

Reference number(s)
2179-H

SPECIALTY QUANTITY LIMIT PROGRAM

NERLYNX (neratinib)

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 all FDA-approved indications 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	FDA-recommended dosing
Nerlynx (neratinib) 40 mg tablet	180 tablets per 30 days	<p>For extended adjuvant treatment of early stage breast cancer: The recommended dose is 240 mg (six tablets) orally once daily, continuously for one year.</p> <p>For advanced or metastatic breast cancer: The recommended dose is 240 mg (six tablets) orally once daily on Days 1-21 of a 21-day cycle until disease progression or unacceptable toxicity.</p>

III. REFERENCE

1. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology; February 2020.