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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Cimzia (certolizumab pegol)

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

Medications	Quantity Limit
Cimzia (certolizumab pegol) 200 mg/mL vial kit*‡	1 vial kit (2 x 200 mg vials) per 28 days
Cimzia (certolizumab pegol) 200 mg/mL prefilled syringe kit*‡	1 syringe kit (2 x 200 mg/mL syringes) per 28 days
Cimzia (certolizumab pegol) 200 mg/mL starter kit*	1 starter kit (6 x 200 mg/mL syringes) (28 day supply, one time fill)

*Initiation of therapy for Crohn's Disease (CD), Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Plaque Psoriasis (Psoriasis Vulgaris) (Ps), or Ankylosing Spondylitis (AS): May approve one starter kit OR up to three vial kits (2 x 200 mg vials per kit) or syringe kits (2 x 200 mg/mL syringes per kit) in the first month (28 days) of treatment.

‡In the treatment of Plaque Psoriasis (Ps): May approve up to an additional 1 vial kit (2 x 200 mg vials) or syringe kit (2 x 200 mg/mL syringes) every 28 days.

APPROVAL CRITERIA

Requests for Cimzia (certolizumab pegol) may be approved for the following:

I. Crohn's disease (CD) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe CD; **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); **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 - Humira

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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(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 Cimzia (certolizumab pegol); **OR**
2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
    a. Pregnant or planning on becoming pregnant;

OR

II. Rheumatoid arthritis (RA) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe RA; **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, leflunomide, or hydroxychloroquine)] (ACR 2015); **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), Humira (adalimumab)] unless the following criteria is met:

1. Individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol); **OR**
2. 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 Cimzia (certolizumab pegol); **OR**
    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 Cimzia (certolizumab pegol) does. An example includes but may not be limited to the following:
    a. Concomitant Crohn's disease: TNFi (agents FDA-approved for both indications) are preferred;

OR

III. Ankylosing spondylitis (AS) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe AS; **AND**

Market Applicability														
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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)]; **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), Humira (adalimumab)] unless the following criteria is met:
    1. Individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol); **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 Cimzia (certolizumab pegol) 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 Cimzia (certolizumab pegol); **OR**
        b. Individual's age; **OR**
        c. Pregnant or planning on becoming pregnant; **OR**
        d. Serious infections or concurrent sepsis;

OR

IV. Psoriatic arthritis (PsA) when each of 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 [such as 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), Humira (adalimumab)] unless the following criteria is met:
    1. Individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol); **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 Cimzia (certolizumab pegol) 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 Cimzia (certolizumab pegol); **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. Individual's age; **OR**
c. Pregnant or planning on becoming pregnant; **OR**
d. Serious infections or concurrent sepsis; **OR**

4. The preferred agent(s) do not have activity against a concomitant clinical condition and Cimzia (certolizumab pegol) 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

V. Plaque psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:

A. Individual is 18 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 2011):
   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 feet, head/neck, or genitalia);

AND

B. 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), Humira (adalimumab)] unless the following criteria is met:
   1. Individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol); **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 Cimzia (certolizumab pegol) 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 Cimzia (certolizumab pegol); **OR**
      b. Individual's age; **OR**
      c. Pregnant or planning on becoming pregnant; **OR**
      d. Serious infections or concurrent sepsis; **OR**
   4. The preferred agent(s) do not have activity against a concomitant clinical condition and Cimzia (certolizumab pegol) does. Examples include but may

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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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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 Cimzia (certolizumab pegol) may **not** be approved for the following:

I. In combination with other TNF antagonists, JAK inhibitors, or other biologic drugs (such as, abatacept, anakinra, rituximab, or vedolizumab); **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
III. Individual has not had a tuberculin skin (TST), or a Centers for Disease control (CDC-) and Prevention -recommended equivalent, to evaluate for latent tuberculosis prior to initiating certolizumab pegol.

Note:
TNFi have black box warnings for serious infections and malignancy. Individuals treated with TNFi are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated prior to TNFi use. Risks and benefits of TNFi should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

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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