PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Ustekinumab Subcutaneous Products Prior Authorization Policy with Dosing

- Stelara® (ustekinumab subcutaneous injection – Janssen Biotech)
- Imuldosa® (ustekinumab-srlf subcutaneous injection – Accord)
- Otulfi™ (ustekinumab-aauz subcutaneous injection – Formycon/Fresenius)
- Pyzchiva™ (ustekinumab-ttwe subcutaneous injection – Sandoz/Samsung, Cordavis)
- Selarsdi™ (ustekinumab-aekn subcutaneous injection – Alvotech/Teva)
- Starjemza™ (ustekinumab-hmny subcutaneous injection – BioThera)
- Steqeyma™ (ustekinumab-stba subcutaneous injection – Celltrion)
- Wezlana™ (ustekinumab-auub subcutaneous injection – Amgen)
- Yesintek™ (ustekinumab-kfce subcutaneous injection – Biocon)
- Ustekinumab subcutaneous injection (Janssen Biotech)
- Ustekinumab-aauz subcutaneous injection (Fresenius)
- Ustekinumab-aekn subcutaneous injection (Teva)
- Ustekinumab-ttwe subcutaneous injection (Quallent)

REVIEW DATE: 07/23/2025; selected revision 10/29/2025, 11/05/2025, 02/11/2026

OVERVIEW

Ustekinumab subcutaneous (SC), an interleukin (IL)-12/23 blocker, is indicated for the following uses:[1,8-14,16]

- **Crohn's disease**, in patients ≥ 18 years of age with moderate to severe active disease.
- **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for phototherapy or systemic therapy.
- **Psoriatic arthritis**, in patients ≥ 6 years of age with active disease.
- **Ulcerative colitis**, in patients ≥ 18 years of age with moderate to severe active disease.

Dosing

A weight-based dose is administered by SC injection under the supervision of a physician or by the patient or a caregiver. The approved dosing listed in the prescribing information are as follows:[1,8-14]

- **Crohn's disease:** Starting 8 weeks after an initial intravenous (IV) dose, the maintenance dose is 90 mg SC injection once every 8 weeks (Q8W).
- **Plaque psoriasis:**
  - Adults weighing ≤ 100 kg: 45 mg SC at Week 0, Week 4, and then once every 12 weeks (Q12W) thereafter.
  - Adults weighing > 100 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing > 100 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.

- **Psoriatic arthritis:**
  - Adults weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - All other adults: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
- **Ulcerative colitis:** Starting 8 weeks after an initial IV dose, the maintenance dose is 90 mg SC Q8W.

Guidelines

Guidelines for the treatment of inflammatory conditions recommend use of ustekinumab SC.

- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] and the American Gastroenterological Association (AGA) [2025] have guidelines for the management of CD in adults.[2,15] Both guidelines recommend upfront use of advanced therapies, rather than step-up therapy after failure of corticosteroids and/or immunomodulators. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio® (vedolizumab IV infusion, SC injection), IL-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib extended-release tablets).
- **Plaque Psoriasis:** Guidelines from the American Academy of Dermatology and National Psoriasis Foundation (2019) recommend ustekinumab as a monotherapy treatment option or in combination with other therapies for adults with moderate to severe disease.[3]
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology (2018) recommend ustekinumab after other agents (e.g., TNFis) have been tried.[4] Ustekinumab may be used in patients who have active disease despite treatment with other agents, particularly in those with concomitant inflammatory bowel disease.[4]
- **Ulcerative Colitis:** The AGA (2024) and the ACG (2025) have clinical practice guidelines on the management of moderate to severe ulcerative colitis.[5,6] In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include TNF inhibitors, Entyvio, IL-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state corticosteroids may be avoided entirely when other effective induction strategies are planned.[6] Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ustekinumab SC. All approvals are provided for the duration listed below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with ustekinumab SC as well as the monitoring required for adverse events and long-term efficacy, initial approval requires ustekinumab SC to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **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.** According to the prescriber, the patient will receive a single induction dose with ustekinumab intravenous within 2 months of initiating therapy with ustekinumab subcutaneous; AND
     - **iii.** The medication is prescribed by or in consultation with a gastroenterologist; OR
   - **B)** Patient is Currently Receiving Ustekinumab Subcutaneous. 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 fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography, computed tomography enterography), 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.

2. **Plaque Psoriasis.** Approve (45 mg syringe/vial) for the duration noted if the patient meets ONE of the following (A or B):
   Note: If the 90 mg syringe is requested, approve if the patient meets ONE of the following:
   - Patient weighs > 100 kg; OR
   - Patient is currently receiving the 90 mg syringe; OR
   - Patient has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy.

   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 6 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
         Note: Examples of traditional systemic agents used for psoriasis include methotrexate, cyclosporine, or acitretin. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has had a 3-month trial or previous intolerance to at least one biologic (other than the requested medication), Otezla/Otezla XR (apremilast tablets/extended-release tablets), or Sotyktu (deucravacitinib tablets). A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for plaque 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)** According to the prescriber, the patient has a contraindication to methotrexate; AND

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

B) Patient is Currently Receiving Ustekinumab Subcutaneous. 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, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND

iii. Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

3. Psoriatic Arthritis. Approve (45 mg syringe/vial) for the duration noted if the patient meets ONE of the following (A or B):

Note: If the 90 mg syringe is requested, approve if the patient meets ONE of the following:

- Patient has moderate to severe plaque psoriasis AND weighs > 100 kg; OR
- Patient is currently receiving the 90 mg syringe; OR
- Patient has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy.

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

i. Patient is ≥ 6 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 Ustekinumab Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

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

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

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

4. Ulcerative Colitis. 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. According to the prescriber, the patient will receive a single induction dose with ustekinumab intravenous within 2 months of initiating therapy with ustekinumab subcutaneous; AND

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

B) Patient is Currently Receiving Ustekinumab Subcutaneous. 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 assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), 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 decreased rectal bleeding.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ustekinumab subcutaneous is not recommended in the following situations:

1. **Ankylosing Spondylitis (AS).** There are other biologic therapies indicated in AS. More data are needed to demonstrate efficacy of ustekinumab in this condition. There is a published proof-of-concept trial evaluating ustekinumab in AS (TOPAS – UsTekinumab for the treatment Of Patients with active Ankylosing Spondylitis).[4] TOPAS was a prospective, open-label study evaluating ustekinumab 90 mg subcutaneous at Weeks 0, 4, and 16 in patients (n = 20) with AS. After Week 16, patients were followed through Week 28. Patients who previously failed to respond to tumor necrosis factor inhibitor (TNFi) were excluded. The primary endpoint was a 40% improvement in disease activity at Week 24 according to the Assessment of SpondyloArthritis International Society (ASAS) criteria (ASAS40) in the intent-to-treat population which included all patients who received at least one dose of ustekinumab. In all, 65% of patients (95% confidence interval [CI]: 41%, 85%; n = 13/20) achieved an ASAS40 response at Week 24. There was at least a 50% improvement of the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) achieved by 55% of patients (95% CI: 32%, 77%; n = 11/20). However, enthesitis (measured by MASES [Maastricht AS Entheses Score] and SPARCC [SPondyloArthritis Research Consortium of Canada] enthesitis indices) and the number of swollen joints were not significantly improved at Week 24. There was a significant reduction of active inflammation on magnetic resonance imaging at Week 24 compared with baseline in sacroiliac joints.

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 drugs (e.g., methotrexate leflunomide, hydroxychloroquine, and sulfasalazine) in combination with this medication.

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. Stelara® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; November 2024.
2. Lichtenstein G, Loftus E, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2025 June;120(6):1225-1264.
3. 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.
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. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
6. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol.* 2025 June;120(6):1187-1224.
7. Poddubnyy D, Hermann KG, Callhoff J, et al. Ustekinumab for the treatment of patients with active ankylosing spondylitis: results of a 28-week, prospective, open-label, proof-of-concept study (TOPAS). *Ann Rheum Dis*. 2014;73(5):817-823.
8. Otulfi® intravenous infusion, subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius; December 2024.
9. Pyzchiva® intravenous infusion, subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; June 2024.
10. Selarsdi® intravenous infusion, subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; October 2024.
11. Steqeyma® intravenous infusion, subcutaneous injection [prescribing information]. Incheon, Republic of Korea: Celltrion; December 2024.
12. Yesintek® intravenous infusion, subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; December 2024.
13. Wezlana® intravenous infusion, subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2025.
14. Imuldosa® intravenous infusion, subcutaneous injection [prescribing information]. Raleigh, NC: Accord; October 2025.
15. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025 Dec;169(7):1397-1448.
16. Starjemza™ intravenous infusion, subcutaneous injection [prescribing information]. Guangzhou, Guang dong, China: Bio-Thera; May 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/28/2023
Selected Revision	**Plaque Psoriasis:** For a patient currently taking Stelara subcutaneous, the timeframe for established on therapy was changed from 90 days to 3 months.	03/27/2024
Annual Revision	**Plaque Psoriasis:** In the Note, psoralen plus ultraviolet A light (PUVA) was removed from the examples of traditional systemic therapies. An additional Note was added that a 3-month trial of PUVA counts as a traditional systemic therapy.	07/17/2024
Selected Revision	**Crohn's Disease**: For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Psoriatic Arthritis**: For initial approvals, a requirement that the patient is ≥ 6 years of age was added. **Ulcerative Colitis**: 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
Selected Revision	Policy name was changed to more generally list Ustekinumab Subcutaneous Products; previously policy was specific to Stelara Subcutaneous. Wezlana subcutaneous was added to the policy; the same criteria apply for Wezlana and for Stelara subcutaneous. Wording for a patient currently receiving Stelara subcutaneous was changed to currently receiving ustekinumab subcutaneous. Wording for a patient who had previously received induction with Stelara intravenous was changed to more generally refer to ustekinumab intravenous.	12/18/2024
Selected Revision	Otulfi, Pyzchiva, Selarsdi, Steqeyma, and Yesintek subcutaneous were added to the policy; the same criteria apply for all ustekinumab subcutaneous products.	01/29/2025
Selected Revision	Ustekinumab-ttwe subcutaneous was added to the policy; the same criteria apply as the other ustekinumab subcutaneous products.	02/19/2025
Selected Revision	Ustekinumab subcutaneous (unbranded Stelara) was added to the policy; the same criteria apply as the other ustekinumab subcutaneous products.	04/23/2025
Selected Revision	Ustekinumab-aekn (unbranded Selarsdi) and Imuldosa subcutaneous were added to the policy; the same criteria apply for all ustekinumab subcutaneous products.	06/25/2025
Annual Revision	**Ulcerative Colitis:** For initial therapy, removed the following options of approval: (1) the patient has tried one systemic therapy; (2) the patient has pouchitis and tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema.	07/23/2025
Selected Revision	**Plaque Psoriasis:** For initial therapy, in the Note, a 3-month trial or prior intolerance to Otezla/Otezla XR (apremilast tablets/extended-release tablets), or Sotyktu (deucravacitinib tablets) was added as an exception to the requirement for a trial of one traditional systemic agent for psoriasis. For initial therapy, the requirement "patient has a contraindication to methotrexate, as determined by the prescriber" was modified to "according to the prescriber, the patient has a contraindication to methotrexate". In the Appendix, Otezla XR (apremilast extended-release tablets) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecular Drugs.	10/29/2025
Selected Revision	Starjemza subcutaneous injection was added to the policy; the same criteria apply as the other ustekinumab subcutaneous products.	11/05/2025
Selected Revision	Ustekinuman-aauz subcutaneous injection was added to the policy; the same criteria apply as the other ustekinumab subcutaneous products. **Crohn's Disease:** For initial therapy, the following options of approval were removed: The patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated; patient has tried one conventional systemic therapy for Crohn's disease along with the associated Note; patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence).	02/11/2026

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
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, 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		
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.