Reference number(s)
2011-A

SPECIALTY GUIDELINE MANAGEMENT

XELJANZ (tofacitinib tablets; oral solution)
XELJANZ XR (tofacitinib extended release tablets)

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.

A. FDA-Approved Indications
1. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
2. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
3. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
4. Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
5. Xeljanz/Xeljanz Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

B. Compendial Uses
1. Axial spondyloarthritis
2. Oligoarticular juvenile idiopathic arthritis
3. Immune checkpoint inhibitor related toxicity

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), axial spondyloarthritis (axSpA), and articular juvenile idiopathic arthritis (JIA)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Ulcerative colitis (UC)

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

C. Immune checkpoint inhibitor-related toxicity: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy or intolerance to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, ankylosing spondylitis, axial spondyloarthritis, and articular juvenile idiopathic arthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Ulcerative colitis: gastroenterologist
D. Immune checkpoint inhibitor related toxicity: hematologist or oncologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active rheumatoid arthritis (RA) when the member has experienced an inadequate response or intolerance to at least one tumor necrosis factor (TNF) inhibitor.

2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Olumiant) indicated for moderately to severely active RA.

B. Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when both of the following criteria are met:
   i. The requested drug will be used in combination with a conventional synthetic drug (e.g., methotrexate, leflunomide, sulfasalazine).
   ii. Member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when both of the following criteria are met:
   i. The requested drug will be used in combination with a conventional synthetic drug (e.g., methotrexate, leflunomide, sulfasalazine).
   ii. Member has previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

C. Ankylosing spondylitis (AS) and axial spondyloarthritis (axSpA)

1. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active axial spondyloarthritis when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq) indicated for active ankylosing spondylitis or active axial spondyloarthritis.

D. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active UC when the member has had an inadequate response or intolerance to at least one TNF inhibitor.

2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq) indicated for moderately to severely active ulcerative colitis.

E. Articular juvenile idiopathic arthritis (JIA)

1. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active articular juvenile idiopathic arthritis when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

2. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active articular juvenile idiopathic arthritis.

F. Immune checkpoint inhibitor-related toxicity

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related colitis when the member has experienced an inadequate response, intolerance, or contraindication to infliximab or vedolizumab.

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult 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. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for 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. Axial disease
6. Skin and/or nail involvement

C. Ankylosing spondylitis (AS) and axial spondyloarthritis (axSpA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for active ankylosing spondylitis or active axial spondyloarthritis 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)

D. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for all adult 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 adult 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)

E. Articular juvenile idiopathic arthritis (JIA)

Authorization of 12 months may be granted for all members 2 years of age and older (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

F. Immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

VI. OTHER

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested drug to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested drug.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drugs, targeted synthetic drugs, or potent immunosuppressants such as azathioprine or cyclosporine.

VII. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VIII. REFERENCES

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; January 2022.
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, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79:685-699.
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.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum*. 2018;71:5-32.
8. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroentrol*. 2019;114:384-413.
9. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on June 15, 2022 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.
10. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020; 158:1450.
11. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *Arthritis Care Res (Hoboken).* 2019; 71(6):717-734.
12. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
13. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021.
14. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 17, 2022.
15. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613. doi:10.1002/art.41042.
16. Gossec L, Baraliakos X, Kerschbaumer A. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
17. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;0:1-14.
18. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.

19. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.