

SPECIALTY QUANTITY LIMIT PROGRAM

ERLEADA (apalutamide)

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for the treatment of non-metastatic castration-resistant prostate cancer fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

II. COVERED QUANTITIES

Medication	Standard Limit	Exception Limit	FDA-recommended dosing
Erleada 60 mg	120 per 30 days	Not applicable	240 mg (four 60 mg tablets) once daily Dose reduction due to adverse events: If patient experiences greater than or equal to grade 3 toxicity, hold dosing until symptoms improve, then resume at the same dose or a reduced dose (180 mg or 120 mg)

III. REFERENCES

1. Erleada [package insert]. Horsham, PA: Janssen Products, LP; February 2018.