



# Evolut Clinical Guideline 5052.CC for Ustekinumab Products

<b>Guideline Number:</b> EVH_CG_5052.CC	<b><u>Applicable Codes</u></b>	
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## STATEMENT

### General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

### Purpose

The purpose of this guideline is to define the prior authorization process for the ustekinumab products - Stelara<sup>®</sup> and its associated biosimilars. The guideline addresses these products for intravenous administration or subcutaneous administration by a healthcare provider through medical buy and bill. Requests for self-administered subcutaneous utilization should be directed to the pharmacy benefit manager (PBM) for review.

### Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

### Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex<sup>®</sup>, UpToDate<sup>®</sup> Lexidrug<sup>™</sup>, Elsevier Clinical Pharmacology).

## INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

### General Criteria

- Must have a negative tuberculosis skin test collected within the last 6 months
  - Example acceptable testing includes the Tuberculin PPD (purified protein derivative) test or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON<sup>®</sup>-TB Gold In-Tube test (QFT-GIT) or T-SPOT<sup>®</sup>.TB test (T-Spot)]
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baricitinib), or Otezla (apremilast))
- Must have no evidence of serious infection (e.g., pneumonia, cellulitis, aspergillosis)

- Must have documentation or an attestation from the provider that the member is updated on all vaccinations in accordance with current vaccination guidelines
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

## Crohn's Disease (CD)

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active Crohn's disease or fistulizing Crohn's disease, as described in the 2018 ACG guidelines (see **Table 1**)
- Must have an adequate trial (of at least 3 months) and failure of at least one (1) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
  - An adalimumab product
  - Cimzia

## Plaque Psoriasis

- Must be prescribed by, or in consultation with, a dermatologist
- Must be age 6 years or older
- Must have a diagnosis of moderate-to-severe chronic plaque psoriasis 00A0
- Must have documentation of ONE of the following:
  - Affected area(s) include hands, feet, face, neck, scalp, genitals/groin, intertriginous areas
  - Minimum body surface area (BSA) involvement of >10%
  - At least 3% of BSA affected AND the member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) OR pharmacologic treatment with methotrexate, cyclosporine, or acitretin (unless there is a clinical reason to not take pharmacologic treatment – see **Appendix 1**)
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
  - An adalimumab product
  - Enbrel
  - Xeljanz

## Psoriatic Arthritis (PsA)

- Must be prescribed by, or in consultation with, a rheumatologist or dermatologist
- Must be age 6 years or older

- Must have a diagnosis of active psoriatic arthritis, with the severity of disease documented
- For mild-to-moderate disease only, must have ONE of the following:
  - Must have had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) or have a contraindication or intolerance to all drugs (see **Appendix 1**)
  - Must have enthesitis or predominantly axial disease
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
  - An adalimumab product
  - Cimzia
  - Cosentyx
  - Enbrel
  - Xeljanz

## Ulcerative Colitis

- Must be prescribed by, or in consultation with, a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active Ulcerative Colitis, as evidenced by ONE of the following:
  - Dependency on or refractory to corticosteroids
  - Severe endoscopic disease activity (e.g., presence of ulcers)
  - High risk of colectomy
  - Mayo Clinic scores of 6-12, with an endoscopic subscore of 2 or 3
  - Hospitalized with  $\geq 6$  bloody bowel movements per day with at least 1 marker of systemic toxicity (e.g., heart rate  $>90$  beats/min, temperature  $>37.8^{\circ}\text{C}$ , hemoglobin  $<10.5$  g/dL, and/or erythrocyte sedimentation rate  $>30$  mm/h)
- Must have an adequate trial (of at least 3 months) and failure of EACH of the following unless, contraindicated:
  - An adalimumab product
  - Xeljanz

## Immune Checkpoint Inhibitor-Related Toxicity (*off-label supported indication*)

- Must be prescribed by, or in consultation with, a gastroenterologist, hematologist, or oncologist

- Must have had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)

## REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

### General Criteria

- Member must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))

### Crohn's Disease (CD)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Abdominal pain or tenderness
  - Diarrhea
  - Body weight
  - Abdominal mass
  - Hematocrit
  - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
  - Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

### Plaque Psoriasis

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Body surface area (BSA)
  - Signs and Symptoms (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

### Psoriatic Arthritis (PsA)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at

least ONE of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

## **Ulcerative Colitis**

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Stool frequency
  - Rectal bleeding
  - Urgency of defecation
  - C-reactive protein (CRP)
  - Fecal calprotectin (FC)
  - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
  - Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

## **Immune Checkpoint Inhibitor-Related Toxicity (*off-label supported indication*)**

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms.

## APPROVAL DURATIONS

If the above criteria are met, the request will be approved for up to the duration of time dictated below:

<b>Initial Authorization</b>	Up to 1 year
<b>Reauthorization</b>	Up to 1 year

## APPENDICES

### Appendix 1 – Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

### Table 1 – 2018 ACG Clinical Guidelines Classification of Moderate-to-Severe Disease

Moderate-to-Severe Disease	Severe-Fulminant Disease
<ul style="list-style-type: none"> <li>• CDAI 220-450</li> <li>• Have failed treatment for mild to moderate disease</li> <li>• Prominent symptoms such as fever, weight loss, abdominal pain and tenderness, intermittent nausea or vomiting, or anemia</li> <li>• Moderate to severely active endoscopic mucosal disease</li> </ul>	<ul style="list-style-type: none"> <li>• CDAI &gt;450</li> <li>• Persistent symptoms despite glucocorticoids or biologic agents</li> <li>• Individuals presenting with high fever, persistent vomiting, intestinal obstruction, peritoneal signs, cachexia, or evidence of an abscess</li> </ul>

## CODING AND STANDARDS

### Codes

Code	Brand	Description
J3357	Stelara	Injection, Ustekinumab, 1mg
J3358	Stelara IV	Ustekinumab for IV injection, 1mg
J3590	Otulfi	Ustekinumab-aauz
J3590	Steqeyma	Ustekinumab-stba
J3590	Yesintek	Ustekinumab-kfce
Q5137	Wezlana	Injection, Ustekinumab-auub (Wezlana), biosimilar, SC, 1mg
Q5138	Wezlana	Injection, Ustekinumab-auub (Wezlana), biosimilar, IV, 1mg
Q9996	Pyzchiva	Injection, Ustekinumab-ttwe (Pyzchiva), subcutaneous, 1mg
Q9997	Pyzchiva	Injection, Ustekinumab-ttwe (Pyzchiva), intravenous, 1mg
Q9998	Selarsdi	Injection, Ustekinumab-aekn (Selarsdi), 1mg

### Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

## BACKGROUND

Stelara® (ustekinumab) is indicated for the treatment of:

- Patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

- Adult patients (18 years or older) with:
- Active psoriatic arthritis, alone or in combination with methotrexate
- Moderately to severely active Crohn’s disease
- Moderately to severely active ulcerative colitis

## POLICY HISTORY

Date	Summary
March 2024	<ul style="list-style-type: none"> <li>● Renamed guideline Ustekinumab Products</li> <li>● Updated age limit for psoriatic arthritis</li> <li>● Added biosimilars: Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek</li> <li>● Removed prerequisite trials for Crohn’s and ulcerative colitis; added diagnostic criteria for Crohn’s and ulcerative colitis</li> <li>● Added 1 new indication: Immune Checkpoint Inhibitor-Related Toxicity</li> </ul>
March 2022	<ul style="list-style-type: none"> <li>● New Guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

#### Disclaimer

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members’ health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

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