Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 75.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Ustekinumab IV (Stelara IV) and Biosimilars

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Ustekinumab IV (Stelara IV) and Biosimilars

II. Purpose/Objective:
To provide a policy of coverage regarding Ustekinumab IV (Stelara IV) and Biosimilars

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Ustekinumab (Stelara and biosimilars) is a human monoclonal antibody that binds to and interferes with the proinflammatory cytokines, interleukin (IL)-12 and IL-23. Biological effects of IL-12 and IL-23 include natural killer (NK) cell activation, CD4+ T-cell differentiation and activation. Ustekinumab also interferes with the expression of monocyte chemotactic protein-1 (MCP-1), tumor necrosis factor-alpha (TNF-α), interferon-inducible protein-10 (IP-10), and interleukin-8 (IL-8).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Ustekinumab products for Commercial, Exchange, and CHIP lines of business	
Preferred	**Non-preferred**
ustekinumab-kfce IV (Yesintek IV)	ustekinumab IV (Stelara IV)
	ustekinumab-aauz IV (Otulfi IV)
	ustekinumab-ttwe IV (Pyzchiva IV)
	ustekinumab-aekn IV (Selarsdi IV)
	ustekinumab-stba IV (Steqeyma IV)
	ustekinumab-auub IV (Wezlana IV)
	ustekinumab-srlf IV (Imuldosa IV)

Ustekinumab IV (Stelara IV), ustekinumab-srlf IV (Imuldosa IV), ustekinumab-aauz IV (Otulfi IV), ustekinumab-ttwe IV (Pyzchiva IV), ustekinumab-aekn IV (Selarsdi IV), ustekinumab-stba IV (Steqeyma IV), ustekinumab-auub IV (Wezlana IV), ustekinumab-kfce IV (Yesintek IV) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

Crohn's Disease (CD)

- Medical record documentation that the requested ustekinumab product is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that the requested ustekinumab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of 130mg vials as IV infusion (for induction therapy) **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND immunomodulators (e.g. azathioprine and 6-mercaptopurine) OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior

AND

- For nonpreferred ustekinumab product requests, all of the following:
    - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: a preferred adalimumab product*, Cimzia*, Entyvio*, infliximab (or biosimilar) *, or Tysabri* **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Yesintek*

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (6) months.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
    - Facets Rx Count: 520 (HCPCS listed below, will be added and updated as they become available)
    - Quantity Limit: 104 mL per 56 days GPI 14 for the requested ustekinumab product 130 mg vial
    - Quantity limit: 1mL per 56 days GPI 14 for the requested ustekinumab product 90mg Syringe

Ulcerative Colitis

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that the requested ustekinumab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of 130mg vials as IV infusion (for induction therapy) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (azathioprine or 6-mercaptopurine (6-MP)) **AND**
- For nonpreferred ustekinumab product requests, all of the following:
    - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: a preferred adalimumab product*, Entyvio*, Rinvoq*, Simponi*, Xeljanz/Xeljanz XR*, and/or infliximab (or biosimilar)* **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Yesintek*

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (6) months.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
    - Facets Rx Count: 520 (HCPCS listed below, will be added and updated as they become available)
    - Quantity Limit: 104 mL per 56 days GPI 14 for the requested ustekinumab 130 mg vial
    - Quantity limit: 1mL per 56 days GPI 14 for the requested ustekinumab 90mg Syringe

BRAND/BIOSIMILAR NAME	GPI for 130/26 mL IV Solution	HCPCS
Stelara or Ustekinumab (unbranded)	52504070002020	J3358
Otulfi	52504070802020	Q9999
Pyzchiva or Ustekinumab-ttwe	52504070752020	Q9997
Selarsdi	52504070022020	Q9998
Steqeyma	52504070782020	Q5099
Wezlana	52504070032020	Q5138
Yesintek	52504070792020	Q5100
Imuldosa	52504070812020	Q5098

Ustekinumab IV (Stelara IV), ustekinumab-srlf IV (Imuldosa IV), ustekinumab-aauz IV (Otulfi IV), ustekinumab-ttwe IV (Pyzchiva IV), ustekinumab-aekn IV (Selarsdi IV), ustekinumab-stba IV (Steqeyma IV), ustekinumab-auub IV (Wezlana IV), ustekinumab-kfce IV (Yesintek IV) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

Crohn's Disease (CD)

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that the requested ustekinumab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of 130mg vials as IV infusion (for induction therapy)

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (6) months.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (HCPCS listed below, will be added and updated as they become available)

Ulcerative Colitis

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that the requested ustekinumab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of 130mg vials as IV infusion (for induction therapy)

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (6) months.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (HCPCS listed below, will be added and updated as they become available)

BRAND/BIOSIMILAR NAME	HCPCS
Stelara or Ustekinumab (unbranded)	J3358
Otulfi	Q9999
Pyzchiva or Ustekinumab-ttwe	Q9997
Selarsdi	Q9998
Steqeyma	Q5099
Wezlana	Q5138
Yesintek	Q5100
Imuldosa	Q5098

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Stelara [prescribing information]. Horsham, PA: Janssen Biotech Inc; March 2023.
2. Ustekinumab [Prescribing Information]. Horsham PA. Janssen Biotech, Inc. April 2025.
3. Imuldosa [Prescribing Information]. Raleigh NC. Accord BioPharma Inc. October 2024.
4. Otulfi [Prescribing Information]. Lake Zurich IL. Fresenius Kabi USA, LLC. April 2025.
5. Pyzchiva [Prescribing Information]. Princeton NJ. Sandoz Inc. December 2024.
6. Selarsdi [Prescribing Information]. Leesburg VA. Alvotech USA Inc. February 2025.
7. Steqeyma [Prescribing Information]. Jersey City NJ. Celltrion USA, Inc. April 2025.

8. Wezlana [Prescribing Information]. Thousand Oaks CA. Amgen Inc. December 2024.
9. Yesintek [Prescribing Information]. Cambridge MA. Biocon Biologics Inc. November 2024.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 03/10/10

Revised: 09/13; 02/14 (add indication); 09/16/14; 12/30/14 (updated formulary alternatives criteria), 09/15/15 (joint counts removed), 7/19/16 (dosing criteria added), 3/21/17 (Crohn's disease), 3/20/18 (form alt, duplicate therapy), 4/24/18 (per DHS, grandfather), 5/15/18 (peds plaque psoriasis), 4/15/20 (ulcerative colitis, updated QLs), 1/19/21 (pediatric age), 12/23/22 (removal of Stelara SQ/PsO/PsA/reauth, Medicare Carve Out), 12/19/23 (Medicaid business segment), 12/31/23 (references added), 12/2/24 (changed Humira, removed Darwin & Medicaid business segment, LOB table, taglines), 5/13/25 (added biosimilars, conventional therapy, updated QLs), 8/13/25 (Medicare QL, references, QL tables)

Reviewed: 02/12, 4/22/19, 2/1/20, 1/18/22 (Updated Darwin QLs)

MA UM Committee approval: 12/31/23, 12/31/24, 6/9/25, 9/10/25