

Drug Coverage Policy

Effective Date.......10/15/2025
Coverage Policy Number......IP0674
Policy Title.....Entyvio Intravenous
Prior Authorization Policy

Inflammatory Conditions – Entyvio Intravenous Prior Authorization Policy

• Entyvio® (vedolizumab intravenous infusion – Takeda)

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 quidelines. In certain markets, delegated vendor quidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

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Entyvio intravenous (IV), an integrin receptor antagonist, is indicated for the following uses:1

- **Crohn's disease**, in adults with moderately to severely active disease.
- **Ulcerative colitis**, in adults with moderately to severely active disease.

Therapy begins with Entyvio 300 mg IV at Weeks 0, 2, and 6, followed by every 8 weeks thereafter. Alternatively, at Week 6, or at any scheduled Entyvio IV infusion in patients with a clinical response or remission, therapy can be switched to Entyvio SC. Additionally, data from the pivotal trial extension studies provide evidence that shortening the dosing interval in patients who lose clinical response to standard Entyvio dosing can help recapture therapeutic benefit. 8,9

Guidelines

Guidelines for the treatment of inflammatory conditions recommend use of Entyvio.

- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] has guidelines for the management of CD in adults.² 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, interleukin (IL)-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib). If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Guidelines from the American Gastroenterological Association (AGA) [2021] include various biologics among the therapies for moderate to severe CD, for induction and maintenance of remission.³
- **Ulcerative Colitis:** The AGA (2024) and the ACG (2025) have clinical practice guidelines on the management of moderate to severe UC.^{4,5} In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include TNF inhibitors, Entyvio, IL-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state corticosteroids may be avoided entirely when other effective induction strategies are planned.⁵ Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.^{4,5}

Other Uses with Supportive Evidence

There are guidelines and/or published data supporting the use of Entyvio in the following conditions:

- Gastrointestinal Toxicity Associated with Checkpoint Inhibitor Therapy: The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for Management of Immunotherapy-Related Toxicities (version 1.2025 December 20, 2024) recommend Entyvio Intravenous as an option, following corticosteroids, for esophagitis, gastritis, duodenitis, or colitis associated with immune checkpoint inhibitor therapy.⁶
- National Comprehensive Cancer network (NCCN) [version 2.2025 June 5, 2025] list Entyvio Intravenous among the agents used for steroid-refractory acute GVHD. For patients with steroid-refractory acute GVHD, Jakafi® (ruxolitinib tablets) is the only category 1 recommended agent. Other alternative agents recommended by NCCN for acute GVHD (category 2A) include the following: alemtuzumab IV infusion, alpha-1 antitrypsin, antithymocyte globulin, Simulect® (basiliximab), calcineurin inhibitors (e.g., tacrolimus, cyclosporine), Enbrel® (etanercept), extracorporeal photopheresis, infliximab, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, Nipent™ (pentostatin), tocilizumab, urinary-derived human chorionic gonadotropin/epidermal growth factor, and Entyvio® (vedolizumab).

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POLICY STATEMENT

Prior Authorization is required for benefit coverage of Entyvio intravenous. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Entyvio intravenous as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Entyvio intravenous to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Entyvio intravenous is considered medically necessary when ONE of the following is met (1, 2, 3, or 4):

FDA-Approved Indications

- **1. Crohn's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - **A)** <u>Initial Therapy</u>. Approve for 6 months if the patient meets ALL of the following (i, ii, <u>and</u> iii):
 - i. Patient is \geq 18 years of age; AND
 - **ii.** Patient meets ONE of the following (a, b, c, or d):
 - **a)** Patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated in this patient; OR
 - b) Patient has tried one conventional systemic therapy for Crohn's disease; OR Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for Crohn's disease. These patients who have already received a biologic are not required to "step back" and try another agent. A trial of mesalamine does not count as a systemic therapy for Crohn's disease.
 - c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - **d)** Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
 - iii. The medication is prescribed by or in consultation with a gastroenterologist; OR
 - **B)** Patient is Currently Receiving Entyvio Intravenous or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on the requested drug for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least ONE of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.

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b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

Dosing. Approve ONE of the following dosage regimens (A or B):

- **A)** Initial Therapy. Approve ONE of the following (i or ii):
 - **i.** The dose is 300 mg as an intravenous infusion at Weeks 0, 2, and 6, and then no more frequently than once every 8 weeks thereafter; OR
 - ii. The dose is 300 mg as an intravenous infusion administered at Week 0 and 2; OR
- **B)** Patient is Currently Receiving Entyvio Intravenous or Subcutaneous. Approve up to a maximum dose of 300 mg administered intravenously no more frequently than once every 4 weeks.
- **2. Ulcerative Colitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - **A)** <u>Initial Therapy</u>. Approve for 6 months if the patient meets BOTH of the following (i <u>and</u> ii):
 - i. Patient is ≥ 18 years of age; AND
 - ii. The medication is prescribed by or in consultation with a gastroenterologist; OR
 - **B)** Patient is Currently Receiving Entyvio Intravenous or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on Entyvio intravenous or subcutaneous for at least 6 months; AND
 - <u>Note</u>: A patient who has received < 6 months of therapy or who is restarting therapy with Entyvio intravenous or subcutaneous is reviewed under criterion A (Initial Therapy).
 - **ii.** Patient meets at least ONE of the following (a <u>or</u> b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
 - **b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

Dosing. Approve ONE of the following dosage regimens (A or B):

- **A)** <u>Initial Therapy</u>. Approve ONE of the following (i <u>or</u> ii):
 - i. The dose is 300 mg as an intravenous infusion at Week 0, 2, and 6, and then no more frequently than once every 8 weeks thereafter; OR
 - ii. The dose is 300 mg as an intravenous infusion administered at Week 0 and 2; OR
- **B)** Patient is Currently Receiving Entyvio Intravenous or Subcutaneous. Approve up to a maximum dose of 300 mg administered intravenously no more frequently than once every 4 weeks.

Other Uses with Supportive Evidence

3. Gastrointestinal Toxicity Associated with Checkpoint Inhibitor Therapy. Approve for the duration noted if the patient meets ONE of the following (A <u>or</u> B):

<u>Note</u>: Examples of checkpoint inhibitors are Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Yervoy (ipilimumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Bavencio (avelumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), and Libtayo (cemiplimab-rwlc intravenous infusion).

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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 ≥ 18 years of age; AND
 - **ii.** According to the prescriber, patient developed gastrointestinal toxicity while receiving a checkpoint inhibitor; AND
 - **iii.** Patient is symptomatic despite a trial of at least ONE systemic corticosteroid; AND Note: Examples of a corticosteroid include methylprednisolone and prednisone.
 - **iv.** The medication is prescribed by or in consultation with a gastroenterologist or an oncologist; OR
- **B)** <u>Patient is Currently Receiving Entyvio Intravenous</u>. Approve for 1 year if the patient meets BOTH of the following (i <u>and</u> ii):
 - i. Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).
 - **ii.** Patient meets at least ONE of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR Note: Examples of objective measures may include clinically significant improvement or normalization of serum markers (e.g., C-reactive protein), fecal markers (e.g., fecal calprotectin), endoscopic assessment, and/or reduced dosage 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.

Dosing. Approve if dosage regimen meets BOTH of the following (A and B):

- A) The dose is 300 mg as an intravenous infusion administered at Week 0, 2, and 6; AND
- **B)** Subsequent doses are separated by at least 8 weeks
- **4. Graft-Versus-Host Disease.** Approve for the duration noted if the patient meets ONE of the following (A <u>or</u> B):
 - **A)** <u>Initial Therapy</u>. Approve for 1 month if the patient meets ALL of the following (i, ii, iii, <u>and</u> iv):
 - i. Patient is ≥ 18 years of age ; AND
 - ii. Patient has acute graft-versus-host disease; AND
 - iii. Patient has tried at least one systemic medication for graft-versus-host disease; AND

<u>Note</u>: Examples of systemic medications include corticosteroids (e.g., methylprednisolone), antithymocyte globulin, cyclosporine, tacrolimus, mycophenolate mofetil, Jakafi (ruxolitinib), Simulect (basiliximab), an etanercept product, an infliximab product, sirolimus, Nipent (pentostatin), and a tocilizumab product.

- **iv.** The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; OR
- **B)** Patient is Currently Receiving Entyvio Intravenous. Approve for 3 months if the patient meets BOTH of the following (i and ii):
 - **i.** Patient has been established on therapy for at least 1 month; AND $\underline{\text{Note}}$: A patient who has received < 1 month 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 Entyvio); OR

- <u>Note</u>: Examples of objective measures include improvement on endoscopic assessment, normalization of liver function tests, red blood cell count, or platelet count; or resolution of fever or rash.
- **b)** Compared with baseline (prior to initiating Entyvio), patient experienced an improvement in at least one symptom, such as improvement in oral mucosal or gastrointestinal symptoms (e.g., diarrhea, nausea, vomiting, anorexia) or decreased fatigue.

Dosing. Approve if dosage regimen meets BOTH of the following (A and B):

- A) The dose is 300 mg as an intravenous infusion administered at Week 0, 2, and 6; AND
- **B)** Subsequent doses are separated by at least 8 weeks

Conditions Not Covered

Entyvio intravenous for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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 Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

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

Coding Information

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J3380	Injection, vedolizumab, 1mg

References

- 1. Entyvio intravenous infusion [prescribing information]. Deerfield, IL: Takeda; April 2024.
- 2. Lichtenstein G, Loftus E, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2025 June;120(6):1225-1264.
- 3. 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.

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- 4. 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.
- 5. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol.* 2025 June;120(6):1187-1224.
- 6. The NCCN Management of Immunotherapy-Related Toxicities Clinical Practice Guidelines in Oncology (version 1.2025 December 20, 2024). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2025.
- 7. The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 2.2025 June 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2025.
- 8. Loftus EV Jr, Colombel JF, Feagan BG, et al. Long-term Efficacy of Vedolizumab for Ulcerative Colitis. *J Crohns Colitis*. 2017 Apr 1;11(4):400-411.
- 9. Vermeire S, Loftus EV Jr, Colombel JF et al. Long-term Efficacy of Vedolizumab for Crohn's Disease. *J Crohns Colitis.* 2017 Apr 1;11(4):412-424.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024
Annual Revision	Crohn's Disease: Updated dosing to add option of approval for 300 mg intravenous infusion administered at Week 0 and 2. Ulcerative Colitis: Updated dosing to add option of approval for 300 mg intravenous infusion administered at Week 0 and 2.	06/01/2025
Selected Revision	Ulcerative Colitis: For initial therapy, removed the following options of approval: (1) the patient has tried one systemic therapy; (2) the patient has pouchitis and tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema.	09/01/2025
Selected Revision	Gastrointestinal Toxicity Associated with Checkpoint Inhibitor Therapy: This condition and criteria and dosing for approval were added to the policy. Graft-Versus-Host Disease: This condition and criteria and dosing for approval were added to the policy. Crohn's Disease: Dosing was divided into an initial therapy and continuation of therapy regimen. Added an option of approval for 300 mg intravenous infusion administered every 4 weeks for a patient currently receiving Entyvio intravenous or subcutaneous. Ulcerative Colitis: Dosing was divided into an initial therapy and continuation of therapy regimen. Added an option of approval for 300 mg intravenous infusion administered every 4 weeks for a patient currently receiving Entyvio intravenous or subcutaneous.	10/15/2025

The policy effective date is in force until updated or retired.

APPENDIX

	Mechanism of Action	Examples of Indications*				
Biologics						
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC				
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA				
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA				
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC				
Zymfentra ® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC				
Simponi [®] , Simponi Aria [®] (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC				
		IV formulation: AS, PJIA, PsA, RA				
Tocilizumab Products (Actemra [®] IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA				
		IV formulation: PJIA, RA, SJIA				
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA				
Orencia® (abatacept IV infusion,	T-cell costimulation	SC formulation: JIA, PSA, RA				
abatacept SC injection)	modulator	IV formulation: JIA, PsA, RA				
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA				
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA				
Omvoh ® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC				
Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC				
		IV formulation: CD, UC				
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO				
Cosentyx ® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA				
		IV formulation: AS, nr- axSpA, PsA				
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA				
Bimzelx ® (bimekizumab-bkzx SC injection)	Inhibition of IL- 17A/17F	PsO, AS, nr-axSpA, PsA				
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO				
Skyrizi [®] (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC IV formulation: CD, UC				
Tremfya [®] (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC IV formulation: CD, UC				
Entyvio ® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC				
	Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs					
Otezla® (apremilast tablets)Inhibition of PDE4PsO, PsA						

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Cibinqo ™ (abrocitinib tablets)	Inhibition of JAK	AD
	pathways	
Olumiant® (baricitinib tablets)	Inhibition of JAK	RA, AA
	pathways	
Litfulo® (ritlecitinib capsules)	Inhibition of JAK	AA
	pathways	
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK	AA
	pathways	
Rinvoq® (upadacitinib extended-release	Inhibition of JAK	AD, AS, nr-axSpA, RA, PsA,
tablets)	pathways	CD, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK	PsA, PJIA
	pathways	
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral	Inhibition of JAK	RA, PJIA, PsA, UC
solution)	pathways	
Xeljanz® XR (tofacitinib extended-	Inhibition of JAK	RA, PsA, UC
release tablets)	pathways	
Zeposia® (ozanimod tablets)	Sphingosine 1	UC
- ` `	phosphate receptor	
	modulator	
Velsipity® (etrasimod tablets)	Sphingosine 1	UC
•	phosphate receptor	
	modulator	

^{*} Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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