blue of california

Applies To:
tofacitinib (XELJANZ)
tofacitinib extended-release (XELJANZ XR)
tofacitinib oral suspension (XELJANZ)

Diagnosis Considered for Coverage:

- Rheumatoid Arthritis (RA)
- Psoriatic Arthritis (PsA)
- Ulcerative Colitis (UC)
- Polyarticular Juvenile Idiopathic Arthritis (pJIA) – *Xeljanz IR 5 mg or Xeljanz 1 mg/ml solution only*
- Ankylosing spondylitis (AS)

Coverage Criteria:

For diagnosis of rheumatoid arthritis:

- Prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response, intolerable side effect, or contraindication to methotrexate, **and**
- Inadequate response, intolerable side effect or contraindication to a TNF inhibitor, **and**
- Not being used in combination with another targeted immunomodulator (i.e. anti-TNFs, IL-6 inhibitors, JAK inhibitors), **and**
- Dose does not exceed FDA label maximum, **and**
- For Xeljanz oral solution:
    - Patient is >40 kg (88 lb) and unable to swallow a pill.

Coverage Duration: One year

For diagnosis of psoriatic arthritis:

- Prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response or intolerable side effect with one DMARD agent OR patient has a medical reason why methotrexate, leflunomide, and sulfasalazine cannot be used, **and**
- Inadequate response, intolerable side effect or contraindication to a TNF inhibitor, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors, Otezla), **and**
- Dose does not exceed FDA label maximum, and
- For Xeljanz oral solution:
    - Adult patient is >40 kg (88 lb) and unable to swallow a pill.

Coverage Duration: One year

For Xeljanz IR 5 mg or Xeljanz 1 mg/ml solution only and diagnosis of polyarticular juvenile idiopathic arthritis (pJIA):

- Prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response or intolerable side effect with one DMARD agent OR patient has a medical justification why methotrexate cannot be used, **and**
- Inadequate response, intolerable side effect or contraindication to a TNF inhibitor , **and**
- Not being used in combination with other targeted immunotherapies, **and**
- Dose does not exceed FDA label maximum, **and**
- For Xeljanz oral solution:
    - Patient is between 10 kg (22 lb) and 40 kg (88 lb) **OR**
    - Patient is >40 kg (88 lb) and unable to swallow a pill.

Coverage Duration: One year

For diagnosis of ulcerative colitis:

INITIAL AUTHORIZATION
• Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors, S1P modulators), **and** • Inadequate response, intolerable side effect or contraindication to a TNF inhibitor, **and** • Dose does not exceed FDA label maximum, **and** • For Xeljanz oral solution: ○ Adult patient is >40 kg (88 lb) and unable to swallow a pill. *Coverage Duration:* 16 weeks
REAUTHORIZATION
• Patient experienced a reduction is bowel movement frequency and decrease in rectal bleeding (disease remission also based upon endoscopy findings), **and** • Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors, S1P modulators), **and** • Dose does not exceed FDA label maximum.

Coverage Duration: One year

For diagnosis of ankylosing spondylitis:

- Prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response, intolerable side effect or contraindication to a TNF inhibitor, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- One of the following:
    - Patient unable to use NSAIDs due to history of GI bleed or ulcer, **or**
    - For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI), **or**
    - For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy, **and**
- Dose does not exceed FDA label maximum, **and**
- For Xeljanz oral solution:
    - Adult patient is >40 kg (88 lb) and unable to swallow a pill.

Coverage Duration: One year

Effective Date: 01/03/2024