Tremfya® (*guselkumab*)

Clinical summary[1]

Psoriatic arthritis (adults)

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis, manifesting most commonly with peripheral arthritis, dactylitis (inflammation of fingers/toes), enthesitis (inflammation where a tendon or ligament attaches to a bone), and spondylitis (inflammation of the spine).[2]

For patients with multidomain involvement, prioritize selecting a therapy that addresses all affected domains whenever feasible. If that is not an option, focus treatment on the domain that the patient finds most burdensome. Therapies should be chosen using a treat-to-target approach, with adjustments made every three months to achieve remission or low disease activity. 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]

Treatment of PsA 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).[4]

For purposes of this review, the summary is focused on moderate to severe axial and peripheral PsA.

In patients with axial symptoms that do not respond adequately to treatment with NSAIDs (e.g., those with prolonged morning stiffness and severe pain interfering with function), tumor necrosis factor (TNF), an interleukin 17 (IL-17) inhibitor, or a JAK inhibitor is recommended.

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[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. Autoimmune disorders are challenging and complex; this document provides a summary of the treatments and alternatives being reviewed; it does not address other appropriate first-line therapies, therapeutic switching, treatment failure (other than at a high level), comorbidities, complications and detailed patient considerations.

[2]Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. January 2019. PubMed. Accessed 7/24/26.

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

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

Choosing among TNF versus IL-17 versus JAK inhibition may be influenced by comorbid conditions. As an example, IL-17 inhibitors are more effective for severe psoriasis but not for inflammatory bowel disease or iritis, whereas JAK inhibitors are effective for inflammatory bowel disease. In the absence of these considerations, treatment selection is based on patient, physician, and payor preference.[5,6]

In patients with axial symptoms that do not respond adequately to initial therapy with a TNF inhibitor, a second TNF inhibitor, IL-17 inhibitor, or Janus kinase (JAK) inhibitor may be used.[7]

Psoriatic arthritis (children)

Psoriatic juvenile idiopathic arthritis (psJIA), also called juvenile psoriatic arthritis (JPsA), is a subtype of juvenile idiopathic arthritis (JIA) associated with psoriasis; by definition, symptom onset occurs before age 16. Occurrence estimates vary by diagnostic criteria used, ranging from approximately 5% to 8% up to 20% in some series.[8,9,10]

The condition can present with any combination of peripheral arthritis, axial involvement (spine and sacroiliac joints), enthesitis, dactylitis, and uveitis, and its severity ranges from mild, single-joint disease to extensive polyarticular involvement. Cutaneous psoriasis is not always present at diagnosis and may follow joint symptoms by months to years, which can make early recognition challenging. Left inadequately controlled, psJIA carries a risk of permanent joint damage and, in growing children, disruption of normal bone development.[11,12]

No pharmacologic treatment guideline has been developed specifically for psJIA. Management is generally extrapolated from the 2019 American College of Rheumatology/Arthritis Foundation guideline for non-systemic JIA together with current psJIA-focused literature, and shares many features with the treatment of adult PsA in the 2018 American college of

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[5] Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. January 2019. PubMed. Accessed 7/24/26.
[6] Orbai, AM, Scher, JU. Treatment of psoriatic arthritis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)
[7]Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. January 2019. PubMed. Accessed 7/24/26.
[8]Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Epidemiology, clinical manifestations, and diagnosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[9]Brunello F, Tirelli F, Pegoraro L, Dell'Apa F, Alfisi A, Calzamatta G, Folisi C, Zulian F. New Insights on Juvenile Psoriatic Arthritis. Front Pediatr. 2022;10:884727.
[10]Menter A, Cordoro KM, Davis DMR, et al. Joint AAP–NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. Journal of the American Academy of Dermatology. January 2020;82(1):161-201. Free full text (JAAD). Accessed 7/28/26.
[11] Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Epidemiology, clinical manifestations, and diagnosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[12] Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)

rheumatology/national psoriasis foundation guideline for the treatment of psoriatic arthritis described above. [13,14,15]

- Initial therapy typically consists of an NSAID and, for limited joint involvement, intra-articular glucocorticoids. For more extensive peripheral arthritis, a conventional synthetic disease-modifying antirheumatic drug (DMARD) — most often methotrexate — is generally added next, with a biologic agent reserved for patients whose disease remains active despite this step. [16,17]
- Some patients are considered for biologic therapy earlier in the treatment course — most often when higher-risk joints are involved, when disease activity is high, or when axial disease is present, since conventional DMARDs are not effective for axial involvement. [18,19]
- The choice of biologic therapy largely depends on the specific disease areas affected. For example, treatments that work well for skin and peripheral joint issues may not be effective for conditions like axial disease or uveitis. Therefore, selecting a treatment is personalized based on the patient's unique pattern of symptoms and how they have responded to previous treatments, rather than following a strict, fixed order of therapies.[20]

Among the board-selected agents in Table 1, approval status for psJIA specifically varies considerably.

- Etanercept (Enbrel) carries the longest-standing and most extensively used pediatric indication, approved for active JPsA in children as young as 2.[21]

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[13]Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res. 2019;71(6):717-734.

[14]Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)

[15]Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. January 2019. PubMed. Accessed 7/24/26.

[16]Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res. 2019;71(6):717-734.

[17]Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)

[18]Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res. 2019;71(6):717-734.

[19]Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)

[20]Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)

[21]U.S. Food & Drug Administration. Enbrel (etanercept) Prescribing Information. Immunex, Revised 1/2026.

- Secukinumab (Cosentyx) is FDA approved for psJIA at age 2 and older, supported by a dedicated randomized pediatric trial. Ustekinumab (Stelara), guselkumab (Tremfya), and risankizumab (Skyrizi) are each approved for active psJIA at age 6 and older; these approvals rely on extrapolation from adult efficacy data combined with pediatric safety and pharmacokinetic data rather than dedicated pediatric efficacy trials.[22,23,24,25]
- Adalimumab (Humira) is not approved specifically for psJIA but carries a related indication for polyarticular JIA at age 2 and older.[26]
- Ixekizumab (Taltz) is approved for pediatric plaque psoriasis but not currently for psJIA, though emerging trial data suggest possible future expansion.[27]
- Bimekizumab (Bimzelx), tildrakizumab (Ilumya), and infliximab (Remicade) currently carry no pediatric psJIA-specific indication.[28,29,30]
- Although risankizumab, guselkumab, and ustekinumab share the same psJIA indication and extrapolated evidentiary basis, the literature does not treat them interchangeably once axial disease is the primary driver: guselkumab is specifically noted as a consideration for refractory axial arthritis, whereas ustekinumab is generally described as ineffective for axial disease, and risankizumab's role in this specific scenario is not addressed in the literature reviewed. [31,32]

Chronic plaque psoriasis (adults)

Psoriasis is a multisystem chronic inflammatory disorder with multiple cutaneous presentations affecting approximately 3% of the population; chronic plaque psoriasis is the most common presentation of psoriasis. Treatment of chronic plaque psoriasis is generally pursued because of the negative effects psoriasis can have on quality of life. The major treatment modalities

[22]U.S. Food & Drug Administration. Cosentyx (secukinumab) Prescribing Information. Novartis, Revised 4/2026.
[23]U.S. Food & Drug Administration. Stelara (ustekinumab) Prescribing Information. Janssen Biotech Inc., Revised 4/2026.
[24]U.S. Food & Drug Administration. Tremfya (guselkumab) Prescribing Information. Janssen Biotech Inc., Revised 5/2026.
[25]U.S. Food & Drug Administration. Skyrizi (risankizumab-rzaa) Prescribing Information. AbbVie Inc., Revised 06/2026.
[26]U.S. Food & Drug Administration. Humira (adalimumab) Prescribing Information. AbbVie Inc., Revised 12/2025.
[27]U.S. Food & Drug Administration. Taltz (ixekizumab) Prescribing Information. Eli Lilly and Co., Revised 8/2024.
[28]U.S. Food & Drug Administration. Bimzelx (bimekizumab-bkzx) Prescribing Information. UCB Inc., Revised 11/2024.
[29]U.S. Food & Drug Administration. Ilumya (tildrakizumab-asmn) Prescribing Information. Sun Pharma, Revised 12/2025.
[30]U.S. Food & Drug Administration. Remicade (infliximab) Prescribing Information. Janssen Biotech Inc., Revised 2/2025.
[31]Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[32]Nigrovic PA. Psoriatic juvenile idiopathic arthritis: Epidemiology, clinical manifestations, and diagnosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)

include topical, systemic, and phototherapeutic interventions. Factors such as clinical presentation, patient comorbidities, patient preference, and treatment availability influence the approach to treatment. Patient preferences play a primary role in determining treatment modality.[33,34]

- Selection of the primary mode of therapy (topical, phototherapy, or systemic) is an individualized decision based on the extent and location of skin involvement, disease complications, patient comorbidities (e.g., psoriatic arthritis), patient abilities and preferences, and treatment availability; non-systemic therapy is generally sufficient for limited disease. Patient preference plays a central role in therapy selection: efficacy and safety data, quality-of-life impact, dosing schedule, cost, and route of administration should be discussed with the patient before initiating or switching a biologic. [35,36]
- Topical therapy is generally preferred for limited disease (roughly less than 3% to 5% body surface area); phototherapy or systemic therapy is favored instead when disease extent, involvement of special sites (scalp, genitals, palms, soles, or face), or an inadequate response to topical therapy make topical therapy alone less feasible (Grade 2C). [37,38]
- Patients with a comorbidity that also requires systemic therapy (most commonly psoriatic arthritis) are generally treated with an agent that has overlapping benefit for both conditions, since most systemic therapies effective for chronic plaque psoriasis are also effective for psoriatic arthritis. [39]
- UpToDate, a peer-reviewed, continuously updated clinical decision support resource used by healthcare professionals to guide evidence-based practice, suggests the general approach for systemic therapy is to suggest risankizumab (Skyrizi), guselkumab (Tremfya), or ixekizumab (Taltz) rather than other systemic therapies, citing high efficacy and relatively favorable safety profiles for these three agents. [40]

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[33] Feldman SR, Bhutani T. Chronic plaque psoriasis in adults: Overview of management. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 29, 2026.)

[34] Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. April 2019. Free full text (JAAD). Accessed 7/24/2026.

[35] Feldman SR, Bhutani T. Chronic plaque psoriasis in adults: Overview of management. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 29, 2026.)

[36] Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. April 2019. Free full text (JAAD). Accessed 7/24/2026.

[37] Feldman SR, Bhutani T. Chronic plaque psoriasis in adults: Overview of management. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 29, 2026.)

[38] Feldman SR, Soung J. Chronic plaque psoriasis in adults: Treatment of disease requiring phototherapy or systemic therapy. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)

[39] Feldman SR, Bhutani T. Chronic plaque psoriasis in adults: Overview of management. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 29, 2026.)

[40] Feldman SR, Soung J. Chronic plaque psoriasis in adults: Treatment of disease requiring phototherapy or systemic therapy. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)

Plaque psoriasis (children)

Pediatric psoriasis prevalence in the United States is estimated at 0.13%, with moderate-to-severe disease estimated at 0.016%; approximately one-third of adults with psoriasis report disease onset during the first two decades of life.[41]

- Topical therapy remains the preferred initial approach for most children; when disease cannot be adequately controlled with topicals, biologic therapy and narrowband UVB phototherapy are the preferred next steps, with the choice between them guided by comorbidities (e.g., phototherapy is not effective for concurrent psoriatic arthritis although it may reduce the risk of developing PsA), caregiver preference regarding treatment risk, and treatment feasibility.[42,43]
- For children requiring systemic therapy, UpToDate suggests ustekinumab, ixekizumab, secukinumab, or guselkumab rather than other systemic options. Risankizumab (Skyrizi) is not addressed in these recommendations, as its pediatric plaque psoriasis indication (ages 6 and older, for patients who are candidates for systemic therapy or phototherapy) was granted after these clinical practice recommendations were last published; comparative positioning relative to the agents above has not yet been addressed in a guideline or UpToDate update.[44]
- TNF inhibitors are generally reserved for children in whom comorbidities or access limit use of these agents; etanercept specifically has reduced utility due to weekly dosing and comparatively lower efficacy relative to other biologic classes. [45,46]

Inflammatory bowel disease

Inflammatory bowel disease (IBD) is comprised of two major disorders: ulcerative colitis (UC) and Crohn disease (CD). UC affects the colon and is characterized by inflammation of the mucosal layer. CD is characterized by transmural inflammation and may involve any portion of luminal gastrointestinal tract, from the oral cavity to the perianal area.

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[41]Paller AS, Lund EB. Psoriasis in children: Epidemiology, clinical manifestations, and diagnosis. In: UpToDate, Merola JF, Levy ML (Eds), Wolters Kluwer. Topic last updated Apr 22, 2025. (Accessed on July 28, 2026.)

[42]Paller AS, Lund EB. Chronic plaque psoriasis in children: Overview of management. In: UpToDate, Merola JF, Levy ML (Eds), Wolters Kluwer. Topic last updated Jul 10, 2026. (Accessed on July 28, 2026.)

[43] Bar D, Baum S, et al. The role of phototherapy in reducing the risk of psoriatic arthritis among psoriasis patients in the era of biologics. JDDG. December 12, 2025. https://doi.org/10.1111/ddg.15956

[44]Paller AS, Lund EB. Chronic plaque psoriasis in children: Management of disease requiring systemic therapy or phototherapy. In: UpToDate, Merola JF, Levy ML (Eds), Wolters Kluwer. Topic last updated May 21, 2026. (Accessed on July 28, 2026.)

[45]Paller AS, Lund EB. Chronic plaque psoriasis in children: Management of disease requiring systemic therapy or phototherapy. In: UpToDate, Merola JF, Levy ML (Eds), Wolters Kluwer. Topic last updated May 21, 2026. (Accessed on July 28, 2026.)

[46]Menter A, Cordoro KM, Davis DMR, et al. Joint AAP–NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. Journal of the American Academy of Dermatology. January 2020;82(1):161-201. Free full text (JAAD). Accessed 7/28/26.

Ulcerative colitis (adults)

Ulcerative colitis (UC) is a chronic inflammatory disease of the colon whose incidence and prevalence continue to rise. In the United States, UC occurs at an estimated rate of 6.3 per 100,000 person-years, with an age-, sex-, and insurance-standardized prevalence of approximately 305 per 100,000 population — corresponding to roughly 1.25 million people living with the disease based on 2020 census estimates. Onset can occur at any age, but incidence peaks in the third decade of life.[47]

UC is characterized by continuous mucosal inflammation that typically begins in the rectum and extends proximally through the colon without skip areas, distinguishing it from Crohn's disease. Common presenting symptoms include rectal bleeding, urgency, and tenesmus. The clinical course is most often relapsing and remitting, with active disease alternating with periods of remission; a minority of patients have persistent disease activity despite therapy, and a small subset present with acute, severe (fulminant) colitis requiring hospitalization. [48,49]

- Disease severity (mild, moderate, or severe) is classified based on stool frequency, rectal bleeding, and signs of systemic toxicity; severity, together with disease extent (proctitis, left-sided, or extensive colitis), guides selection and sequencing of therapy.[50,51,52]
- For mild to moderate disease, oral and/or topical (rectal) 5-aminosalicylate (5-ASA) agents are first-line therapy; patients who do not respond generally advance to topical or oral glucocorticoids before biologic therapy is considered. [53]
- For moderate to severe disease, biologic agents (with or without an immunomodulator) serve as first-line induction and maintenance therapy. Systemic glucocorticoids may still be used for rapid symptom control but are not appropriate for long-term maintenance.[54]
- Selection among biologic classes is individualized based on coexisting conditions, age, infection risk, prior treatment response, route and frequency preference, and insurance coverage/cost. As examples, anti-TNF therapy is often favored for patients with

[47]Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. Am J Gastroenterol. 2025;120(6):1187-1224.
[48]Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. Am J Gastroenterol. 2025;120(6):1187-1224.
[49]Peppercorn MA, Kane SV. Clinical manifestations, diagnosis, and prognosis of ulcerative colitis in adults. In: UpToDate, Al Hashash J (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[50]Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. Am J Gastroenterol. 2025;120(6):1187-1224.
[51]Al Hashash J, Regueiro M. Medical management of low-risk adult patients with mild to moderate ulcerative colitis. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[52]Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[53]Al Hashash J, Regueiro M. Medical management of low-risk adult patients with mild to moderate ulcerative colitis. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[54]Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)

concomitant inflammatory arthritis; anti-interleukin agents (e.g., ustekinumab, mirikizumab, risankizumab) are often favored for patients with coexisting psoriasis or psoriatic arthritis; and vedolizumab or an anti-interleukin agent is often preferred in older patients or those with recent infection, given comparatively lower infection risk.[55,56]

- Among the Board-selected agents in Table 2 with an adult UC indication — Skyrizi (risankizumab), Entyvio (vedolizumab), Humira (adalimumab), Omvoh (mirikizumab), Remicade (infliximab), Stelara (ustekinumab), and Tremfya (guselkumab) — no single agent is preferred across all patients. Guideline authors note infliximab, adalimumab, and golimumab are effective for inducing remission of moderately to severely active UC; and "considerable evidence" specifically for infliximab. Vedolizumab or an anti-IL-23 strategy may be favored in patients at higher risk for infectious complications.[57]
- Patients who do not respond to an initial biologic are generally switched to an agent from a different biologic class rather than a second agent within the same class, since comparative data on sequencing within a class remain limited. [58,59]

Crohn's disease[60]

Crohn's disease (CD) is a chronic, transmural inflammatory disease of the gastrointestinal tract whose incidence and prevalence have been steadily increasing in the United States and worldwide. Using the same national commercial and public insurance claims methodology applied to ulcerative colitis, the incidence of CD has been estimated to be somewhat lower than that of UC, though both diseases continue to rise in frequency. Onset most commonly occurs before age 40, and the anatomic location of disease established at diagnosis (ileal, colonic, or ileocolonic) tends to remain stable over time.[61]

Unlike the continuous, mucosal-only involvement of UC, CD is characterized by transmural inflammation that may affect any portion of the gastrointestinal tract from the mouth to the

[55]Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[56]Farrell RJ, Kinnucan J. Dosing and monitoring of biologic agents and small molecules for treating ulcerative colitis in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[57] Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. Am J Gastroenterol. 2025;120(6):1187-1224.
[58]Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[59]Farrell RJ, Kinnucan J. Dosing and monitoring of biologic agents and small molecules for treating ulcerative colitis in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 30, 2026.)
[60]Terminology Note: "Crohn's disease" and "Crohn disease" are used interchangeably throughout the cited literature and refer to the identical condition — the variation reflects differing style conventions among source organizations (e.g., AGA retains the possessive form; AMA style and some tertiary references, including UpToDate, favor the non-possessive eponym). This document uses Crohn's Disease for consistency in body text; source titles are reproduced as published in the reference list.
[61]Lichtenstein GR, Loftus EV, Afzali A, Long MD, Barnes EL, Isaacs KL, Ha CY. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025;120:1225-1264.

perianal area. Approximately 80% of patients have small bowel involvement (most often the distal ileum), about 50% have ileocolonic disease, and roughly 20% have disease limited to the colon; about one-third of patients develop perianal disease over the course of illness. Cardinal symptoms include abdominal pain, chronic intermittent diarrhea (with or without gross bleeding), fatigue, and weight loss. Because of its transmural nature, CD is prone to complications such as strictures, fistulas, and abscesses; up to half of patients develop one of these complications within 20 years of diagnosis, and approximately half will eventually require surgery. [62,63]

Patients are stratified as low-risk (mild) or moderate to severe based on factors such as extent and location of bowel involvement, presence of complications, and prior treatment response; this classification guides selection and sequencing of therapy. [64,65,66]

- For low-risk, mild disease involving the ileum and/or proximal colon, oral budesonide is first-line therapy for inducing remission; oral 5-aminosalicylates or prednisone are alternatives for patients with diffuse colonic or left-sided involvement, or who prefer to avoid budesonide. Immunomodulators and biologic therapy are reserved for patients who cannot taper off glucocorticoids or who relapse after an initial response. [67]
- For moderate to severe disease, biologic therapy (with or without an immunomodulator) serves as first-line induction and maintenance treatment. Options for biologic-naïve patients include anti-TNF therapy, an anti-interleukin agent, or vedolizumab; systemic glucocorticoids may still be used for rapid symptom control but are not appropriate for long-term maintenance. [68]
- Selection among biologic classes is individualized. Anti-TNF therapy combined with an immunomodulator is generally preferred for patients with fistulizing disease; vedolizumab or an anti-interleukin agent is often preferred for patients over age 60 or with a history of malignancy or serious infection, given comparatively lower infection

[62]Lichtenstein GR, Loftus EV, Afzali A, Long MD, Barnes EL, Isaacs KL, Ha CY. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025;120:1225-1264.
[63]Peppercorn MA, Kane SV. Clinical manifestations, diagnosis, and prognosis of Crohn disease in adults. In: UpToDate, Al Hashash J, Jaffe T (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)
[64]Lichtenstein GR, Loftus EV, Afzali A, Long MD, Barnes EL, Isaacs KL, Ha CY. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025;120:1225-1264.
[65]Regueiro M, Al Hashash J. Overview of the medical management of mild (low risk) Crohn disease in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)
[66]Al Hashash J, Regueiro M. Medical management of moderate to severe Crohn disease in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)
[67]Regueiro M, Al Hashash J. Overview of the medical management of mild (low risk) Crohn disease in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)
[68]Al Hashash J, Regueiro M. Medical management of moderate to severe Crohn disease in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)

risk; and an anti-interleukin agent is generally favored over a second anti-TNF agent for patients with prior anti-TNF exposure or nonresponse. [69]**Error! Bookmark not defined.**

- Among the Board-selected agents in Table 2 with an adult CD indication — Skyrizi (risankizumab), Entyvio (vedolizumab), Humira (adalimumab), Remicade (infliximab), Stelara (ustekinumab), and Tremfya (guselkumab) — no single agent is preferred across all patients. Comparative trial data favor risankizumab over ustekinumab in patients with prior anti-TNF exposure, with higher clinical and endoscopic remission rates reported, and guideline authors recommend risankizumab over ustekinumab in this setting. [70,71]
- Patients who do not respond to an initial biologic, or who lose response over time, are generally transitioned to an agent from a different biologic class rather than a second agent within the same class. [72]

Clinical comparison

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

Drug	Indications						Biosimilar availability
	Adult PsO	Pediatric PsO	Adult PsA	Pediatric PsA	Adult CD	Adult UC	
Skyrizi	Yes	≥ 6 years	Yes	≥ 6 years	Yes	Yes	~2028
Bimzelx	Yes	-	Yes	-	-	-	-
Cosentyx	Yes	≥ 6 years	Yes	≥ 2 years	-	-	Pending Approval
Enbrel	Yes	≥ 4 years	Yes	≥ 2 years	-	-	Approved, expected launch ~2029
Entyvio	-	-	-	-	Yes	Yes	Erelzi and Eticovo approved, expected launch ~2029
Humira	Yes	-	Yes	-	Yes	Yes	Several launched 2023
Ilumya	Yes	-	-	-	-	-	-

[69]Al Hashash J, Regueiro M. Medical management of moderate to severe Crohn disease in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)
[70]Lichtenstein GR, Loftus EV, Afzali A, Long MD, Barnes EL, Isaacs KL, Ha CY. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025;120:1225-1264.
[71]Al Hashash J, Regueiro M. Medical management of moderate to severe Crohn disease in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)
[72]Al Hashash J, Regueiro M. Medical management of moderate to severe Crohn disease in adults. In: UpToDate, Kane SV (Ed), Wolters Kluwer. (Accessed on July 24, 2026.)

Drug	Indications						Biosimilar availability
	Adult PsO	Pediatric PsO	Adult PsA	Pediatric PsA	Adult CD	Adult UC	
Omvoh	-	-	-	-	Yes	Yes	-
Remicade	Yes	-	Yes	-	Yes	Yes	Several launched 2016
Stelara	Yes	≥ 6 years	Yes	≥ 6 years	Yes	Yes	Several launched 2025
Taltz	Yes	≥ 6 years	Yes	-	-	-	-
Tremfya	Yes	≥ 6 years	Yes	≥ 6 years	Yes	Yes	-
Products may have additional FDA-approved indications not included in the table							

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

Appendix A: Clinical information

Drug indications[73]

- FDA approved:
    - Tremfya is an interleukin-23 antagonist indicated for the treatment of:
        - adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe **plaque psoriasis (PsO)** and who are candidates for systemic therapy or phototherapy.
        - adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active **psoriatic arthritis (PsA)**.
        - adults with moderately to severely active **ulcerative colitis (UC)**.
        - adults with moderately to severely active **Crohn's disease (CD)**.

Clinical efficacy

Efficacy in moderate-to-severe plaque psoriasis in adults

In trials PsO1 and PsO2, 1443 subjects were randomized to either Tremfya, placebo or U.S. licensed adalimumab. Both trials assessed the responses at Week 16 compared to placebo for the two co-primary endpoints: the proportion of subjects who achieved an IGA score of 0 ("cleared") or 1 ("minimal") and the proportion of subjects who achieved at least a 90% reduction from baseline in the PASI composite score (PASI 90). [74,75]

Table 2 Clinical Efficacy in Plaque Psoriasis in Adults

Endpoint	PsO1		PsO2	
	Tremfya N=329	Placebo N=174	Tremfya N=496	Placebo N=248
IGA response of 0 or 1, n (%)	280 (85)	12 (7)	417 (84)	21 (8)
PASI 90, n (%)	241 (73)	5 (3)	347 (70)	6 (2)

[73] U.S. Food & Drug Administration. *Tremfya (guselkumab) Prescribing Information*. Janssen Biotech Inc., Revised 5/2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761061s034lbl.pdf

[74] A Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis (VOYAGE 1). Retrieved from https://clinicaltrials.gov/study/NCT00079937?tab=study

[75] 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

Additional studies further demonstrated clinical efficacy in adult and pediatric patients.[76,77,78]

Efficacy in active psoriatic arthritis in adults

The safety and efficacy of Tremfya were assessed in 3 randomized, double-blind, placebo-controlled trials in adult subjects with active psoriatic arthritis (PsA) who had inadequate response to standard therapies. In trials PsA1 and PsA2, efficacy was evaluated in 381 and 739 subjects, respectively, who were treated with placebo SC, Tremfya 100 mg SC at Weeks 0, 4 and every 8 weeks (q8w) thereafter, or Tremfya 100 mg SC every 4 weeks. In trial PsA3, efficacy was evaluated in 1,020 subjects who were treated with placebo SC, Tremfya 100 mg SC at Weeks 0, 4 and every 8 weeks thereafter, or Tremfya 100 mg SC every 4 weeks. The primary endpoint in all trials was the percentage of subjects achieving an ACR20 response at Week 24. [79,80,81]

In trials PsA1 and PsA2, subjects treated with Tremfya 100 mg every 8 weeks demonstrated a greater clinical response including ACR20, compared with placebo at Week 24. Subjects in trial PsA3 showed a greater ACR20 response when treated with Tremfya 100 mg every 8 weeks compared with placebo at Week 16 (65% vs. 41%) and Week 24 (68% vs. 47%).

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

In trials CD1 and CD2, 360 and 361 subjects, respectively, were randomized to receive intravenous Tremfya 200 mg or placebo at Weeks 0, 4, and 8. Tremfya demonstrated higher rates of clinical remission (defined as CDAI score <150) at week 12 compared to placebo.[82]

Table 3 Clinical efficacy in Crohn's disease in adults

Endpoint	CD1		CD2	
	Tremfya	Placebo	Tremfya	Placebo

[76] A Study of Guselkumab in Participants With Moderate to Severe Plaque-type Psoriasis and an Inadequate Response to Ustekinumab (NAVIGATE). Retrieved from https://clinicaltrials.gov/study/NCT02203032?term=NCT02203032&viewType=Card&rank=1

[77] Efficacy and Safety Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis. Retrieved from https://clinicaltrials.gov/study/NCT02905331?term=NCT02905331&viewType=Card&rank=1

[78] A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Guselkumab for the Treatment of Chronic Plaque Psoriasis in Pediatric Participants (PROTOSTAR). Retrieved from https://clinicaltrials.gov/study/NCT03451851?term=NCT03451851&viewType=Card&rank=1

[79] A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti -Tumor Necrosis Factor (TNF) Alpha Agent(s) (Discover-1). Retrieved from https://clinicaltrials.gov/study/NCT03162796?term=NCT03162796&viewType=Card&rank=1

[80] A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis. Retrieved from https://clinicaltrials.gov/study/NCT03158285?term=NCT03158285&viewType=Card&rank=1

[81] A Study of Guselkumab in Participants With Active Psoriatic Arthritis (APEX). Retrieved from https://clinicaltrials.gov/study/NCT04882098?term=NCT04882098&viewType=Card&rank=1

[82] A Study of the Efficacy and Safety of Guselkumab in Participants With Moderately to Severely Active Crohn's Disease (GALAXI). Retrieved from https://clinicaltrials.gov/study/NCT03466411?term=NCT03466411&viewType=Card&rank=1

	N=285	N=76	Treatment difference	N=288	N=72	Treatment difference
Clinical remission at week 12	47%	20%	27%	47%	15%	31%

Efficacy in moderately to severely active ulcerative colitis in adults

In the 12-week induction trial (UC1), 701 adult subjects with moderately to severely active ulcerative colitis were randomized 3:2 to receive either Tremfya 200 mg or placebo by intravenous infusion at Week 0, Week 4, and Week 8. The primary endpoint was clinical remission at Week 12 as defined by the modified Mayo score (mMS). Those treated with Tremfya had a clinical remission treatment difference of 15% compared to placebo.[83]

The maintenance trial (UC2) evaluated 568 subjects who received one of two intravenous TREMFYA induction regimens, including the recommended 200 mg regimen, for 12 weeks in trials UC1 or UC3 (induction dose-finding study) and demonstrated clinical response per mMS after 12 weeks. Subjects were re-randomized to receive a subcutaneous maintenance regimen of either Tremfya 100 mg every 8 weeks, Tremfya 200 mg every 4 weeks, or placebo for up to an additional 44 weeks. The primary endpoint was clinical remission at Week 44 defined by mMS. Fifty percent of those treated with Tremfya 200mg experienced clinical remission, for a treatment difference of 30% versus placebo.

Clinical safety

- FDA safety warnings and precautions:
  - Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur.
  - Infections: Tremfya may increase the risk of infections.
  - Tuberculosis (TB): Evaluate for TB prior to initiating treatment with Tremfya.
  - Hepatotoxicity: Drug-induced liver injury has been reported.
  - Immunizations: Avoid use of live vaccines.
- Contraindications:
  - History of serious hypersensitivity reactions to guselkumab or to any of the excipients.
- Common side effects:
  - Plaque psoriasis and psoriatic arthritis (≥1%): upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections.
  - Ulcerative colitis (≥3%): injection site reactions, arthralgia, upper respiratory tract infections, headache, gastroenteritis, fatigue, pyrexia, and rash.

[83] 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

- Crohn's disease (≥3%): respiratory tract infections, abdominal pain, injection site reactions, headache, fatigue, arthralgia, diarrhea, and gastroenteritis.

Therapeutic alternatives

Table 4 Therapeutic alternative classes and selected FDA-approved indications

Drug	Class	Indications					
		Adult PsO	Peds PsO	Adult PsA	Peds PsA	Adult CD	Adult UC
Skyrizi (risankizumab-rzaa)	IL-23 antagonist	Yes	≥ 6 years	Yes	≥ 6 years	Yes	Yes
Bimzelx (bimekizumab-bkzx)[84]	IL-17A and F antagonist	Yes	-	Yes	-	-	-
Cosentyx (secukinumab)[85]	IL-17A antagonist	Yes	≥ 6 years	Yes	≥ 2 years	-	-
Enbrel (etanercept)[86]	TNF blocker	Yes	≥ 4 years	Yes	≥ 2 years	-	-
Entyvio (vedolizumab)[87]	Integrin receptor antagonist	-	-	-	-	Yes	Yes
Humira (adalimumab)[88]	TNF blocker	Yes	-	Yes	-	Yes	Yes
Ilumya (tildrakizumab-asmn)[89]	IL-23 antagonist	Yes	-	-	-	-	-
Omvoh (mirikizumab-mrkz)[90]	IL-23 antagonist	-	-	-	-	Yes	Yes
Remicade (infliximab)[91]	TNF blocker	Yes	-	Yes	-	Yes	Yes

[84] U.S. Food & Drug Administration. Bimzelx (bimekizumab-bkzx) Prescribing Information. UCB Inc., Revised 11/2024.
[85] U.S. Food & Drug Administration. Cosentyx (secukinumab) Prescribing Information. Novartis, Revised 4/2026.
[86] U.S. Food & Drug Administration. Enbrel (etanercept) Prescribing Information. Immunex, Revised 1/2026.
[87] U.S. Food & Drug Administration. Entyvio (vedolizumab) Prescribing Information. Takeda, Revised 2/2026.
[88] U.S. Food & Drug Administration. Humira (adalimumab) Prescribing Information. AbbVie Inc., Revised 12/2025.
[89] U.S. Food & Drug Administration. Ilumya (tildrakizumab-asmn) Prescribing Information. Sun Pharma, Revised 12/2025.
[90] U.S. Food & Drug Administration. Omvoh (mirikizumab-mrkz) Prescribing Information. Eli Lilly and Co., Revised 10/2025.
[91] U.S. Food & Drug Administration. Remicade (infliximab) Prescribing Information. Janssen Biotech Inc., Revised 2/2025.

Drug	Class	Indications					
		Adult PsO	Peds PsO	Adult PsA	Peds PsA	Adult CD	Adult UC
Stelara (ustekinumab)[92]	IL-12 and -23 antagonist	Yes	≥ 6 years	Yes	≥ 6 years	Yes	Yes
Taltz (ixekizumab)[93]	IL-17A antagonist	Yes	≥ 6 years	Yes	-	-	-
Tremfya (guselkumab)[94]	IL-23 antagonist	Yes	≥ 6 years	Yes	≥ 6 years	Yes	Yes
Products may have additional FDA-approved indications not included in the table							

Table 5 Summary of key clinical trials – adult plaque psoriasis[95]

Trial	Population (treatment/ placebo)	Endpoint	PGA/rPGA/sPGA/IGA of 0 or 1, N (%)	
			Treatment	Placebo
Tremfya Study PsO1[96]	329/174	Week 16	280 (85)	12 (7)
Tremfya Study PsO2[97]	496/248	Week 16	417 (84)	21 (8)
Bimzelx Ps-1[98]	321/83	Week 16	270 (84)	4 (5)
Bimzelx Ps-2[99]	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)

[92]U.S. Food & Drug Administration. Stelara (ustekinumab) Prescribing Information. Janssen Biotech Inc., Revised 4/2026.

[93] U.S. Food & Drug Administration. Taltz (ixekizumab) Prescribing Information. Eli Lilly and Co., Revised 8/2024.

[94] U.S. Food & Drug Administration. Tremfya (guselkumab) Prescribing Information. Janssen Biotech Inc., Revised 5/2026.

[95] 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.

[96] 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

[97] 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

[98] 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

[99] 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[100]	309/154	Week 12	179 (58)	11 (7)
Ilumya Trial 3[101]	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)
Skyrizi Ps-1	304/102	Week 16	267 (88)	8 (8)
Skyrizi Ps-2	294/98	Week 16	246 (84)	5 (5)
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[102]	433/431	Week 12	354 (82)	14 (3)
Taltz Trial 2[103]	351/168	Week 12	292 (83)	4 (2)
Taltz Trial 3[104]	385/193	Week 12	310 (81)	13 (7)

[a] 300 mg treatment group
[b] 50 mg treatment group
[c] 5 mg/kg treatment group
[d] 90 mg treatment group

Table 6 Summary of key clinical trials – ulcerative colitis[105]

Trial	Endpoint	Placebo	Treatment	Treatment Difference
	Week 12	N=280	N=421	

[100] 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

[101] 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

[102] 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

[103] 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

[104] 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

[105] 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.

Tremfya Trial UC1[106]		8%	23%	15%
Entyvio SC UC Trial[107]	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[108]	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
Skyrizi Trial UC-1[109]	Week 12	N=320	N=646	
		8%	24%	16%
Stelara Trial UC-1[110]	Week 8	N=319	N=322	
		7%	19%	12%
*5 mg/kg treatment group NR = not reported				

Table 7 Selected safety and therapeutic considerations[111]

Drug	Hyper-sensitivity	Infections	TB	Hepato-toxicity	Immuniz-ations	Malignancy
Tremfya	Yes	Yes	Yes	Yes	Yes	-
Bimzelx	-	Yes	Yes	Yes	Yes	-
Cosentyx	Yes	Yes	Yes	-	Yes	-
Enbrel	Yes	**Yes**	-	-	-	**Yes**

[106] 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

[107] 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

[108] 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

[109] 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

[110] 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

[111] "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.

Entyvio	Yes	Yes	-	-	-	-
Humira	Yes	**Yes**	-	-	-	**Yes**
Ilumya	Yes	Yes	Yes	-	Yes	-
Omvoh	Yes	Yes	Yes	Yes	Yes	-
Remicade	Yes	**Yes**	-	Yes	Yes	**Yes**
Skyrizi	Yes	Yes	Yes	Yes	Yes	-
Stelara	Yes	Yes	Yes	-	Yes	Yes
Taltz	Yes	Yes	Yes	-	Yes	-
Bold text indicates a boxed warning.						

Table 8 Route and adult dosing

Drug	Formulation	Induction Dosing	Maintenance Dosing
Tremfya	SC/IV	PsO, PsA: 100 mg SC at weeks 0 and 4 CD, UC: 200 mg IV or 400 mg SC at weeks 0, 4 and 8	PsO, PsA: 100 mg SC every 8 weeks CD, UC: 100 mg SC at week 16 and every 8 weeks thereafter or 200 mg SC at week 12 and every 4 weeks thereafter
Bimzelx	SC	PsO: 320 mg SC at weeks 0, 4,8, 12 and 16 PsA: No induction	PsO: 320 mg SC every 4 weeks PsA: 160 mg SC every 4 weeks
Cosentyx	IV/SC	PsO: 300 mg SC at weeks 0, 1, 2, 3, and 4 PsA: 150 mg SC at weeks 1, 2, 3, and 4 (induction is optional)	PsO: 300 mg every 4 weeks PsA: 150 mg every 4 weeks
Enbrel	SC	PsO: 50 mg twice weekly for 3 months PsA: No induction	PsO: 50 mg weekly 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 108 mg SC every two weeks
Humira	SC	PsO: 80 mg SC PsA: No induction CD, UC: 160 mg SC on day 1, 80 mg on day 15	PsO, PsA, CD, UC: 40 mg SC every 2 weeks

Drug	Formulation	Induction Dosing	Maintenance Dosing
Ilumya	SC	100 mg SC at weeks 0 and 4	100 mg SC every 12 weeks
Omvoh	IV/SC	CD: 900 mg IV at weeks 0, 4 and 8 UC: 300 mg IV at weeks 0, 4 and 8	CD: 300 mg SC every 4 weeks 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
Skyrizi	IV/SC	PsO, PsA: 150 mg SC at weeks 0 and 4 CD: 600 mg IV at weeks 0, 4 and 8 UC: 1,200 mg IV at weeks 0, 4 and 8	PsO, PsA: 150mg SC every 12 weeks CD, UC: 180 mg or 360 mg SC at week 12, then every 8 weeks
Stelara	IV/SC	PsO, PsA: 45 mg SC at weeks 0 and 4 CD, UC: 390 mg IV*	PsO, PsA: 45 mg SC every 12 weeks 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 PsA: 160 mg SC at week 0	PsO, PsA: 80 mg SC every 4 weeks
*Dosing is based on a 75 kg patient			

Table 9 Dosing in pediatric PsO and PsA

Drug	Induction Dosing	Maintenance Dosing
Tremfya	≥ 40 kg: 100 mg SC at weeks 0 and 4	≥ 40 kg: 100 mg SC every 8 weeks
Cosentyx	< 50 kg: 75 mg ≥ 50 kg: 150 mg SC at weeks 0, 1, 2, 3, and 4	< 50 kg: 75 mg ≥ 50 kg: 150 mg SC every 4 weeks
Enbrel	No induction dosing	0.8 mg/kg weekly (max 50 mg weekly)
Skyrizi	<40 kg: 55 mg ≥ 40 kg: 150 mg SC at weeks 0 and 4	<40 kg: 55 mg ≥ 40 kg: 150 mg SC every 12 weeks

Drug	Induction Dosing	Maintenance Dosing
Stelara	< 60 kg: 0.75 mg/kg 60 – 100 kg: 45 mg > 100 kg: 90 mg SC at weeks 0 and 4	< 60 kg: 0.75 mg/kg 60 – 100 kg: 45 mg > 100 kg: 90 mg SC every 12 weeks
Taltz (PsO only)	< 25 kg: 40 mg 25 – 50 kg: 80 mg > 50 kg: 160 mg SC at week 0	< 25 kg: 20 mg 25 – 50 kg: 40 mg > 50 kg: 80 mg SC every 4 weeks

Clinical benefits and disadvantages

The considerations below reflect guideline- and label-level information for the 11 board-selected therapeutic alternatives only. Consistent with the limitation noted for the trial data elsewhere in this document, these benefits and disadvantages are not derived from head-to-head efficacy comparisons and should not be read as implying one agent is more effective than another. Meaningful differences between the agents is centered on route/frequency of administration, monitoring burden, and safety-driven restrictions on use.

Table 10 Clinical benefits and disadvantages

Drug	Clinical benefits	Clinical disadvantages
Tremfya	Broadest approval of agents reviewed. Dosing at 8 week intervals may improve adherence.	PsJIA approval relies on extrapolation from adult efficacy data combined with pediatric safety and pharmacokinetic data rather than dedicated pediatric efficacy trials.
Bimzelx	Dosing at 4 week intervals may improve adherence. Only available in a SC formulation, no infusion center visit is required. No induction is required for PsA	Il-17 therapy is associated with an increased risk for candidiasis; the risk of mild candidiasis is greatest with bimekizumab. Il-17 therapies may be associated with a higher rate of exacerbations of IBD.
Cosentyx	Dosing at 4 week intervals may improve adherence. Induction dose is optional for PsA. Biosimilar approval is pending. PsJIA approval is supported by a randomized pediatric trial.	Il-17 therapies may be associated with a higher rate of exacerbations of IBD and are generally avoided or used with caution.

Drug	Clinical benefits	Clinical disadvantages
Enbrel	Only available in a SC formulation, no infusion center visit is required which may improve adherence. No induction dose is required for PsA. Multiple biosimilars are available.	Weekly dosing may be less attractive to patients. Biosimilars are approved; however, their launch appears to be delayed to 2029. TNF agents carry black boxed warnings for infection risk (TB, bacterial sepsis, and invasive fungal infections) and malignancies (lymphoma and others) in children and adolescents.
Entyvio	IV dosing at 8 week intervals may improve adherence.	SC dosing every 2 weeks may be less favorable for adherence than other options. Biosimilars are approved; however, their launch appears to be delayed to 2029.
Humira	Only available in a SC formulation, no infusion center visit is required which may improve adherence. Multiple biosimilars are available.	Dosed at 2 week intervals. TNF agents carry black boxed warnings for infection risk (TB, bacterial sepsis, and invasive fungal infections) and malignancies (lymphoma and others) in children and adolescents.
Ilumya	Only available in a SC dose with 12 week dosing intervals; extended dosing, favorable injection site, and lack of an infusion center visit may improve adherence.	Tildrakizumab may be less effective than other IL-23 agents for the treatment of chronic plaque psoriasis in adults.
Omvoh	Dosing at 4 week intervals may improve adherence.	Fewer approved FDA indications.
Remicade	Dosing at 8 week intervals may improve adherence. Several biosimilars are available.	Available IV only, requiring an infusion center visit which could impact adherence. TNF agents carry black boxed warnings for infection risk (TB, bacterial sepsis, and invasive fungal

Drug	Clinical benefits	Clinical disadvantages
		infections) and malignancies (lymphoma and others) in children and adolescents.
Skyrizi	Broadest approval of agents reviewed. Dosing at 8 or 12 week intervals may improve adherence.	PsJIA approval relies on extrapolation from adult efficacy data combined with pediatric safety and pharmacokinetic data rather than dedicated pediatric efficacy trials. The IMMerge trial in plaque psoriasis showed that Risankizumab had a slower onset of action at secukinumab through week 4, but was noninferior at 16 weeks and more effective at week 52; this may be important if a faster onset is desired or necessary.
Stelara	Broadest approval of agents reviewed. Dosing at 8-12 week intervals may improve adherence. Several biosimilars are available.	PsJIA approval relies on extrapolation from adult efficacy data combined with pediatric safety and pharmacokinetic data rather than dedicated pediatric efficacy trials.
Taltz	Dosing at 4 week intervals may improve adherence.	Can trigger or worsen IBD