UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Cimzia Utilization Management Medical Policy
- Cimzia® (certolizumab pegol subcutaneous injection [lyophilized powder or solution] – UCB)

REVIEW DATE: 03/27/2024

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).

Dosing Information

Approved induction dosing is 400 mg given subcutaneously at Weeks 0, 2, and 4. For psoriasis, maintenance dosing is 400 mg given every 2 weeks. For other indications, maintenance dosing is generally given as 400 mg subcutaneously per 28-day period. This dose may be administered as a single 200 mg injection given once every 2 weeks or as two 200 mg doses (400 mg dose) given once every 4 weeks. Of note, if a patient who has rheumatoid arthritis is in remission, guidelines from the American College of Rheumatology (ACR) [2021] mention tapering (reducing the dose or dosing frequency) as an option for patients with rheumatoid arthritis who have been at target (low disease activity or remission) for at least 6 months prior to tapering.[6]

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 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

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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]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Cimzia. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 a patient 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cimzia is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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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 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 Spondylarthropathies (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.

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Dosing. Approve ONE of the following regimens (A, B, or C):

A) For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously no more frequently than once every 2 weeks; OR

B) For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR

C) For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

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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 ≥ 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.

Dosing. Approve ONE of the following regimens (A, B, or C):

A) For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

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B) For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
C) For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

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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 BOTH of the following (i and ii):
- **i.** 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
- **ii.** 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 Spondylarthropathies (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.

Dosing. Approve ONE of the following regimens (A, B, or C):
A) For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

B) For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
C) For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

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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

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Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light (PUVA). 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.

Dosing. Approve ONE of the following (A or B):

A) For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 2 weeks; OR

B) For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

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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 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 Consortuium 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;

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improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

Dosing. Approve ONE of the following regimens (A, B, or C):

A) For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

B) For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR

C) For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

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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 BOTH of the following (i and ii):
- **i.** 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.
- **ii.** 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.

Dosing. Approve ONE of the following regimens (A, B, or C):

A) For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

B) For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR

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C) For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

Other Uses with Supportive Evidence

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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, and iii):
   - **i.** Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet; AND
   - **ii.** Patient has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD); AND
     Note: Examples include methotrexate, leflunomide, and sulfasalazine.
   - **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.** 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.

   Dosing. Approve ONE of the following regimens (A, B, or C):
   A) For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
   - **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
   - **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

   B) For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
   C) For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cimzia is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Cimzia should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of AEs with combinations and lack of data supportive of additional efficacy.

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

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cimzia® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; December 2022.
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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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/05/2023
Annual Revision	**Plaque Psoriasis:** For a patient currently taking Cimzia, the timeframe for established on therapy was changed from 90 days to 3 months.	03/27/2024

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APPENDIX

	Mechanism of Action	Examples of Inflammatory 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
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, 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
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA, PMR
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
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-17RA	PsO
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A and IL-17F	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
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Omvoh® (mirikizumab-mrkz SC injection, mirikizumab-mrkz IV infusion)	Inhibition of IL-23	UC
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion, vedolizimab SC injection)	Integrin receptor antagonist	SC formulation: UC
		IV formulation: CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Sotyktu™ (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). 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; PMR – Polymyalgia rheumatic; ^ 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; TYK2 –Tyrosine kinase 2.

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