Reference number(s) 2282-H

# SPECIALTY QUANTITY LIMIT PROGRAM

## **IMBRUVICA** (ibrutinib)

### 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 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	FDA-recommended dosing	Standard Limit
Imbruvica (ibrutinib)	Mantle Cell Lymphoma and Marginal Zone	30 per 30 days
70 mg capsules	<b>Lymphoma:</b> 560 mg orally once daily until disease	
Imbruvica (ibrutinib)	progression or unacceptable toxicity	30 per 30 days
140 mg capsules		
Imbruvica (ibrutinib)	Chronic Lymphocytic Leukemia/Small Lymphocytic	30 per 30 days
140 mg tablets	Lymphoma and Waldenström's Macroglobulinemia:	
Imbruvica (ibrutinib)	420 mg orally once daily until disease progression or	30 per 30 days
280 mg tablets	unacceptable toxicity	
Imbruvica (ibrutinib)		30 per 30 days
420 mg tablets	Chronic Graft versus Host Disease (cGVHD): 420 mg	
Imbruvica (ibrutinib)	orally once daily until cGVHD progression, recurrence of	30 per 30 days
560 mg tablets	an underlying malignancy, or unacceptable toxicity	
	Hepatic impairment (Child-Pugh class B): 70 mg to 140 mg orally daily	
	Dose modifications due to adverse events or drug	
	interactions: 70 mg to 420 mg orally once daily	

#### **III. REFERENCES**

1. Imbruvica [package insert]. Sunnyvale, CA: Pharmacyclics LLC; February 2018.

Specialty Quantity Limit Imbruvica P2017b.docx

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