ATRIO HEALTH PLANS

Stelara & Biosimilars Step Therapy

Preferred: **Stelara** (ustekinumab) J3357, **Steqeyma** (ustekinumab-stba) Q5099, **Pyzchiva** (ustekinumab-ttwe) Q9997

Non-preferred: **Imuldosa** (ustekinumab-srlf) Q5098**, Yesintek** (ustekinumab-kfce) Q5100, **Wezlana** (ustekinumab-auub) Q5138, **Selarsdi** (ustekinumab-aekn) Q9998, **Otulfi** (ustekinumab-aauz) Q9999

Prior Authorization Step Therapy **Medicare Part B Request Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **260 mg IV** ☐ **390 mg IV** ☐ **520 mg IV** ☐ **Single Dose;**
☐ **45 mg SUBQ** ☐ **90 mg SUBQ** -- ☐ **Induction (weeks 0 and 4)** ☐ **Maintenance every** ☐ **8 weeks** ☐ **12 weeks**
☐ **Other Regimen**_____

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Preferred: **(PA REQUIRED)**
☐ Stelara ☐ Pyzchiva ☐ Steqeyma
☐ Non-Preferred: **(PA REQUIRED)**
☐ Imuldosa ☐ Otulfi ☐ Selarsdi ☐ Wezlana ☐ Yesintek
☐ Member has tried/failed AT LEAST 3 months of an injectable Preferred alternative

☐ **Crohn's disease (CD)** when each of the following criteria are met:
- ☐ Individual is 6 years of age or older with moderate to severe CD; AND
- ☐ Individual has had an inadequate response to or is intolerant of conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]); OR
- ☐ Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;

☐ **Ulcerative colitis (UC)** when each of the following criteria are met:
- ☐ Individual is 5 years of age or older with moderate to severe UC; AND
- ☐ Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); OR
- ☐ Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

☐ **Psoriatic arthritis (PsA)** when each of the following criteria are met:
- ☐ Individual is 18 years of age or older with moderate to severe PsA; AND
- ☐ Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; OR
- ☐ Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

☐ **Plaque psoriasis (Ps)** when each of the following criteria are met:
- ☐ Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following:
  - ☐ Plaque Ps involving greater than three percent (3%) body surface area (BSA); OR
  - ☐ Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); AND
- ☐ Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); OR
- ☐ Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

☐ **Hidradenitis suppurativa (HS)** when each of the following criteria are met: (**Stelara ONLY**)
- ☐ Individual is 12 years of age or older; AND
- ☐ Individual has moderate to severe HS (Hurley stage II or Hurley stage III disease); AND
- ☐ Individual has had an inadequate response to or is intolerant of conventional therapy (such as oral antibiotics); OR
- ☐ Individual has a contraindication to oral antibiotics;

☐ **Other indication**: _____
- ☐ Medical documentation to support the indication and use is attached and meets compendial guidelines.

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**
If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.
If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Anti-Inflammatory Therapy PA

Drug Name(s):

STELARA	**USTEKINUMAB**	**IMULDOSA**	**USTEKINUMAB-SRLF**
STEQEYMA	**USTEKINUMAB-STBA**	**YESINTEK**	**USTEKINUMAB-KFCE**
WEZLANA	**USTEKINUMAB-AUUB**	**PYZCHIVA**	**USTEKINUMAB-TTWE**
SELARSDI	**USTEKINUMAB-AEKN**	**OTULFI**	**USTEKINUMAB-AAUZ**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: S**telara, Steqeyma or Pizchiva** OR
   - There is clinical documentation stating formulary alternatives are contraindicated.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 12 months

FDA Indications:

Stelara & Biosimilars

- Crohn's disease (Moderate to Severe
- Plaque psoriasis (Moderate to Severe)
- Psoriatic arthritis, Active, alone or in combination with methotrexate
- Ulcerative colitis (Moderate to Severe), Active

Off-Label Uses:

Stelara (only)

- Hidradenitis suppurativa

Age Restrictions:

6 years or older

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/631981/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/C74794/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=929484&contentSetId=100&title=Ustekinumab&servicesTitle=Ustekinumab&brandName=Stelara&UserMdxSearchTerm=Stelara#