

Reference number
3148-H

SPECIALTY QUANTITY LIMIT PROGRAM

NUBEQA (darolutamide)

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If the member's plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization.

II. COVERED QUANTITIES

Medication	Standard Limit	FDA-Recommended dosing
Nubeqa 300 mg tablets	120 per 30 days	Initial dose: 600mg (two 300mg tablets) twice daily Dose adjustments due to adverse reactions: <ul style="list-style-type: none"> • Withhold dosing or reduce to 300mg twice daily until symptoms improve. Then the treatment may be resumed at a dose of 600mg twice daily. • Dose reduction below 300mg twice daily is not recommended.

III. REFERENCE

1. Nubeqa [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc.; July 2019.