Clinical Policy Title:	darolutamide
Policy Number:	RxA.414
Drug(s) Applied:	Nubeqa®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of one of the following (a or b):
   a. Non-metastatic castration resistant prostate cancer;
   b. Metastatic castration-sensitive prostate cancer.
2. 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

Approval Duration

All Lines of Business (except Medicare): 12 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 04.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Initial approval criteria I.A.4.a.ii added to include monotherapy prescribing method. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by	08/26/2020	09/14/2020

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.

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RxAdvance…". 4. Approval duration was updated in initial approval as well as in continued therapy approval. 5. References were updated.		
Policy was reviewed: 1. Initial Approval Criteria and Continue Therapy Approval Criteria were updated to remove HIM approval duration. 2. Continued Therapy Approval Criteria I.A.4 was updated to remove "as monotherapy…". 3. References were reviewed and updated.	06/03/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	03/24/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to include new combination therapy criteria If request is for mHSPC, Nubeqa is prescribed in combination with docetaxel. 2. References were reviewed and updated.	04/24/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024
Policy was reviewed: 1. Added new FDA approved indication: Metastatic castration-sensitive prostate cancer.	6/26/2025	N/A
Policy reviewed.	12/11/2025	12/11/2025

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