

SPECIALTY QUANTITY LIMIT PROGRAM

JAKAFI (ruxolitinib)

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 |
|--------------------------------------|--|----------------|
| Jakafi (ruxolitinib) 5mg tablets | <p>Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis:</p> <ul style="list-style-type: none"> The recommended starting dose of Jakafi is based on platelet count. Doses may be titrated based on safety and efficacy. The starting dose for platelet count of $> 200 \times 10^9/L$ is 20 mg orally twice daily. The starting dose for platelet count of $100 \times 10^9/L$ to $200 \times 10^9/L$ is 15 mg orally twice daily. The starting dose for platelet count of $50 \times 10^9/L$ to $< 100 \times 10^9/L$ is 5 mg orally twice daily. If the response is insufficient and platelet and neutrophil counts are adequate, doses may be increased in 5 mg twice daily increments to a maximum of 25 mg twice daily. <p>Polycythemia vera:</p> <ul style="list-style-type: none"> The recommended starting dose of Jakafi is 10 mg orally twice daily. Doses may be titrated based on safety and efficacy. If response is insufficient and platelet, hemoglobin, and neutrophil counts are adequate, doses may be increased in 5 mg twice daily increments to a maximum of 25 mg twice daily. For hemoglobin of 8 to less than 10 g/dL or platelet count 50 to less than $75 \times 10^9/L$: reduce dose by 5 mg twice daily. For patients on 5 mg twice daily, decrease the dose to 5 mg once daily. | 60 per 30 days |
| Jakafi (ruxolitinib) 10mg tablets | | 60 per 30 days |
| Jakafi (ruxolitinib) 15mg tablets | | 60 per 30 days |
| Jakafi (ruxolitinib) 20mg tablets | | 60 per 30 days |
| Jakafi (ruxolitinib) 25mg tablets | | 60 per 30 days |

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| Reference number(s) |
| 2284-H |

III. REFERENCES

1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; March 2016.