

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Stelara (ustekinumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Stelara (ustekinumab) 130mg/26 mL (5 mg/mL) vial	4 vials (8 week supply, one time fill)
Stelara (ustekinumab) 45 mg/0.5 mL vial*	1 vial per 84 days (12 weeks)
Stelara (ustekinumab) 45 mg/0.5 mL single-use prefilled syringe*†	1 syringe per 84 days (12 weeks)
Stelara (ustekinumab) 90 mg/1 mL single-use prefilled syringe*#^	1 syringe per 84 days (12 weeks)

*Initiation of therapy for Plaque Psoriasis (Ps) (Psoriasis vulgaris) or Psoriatic Arthritis (PsA) in individuals less than or equal to 100 kg (220 lbs.): May approve 1 (one) additional syringe (45mg/0.5mL) in the first 84 days (12 weeks) of treatment.

†Initiation of therapy for PsA in individuals greater than or equal to 100 kg (220 lbs.): May approve 1 (one) additional syringe or vial (45 mg/0.5 mL) in the first 84 days (12 weeks) of treatment.

#Initiation of therapy for moderate to severe Plaque Ps (Psoriasis vulgaris) or concomitant PsA in individuals greater than 100 kg (220 lbs.): May approve 1 (one) additional syringe (90 mg/1 mL) in the first 84 days (12 weeks) of treatment.

^Maintenance therapy for adult Crohn's Disease: May approve 1 (one) syringe (90 mg/1 mL) every 8 weeks (56 days).

Requests for Stelara (ustekinumab) 90 mg/1mL may only be approved if the individual weighs greater than 100 kilograms (220 pounds) for diagnosis of concomitant PsA OR Plaque Ps (Psoriasis vulgaris), in addition to meeting the approval criteria below.

Requests for Stelara (ustekinumab) 90 mg/1mL are not subject to weight limits for diagnosis of Crohn's Disease.

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APPROVAL CRITERIA

Requests for Stelara (ustekinumab) may be approved for the following:

- I. Crohn's disease (CD) when the following criteria are met:
 - A. Individual is 18 years of age or older with moderate to severe (CD); **AND**
 - B. Individual has had and inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) or a tumor necrosis factor (TNF) antagonist;

AND

- C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologics include - Humira (adalimumab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)] unless the following criteria is met:
 1. Individual has been receiving and is maintained on a stable dose of Stelara (ustekinumab); **OR**
 2. The preferred agent is not FDA-approved and does not have an accepted off-label use per the off-label policy for the prescribed indication and Stelara (ustekinumab) does; **OR**
 3. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Stelara (ustekinumab); **OR**
 - b. Individual's age; **OR**
 - c. Pregnant or planning on becoming pregnant; **OR**
 - d. Serious infections or concurrent sepsis; **OR**
 4. The individual has either concomitant clinical condition:
 - a. Demyelinating disease; **OR**
 - b. Heart failure with documented left ventricular dysfunction; **OR**
 - c. Malignancy [such as but not limited to, solid or hematologic cancers and excluding superficial skin cancers (such as basal and squamous cell)]; **OR**
 5. The preferred agent(s) do not have activity against a concomitant clinical condition and Stelara (ustekinumab) does. Examples include but may not be limited to the following:
 - a. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
 - b. Concomitant Rheumatoid Arthritis: TNFi agents are preferred;

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OR

II. Psoriatic arthritis (PsA) when the following criteria are met:

- A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) such as methotrexate, sulfasalazine, or leflunomide)];

AND

- C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents. [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab)] unless the following criteria is met;
 - 1. Individual has been receiving and is maintained on a stable dose of Stelara (ustekinumab); **OR**
 - 2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Stelara (ustekinumab) does; **OR**
 - 3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Stelara (ustekinumab); **OR**
 - b. Individual’s age; **OR**
 - c. Pregnant or planning on becoming pregnant; **OR**
 - d. Serious infections or concurrent sepsis; **OR**
 - 4. The individual has either concomitant clinical condition:
 - a. Demyelinating disease; **OR**
 - b. Heart failure with documented left ventricular dysfunction; **OR**
 - 5. The preferred agent(s) do not have activity against a concomitant clinical condition and Stelara (ustekinumab) does. Examples include but may not be limited to the following:
 - a. Concomitant Crohn’s Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
 - b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred;

OR

III. Plaque psoriasis (Ps) (psoriasis vulgaris) when the following criteria are met:

- A. Individual is 12 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following:

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1. Plaque Ps (psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA); **OR**
2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of the feet, head/neck, or genitalia);

AND

- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

AND

- C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents. [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab)] unless the following criteria is met;
1. Individual has been receiving and is maintained on a stable dose of Stelara (ustekinumab); **OR**
 2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Stelara (ustekinumab) does; **OR**
 3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Stelara (ustekinumab); **OR**
 - b. Individual's age; **OR**
 - c. Pregnant or planning on becoming pregnant; **OR**
 - d. Serious infections or concurrent sepsis; **OR**
 4. The individual has either concomitant clinical condition:
 - a. Demyelinating disease; **OR**
 - b. Heart failure with documented left ventricular dysfunction; **OR**
 5. The preferred agent(s) do not have activity against a concomitant clinical condition and Stelara (ustekinumab) does. Examples include but may not be limited to the following:
 - a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
 - b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

Requests for Stelara (ustekinumab) may **not** be approved for the following:

- I. In combination with phototherapy; **OR**

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- II. In combination with JAK inhibitors or other biologic drugs (such as TNF antagonists); **OR**
- III. History of reversible posterior leukoencephalopathy syndrome ; **OR**
- IV. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
- V. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent test to evaluate for latent tuberculosis prior to initiating ustekinumab.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Menter A, Korman NJ, Elmets CA et al for the American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol*. 2011; 65: 137-174.
6. American Gastroenterological Association. Identification, assessment and initial medical treatment of Crohn's disease Clinical Care Pathway. Available at <https://gastro.org/guidelines/ibd-and-bowel-disorders>. Accessed on: September 14, 2018.
7. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. *Am J Gastroenterol* 2018; 113:481–517.

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