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)

CG-DRUG-65

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

Medications	Strength	Quantity Limit
Cimzia (certolizumab pegol)	1 pack or kit = 2 x 200mg vials	1 pack or kit (2 x 200mg vials) per 28 days
	1 syringe kit = 2 x 200mg/ml syringes	1 syringe kit (2 x 200mg/ml syringes) per 28 days
	Starter kit = 6 x 200mg/ml	May approve 1 starter kit OR up to three packs (2 X 200mg vials) or syringe kits (2 x 200mg/ml syringes) **one time only** for the first month for initial dosing. **Note:** Pack content = 2 vials or syringes each containing 200mg

APPROVAL CRITERIA

Cimzia (certolizumab pegol) may be approved when criteria are met for any of the following indications:

I. **Crohn's Disease** when the following criteria are met:
   A. Individual is 18 years of age or older; **AND**
   B. Individual has a diagnosis of moderately to severely active Crohn's Disease; **AND**
   C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapies (such as 5-Aminosalicylic acid products, systemic

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

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corticosteroids, or immunosuppressants) and Cimzia (certolizumab pegol) is used for one of the following:

1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical response; **AND**

D. 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 (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** when the following criteria are met:

A. Individual is 18 years of age or older; **AND**

B. Individual has a diagnosis of moderately to severely active Rheumatoid Arthritis; **AND**

C. Agent is used for **any** of the following reasons:

1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical response; **OR**
3. To improve physical function; **AND**

D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more nonbiologic DMARDs (disease-modifying antirheumatic drugs); **AND**

E. 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**

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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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 the following are met:
A. Individual is 18 years of age or older with active ankylosing spondylitis; **AND**
B. Agent is being used to reduce signs or symptoms of the disease; **AND**
C. Individual has failed to respond to, is intolerant of, or has medical contraindication to conventional therapy (such as NSAIDs or nonbiologic DMARDs); **AND**
D. 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** when the following are met:
A. Individual is 18 years of age or older with active psoriatic arthritis; **AND**
B. Agent is being used for **any** of the following reasons:
    1. To reduce signs or symptoms; **OR**
    2. To induce or maintain clinical response; **OR**
    3. To improve physical function; **AND**
C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as nonbiologic DMARDs); **AND**
D. 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)

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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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 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.

Cimzia (certolizumab pegol) may **not** be approved for individuals with any of the following:

A. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **or**
B. Individuals who have not had a tuberculin skin (TST), or a CDC-recommended equivalent, to evaluate for latent tuberculosis; **or**
C. Using in combination with other TNF antagonists; **or**
D. Using in combination with tofacitinib citrate; **or**
E. Using in combination with the following non-TNF immunomodulatory drugs: abatacept (Orencia), anakinra (Kineret), natalizumab (Tysabri), or rituximab (Rituxan).

Note: Cimzia (certolizumab pegol) has a black box warning related to the increased risk of developing serious infections that could result in hospitalization or death. Individuals should be closely monitored for the development of infection during and after treatment with

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

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discontinuation of therapy if the individual develops a serious infection or sepsis. Reported infections include: Tuberculosis, invasive fungal infections (including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens (including Legionella and Listeria). The risks and benefits of treatment with Cimzia should be considered prior to initiating in individuals with chronic or recurrent infection. Cimzia is not indicated for the use in pediatric individuals due to reports of lymphoma and other malignancies developing in children and adolescents treated with tumor necrosis factor (TNF) blockers.

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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