Reference number(s)
2091-H

SPECIALTY QUANTITY LIMIT PROGRAM

XELJANZ (tofacitinib)
XELJANZ XR (tofacitinib extended release)

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	Standard Limit	FDA-recommended dosing
Xeljanz 5 mg tablet	60 tablets per 30 days	RA/PsA: • 5 mg twice daily • Dose adjustment: reduce to 5 mg once daily for patients: ○ Receiving strong CYP3A4 inhibitors ○ Receiving a moderate CYP3A4 inhibitor with a strong CYP2C19 inhibitor (coadministration with strong CYP3A4 inducer is not recommended) ○ With moderate or severe renal impairment ○ With moderate hepatic impairment (not recommended for patients with severe hepatic impairment) Ulcerative colitis: <u>Induction</u> • 10 mg twice daily for at least 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed, continue 10 mg twice daily for a maximum of 16 weeks. Discontinue 10 mg twice daily after 16 weeks if adequate therapeutic response is not achieved. • <u>Maintenance</u> 5 mg twice daily. Use of 10 mg twice daily beyond induction should be limited to those with loss of response and used for the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.
Xeljanz 10 mg tablet	60 tablets per 30 days	

Medication	Standard Limit	FDA-recommended dosing
Xeljanz XR 11 mg tablet	30 tablets per 30 days	RA/PsA/UC: • 11 mg once daily
Xeljanz XR 22 mg tablet	30 tablets per 30 days	Ulcerative colitis: <u>Induction:</u> 22 mg once daily for at least 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed continue 22 mg once daily for a maximum of 16 weeks. Discontinue 22 mg once daily after 16 weeks if adequate therapeutic response is not achieved. <u>Maintenance:</u> 11 mg once daily. For patients with loss of response during maintenance treatment, a dosage of 22 mg once daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.

Abbreviations: RA = rheumatoid arthritis; PsA = psoriatic arthritis; UC = ulcerative colitis

III. REFERENCE

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; December 2019.