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	X

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Erelzi (etanercept-szzs)

CG-DRUG-64, CG-DRUG-65

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

Washington Medicaid – See State Specific Mandates

Medications	Quantity Limit
Erelzi (etanercept-szzs) 25 mg/0.5 mL prefilled syringe	8 syringes per 28 days*
Erelzi (etanercept-szzs) 50 mg/0.5 mL prefilled syringe, Sensoready® pen	4 syringes/pens per 28 days*

*Initiation of therapy for adult Plaque Psoriasis (Ps): May approve up to 2 (two) additional 25 mg vials (25 mg/mL) or syringes [(25 mg/0.5 mL (0.51 mL)] **OR** 1 (one) additional 50 mg syringe [50 mg/mL (0.98 mL)], pen (50 mg/0.5 mL), or autoinjector [50 mg/mL (0.98 mL)] per week in the first 3 months (84 days) of treatment.

APPROVAL CRITERIA

I. Diagnosis of Rheumatoid Arthritis
   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 for 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 one or more non biologic disease modifying anti-rheumatic agents (DMARDs);

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 are met:
      1. Individual has been receiving and is maintained on a stable dose of Erelzi (etanercept-szzs); **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	X

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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 Erelzi (etanercept-szzs); **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 Erelzi (etanercept-szzs) 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

II. Diagnosis of Active Ankylosing Spondylitis
   A. Individual is 18 years of age or older; **AND**
   B. Individual has diagnosis of active Ankylosing Spondylitis; **AND**
   C. Agent is used to reduce signs or symptoms of the disease; **AND**
   D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as NSAIDs or non biologic DMARDs);

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 are met:
      1. Individual has been receiving and is maintained on a stable dose of Erelzi (etanercept-szzs); **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 Erelzi (etanercept-szzs)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 Erelzi (etanercept-szzs); **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;

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	X

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OR

III. Diagnosis of Juvenile Idiopathic Arthritis
   A. Individual is 2 years of age or older; **AND**
   B. Individuals with a diagnosis of moderate to severely active juvenile idiopathic 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; **AND**
   D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more non biologic disease modifying anti-rheumatic agents (DMARDs);

AND

   E. Individual has had a trial (medication samples/coupons/discount cards are excluded from 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 are met:
      1. Individual has been receiving and is maintained on a stable dose of Erelzi (etanercept-szzs); **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 Erelzi (etanercept-szzs) 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 Erelzi (etanercept-szzs); **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

IV. Diagnosis of Psoriatic Arthritis Individual is 18 years of age or older; **AND**
   A. Individual has active psoriatic arthritis; **AND**
   B. 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 inhibit the progression of structural damage; **OR**
      4. To improve physical function; **AND**
   C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to

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	X

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conventional therapy. (such as non biologic 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 are met:

1. Individual has been receiving and is maintained on a stable dose of Erelzi (etanercept-szzs); **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 Erelzi (etanercept-szzs) 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 Erelzi (etanercept-szzs) ; **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 Erelzi (etanercept-szzs) 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. Diagnosis of Plaque Psoriasis (Psoriasis Vulgaris)
   A. Individual is 4 years of age or older; **AND**
   B. Individual has a diagnosis of chronic moderate to severe plaque psoriasis (psoriasis vulgaris) (that is, extensive or disabling) with EITHER of the following:
      1. Plaque psoriasis (psoriasis vulgaris) involving greater than 5% of body surface area ; **OR**
      2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% of body surface area involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
   C. Agent is used for **any** of the following reasons:

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	X

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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 the use of phototherapy or other systemic therapies (such as methotrexate, acitretin, or cyclosporine);

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 are met:
    1. Individual has been receiving and is maintained on a stable dose of Erelzi (etanercept-szzs); **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 Erelzi (etanercept-szzs)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 Erelzi (etanercept-szzs); **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 Erelzi (etanercept-szzs) 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.

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	X

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Erelzi may **not** be approved for an individual with any of the following:

I. In combination with other TNF antagonists; **OR**
II. In combination with tofacitinib citrate; **OR**
III. In combination with the following non-TNF immunomodulatory drugs: abatacept, anakinra, cyclophosphamides, or vedolizumab; **OR**
IV. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **OR**
V. Individual has not had a tuberculin skin test, or a CDC-recommended equivalent, to evaluate for latent tuberculosis prior to initiating therapy; **OR**
VI. If the above approval criteria are not met and for all other indications, including but not limited to treatment of asthma, disc-herniation-induced radiculopathy or sciatica, graft-versus-host disease, inclusion-body myositis, inflammatory bowel disease, hidradenitis suppurativa, sarcoidosis, septic shock, Sjogren's syndrome, and Wegener's granulomatosis.

Note: Erelzi (etanercept-szzs) 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 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 Erelzi should be considered prior to initiating in individuals with chronic or recurrent infection. Erelzi 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	Date effective	Mandate details (including specific bill if applicable)
Washington	1/1/2018	Washington State PDL prefers Enbrel and Humira; all other clinical criteria apply

Key References:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
CRX-ALL-0274-18

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	X

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Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
CRX-ALL-0274-18