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

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Stelara (ustekinumab)

CG-DRUG-69

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 (psoriasis vulgaris) or Psoriatic Arthritis 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 Psoriatic Arthritis 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 Psoriasis (psoriasis vulgaris) or concomitant Psoriatic Arthritis 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 Psoriatic Arthritis OR Plaque Psoriasis (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.

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

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APPROVAL CRITERIA

Stelara (ustekinumab) may be approved when the following criteria are met:

I. Crohn's disease when the following criteria are met:
   A. 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**

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

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b. Concomitant Rheumatoid Arthritis: TNFi agents are preferred;

AND

B. Individual is 18 years of age or older with moderately to severely active Crohn's disease; **AND**

C. Individual has failed to respond to, lost response to, is intolerant of, or has a medical contraindication to either of the following:
   1. A tumor necrosis factor antagonist drug; **OR**
   2. Conventional drug therapy, such as aminosalicylate products (for example, mesalamine, sulfasalazine) or an immunomodulatory drug (for example, azathioprine , 6-mercaptopurine , or methotrexate ; **OR**

D. Individual has failed to respond to, is intolerant of, or has demonstrated dependence on systemic corticosteroids; **AND**

E. Individual is using Stelara (ustekinumab) for one of the following:
   1. To reduce signs or symptoms; **OR**
   2. To induce or maintain clinical response or remission;

OR

II. Psoriatic arthritis when the following criteria are met:

A. 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:

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

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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;

AND

B. Individual is 18 years of age or older with active psoriatic arthritis ; **AND**
C. Individual is using Stelara (ustekinumab) for any of the following reasons:
    1. To reduce signs or symptoms; **OR**
    2. To induce or maintain clinical response; **OR**
    3. To inhibit the progression of structural damage; **OR**
    4. To improve physical function;

AND

D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as nonbiologic disease-modifying antirheumatic drugs);

OR

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

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

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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;

AND

B. Individual is 12 years of age or older with chronic moderate to severe plaque psoriasis (psoriasis vulgaris) with either of the following:
    1. Plaque psoriasis (psoriasis vulgaris) involving greater than 5% body surface area ; **OR**
    2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% body surface area involving sensitive areas or areas that significantly impact daily function (such as palms, soles of the feet, head/neck, or genitalia);

AND

C. Individual is using Stelara (ustekinumab) for any of the following reasons:
    1. To reduce signs or symptoms; **OR**
    2. To induce or maintain clinical response;

AND

D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate).

Stelara (ustekinumab) may **not** be approved for an individual with any of the following:

A. When used in combination with other immunosuppressive therapy or phototherapy for the treatment of plaque psoriasis (psoriasis vulgaris); **OR**
B. History of Reversible Posterior Leukoencephalopathy Syndrome ; **OR**
C. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **OR**
D. Individual has not had a tuberculin skin test or a Centers for Disease Control and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Stelara (ustekinumab).

Requests for Stelara (ustekinumab) may **not** be approved for the treatment of all other indications, including, but not limited to treatment of Ankylosing spondylitis, and relapsing-remitting multiple sclerosis, Sarcoidosis, and Rheumatoid arthritis .

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

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

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Key References:

1. American Academy of Dermatology (AAD). American Academy of Dermatology Association (AADA). Guidelines of care for management of psoriasis and psoriatic arthritis. May 2008. Available at: http://www.aad.org/education-and-quality-care/clinical-guidelines. Accessed on October 16, 2017.
2. Centers for Disease Control (CDC) and Prevention. Updated guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection - United States, 2010; 59(No. RR 5):1-28. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf. Accessed on October 16, 2017.
3. Khanna R, Preiss JC, MacDonald JK, Timmer A. Anti-IL-12/23p40 antibodies for induction of remission in Crohn's disease. Cochrane Database Syst Rev. 2015;(5):CD007572.
4. Stelara [Product Information], Horsham, PA. Janssen Biotech, Inc.; October 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125261s138lbl.pdf. Accessed on October 16, 2017.
5. Ustekinumab. In: DrugPoints® System (electronic). Truven Health Analytics, Greenwood Village, CO. Updated October 6, 2017. Available at: http://www.micromedexsolutions.com. Accessed on October 16, 2017.