VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Stelara Subcutaneous Prior Authorization Policy with Dosing
- Stelara® (ustekinumab subcutaneous injection – Janssen Biotech)

REVIEW DATE: 06/22/2022; selected revision 08/31/2022

OVERVIEW

Stelara subcutaneous, an interleukin-12/23 blocker, is indicated for the following uses:[1]

- **Crohn's disease**, in patients ≥ 18 years of age with moderate to severe active disease.
- **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for phototherapy or systemic therapy.
- **Psoriatic arthritis**, in patients ≥ 6 years of age with active disease.
- **Ulcerative colitis**, in patients ≥ 18 years of age with moderate to severe active disease.

Dosing

A weight-based dose is administered by subcutaneous (SC) injection under the supervision of a physician or by the patient or a caregiver. Here is the approved dosing listed in the prescribing information:

- **Crohn's disease:** Starting 8 weeks after an initial intravenous (IV) dose, the maintenance dose is 90 mg SC injection once every 8 weeks (Q8W).
- **Plaque psoriasis:**
  - Adults weighing ≤ 100 kg: 45 mg SC at Week 0, Week 4, and then once every 12 weeks (Q12W) thereafter.
  - Adults weighing > 100 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing > 100 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
- **Psoriatic arthritis:**
  - Adults weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then every Q12W thereafter.
  - All other adults: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
- **Ulcerative colitis:** Starting 8 weeks after an initial IV dose, the maintenance dose is 90 mg SC Q8W.

Guidelines

Guidelines for the treatment of inflammatory conditions recommend use of Stelara subcutaneous.

- **Crohn's Disease:** The American College of Gastroenterology has guidelines for Crohn's disease (2018).[2] Stelara is a treatment option in patients who have moderate to severe disease despite

treatment with another agent (e.g., corticosteroid, thiopurine, methotrexate, or tumor necrosis factor inhibitors [TNFis]).

- **Plaque Psoriasis:** Guidelines (2019) from the American Academy of Dermatology and National Psoriasis Foundation recommend Stelara as a monotherapy treatment option or in combination with other therapies for adults with moderate to severe disease.[3]
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology (2018) recommend Stelara after other agents (e.g., TNFis) have been tried.[4] Stelara may be used in patients who have active disease despite treatment with other agents, particularly in those with concomitant inflammatory bowel disease.[4]
- **Ulcerative Colitis:** Guidelines from the American Gastroenterological Association (2020) recommend Stelara for moderate to severe ulcerative colitis.[6] Stelara is not addressed in the 2019 American College of Gastroenterology guidelines for ulcerative colitis.[5] These guidelines note that the following agents can be used for induction of remission in moderately to severely active disease: Uceris® (budesonide extended-release tablets); oral or IV systemic corticosteroids, Entyvio® (vedolizuamb IV infusion), Xeljanz® (tofacitinib tablets, extended-release tablets), or TNFis (adalimumab, Simponi® subcutaneous [golimumab SC injection], infliximab).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Stelara subcutaneous. Because of the specialized skills required for evaluation and diagnosis of patients treated with Stelara subcutaneous as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Stelara subcutaneous to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration listed below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Stelara subcutaneous is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Crohn's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets one of the following conditions (a, b, c, or d):
       - **a)** Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
       - **b)** Patient has tried one conventional systemic therapy for Crohn's disease; OR
         Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for Crohn's disease. A patient who has already received a biologic is not required to "step back" and try another agent.
       - **c)** Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR

d) Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND

iii. According to the prescriber, the patient will receive a single induction dose with Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous; AND

iv. The medication is prescribed by or in consultation with a gastroenterologist.

B) Patient is Currently Receiving Stelara Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography, computed tomography enterography), endoscopic assessment, and/or reduced dose of corticosteroids.

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

2. Plaque Psoriasis. Approve (45 mg syringe/vial) for the duration noted if the patient meets ONE of the following (A or B):
Note: If the 90 mg syringe is requested, approve if the patient meets one of the following:

- patient weighs > 100 kg; OR
- patient is currently receiving the 90 mg syringe; OR
- patient has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy.

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):

i. Patient is ≥ 6 years of age; AND

ii. Patient meets ONE of the following conditions (a or b):

a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples of traditional systemic agents used for psoriasis include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

b) Patient has a contraindication to methotrexate as determined by the prescriber; AND

iii. The medication is prescribed by or in consultation with a dermatologist.

B) Patient is Currently Receiving Stelara Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on the requested drug for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND

iii. Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

3. Psoriatic Arthritis. Approve (45 mg syringe/vial) for the duration noted if the patient meets ONE of the following (A or B):

Note: If the 90 mg syringe is requested, approve if the patient meets one of the following:

- patient has moderate to severe plaque psoriasis AND weighs > 100 kg; OR
- patient is currently receiving the 90 mg syringe; OR
- patient has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy.

A) Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.

B) Patient is Currently Receiving Stelara Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

4. Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) Patient has had a trial of one systemic agent for ulcerative colitis; OR
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for ulcerative colitis.

b) Patient meets BOTH of the following [(1) and (2)]:

(1) Patient has pourchitis; AND

(2) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND

Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

iii. According to the prescriber, the patient will receive a single induction dose with Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous; AND

iv. The medication is prescribed by or in consultation with a gastroenterologist.

B) Patient is Currently Receiving Stelara Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Stelara subcutaneous is not recommended in the following situations:

1. **Ankylosing Spondylitis.** There are other biologic therapies indicated in ankylosing spondylitis (e.g., Cimzia® [certolizumab pegol subcutaneous injection], etanercept, adalimumab, infliximab, Simponi subcutaneous, Cosentyx™ [secukinumab subcutaneous injection]). More data are needed to demonstrate efficacy of Stelara in this condition. There is a published proof-of-concept trial evaluating Stelara in ankylosing spondylitis (n = 20).[7] Patients who previously failed to respond to TNFi were excluded, but patients who discontinued a TNFi for reasons other than lack of efficacy were allowed to enroll. In all, 65% of patients (n = 13/20) achieved an ASAS40 response at Week 24. There was at least a 50% improvement of the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) achieved by 55% of patients (n = 11/20). However, enthesitis (measured by MASES [Maastricht AS Entheses Score] and SPARCC [SPondyloArthritis Research Consortium of Canada] enthesitis indices) and the number of swollen joints were not significantly improved at Week 24. There was a significant reduction of active inflammation on magnetic resonance imaging at Week 24 compared with baseline in sacroiliac joints.

2. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Stelara should not be administered in combination with another biologic agent or with a targeted synthetic DMARD used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of additive efficacy. Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Stelara.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Stelara® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; July 2022.

2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: management of Crohn's disease in adults. *Am J Gastroenterol.* 2018;113(4):481-517.
3. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
6. Feuerstein JD, Isaac s KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020;158:1450-1461.
7. Poddubnyy D, Hermann KG, Callhoff J, et al. Ustekinumab for the treatment of patients with active ankylosing spondylitis: results of a 28-week, prospective, open-label, proof-of-concept study (TOPAS). *Ann Rheum Dis*. 2014;73(5):817-823.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/01/2021
Selected Revision	**Crohn's Disease:** Exceptions were added for a patient who has fistulizing disease or previous ileocolonic resection. A patient with one of these conditions is not required to try another therapy prior to Stelara.	09/22/2021
Selected Revision	**Crohn's Disease:** Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving this drug, it was clarified that this applies to a patient who is taking for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. **Plaque Psoriasis:** Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving the requested drug, it was clarified that this applies to a patient who is taking the drug for ≥ 90 days. Requirements were added for a patient who is currently taking, that there is has at least one objective and at least one subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. **Psoriatic Arthritis:** Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving this drug, it was clarified that this applies to a patient who is taking for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. **Ulcerative Colitis:** Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving this drug, it was clarified that this applies to a patient who is taking for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.	12/01/2021
Early Annual Revision	**Ulcerative Colitis:** An exception was added for a patient who has pouchitis and has tried a listed therapy (i.e., an antibiotic, probiotic, corticosteroid enema, or mesalamine enema). A patient who meets this exception is not required to try another therapy prior to Stelara.	06/22/2022
Update	No criteria changes. The Overview was updated to include the expanded age indication (≥ 6 years of age) for Psoriatic Arthritis (previously was ≥ 18 years of age).	08/02/2022
Selected Revision	The policy name was changed to include "With Dosing". **Plaque Psoriasis:** The approval was updated to apply to the 45 mg syringe/vial. The 90 mg syringe may be approved if the patient weighs > 100 kg, is currently receiving the 90 mg syringe, or has received standard dosing with the 45 mg syringe/vial for at	08/31/2022

	least 3 months with inadequate efficacy. For both strengths, existing criteria for psoriasis also apply. **Psoriatic Arthritis:** The approval was updated to apply to the 45 mg syringe/vial. The 90 mg syringe may be approved if the patient has moderate to severe plaque psoriasis and weighs > 100 kg, is currently receiving the 90 mg syringe, or has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy. For both strengths, existing criteria for psoriasis also apply.	

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, RA, PsA, UC
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.