

# **PRIOR AUTHORIZATION POLICY**

**POLICY:** Inflammatory Conditions – Skyrizi Subcutaneous Prior Authorization

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• Skyrizi<sup>®</sup> (risankizumab-rzaa subcutaneous injection – Abbvie)

**REVIEW DATE:** 06/25/2025

#### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS, COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

# CIGNA NATIONAL FORMULARY COVERAGE:

### **OVERVIEW**

Skyrizi subcutaneous (SC), an interleukin (IL)-23 blocker, is indicated for the following uses:

- Crohn's disease, in patients with moderate to severe active disease.
- **Plaque psoriasis**, for the treatment of adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- Psoriatic arthritis, for treatment of adults with active disease.
- Ulcerative colitis, in adults with moderate to severe active disease.

Skyrizi is also available in an intravenous (IV) formulation that is indicated only in Crohn's disease and ulcerative colitis. It is administered as an IV infusion at Weeks 0, 4, and 8 for induction, followed by Skyrizi SC once every 8 weeks thereafter for maintenance. Skyrizi SC is available as a 180 mg or 360 mg single-dose prefilled cartridge for use with an on-body injector for use in Crohn's disease and ulcerative colitis. For other conditions, Skyrizi is available as a 150 mg single-dose prefilled pen and as a 75 mg or 150 mg prefilled syringe.

### **Guidelines**

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

- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] has guidelines for the management of Crohn's disease in adults.<sup>5</sup> In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio, IL-23 inhibitors, IL-12/23 inhibitors, and Rinvoq. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Guidelines from the American Gastroenterological Association (2021) include various biologics among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.<sup>6</sup>
- **Plaque Psoriasis:** Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) for management of psoriasis with biologics have been published.<sup>2</sup> These guidelines list Skyrizi as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (2025) recommend biologics (including Skyrizi SC) as second-line therapy for most patients requiring systemic treatment when there is inadequate response, contraindication, or intolerance to conventional systemic agents (e.g., methotrexate, cyclosporine, acitretin).<sup>3</sup>
- Psoriatic Arthritis: Guidelines from the American College of Rheumatology (2019) recommend TNF inhibitors over other biologics for use in treatment-naïve patients with psoriatic arthritis and in those who were previously treated with an oral therapy.<sup>4</sup>
- **Ulcerative colitis (UC):** The American Gastroenterological Association (AGA) [2024] and the ACG (2025) have clinical practice guidelines on the management of moderate to severe UC.<sup>7,8</sup> 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. 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 Skyrizi SC. 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 patients treated with Skyrizi SC as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Skyrizi SC to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Skyrizi® (risankizumab-rzaa subcutaneous injection – Abbvie)

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

# **FDA-Approved Indications**

**1. Crohn's Disease.** Approve Skyrizi Subcutaneous (<u>on-body injector</u>) for the duration noted if the patient meets ONE of the following (A <u>or</u> B):

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- **A)** <u>Initial Therapy</u>. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, <u>and</u> iv):
  - i. Patient is  $\geq$  18 years of age; AND
  - **ii.** According to the prescriber, the patient will receive induction dosing with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous; AND
  - **iii.** Patient meets ONE of the following (a, b, c, or d):
    - **a)** Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
      Note: Examples of corticosteroids are prednisone or methylprednisolone.
    - **b)** Patient has tried one other conventional systemic therapy for Crohn's disease; OR
      - <u>Note</u>: 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 medication. A biosimilar of the requested biologic <u>does not count</u>. Refer to <u>Appendix</u> for examples of biologics used for Crohn's disease. A trial of mesalamine does <u>not</u> count as a systemic agent for Crohn's disease.
    - 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 Skyrizi 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 <a href="Note">Note</a>: 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 Skyrizi); 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 Skyrizi), 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 Skyrizi Subcutaneous (<u>pens or syringes</u>) for the duration noted if the patient meets ONE of the following (A or B):
  - **A)** <u>Initial Therapy</u>. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
    - i. Patient is ≥ 18 years of age; AND
    - **ii.** Patient meets ONE of the following (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 for psoriasis include methotrexate, cyclosporine, or acitretin tablets. 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 already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
- **b)** Patient has a contraindication to methotrexate, as determined by the prescriber; AND
- iii. The medication is prescribed by or in consultation with a dermatologist; OR
- **B)** Patient is Currently Receiving Skyrizi 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 <u>Note</u>: 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 Skyrizi Subcutaneous (<u>pens or syringes</u>) for the duration noted if the patient meets ONE of the following (A <u>or</u> B):
  - **A)** <u>Initial Therapy</u>. 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 Skyrizi 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 <a href="Note">Note</a>: A patient who has received < 6 months of therapy or who is restarting therapy with Skyrizi 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 Skyrizi); OR <a href="Note">Note</a>: Examples of objective 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 Skyrizi), 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; or decreased soft tissue swelling in joints or tendon sheaths.
- **4. Ulcerative Colitis.** Approve Skyrizi Subcutaneous (<u>on-body injector</u>) for the duration noted if the patient meets ONE of the following (A <u>or</u> B):
  - **A)** <u>Initial Therapy</u>. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, <u>and</u> iv):

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- i. Patient is ≥ 18 years of age; AND
- **ii.** According to the prescriber, the patient will receive three induction doses with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous; AND
- **iii.** Patient meets ONE of the following (a <u>or</u> b):
  - a) Patient has had a trial of one systemic agent for ulcerative colitis; OR Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for ulcerative colitis.
  - **b)** Patient meets BOTH of the following [(1) and (2)]:
    - (1) Patient has pouchitis; AND
    - (2) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND

<u>Note</u>: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

- iv. The medication is prescribed by or in consultation with a gastroenterologist; OR
- **B)** Patient is Currently Receiving Skyrizi 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 <u>Note</u>: 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
      - <u>Note</u>: 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.
- Skyrizi<sup>®</sup> (risankizumab-rzaa subcutaneous injection Abbvie)

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

#### **CONDITIONS NOT COVERED**

1. 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 <a href="Appendix">Appendix</a> 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.

<u>Note</u>: This does NOT exclude the use of conventional synthetic disease-modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

#### REFERENCES

- 1. Skyrizi<sup>®</sup> subcutaneous injection or intravenous infusion [prescribing information]. North Chicago, IL: AbbVie; May 2025.
- 2. 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.
- Nast A, Spuls PI, Dressler C, et al. EuroGuiDerm guideline for the systemic treatment of psoriasis vulgaris. Updated February 2025. Available at: <a href="https://www.guidelines.edf.one/guidelines/psoriasis-guideline">https://www.guidelines.edf.one/guidelines/psoriasis-guideline</a>. Accessed on: 06/13/2025.
- 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. 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.
- 6. 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.
- 7. 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.
- 8. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol.* 2025 June;120(6):1187-1224.

### **HISTORY**

| Type of<br>Revision  | Summary of Changes  | Review<br>Date |
|----------------------|---|----------------|
| Annual<br>Revision   | No criteria changes.  | 06/22/2023     |
| Selected<br>Revision | <b>Plaque Psoriasis:</b> For a patient currently taking Skyrizi subcutaneous, the timeframe for established on therapy was changed from 90 days to 3 months.  | 03/27/2024     |
| Annual<br>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.  Ulcerative colitis: The newly approved indication was added to the policy   | 06/26/2024     |
| Selected<br>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 ≥ 18 years of age was added.  Conditions Not Covered  : 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<br>Revision   | No criteria changes.  | 06/25/2025     |

# **APPENDIX**

| Biologics   Adalimumab SC Products (Humira®, biosimilars)   Inhibition of TNF   AS, CD, JIA, PsO, PsA, RA, Ucinjection)   Inhibition of TNF   AS, CD, nr-axSpA, PsO, PsA, RA   | APPENDIX                               | Machanian C 4 ::       | Francisco of Tarlian *       |
|--|--|------------------------|------------------------------|
| Adalimumab SC Products (Humira®, biosimilars)   Inhibition of TNF   AS, CD, JIA, PsO, PsA, RA, Ubiosimilars   Cimzia® (certolizumab pegol SC injection)   Inhibition of TNF   AS, CD, nr-axSpA, PsO, PsA, RA   Inhibition of TNF   AS, CD, nr-axSpA, PsO, PsA, RA   Inhibition of TNF   AS, JIA, PsO, PsA, RA   Inhibition of TNF   AS, JIA, PsO, PsA, RA   Inhibition of TNF   AS, JIA, PsO, PsA, RA   Inhibition of TNF   AS, CD, PsO, PsA, RA   Inhibition of TNF   Inhibition of TNF   AS, CD, PsO, PsA, RA   Inhibition of TNF   Inhibi   | Distantes                              | Mechanism of Action    | Examples of Indications*     |
| Cimzia® (certolizumab pegol SC injection)         Inhibition of TNF RA         AS, CD, nr-axSpA, PsO, PsA, RA           Etanercept SC Products (Enbrel®, biosimilars)         Inhibition of TNF Diosimilars         AS, JIA, PsO, PsA, RA           Infliximab IV Products (Remicade®, biosimilars)         Inhibition of TNF Diosimilars         AS, CD, PsO, PsA, RA, UC           Zymfentra® (infliximab-dyyb SC injection)         Inhibition of TNF Diosimilars         SC formulation: AS, PsA, RA, UC           Tocilizumab SC injection, golimumab SC injection, diosimilar; Actemra SC, biosimilar)         Inhibition of IL-6         SC formulation: AS, PsA, RA, SIIA           Kevzara® (sarilumab SC injection)         Inhibition of IL-6         RA         SC formulation: PJIA, RA, SJIA           Orencia® (abatacept IV infusion, abatacept SC injection)         T-cell costimulation modulator         SC formulation: JIA, PSA, RA           Rituximab IV Products (Rituxan®, biosimilars)         Inhibition of IL-1         JIA*, RA           Kineret® (anakinra SC injection)         Inhibition of IL-1         JIA*, RA           Omvoh® (mirikizumab IV infusion, secukinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)         Inhibition of IL-12/23         SC formulation: CD, UC           Silia® (broadalumab SC injection)         Inhibition of IL-17A         AS, nr-axSpA, PsA, PsA           Taltz® (ixekizumab SC injection)         Inhibition of IL-17A         AS, nr-axSpA, PsA         PsO, AS,  |  | Tabibition of TNE      | AC CD IIA D-O D A DA ''C     |
| Injection   RA   RA   Stanercept SC Products (Enbrel®, biosimilars)   Infiliximab IV Products (Remicade®, biosimilars)   Infiliximab IV Products (Remicade®, biosimilars)   Inhibition of TNF   AS, CD, PsO, PsA, RA, UC   Diosimilars   Inhibition of TNF   AS, CD, PsO, PsA, RA, UC   Inhibition of TNF   CD, UC   Inhibition of TNF   SC formulation: AS, PsA, RA   UC   IV formulation: PsIIA, RA, SiIIA   IV formulation: PsiIA, PsA, RA   IV formulation: PsiIA, PsA, RA   Rabatacept SC injection)   T-cell costimulation   SC formulation: JiIA, PsA, RA   Rituximab IV Products (Rituxan®, biosimilars)   IV formulation: JiIA, PsA, RA   RA   IV formulation: JiIA, PsA, RA   IV formulation: CD, UC   Inhibition of IL-1   IV formulation: CD, UC   Inhibition of IL-12/23   SC formulation: CD, UC   Siliq® (brodalumab SC injection)   Inhibition of IL-17A   SC formulation: As, RA, nr-axSpA, PsO, PsA   IV formulation: As, RA, nr-axSpA, PsO, PsA   INhibition of IL-17A   PsO   Inhibition of IL-17A   PsO   Inhibition of IL-23   SC formulation: CD, UC   Inhibition of IL-23   SC formulation: CD, PSA, PSO, UC   IV formulation: CD, UC   IV for   | biosimilars)                           |                        |                              |
| Etanercept SC Products (Enbrel®, biosimilars)  |  | Inhibition of TNF      | RA                           |
| Infliximab IV Products (Remicade®, biosimilars)  | Etanercept SC Products (Enbrel®,       | Inhibition of TNF      |                              |
| Zymfentra® (infliximab-dyyb SC injection)  | Infliximab IV Products (Remicade®,     | Inhibition of TNF      | AS, CD, PsO, PsA, RA, UC     |
| SC injection, golimumab IV infusion)  Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)  Kevzara® (sarilumab SC injection)  Orencia® (abatacept IV infusion, abatacept SC injection)  Kineret® (anakinra SC injection)  Ormoh® (mirikizumab IV infusion, biosimilar; Stelara SC, biosimilar)  Inhibition of IL-1  Ormoh® (mirikizumab IV infusion, sC injection)  Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)  Inhibition of IL-12/23  SC formulation: JIA, PSA, RA  RA  CD20-directed cytolytic antibody  Kineret® (anakinra SC injection)  Inhibition of IL-1  JIA^, RA  CD, UC  Inhibition of IL-12/3  SC formulation: CD, PSO, PSA, UC  IV formulation: CD, UC  Siliq® (brodalumab SC injection)  Cosentyx® (secukinumab SC injection)  Inhibition of IL-17A  SSC formulation: AS, RRA, nr-axSpA, PSA  IV formulation: AS, nr-axSpA, PSA  IV formulation: AS, nr-axSpA, PSA  IV formulation: AS, nr-axSpA, PSA  Inhibition of IL-17A  AS, nr-axSpA, PSA  Ilmya® (tildrakizumab-bkzx SC injection)  Inhibition of IL-23  injection)  Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)  Inhibition of IL-23  Inhibition of IL-23  Inhibition of IL-23  Inhibition of IL-23  SC formulation: CD, PSA, PSO, UC  IV formulation: CD, PSA, PSO, UC  IV formulation: CD, PSA, PSO, UC   | Zymfentra® (infliximab-dyyb SC         | Inhibition of TNF      | CD, UC                       |
| Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)    Revzara® (sarilumab SC injection)  | Simponi®, Simponi Aria® (golimumab     | Inhibition of TNF      |                              |
| biosimilar; Actemra SC, biosimilar)    SJIA   IV formulation: PJIA, RA, SJIA   IV formulation: PJIA, RA, SJIA  |  |                        | PsA, RA                      |
| SJIA   |  | Inhibition of IL-6     | SJIA                         |
| Orencia® (abatacept IV infusion, abatacept SC injection)T-cell costimulation modulatorSC formulation: JIA, PSA, RARituximab IV Products (Rituxan®, biosimilars)CD20-directed cytolytic antibodyRAKineret® (anakinra SC injection)Inhibition of IL-1JIA^, RAOmvoh® (mirikizumab IV infusion, SC injection)Inhibition of IL-23CD, UCUstekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)Inhibition of IL-12/23SC formulation: CD, PSO, PSA, UC<br>IV formulation: CD, UCSiliq® (brodalumab SC injection)Inhibition of IL-17PSOCosentyx® (secukinumab SC injection; secukinumab IV infusion)Inhibition of IL-17ASC formulation: AS, ERA, nr. axSpA, PsO, PsA<br>IV formulation: AS, nr. axSpA, PsO, PsATaltz® (ixekizumab SC injection)Inhibition of IL-17AAS, nr-axSpA, PsO, PsABimzelx® (bimekizumab-bkzx SC injection)Inhibition of IL-17APsO, AS, nr-axSpA, PsO, PsAIlumya® (tildrakizumab-asmn SC injection)Inhibition of IL-23PsOSkyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)Inhibition of IL-23SC formulation: CD, PSA, PsO, UCIV formulation: CD, UC  |  |                        |                              |
| abatacept SC injection)  Rituximab IV Products (Rituxan®, biosimilars)  Kineret® (anakinra SC injection)  Comvoh® (mirikizumab IV infusion, SC injection)  Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)  Ustekinumab SC injection)  Inhibition of IL-12  SC formulation: CD, PsO, PsA, UC  IV formulation: CD, UC  Siliq® (brodalumab SC injection)  Cosentyx® (secukinumab SC injection; secukinumab IV infusion)  Inhibition of IL-17  Foo  Cosentyx® (ixekizumab SC injection)  Inhibition of IL-17A  SC formulation: AS, ERA, nr. axSpA, PsO, PsA  IV formulation: AS, nr-axSpA, PsO, PsA  IV formulation: AS, nr-axSpA, PsO, PsA  Inhibition of IL-17A  Bimzelx® (bimekizumab-bkzx SC injection)  Inhibition of IL-17B  Ilumya® (tildrakizumab-asmn SC injection)  Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)  Inhibition of IL-23  SC formulation: D, PsO, PsO, PsO, PsO, PsO, PsO, PsO, PsO   |  |                        | RA                           |
| Rituximab IV Products (Rituxan®, biosimilars)  | Orencia® (abatacept IV infusion,       | T-cell costimulation   | SC formulation: JIA, PSA, RA |
| Biosimilars   Action   Biosimilars   Biosimilars   Biosimilars   Biosimilars   Biosimilars   Biosimilar   B   | abatacept SC injection)                | modulator              | IV formulation: JIA, PsA, RA |
| Kineret® (anakinra SC injection)Inhibition of IL-1JIA^, RAOmvoh® (mirikizumab IV infusion, SC injection)Inhibition of IL-23CD, UCUstekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)Inhibition of IL-12/23SC formulation: CD, PsO, PsA, UCSiliq® (brodalumab SC injection)Inhibition of IL-17PsOCosentyx® (secukinumab SC injection; secukinumab IV infusion)Inhibition of IL-17ASC formulation: AS, ERA, nr. axSpA, PsO, PsATaltz® (ixekizumab SC injection)Inhibition of IL-17AAS, nr-axSpA, PsO, PsABimzelx® (bimekizumab-bkzx SC injection)Inhibition of IL-17APsO, AS, nr-axSpA, PsO, PsAIlumya® (tildrakizumab-asmn SC injection)Inhibition of IL-23PsOSkyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)Inhibition of IL-23SC formulation: CD, PSA, PsO, UCIV formulation: CD, UC  |  |                        | RA                           |
| Omvoh® (mirikizumab IV infusion, SC injection)Inhibition of IL-23CD, UCUstekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)Inhibition of IL-12/23SC formulation: CD, PsO, PsA, UCSiliq® (brodalumab SC injection)Inhibition of IL-17PsOCosentyx® (secukinumab SC injection; secukinumab IV infusion)Inhibition of IL-17ASC formulation: AS, ERA, nraxSpA, PsO, PsATaltz® (ixekizumab SC injection)Inhibition of IL-17AAS, nr-axSpA, PsO, PsABimzelx® (bimekizumab-bkzx SC injection)Inhibition of IL-17APsO, AS, nr-axSpA, PsO, PsAIlumya® (tildrakizumab-asmn SC injection)Inhibition of IL-23PsOSkyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)Inhibition of IL-23SC formulation: CD, PSA, PsO, UCIV formulation: CD, UC  | Kineret® (anakinra SC injection)       |                        | JIA^, RA                     |
| Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)Inhibition of IL-12/23SC formulation: CD, PsO, PsA, UC IV formulation: CD, UCSiliq® (brodalumab SC injection)Inhibition of IL-17PsOCosentyx® (secukinumab SC injection; secukinumab IV infusion)Inhibition of IL-17A IV formulation: AS, ERA, nr-axSpA, PsO, PsA IV formulation: AS, nr-axSpA, PsO, PsA IV formulation: AS, nr-axSpA, PsO, PsA INhibition of IL-17A INhibition of IL-17A INhibition of IL-17A IIumya® (tildrakizumab-asmn SC injection)Inhibition of IL-23 INhibition of IL-23PsOSkyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)Inhibition of IL-23 INhibition of IL-23 INhibition: CD, PSA, PsO, UCSC formulation: CD, PSA, PsO, UC  | Omvoh® (mirikizumab IV infusion, SC    |                        |                              |
| Siliq® (brodalumab SC injection)Inhibition of IL-17PsOCosentyx® (secukinumab SC injection; secukinumab IV infusion)Inhibition of IL-17ASC formulation: AS, ERA, nr. axSpA, PsO, PsATaltz® (ixekizumab SC injection)Inhibition of IL-17AAS, nr-axSpA, PsO, PsABimzelx® (bimekizumab-bkzx SC injection)Inhibition of IL-17APsO, AS, nr-axSpA, PsAIlumya® (tildrakizumab-asmn SC injection)Inhibition of IL-23PsOSkyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)Inhibition of IL-23SC formulation: CD, PSA, PsO, UCIV formulation: CD, UC  |  | Inhibition of IL-12/23 | PsA, UC                      |
| Cosentyx® (secukinumab SC injection;<br>secukinumab IV infusion)Inhibition of IL-17ASC formulation: AS, ERA, nr-<br>axSpA, PsO, PsATaltz® (ixekizumab SC injection)Inhibition of IL-17AAS, nr-axSpA, PsO, PsABimzelx® (bimekizumab-bkzx SC<br>injection)Inhibition of IL-<br>17A/17FPsO, AS, nr-axSpA, PsAIlumya® (tildrakizumab-asmn SC<br>injection)Inhibition of IL-23PsOSkyrizi® (risankizumab-rzaa SC<br>injection, risankizumab-rzaa IV infusion)Inhibition of IL-23SC formulation: CD, PSA,<br>PSO, UCIV formulation: CD, UC  |  |                        |                              |
| secukinumab IV infusion)    axSpA, PsO, PsA     IV formulation: AS, nr-axSpA, PsA     IV formulation: AS, nr-axSpA, PsA     IV formulation: AS, nr-axSpA, PsA     Inhibition of IL-17A     AS, nr-axSpA, PsO, PsA     Inhibition of IL-17A     Inhibition of IL-17A     Inhibition of IL-17A     Inhibition of IL-23     Inhibition of IL-23     Inhibition of IL-23     SC formulation: CD, PSA, PsO, UC     IV formulation: CD, UC     I |  |                        |                              |
| Taltz® (ixekizumab SC injection)  Bimzelx® (bimekizumab-bkzx SC injection)  Ilumya® (tildrakizumab-asmn SC injection)  Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)  As, nr-axSpA, PsO, PsA PsO, AS, nr-axSpA, PsA  PsO, AS, nr-axSpA, PsA  PsO  Inhibition of IL-23  SC formulation: CD, PSA, PsO, UC  IV formulation: CD, UC   |  | Inhibition of IL-17A   | axSpA, PsO, PsA              |
| Bimzelx® (bimekizumab-bkzx SC injection)Inhibition of IL- 17A/17FPsO, AS, nr-axSpA, PsAIlumya® (tildrakizumab-asmn SC injection)Inhibition of IL-23PsOSkyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)Inhibition of IL-23SC formulation: CD, PSA, PsO, UCInhibition of IL-23Inhibition of IL-23Inhibition of IL-23   |  |                        | axSpA, PsA                   |
| injection)  Ilumya® (tildrakizumab-asmn SC injection)  Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)  Inhibition of IL-23  SC formulation: CD, PSA, PSO, UC  IV formulation: CD, UC   |  |                        |                              |
| injection)  Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)  Inhibition of IL-23 SC formulation: CD, PSA, PsO, UC IV formulation: CD, UC  | injection)                             |                        | PsO, AS, nr-axSpA, PsA       |
| injection, risankizumab-rzaa IV infusion)  PsO, UC  IV formulation: CD, UC   |  | Inhibition of IL-23    | PsO                          |
|  |  | Inhibition of IL-23    | PsO, UC                      |
| Tremfya® (guselkumab SC injection, Inhibition of IL-23 SC formulation: CD, PsA,  |  |                        |                              |
| guselkumab IV infusion) PsO, UC  |  | Inhibition of IL-23    | PsO, UC                      |
| IV formulation: CD, UC   |  |                        |                              |
| Entyvio® (vedolizumab IV infusion,<br>vedolizumab SC injection)Integrin receptor<br>antagonistCD, UC   | vedolizumab SC injection)              | antagonist             |                              |
| Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs  |  |                        |                              |
| Otezla® (apremilast tablets)Inhibition of PDE4PsO, PsA   |  | Inhibition of PDE4     | PsO, PsA                     |
| Cibinqo™ (abrocitinib tablets)Inhibition of JAK<br>pathwaysAD  | <b>Cibinqo</b> ™ (abrocitinib tablets) |                        | AD                           |
| Olumiant® (baricitinib tablets)  Inhibition of JAK pathways  RA, AA  | Olumiant® (baricitinib tablets)        | Inhibition of JAK      | RA, AA                       |

| Inhibition of JAK  | AA  |
|--------------------|---|
| pathways           |   |
| Inhibition of JAK  | AA  |
| pathways           |   |
| Inhibition of JAK  | AD, AS, nr-axSpA, RA, PsA,  |
| pathways           | CD, UC  |
| Inhibition of JAK  | PsA, PJIA   |
| pathways           | ·   |
| Inhibition of TYK2 | PsO   |
| Inhibition of JAK  | RA, PJIA, PsA, UC   |
| pathways           |   |
| Inhibition of JAK  | RA, PsA, UC   |
| pathways           |   |
| Sphingosine 1      | UC  |
| phosphate receptor |   |
| modulator          |   |
| Sphingosine 1      | UC  |
| phosphate receptor |   |
| modulator          |   |
|                    | pathways Inhibition of JAK pathways Inhibition of JAK pathways Inhibition of JAK pathways Inhibition of TYK2 Inhibition of JAK pathways Inhibition of JAK pathways Inhibition of JAK pathways Sphingosine 1 phosphate receptor modulator Sphingosine 1 phosphate receptor |

<sup>\*</sup> 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

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