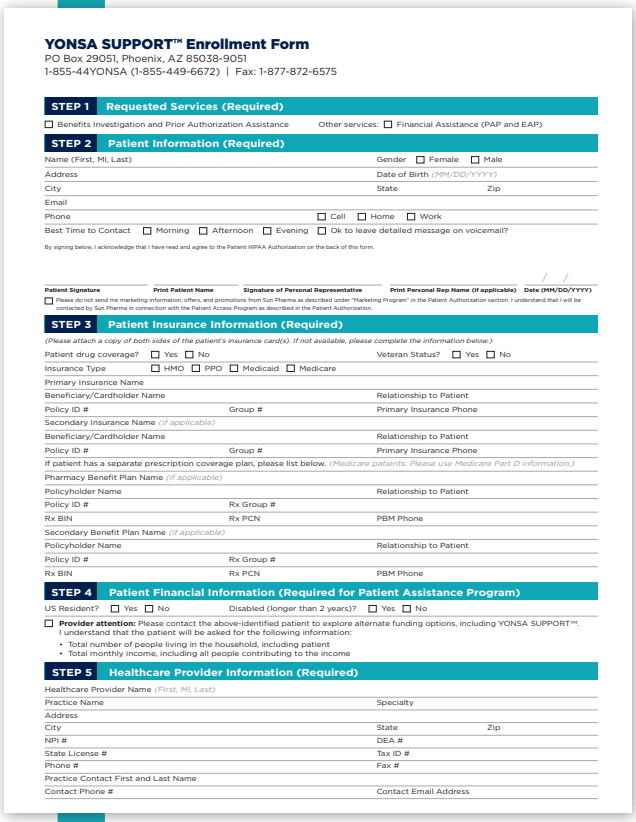
Permanently discontinue treatment with abiraterone acetate for patients who develop a concurrent elevation of ALT greater than 3 x ULN and total bilirubin greater than 2 x ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

The safety of YONSA® re-treatment of patients who develop AST or ALT greater than or equal to 20X ULN and/or bilirubin greater than or equal to 10X ULN is unknown.

Please see additional Important Safety Information throughout this document and full Prescribing Information at www.YonsaRX.com/Yonsa-PI.

How to Complete the YONSA SUPPORT™ Enrollment Form

The YONSA SUPPORT™ Enrollment Form is the first step to getting your patients started with our comprehensive patient services. Use this guide to ensure your form is fully and accurately completed. Contact your Field Reimbursement Manager with any questions about prescribing YONSA®.



YONSA SUPPORT™ Enrollment Form
PO Box 29051, Phoenix, AZ 85038-9051
1-855-44YONSA (1-855-449-6672) | Fax: 1-877-872-6575

STEP 1 Requested Services (Required)

☐ Benefits Investigation and Prior Authorization Assistance Other services: ☐ Financial Assistance (PAP and EAP)

STEP 2 Patient Information (Required)

Name (First, MI, Last) Gender ☐ Female ☐ Male
Address Date of Birth *(MM/DD/YYYY)*
City State Zip
Email
Phone ☐ Cell ☐ Home ☐ Work
Best Time to Contact ☐ Morning ☐ Afternoon ☐ Evening ☐ Ok to leave detailed message on voicemail?

By signing below, I acknowledge that I have read and agree to the Patient HIPAA Authorization on the back of this form.

Patient Signature **Print Patient Name** **Signature of Personal Representative** **Print Personal Rep Name (if applicable)** **Date (MM/DD/YYYY)**

☐ Please do not send me marketing information, offers, and promotions from Sun Pharma as described under "Marketing Program" in the Patient Authorization section. I understand that I will be contacted by Sun Pharma in connection with the Patient Access Program as described in the Patient Authorization.

STEP 3 Patient Insurance Information (Required)

(Please attach a copy of both sides of the patient's insurance card(s). If not available, please complete the information below.)

Patient drug coverage? ☐ Yes ☐ No Veteran Status? ☐ Yes ☐ No
Insurance Type ☐ HMO ☐ PPO ☐ Medicaid ☐ Medicare
Primary Insurance Name
Beneficiary/Cardholder Name Relationship to Patient
Policy ID # Group # Primary Insurance Phone
Secondary Insurance Name *(if applicable)*
Beneficiary/Cardholder Name Relationship to Patient
Policy ID # Group # Primary Insurance Phone
If patient has a separate prescription coverage plan, please list below. *(Medicare patients: Please use Medicare Part D information.)*
Pharmacy Benefit Plan Name *(if applicable)*
Policyholder Name Relationship to Patient
Policy ID # Rx Group #
Rx BIN Rx PCN PBM Phone
Secondary Benefit Plan Name *(if applicable)*
Policyholder Name Relationship to Patient
Policy ID # Rx Group #
Rx BIN Rx PCN PBM Phone

STEP 4 Patient Financial Information (Required for Patient Assistance Program)

US Resident? ☐ Yes ☐ No Disabled (longer than 2 years)? ☐ Yes ☐ No

☐ **Provider attention:** Please contact the above-identified patient to explore alternate funding options, including YONSA SUPPORT™. I understand that the patient will be asked for the following information:
- Total number of people living in the household, including patient
- Total monthly income, including all people contributing to the income

STEP 5 Healthcare Provider Information (Required)

Healthcare Provider Name *(First, MI, Last)*
Practice Name Specialty
Address
City State Zip
NPI # DEA #
State License # Tax ID #
Phone # Fax #
Practice Contact First and Last Name
Contact Phone # Contact Email Address

1 **Choose from the individual services below:**

BI AND PA ASSISTANCE

YONSA SUPPORT™ will initiate a BI of the patient's insurance coverage for YONSA® and/or obtain information on any associated PA requests/appeals and/or route patient information to a specialty pharmacy.

FINANCIAL ASSISTANCE

Co-pay Program (eligible commercially insured patients)
YONSA SUPPORT™ will determine a patient's eligibility and enroll him/her into the Co-pay Program for YONSA®.

Early Access Program (EAP)
YONSA SUPPORT™ will enroll patients facing a delay in coverage into EAP. EAP will provide free product for up to 30 days.

Patient Assistance Program (PAP)
Noncommercial: If applicable, YONSA SUPPORT™ will research alternate forms of funding (including PAP) and, if the patient is eligible, will help with enrollment.

Claim denial assistance
YONSA SUPPORT™ will, if applicable, initiate review and research of a patient's denied claim.

2 **Complete all patient information, including communication preferences.**

Have your patient read the Patient HIPAA Authorization in Section 8 and then sign. YONSA SUPPORT™ cannot provide assistance without a signature from your patient or his/her legal guardian.

3 Please attach a copy of both sides of your patient's insurance card(s). If you do not have a copy of your patient's insurance card(s), please fill out all the required information in this section.

4 If you would like to enroll your patient in PAP, fill out this section. Let your patient know that additional information will be requested by YONSA SUPPORT™.

5 Be sure to fill out the required information about your practice.

Providers must sign the enrollment form so that the prescription can be processed. Stamped signatures cannot be accepted.

Please see additional Important Safety Information throughout this document and full Prescribing Information at www.YonsaRX.com/Yonsa-PI.

YONSA SUPPORT™ Enrollment Form

PO Box 29051, Phoenix, AZ 85038-9051
1-855-44YONSA (1-855-449-6672) | Fax: 1-877-872-6575

STEP 1 Requested Services (Required)

☐ Benefits Investigation and Prior Authorization Assistance Other services: ☐ Financial Assistance (PAP and EAP)

STEP 2 Patient Information (Required)

Name (First, MI, Last)	Gender ☐ Female ☐ Male
Address	Date of Birth *(MM/DD/YYYY)*
City	State Zip
Email	
Phone	☐ Cell ☐ Home ☐ Work
Best Time to Contact ☐ Morning ☐ Afternoon ☐ Evening	☐ Ok to leave detailed message on voicemail?

By signing below, I acknowledge that I have read and agree to the Patient HIPAA Authorization on the back of this form.

Patient Signature	Print Patient Name	Signature of Personal Representative	Print Personal Rep Name (if applicable)	Date (MM/DD/YYYY)
				/ /

☐ Please do not send me marketing information, offers, and promotions from Sun Pharma as described under "Marketing Program" in the Patient Authorization section. I understand that I will be contacted by Sun Pharma in connection with the Patient Access Program as described in the Patient Authorization.

STEP 3 Patient Insurance Information (Required)

(Please attach a copy of both sides of the patient's insurance card(s). If not available, please complete the information below.)

Patient drug coverage? ☐ Yes ☐ No		Veteran Status? ☐ Yes ☐ No
Insurance Type ☐ HMO ☐ PPO ☐ Medicaid ☐ Medicare		
Primary Insurance Name		
Beneficiary/Cardholder Name		Relationship to Patient
Policy ID #	Group #	Primary Insurance Phone
Secondary Insurance Name *(if applicable)*		
Beneficiary/Cardholder Name		Relationship to Patient
Policy ID #	Group #	Primary Insurance Phone
If patient has a separate prescription coverage plan, please list below. *(Medicare patients: Please use Medicare Part D information.)*		
Pharmacy Benefit Plan Name *(if applicable)*		
Policyholder Name		Relationship to Patient
Policy ID #	Rx Group #	
Rx BIN	Rx PCN	PBM Phone
Secondary Benefit Plan Name *(if applicable)*		
Policyholder Name		Relationship to Patient
Policy ID #	Rx Group #	
Rx BIN	Rx PCN	PBM Phone

STEP 4 Patient Financial Information (Required for Patient Assistance Program)

US Resident? ☐ Yes ☐ No Disabled (longer than 2 years)? ☐ Yes ☐ No

☐ **Provider attention:** Please contact the above-identified patient to explore alternate funding options, including YONSA SUPPORT™. I understand that the patient will be asked for the following information:

- Total number of people living in the household, including patient
- Total monthly income, including all people contributing to the income

STEP 5 Healthcare Provider Information (Required)

Healthcare Provider Name *(First, MI, Last)*		
Practice Name		Specialty
Address		
City		State Zip
NPI #		DEA #
State License #		Tax ID #
Phone #		Fax #
Practice Contact First and Last Name		
Contact Phone #		Contact Email Address

IF YOU OR YOUR PATIENTS HAVE ANY QUESTIONS ABOUT YONSA SUPPORT™ PLEASE CONTACT 1-855-44YONSA (1-855-449-6672)

Visit us at www.YonsaRx.com

Yonsa®
(abiraterone acetate)
125 mg tablets

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions (≥10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

DRUG INTERACTIONS

Based on *in vitro* data, YONSA® is a substrate of CYP3A4. In a drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during YONSA® treatment. If a strong CYP3A4 inducer must be co-administered, increase the YONSA® dosing frequency only during the co-administration period.

Abiraterone is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid coadministration of abiraterone acetate with substrates of CYP2D6 with a narrow therapeutic index (e.g., thioridazine). If alternative treatments cannot be used, exercise caution and consider a dose reduction of the concomitant CYP2D6 substrate drug.

In a CYP2C8 drug-drug interaction trial in healthy subjects, the AUC of pioglitazone (CYP2C8 substrate) was increased by 46% when pioglitazone was given together with an abiraterone acetate single dose equivalent to YONSA® 500 mg. Therefore, patients should be monitored closely for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly with abiraterone acetate.

USE IN SPECIFIC POPULATIONS

- **Females and Males of Reproductive Potential: Advise male patients with female partners of reproductive potential to use effective contraception**.
- Do not use YONSA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

Please see additional Important Safety Information throughout this document and full Prescribing Information at www.YonsaRX.com/Yonsa-PI.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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