

Drug Policy

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| Policy: | 201012 | Initial Effective Date: 12/22/2010 Annual Review Date: 02/19/2026 Last Revised Date: 02/19/2026 |
| Code(s): | HCPCS J3357, J3358 | |
| SUBJECT: | Stelara™ (ustekinumab for subcutaneous [SC] injection – Janssen Biotech) Imuldosa® (ustekinumab-srlf subcutaneous injection – Accord) Otulfi™ (ustekinumab-aaaz subcutaneous injection – Formycon/Fresenius) Pyzchiva™ (ustekinumab-ttwe subcutaneous injection – Sandoz/Samsung) Selarsdi (ustekinumab-aekn subcutaneous injection – Alvotech/Teva) Steqeyma™ (ustekinumab-stba subcutaneous injection – Celltrion) Starjemza (Ustekinumab-hmny) Wezlana (ustekinumab-auub subcutaneous injection – Amgen) Yesintek™ (ustekinumab-kfce subcutaneous injection – Biocon) Ustekinumab subcutaneous injection (Janssen Biotech) Ustekinumab-aekn subcutaneous injection (Teva) ustekinumab-ttwe subcutaneous injection (Quallent) *-denotes not yet launched | |

Subject to: Site of Care
 Medication Sourcing

Prior approval is required for some or all of the procedure codes listed in this Corporate Medical Policy.

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Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider’s office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please [click here](#).

Overview

Ustekinumab subcutaneous, an interleukin-12/23 blocker, is indicated for the following uses:^{1,8-14}

- **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.

POLICY STATEMENT

This policy involves the use of ustekinumab. Prior authorization is recommended for medical benefit coverage of ustekinumab. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with ustekinumab as well as the monitoring required for AEs and long-term efficacy, initial approval requires ustekinumab be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. Ustekinumab SC is subject to the **Inflammatory Conditions Care Value Step Therapy**.

Preferred and Non-Preferred Products.

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| Step 1 Preferred Products | <ul style="list-style-type: none"> • Imuldosa SC • Selarsdi SC • ustekinumab-ttwe SC • Yesintek SC |
| Step 2 Non-Preferred Products (directed to ONE Preferred Product) [documentation required] | <ul style="list-style-type: none"> • Stelara SC |
| Non-Preferred Products (directed to ALL of the Preferred Products) [documentation required] | <ul style="list-style-type: none"> • Otulfi SC/Ustekinumab-aaaz • Pyzchiva SC • Starjemza SC • Steqeyma SC |

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| | <ul style="list-style-type: none"> • Ustekinumab SC • Ustekinumab-aekn SC • Wezlana SC |
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SC – subcutaneous.

THIS APPLIES TO PHARMACY BENEFIT ONLY

Food and Drug Administration (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 the following criteria (i, ii, iii and iv):
 - 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 patient meets one of the following (a, b, c, or d):
 - a. The patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
 - b. The patient has tried one conventional systemic therapy for Crohn’s disease; OR
Note: Examples of conventional systemic therapy for Crohn’s disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for Crohn’s disease. A patient who has already received a biologic is not required to “step back” and try another agent.
 - c. Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - d. Patient had ileocolonic resection (to reduce the chance of Crohn’s disease recurrence); AND
 - iv. The medication is prescribed by or in consultation with a gastroenterologist; OR
 - B) Patient is Currently Receiving Ustekinumab SC. 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.

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Approval Duration

Initial Approval = 6 months (180 days)

Re-authorization = 1 year (365 days)

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 A for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis, Otezla/Otezla XR, or Sotyktu 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.

Dosing in Plaque Psoriasis.

- Adult Subcutaneous Recommended Dosage

| Weight Range (kilograms) | Recommended Dosage |
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| Less than or equal to 100 kg | 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks |
| greater than 100 kg | 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks |

- **Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage**
 - Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

| Weight Range (kilograms) | Recommended Dosage |
|--|--------------------|
| Less than 60 kg (Not applicable to Slearsdi) | 0.75 mg/kg |
| 60 kg to 100 kg | 45 mg |
| Greater than 100 kg | 90 mg |

Approval Duration

Initial Approval = 3 months (90 days)

Re-authorization = 1 year (365 days)

- 3. Psoriatic Arthritis (PsA):** 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 \geq 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).

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- 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 in Psoriatic Arthritis.

- Adult Subcutaneous Recommended Dosage
 - The recommended dosage is 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks
 - For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, The recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks
- Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage
 - Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

| Weight Range (kilograms) | Recommended Dosage |
|--|--------------------|
| Less than 60 kg (Not applicable to Slearsdi) | 0.75 mg/kg |
| 60 kg to 100 kg | 45 mg |
| Greater than 100 kg with co-existent moderate-to-severe plaque psoriasis | 90 mg |

Approval Duration

Initial Approval = 6 months (180 days)

Re-authorization = 1 year (365 days)

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 \geq 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

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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.

Approval Duration

Initial Approval = 6 months (180 days)

Re-authorization = 1 year (365 days)

CRITERIA NOT RECOMMENDED FOR APPROVAL:

Ustekinumab has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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 inhibitors (TNFis) 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. In addition, 55% of patients (95% CI: 32%, 77%; n = 11/20) achieved at least a 50% improvement of the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index). 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. **Concurrent use with Otezla.** No evidence to suggest that combination use of Otezla with ustekinumab is superior to monotherapy.
4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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Documentation Requirements:

The Company reserves the right to request additional documentation and to deny reimbursement when it has determined that the services performed were not medically necessary, investigational and/or a pattern of practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.

Prior approval is required for HCPCS Code J3357, J3358

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Edits and Denials:

Prior Approval: Prior approval is required for Stelara (HCPCS Code J3357 and J3358). Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician consultant for review if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J3357 and J3358** will edit with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

| HCPCS Code(s): | |
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| J3357 | Ustekinumab, for subcutaneous injection, 1 mg |
| J3358 | Ustekinumab, for Intravenous Injection, 1 mg (Effective date 1/1/2018) |

Appendix A

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

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| 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 | UC, CD |
| Ustekinumab Products (Stelara® SC injection, biosimilar; Stelara® IV infusion, 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 |
| Ilumya™ (tildrakizumab-asmm 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.