Medical Necessity Guidelines:
Anti-inflammatory Agents

Effective: January 1, 2023

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>If REQUIRED, submit supporting clinical documentation pertinent to service request.</td>
<td>Yes ☒ No ☐</td>
</tr>
</tbody>
</table>

Applies to:

**Commercial Products**
- ☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
- ☒ Tufts Health Plan Commercial products; Fax 617-673-0988
  CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**
- ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
- ☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
- ☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
- ☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
  *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

**Senior Products**
- ☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
- ☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
- ☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
- ☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

**Food and Drug Administration (FDA) Approved Indications:**

**Actemra®** (tocilizumab) for intravenous use is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:
- Rheumatoid Arthritis (RA)
- Giant Cell Arteritis (GCA)
- Polyarticular Juvenile Idiopathic Arthritis (PJIA)
- Systemic Juvenile Idiopathic Arthritis (SJIA)
- Cytokine Release Syndrome (CRS)

**Avsola®** (infliximab-axxq) is a tumor necrosis factor (TNF) blocker indicated for:
- Crohn’s Disease (CD)
- Pediatric Crohn’s Disease
- Ulcerative Colitis (UC)
- Pediatric Ulcerative Colitis
- Rheumatoid Arthritis (RA)
- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)
Entyvio® (vedolizumab) is an integrin receptor antagonist indicated in adults for the treatment of:
- Moderately to severely active Ulcerative Colitis (UC)
- Moderately to severely active Crohn’s disease (CD)

Ilumya® (tildrakizumab-asmn) is an interleukin-23 antagonist indicated for the treatment of adults with:
- Moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

Inflectra® (infliximab-dyyb) is a tumor necrosis factor (TNF) blocker indicated for:
- Crohn's Disease (CD)
- Pediatric Crohn's Disease
- Ulcerative Colitis (UC)
- Pediatric Ulcerative Colitis
- Rheumatoid Arthritis (RA) in combination with methotrexate
- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)

Infliximab (infliximab) is a tumor necrosis factor (TNF) blocker indicated for:
- Crohn's Disease (CD)
- Pediatric Crohn's Disease
- Ulcerative Colitis (UC)
- Pediatric Ulcerative Colitis
- Rheumatoid Arthritis (RA) in combination with methotrexate
- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)

Orencia® (abatacept) is a selective T cell costimulation modulator indicated for:
- Moderately to severely active rheumatoid arthritis (RA) in adults
- Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
- Adult patients with active psoriatic arthritis (PsA)
- Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

Remicade® (infliximab) is a tumor necrosis factor (TNF) blocker indicated for:
- Crohn's Disease (CD)
- Pediatric Crohn's Disease
- Ulcerative Colitis (UC)
- Pediatric Ulcerative Colitis
- Rheumatoid Arthritis (RA) in combination with methotrexate
- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)

Renflexis® (infliximab-abda) is a tumor necrosis factor (TNF) blocker indicated for:
- Crohn's Disease (CD)
- Pediatric Crohn's Disease
- Ulcerative Colitis (UC)
- Pediatric Ulcerative Colitis
- Rheumatoid Arthritis (RA) in combination with methotrexate
- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)

**Simponi Aria®** (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of:
- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate
- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older
- Adult patients with active Ankylosing Spondylitis (AS)
- Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older

**Stelara®** (ustekinumab) for intravenous use is a human interleukin-12 and -23 antagonist indicated for the treatment of patients with:
- Moderately to severely active Crohn’s disease (CD)
- Moderately to severely active ulcerative colitis (UC)

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**Clinical Guideline Coverage Criteria**

**PREFERRED PRODUCTS**

**Inflectra** (infliximab-dyyb), **Infliximab** (infliximab), and **Remicade** (infliximab).
The Plan may cover Inflectra (infliximab-dyyb), Infliximab (infliximab) or Remicade (infliximab) for Members when the following clinical criteria are met:

**Ankylosing spondylitis (AS)**
1. Documented diagnosis of ankylosing spondylitis  
   AND
2. Documentation of one (1) of the following:
   a. The prescribing physician is a rheumatologist
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of ankylosing spondylitis
   c. The Member is new to the plan and has been stable on Inflectra (infliximab-dyyb), Infliximab (infliximab) or Remicade (infliximab) prior to enrollment

**Crohn’s disease (CD) and Ulcerative colitis (UC)**
1. Documented diagnosis of one (1) of the following:
   a. Crohn’s disease
   b. Ulcerative colitis  
   AND
2. The prescribing physician is a gastroenterologist  
   AND
3. The Member is six (6) years of age or older  
   AND
4. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to an appropriate trial with at least two (2) of the following or the provider has indicated clinical inappropriateness with ALL of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicylates (e.g., sulfasalazine)
      iii. 6-mercaptopurine (6-MP) and/or azathioprine
      iv. Methotrexate
   
   OR
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of Crohn’s disease or ulcerative colitis
   
   OR
c. The Member is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease

OR

d. The Member is new to the plan and has been stable on Inflectra (infliximab-dyyb), Infliximab (infliximab) or Remicade (infliximab) prior to enrollment

**Plaque psoriasis (PsO)**

1. Documented diagnosis of plaque psoriasis

2. The prescribing physician is a dermatologist

3. The Member is 18 years of age or older

4. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to phototherapy used in combination with at least one (1) of the following agents or the provider has indicated clinical inappropriateness with ALL of the following:
      i. Soriatane (acitretin)
      ii. Methotrexate
      iii. Cyclosporine
   OR

   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of plaque psoriasis

   OR

   c. The Member is new to the plan and has been stable on Inflectra (infliximab-dyyb), Infliximab (infliximab) or Remicade (infliximab) prior to enrollment

**Psoriatic arthritis (PsA)**

1. Documented diagnosis of psoriatic arthritis

2. The prescribing physician is a rheumatologist

3. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate or sulfasalazine for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate AND sulfasalazine

   OR

   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis

   OR

   c. The Member is new to the plan and has been stable on Inflectra (infliximab-dyyb), Infliximab (infliximab) or Remicade (infliximab) prior to enrollment

**Rheumatoid arthritis (RA)**

1. Documented diagnosis of rheumatoid arthritis

2. The prescribing physician is a rheumatologist

3. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate
b. The Member has tried and failed treatment with another biological agent indicated for the treatment of rheumatoid arthritis

OR

c. The Member is new to the plan and has been stable on Inflectra (infliximab-dyyb), Infliximab (infliximab) or Remicade (infliximab) prior to enrollment

**Simponi Aria** (golimumab)
The Plan may cover Simponi Aria for Members when the following clinical criteria are met:

**Polyarticular juvenile idiopathic arthritis (pJIA)**
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. The Member is two (2) years of age or older
   AND
4. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate
   OR
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of polyarticular juvenile idiopathic arthritis
   OR
   c. The Member is new to the plan and has been stable on Simponi Aria (golimumab) prior to enrollment

**Ankylosing spondylitis (AS)**
1. Documented diagnosis of ankylosing spondylitis
   AND
2. Documentation of one (1) of the following:
   a. The prescribing physician is a rheumatologist
   OR
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of ankylosing spondylitis
   OR
   c. The Member is new to the plan and has been stable on Simponi Aria (golimumab) prior to enrollment

**Psoriatic arthritis (PsA)**
1. Documented diagnosis of psoriatic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate or sulfasalazine for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate or sulfasalazine
   OR
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis
   OR
   c. The Member is new to the plan and has been stable on Simponi Aria (golimumab) prior to enrollment
**Rheumatoid arthritis (RA)**
1. Documented diagnosis of rheumatoid arthritis

AND

2. The prescribing physician is a rheumatologist

AND

3. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate

OR

b. The Member has tried and failed treatment with another biological agent indicated for the treatment of rheumatoid arthritis

OR

C. The Member is new to the plan and has been stable on Simponi Aria (golimumab) prior to enrollment

**Stelara** (ustekinumab) for intravenous infusion

The plan may cover Stelara (ustekinumab) for intravenous infusion for Members when the following clinical criteria are met:

**Crohn’s disease (CD) and Ulcerative colitis (UC)**
1. Documented diagnosis of one (1) of the following:
   a. Crohn’s disease
   b. Ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. The Member is six (6) years of age or older

AND

4. Documentation of one (1) of the following:
   a. The Member has demonstrated an inadequate response to an appropriate trial with at least two (2) of the following or the provider has indicated clinical inappropriateness of all of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicylates (e.g., sulfasalazine)
      iii. 6-mercaptopurine (6-MP) and/or azathioprine
      iv. Methotrexate

OR

b. The Member has tried and failed treatment with another biological agent indicated for the treatment of Crohn’s disease or ulcerative colitis

OR

C. The Member is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease

OR

d. The Member is new to the plan and has been stable on Stelara (ustekinumab) prior to enrollment

**NON-PREFERRED PRODUCTS**

**Actemra** (tocilizumab) – intravenous

The Plan may cover Actemra intravenous injection for Members when the following clinical criteria are met:

**Cytokine release syndrome (CRS)**
1. Documented diagnosis of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome

**Giant Cell Arteritis**
1. Documented diagnosis of giant cell arteritis
2. The prescribing physician is a rheumatologist or neurologist
3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with corticosteroids:
   a. Corticosteroids (e.g., prednisone)
   b. Immunosuppressants (e.g., methotrexate)

**Polyarticular juvenile idiopathic arthritis (pJIA)**
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis
2. The prescribing physician is a rheumatologist
3. The Member is two (2) years of age or older
4. The Member has demonstrated an inadequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate
5. The Member has tried and failed treatment with Simponi Aria (golimumab) or the provider has indicated clinical inappropriateness with or contraindication to treatment with Simponi Aria (golimumab)

**Rheumatoid arthritis (RA)**
1. Documented diagnosis of rheumatoid arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one (1) of the following (3a and 3b or 3c):
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate
   b. The Member has tried and failed treatment with at least one (1) of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with ALL:
      i. Inflectra (infliximab-dyyb)
      ii. Infliximab (infliximab)
      iii. Remicade (infliximab)
      iv. Simponi Aria (golimumab)
   OR
   c. The Member is new to the plan and stable on Actemra (tocilizumab) and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Systemic juvenile idiopathic arthritis (sJIA)**
1. Documented diagnosis of systemic juvenile idiopathic arthritis
2. The prescribing physician is a rheumatologist
3. The Member has demonstrated an inadequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate

**Entyvio (vedolizumab)**
The Plan may cover Entyvio (vedolizumab) for Members when the following clinical criteria are met:

**Crohn’s disease (CD) and Ulcerative colitis (UC)**
1. Documented diagnosis of one of the following:
   a. Crohn’s disease
   b. Ulcerative colitis

2. The prescribing physician is a gastroenterologist

3. The Member is 18 years of age or older

4. Documentation of one (1) of the following (4a and 4b or 4c):
   a. The Member is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease OR the Member has demonstrated an inadequate response to an appropriate trial with at least two of the drugs listed below or the provider has indicated clinical inappropriateness to ALL of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicylates (e.g., sulfasalazine)
      iii. 6-mercaptopurine and/or azathioprine
      iv. Methotrexate

   b. The Member has tried and failed treatment with at least one (1) of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with ALL:
      i. Inflectra (infliximab-dyyb)
      ii. Infliximab (infliximab)
      iii. Remicade (infliximab)
      iv. Simponi Aria (golimumab)

   c. The Member is new to the plan and stable on Entyvio (vedolizumab) and the prescribing physician has documented that changing to the preferred product would result in adverse clinical outcomes

Ilumya (tildrakizumab-asmn)
The Plan may cover Ilumya for Members when all of the following clinical criteria are met:

**Plaque psoriasis (PsO)**
1. Documented diagnosis of plaque psoriasis

2. The prescribing physician is a dermatologist

3. The Member is 18 years of age or older

4. Documentation of one (1) of the following (4a and 4b or 4c):
   a. The Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with ALL of the following:
      i. Soriatane (acitretin)
      ii. Methotrexate
      iii. Cyclosporine

   b. The Member has tried and failed treatment with at least one (1) of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with ALL:
      i. Inflectra (infliximab-dyyb)
      ii. Infliximab (infliximab)
      iii. Remicade (infliximab)
      iv. Simponi Aria (golimumab)

   c. The Member is new to the plan and stable on Ilumya (tildrakizumab-asmn) and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
Avsola (infliximab-axxq) or Renflexis (infliximab-abda)
In addition to the coverage criteria for Inflectra (infliximab-dyyb), Infliximab (infliximab), and Remicade, the plan may authorize coverage of Avsola or Renflexis for Members when the following criteria are met:

1. Documentation of one (1) of the following:
   a. For Crohn’s disease, plaque psoriasis, or ulcerative colitis:
      • The Member has tried and failed treatment with or the provider has indicated clinical inappropriateness with or contraindication to treatment with Inflectra (infliximab-dyyb), Infliximab (infliximab) or Remicade (infliximab)
      OR
   b. For ankylosing spondylitis, psoriatic arthritis, or rheumatoid arthritis:
      • The Member has tried and failed treatment with at least one of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with ALL of the following:
        i. Inflectra (infliximab-dyyb)
        ii. Infliximab (infliximab)
        iii. Remicade (infliximab)
        iv. Simponi Aria (golimumab)
      OR
   c. The Member is new to the plan and stable on the requested agent (Avsola or Renflexis) and the prescribing physician has documented that changing to the preferred product(s) would result in adverse clinical outcome

Orencia (abatacept) – intravenous
The Plan may cover Orencia intravenous for Members when the following clinical criteria are met:

**Polyarticular juvenile idiopathic arthritis (pJIA)**
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. The Member is two (2) years of age or older
   AND
4. The Member has demonstrated an inadequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate
   AND
5. The Member has tried and failed treatment with Simponi Aria (golimumab) or the provider has indicated clinical inappropriateness with or contraindication to treatment with Simponi Aria (golimumab)

**Prophylaxis for Acute Graft versus Host Disease (GVHD)**
1. Documented diagnosis of acute graft versus host disease
   AND
2. The Member is at least two (2) years of age or older
   AND
3. Documentation the Member is undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated-donor
   AND
4. Documentation that Orencia (abatacept) intravenous will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate

**Psoriatic arthritis (PsA)**
1. Documented diagnosis of psoriatic arthritis
   AND
2. The prescribing physician is a rheumatologist
3. Documentation of one (1) of the following (3a and 3b or 3c):
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate or sulfasalazine for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate and sulfasalazine

   AND

   b. The Member has tried and failed treatment with at least one (1) of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with ALL:
      i. Inflectra (infliximab-dyyb)
      ii. Infliximab (infliximab)
      iii. Remicade (infliximab)
      iv. Simponi Aria (golimumab)

   OR

   c. The Member is new to the plan and stable on Orencia (abatacept) and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Rheumatoid arthritis (RA)
1. Documented diagnosis of rheumatoid arthritis

   AND

2. The prescribing physician is a rheumatologist

   AND

3. Documentation of one (1) of the following (3a and 3b or 3c):
   a. The Member has demonstrated an adequate response to optimal doses of methotrexate for at least three (3) months or the provider has indicated clinical inappropriateness with methotrexate

   AND

   b. The Member has tried and failed treatment with at least one (1) of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with ALL:
      i. Inflectra (infliximab-dyyb)
      ii. Infliximab (infliximab)
      iii. Remicade (infliximab)
      iv. Simponi Aria (golimumab)

   OR

   c. The Member is new to the plan and stable on Orencia (abatacept) and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Limitations
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
- Maximal doses of methotrexate are defined as 15 to 25 mg per week depending on the patient’s tolerance.
- For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
- Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.
- Approval of Actemra (tocilizumab) for intravenous injection for cytokine release syndrome will be limited to 1 month.

Codes
The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0129</td>
<td>Injection, abatacept, per 10 mg</td>
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<tr>
<td>J1602</td>
<td>Injection, golimumab, 1 mg, for intravenous use</td>
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<tr>
<td>J0717</td>
<td>Injection, certolizumab pegol, 1 mg</td>
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<tr>
<td>HCPCS Codes</td>
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<tr>
<td>J1745</td>
<td>Injection, infliximab, excludes biosimilar, 10mg</td>
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<td>J3245</td>
<td>Injection, tildrakizumab, 1 mg</td>
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<td>J3262</td>
<td>Injection, tocilizumab, 1 mg</td>
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<tr>
<td>J3358</td>
<td>Ustekinumab, for intravenous injection, 1 mg</td>
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<td>J3380</td>
<td>Injection, vedolizumab, 1 mg</td>
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<td>Q5103</td>
<td>Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg</td>
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<td>Q5104</td>
<td>Injection, infliximab-adba-biosimilar, (renflexis), 10 mg</td>
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<tr>
<td>Q5121</td>
<td>Injection, infliximab-axxq, biosimilar, (avsola), 10 mg</td>
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</tbody>
</table>

References:


27. Hunder GG. Treatment of giant cell (temporal) arteritis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on September 7, 2018).


46. Landewé R, Braun J, Deodhar A, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-


study to evaluate the safety and efficacy of golimumab induction therapy, administered subcutaneously, in patients with moderately to severely active ulcerative colitis: Results from the PURSUIT SC study. DDW abstract 2012.


83. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; August 2022.


Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.