Effective Date: 9/2018
Reviewed: 9/2018, 10/2019, 8/2020, 12/2020, 5/2021, 6/2021, 5/2022, 7/2022, 12, 2022 Scope: Medicaid

XELJANZ (tofacitinib)
XELJANZ XR (tofacitinib extended-release tablets)
XELJANZ SOLUTION (tofacitinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Moderately to severely active rheumatoid arthritis
B. Active psoriatic arthritis
C. Active ankylosing spondylitis
D. Moderately to severely active ulcerative colitis
E. Active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INTIAL AND RENEWAL CRITERIA

For all indications:

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

III. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Rheumatoid arthritis (RA)
   i. For initial requests:
      i. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
      ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
   ii. For continuation requests: Chart notes or medical record documentation supporting positive clinical response

B. Psoriatic arthritis (PsA)
    i. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
    ii. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Ankylosing spondylitis (AS)
    i. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
    ii. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Ulcerative colitis (UC)
    i. Initial requests
        i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
        ii. Chart notes or medical record documentation of hospitalization due to acute, severe ulcerative colitis (if applicable).
    ii. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

E. Articular juvenile idiopathic arthritis:
    i. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
    ii. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

IV. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received tofacitinib or any other biologic DMARD are exempt from requirements related to TB screening in this Policy.]*
- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:

1. Member meets either of the following criteria:
    i. Member has been tested for either of the following biomarkers and the test was positive:
        a. Rheumatoid factor (RF)
        b. Anti-cyclic citrullinated peptide (anti-CCP)
    ii. Member has been tested for ALL of the following biomarkers:
        a. RF
        b. Anti-CCP
        c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
2. Prescribed by, or in consultation with, a specialist in rheumatology.
3. Member has experienced an inadequate response or intolerance to at least one of the following: Enbrel, Humira, Kevzara, or Rinvoq.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis in members who are 18 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
2. Documented active disease and member has experienced an inadequate response or intolerance to at least one of the following: Enbrel, Humira, Cosentyx, Skyrizi, Otezla or Rinvoq
3. Tofacitinib is used in combination with a nonbiologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

C. Active ankylosing spondylitis (AS)

Authorization of 12 months may be granted for treatment of active ankylosing spondylitis in members 18 years of age or older when both of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
2. Documented active disease for AS
3. Member has experience an inadequate response or has a contraindication to TWO (2) NSAIDs
4. Member has experienced an inadequate response or intolerance to at least one of the following: Enbrel, Humira, Cosentyx, or Rinvoq.

D. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active UC if the member has had an inadequate response or intolerance to at least one of the following: Humira, or Rinvoq or for members who have been hospitalized for acute, severe UC (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia) and is prescribed by, or in consultation with, a gastroenterologist.

E. Active articular juvenile idiopathic arthritis

Authorization of 12 months may be granted for treatment of active articular juvenile idiopathic arthritis in members two years of age or older when both of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in rheumatology.
2. Member has experienced an inadequate response or intolerance to at least one of the following: Humira or Enbrel

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V. CONTINUATION OF THERAPY

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain a positive clinical response.

C. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

D. Active ankylosing spondylitis (AS)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

E. Moderately to severely active ulcerative colitis (UC)

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation

iv. C-reactive protein (CRP)
v. Fecal calprotectin (FC)
vi. Endoscopic appearance of the mucosa
vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

D. Active articular juvenile idiopathic arthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

VI. QUANTITY LIMIT

Xeljanz has a quantity limit of 2 tablets per day.
Xeljanz XR has a quantity limit of 1 tablet per day.
Xeljanz solution has a quantity limit of 10ml per day.

VII. REFERENCES

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; September 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
3. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017;*0*:1-18.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011;65(1):137-174.
5. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis.* 2016;75(3):499-510.
6. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol.* 2011;106(Suppl 1):S2-S25.