

This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input checked="" type="checkbox"/>
Standard Control – Choice (SCCF)	<input checked="" type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input checked="" type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input checked="" type="checkbox"/>
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	<input type="checkbox"/>
Aetna Individual Lives (IVL)	<input type="checkbox"/>
Value (VF)	<input checked="" type="checkbox"/>

Formulary	Applies
New to Market (NTM)	<input type="checkbox"/>
Standard Formulary Chart (SFC)	<input checked="" type="checkbox"/>
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	<input type="checkbox"/>
Advanced Control Specialty Formulary Chart (ACSFC)	<input checked="" type="checkbox"/>
Value Formulary Chart (VFC)	<input checked="" type="checkbox"/>
Medical Benefit	<input type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Medical Benefit: Managed Medicaid (MMMB)	<input type="checkbox"/>
Medicare Part B	<input type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input type="checkbox"/>

# Exceptions Criteria

## Prostate Cancer Agents

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

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Advanced Control Specialty Formulary Chart (ACSFC), Standard Control Formulary Chart (SFC), and Value Formulary Chart (VFC).

## Plan Design Summary

This program applies to the prostate cancer products specified in this document. 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

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	<ul style="list-style-type: none"> <li>• abiraterone (generic)</li> <li>• bicalutamide (generic)</li> <li>• Erleada (apalutamide)</li> <li>• Nubeqa (darolutamide)</li> <li>• Xtandi (enzalutamide)</li> <li>• Yonsa (abiraterone)</li> </ul>
Target	<ul style="list-style-type: none"> <li>• Zytiga (abiraterone)</li> </ul>

## 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 Zytiga 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, had a documented intolerable adverse event or has a contraindication with at least 2 of the preferred products: a) bicalutamide, b) Erleada, c) Nubeqa, d) Xtandi, and e) Yonsa.

## References

1. Abiraterone [package insert]. Weston, FL: Apotex Corp.; October 2021.
2. Bicalutamide [package insert]. Weston, FL: Apotex Corp.; August 2012.
3. Erleada [package insert]. Horsham, PA: Janssen Products, LP; August 2024.
4. Nubeqa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2023.
5. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; November 2023.
6. Yonsa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.
7. Zytiga [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2021.