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 Policy Number: C10424-A

Stelara (ustekinumab) and Biosimilars

PRODUCTS AFFECTED

Imuldosa (ustekinumab-srlf), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), Selarsdi (ustekinumab-aekn), Stelara (ustekinumab), Steqeyma (ustekinumab-stba), ustekinumab, ustekinumab-aekn, ustekinumab-ttwe, Wezlana (ustekinumab-aaub), Yesintek (ustekinumab-kfce)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Plaque psoriasis (Ps), Active psoriatic arthritis (PsA), Crohn's disease (CD), Ulcerative colitis (UC)

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:

1. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B,

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tuberculosis, etc.), including clinically important localized infections, according to the FDA label
AND

2. Member is not on concurrent treatment or will not be used in combination with TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
3. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
AND
(b) If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
[DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]
MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
OR

4. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN
ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:

- a. Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, or is contraindicated (i.e., an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)

[DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]

B. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Documented treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine OR
(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]

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OR

(c) Documentation member has severe psoriasis [PASI ≥ 12 , BSA of $>5-10\%$, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

AND

4. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor

NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

C. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA $\geq 3\%$ OR $< 3\%$ body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)

AND

2. (a) Documentation of treatment failure or serious side effects to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus

OR

(b) Documentation of treatment failure to Phototherapy for ≥ 3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation. Provider to submit documentation of duration of treatment, dates of treatment, or number of sessions.

OR

(c) Documentation of contraindication to systemic therapy and phototherapy

NOTE: Contraindications to phototherapy include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time.

AND

3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

D. CROHN'S DISEASE:

1. Documentation of a diagnosis of Crohn's Disease

AND

2. Member has one or more high risk feature:

- i. Diagnosis at a younger age (<30 years old)
- ii. History of active or recent tobacco use
- iii. Elevated C-reactive protein and/or fecal calprotectin levels
- iv. Deep ulcers on colonoscopy
- v. Long segments of small and/or large bowel involvement
- vi. Perianal disease
- vii. Extra-intestinal manifestations
- viii. History of bowel resections

AND

3. (a) Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (>3 months) of ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate) up to maximally indicated doses

OR

(b) Prescriber provides documented medical justification that supports the inability to use immunomodulators

- i. Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids

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- ii. High-risk factors for intestinal complications may include: Initial extensive ileal, ileocolonic, or proximal GI involvement, Initial extensive perianal/severe rectal disease, Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas), Deep ulcerations, Penetrating, stricturing or stenosis disease and/or phenotype, Intestinal obstruction, or abscess
- iii. High risk factors for postoperative recurrence may include: Less than 10 years duration between time of diagnosis and surgery, Disease location in the ileum and colon, Perianal fistula, Prior history of surgical resection, Use of corticosteroids prior to surgery

AND

- 4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
- AND
- 5. FOR INITIAL SC THERAPY: The member has received a single induction dose with ustekinumab IV within 2 months of initiating therapy with ustekinumab SC

E. ULCERATIVE COLITIS:

- 1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
- AND
- 2. (a) Documentation of treatment failure, serious side effects or clinical contraindication to a 2- month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently.
NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion]) also counts as a trial of one systemic agent for UC.
- OR
- b) Member has severe disease indicated by one or more of the following: > 6 stools per day, frequent bloody stools, frequent urgency or incontinence, laboratory abnormalities (i.e., anemia, elevated CRP, low albumin), severe indicators on endoscopy or imaging (i.e., mucosal inflammation, extensive colitis)
- OR
- c) Documentation the member has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® (hydrocortisone enema, generics)], or topical mesalamine
- AND
- 3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
- AND
- 4. FOR INITIAL SC THERAPY: The member has received a single induction dose with ustekinumab IV within 2 months of initiating therapy with ustekinumab SC

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

- 1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
- AND
- 2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
- AND
- 3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
- AND
- 4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

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DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:

CROHN'S DISEASE/ULCERATIVE COLITIS: Prescribed by or in consultation with a board-certified gastroenterologist or colorectal surgeon

PSORIATIC ARTHRITIS (PsA): Prescribed by or in consultation with a board-certified rheumatologist or dermatologist

CHRONIC PLAQUE PSORIASIS: Prescribed by or in consultation with a board-certified dermatologist

[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Plaque Psoriasis, Psoriatic Arthritis: 6 years of age and older

All other indications: 18 Years of age or older

QUANTITY:

Plaque Psoriasis in adults:

≤100kg: 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks

>100kg: 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks

Plaque Psoriasis pediatrics (6 years of age through 17 years of age): Weight based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter

< 60kg: 0.75mg/kg

60kg- 100kg: 45mg

> 100kg: 90 mg

Psoriatic Arthritis in adults: 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks

Psoriatic Arthritis with moderate-to-severe Psoriasis in adults >100 kg: 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks

Psoriatic Arthritis pediatrics (6 years of age through 17 years of age): Weight based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter

< 60kg: 0.75mg/kg

>60kg: 45mg

> 100kg with co-existent moderate-to-severe plaque psoriasis: 90 mg

Crohn's Disease and Ulcerative Colitis Initial: Single IV infusion using weight-based dosing:

up to 55kg: 260 mg (2 vials)

> 55 to 85kg: 390mg (3 vials)

> 85kg: 520mg (4 vials)

Crohn's Disease and Ulcerative Colitis Maintenance of Remission:

90 mg subcutaneously 8 weeks after IV induction, then 90mg every 8 weeks thereafter

When requests for off-label dosing, dose escalation, or dose intensification are received, requests will be reviewed for evidence that current or standard dosing is not adequate to produce a therapeutic level of drug (e.g., pharmacokinetic failure), clinical failure or significant loss of response is present, and the requested dosing is established as safe and effective for the condition. There are certain situations where no additional amount of drug is likely to produce or recapture clinical effect because the condition is no longer responsive to the drug (e.g., pharmacodynamic failure) or the drug cannot reach the site of activity at sufficient levels. Review the following items to determine if the requested dosing is medically necessary:

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1. *FDA or compendium-supported dosing and therapeutic monitoring recommendations for the drug*
AND
2. *Member claims/adherence history*
AND
3. *Clinical documentation of the member's response to current or standard dosing regimens (disease activity indices if commonly used in clinical practice or documentation to approximate them may be necessary to demonstrate the response)*
AND
4. *In conjunction with documented clinical failure or loss of response or wearing off of effect, test results that demonstrate failure of current or standard dosing to reach established treatment thresholds (e.g., established therapeutic monitoring recommendations)*
AND
5. *If applicable, documentation showing the member does not have conditions which make achieving a therapeutic level of drug unlikely even with dose intensification (e.g., dose intensification may be futile due to the presence of anti-drug antibodies, protein losing enteropathy, nephrotic syndrome, severe drug excretion or malabsorption issues, etc.)*
AND
6. *In certain situations, documentation, or peer-to-peer determination that re-induction cannot be tried to recapture response as an alternative to long term dose escalation or intensification*

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous, Intravenous

DRUG CLASS:

Interleukin Antagonists, Antipsoriatics - Systemic

FDA-APPROVED USES:

Indicated for the treatment of:

Adult patients with:

- moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA)
- moderately to severely active Crohn's disease (CD)
- moderately to severely active ulcerative colitis.

Pediatric patients 6 years and older with:

- moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA)

NOTE: Information in chart is accurate as of the time of this writing. Please refer to the individual product label.

Product	Interchangeable?	Approved Formulations
Stelara ustekinumab		130 mg vial 45 mg vial 45 mg prefilled syringe

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		90 mg prefilled syringe
Imuldosa	No	130 mg vial 45 mg prefilled syringe 90 mg prefilled syringe
Otulfi	Yes	130 mg vial 45 mg vial 45 mg prefilled syringe 90 mg prefilled syringe
Pyzchiva ustekinumab-ttwe	Yes	130 mg vial 45 mg vial 45 mg prefilled syringe 90 mg prefilled syringe 45 mg autoinjector 90 mg autoinjector
Selarsdi ustekinumab-aekn	Yes	130 mg vial 45 mg prefilled syringe 90 mg prefilled syringe
Steqeyma	Yes	130 mg vial 45 mg prefilled syringe 90 mg prefilled syringe
Wezlana	Yes	130 mg vial 45 mg vial 45 mg prefilled syringe 90 mg prefilled syringe
Yesintek	Yes	130 mg vial 45 mg vial 45 mg prefilled syringe 90 mg prefilled syringe

COMPENDIAL APPROVED OFF-LABELED USES:

None

NOTE TO REVIEWER: Requests for the following indications should be reviewed for approval through Molina Off-Label policy (see Background for additional information): Immunotherapy related diarrhea or colitis

APPENDIX

APPENDIX:

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

State Specific Information

State Marketplace

Illinois (Source: [Illinois General Assembly](#))

“(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this

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Section shall be honored for 12 months following the date of the approval or until renewal of the plan.”

Texas (Source: [Texas Statutes, Insurance Code](#))

“Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.

(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease.

(b) This section does not apply to:

(1) opioids, benzodiazepines, barbiturates, or carisoprodol;

(2) prescription drugs that have a typical treatment period of less than 12 months;

(3) drugs that:

(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and

(B) must have specific provider assessment; or

(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use.”

APPENDIX 1:

A biosimilar is a highly similar version of a brand name biological drug that meets strict controls for structural, pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product. Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.¹

As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising patient satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products>. Accessed October 8, 2019.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Stelara is indicated for the treatment of those ≥ 12 years of age with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, for adult patients ≥ 18 years of age with active psoriatic arthritis (PsA) alone or in combination with methotrexate (MTX), and for moderate to severe active Crohn's Disease, in patients who have failed or were intolerant to immunomodulators or corticosteroids, but never failed a tumor necrosis factor inhibitor (TNFi), or in patients who failed or were intolerant to at least one TNFi. Stelara is a human immunoglobulin G (IgG) 1k monoclonal antibody against the p40 subunit of the interleukin (IL)-12 and IL-23 cytokines, which are involved in inflammatory and immune responses. It is administered by subcutaneous (SC) injection under the supervision of a physician, although with proper training patients may self-inject. Stelara for intravenous (IV) infusion is indicated for the treatment of adults ≥ 18 years of age with moderate to severe active Crohn's disease, in patients who have failed or were intolerant to immunomodulators or corticosteroids, but never failed a tumor necrosis factor inhibitor (TNFi), or in patients who failed or were intolerant to at least one TNFi. It is a human immunoglobulin G (IgG) 1k monoclonal antibody against the p40 subunit of the interleukin (IL)-12 and IL-23 cytokines, which are involved in inflammatory and immune responses. In Crohn's disease, a single weight-based dose is administered by IV infusion. Following induction therapy with the IV product, the recommended maintenance is Stelara for subcutaneous (SC) injection, given as a 90 mg SC injection administered 8 weeks after the initial IV dose, then once every 8 weeks (Q8W) thereafter.

AGA Guidelines Moderate to Severe Ulcerative Colitis

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Recommendations from the recent 2020 guideline update include:

- In adult outpatients with moderate to severe UC who are naïve to biologic agents, the AGA suggests using infliximab or vedolizumab rather than adalimumab, for induction of remission.
- Updated FDA recommendations (July 26, 2019) on indications for use of tofacitinib in UC recommends its use only after failure of or intolerance to TNF-a antagonists.
- In adult outpatients with moderate to severe UC who have previously been exposed to infliximab, particularly those with primary nonresponse, the AGA suggests using ustekinumab or tofacitinib rather than vedolizumab or adalimumab for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests against using methotrexate monotherapy for induction or maintenance of remission
- In adult outpatients with active moderate to severe UC, the AGA suggests using biologic monotherapy (TNF-a antagonists, vedolizumab, or ustekinumab) or tofacitinib rather than thiopurine monotherapy for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests combining TNF-a antagonists, vedolizumab or ustekinumab with thiopurines or methotrexate rather than biologic monotherapy.
- In adult outpatients with moderate to severe UC who have achieved remission with biologic agents and/or immunomodulators or tofacitinib, the AGA suggests against continuing 5-ASA for induction and maintenance of remission.

The American College of Gastroenterology 2025 UC guidelines encompass recommendations for mild, moderate to severe, and hospitalized UC. These guidelines broadly recommend biologic agents (including sphingosine 1-phosphate receptor modulators, JAK inhibitors, and interleukins).

Wezlana (ustekinumab-aaub) was approved as a biosimilar to Stelara (ustekinumab). Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of Wezlana has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s), strength(s), dosage form(s), and route(s) of administration) described in its Full Prescribing Information.

Immunotherapy related diarrhea or colitis

Recent NCCN guidelines include use of ustekinumab for moderate and severe diarrhea and colitis (grade 2 and above) related to immune checkpoint inhibitor therapy. If no response to treatment with steroids, consider adding infliximab or vedolizumab. For infliximab and/or vedolizumab refractory colitis, consider tofacitinib or ustekinumab. Refer to NCCN guidelines for management of immunotherapy related toxicities.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of ustekinumab are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to ustekinumab include: hypersensitivity to ustekinumab or to any of the excipients, avoid concurrent use of live vaccines, avoid starting ustekinumab during any clinically important active infection.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry- standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim

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payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
J3358	Ustekinumab, for intravenous injection, 1mg
Q5098	Injection, ustekinumab-srlf (imulduosa), biosimilar, 1 mg
Q5099	Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg
Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9997	Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9998	Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg
Q9999	Injection, ustekinumab-aaau (otulfi), biosimilar, 1 mg

AVAILABLE DOSAGE FORMS:

Stelara SOLN 130MG/26ML IV soln, SOLN 45MG/0.5ML single-dose vial, SOSY 45MG/0.5ML prefilled syringe, SOSY 90MG/ML prefilled syringe

Imulduosa SOLN 130MG/26ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Otulfi SOLN 130MG/26ML, SOLN 45MG/0.5ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Pyzchiva SOAJ 45MG/0.5ML, SOAJ 90MG/ML, SOLN 130MG/26ML, SOLN 45MG/0.5ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Selarsdi SOLN 130MG/26ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Steqeyma SOLN 130MG/26ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Ustekinumab SOLN 130MG/26ML, SOLN 45MG/0.5ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Ustekinumab-aekn SOSY 45MG/0.5ML, SOSY 90MG/ML

Ustekinumab-ttwe SOLN 130MG/26ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Wezlana SOLN 130MG/26ML, SOLN 45MG/0.5ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

Yesintek SOLN 130MG/26ML, SOLN 45MG/0.5ML, SOSY 45MG/0.5ML, SOSY 90MG/ML

REFERENCES

1. Stelara (ustekinumab) injection, for subcutaneous or intravenous use [prescribing information]. Horsham, PA: Janssen Biotech, Inc. June 2025.
2. Imulduosa (ustekinumab-srlf) injection, for subcutaneous or intravenous use [prescribing information]. Raleigh, NC: Accord BioPharma Inc.; October 2024.
3. Otulfi (ustekinumab-aaau) injection, for subcutaneous or intravenous use [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; May 2025.
4. Pyzchiva (ustekinumab-ttwe) injection, for subcutaneous or intravenous use [prescribing information]. Princeton, NJ: Sandoz Inc.; June 2025.
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information FDA-Approved Uses Appendix Background Coding/Billing Information Available Dosage Forms References	Q4 2025
REVISION- Notable revisions: Title Products Affected Required Medical Information Appendix Background Contraindications/Exclusions/Discontinuation Coding/Billing Information Available Dosage Forms References	Q1 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q4 2024

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REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Place of Administration Drug Class FDA-Approved Uses Background Coding/Billing Information Available Dosage Forms	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses Compendial Approved Off-Labeled Uses Background Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file