# Skyrizi® (risankizumab-rzaa)

## Clinical summary[1]

Treatment of immune disorders is complex, and highly dependent on level of disease (minimal, mild, or moderate to severe), level of disease activity (such as highly active) and comorbid conditions such as obesity, depression, anxiety, presence of cardiovascular disease or other inflammatory diseases (such as inflammatory bowel disease) and, in the case of joint involvement, the area or areas of the body that are impacted.[2] Treatment decisions should align with the patient's goals and preferences, emphasizing shared decision-making in selecting the treatment target. Patients may also have specific preferences regarding medications, including factors such as the route of administration, dosing frequency, and potential side effects.[3]

### Clinical comparison

*Table 1 Clinical comparison of the review drug and its therapeutic alternatives*

| Drug | Indications | | | | Biosimilar availability |
|---|---|---|---|---|---|
| | Plaque psoriasis | Psoriatic arthritis | Crohn's disease | Ulcerative colitis | |
| **Skyrizi** | Yes | Yes | Yes | Yes | ~2028 |
| **Bimzelx** | Yes | Yes | - | - | - |
| **Cosentyx** | Yes | Yes | - | - | Pending Approval |
| **Enbrel** | Yes | Yes | - | - | Approved, expected launch ~2029 |
| **Entyvio** | - | - | Yes | Yes | Erelzi and Eticovo approved, expected launch ~2029 |
| **Humira** | Yes | Yes | Yes | Yes | Several launched 2023 |
| **Ilumya** | Yes | - | - | - | - |

[1] This summary focuses on the use of systemic therapy, specifically the biologic agents used in treatment and identified in Table 1. For purposes of the clinical reviews, the alternatives are limited to those identified by the board. There are other alternatives that may also be appropriate, including drugs approved after the alternatives were selected.

[2] Ritchlin C, Ogdie A. Treatment of peripheral psoriatic arthritis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)

[3] Orbai, A, Scher J. Treatment of arthritis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)

| Drug | Indications | | | | Biosimilar availability |
|---|---|---|---|---|---|
| | Plaque psoriasis | Psoriatic arthritis | Crohn's disease | Ulcerative colitis | |
| **Omvoh** | - | - | * | Yes | - |
| **Remicade** | Yes | Yes | Yes | Yes | Several launched 2016 |
| **Stelara** | Yes | Yes | Yes | Yes | * |
| **Taltz** | Yes | Yes | - | - | - |
| **Tremfya** | Yes | Yes | * | Yes | - |
| *See Notes for additional information | | | | | |

## Significant developments

Not all indications are included in the table; all comparisons are based upon the label in effect at the time of the drug's selection by the board for review in 2024. Therapeutic alternatives do not include any new molecular entities approved after 2024 or other agents (same or different class) that may also be approved for the reviewed indications. The following updates were made to Skyrizi or an identified therapeutic alternative after 2024.

- Skyrizi was approved for pediatric plaque psoriasis and psoriatic arthritis in 2025.
- Stelara biosimilars were launched in 2025.
- Omvoh and Tremfya were approved for Crohn's disease in adults in 2025.
- Omvoh received approval for new subcutaneous strengths and devices in 2025.
- Pediatric indications for Tremfya for plaque psoriasis and psoriatic arthritis were added in 2025.
- Pediatric indications for Skyrizi for plaque psoriasis and psoriatic arthritis were added in 2026.
- Stelara received a pediatric Crohn's disease indication in 2026.

Additional information on the drug and therapeutic equivalents is included in Appendix A.

# Appendix A: Clinical information

## Drug indications[4]

- FDA approved:
    - Skyrizi is an interleukin-23 antagonist indicated for the treatment of:
        - moderate-to-severe **plaque psoriasis (PsO)** in adults who are candidates for systemic therapy or phototherapy.
        - active **psoriatic arthritis (PsA)** in adults and pediatric patients 6 years of age and older.
        - moderately to severely active **Crohn's disease (CD)** in adults.
        - moderately to severely active **ulcerative colitis (UC)** in adults.

## Clinical efficacy

**Efficacy in moderate-to-severe plaque psoriasis**

Two multicenter, randomized, double-blind trials (PsO-1 and PsO-2) enrolled 997 subjects 18 years of age and older with moderate-to-severe plaque psoriasis, who received treatment at Weeks 0, 4, and every 12 weeks thereafter. Both trials assessed the responses at Week 16 compared with placebo for the two co-primary endpoints: the proportion of subjects who achieved an sPGA score of 0 (“clear”) or 1 (“almost clear”) and the proportion of subjects who achieved at least a 90% reduction from baseline PASI (PASI 90).[5,6]

*Table 2 Clinical Efficacy in Plaque Psoriasis in Adults*

| Endpoint | PsO-1 | | PsO-2 | |
|---|---|---|---|---|
| | Skyrizi | Placebo | Skyrizi | Placebo |
| | N=304 | N=102 | N=294 | N=98 |
| **sPGA 0 or 1 ("clear or almost clear"), n (%)** | 267 (88) | 8 (8) | 246 (84) | 5 (5) |
| **PASI 90, n (%)** | 229 (75) | 5 (5) | 220 (75) | 2 (2) |

[4] U.S. Food & Drug Administration. Skyrizi (risankizumab-rzaa) Prescribing Information. AbbVie Inc., Revised 06/2024.
[5] BI 655066 (Risankizumab) Compared to Placebo and Active Comparator (Ustekinumab) in Patients With Moderate to Severe Chronic Plaque Psoriasis. Retrieved from https://clinicaltrials.gov/study/NCT02684370?term=NCT02684370&viewType=Card&rank=1
[6] BI 655066 Versus Placebo & Active Comparator (Ustekinumab) in Patients With Moderate to Severe Chronic Plaque Psoriasis. Retrieved from https://clinicaltrials.gov/study/NCT02684357?term=NCT02684357&viewType=Card&rank=1

Additional studies further demonstrate clinical efficacy in adult patients.[7,8,9]

**Efficacy in active psoriatic arthritis in adults**

The efficacy of Skyrizi was assessed in 1,407 subjects in 2 randomized, double-blind, placebo-controlled trials (PsA-1 and PsA-2) in subjects 18 years and older with active psoriatic arthritis (PsA). For both trials, the primary endpoint was the proportion of subjects who achieved an American College of Rheumatology (ACR) 20 response at Week 24. In both trials, treatment with Skyrizi resulted in significant improvement in measures of disease activity compared with placebo at Week 24.[10,11]

**Efficacy in moderately to severely active Crohn's disease**

In two 12-week induction trials (CD-1 and CD-2), subjects with moderately to severely active Crohn's disease were randomized to receive Skyrizi 600 mg, Skyrizi 1,200 mg, or placebo as an intravenous infusion at Week 0, Week 4, and Week 8. The co-primary endpoints were clinical remission and endoscopic response at Week 12. Onset of clinical response and clinical remission based on CDAI occurred as early as Week 4 in a greater proportion of subjects treated with the Skyrizi 600 mg induction regimen compared to placebo. The Skyrizi 1,200 mg dosage did not demonstrate additional treatment benefit over the 600 mg dosage and is not a recommended regimen.[12]

The maintenance trial CD-3 evaluated 382 subjects who achieved clinical response, defined as a reduction in CDAI of at least 100 points from baseline after 12 weeks of induction treatment with intravenous Skyrizi, in trials CD-1 and CD-2. Subjects were randomized to receive a maintenance regimen of Skyrizi 180 mg or Skyrizi 360 mg or placebo at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks. The co-primary endpoints in CD-3 were clinical remission and endoscopic response at Week 52. Endoscopic remission was observed at Week 52 in 33% (44/135) of subjects treated with the Skyrizi 180 mg maintenance regimen and 41% (48/117) of subjects treated with the Skyrizi 360 mg maintenance regimen, compared to

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[7] BI 655066 / ABBV-066 (Risankizumab) in Moderate to Severe Plaque Psoriasis With Randomized Withdrawal and Re-treatment. Retrieved from https://clinicaltrials.gov/study/NCT02672852?term=NCT02672852&viewType=Card&rank=1

[8] BI 655066/ABBV-066 (Risankizumab) Compared to Active Comparator (Adalimumab) in Patients With Moderate to Severe Chronic Plaque Psoriasis. Retrieved from https://clinicaltrials.gov/study/NCT02694523?term=NCT02694523&viewType=Card&rank=1

[9] Study to Assess the Safety and Efficacy of Subcutaneously Injected Risankizumab in Adult Participants With Genital or Scalp Psoriasis (UnlIMMited). Retrieved from https://clinicaltrials.gov/study/NCT05969223?term=NCT05969223&viewType=Card&rank=1

[10] A Study Comparing Risankizumab to Placebo in Participants With Active Psoriatic Arthritis (PsA) Who Have a History of Inadequate Response to or Intolerance to at Least One Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy (KEEPsAKE 1). Retrieved from https://clinicaltrials.gov/study/NCT03675308?term=NCT03675308&viewType=Card&rank=1

[11] A Study Comparing Risankizumab to Placebo in Participants With Active Psoriatic Arthritis Including Those Who Have a History of Inadequate Response or Intolerance to Biologic Therapy(Ies) (KEEPsAKE2). Retrieved from https://clinicaltrials.gov/study/NCT03671148?term=NCT03671148&viewType=Card&rank=1

[12] A Study of the Efficacy and Safety of Risankizumab in Participants With Moderately to Severely Active Crohn's Disease. Retrieved from https://clinicaltrials.gov/study/NCT03105128?term=NCT03105128%20&viewType=Card&rank=1

13% (17/130) of subjects treated with placebo. This endpoint was not statistically significant under the prespecified multiple testing procedure.

**Efficacy in moderately to severely active ulcerative colitis**

In the 12-week induction trial (UC-1), 966 subjects with moderately to severely active ulcerative colitis were randomized and received Skyrizi 1,200 mg or placebo as an intravenous infusion at Week 0, Week 4, and Week 8. The primary endpoint was clinical remission defined using the modified Mayo score (mMS) at Week 12. The proportion of subjects who had no nocturnal bowel movements was greater in subjects treated with Skyrizi compared to placebo at Week 12 (67% vs 43%).[13]

The maintenance trial (UC-2) evaluated 547 subjects who received one of three Skyrizi induction regimens, including the 1,200 mg regimen, for 12 weeks in Trials UC-1 or UC-3 and demonstrated clinical response per mMS after 12 weeks. A greater proportion of subjects treated with Skyrizi 180 mg and Skyrizi 360 mg compared to placebo achieved endoscopic remission at Week 52 (23% and 24% vs 15%).[14]

## Clinical safety

- FDA safety warnings and precautions:
    - Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur.
    - Infections: Skyrizi may increase the risk of infection.
    - Tuberculosis (TB): Evaluate for TB prior to initiating treatment with Skyrizi.
    - Hepatotoxicity: Drug-induced liver injury during induction treatment of inflammatory bowel disease has been reported.
    - Immunizations: Avoid use of live vaccines.
- Contraindications:
    - Skyrizi is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients.
- Common side effects:
    - Plaque Psoriasis and Psoriatic Arthritis (≥ 1%): upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.
    - Crohn's Disease (>3%):
        - Induction: upper respiratory infections, headache, and arthralgia.
        - Maintenance: arthralgia, abdominal pain, injection site reactions, anemia, pyrexia, back pain, arthropathy, and urinary tract infection.

[13] A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Participants With Moderately to Severely Active Ulcerative Colitis. Retrieved from https://clinicaltrials.gov/study/NCT03398148?term=NCT03398148&viewType=Card&rank=1

[14] A Study to Assess the Efficacy and Safety of Risankizumab in Participants With Ulcerative Colitis (COMMAND). Retrieved from https://clinicaltrials.gov/study/NCT03398135?term=NCT03398135&viewType=Card&rank=1

- Ulcerative Colitis (≥3%):
  - Induction: arthralgia.
  - Maintenance: arthralgia, pyrexia, injection site reactions, and rash.

## Therapeutic alternatives

*Table 3 Therapeutic alternative classes and selected FDA-approved indications*

| Drug | Class | Indications | | | |
|---|---|---|---|---|---|
| | | Adult PsO | Adult PsA | Adult CD | Adult UC |
| **Skyrizi (risankizumab-rzaa)** | IL-23 antagonist | Yes | Yes | Yes | Yes |
| **Bimzelx (bimekizumab-bkzx)**[15] | IL-17A and F antagonist | Yes | Yes | - | - |
| **Cosentyx (secukinumab)**[16] | IL-17A antagonist | Yes | Yes | - | - |
| **Enbrel (etanercept)**[17] | TNF blocker | Yes | Yes | - | - |
| **Entyvio (vedolizumab)**[18] | Integrin receptor antagonist | - | - | Yes | Yes |
| **Humira (adalimumab)**[19] | TNF blocker | Yes | Yes | Yes | Yes |
| **Ilumya (tildrakizumab-asmn)**[20] | IL-23 antagonist | Yes | - | - | - |
| **Omvoh (mirikizumab-mrkz)**[21] | IL-23 antagonist | - | - | * | Yes |
| **Remicade (infliximab)**[22] | TNF blocker | Yes | Yes | Yes | Yes |

[15] U.S. Food & Drug Administration. Bimzelx (bimekizumab-bkzx) Prescribing Information. UCB Inc., Revised 11/2024.
[16] U.S. Food & Drug Administration. Cosentyx (secukinumab) Prescribing Information. Novartis, Revised 8/2024.
[17] U.S. Food & Drug Administration. Enbrel (etanercept) Prescribing Information. Immunex, Revised 9/2024.
[18] U.S. Food & Drug Administration. Entyvio (vedolizumab) Prescribing Information. Takeda, Revised 4/2024.
[19] U.S. Food & Drug Administration. Humira (adalimumab) Prescribing Information. AbbVie Inc., Revised 11/2023.
[20] U.S. Food & Drug Administration. Ilumya (tildrakizumab-asmn) Prescribing Information. Sun Pharma, Revised 4/2024.
[21] U.S. Food & Drug Administration. Omvoh (mirikizumab-mrkz) Prescribing Information. Eli Lilly and Co., Revised 4/2024.
[22] U.S. Food & Drug Administration. Remicade (infliximab) Prescribing Information. Janssen Biotech Inc., Revised 10/2021.

| Drug | Class | Indications | | | |
|---|---|---|---|---|---|
| | | Adult PsO | Adult PsA | Adult CD | Adult UC |
| **Stelara (ustekinumab)[23]** | IL-12 and -23 antagonist | Yes | Yes | Yes | Yes |
| **Taltz (ixekizumab)[24]** | IL-17A antagonist | Yes | Yes | - | - |
| **Tremfya (guselkumab)[25]** | IL-23 antagonist | Yes | Yes | * | Yes |

IL = interleukin
TNF = tumor necrosis factor
Products may have additional FDA-approved indications not included in the table
* Omvoh and Tremfya were approved for Crohn's disease in Adults in 2025.

*Table 4 Summary of key clinical trials – adult plaque psoriasis[26]*

| Trial | Population (treatment/ placebo) | Endpoint | PGA/rPGA/sPGA/IGA of 0 or 1, N (%) | |
|---|---|---|---|---|
| | | | Treatment | Placebo |
| **Skyrizi Ps-1** | 304/102 | Week 16 | 267 (88) | 8 (8) |
| **Skyrizi Ps-2** | 294/98 | Week 16 | 246 (84) | 5 (5) |
| **Bimzelx Ps-1[27]** | 321/83 | Week 16 | 270 (84) | 4 (5) |
| **Bimzelx Ps-2[28]** | 349/86 | Week 16 | 323 (93) | 1 (1) |
| **Cosentyx PsO1[a]** | 245/248 | Week 12 | 160 (65) | 6 (2) |
| **Cosentyx PsO2[a]** | 327/326 | Week 12 | 202 (62) | 9 (3) |
| **Cosentyx PsO3[a]** | 59/59 | Week 12 | 40 (68) | 0 (0) |
| **Cosentyx PsO4[a]** | 60/61 | Week 12 | 44 (73) | 0 (0) |
| **Enbrel Study I[b]** | 168/168 | Month 3 | 79 (47) | 8 (5) |

[23]U.S. Food & Drug Administration. Stelara (ustekinumab) Prescribing Information. Janssen Biotech Inc., Revised 11/2024.
[24] U.S. Food & Drug Administration. Taltz (ixekizumab) Prescribing Information. Eli Lilly and Co., Revised 8/2024.
[25] U.S. Food & Drug Administration. Tremfya (guselkumab) Prescribing Information. Janssen Biotech Inc., Revised 9/2024.
[26] Data are presented from separate pivotal trials for each agent. Trials are not direct head-to-head comparative trials; differences in trial design, patient population, and follow-up duration preclude direct statistical comparison of the results shown.
[27] A Study to Evaluate the Efficacy and Safety of Bimekizumab Compared to Placebo and an Active Comparator in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis (BE VIVID). Retrieved from https://clinicaltrials.gov/study/NCT03370133?term=NCT03370133&viewType=Card&rank=1
[28] A Study With a Initial Treatment Period Followed by a Randomized-withdrawal Period to Evaluate the Efficacy and Safety of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis (BE READY). Retrieved from https://clinicaltrials.gov/study/NCT03410992?term=NCT03410992&viewType=Card&rank=1

| Trial | Population (treatment/ placebo) | Endpoint | PGA/rPGA/sPGA/IGA of 0 or 1, N (%) | |
|---|---|---|---|---|
| | | | Treatment | Placebo |
| **Enbrel Study II**[b] | 203/204 | Month 3 | 109 (54) | 7 (3) |
| **Humira Study Ps-I** | 814/398 | Week 16 | 506 (62) | 17 (4) |
| **Humira Study Ps-II** | 99/48 | Week 16 | 70 (71) | 5 (10) |
| **Ilumya Trial 2**[29] | 309/154 | Week 12 | 179 (58) | 11 (7) |
| **Ilumya Trial 3**[30] | 307/156 | Week 12 | 168 (55) | 7 (4) |
| **Remicade Psoriasis Study I**[c] | 301/77 | Week 10 | 242 (80) | 2 (3) |
| **Remicade Psoriasis Study II**[c] | 314/208 | Week 10 | 234 (75) | 2 (1) |
| **Remicade Psoriasis Study III**[c] | 99/51 | Week 10 | 89 (90) | 5 (10) |
| **Stelara Ps Study 1**[d] | 256/255 | Week 12 | 156 (61) | 10 (4) |
| **Stelara Ps Study 2**[d] | 411/410 | Week 12 | 300 (73) | 18 (4) |
| **Taltz Trial 1**[31] | 433/431 | Week 12 | 354 (82) | 14 (3) |
| **Taltz Trial 2**[32] | 351/168 | Week 12 | 292 (83) | 4 (2) |
| **Taltz Trial 3**[33] | 385/193 | Week 12 | 310 (81) | 13 (7) |
| **Tremfya Study PsO1**[34] | 329/174 | Week 16 | 280 (85) | 12 (7) |
| **Tremfya Study PsO2**[35] | 496/248 | Week 16 | 417 (84) | 21 (8) |

A PGA/rPGA/sPGA/IGA score of 0 or 1 indicates clear or almost-clear skin
[a] 300 mg treatment group
[b] 50 mg treatment group
[c] 5 mg/kg treatment group
[d] 90 mg treatment group

[29] A Study to Evaluate the Efficacy and Safety of Subcutaneous MK-3222, Followed by an Optional Long-Term Safety Extension Study, in Participants With Moderate-to-Severe Chronic Plaque Psoriasis (MK-3222-010) (reSURFACE 1). Retrieved from https://clinicaltrials.gov/study/NCT01722331?term=NCT01722331&viewType=Card&rank=1

[30] A Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222/MK-3222) in Participants With Moderate-to-Severe Chronic Plaque Psoriasis Followed by a Long-term Extension Study (MK-3222-011) (reSURFACE 2). Retrieved from https://clinicaltrials.gov/study/NCT01729754?term=NCT01729754&viewType=Card&rank=1

[31] A Phase 3 Study in Participants With Moderate to Severe Psoriasis (UNCOVER-1). Retrieved from https://clinicaltrials.gov/study/NCT01474512?term=NCT01474512&viewType=Card&rank=1

[32] A Phase 3 Study in Participants With Moderate to Severe Psoriasis (UNCOVER-2) (UNCOVER-2). Retrieved from https://clinicaltrials.gov/study/NCT01597245?term=NCT01597245&viewType=Card&rank=1

[33] A Study in Participants With Moderate to Severe Psoriasis (UNCOVER-3) (UNCOVER-3). Retrieved from https://clinicaltrials.gov/study/NCT01646177?term=NCT01646177&viewType=Card&rank=1

[34] A Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis (VOYAGE 1). Retrieved from https://clinicaltrials.gov/study/NCT02207231?term=NCT02207231&viewType=Card&rank=1

[35] A Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis With Randomized Withdrawal and Retreatment (VOYAGE 2). Retrieved from https://clinicaltrials.gov/study/NCT02207244?term=NCT02207244&viewType=Card&rank=1

*Table 5 Summary of key clinical trials – ulcerative colitis*[36]

| Trial | Endpoint | Clinical Remission | | Treatment difference |
|---|---|---|---|---|
| | | Placebo | Treatment | |
| **Skyrizi Trial UC-1**[37] | Week 12 | N=320 | N=646 | |
| | | 8% | 24% | 16% |
| **Entyvio SC UC Trial**[38] | Week 6 | N=56 | N=105 | |
| | | 14% | 46% | 32% |
| **Humira Study UC-I** | Week 8 | N=130 | N=130 | |
| | | 9.2% | 18.5% | 9.3% |
| **Humira Study UC-II** | Week 8 | N=246 | N=248 | |
| | | 9.3% | 16.5% | 7.2% |
| **Omvoh Study UC-1**[39] | Week 12 | N=267 | N=795 | |
| | | 15% | 24% | 10% |
| **Remicade Study UC I*** | Week 8 | N=121 | N=121 | |
| | | 15% | 39% | NR |
| **Remicade Study UC II*** | Week 8 | N=123 | N=121 | |
| | | 6% | 34% | NR |
| **Stelara Trial UC-1**[40] | Week 8 | N=319 | N=322 | |
| | | 7% | 19% | 12% |
| **Tremfya Trial UC1**[41] | Week 12 | N=280 | N=421 | |
| | | 8% | 23% | 15% |

Clinical remission as defined by the modified Mayo score
*5 mg/kg treatment group
NR = not reported

[36] Data are presented from separate pivotal trials for each agent. Trials are not direct head-to-head comparative trials; differences in trial design, patient population, and follow-up duration preclude direct statistical comparison of the results shown.
[37] A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Participants With Moderately to Severely Active Ulcerative Colitis. Retrieved from https://clinicaltrials.gov/study/NCT03398148?term=NCT03398148&viewType=Card&rank=1
[38] Efficacy and Safety of Vedolizumab Subcutaneously (SC) as Maintenance Therapy in Ulcerative Colitis. Retrieved from https://clinicaltrials.gov/study/NCT02611830?term=NCT02611830&viewType=Card&rank=1
[39] An Induction Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT 1). Retrieved from https://clinicaltrials.gov/study/NCT03518086?term=NCT03518086&viewType=Card&rank=1
[40] A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI). Retrieved from https://clinicaltrials.gov/study/NCT02407236?term=NCT02407236&viewType=Card&rank=1
[41] A Study of Guselkumab in Participants With Moderately to Severely Active Ulcerative Colitis (QUASAR). Retrieved from https://clinicaltrials.gov/study/NCT04033445?term=NCT04033445&viewType=Card&rank=1

*Table 6 Selected safety and therapeutic considerations*[42]

| Drug | Hyper-sensitivity | Infections | TB | Hepato-toxicity | Immuniz-ations | Malignancy |
|---|---|---|---|---|---|---|
| **Skyrizi** | Yes | Yes | Yes | Yes | Yes | - |
| **Bimzelx** | - | Yes | Yes | Yes | Yes | - |
| **Cosentyx** | Yes | Yes | Yes | - | Yes | - |
| **Enbrel** | Yes | **Yes** | - | - | - | **Yes** |
| **Entyvio** | Yes | Yes | - | - | - | - |
| **Humira** | Yes | **Yes** | - | - | - | **Yes** |
| **Ilumya** | Yes | Yes | Yes | - | Yes | - |
| **Omvoh** | Yes | Yes | Yes | Yes | Yes | - |
| **Remicade** | Yes | **Yes** | - | Yes | Yes | **Yes** |
| **Stelara** | Yes | Yes | Yes | - | Yes | Yes |
| **Taltz** | Yes | Yes | Yes | - | Yes | - |
| **Tremfya** | Yes | Yes | Yes | * | Yes | - |
| Bold text indicates a boxed warning.<br>*Warning/precaution added to the PI after 2024 | | | | | | |

*Table 7 Route and adult dosing*

| Drug | Formulation | Induction Dosing | Maintenance Dosing |
|---|---|---|---|
| **Skyrizi** | IV/SC | PsO, PsA: 150 mg SC at weeks 0 and 4<br>CD: 600 mg IV at weeks 0, 4 and 8<br>UC: 1,200 mg IV at weeks 0, 4 and 8 | PsO, PsA: 150mg SC every 12 weeks<br>CD, UC: 180 mg or 360 mg SC at week 12, then every 8 weeks |
| **Bimzelx** | SC | PsO: 320 mg SC at weeks 0, 4,8, 12 and 16<br>PsA: No induction | PsO: 320 mg SC every 4 weeks<br>PsA: 160 mg SC every 4 weeks |

[42] "Yes" indicates the inclusion in the Warnings and Precautions section of the drug's package insert. A dash indicates the consideration was not included in this section. This is not an exhaustive list of safety concerns or adverse reactions.

| Drug | Formulation | Induction Dosing | Maintenance Dosing |
|---|---|---|---|
| **Cosentyx** | IV/SC | PsO: 300 mg SC at weeks 0, 1, 2, 3, and 4<br>PsA: 150 mg SC at weeks 1, 2, 3, and 4 (induction is optional) | PsO: 300 mg every 4 weeks<br>PsA: 150 mg every 4 weeks |
| **Enbrel** | SC | PsO: 50 mg twice weekly for 3 months<br>PsA: No induction | PsO: 50 mg weekly<br>PsA: 50 mg weekly ± methotrexate |
| **Entyvio** | IV/SC | 300 mg IV at weeks 0 and 2 | Starting week 6, 300 mg IV every 8 weeks or<br>108 mg SC every two weeks |
| **Humira** | SC | PsO: 80 mg SC at week 0<br>PsA: No induction<br>CD, UC: 160 mg SC on day 1, 80 mg on day 15 | PsO, PsA, CD, UC: 40 mg SC every 2 weeks |
| **Ilumya** | SC | 100 mg SC at weeks 0 and 4 | 100 mg SC every 12 weeks |
| **Omvoh** | IV/SC | UC: 300 mg IV at weeks 0, 4 and 8 | UC: 200 mg SC every 4 weeks |
| **Remicade** | IV | PsO, PsA, CD, UC: 5 mg/kg at 0, 2, and 6 weeks | PsO, PsA, CD, UC: 5 mg/kg every 8 weeks |
| **Stelara** | IV/SC | PsO, PsA: 45 mg SC at weeks 0 and 4<br>CD, UC: 390 mg IV* | PsO, PsA: 45 mg SC every 12 weeks<br>CD, UC: 90 mg SC every 8 weeks* |
| **Taltz** | SC | PsO: 160 mg SC at week 0, followed by 80 mg SC at weeks 2, 4, 6, 8, 10, and 12<br>PsA: 160 mg SC at week 0 | PsO, PsA: 80 mg SC every 4 weeks |
| **Tremfya** | SC/IV | PsO, PsA: 100 mg SC at weeks 0 and 4<br>UC: 200 mg IV or 400 mg SC at weeks 0, 4 and 8 | PsO, PsA: 100 mg SC every 8 weeks<br>UC: 100 mg SC at week 16 and every 8 weeks thereafter or<br>200 mg SC at week 12 and every 4 weeks thereafter |
| *Dosing is based on a 75 kg patient | | | |