

This policy applies to the following:

✓	Standard Opt-in	PDPD	Marketplace	Medical Benefit	Medicare Part B	Reference #
	Standard Opt-out	ACSF	MMT	Medical Benefit: Biosimilars First	Medicare Part B: Biosimilars First	3221-D
	VF	Balanced	Medical Benefit: Managed Medicaid	Medical Benefit: Add-on	Medicare Part B: Add-on	

## EXCEPTIONS CRITERIA PROSTATE CANCER AGENTS

### PREFERRED PRODUCTS: ABIRATERONE, BICALUTAMIDE, XTANDI, YONSA

#### POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

#### I. PLAN DESIGN SUMMARY

This program applies to the prostate cancer products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

**Table. Prostate Cancer Agents**

	Product(s)
Preferred	<ul style="list-style-type: none"> <li>Abiraterone</li> <li>Bicalutamide</li> <li>Xtandi (enzalutamide)</li> <li>Yonsa (abiraterone)</li> </ul>
Targeted	<ul style="list-style-type: none"> <li>Zytiga (abiraterone)</li> </ul>

#### II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for the targeted product is provided when all of the following are met:

- Member has failed treatment with the preferred product abiraterone due to a documented intolerable adverse event that was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and generic medication).
- Member has experienced disease progression or a documented intolerable adverse event with at least one of the other preferred products: bicalutamide, Xtandi, Yonsa.<sup>5</sup>

This policy applies to the following:

✓	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
3221-D

## REFERENCES

1. Bicalutamide [package insert]. Sellersville, PA: Teva Pharmaceuticals USA; June 2009.
2. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; August 2020.
3. Yonsa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2018.
4. Zytiga [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2019.
5. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Genitourinary Oncology Programs. October 2019.