

Clinical Policy Title:	abiraterone
Policy Number:	RxA.325
Drug(s) Applied:	Yonsa®, abiraterone
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Castration resistant (chemical or surgical) prostate cancer (CRPC) (must meet all):

1. Diagnosis of metastatic CRPC
2. The medication is used in combination with prednisone;
3. Patient meets ONE of the following (i or ii):
 - i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog;
 - ii. Patient has had a bilateral orchiectomy.
4. Trial and failure, contraindication, or intolerance to Xtandi.

B. Metastatic castration-sensitive prostate cancer (CSPC) (must meet all):

1. Diagnosis of high risk metastatic CSPC;
2. Request is for abiraterone;
3. The medication is used in combination with prednisone;
4. Patient meets ONE of the following (ior ii):
 - i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog;
 - ii. Patient has had a bilateral orchiectomy

Approval duration:

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate Cancer Version 01.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 21, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Policy title was updated. 2. Indications were updated. 3. Initial Approval criteria updated. 4. Continued Therapy Approval criteria II.A.1 was rephrased. 5. References were updated. 	<p>07/28/2020</p>	<p>09/14/2020</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial and Continued therapy criteria approval duration was updated to remove HIM approval duration. 2. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated. 	<p>05/31/2021</p>	<p>09/14/2021</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.5.a was updated to include "Can use dexamethasone 1 mg/day in place of prednisone". 2. Initial Approval Criteria I.A.6.a.i was updated to include "Can use dexamethasone 1 mg/day in place of methylprednisolone". 3. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 4. References were reviewed and updated. 	<p>6/4/2021</p>	<p>09/14/2021</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5: Updated combination therapy criteria from For Zytiga® requests: prescribed in combination with prednisone <ol style="list-style-type: none"> a. Can use dexamethasone 1 mg/day in place of prednisone to For Zytiga® requests: prescribed in combination with prednisone (Can use dexamethasone 1 mg/day in place of prednisone. 2. Initial Approval Criteria, I.A.6.a.: Updated combination therapy 	<p>3/16/2022</p>	<p>07/18/2022</p>

<p>criteria from For Yonsa® requests, both of the following (a and b):</p> <ul style="list-style-type: none"> a. Prescribed in combination with methylprednisolone <ul style="list-style-type: none"> i. Can use dexamethasone 1 mg/day in place of methylprednisolone); to For Yonsa® requests, both of the following (a and b): a. Prescribed in combination with methylprednisolone (Can use dexamethasone 1 mg/day in place of methylprednisolone); <p>3. References reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Initial Approval Criteria I.A.4: Updated to remove requirements for history of bilateral orchiectomy, previously filled androgen deprivation therapy (ADT) and using ADT concurrently. 2. Initial Approval Criteria I.A.4: Updated to add that Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy. 3. References reviewed and updated. 	04/21/2023	7/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy update:</p> <ul style="list-style-type: none"> 1. Reflect 1/1 changes 2. Remove dosing, prescriber 	1/1/2024	1/1/2024
<p>Policy was reviewed.</p> <ul style="list-style-type: none"> 1. Updated continuation of therapy language. 2. References reviewed and updated. 	03/21/2025	04/10/2025
<p>Policy was reviewed.</p> <ul style="list-style-type: none"> 1. Metastatic high-risk castration-sensitive prostate cancer (CSPC) for abiraterone. 	5/19/2025	N/A
<p>Policy was reviewed.</p>	12/11/2025	12/11/2025