UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Orencia Intravenous Utilization Management Medical Policy
- Orencia® (abatacept intravenous infusion – Bristol Myers Squibb)

REVIEW DATE: 09/16/2026

OVERVIEW

Orencia intravenous, a selective T-cell costimulation modulator, is indicated for the following uses:[1]

- **Graft-versus-host disease (GVHD)**, for prophylaxis of acute GVHD in combination with a calcineurin inhibitor and methotrexate, in patients ≥ 2 years of age undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated donor.
- **Juvenile idiopathic arthritis (JIA)**, in patients ≥ 2 years of age with moderately to severely active polyarticular disease.
- **Psoriatic arthritis (PsA)**, in adults with active disease.
- **Rheumatoid arthritis**, in adults with moderately to severely active disease.

Orencia is not recommended for use concomitantly with other potent immunosuppressants such as biologics or Janus kinase inhibitors. Orencia is available as an intravenous infusion that is dosed on body weight. There is also a subcutaneous injection available in prefilled syringes. Of note, the subcutaneous injection is approved for use in patients ≥ 2 years of age with PsA and JIA, as well as rheumatoid arthritis in adults. Some adults initiating therapy with Orencia subcutaneous will receive a single loading dose with Orencia intravenous.

Guidelines

Orencia is addressed in guidelines for treatment of various inflammatory conditions.

- **GVHD:** Guidelines for hematopoietic cell transplantation from the National Comprehensive Cancer Network (NCCN) [version 3.2026 – July 30, 2026] list Orencia intravenous among the alternative agents used for steroid-refractory chronic GVHD and as a component of prophylactic strategies.[9] For patients with steroid-refractory chronic GVHD, Jakafi® (ruxolitinib tablets) is the only category 1 recommended agent and is FDA-approved. Other FDA-approved agents recommended (category 2A) include Imbruvica® (ibrutinib), Rezurock® (belumosudil), and Niktimvo™ (axatilimab-csfr). Alternative agents recommended by NCCN for chronic GVHD (category 2A) include the following: Orencia intravenous, alemtuzumab, calcineurin inhibitors (e.g., tacrolimus, cyclosporine), etanercept, extracorporeal photopheresis, hydroxychloroquine, imatinib, interleukin-2, low-dose methotrexate, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, pentostatin, and rituximab. Dosing of Orencia in the supportive reference was up to 10 mg/kg intravenously with the first three doses given at 2-week intervals; with one month after the third dose, doses 4 through 6 were administered at 4-week intervals.[12] The treating physician had the discretion to continue monthly doses of abatacept for up to a total of 12 doses of extended-duration therapy.
- **JIA:** Guidelines from American College of Rheumatology (ACR) [2019] list biologics among the treatment options for subsequent therapy in patients with polyarthritis.[3,] Initial therapy with a biologic may be considered for patients with risk factors and involvement of high-risk joints (e.g., cervical spine, wrist, or hip), high disease activity, and/or those judged to be at high risk of disabling joint damage. In patients with active sacroiliitis or enthesitis despite nonsteroidal anti-inflammatory drug use, a tumor necrosis factor inhibitor (TNFi) is recommended. The 2021 ACR Juvenile Idiopathic Arthritis (JIA) guideline includes Orencia as an option for residual arthritis in

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

patients with or without macrophage activation syndrome (MAS) after incomplete response to IL-1 and/or IL-6 inhibitors.[13]

- **PsA:** Guidelines from ACR (2018) recommend TNFis over other biologics for use in treatment-naïve patients with PsA and in those who were previously treated with an oral therapy.[4] However, Orencia may be considered over other biologics in patients with recurrent or serious infections.
- **Rheumatoid Arthritis:** Guidelines from the 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.[2]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Orencia intravenous. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. 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). Because of the specialized skills required for evaluation and diagnosis of patients treated with Orencia intravenous as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Orencia intravenous to be prescribed by or in consultation with a physician who specializes in the condition being treated. 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. For prevention of GVHD, the approval duration is for 60 days, which is an adequate duration for the patient to receive four doses.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

---

1. **Graft-Versus-Host Disease – Prevention.** Approve for 4 doses if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 2 years of age; AND
   - **B)** Orencia is being used for prevention of acute graft-versus-host disease; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

   Dosing. Approve if dosing meets ONE of the following (A or B):
   - **A)** Patient is ≥ 6 years of age: Approve up to 10 mg/kg to a maximum of 1,000 mg per dose; OR
   - **B)** Patient is ≥ 2 and < 6 years of age: Approve up to 15 mg/kg.

---

2. **Juvenile Idiopathic Arthritis (JIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   Note: This includes JIA regardless of type of onset. JIA is also referred to as Juvenile Rheumatoid Arthritis.
   - **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 (a, b, c, or d):
       - **a)** Patient has tried one other agent for this condition; OR

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

Note: Examples of therapies which could have been tried include methotrexate, sulfasalazine, leflunomide, and a nonsteroidal anti-inflammatory drug (NSAID). A biologic other than the requested drug also counts as a trial of one agent for JIA. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for JIA.

b) Patient will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide; OR

c) Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR
Note: Examples of absolute contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, 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 Orencia (Intravenous or Subcutaneous). 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 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 the requested drug), 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 if dosing meets BOTH of the following (A and B):

A) The weight-based dose meets ONE of the following (i, ii, or iii):

i. 10 mg/kg if the patient weighs < 75 kg; OR

ii. 750 mg if the patient weighs 75 kg to 100 kg; OR

iii. 1,000 mg if the patient weighs > 100 kg; AND

B) The dose is administered at Weeks 0, 2, and 4, then every 4 weeks thereafter

---

3. 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; OR

B) Patient is Currently Receiving Orencia (Intravenous or Subcutaneous). 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):

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

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.

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

A) The dose is based on the patient's weight and meets ONE of the following (i, ii, or iii):
- **i.** 500 mg if the patient weighs < 60 kg; OR
- **ii.** 750 mg if the patient weighs 60 kg to 100 kg; OR
- **iii.** 1,000 mg if the patient weighs > 100 kg; AND

B) The dose is administered at Weeks 0, 2, and 4, then every 4 weeks thereafter.

---

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 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 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 Orencia (Intravenous or Subcutaneous). 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).

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

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 if dosing meets BOTH of the following (A and B):

A) The dose is based on the patient's weight and meets ONE of the following (i, ii, or iii):
- **i.** 500 mg if the patients weighs < 60 kg; OR
- **ii.** 750 mg if the patient weighs 60 kg to 100 kg; OR
- **iii.** 1,000 mg if the patient weighs > 100 kg; AND

B) The dose is administered at Weeks 0, 2, and 4, then every 4 weeks thereafter.

Other Uses with Supportive Evidence

---

5. Chronic Graft-Versus-Host Disease – Treatment. 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 has chronic graft-versus-host disease; AND
- **ii.** Patient has tried at least one systemic medication for graft-versus-host disease; AND
  Note: Examples of systemic medications include systemic corticosteroids (methylprednisolone, prednisone), Jakafi (ruxolitinib), Rezurock (belumosudil), Niktimvo (axatilimab-csfr), cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica (ibrutinib), imatinib, hydroxychloroquine, methotrexate, Nipent (pentostatin), interleukin-2 (e.g., Proleukin [aldesleukin]), sirolimus, a rituximab product, or an etanercept product.
- **iii.** The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; OR

B) Patient has Already Received Orencia Intravenous. Approve for 1 year if the patient meets at least ONE of the following (i or ii):
- **i.** 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 normalization of liver function tests, red blood cell count, or platelet count; or resolution of fever or rash.
- **ii.** 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 up to 10 mg/kg with doses administered intravenously at Weeks 0, 2, and 4, then every 4 weeks thereafter.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Orencia intravenous is not recommended in the following situations:

1. Ankylosing Spondylitis. In an open-label Phase II trial, Orencia was administered intravenously on Days 1, 15, 29, and every 28 days thereafter to patients with active ankylosing spondylitis.[5] Patients received a fixed dosage of Orencia of approximately 10 mg/kg based on body weight. The primary endpoint was a 40% improvement in disease activity at Week 24 in the Assessment of SpondyloArthritis international Society criteria (ASAS 40). At Week 24, the ASAS 40 was 13.3% (n = 2/15) in TNFi-naïve patients compared with no responses in patients who had previously failed TNFis (n = 15). ASAS 20 response was 26.7% (n = 4/15) in TNFi-naïve patients compared with 20% (n =

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

3/15) in those who had previously failed TNFis. A major response was not shown with Orencia treatment.

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 DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

3. **Inflammatory Bowel Disease (i.e., Crohn's Disease, Ulcerative Colitis).** In placebo-controlled trials evaluating the efficacy of Orencia intravenous for induction and maintenance in adults with active, moderate to severe Crohn's disease (n = 451) and ulcerative colitis (n = 490), Orencia was no more effective than placebo.[6] Patients were randomized to Orencia 30 mg, 10 mg, or 3 mg/kg (according to body weight) or placebo and dosed at Weeks 0, 2, 4, and 8. A total of 90 patients with Crohn's disease and 131 patients with ulcerative colitis who responded to induction were then randomized to Orencia 10 mg/kg or placebo every 4 weeks through Week 52. When used for induction of Crohn's disease, 17.2%, 10.2%, and 15.5% of patients receiving Orencia 30 mg, 10 mg, and 3 mg/kg achieved a clinical response at Weeks 8 and 12 compared with 14.4% of patients receiving placebo (P = not significant [NS] for all comparisons). In patients with Crohn's disease, response and remission at Week 52 were not significantly different between the Orencia intravenous and placebo treatment groups. When used as induction therapy in ulcerative colitis, 21.4%, 19.0%, and 20.3% of patients receiving Orencia 30 mg, 10 mg, and 3 mg/kg achieved a clinical response at Week 12 compared with 29.5% of patients receiving placebo (P = 0.043 for 10 mg/kg vs. placebo; other comparisons P = NS). At Week 52, 12.5% (n = 8/64) and 14.1% (n = 9/64) of patients with ulcerative colitis were in remission (P = NS) and 17.2% of patients in each treatment group (n = 11/64 for each group) had achieved a response.

4. **Psoriasis**. (Note: Patients with concomitant plaque psoriasis and psoriatic arthritis may be reviewed under the psoriatic arthritis criteria above.) In the pivotal trial evaluating Orencia subcutaneous for psoriatic arthritis, there was not a significant difference at Week 24 in the proportion of patients with a 50% reduction in the Psoriasis Area and Severity Index (PASI 50) response vs. placebo ± conventional synthetic (cs)DMARD (27% vs. 20% with placebo ± csDMARD; P = NS).[8] In a multicenter, Phase I, 26-week, open-label dose-escalation study, 43 patients with stable plaque psoriasis (10% to 49% body surface area involvement) received four doses of Orencia given as a 1-hour intravenous infusion on Days 1, 3, 16, and 29.[7] The starting dose was 0.5 mg/kg. Four to six patients were accrued to each of eight dose levels: 0.5, 1, 2, 4, 8, 16, 25, and 50 mg/kg. A parallel control group was matched for age and overall disease severity. In all, 46% of patients on Orencia achieved a 50% or greater sustained improvement in clinical disease activity (Physician's Global Assessment of disease activity) compared with baseline psoriasis evaluation. Progressively greater effects were observed with the highest doses. Further studies are needed to establish safety and efficacy, as well as appropriate dosing in plaque psoriasis.

5. 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. Orencia® intravenous infusion [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2024.
2. 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.

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

3. 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 Rheumatol*. 2019;71(6):717-734.
4. 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.
5. Song IH, Heldmann F, Rudwaleit M, et al. Treatment of active ankylosing spondylitis with abatacept: an open-label, 24-week pilot study. *Ann Rheum Dis*. 2011;70(6):1108-1110.
6. Sandborn WJ, Colombel JF, Sands BE, et al. Abatacept for Crohn's disease and ulcerative colitis. *Gastroenterology*. 2012;143(1):62-69.
7. Abrams JR, Lebwohl MG, Guzzo CA, et al. CTLA4Ig-mediated blockade of T-cell costimulation in patients with psoriasis vulgaris. *J Clin Invest.* 1999;103:1243-1252.
8. Mease PJ, Gottlieb AB, van der Heijde D, et al. Efficacy and safety of abatacept, a T-cell modulator, in a randomised, double-blind, placebo-controlled, phase III study in psoriatic arthritis. *Ann Rheum Dis*. 2017;76(9):1550-1558.
9. The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 3.2026 – July 30, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 11, 2026.
10. Al-Homsi AS, Cirrone F, Wo S, et al. PTCy, abatacept, and a short course of tacrolimus for GVHD prevention after haploidentical transplantation. *Blood Adv*. 2023 Jul;7(14):3604-3611.
11. Al-Homsi AS, DeFor TE, Cole K, et al. CAST regimen for GvHD prophylaxis: a CIBMTR propensity score-matched analysis. *Transplant Cell Ther*. 2024 Nov;30(11):1092-1098.
12. Nahas MR, Soiffer RJ, Kim HT, et al. Phase 1 clinical trial evaluating abatacept in patients with steroid-refractory chronic graft-versus-host disease. *Blood*. 2018;131(25):2836-2845.
13. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/13/2024
Selected Revision	**Juvenile Idiopathic Arthritis:** For initial approvals, a requirement that the patient is ≥ 2 years of age was added. **Psoriatic Arthritis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Rheumatoid Arthritis:** 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
Annual Revision	No criteria changes.	03/19/2025
Annual Revision	**Graft-Versus-Host Disease – Prevention:** Requirements removed that the patient will also receive a calcineurin inhibitor and methotrexate for the prevention of acute graft-versus-host disease, and that the patient will undergo hematopoietic stem cell transplantation from a matched unrelated donor or 1 allele-mismatched unrelated donor. The approval duration was increased to 60 days; this has been updated in the Policy Statement. **Chronic Graft-Versus-Host Disease – Treatment:** This new condition for approval was added to the policy under Other Uses with Supportive Evidence. **Appendix:** Otezla XR (apremilast extended-release tablets) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecular Drugs.	03/18/2026
Selected Revision	**Chronic Graft-Versus-Host Disease – Treatment:** Dosing interval was changed from doses separated by at least 2 weeks to doses administered at Weeks 0, 2, and 4, then every 4 weeks thereafter.	04/01/2026
Early Annual Revision	Generics for Xeljanz and Xeljanz XR were added to the appendix. Icotyde (icotrokinra tablets) was added to the appendix.	09/16/2026

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

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, PJIA, 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
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	PJIA, 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, biosimilar; Stelara SC, biosimilar)	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		
Icotyde® (icotrokinra tablets)	Inhibition of IL-23	PsO
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, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO, PsA
Tofacitinib tablets/oral solution (Xeljanz®, generics)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Tofacitinib XR extended release tablets (Xeljanz® XR, generics)	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; PJIA – Polyarticular juvenile idiopathic arthritis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.