CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Tocilizumab Intravenous Products Utilization Management Medical Policy
- Actemra® (tocilizumab intravenous infusion – Genentech/Roche)
- Avtozma® (tocilizumab-anoh intravenous infusion – Celltrion)
- Tofidence™ (tocilizumab-bavi intravenous infusion – Biogen)
- Tyenne® (tocilizumab-aazg intravenous infusion – Fresenius Kabi)

REVIEW DATE: 04/23/2025; selected revision 06/11/2025, 08/13/2025, 09/24/2025, 10/29/2025, 12/03/2025

OVERVIEW

Tocilizumab intravenous infusion, an interleukin-6 (IL-6) receptor inhibitor, is indicated for the following conditions:[1]

- **Coronavirus Disease 2019 (COVID-19)**, in hospitalized adults and pediatric patients ≥ 2 years of age who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Of note, this policy does not target this indication.
- **Cytokine release syndrome**, in patients ≥ 2 years of age with severe or life-threatening disease associated with chimeric antigen receptor (CAR) T-cell therapy.
- **Giant cell arteritis** in adults.
- **Polyarticular juvenile idiopathic arthritis**, for the treatment of active disease in patients ≥ 2 years of age.
- **Rheumatoid arthritis**, for treatment of adults with moderate to severe active disease who have had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDs).
- **Systemic juvenile idiopathic arthritis**, for the treatment of active disease in patients ≥ 2 years of age.

Dosing Information

In rheumatoid arthritis, many dose modifications are recommended for the management of dose-related laboratory changes such as increased liver enzymes, neutropenia, and thrombocytopenia.[1] In conditions other than rheumatoid arthritis, reduced dosing of tocilizumab intravenous generally follows the recommendations for rheumatoid arthritis. Dose interruptions of tocilizumab intravenous are recommended for certain laboratory abnormalities and are similar to those recommended in rheumatoid arthritis. Dosing modifications are determined by the prescriber. Specifically for cytokine release syndrome associated with CAR T-cell therapy, the median number of tocilizumab intravenous doses administered in the pivotal trial was one dose (range, 1 to 4 doses).

Guidelines/Clinical Efficacy

IL-6 blockers are mentioned in multiple guidelines for treatment of inflammatory conditions. Clinical data also support use of tocilizumab in other conditions.

- **Giant Cell Arteritis:** Recommendations from the European League Against Rheumatism (EULAR) [2023] state the diagnosis of giant cell arteritis may be made without biopsy if there is a high suspicion of giant cell arteritis and a positive imaging test.[3] In the pivotal trial evaluating tocilizumab subcutaneous for giant cell arteritis (n = 251), patients were treated with corticosteroids in an open-label fashion (20 mg to 60 mg/day) during the screening period prior to treatment with

tocilizumab subcutaneous.[4,5] Sustained remission at Week 52 was achieved in 56% of patients who received tocilizumab subcutaneous every week + 26-week prednisone taper and 53% of patients who received Actemra every other week + 26-week prednisone taper vs. in 14% of patients in the 26-week prednisone taper and 18% of patients in the 52-week prednisone taper.

- **Immunotherapy-Related Toxicities:** The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for Management of Immunotherapy-Related Toxicities (version 1.2025 – December 20, 2024) give specific recommendations for use of tocilizumab in the management of immune checkpoint inhibitor-related toxicities, chimeric antigen receptor (CAR) T-cell-related toxicities, and lymphocyte engager-related toxicities.[2]
  - For immune checkpoint inhibitor-related toxicities, tocilizumab is a recommended option if non-responsive to steroids for HLH-like syndrome, inflammatory arthritis, giant cell arteritis, severe pneumonitis, and hepatobiliary adverse events (e.g., elevated ALT/AST).
  - For cytokine release syndrome (CRS) and CAR T-cell-related toxicities, tocilizumab is recommended for all grades of disease.
  - For lymphocyte-engager-related toxicities, prophylactic use of tocilizumab to reduce the risk of CRS when administering teclistamab-cqyv (Tecvayli®) can be considered. In addition, the NCCN clinical practice guidelines for Multiple Myeloma (version 1.2026 – June 24, 2025) have a consideration for the use of tocilizumab given prophylactically to reduce the risk of CRS prior to the first dose of bispecific antibodies (e.g., elranatamab-bcmm [Elrexfio™], talquetamab-tgvs [Talvey™], teclistamab-cqyv [Tecvayli®]).[15] The NCCN clinical practice guidelines for acute lymphoblastic leukemia (version 2.2025 – June 27, 2025) suggest supportive care use of tocilizumab for patients with severe CRS with blinatumomab (Blincyto®).[16]
- **Polyarticular Juvenile Idiopathic Arthritis:** Guidelines for the treatment of juvenile idiopathic arthritis from the American College of Rheumatology (ACR) [2021] address oligoarthritis and temporomandibular joint (TMJ) arthritis.[6] For oligoarthritis, a biologic is recommended following a trial of a conventional synthetic DMARD. In patients with TMJ arthritis, scheduled nonsteroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids are recommended first-line. A biologic is a therapeutic option if there is an inadequate response or intolerance. Additionally, rapid escalation to a biologic ± conventional synthetic DMARD (methotrexate preferred) is often appropriate given the impact and destructive nature of TMJ arthritis. In these guidelines, there is not a preferred biologic that should be initiated for JIA. ACR/Arthritis Foundation has guidelines for the treatment of juvenile idiopathic arthritis (2019) specific to juvenile non-systemic polyarthritis, sacroiliitis, and enthesitis.[7] For patients without risk factors, initial therapy with a DMARD is conditionally recommended over a biologic (including tocilizumab). Biologics (e.g., Actemra) are conditionally recommended as initial treatment when combined with a DMARD over biologic monotherapy.
- **Polymyalgia Rheumatica:** Guidelines from the European League Against Rheumatism (EULAR)/ACR (2015) were published prior to approval of tocilizumab for this condition.[8] The minimum effective individualized duration of glucocorticoid therapy is strongly recommended.
- **Rheumatoid Arthritis:** Guidelines from ACR (2021) recommend addition of a biologic or a targeted synthetic DMARD for a patient taking the maximum tolerated dose of methotrexate who is not at target.[9]
- **Still's Disease (Systemic Juvenile Idiopathic Arthritis [sJIA] and Adult Onset Still's Disease [AOSD]):** The European Alliance of Associations for Rheumatology (EULAR) and Pediatric Rheumatology European Society (PReS) joint clinical guidelines for management of Still's disease (2024) recognize sJIA and AOSD as the same disease, differing only in age of onset. Therefore,

they can collectively be referred to as Still's disease.[10] Guidelines recommend an IL-1 or an IL-6 inhibitor be initiated as early as possible when the diagnosis is established.

- **Castleman Disease:** The NCCN clinical practice guidelines for Castleman Disease (version 1.2026 – November 24, 2025) list tocilizumab intravenous (IV) as a first-line therapy for unicentric Castleman disease in patients who are negative for human immunodeficiency virus-1 (HIV-1) and human herpesvirus-8 (HHV8).[11] For second-line or subsequent therapy for relapsed/refractory or progressive unicentric Castleman disease, tocilizumab is also listed as an option if there is a shortage of siltuximab IV (Sylvant®) or if it is not available (if HIV-negative and HHV8-negative and surgically unresectable/incomplete resection). For multicentric Castleman disease, tocilizumab IV is recommended as a first-line therapy for nonsevere disease when HIV-1-negative and HHV8-negative and for fulminant or severe disease that is HHV8-negative. Tocilizumab is also an alternative regimen for subsequent therapy for multicentric Castleman disease that has progressed following treatment of relapsed/refractory or progressive disease.
- **COVID-19 (Coronavirus Disease 2019):** The Infectious Diseases Society of America (IDSA) has developed treatment guidelines for the management of COVID-19 and address the use of Olumiant.[12] Tocilizumab is recommended for hospitalized patients with progressive severe or critical COVID-19 who have elevated markers of systemic inflammation.
- **Graft-Versus-Host Disease (GVHD):** Guidelines for hematopoietic cell transplantation from the National Comprehensive Cancer network (NCCN) [version 2.2025 – June 5, 2025] list tocilizumab among the agents used for steroid-refractory acute GVHD in conjunction with corticosteroids.[14] NCCN cites several small or retrospective studies that utilized dosing of 8 mg/kg IV with variable frequency ranging from every 2 weeks to every 4 weeks. For patients with steroid-refractory acute GVHD, Jakafi® (ruxolitinib tablets) is the only category 1 recommended agent. Other alternative agents recommended by NCCN for acute GVHD (category 2A) include the following: alemtuzumab intravenous infusion, alpha-1 antitrypsin, anti-thymocyte globulin, Simulect® (basiliximab intravenous injection), calcineurin inhibitors (e.g., tacrolimus, cyclosporine), an etanercept product, extracorporeal photopheresis, an infliximab product, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, Nipent™ (pentostatin intravenous injection), a tocilizumab product, urinary-derived human chorionic gonadotropin/epidermal growth factor, and Entyvio® (vedolizumab intravenous infusion).
- **Vacuoles E1 Enzyme X-linked Autoinflammatory Somatic (VEXAS) Syndrome:** VEXAS syndrome is an adult-onset autoinflammatory condition caused by somatic mutations in the *UBA1* gene, which disrupts the function of the E1 enzyme responsible for protein cleanup inside cells. This leads to a buildup of damaged proteins, triggering widespread inflammation. It presents with a combination of systemic inflammation and hematologic abnormalities. The American College of Rheumatology (ACR) [2025] provides a guidance statement for the diagnosis and management of VEXAS syndrome.[17] Regarding diagnosis, ACR notes that the majority of patients with typical VEXAS have missense or splice site mutations at exon 3 of *UBA1*. For patients that are negative with genetic testing for mutations in *UBA1*, clinicians should ensure that testing covers the complete gene and consider testing a bone marrow sample. For treatment of inflammatory manifestations, corticosteroids are recommended. ACR lists tocilizumab IV or SC as a potential treatment option for relapse or as a corticosteroid-sparing agent. Recommended dosing is not provided by the ACR and is not well-characterized in the literature. Most published case reports utilize dosing consistent with rheumatoid arthritis (tocilizumab 8 mg/kg IV every 4 weeks or 162 mg SC every week).[18-20]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of tocilizumab intravenous products. The intent of this policy is to provide recommendations for appropriate uses; the acute treatment of COVID-19 in hospitalized patients is not addressed in this policy. 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 tocilizumab intravenous as well as the monitoring required for adverse events and long-term efficacy, initial approval requires tocilizumab intravenous to be prescribed by or in consultation with a physician who specializes in the condition being treated.

*Indications and/or approval conditions noted with **[EviCore]** are managed by EviCore healthcare for those clients who use EviCore for oncology and/or oncology-related reviews. For these conditions, a prior authorization review should be directed to EviCore at www.EviCore.com.*

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tocilizumab Intravenous Products is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. **Cytokine Release Syndrome Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy.** ***[EviCore]*** Approve for 1 week (which is an adequate duration to receive four doses) if prescribed for a patient who has been or will be treated with a CAR T-cell therapy.
   Note: Examples of CAR T-cell therapy include Abecma (idecabtagene vicleucel intravenous infusion), Aucatzyl (obecabtagene autoleucel intravenous infusion), Breyanzi (lisocabtagene maraleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene intravenous infusion), and Yescarta (axicabtagene ciloleucel intravenous infusion).

   Dosing. Approve dosing that meets BOTH of the following (A and B):
   A) Each individual dose must meet ONE of the following (i or ii):
      i. Patient is < 30 kg: Approve up to 12 mg/kg to a maximum of 800 mg per dose; OR
      ii. Patient is ≥ 30 kg: Approve up to 8 mg/kg to a maximum of 800 mg per dose; AND
   B) Approve up to four doses if there will be an interval of at least 8 hours between doses.

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2. **Giant Cell Arteritis.** 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 has tried or is currently taking a systemic corticosteroid, or systemic corticosteroids are contraindicated; AND
      Note: An example of a systemic corticosteroid is prednisone.

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

B) Patient is Currently Receiving a Tocilizumab Subcutaneous or Intravenous Product. 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 a tocilizumab product); OR
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), resolution of fever, and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating a tocilizumab product), patient experienced an improvement in at least one symptom, such as decreased headache, scalp, or jaw pain; decreased fatigue; and/or improved vision.

Dosing. Approve dosing that meets BOTH of the following (A and B):

A) Approve up to 6 mg/kg to a maximum of 600 mg per dose; AND

B) There must be an interval of at least 4 weeks between doses.

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3. Polyarticular Juvenile Idiopathic 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 ≥ 2 years of age; AND

ii. Patient meets ONE of the following conditions (a, b, c, or d):

a) Patient has tried one other systemic therapy for this condition; OR
Note: Examples of other systemic therapies include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID). A biologic (refer to **Appendix** for examples of biologics used for polyarticular juvenile idiopathic arthritis) also counts as a trial of one systemic therapy.

b) Patient will be starting on a tocilizumab intravenous product concurrently with methotrexate, sulfasalazine, or leflunomide; OR

c) Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR
Note: Examples of absolute contraindication to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, and blood dyscrasias.

d) Patient has aggressive disease, as determined by the prescriber; AND

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

B) Patient is Currently Receiving a Tocilizumab Intravenous or Subcutaneous Product. 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 with this medication 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 a tocilizumab product); OR
Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS),

Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating a tocilizumab product), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

Dosing. Approve dosing that meets BOTH of the following (A and B):

A) Each individual dose must meet ONE of the following (i or ii):

i. Patient is < 30 kg: Approve up to 10 mg/kg up to a maximum of 800 mg per dose; OR

ii. Patient is ≥ 30 kg: Approve up to 8 mg/kg up to a maximum of 800 mg per dose; AND

B) There must be an interval of at least 4 weeks between doses.

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4. 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 ≥ 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 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 (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; OR

B) Patient is Currently Receiving a Tocilizumab Intravenous or Subcutaneous Product. 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) 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 dosing that meets BOTH of the following (A and B):

A) Approve up to 8 mg/kg to a maximum of 800 mg per dose; AND

B) There must be an interval of at least 4 weeks between doses.

5. Systemic Juvenile Idiopathic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Systemic juvenile idiopathic arthritis (SJIA) and adult-onset Still's disease (AOSD) are considered the same disease (Still's disease) but differ in age of onset. For a patient ≥ 18 years of age, refer to AOSD indication below.

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
- **i.** Patient is ≥ 2 years of age; AND
- **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR

B) Patient is Currently Receiving a Tocilizumab Intravenous or Subcutaneous Product. 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 with this medication 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 resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
  - **b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve dosing that meets BOTH of the following (A and B):

A) Each individual dose must meet ONE of the following (i or ii):
- **i.** Patient is < 30 kg: Approve up to 12 mg/kg per dose; OR
- **ii.** Patient is ≥ 30 kg: Approve up to 8 mg/kg per dose.

B) There must be an interval of at least 1 week between doses.

Other Uses with Supportive Evidence

6. Castleman Disease. ***[EviCore]*** Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Approval. 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.** If unicentric disease, the patient is negative for human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV8); AND
- **iii.** The medication is prescribed by or in consultation with an oncologist or hematologist; OR

B) Patient is Currently Receiving a Tocilizumab Intravenous or Subcutaneous Product. 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 with this medication 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 clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate, fibrinogen, albumin, and/or hemoglobin), increased body mass index, and/or reduction in lymphadenopathy.

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as improvement or resolution of constitutional symptoms (e.g., fatigue, physical function).

Dosing. Approve dosing that meets BOTH of the following (A and B):

A) Approve up to 8 mg/kg per dose.

B) There must be an interval of at least 1 week between doses.

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7. Cytokine Release Syndrome Associated with Bispecific Antibodies. ***[EviCore]*** Approve for 1 week (which is an adequate duration to receive four doses) if prescribed for a patient who has been or will be treated with a bispecific antibody.

Note: Examples of bispecific antibodies include: Elrexfio (elranatamab-bcmm subcutaneous injection), Lynozyfic (linvoseltamab-gcpt intravenous infusion), Talvey (talquetamab-tgvs subcutaneous injection), and Tecvayli (teclistamab-cqyv subcutaneous injection).

Dosing. Approve dosing that meets BOTH of the following (A and B):

A) Each individual dose must meet ONE of the following (i or ii):

i. Patient is < 30 kg: Approve up to 12 mg/kg to a maximum of 800 mg per dose; OR

ii. Patient is ≥ 30 kg: Approve up to 8 mg/kg to a maximum of 800 mg per dose; AND

B) Approve up to four doses if there will be an interval of at least 8 hours between doses.

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8. Graft-Versus-Host Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 1 month if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has acute graft-versus-host disease; AND

iii. Patient has tried at least one systemic medication for graft-versus-host disease; AND
Note: Examples of systemic medications include corticosteroids (e.g., methylprednisolone), antithymocyte globulin, cyclosporine, tacrolimus, mycophenolate mofetil, Jakafi (ruxolitinib), Simulect (basiliximab), an etanercept product, an infliximab product, sirolimus, Nipent (pentostatin), and Entyvio (vedolizumab).

iv. The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; OR

B) Patient is Currently Receiving a Tocilizumab Intravenous Product. Approve for 3 months if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 1 month; AND
Note: A patient who has received < 1 month 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 are normalization of liver function tests, red blood cell count, or platelet count; or resolution of fever or rash.

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as improvement in skin, oral mucosal, ocular, or gastrointestinal symptoms (e.g., nausea, vomiting, anorexia).

Dosing. Approve dosing that meets BOTH of the following (A and B):
A) Approve up to 8 mg/kg per dose.
B) There must be an interval of at least 2 weeks between doses.

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9. Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Examples of checkpoint inhibitors are Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Yervoy (ipilimumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Bavencio (avelumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), and Libtayo (cemiplimab-rwlc intravenous infusion).

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv and v):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** According to the prescriber, patient developed an immunotherapy-related toxicity; AND
- **iii.** Patient developed this immunotherapy-related toxicity while receiving a checkpoint inhibitor; AND
- **iv.** Patient is symptomatic despite a trial of at least ONE systemic corticosteroid; AND
  Note: Examples of a corticosteroid include methylprednisolone and prednisone.
- **v.** The medication is prescribed by or in consultation with a rheumatologist, hepatologist, gastroenterologist, pulmonologist, or oncologist; OR

B) Patient is Currently Receiving a Tocilizumab Intravenous Product. 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 with this medication 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 are dependent upon organ involvement but may include clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate) or laboratory parameters (e.g., liver function tests), and/or reduced dosage of corticosteroids.
  - **b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve dosing that meets BOTH of the following (A and B):
A) Approve up to 8 mg/kg to a maximum of 800 mg per dose.
B) There must be an interval of at least 4 weeks between doses.

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10. Polymyalgia Rheumatica. 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 has tried one systemic corticosteroid; AND
Note: An example of a systemic corticosteroid is prednisone.
iii. The medication is prescribed by or in consultation with a rheumatologist; OR

B) Patient is Currently Receiving a Tocilizumab Subcutaneous or Intravenous Product. 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 a tocilizumab product); OR
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), resolution of fever, and/or reduced dosage of corticosteroids.
b) Compared with baseline (prior to initiating a tocilizumab product), patient experienced an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness; improved range of motion; and/or decreased fatigue.

Dosing. Approve dosing that meets BOTH of the following (A and B):
A) Approve up to 6 mg/kg to a maximum of 600 mg per dose; AND
B) There must be an interval of at least 4 weeks between doses.

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11. Still's Disease, Adult Onset. Approve for the duration noted if the patient meets the following criteria (A or B):
Note: Adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) are considered the same disease (Still's disease) but differ in age of onset. For a patient < 18 years of age, refer to the SJIA indication above.

A) Initial Therapy. Approve for 6 months if the patient meets ALL 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

B) Patient is Currently Receiving a Tocilizumab Intravenous or Subcutaneous Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
i. Patient has been established on this medication for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication 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 resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve dosing that meets BOTH of the following (A and B):

A) Approve up to 8 mg/kg per dose.
B) There must be an interval of at least 2 weeks between doses.

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12. Vacuoles E1 Enzyme X-linked Autoinflammatory Somatic (VEXAS) Syndrome. 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, iii, and iv):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has a molecular genetic test demonstrating pathogenic or likely pathogenic *UBA1* gene variant; AND
- **iii.** Patient meets ONE of the following (a or b):
  - **a)** Patient has tried or is currently taking a systemic corticosteroid; OR
  - **b)** Systemic corticosteroids are contraindicated; AND
- **iv.** The medication is prescribed by or in consultation with a rheumatologist, hematologist, dermatologist, immunologist, or specialist in the treatment of autoinflammatory conditions; OR

B) Patient is Currently Receiving a Tocilizumab Intravenous or Subcutaneous Product. 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 with this medication 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 resolution of fever, improvement in skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
  - **b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased joint pain, decreased fatigue, decreased cough and/or dyspnea, improved ocular symptoms, and/or improved function or activities of daily living.

Dosing. Approve dosing that meets BOTH of the following (A and B):
A) Approve up to 8 mg/kg; AND
B) There must be an interval of at least 4 weeks between doses.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of a Tocilizumab Intravenous Product is not recommended in the following situations:

1. **COVID-19 (Coronavirus Disease 2019).** Tocilizumab intravenous is only indicated in hospitalized adults with COVID who are receiving systemic corticosteroids and requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).[1,12] For COVID-19, the dose is 8 mg/kg (to a maximum of 800 mg) given as a single intravenous infusion. A second dose may be administered at least 8 hours after the initial infusion if clinical signs or symptoms worsen or do not improve after the first dose.

2. **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 disease-modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with this medication.

3. **Crohn's Disease.** In a 12-week pilot study conducted in Japan, 36 adults with active Crohn's disease (Crohn's Disease Activity Index [CDAI] ≥ 150 and increased C-reactive protein) were randomized, in a double-blind fashion to tocilizumab 8 mg/kg intravenous every 2 weeks; or alternating infusions of tocilizumab 8 mg/kg every 4 weeks and placebo (i.e., alternating with placebo every 2 weeks), or to placebo every 2 weeks.[13] At baseline the CDAI means ranged from 287 to 306. Patients had been treated with corticosteroids, mesalamine-type drugs, metronidazole, or elemental diet. Six patients in the placebo group, four patients on tocilizumab intravenous every 4 weeks and one patient on tocilizumab intravenous every 2 weeks dropped out. The mean reduction in the CDAI score in the tocilizumab 8 mg/kg every 2 week group was 88 points (from mean 306 to 218). Further studies are needed.

3. 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. Actemra® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; August 2025.
2. The NCCN Management of Immunotherapy-Related Toxicities Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2025.
3. Dejaco C, Ramiro S, Bond M, eta al. EULAR recommendations for the use of imaging in large vessel vasculitis in clinical practice: 2023 update. *Ann Rheum Dis*. 2023:ard-2023-224543.
4. Tuckwell K, Collinson N, Dimonaco S, et al. Newly diagnosed vs. relapsing giant cell arteritis: baseline data from the GiACTA trial. *Semin Arthritis Rheum*. 2017;46(5):657-664.
5. Stone JH, Tuckwell K, Dimonaco S, et al. Trial of tocilizumab in giant-cell arteritis. *N Engl J Med*. 2017 ;377(4):317-328.
6. 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 Care Res*. 2022 Apr;74(4):521-537.
7. Ringold S, Angeles-Han ST, 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.
8. Dejaco C, Singh YP, Perel P, et al. 2015 Recommendations for the management of polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. *Ann Rheum Dis.* 2015;74(10):1799-807.
9. 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.
10. Fautrel B, Mitrovic S, De Matteis A, et al. EULAR/PReS recommendations for the diagnosis and management of Still's disease, comprising systemic juvenile idiopathic arthritis and adult-onset Still's disease. *Ann Rheum Dis.* 2024;83(12):1614-1627.
11. The NCCN Castleman Disease Clinical Practice Guidelines in Oncology (version 1.2026 – November 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 25, 2025.
12. Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America Guidelines on the treatment and management of patients with COVID-19. August 12, 2024. Available at: https://www.idsociety.org/COVID19guidelines. Accessed April 02, 2025.
13. Ito H, Takazoe M, Fukuda Y, et al. A pilot randomized trial of a human anti-interleukin-6 receptor monoclonal antibody in active Crohn's disease. *Gastroenterology*. 2004;126:989-996.
14. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 2.2025 – June 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2025.

15. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2026 – June 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2025.
16. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – June 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2025.
17. Mekinian AM, Georgin-Lavaille S, Ferrada MA, et al. American College of Rheumatology Guidance Statement for Diagnosis and Management of VEXAS Developed by the International VEXAS Working Group Expert Panel. *Arthritis Rheumatol*. 2025 Aug 11. doi: 10.1002/art.43287 [Online ahead of print].
18. Kunishita Y, Kirino Y, Tscuchida N, et al. Case report: tocilizumab treatment for VEXAS syndrome with relapsing polychondritis: a single-center, 1-year longitudinal observational study in Japan. *Front Immunol*. 2022 Jun 13: 13:901063.
19. Tozaki N, Tawada C, Niwa H, et al. A case of VEXAS syndrome (vacuoles, E1 enzyme, X-linked, autoinflammatory, somatic) with decreased oxidative stress levels after oral prednisone and tocilizumab treatment. *Front Med (Lausanne)*. 2022;9:1046820.
20. Goyal A, Narayanan D, Wong W, et al. Tocilizumab for treatment of cutaneous and systemic manifestations of vacuoles, E1 enzyme, X-linked, autoinflammatory, somatic (VEXAS) syndrome without myelodysplastic syndrome. *JAAD Case Rep*. 2022;23:15–9.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/10/2023
Early Annual Revision	Tyenne (biosimilar to Actemra Intravenous) was added to the policy with the same criteria as Actemra Intravenous. Policy was renamed as Inflammatory Conditions – Tocilizumab Intravenous Products. Throughout the policy, wording was changed from Actemra to tocilizumab. **Systemic Juvenile Idiopathic Arthritis:** The Note was revised to remove tumor necrosis factor inhibitors from the examples of other systemic therapies that could have been tried prior to Actemra subcutaneous. **Still's Disease, Adult Onset:** The condition was changed to as listed (previously was Still's Disease). Exceptions were added for a patient who, according to the prescriber, had moderate to severe active systemic features or active systemic features and concerns of progression to macrophage activation syndrome; a patient with these features is not required to try a corticosteroid or a disease-modifying antirheumatic drug prior to tocilizumab intravenous. **Castleman Disease:** For initial therapy, requirements were added that the patient is negative for the human immunodeficiency virus and human herpesvirus-8 and that the patient has relapsed or refractory disease.	04/24/2024
Selected Revision	Tofidence intravenous was added to the policy with the same criteria as the other tocilizumab intravenous products.	06/06/2024
Selected Revision	**Cytokine Release Syndrome Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy:** A Note regarding Coronavirus Disease 2019 was removed (no longer needed). **Giant Cell Arteritis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Polyarticular Juvenile Idiopathic Arthritis:** For initial approvals, a requirement that the patient is ≥ 2 years of age was added. **Rheumatoid Arthritis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Systemic Juvenile Idiopathic Arthritis:** For initial approvals, a requirement that the patient is ≥ 2 years of age was added. **Castleman Disease:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Polymyalgia Rheumatica:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Still's Disease, Adult Onset:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Conditions Not Recommended for Approval:** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).	09/11/2024

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Annual Revision	Updated policy statement to indicate that the acute treatment of COVID-19 in hospitalized patients is not addressed in this policy. **Cytokine Release Syndrome Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy:** Aucatzyl (obecabtagene autoleucel) and Carvykti (ciltacabtagene autoleucel) were added to the Note as examples of CAR T-cell therapy. **Still's Disease, Adult Onset:** Added a Note that a previous trial of one biologic (e.g., Ilaris [canakinumab subcutaneous injection], Kineret [anakinra subcutaneous injection]) other than the requested drug also counts towards a trial of one other conventional systemic agent for Still's disease. A biosimilar of the requested biologic does not count. **Conditions Not Recommended for Approval:** Treatment of COVID-19 in a non-hospitalized patient was changed to more generally state COVID-19.	04/23/2025
Selected Revision	**Giant Cell Arteritis:** The requirement that the patient has tried one systemic corticosteroid was changed to now specify the patient has tried or currently is taking a systemic corticosteroid, unless a systemic corticosteroid is contraindicated. **Systemic Juvenile Idiopathic Arthritis:** The following Note was added "Systemic juvenile idiopathic arthritis (SJIA) and adult-onset Still's disease (AOSD) are considered the same disease (Still's disease) but differ in age of onset. For a patient ≥ 18 years of age, refer to AOSD indication." Additionally, the requirement for a previous trial of one other systemic therapy was removed. **Still's Disease, Adult-Onset**: The following Note was added "Adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) are considered the same disease (Still's disease) but differ in age of onset. For a patient < 18 years of age, refer to the SIJA indication". Additionally, for initial therapy, the following requirements were removed: "Patient has tried one corticosteroid and had an inadequate response to one conventional synthetic disease-modifying antirheumatic drug" and "According to the prescriber, patient has at least moderate to severe active systemic features of this condition or active systemic features with concerns of progression to macrophage activation syndrome."	06/11/2025
Selected Revision	**Cytokine Release Syndrome Associated with Bispecific Antibodies:** This was added as a condition of approval. **Graft-Versus-Host Disease:** This was added as a condition of approval. **Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy:** This condition was expanded from inflammatory arthritis to immunotherapy-related toxicities associated with checkpoint inhibitors. Requirements were added that, according to the prescriber, the patient developed an immunotherapy-related toxicity, and that the patient developed this immunotherapy-related toxicity while receiving a checkpoint inhibitor. The requirement that the patient has tried at least one non-steroidal anti-inflammatory drug was removed. Gastroenterologist, hepatologist, and pulmonologist were added as accepted specialists to the specialist requirement. For a patient currently receiving tocilizumab, prior use of the subcutaneous product was removed. In addition, the Note of examples of objective measures was modified to include that they are dependent upon organ involvement and laboratory parameters (e.g., liver function tests) were added to the list of examples.	08/13/2025
Selected Revision	Avtozma was added to the policy with the same criteria as the other tocilizumab intravenous products.	09/24/2025
Selected Revision	**Castleman Disease:** For initial therapy, the requirements that the patient is negative for human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8) and that the medication is being used for relapsed or refractory disease are modified to apply for those patients with unicentric disease and will not apply for those patients with multicentric disease. "Relapsed or refractory" was modified to "relapsed/refractory or progressive" disease. **Appendix:** Otezla XR (apremilast extended-release tablet) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs.	10/29/2025
Selected Revision	**Castleman Disease:** For initial therapy, the requirement for unicentric disease that the patient have relapsed/refractory or progressive disease was removed. **Vacuoles E1 Enzyme X-linked Autoinflammatory Somatic (VEXAS) Syndrome:** This was added as a condition of approval.	12/03/2025

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, biosimilars; Actemra SC, biosimilars)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (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
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars)	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, AS, nr-axSpA, PsA
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: CD, PsA, PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Otezla XR™ (apremilast extended-release 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, CD, 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.