Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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 (CD) and Ulcerative Colitis (UC): 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 concomitant diagnosis of PsA and moderate to severe Plaque Ps (Psoriasis vulgaris) OR diagnosis of moderate to severe 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 or Ulcerative Colitis.

APPROVAL CRITERIA

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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 acceptable due to concomitant clinical conditions, including 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. Pregnant or planning on becoming pregnant; **OR**
         c. Serious infections or concurrent sepsis; **OR**
      3. 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

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**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

2. The preferred agents are not acceptable due to concomitant clinical conditions, including 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. Pregnant or planning on becoming pregnant; **OR**
    c. Serious infections or concurrent sepsis;
3. The individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction; **OR**
4. 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 (AAD 2019):
    1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) body surface area (BSA); **OR**
    2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) 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 – Cosentyx (secukinumab), 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 acceptable due to concomitant clinical conditions, including 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**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

b. Individual's age; **OR**
c. Pregnant or planning on becoming pregnant; **OR**
d. Serious infections or concurrent sepsis;

OR

3. 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

IV. Ulcerative colitis (UC) when the following criteria are met:
    A. Individual is 18 years of age or older with moderate to severe UC; **AND**
    B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants), a TNF antagonist, or vedolizumab;

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 acceptable due to concomitant clinical conditions, including 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. Pregnant or planning on becoming pregnant; **OR**
            c. Serious infections or concurrent sepsis; **OR**
        3. 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)].

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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

I. All other indications not included above; **OR**
II. In combination with phototherapy; **OR**
III. In combination with JAK inhibitors, apremilast, or other biologic drugs (such as TNF antagonists); **OR**
IV. History of reversible posterior leukoencephalopathy syndrome ; **OR**
V. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
VI. 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 N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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