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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Biologicals	**Original Policy Date:**	November 15, 2013
Subject:	Stelara	**Page:**	1 of 12

Last Review Date: September 6, 2024

Stelara

Description

Stelara (ustekinumab)

Pyzchiva* (ustekinumab-ttwe)

Selarsdi* (ustekinumab-aekn)

*These medications are included in this policy but are not available on the market as of yet

Background

Stelara and its biosimilars are human interleukin-12 (IL-12) and interleukin-23 (IL-23) antagonists indicated for the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Stelara and its biosimilars targets IL-12 and IL-23, reducing inflammation and relieving symptoms of joint pain, swelling, stiffness, plaque thickness, scaling, and redness in psoriatic arthritis and plaque psoriasis, and has been shown to significantly decrease disease activity in patients with moderately to severely active Crohn's disease and ulcerative colitis (1-3).

Regulatory Status

FDA-approved indications: Stelara and its biosimilars are human interleukin-12 and -23 antagonists indicated for the treatment of: (1-3)

Adult patients with:

1. Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy

2. Active psoriatic arthritis (PsA)
3. Moderately to severely active Crohn's disease (CD)
4. Moderately to severely active ulcerative colitis (UC)

Pediatric patients 6 years and older with:

1. Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
2. Active psoriatic arthritis (PsA)

Stelara and its biosimilars may increase the risk of infections and reactivation of latent infections such as bacterial, fungal, and viral infections. Stelara and its biosimilars should not be given to patients with any clinically important active infection until the infection resolves or is adequately treated. Serious infections that require hospitalization may occur such as diverticulitis, cellulitis, pneumonia, appendicitis, sepsis, and cholecystitis (1-3).

Evaluate patients for tuberculosis infection prior to initiating treatment with Stelara or its biosimilars. Do not administer Stelara or its biosimilars to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering Stelara or its biosimilars. Consider anti-tuberculosis therapy prior to initiation of Stelara or its biosimilars in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Stelara or its biosimilars should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1-3).

Stelara and its biosimilars are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among subjects who received Stelara or its biosimilars. There have been post-marketing reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving Stelara or its biosimilars who had pre-existing risk factors for developing non-melanoma skin cancer. All patients receiving Stelara or its biosimilars should be monitored for the appearance of non-melanoma skin cancer. Patients greater than 60 years of age, those with a medical history of prolonged immunosuppressant therapy, and those with a history of PUVA treatment should be followed closely (1-3).

Safety and effectiveness of Stelara and its biosimilars in pediatric patients less than 6 years of age with plaque psoriasis have not been established (1-3).

Safety and effectiveness of Stelara and its biosimilars in pediatric patients less than 18 years of age with psoriatic arthritis, Crohn's disease, or ulcerative colitis have not been established (1-3).

Related policies

Ilumya, Skyrizi, Tremfya

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Stelara and its biosimilars may be considered **medically necessary** if the conditions indicated below are met.

Stelara and its biosimilars may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe plaque psoriasis (PsO)
    a. 6 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
        i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
    c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight – 0.75 mg/kg every 12 weeks
        ii. Subcutaneous administration: Patients 6-17 years of age 60 kg to 100 kg weight and adult patients less than or equal to 100 kg weight – 45 mg every 12 weeks
        iii. Subcutaneous administration: Patients greater than 100 kg weight – 90 mg every 12 weeks
    d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products [Enbrel (all ages) or Humira (age 12+ only)] if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Active psoriatic arthritis (PsA)
    a. 6 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
    c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. Subcutaneous administration: Patients 18 years of age or older - 45 mg every 12 weeks
        ii. Subcutaneous administration: Patients 6 years of age or older, weight greater than 100 kg, with concurrent moderate to severe plaque psoriasis – 90 mg every 12 weeks
        iii. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight - 0.75 mg/kg every 12 weeks
        iv. Subcutaneous administration: Patients 6-17 years of age and greater than or equal to 60 kg weight - 45 mg every 12 weeks
    d. Age 12+, Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Moderate to severely active Crohn's disease (CD)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
    c. Prescriber will initiate dosing with a single intravenous infusion with **ONE** of the following:
        i. IV infusion: 55 kg or less – 260 mg
        ii. IV infusion: >55 kg to 85 kg – 390 mg
        iii. IV infusion: More than 85 kg – 520 mg
    d. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 90 mg every 8 weeks
    e. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Moderate to severely active ulcerative colitis (UC)

a. 18 years of age or older
b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
c. Prescriber will initiate dosing with a single intravenous infusion with **ONE** of the following:
    i. IV infusion: 55 kg or less – 260 mg
    ii. IV infusion: >55 kg to 85 kg – 390 mg
    iii. IV infusion: More than 85 kg – 520 mg
d. Prescriber will not exceed the FDA labeled maintenance dose of the following:
    i. Subcutaneous administration: 90 mg every 8 weeks
e. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** diagnoses:

1. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
4. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Plaque psoriasis (PsO)
    a. 6 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight – 0.75 mg/kg every 12 weeks

ii. Subcutaneous administration: Patients 6-17 years of age and 60 kg to 100 kg weight and adult patients less than or equal to 100 kg weight – 45 mg every 12 weeks
iii. Subcutaneous administration: Patients greater than 100 kg weight – 90 mg every 12 weeks

c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products [Enbrel (all ages) or Humira (age 12+ only)] if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Psoriatic arthritis (PsA)
   a. 6 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
      i. Subcutaneous administration: Patients 18 years of age or older - 45 mg every 12 weeks
      ii. Subcutaneous administration: Patients 6 years of age or older, weight greater than 100 kg, with concurrent moderate to severe plaque psoriasis – 90 mg every 12 weeks
      iii. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight - 0.75 mg/kg every 12 weeks
      iv. Subcutaneous administration: Patients 6-17 years of age and greater than or equal to 60 kg weight - 45 mg every 12 weeks
   c. Age 12+, Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Crohn's disease (CD)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. Subcutaneous administration: 90 mg every 8 weeks
   c. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Ulcerative colitis (UC)

a. 18 years of age or older
b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
   i. Subcutaneous administration: 90 mg every 8 weeks
c. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** diagnoses:

1. Condition has improved or stabilized with Stelara
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
4. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Plaque psoriasis (PsO)	**Weight ≤100kg** 45 mg SC vial/syringe **Weight > 100kg** 90 mg SC syringe	5 units per 365 days (dosed initially, 4 weeks later, then every 12 weeks)
Psoriatic arthritis (PsA)	45 mg SC vial/syringe **Concurrent moderate to severe plaque psoriasis and weight > 100kg** 90 mg SC syringe	
Crohn's disease (CD)	130 mg IV vial 90 mg SC syringe	**Weight ≤55kg** 2 IV vials (1 dose) + 1 SC syringe per 56 days **Weight > 55kg to 85kg** 3 IV vials (1 dose) + 1 SC syringe per 56 days
Ulcerative colitis (UC)		

		Weight > 85kg 4 IV vials (1 dose) + 1 SC syringe per 56 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Plaque psoriasis (PsO)	**Weight ≤100kg** 45 mg SC vial/syringe **Weight > 100kg** 90 mg SC syringe	1 unit per 84 days
Psoriatic arthritis (PsA)	45 mg SC vial/syringe **Concurrent moderate to severe plaque psoriasis and weight > 100kg** 90 mg SC syringe	
Crohn's disease (CD)	90 mg SC syringe	1 SC syringe per 56 days
Ulcerative colitis (UC)		

Duration 18 months

Rationale

Summary

Stelara and its biosimilars are human interleukin-12 (IL-12) and interleukin-23 (IL-23) antagonists indicated for the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Stelara and its biosimilars target IL-12 and IL-23, reducing inflammation and relieving symptoms of joint pain, swelling, stiffness, plaque thickness, scaling, and redness in psoriatic arthritis and plaque psoriasis, and have been shown to significantly decrease disease activity in patients with moderately to severely active Crohn's disease and ulcerative colitis. Stelara and its biosimilars may increase the risk of infections and reactivation of latent infections such as bacterial, fungal, and viral infections. Stelara and its biosimilars should not be given to patients with any clinically important active infection until the infection resolves or is adequately treated. Stelara and its biosimilars should not be administered to patients with active TB. Stelara and its biosimilars may increase the risk of malignancy (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Stelara and its biosimilar while maintaining optimal therapeutic outcomes.

References

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2024.
2. Selarsdi [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2024.
3. Pyzchiva [package insert]. Princeton, NJ: Sandoz Inc.; June 2024.

Policy History

Date	Action
October 2013	Addition to PA
December 2013	Annual editorial review by the PMPC
September 2014	Annual editorial review and renewal limit to 18 months
September 2016	Annual editorial review and reference update Addition of not to be used in combination with any other biologic DMARD or targeted synthetic DMARD Addition of not given concurrently with live vaccines per SME Policy number change from 5.18.04 to 5.90.04
October 2016	Addition of Crohn's disease to diagnoses in initiation and renewal criteria Addition of criteria to Crohn's disease diagnosis in initiation: must have inadequate treatment response to one of the following: immunomodulators, corticosteroids, or TNF blockers
December 2016	Annual review
September 2017	Annual editorial review Addition of FDA dosing requirement questions for all indications
October 2017	Addition of PsO dosing for 12 yrs. of age and older
December 2017	Annual review
June 2018	Addition of IV initiation dosing for CD Addition of additional requirements to initiation criteria For diagnosis of PsA: inadequate response, intolerance or contraindication to a 3-month trial of at least **ONE** conventional DMARD For diagnosis of PsO: inadequate response, intolerance, or contraindication to either conventional systemic therapy or phototherapy and if the patient is intolerant or contraindicated to either therapy then the other treatment option needs to be tried For diagnosis of CD: inadequate response, intolerance or contraindication to at least ONE conventional therapy option and prescriber will initiate dosing of patient with one infusion Addition of Appendix 1 & 2
September 2018	Annual editorial review and reference update

September 2019	Annual review
November 2019	Addition of indication: ulcerative colitis. Revised initial dosing requirements for CD
December 2019	Annual review. Addition of requirement to trial preferred product
August 2020	Revised age requirement for plaque psoriasis from 12 and older to 6 and older. Also revised the dosage questions for plaque psoriasis. Clarifying language added to pharmacy benefit
September 2020	Annual review
December 2020	Annual editorial review. Revised requirements to t/f preferred products to apply to Blue Focus patients only. Added PA quantity limits
February 2021	Revised psoriatic arthritis dosing requirement and quantity limits chart
March 2021	Annual editorial review and reference update. Revised background and summary sections. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 1 updated.
June 2021	Annual review
March 2022	Added Conventional Therapy Options for UC chart under Appendix 2
June 2022	Annual review
August 2022	Per PI update, changed PsA age to 6 and older from 18 and older and updated PsA dosing agreements
September 2022	Annual review
December 2022	Annual review and reference update
September 2023	Annual review
March 2024	Annual editorial review. Revised FDA dosing language
May 2024	Addition of biosimilar Selarsdi
June 2024	Annual review and reference update
July 2024	Addition of biosimilar Pyzchiva
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant

deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 – List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis: a. Metronidazole, ciprofloxacin

b. Alternative: rectal mesalamine