Biologic and Immunomodulatory Drug Therapy Policy

**BENEFIT APPLICATION**

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

**DESCRIPTION**

The intent of the Biologic and Immunomodulatory Drug Therapy Criteria is to ensure appropriate therapy selection according to the Food and Drug Administration (FDA)-approved product labeling and/or clinical guidelines and/or clinical trials. The criteria will encourage the use of first-line conventional agents, many of which are available as generics, when appropriate, as supported by literature and guidelines. The criteria will also require the use of the health plan’s preferred tumor necrosis factor (TNF)α-inhibitors (Enbrel [etanercept] and Humira [adalimumab]) prior to the use of both non-preferred TNF-inhibitors (Cimzia [certolizumab pegol], Inflectra [infliximab-dyyb], Simponi [golimumab], Simponi Aria [golimumab] and Remicade [infliximab]), and non-TNF agents (Actemra [tocilizumab], Entyvio [vedolizumab], Kineret [anakinra], Orencia [abatacept], Rituxan [rituximab], Stelara [ustekinumab], and Xeljanz [tocilinitib]), with the exceptions of Otezla [apremilast], Cosentyx [secukinumab, and Taltz (ixekizumab) which have no requirement that anti-TNF or non-TNF agents be used prior to approval.

Trials of both preferred TNF-inhibitors will only be required for patients with a diagnosis for which both preferred products are indicated; patients with a diagnosis for which only one of the preferred TNF-inhibitors is indicated will only be required to try that specific agent. Trials of the preferred TNF-inhibitors are not required for members who have a medical reason that precludes TNF-inhibitor use.

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<th>FDA Approved Indications</th>
<th>Rheumatoid Arthritis (RA)</th>
<th>Juvenile Idiopathic Arthritis (JIA)</th>
<th>Psoriatic Arthritis (PsA)</th>
<th>Psoriasis (Ps)</th>
<th>Ankylosing Spondylitis (AS)</th>
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**FDA Approved Indications**

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*Pediatric indication

**POLICY**

I. **Actemra (tocilizumab)** may be considered **medically necessary** when the following criteria are met:

a) Adult patients being treated for moderately to severely active **Rheumatoid Arthritis** by, or under the direct supervision of, a rheumatologist:

   1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

   OR

   1. Who have inadequate disease control despite an adequate trial of methotrexate (or an alternative non-biologic disease-modifying antirheumatic drug (DMARD) in the event of methotrexate contraindication or intolerance); AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

b) Pediatric patients 2 years of age and older being treated for **Juvenile Idiopathic Arthritis** by, or under the direct supervision of, a rheumatologist:

   1. Who have systemic JIA (sJIA) and have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, glucocorticoids, NSAIDs) or have contraindications to ALL systemic therapies

   OR
1. Who have non-systemic/polyarticular JIA (pJIA) and have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, sulfasalazine, glucocorticoids NSAIDs) or have contraindications to ALL systemic therapies; **AND**

2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria**

II. **Cimzia (certolizumab pegol)** may be considered **medically necessary** when the following criteria are met:

a) Adult patients being treated for active **Ankylosing Spondylitis** by, or under the direct supervision of, a rheumatologist who have failed therapy with both preferred TNF-inhibitors: Enbrel and Humira

b) Adult patients being treated for moderately to severely active **Crohn’s Disease** by, or under the direct supervision of, a gastroenterologist:
1. Who have failed to respond to conventional systemic therapy; **AND**
2. Who have failed the preferred TNF-inhibitor, Humira

c) Adult patients being treated for active **Psoriatic Arthritis** by, or under the direct supervision of, a dermatologist or rheumatologist:
1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis; **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira **OR**
1. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira **OR**
1. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira **OR**
1. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

d) Adult patients being treated for moderately to severely active **Rheumatoid Arthritis** by, or under the direct supervision of, a rheumatologist:
1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira **OR**
1. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria**

III. **Cosentyx (secukinumab)** may be considered **medically necessary** when the following criteria are met:
a) Adult patients being treated for **Plaque Psoriasis** by, or under the direct supervision of, a dermatologist:
   1. Who have either moderate to severe symptoms affecting 5% or more of their body surface area or symptoms affecting the face, feet, hands or genitals
   OR
   1. Who have inadequate disease control despite trial of a topical therapy or have contraindications to ALL of these therapies; **AND**
   2. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative systemic agent in the event of methotrexate contraindication or intolerance)

b) Adult patients being treated for active **Ankylosing Spondylitis** by, or under the direct supervision of, a rheumatologist

c) Adult patients being treated for active **Psoriatic Arthritis** by, or under the direct supervision of, a dermatologist or rheumatologist:
   1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis:
   OR
   2. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication); **OR**
   3. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance)

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria**

IV. **Enbrel (etanercept)** may be considered medically necessary when the following criteria are met:

a) Adult patients being treated for active **Ankylosing Spondylitis** by, or under the direct supervision of, a rheumatologist

b) Adult patients being treated for active **Psoriatic Arthritis** by, or under the direct supervision of, a dermatologist or rheumatologist:
   1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis:
   OR
   2. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication); **OR**
   3. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance)

c) Adult patients being treated for moderately to severely active **Rheumatoid Arthritis** by, or under the direct supervision of, a rheumatologist:
   1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; **OR**
   2. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance)

d) Pediatric patients 2 years of age and older being treated for moderately to severely active **Juvenile Idiopathic Arthritis** by, or under the direct supervision of, a rheumatologist:
1. Who have systemic JIA (sJIA) and have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, glucocorticoids, NSAIDs) or have contraindications to ALL systemic therapies
OR
2. Who have non-systemic/polyarticular (pJIA) and have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, sulfasalazine, glucocorticoids, NSAIDs) or have contraindications to ALL systemic therapies

e) Pediatric patients 4 years of age and older and adult patients being treated for Plaque Psoriasis by, or under the direct supervision of, a dermatologist:
   1. Who have either moderate to severe symptoms affecting 5% of their body surface area or symptoms affecting the face, feet, hands or genitals
   OR
   1. Who have inadequate disease control despite trial of a topical therapy or have contraindications to ALL of these therapies; AND
   2. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative systemic agent in the event of methotrexate contraindication or intolerance)

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria

V. Entyvio (vedolizumab) may be considered medically necessary when the following criteria are met:
   a) Adult patients being treated for moderately to severely active Crohn’s Disease by, or under the direct supervision of, a gastroenterologist:
      1. Who have tried and failed conventional systemic therapy; AND
      2. Who have tried and failed preferred TNF-inhibitor, Humira, or who meet warning criteria precluding use of Humira
   b) Adult patients being treated for moderately to severely active Ulcerative Colitis by, or under the direct supervision of, a gastroenterologist:
      1. Who have failed to respond to at least ONE conventional therapy (e.g. thiopurines, oral aminosalicylates, systemic corticosteroids); AND
      2. Who have tried and failed preferred TNF-inhibitor, Humira, or who meet warning criteria precluding use of Humira

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria

VI. Humira (adalimumab) may be considered medically necessary when the following criteria are met:
   a) Adult patients being treated for moderate to severe Hidradenitis Suppurativa
   b) Adult patients being treated for active Ankylosing Spondylitis by, or under the direct supervision of, a rheumatologist
   c) Adult patients being treated for active Psoriatic Arthritis by, or under the direct supervision of, a dermatologist or rheumatologist:
      1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis; OR
      2. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance);
3. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance)

d) Adult patients being treated for moderately to severely active **Rheumatoid Arthritis** by, or under the direct supervision of, a rheumatologist:

1. Who have early RA with high disease activity and poor prognostic factors;
2. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance)

e) Pediatric patients 2 years of age and older being treated for moderately to severely active **Juvenile Idiopathic Arthritis** by, or under the direct supervision of, a rheumatologist:

1. Who have systemic JIA (sJIA) and have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, glucocorticoids, NSAIDs) or have contraindications to ALL systemic therapies
2. Who have non-systemic/polyarticular (pJIA) and have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, sulfasalazine, glucocorticoids, NSAIDs) or have contraindications to ALL systemic therapies

f) Adult patients being treated for **Plaque Psoriasis** by, or under the direct supervision of, a dermatologist:

1. Who have either moderate to severe symptoms affecting 5% of their body surface area or symptoms affecting the face, feet, hands or genitals
2. Who have inadequate disease control despite trial of a topical therapy or have contraindications to ALL of these therapies; AND
3. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative systemic agent in the event of methotrexate contraindication or intolerance)

h) Adult patients being treated for moderately to severely active **Ulcerative Colitis** by, or under the direct supervision of, a gastroenterologist who have failed to respond to conventional therapy

i) Pediatric patients 6 years of age and older with moderately to severely active **Crohn's Disease** by, or under the direct supervision of, a gastroenterologist who have failed to respond to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

j) Patients being treated for sight-threatening **Uveitis**:

1. Who have failed to respond to at least conventional therapies or have medical contraindications to use

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria**
VII. **Kineret (anakinra)** may be considered **medically necessary** when the following criteria are met:

a) Adult patients being treated for moderately to severely active *Rheumatoid Arthritis* by, or under the direct supervision of, a rheumatologist:
   1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; **AND**
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use **OR**
      1. Who have inadequate disease control despite an adequate trial of methotrexate (or an alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
      2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

b) Pediatric patients 2 years of age or older being treated for active systemic *Juvenile Idiopathic Arthritis (SJIA)* by, or under the direct supervision of, a rheumatologist

c) Adult patients being treated for idiopathic recurrent pericarditis that have failed conventional therapies (i.e. NSAIDs, colchicine, and corticosteroids), unless contraindicated

**In addition, patients must meet the requirements of the Biologic Safety Screening Criteria**

VIII. **Orencia (abatacept)** may be considered medically necessary when the following criteria are met:

a) Adult patients being treated for moderately to severely active *Rheumatoid Arthritis* by, or under the direct supervision of, a rheumatologist:
   1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; **AND**
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use **OR**
      1. Who have inadequate disease control despite an adequate trial of methotrexate (or an alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
      2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

b) Pediatric patients 6 years of age and older being treated for moderately to severely active *Juvenile Idiopathic Arthritis* by, or under the direct supervision of, a rheumatologist:
   1. Who have non-systemic/polyarticular JIA (pJIA) and who have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, sulfasalazine, glucocorticoids, NSAIDs) OR have contraindication to ALL systemic therapies; **AND**
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use **OR**
      1. Who have systemic JIA (sJIA) and have tried and failed ONE oral systemic therapy (leflunomide, methotrexate, glucocorticoids, NSAIDs) OR have contraindications to ALL systemic therapies

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria**
IX. **Otezla (apremilast)** may be considered medically necessary when the following criteria are met:
   a) Adult patients being treated for *Plaque Psoriasis* by, or under the direct supervision of, a dermatologist:
      1. Who have either moderate to severe symptoms affecting 5% or more of their body surface area or symptoms affecting the face, feet, hands or genitals
         OR
      1. Who have inadequate disease control despite trial of a topical therapy or have contraindications to ALL of these therapies; **AND**
      2. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative systemic agent in the event of methotrexate contraindication or intolerance)

   b) Adult patients being treated for active *Psoriatic Arthritis* by, or under the direct supervision of, a dermatologist or rheumatologist:
      1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis
         OR
      2. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance)
         OR
      3. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance);

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria**

X. **Remicade (infliximab)** and **Inflectra (infliximab-dyyb)** may be considered medically necessary when the following criteria are met:
   a) Adult patients being treated for active *Ankylosing Spondylitis* by, or under the direct supervision of, a rheumatologist who have failed therapy with both preferred TNF-inhibitors: Enbrel and Humira

   b) Adult patients being treated for active *Psoriatic Arthritis* by, or under the direct supervision of, a dermatologist or rheumatologist:
      1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis; **AND**
      2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira
         OR
      1. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
      2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira
         OR
      1. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
      2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

   c) Adult patients being treated for moderately to severely active *Rheumatoid Arthritis* by, or under the direct supervision of, a rheumatologist:
      1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira
OR
1. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

d) Pediatric patients 6 years of age and older being treated for moderately to severely active Crohn’s Disease by, or under the direct supervision of, a gastroenterologist:
   1. Who have failed to respond to conventional therapy; AND
   2. Who have failed therapy with the preferred TNF-inhibitor, Humira
OR
   1. The patient has fistulizing disease

e) Adult patients being treated for moderately to severely active Crohn’s Disease by, or under the direct supervision of, as gastroenterologist:
   1. Who have tried and failed to respond to conventional therapy; AND
   2. Who have failed therapy with the preferred TNF-inhibitor, Humira
OR
   1. The patient has fistulizing disease

f) Adult patients being treated for Plaque Psoriasis by, or under the direct supervision of, a dermatologist:
   1. Who have either moderate to severe symptoms affecting 5% of their body surface area or symptoms affecting the face, feet, hands or genitals; AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira
OR
   1. Who have inadequate disease control despite trial of a topical therapy or have contraindications to ALL of these therapies; AND
   2. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative systemic agent in the event of methotrexate contraindication or intolerance); AND
   3. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

g) Pediatric patients 6 years of age and older being treated for moderately to severely active Ulcerative Colitis by, or under the direct supervision of, a gastroenterologist:
   1. Who have failed to respond to conventional therapy
OR
   2. Who have an acute severe exacerbation of ulcerative colitis, which is steroid refractory and deemed a medical emergency

h) Adult patients being treated for moderately to severely active Ulcerative Colitis by, or under the direct supervision of, a gastroenterologist:
   1. Who have failed to respond to conventional therapy; AND
   2. Who have failed the preferred TNF-inhibitor, Humira
OR
   1. Who have an acute severe exacerbation of ulcerative colitis, which is steroid refractory and deemed a medical emergency

i) Patients who are being treated for sight-threatening Uveitis:
1. Who have failed to respond to at least three conventional therapies or have contraindications to use **AND**
2. Who have failed the preferred TNF-inhibitor, Humira

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria**

**XI. Rituxan (rituximab)** may be considered medically necessary when the following criteria are met:

a) Adult patients being treated for moderately to severely active **Rheumatoid Arthritis** by, or under the direct supervision of, a rheumatologist:

1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use, or results in Rituxan being a preferred biologic option (e.g., history of malignancy)

**OR**

1. Who have inadequate disease control despite an adequate trial of methotrexate (or an alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); **AND**
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use, or results in Rituxan being a preferred biologic option (e.g., history of malignancy)

b) **Rituxan (rituximab)** may also be considered medically necessary for, **but not limited to**, the following indications:

1. First-line treatment of follicular, CD20+, B-cell non-Hodgkin's lymphoma (NHL) in combination with cyclophosphamide, vincristine and prednisolone/prednisone (CVP) chemotherapy
2. Treatment of low-grade, CD20+, B-cell NHL in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP therapy
3. Treatment of patients with relapsed or refractory, low-grade or follicular, CD20+, B-cell NHL
4. First-line treatment of diffuse large B-cell, CD20+ NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
5. Second-line monotherapy or adjunct therapy for moderately to severely active rheumatoid arthritis in adults
6. Treatment of relapsed or refractory Waldenström's macroglobulinemia
7. Treatment of idiopathic thrombocytopenic purpura
8. Treatment of autoimmune thrombocytopenic purpura
9. First- or second-line adjunct therapy for mantle cell lymphoma (MCL)
10. First-line treatment of chronic lymphocytic leukemia (CLL) in combination with fludarabine or fludarabine and cyclophosphamide
11. Treatment of patients with relapsed or refractory CLL.
12. Treatment of primary cutaneous marginal zone or follicle center B-cell lymphoma
13. Treatment of primary cutaneous diffuse large B-cell lymphoma, leg type
14. Treatment of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitides (e.g., Wegener's granulomatosis, renal vasculitis, microscopic polyangiitis, Churg-Strauss syndrome)
15. As single-agent maintenance therapy in patients with follicular, CD20-positive, B-cell NHL who have achieved a complete or partial response to Rituxan in combination with chemotherapy
16. Treatment of autoimmune hemolytic anemia refractory to conventional treatments including corticosteroids and/or splenectomy, or when conventional treatments are contraindicated or not tolerated

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria

XII. Simponi (golimumab) may be considered medically necessary when the following criteria are met:

a) Adult patients being treated for active **Ankylosing Spondylitis** by, or under the direct supervision of, a rheumatologist who have failed therapy with both preferred TNF-inhibitors: Enbrel and Humira

b) Adult patients being treated for active **Psoriatic Arthritis** by, or under the direct supervision of, a dermatologist or rheumatologist:
   1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis; AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira OR
   1. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira OR
   1. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

c) Adult patients being treated for moderately to severely active **Rheumatoid Arthritis** by, or under the direct supervision of, a rheumatologist:
   1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira OR
   1. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

d) Adult patients being treated for moderately to severely active **Ulcerative Colitis** by a gastroenterologist:
   1. Who have failed to respond to at least ONE conventional therapy (e.g. thiopurines, oral aminosalicylates, systemic corticosteroids); AND
   2. Who have tried and failed preferred TNF-inhibitor, Humira

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria

XIII. Simponi Aria (golimumab) may be considered medically necessary when the following criteria are met:

a) Adult patients being treated for moderately to severely active **Rheumatoid Arthritis** by, or under the direct supervision of, as rheumatologist:
1. Who have early RA (disease duration <6 months) with high disease activity and poor prognostic factors; AND
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

OR

1. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria XIV. Stelara (ustekinumab) may be considered medically necessary when the following criteria are met:***

**a)** Adult patients being treated for Plaque Psoriasis by, or under the direct supervision of, a dermatologist:

1. Who have either moderate to severe symptoms affecting 5% or more of their body surface area or symptoms affecting the face, feet, hands or genitals; AND
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

OR

1. Who have inadequate disease control despite trial of a topical therapy or have contraindications to ALL of these therapies; AND
2. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative systemic agent in the event of methotrexate contraindication or intolerance); AND
3. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

**b)** Adult patients being treated for active Psoriatic Arthritis by, or under the direct supervision of, a dermatologist or rheumatologist:

1. Who have adverse prognostic factors and predominantly axial disease or severe enthesitis; AND
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

OR

1. Who have adverse prognostic factors and inadequate disease control despite methotrexate therapy (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

OR

1. Who have inadequate disease control despite trials of NSAID therapy and methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

**c)** Adult patients being treated for moderately to severely active Crohn’s Disease by, or under the direct supervision of, a gastroenterologist:

1. Who have failed to respond to conventional systemic therapy; AND
2. Who have failed the preferred TNF-inhibitor, Humira
**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria XV. Taltz (ixekizumab) may be considered medically necessary when the following criteria are met:

a) Adult patients being treated for moderate to severe plaque psoriasis by, or under the direct supervision of, a dermatologist:
   a. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   b. Member meets any of the following criteria:
      i. Member has had an insufficient response to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin despite adequate dosing and duration.
      ii. Member has had an intolerance or adverse event to a trial of phototherapy or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
      iii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin. Examples of clinical reasons include:
         1. Alcoholism, alcoholic liver disease or other chronic liver disease
         2. Breastfeeding
         3. Cannot be used due to risk of treatment-related toxicity
         4. Drug interaction
         5. Pregnancy or planning pregnancy (male or female)
         6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
         7. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

**In addition, patients must meet the requirements of the Biologic Safety Screening Criteria XVI. Xeljanz (tofacitinib) and Xeljanz XR (tofacitinib extended release) may be considered medically necessary when the following criteria are met:

b) Adult patients being treated for Rheumatoid Arthritis by, or under the direct supervision of, a rheumatologist:
   1. Who have inadequate disease control despite an adequate trial of methotrexate (or alternative non-biologic DMARD in the event of methotrexate contraindication or intolerance); AND
   2. Who have failed therapy with BOTH preferred TNF-inhibitors: Enbrel and Humira, unless a medical condition precludes TNF-inhibitor use

**In addition, all patients must meet the requirements of the Biologic Safety Screening Criteria

<table>
<thead>
<tr>
<th>Safety Screening Criteria for Biologic and Immunomodulatory Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient will NOT be receiving therapy with another biologic agent.</td>
</tr>
<tr>
<td>Patient does NOT have an active infection or history of chronic infection.</td>
</tr>
<tr>
<td>(not required for Otezla)</td>
</tr>
<tr>
<td>Patient has received all age appropriate vaccinations concordant with CDC guidance. Any live vaccinations have been administered at least 30 days prior to intended start of requested biologic.</td>
</tr>
<tr>
<td>(not required for Otezla)</td>
</tr>
</tbody>
</table>
Patient has been evaluated for hepatitis B. Patient does **NOT** have untreated chronic hepatitis B or treated chronic hepatitis B with Child-Pugh class B and higher.  
(not required for Cosentyx, Entyvio, Kineret, Otezla, Stelara, or Taltz)

| Tuberculosis evaluation and treatment are concordant with ACR Recommendations  
(not required for Kineret, Otezla, or Rituxan) |

Patient does **NOT** have a diagnosis of a neural demyelinating disorder (e.g. multiple sclerosis, optic neuritis)  
(not required for Cosentyx, Entyvio, Kineret, Orecia, Otezla, Rituxan, Stelara, Taltz, Xeljanz, or Xeljanz XR)

**Approval** for the biologic and immunomodulatory drugs within this policy will be for **lifetime**.

**Quantity limits apply.**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Actemra®</td>
<td>Tocilizumab IV 40 mL (800 mg) per 28 days</td>
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<tr>
<td></td>
<td>Tocilizumab SC 4 syringes per 28 days</td>
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<tr>
<td>Cimzia®</td>
<td>Certolizumab pegol Initiation of therapy: 3 maintenance kits (or 1 starter kit) per first 28 days Maintenance: 1 kit per 28 days</td>
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<tr>
<td>Cosentyx® prefilled syringe</td>
<td>Secukinumab Initiation of therapy: 10 syringes per 28 days Maintenance: 2 syringes per 28 days</td>
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</tr>
<tr>
<td>Enbrel®</td>
<td>Etanercept 8 syringes per 28 days</td>
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</tr>
<tr>
<td>Humira®</td>
<td>Adalimumab Initiation of therapy: 1 starter kit per first 28 days Maintenance: 4 syringes or pens per 28 days</td>
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</tr>
<tr>
<td>Kineret®</td>
<td>Anakinra 28 syringes per 28 days</td>
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<tr>
<td>Orecia®</td>
<td>Abatacept 4 vials or syringes per 28 days</td>
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<tr>
<td>Otezla®</td>
<td>Apremilast 60 tablets per 30 days</td>
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<tr>
<td>Rituxan®</td>
<td>Rituximab 200 mL (2000 mg) per 30 days</td>
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<tr>
<td>Simponi®</td>
<td>Golimumab 1 syringe per 30 days</td>
<td></td>
</tr>
<tr>
<td>Xeljanz®</td>
<td>Tofacitinib 60 tablets per 30 days</td>
<td></td>
</tr>
<tr>
<td>Xeljanz® XR</td>
<td>Tofacitinib 30 tablets per 30 days</td>
<td></td>
</tr>
</tbody>
</table>

**PROCEDURES AND BILLING CODES**

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.
- J0129 Injection, abatacept, 10 mg
- J0135 Injection, adalimumab, 20 mg

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• J0718 Injection, certolizumab pegol, 1 mg
• J1438 Injection, etanercept, 25 mg
• J1602 Injection, golimumab, 1 mg, for intravenous use
• J1745 Injection infliximab, 10 mg (applies to Remicade product only; not biosimilar: Inflectra)
• J3262 Injection, tocilizumab, 1 mg
• J3357 Injection, ustekinumab, 1 mg
• C9487 Intravenous injection, ustekinumab, 1 mg
• J9310 Injection, rituximab, 100 mg
• J3380 Injection, vedolizumab 1mg
• J3490 Unclassified drugs
• J3590 Unclassified biologics

REFERENCES

• Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2016.
• Turner D et al. Consensus for managing acute severe ulcerative colitis in children; a systematic review and joint statement from ECCO, ESPGHAN, and the Porto IBD working group of ESPHAN. Am J Gastroenterol 2011; 106:574–588

POLICY HISTORY

Policy #: 05.01.54
Policy Creation: January 2013
Reviewed: July 2016
Revised: March 2017
Current Effective Date: April 1, 2017