Cytokine and CAM Antagonists: JAK Inhibitors Utilization Management Criteria

Therapeutic Class:	Cytokine and CAM Antagonists: JAK Inhibitors
Non-Preferred Agents:	Cibinqo (abrocitinib), Rinvoq (upadactinib), Olumiant (baricitinib), Xeljanz solution (tofacitinib), Xeljanz XR (tofacitinib)
Preferred Agent:	Xeljanz IR tablet (tofacitinib) 5 mg and 10 mg strengths
Implementation Date:	1/1/2026
Prepared For:	CT Medicaid
PDL Status:	Non-preferred
Purpose:	The Cytokine and Cell Adhesion Molecule (CAM) Antagonists, Janus kinase (JAK) inhibitors, are synthetic small-molecule drugs that inhibit the activity and response of Janus kinases and their signaling pathways. JAK inhibitors are useful in treating conditions that result from overreactive JAK signaling and are indicated for various autoimmune conditions. Atopic dermatitis (AD) is a chronic skin condition, also known as eczema, which causes inflammation, redness, and irritation. It is the most common type of eczema in children. Ankylosing Spondylitis (AS) is a chronic type of arthritis that causes inflammation in the joints and ligaments of the spine. It can also affect peripheral joints like the knees, ankles, and hips. Coronavirus Disease 19 (COVID-19) is a disease caused by a virus named SARS -CoV-2 that can be very contagious and spreads quickly. Non-radiographic ankylosing spondyloarthritis (nr-AxSpA) is a type of inflammatory arthritis that affects the spine as well as other parts of the body. However, it does not show damage to joints or ligaments on X-rays or MRI. Polyarticular course (pcJIA) is a type of juvenile idiopathic arthritis, which is an autoimmune disease that affects five or more joints within the first six months of disease onset, resulting in chronic inflammation. Psoriatic Arthritis (PsA) is a chronic inflammatory condition that can affect the joints and the skin. Although the exact cause is not fully known, it's believed that overproduction of molecules such as interleukin (IL)-17A, triggers an inflammatory response that contributes to pain and swelling in the joints and tendons as well as skin plaques. Rheumatoid arthritis (RA) is an autoimmune and inflammatory disease where the immune system attacks healthy cells in the body resulting in inflammation mainly in the joints. Ulcerative Colitis (UC) is a chronic inflammatory disease that affects the colon which can lead to damage in its lining resulting in symptoms such as bowel urgency, blood in stool and frequent bowel movements. Tofacitinib, used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, and juvenile idiopathic arthritis, and upadacitinib, used to treat Crohn's disease, rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis, and polyarticular juvenile idiopathic arthritis (pJIA), are the JAK inhibitors with the most Food and Drug Administration (FDA)-approved indications for use. Baricitinib has three approved indications (i.e., rheumatoid arthritis, coronavirus disease 2019, and alopecia areata), while abrocitinib has only one approved indication (i.e., atopic dermatitis). Of note, baricitinib is

	approved as a treatment for COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. All the JAK inhibitors are available as oral tablets (immediate and/or extended-release); however, tofacitinib and upadacitinib are also available as an oral solution. Caution is warranted during the use of these agents, as all carry a boxed warning regarding an increased risk of serious infection and a higher rate of all-cause mortality, malignancy, major adverse cardiovascular events, and thrombosis as compared to tumor necrosis factor (TNF) blockers. Therefore, most approved JAK inhibitor indications are in patients with an inadequate response or intolerance to one or more TNF blockers. When included, treatment guidelines generally list the JAK inhibitors among second-line recommendations for approved indications. Indirect comparative data suggest that upadacitinib for atopic dermatitis and ulcerative colitis may provide the greatest efficacy compared to other active treatments; however, its efficacy may be limited by a higher incidence of adverse effects.

Table 1. Cytokine and CAM Antagonists: JAK Inhibitor Agents

Generic Name	Brand Name	Approved Indications	Route of Administration	Generic Availability
Abrocitinib	Cibinqo™	AD	PO	N
Baricitinib	Olumiant®	AA, COVID-19, RA	PO	N
Tofacitinib	Xeljanz®; Xeljanz® XR	AS, pcJIA, PsA, RA, UC	PO	Y
Upadacitinib	Rinvoq®; Rinvoq® LQ	AD, AS, CD, nr-axSpA, pJIA, PsA, RA, UC, GCA	PO	N

Abbreviations: AA, alopecia areata; AD, atopic dermatitis; AS, ankylosing spondylitis; COVID-19, coronavirus disease 2019; GCA, giant cell arteritis; nr-axSpA, non-radiographic axial spondyloarthritis; pcJIA, polyarticular course juvenile idiopathic arthritis; pJIA, polyarticular juvenile idiopathic arthritis; PsA, psoriatic arthritis; PO, oral; RA, rheumatoid arthritis; UC, ulcerative colitis.

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes.

General Approval Criteria:

- Claim is for a preferred agent (Xeljanz IR) **OR**
- Requested agent is **NOT** used in combination with other targeted immunomodulators **AND**
- Patient does **NOT** have active TB, hepatitis B/C, or other active infection prior to initiation **AND**
- For specific formulation requests
  - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
  - **For generic requests when a therapeutically equivalent brand is preferred:** Provider must provide a documented medical reason the preferred brand formulation cannot be used
  - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Initial Therapy – ALL the following must be met:

For Alopecia Areata (Olumiant, Leqselvi, Litfulo)

- Indication not covered

For Coronavirus Disease 2019 (Olumiant)

- Limited to inpatient use. Not payable for outpatient use for this indication

For Crohn's Disease (Rinvoq):

- Prescribed by or in consultation with a gastroenterologist
- Documented diagnosis of Crohn's Disease with moderate to severe disease severity
- Adequate trial of a TNF inhibitor as defined by manufacturer **OR** Documented adverse drug event or adverse drug reaction (ADE/ADR) to TNF inhibitor **OR**
- Provider attests that a TNF inhibitor is not advisable (must provide documentation of medical reason why patient is unable to receive a TNF inhibitor) **AND** patient has tried and failed one other systemic therapy approved for the treatment of Crohn's disease (must provide documentation of alternate systemic therapy agent(s) trialed and failed)

For rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis or psoriatic arthritis (Olumiant, Xeljanz sln, Xeljanz XR, Rinvoq*):*

- Prescribed by or in consultation with a rheumatologist
- Documentation of diagnosis (listed above) with moderate to severe disease activity
- Adequate trial of a TNF inhibitor as defined by manufacturer or documented ADE/ADR
- Adequate trial of preferred Xeljanz (30 days) or documented ADE/ADR
- In addition, the following age limits apply:
    - Olumiant: Patient age 18 years and older
    - Xeljanz sln: Patient age 2 years and older. *(Trial and failure of preferred dosage form is not required for patients unable to swallow solid dosage forms)*
    - Xeljanz XR: Patient age 18 years and older
    - Rinvoq: 2 years and older (not recommended for pediatric patients less than 30 kg)
    - Rinvoq liq: 2 years and older

For Non-Radiographic Axial Spondyloarthritis (Rinvoq):

- Prescribed by or in consultation with a rheumatologist
- Documentation of active non-radiographic axial spondyloarthritis with objective signs of inflammation noted
- Patient age 18 years or older
- Adequate trial of a TNF inhibitor as defined by manufacturer or documented ADE/ADR

For Giant Cell Arteritis (GCA) (Rinvoq):

- Prescribed by or in consultation with a rheumatologist
- Documentation of diagnosis of GCA
- Patient aged 18 years and older
- Documented trial and failure of oral glucocorticoids and/or documentation of need for a steroid-sparing agent

For Ulcerative Colitis (Rinvoq and Xeljanz XR, Xeljanz sln):

- Prescribed by or in consultation with a gastroenterologist
- Documentation of UC diagnosis with moderate to severe disease activity
- Adequate trial of a TNF inhibitor as defined by manufacturer or documented ADE/ADR **OR** Request is for Rinvoq **AND** provider attests that a TNF inhibitor is not advisable (must provide documentation of medical reason why patient is unable to receive a TNF inhibitor)
- Adequate trial (30 days) of preferred Xeljanz or documented ADE/ADR

For Atopic Dermatitis (Cibinqo and Rinvoq):

- Prescribed by or in consultation with dermatologist, immunologist or allergist
- Documentation of moderate-to severe atopic dermatitis
- Patient aged 12 years and older
- Adequate trial and failure of **one** of the following classes of therapy for 30 days as documented in chart notes:
  - Topical corticosteroid
  - Topical calcineurin inhibitor
  - PDE – 4 inhibitor
  - Oral corticosteroids
  - Oral immunosuppressant
  - Phototherapy

Additional approval criteria for **Xeljanz XR 22 mg tablets**: Documentation of why participant cannot utilize Xeljanz IR or Xeljanz XR 11 mg tablets.

Initial PA length: 6 months

Continuation Therapy: All of the following are met

- Documented compliance on current therapy regimen
- Adequate clinical response documented by provider
- Requested agent is not being used for the treatment of Alopecia Areata (indication not covered)
- For specific formulation requests
  - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
  - **For generic requests when a therapeutically equivalent brand is preferred:** Provider must provide a documented medical reason the preferred brand formulation cannot be used
  - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Continuation Length: 1 year

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Date	Version	Revisions
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