



Drug Coverage Policy

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Coverage Policy Number.....IP0672
Policy Title...Cimzia Prior Authorization
Policy

Inflammatory Conditions – Cimzia Prior Authorization Policy

- Cimzia® (certolizumab pegol subcutaneous injection [lyophilized powder or solution] – UCB)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Cimzia, a tumor necrosis factor inhibitor (TNFi), is indicated for the following uses:¹

- **Ankylosing spondylitis**, for the treatment of adults with active disease.

- **Crohn's disease**, for reducing signs and symptoms and maintaining clinical responses in adults with moderate to severe active disease who have had an inadequate response to conventional therapy.
- **Non-radiographic axial spondyloarthritis**, in patients with objective signs of inflammation.
- **Plaque psoriasis**, for the treatment of adults with moderately to severely active disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, for the treatment of adult patients with active disease.
- **Rheumatoid arthritis**, for the treatment of adults with moderately to severely active disease.

Cimzia may be used as monotherapy or in combination with conventional synthetic disease-modifying antirheumatic drugs (csDMARDs).

Guidelines

TNFis feature prominently in guidelines for treatment of inflammatory conditions.

- **Axial Spondyloarthritis and Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondyloarthritis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).² TNFis are recommended for the initial biologic. In those who are secondary nonresponders to a TNFi, a second TNFi is recommended over switching out of the class.
- **Crohn's Disease:** The American College of Gastroenterology has guidelines for Crohn's disease (2018).³ TNFis are listed as an option for disease that is resistant to corticosteroids, severely active disease, perianal fistulizing disease, and maintenance of remission. In post-operative Crohn's disease, a TNFi should be started within 4 weeks of surgery to prevent recurrence. Guidelines from the American Gastroenterological Association (2021) include TNFis among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.⁷
- **Plaque Psoriasis:** Guidelines from the American Academy of Dermatologists and National Psoriasis Foundation (2019) recommend TNFis as a monotherapy treatment option for adults with moderate to severe disease.⁴ Based on extrapolation of data, Cimzia is likely to have class characteristics similar to the other TNFis.
- **Psoriatic Arthritis:** Guidelines from ACR (2018) generally recommend treatment with a TNFi over other therapies as initial treatment for patients who are treatment-naïve.⁵
- **Rheumatoid Arthritis:** Guidelines from ACR (2021) recommend addition of a biologic or a targeted synthetic disease modifying anti-rheumatic drug (DMARD) for a patient taking the maximum tolerated dose of methotrexate who is not at target.⁶

Medical Necessity Criteria

POLICY STATEMENT

Prior Authorization is required for prescription benefit coverage of Cimzia. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1

month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cimzia as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cimzia to be prescribed by or in consultation with a physician who specializes in the condition being treated.

NOTE: This product also requires the use of preferred products before approval of the requested product. Refer to the respective *Inflammatory Conditions Preferred Specialty Management Policy for Employer Plans (PSM001)* or *Individual and Family Plans (PSM002)* for additional preferred product criteria requirements and exceptions.

Cimzia is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, 6, or 7):

FDA-Approved Indications

- 1. Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve for 6 months if the patient meets BOTH of the following (i and ii):
 - a. Patient is \geq 18 years of age; AND
 - b. The medication is prescribed by or in consultation with a rheumatologist.
 - B) Patient is Currently Receiving Cimzia.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least ONE of the following (a or b):
 - a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
- 2. Crohn's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is \geq 18 years of age; AND
 - ii. Patient meets ONE of the following (a, b, c, or d):
 - a)** Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
 - b)** Patient has tried one other conventional systemic therapy for Crohn's disease; OR
Note: Examples of systemic therapies for Crohn's disease include azathioprine, 6-mercaptopurine, and methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the

requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic agent for Crohn's disease.

- c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
- d) Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND

iii. The medication is prescribed by or in consultation with a gastroenterologist.

- B) Patient is Currently Receiving Cimzia.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least ONE of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.
 - b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

3. Non-Radiographic Axial Spondyloarthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
- i. Patient is \geq 18 years of age; AND
 - ii. Patient has objective signs of inflammation, defined as at least ONE of the following (a or b):
 - a) C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
 - b) Sacroiliitis reported on magnetic resonance imaging (MRI); AND
 - iii. The medication is prescribed by or in consultation with a rheumatologist.
- B) Patient is Currently Receiving Cimzia.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i. Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least ONE of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

- 4. Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy.** Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
- i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient meets ONE of the following conditions (a or b):
 - a)** Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, or acitretin tablets. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
 - b)** Patient has a contraindication to methotrexate, as determined by the prescriber; AND
 - iii.** The medication is prescribed by or in consultation with a dermatologist.
- B) Patient is Currently Receiving Cimzia.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
- i.** Patient has been established on the requested drug for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
 - ii.** Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area affected by psoriasis, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
 - iii.** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.
- 5. Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy.** Approve for 6 months if the patient meets BOTH of the following (i and ii):
- i.** Patient is ≥ 18 years of age; AND
 - ii.** The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.
- B) Patient is Currently Receiving Cimzia.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i.** Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
 - ii.** Patient meets at least ONE of the following (a or b):
 - a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

- b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

6. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):

- i. Patient is \geq 18 years of age; AND
- ii. Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND

Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial of at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.

iii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i. Patient has been established on the requested drug for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

- ii. Patient meets at least ONE of the following (a or b):

a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR

Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).

b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

Other Uses with Supportive Evidence

7. Spondyloarthritis, Other Subtypes. Approve for the duration noted if the patient meets ONE of the following conditions (A or B):

Note: Examples of other subtypes of spondyloarthritis include undifferentiated arthritis and reactive arthritis (Reiter's disease). For ankylosing spondylitis, psoriatic arthritis, or non-radiographic axial spondyloarthritis, refer to the respective criteria under FDA-approved indications.

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):

- i. Patient is \geq 18 years of age; AND
- ii. Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet; AND
- iii. Patient has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD); AND

Note: Examples include methotrexate, leflunomide, and sulfasalazine.

iv. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on the requested drug for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

ii. Patients meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug. This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

References

1. Cimzia® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; December 2022.
2. 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.
3. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: management of Crohn's Disease in adults. *Am J Gastroenterol.* 2018;113(4):481-517.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072.

5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.
6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123.
7. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024

The policy effective date is in force until updated or retired.

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira [®] , biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia[®] (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel [®] , biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade [®] , biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra[®] (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi[®], Simponi Aria[®] (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra [®] IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kezara[®] (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia[®] (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan [®] , biosimilars)	CD20-directed cytolytic antibody	RA

Kineret [®] (anakinra SC injection)	Inhibition of IL-1	JIA [^] , RA
Omvo [®] (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
Stelara [®] (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq [®] (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx [®] (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz [®] (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx [®] (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO
Ilumya [®] (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi [®] (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya [®] (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC
		IV formulation: UC
Entyvio [®] (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC

	Mechanism of Action	Examples of Indications*
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla [®] (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo [™] (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant [®] (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo [®] (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi [®] (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq [®] (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq [®] LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu [®] (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz [®] (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz [®] XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia [®] (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity [®] (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA –

Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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