Generic Name: Etanercept

Therapeutic Class or Brand Name: Enbrel®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 6629003000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 8/23/2018

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

A. Active Ankylosing Spondylitis and criteria 1 and 2 are met:

1. Diagnosis must be established by a rheumatologist.
2. Minimum age requirement: 18 years old.

B. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
2. Diagnosis must be established by a rheumatologist.
3. Minimum age requirement: 18 years old.

C. Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to at least one DMARD (i.e. methotrexate, etc.).
2. Diagnosis must be established by a rheumatologist.
3. Minimum age requirement: 2 years old.

D. Active Psoriatic Arthritis and criteria 1 and 2 are met:

1. Diagnosis must be established by a rheumatologist or dermatologist.
2. Minimum age requirement: 18 years old.

E. Chronic Moderate to Severe Plaque Psoriasis and criteria 1 through 4 are met:

1. History of treatment failure, intolerance, or contraindication with phototherapy or photochemotherapy.
2. History of treatment failure, intolerance, or contraindication with at least one appropriate systemic agent (i.e. cyclosporine, methotrexate, acitretin, etc.).
3. Diagnosis must be established by a dermatologist or a rheumatologist.
4. Minimum age requirement: 18 years old.

II. Absence of active serious infection or sepsis.

III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Coadministration of Enbrel® with another biologic DMARD, cyclophosphamide, Otezla® (apremilast), or Xeljanz®/ XR (tofacitinib). Examples of biologic DMARDs include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Entyvio® (vedolizumab)
  - Kevzara® (sarilumab)
  - Kineret® (anakinra)
  - Orencia® (abatacept)
  - Rituxan® (rituximab)
  - Siliq™ (brodalumab)
  - Stelara® (ustekinumab)
  - Taltz® (Ixekizumab)
  - TNF inhibitors [Cimzia® (certolizumab pegol), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis™ (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
  - Tremfya™ (guselkumab)
  - Tysabri® (natalizumab)

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Rheumatologic conditions (Ankylosing Spondylitis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis):
    - Quantities of up to 4 of the 50mg syringes, or 8 of the 25mg syringes or vials, every 28 days.
- Plaque Psoriasis:
    - Quantities of up to 8 of the 50mg syringes every 28 days for the first 3 months, then in quantities of up to 4 of the 50mg syringes, or 8 of the 25mg syringes or vials, every 28 days thereafter.

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

Appendix

N/A

References

1. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru444reg.pdf.
2. www.drugs.com.
3. https://npsonline.pti-nps.com.
4. http://pi.amgen.com/united_states/enbrel/derm/enbrel_pi.pdf.

Historical Tracking of Changes Made to Policy

Date	Notes/Changes
8/23/2018	**1. Changed** obsolete URL in Reference #1 (http://blue.regence.com/trgmedpol/drugs/dru035.pdf) **to** https://reg.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru444reg.pdf.

11/21/2017	2. **Added** "Kevzara® (sarilumab)"**,** "Siliq™ (brodalumab)"**, and** "Tremfya™ (guselkumab)" **to list under Exclusion Criteria**. 3. **Added** "Inflectra® (infliximab-dyyb)" **and** "Renflexis™ (infliximab-abda)" **following TNF Inhibitors to list under Exclusion Criteria**.
9/20/2016	1. **Reinserted** "Refer to Plan for individual adoption of specific Medication Policies" **in disclaimer**.
8/26/2016	1. **Changed** "IV. Refer to plan document for the list of preferred products. If Enbrel® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product" **to** "IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s)" **under Prior Authorization Criteria**. 2. **Changed** "Coadministration of Enbrel® with…Xeljanz®…" **to** "Coadministration of Enbrel® with…Xeljanz®/ XR (tofacitinib)…" **under Exclusion Criteria**. 3. **Changed** "Cosentyx™" **to** "Cosentyx®" **under Exclusion Criteria**. 4. **Added** "Taltz® (Ixekizumab)" **to list under Exclusion Criteria**. 5. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Enbrel%20all%20indications%202014-12-26.pdf" **under References** (link no longer valid).
3/2/2015	1. **Added** "Cosentyx™ (secukinumab)" **to list under Exclusion Criteria.**
2/27/2015	1. **Changed** "Documented diagnosis of one of the following conditions A through D…: A. Moderate to Severe Rheumatoid Arthritis or Psoriatic Arthritis and criteria 1 through 4 are met: 1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.); 2. The number of swollen joints and tender joints must be 3 or more; 3. Diagnosis must be established by a rheumatologist; 4. Minimum age requirement: 18 years old; B. Ankylosing Spondylitis…; C. Juvenile Idiopathic Arthritis…; D. Moderate to Severe Plaque Psoriasis…" **to** "Documented diagnosis of one of the following conditions A through E…: A. Active Ankylosing Spondylitis…; B. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 3 are met: 1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.); 2. Diagnosis must be established by a rheumatologist; 3. Minimum age requirement: 18 years old; C. Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis…; D. Active Psoriatic Arthritis and criteria 1 and 2 are met: 1. Diagnosis must be established by a rheumatologist or dermatologist; 2. Minimum age requirement: 18 years old; E. Chronic Moderate to Severe Plaque Psoriasis…" **under Prior Authorization Criteria**. 2. **Changed** "Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition" **to** "Absence of active serious infection or sepsis" **under Prior Authorization Criteria**. 3. **Changed** "Documented failure, intolerance, or contraindication to ALL preferred products (refer to plan document for the list of preferred products)" **to** "Refer to plan document for the list of preferred products. If Enbrel® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product" **under Prior Authorization Criteria**. 4. **Changed** "Enbrel® may not be given with other biologic agents such as Interferon, experimental medications, or combinations" **to** "Coadministration of Enbrel® with another biologic DMARD, cyclophosphamide, Otezla® (apremilast), or Xeljanz® (tofacitinib). Examples of biologic DMARDs include the following: Actemra® (tocilizumab); Entyvio® (vedolizumab); Kineret® (anakinra); Orencia® (abatacept); Rituxan® (rituximab); Stelara® (ustekinumab); TNF inhibitors [Cimzia® (certolizumab pegol), Humira® (adalimumab), Remicade® (infliximab), Simponi®/Simponi® Aria® (golimumab)]; Tysabri® (natalizumab)" **under Exclusion Criteria**. 5. **Changed order of listed Rheumatologic conditions from** "Rheumatoid Arthritis, Psoriatic

	Arthritis, Ankylosing Spondylitis, Juvenile Idiopathic Arthritis" **to** "Ankylosing Spondylitis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis" **under Quantity/Days Supply Restrictions**. 6. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/allentries.php" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Enbrel%20all%20indications%202014-12-26.pdf" **under References**.
10/15/2013	1. **Adapted policy to new format**. 2. **Added** "Documented failure, intolerance, or contraindication to ALL preferred products (refer to plan document for the list of preferred products)" **requirement**. 3. **Changed criteria for Moderate to Severe Rheumatoid Arthritis or Psoriatic Arthritis from:** "History of treatment, incomplete response, or intolerance to Methotrexate, or one other DMARD or second line drug (azathioprine, sulphadiazine, leflunomide, penicillamine, hydroxychloroquine, etc.); The number of swollen joints must be 6 or more and the number of tender joints must be 9 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER); Rheumatology consultation within the last 60 days; Minimum age requirement: 18 year old" **to** "History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.); The number of swollen joints and tender joints must be 3 or more; Diagnosis must be established by a rheumatologist; Minimum age requirement: 18 years old". 4. **Changed criteria for Ankylosing Spondylitis from:** "Rheumatology consultation within the last 60 days; Minimum age requirement: 18 years old" **to** "Diagnosis must be established by a rheumatologist; Minimum age requirement: 18 years old". 5. **Changed criteria for Juvenile Idiopathic Arthritis from:** "Documentation of failed treatment on at least one DMARD; Rheumatology consultation within the last 60 days; Minimum age requirement: 2 years old" **to** "History of treatment failure, intolerance, or contraindication to at least one DMARD (i.e. methotrexate, etc.); Diagnosis must be established by a rheumatologist; Minimum age requirement: 2 years old". 6. **Changed criteria for Moderate to Severe Plaque Psoriasis from:** "History of incomplete response or intolerance to one appropriate systemic agent or photo therapy; Dermatology consultation within the last 60 days; Minimum age requirement: 18 years old" **to** "History of treatment failure, intolerance, or contraindication with phototherapy or photochemotherapy; History of treatment failure, intolerance, or contraindication with at least one appropriate systemic agent (i.e. cyclosporine, methotrexate, acitretin, etc.); Diagnosis must be established by a dermatologist or a rheumatologist; Minimum age requirement: 18 years old". 7. **Changed quantity restriction** of "16ml per 28 days on 25mg, 8ml per 28 days on 50mg" under "Quantity/Days Supply Restrictions" section **to** "Rheumatologic conditions (Rheumatoid

	Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Juvenile Idiopathic Arthritis): Quantities of up to 4 of the 50mg syringes, or 8 of the 25mg syringes or vials, every 28 days; Plaque Psoriasis: Quantities of up to 8 of the 50mg syringes every 28 days for the first 3 months, then in quantities of up to 4 of the 50mg syringes, or 8 of the 25mg syringes or vials, every 28 days thereafter." 8. **Updated references** to include specific Regence policy referred to and Enbrel Prescribing Information.