

# Infliximab

**Policy Number:** CS2026D0004AZ  
**Effective Date:** April 1, 2026

[➔ Instructions for Use](#)

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<b>Related Community Plan Policy</b>
<ul style="list-style-type: none"> <li><a href="#">Maximum Dosage and Frequency</a></li> </ul>
<b>Commercial Policy</b>
<ul style="list-style-type: none"> <li><a href="#">Infliximab (Avsola®, Inflectra®, Remicade®, &amp; Renflexis®)</a></li> </ul>

## Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

<b>State</b>	<b>Policy/Guideline</b>
Arizona	Refer to the state’s Medicaid clinical policy
Indiana	Refer to the state’s Medicaid clinical policy
Kansas	Refer to the state’s Medicaid clinical policy
North Carolina	None
Ohio	<a href="#">Infliximab (for Ohio Only)</a>
Pennsylvania	Refer to the state’s Medicaid clinical policy
Texas	Refer to the state’s Medicaid clinical policy. Use drug specific criteria found within the <i>Texas Medicaid Provider Procedures Manual</i> if available for the specific product, otherwise this medical benefit drug policy applies
Washington	Refer to the state’s Medicaid clinical policy

The [Preferred Product](#) language and the [Preferred Product Criteria](#) do not apply to the states of Florida, Virginia\*, Texas, and Wisconsin.

\*Refer to the Virginia DMAS’ Common Core Formulary for preferred product criteria.

## Coverage Rationale

This policy refers to infliximab products administered by intravenous (IV) route.

Infliximab for self-administered subcutaneous injection [i.e., Zymfentra (infliximab-dyyb)] is obtained under the pharmacy benefit.

This policy refers to the following infliximab products:

- Avsola® (infliximab-axxq)
- Inflectra® (infliximab-dyyb)
- Remicade® (infliximab)

- Renflexis® (infliximab-abda)
- Any FDA-approved infliximab biosimilar product not listed here\*

\*Any U.S. Food and Drug Administration approved and launched infliximab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare.

## Preferred Product

Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb), and Renflexis® (infliximab-abda) are the preferred infliximab products. Coverage will be provided for Avsola®, Inflectra®, or Renflexis® contingent on the coverage criteria in the [Diagnosis-Specific Criteria](#) section.

Coverage for Remicade® (infliximab) or other non-preferred infliximab products will be provided contingent on the criteria in this section and the coverage criteria in the [Diagnosis-Specific Criteria](#) section. In order to continue coverage, members already on Remicade, or other non-preferred infliximab products will be required to change therapy to Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb), or Renflexis® (infliximab-abda) unless they meet the criteria in this section.

## Preferred Product Criteria

**Treatment with Remicade®, or other non-preferred infliximab biosimilar products, is medically necessary for the indications outlined in this policy when both of the following criteria are met:**

- **One** of the following:
  - **Both** of the following:
    - Documentation of a trial of at least 14 weeks of Avsola®, Inflectra®, or Renflexis® resulting in minimal clinical response to therapy and residual disease activity; **and**
    - Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Remicade® or other infliximab biosimilar product than experienced with Avsola®, Inflectra®, and Renflexis®
  - or
  - **Both** of the following:
    - Documentation of intolerance, contraindication, or adverse event to Avsola®, Inflectra®, or Renflexis®; **and**
    - Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Remicade® or other infliximab biosimilar product
- and**
- Patient has not had a loss of a favorable response after established maintenance therapy with Avsola®, Inflectra®, or Renflexis®, or other infliximab biosimilar product

## Diagnosis-Specific Criteria

“Infliximab” will be used to refer to all infliximab products.

## Ankylosing Spondylitis

**Infliximab is proven and medically necessary for the treatment of ankylosing spondylitis when all of the following criteria are met:**

- For **initial therapy**, **all** of the following:
  - Diagnosis of ankylosing spondylitis (AS); **and**
  - **One** of the following:
    - History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced; **or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)]; **or**
    - Patient is currently on infliximab
  - and**
  - Infliximab is dosed according to U.S. Food and Drug Administration (FDA)-labeled dosing for ankylosing spondylitis; **and**
  - Patient is not receiving infliximab in combination with a systemic Targeted Immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and**
  - Prescribed by or in consultation with a rheumatologist; **and**

- Initial authorization is for no more than 12 months
- For **continuation of therapy**, all of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for ankylosing spondylitis; **and**
  - Patient is not receiving infliximab in combination with a systemic Targeted Immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

## ***Crohn's Disease***

**Infliximab is proven and medically necessary for the treatment of Crohn's disease when all of the following criteria are met:**

- For **initial therapy**, all of the following:
    - Diagnosis of moderately to severely active Crohn's disease; **and**
    - **One** of the following:
      - Disease is considered high risk (e.g., fistulizing, structuring, luminal, perianal, extensive disease, growth delay); **or**
      - History of failure to one of the following conventional therapies at up to maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced:
        - Corticosteroids (e.g., prednisone, methylprednisolone, budesonide); **or**
        - 6-mercaptopurine (Purinethol); **or**
        - Azathioprine (Imuran); **or**
        - Methotrexate (Rheumatrex, Trexall)
    - **or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab]; **or**
    - Patient is currently on infliximab
  - and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for Crohn's disease; **and**
  - Patient is not receiving infliximab in combination with a systemic Targeted Immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same; **and**
  - Prescribed by or in consultation with a gastroenterologist; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, all of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for Crohn's disease; **and**
  - Patient is not receiving infliximab in combination with a systemic Targeted Immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

## ***Noninfectious Uveitis***

**Infliximab is proven and medically necessary for the treatment of noninfectious uveitis when all of the following criteria are met:**

- For **initial therapy**, all of the following:
  - Diagnosis of refractory noninfectious uveitis that is causing or threatening vision loss (e.g., noninfectious uveitis associated with Behçet's or Reiter's syndromes); **and**
  - History of failure, contraindication, or intolerance to **all** of the following:
    - Topical corticosteroids; **and**
    - Systemic corticosteroids; **and**
    - Immunosuppressive drugs (e.g., azathioprine, cyclosporine, or methotrexate)
  - **and**
  - Infliximab is dosed no higher than 5 mg/kg, administered at week 0, 2, 6, and every 8 weeks thereafter; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator (e.g., adalimumab) for treatment of the same condition; **and**
  - Prescribed by or in consultation with one of the following:

- Rheumatologist; **or**
- Ophthalmologist
- and**
- Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed no higher than 5 mg/kg, administered every 8 weeks; **and**
  - Patient is not receiving infliximab in combination with a systemic Targeted Immunomodulator (e.g., adalimumab) for treatment of the same condition; **and**
  - Reauthorization is for no more than 12 months

## ***Plaque Psoriasis***

**Infliximab is proven and medically necessary for the treatment of plaque psoriasis when all of the following criteria are met:**

- For **initial therapy**, **all** of the following:
    - Diagnosis of chronic severe plaque psoriasis (i.e., extensive and/or disabling); **and**
    - **One** of the following:
      - **All** of the following:
        - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; **and**
        - History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced:
          - Corticosteroids (e.g., betamethasone, clobetasol, desonide); **or**
          - Vitamin D analogs (e.g., calcitriol, calcipotriene); **or**
          - Tazarotene; **or**
          - Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus); **or**
          - Anthralin; **or**
          - Coal tar
      - and**
      - History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced
    - or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]; **or**
    - Patient is currently on infliximab
  - and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for plaque psoriasis; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and**
  - Prescribed by or in consultation with a dermatologist; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for plaque psoriasis; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

## ***Psoriatic Arthritis***

**Infliximab is proven and medically necessary for the treatment of psoriatic arthritis when all of the following criteria are met:**

- For **initial therapy**, **all** of the following:
  - Diagnosis of psoriatic arthritis (PsA); **and**
  - **One** of the following:
    - History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced; **or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orenzia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]; **or**
    - Patient is currently on infliximab
  - and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for psoriatic arthritis; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orenzia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and**
  - Prescribed by or in consultation with one of the following:
    - Rheumatologist; **or**
    - Dermatologist
  - and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for psoriatic arthritis; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orenzia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same; **and**
  - Reauthorization is for no more than 12 months

## ***Rheumatoid Arthritis***

**Infliximab is proven and medically necessary for the treatment of rheumatoid arthritis when all of the following criteria are met:**

- For **initial therapy**, **all** of the following:
  - Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and**
  - **One** of the following:
    - History of failure intolerance to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced; **or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orenzia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]; **or**
    - Patient is currently on infliximab
  - and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for rheumatoid arthritis; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orenzia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
  - Prescribed by or in consultation with a rheumatologist; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for rheumatoid arthritis; **and**

- Patient is not receiving infliximab in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
- Reauthorization is for no more than 12 months

## ***Sarcoidosis***

**Infliximab is proven and medically necessary for the treatment of sarcoidosis when all of the following criteria are met:**

- For **initial therapy**, **all** of the following:
  - Diagnosis of sarcoidosis; **and**
  - History of failure, contraindication, or intolerance to corticosteroids (e.g., prednisone, methylprednisolone); **and**
  - History of failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, azathioprine); **and**
  - Infliximab is dosed no higher than 10 mg/kg, administered at week 0, 2, then once every 4 to 6 weeks thereafter; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator for treatment of the same indication; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed no higher than 10 mg/kg, administered every 4 to 6 weeks; **and**
  - Patient is not receiving infliximab in combination with a systemic targeted immunomodulator for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

## ***Ulcerative Colitis***

**Infliximab is proven and medically necessary for the treatment of ulcerative colitis when all of the following criteria are met:**<sup>1,57,61</sup>

- For **initial therapy**, **all** of the following:
  - Diagnosis of moderately to severely active ulcerative colitis (UC); **and**
  - **One** of the following:
    - History of failure, contraindication, or intolerance to at least one conventional therapy (e.g., 6-mercaptopurine, aminosalicylate, azathioprine, corticosteroids); **or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission medical records (document drug, date, and duration of therapy) [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)]; **or**
    - Patient is currently on infliximab
  - and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for UC; **and**
  - Patient is not receiving infliximab in combination with a systemic Targeted Immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication; **and**
  - Prescribed by or in consultation with a gastroenterologist; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Documentation of positive clinical response to infliximab; **and**
  - Infliximab is dosed according to U.S. FDA-labeled dosing for UC; **and**
  - Patient is **not** receiving infliximab in combination with a systemic Targeted Immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

## ***Acute Graft-Versus-Host Disease (GVHD)***

**Infliximab is proven and medically necessary for the treatment of acute graft-versus-host disease (GVHD) when all of the following criteria are met:**

- For **initial therapy**, all of the following:
  - Diagnosis of steroid-refractory acute GVHD; **and**
  - **One** of the following:
    - Patient is receiving infliximab in combination with systemic corticosteroids; **or**
    - Patient is intolerant to systemic corticosteroid therapy**and**
  - Initial authorization is for no more than 4 doses
- For **continuation of therapy**, all of the following:
  - Documentation of positive clinical response; **and**
  - Patient continues to experience acute GVHD; **and**
  - **One** of the following:
    - Patient is receiving infliximab in combination with systemic corticosteroids; **or**
    - Patient is intolerant to systemic corticosteroid therapy**and**
  - Reauthorization is for no more than 4 doses

### ***Immune Checkpoint Inhibitor-Related Toxicities***

**Infliximab is proven and medically necessary for the treatment of immune checkpoint inhibitor-related toxicities when all of the following criteria are met:**

- For **initial therapy**, all of the following:
  - Patient has recently received checkpoint inhibitor therapy [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]; **and**
  - Diagnosis of an immune checkpoint inhibitor-related toxicity; **and**
  - Patient has had inadequate improvement in toxicities or symptoms despite systemic corticosteroid therapy of [adequate dose and duration for the diagnosis](#); **and**
  - **One** of the following:
    - Patient is receiving infliximab in combination with systemic corticosteroids; **or**
    - Patient is intolerant to systemic corticosteroid therapy**and**
  - Initial authorization is for no more than 4 doses
- For **continuation of therapy**, all of the following:
  - Documentation of positive clinical response; **and**
  - Patient continues to experience toxicities from treatment with immune checkpoint inhibitor therapy; **and**
  - **One** of the following:
    - Patient is receiving infliximab in combination with systemic corticosteroids; **or**
    - Patient is intolerant to systemic corticosteroid therapy**and**
  - Reauthorization is for no more than 4 doses

There may be other conditions that qualify as serious, rare diseases for which the use of infliximab may be appropriate.

**Infliximab is unproven and not medically necessary for the treatment of:**

- Hidradenitis suppurativa
- Juvenile idiopathic arthritis (juvenile rheumatoid arthritis)
- Myelodysplastic syndromes
- Reiter's syndrome
- Sjögren's syndrome
- Still's disease
- Undifferentiated spondyloarthropathy
- Wegener's granulomatosis

Infliximab is unproven for the treatment of the above conditions because statistically robust randomized controlled trials are needed to address the issue of whether infliximab has sufficient superiority in clinical efficacy compared to other available treatments to justify the inherent clinical risk in the use of a monoclonal antibody anti-tumor necrosis factor agent.

## Applicable Codes

The following list(s) of procedure codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J1745	Injection, infliximab, excludes biosimilar, 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg

Diagnosis Code	Description
D86.0	Sarcoidosis of lung
D86.1	Sarcoidosis of lymph nodes
D86.2	Sarcoidosis of lung with sarcoidosis of lymph nodes
D86.3	Sarcoidosis of skin
D86.81	Sarcoid meningitis
D86.82	Multiple cranial nerve palsies in sarcoidosis
D86.83	Sarcoid iridocyclitis
D86.84	Sarcoid pyelonephritis
D86.85	Sarcoid myocarditis
D86.86	Sarcoid arthropathy
D86.87	Sarcoid myositis
D86.89	Sarcoidosis of other sites
D86.9	Sarcoidosis, unspecified
D89.810	Acute graft-versus-host disease
H20.041	Secondary noninfectious iridocyclitis, right eye
H20.042	Secondary noninfectious iridocyclitis, left eye
H20.043	Secondary noninfectious iridocyclitis, bilateral
H20.049	Secondary noninfectious iridocyclitis, unspecified eye
H20.10	Chronic iridocyclitis, unspecified eye
H20.11	Chronic iridocyclitis, right eye
H20.12	Chronic iridocyclitis, left eye
H20.13	Chronic iridocyclitis, bilateral
H20.821	Vogt-Koyanagi syndrome, right eye
H20.822	Vogt-Koyanagi syndrome, left eye
H20.823	Vogt-Koyanagi syndrome, bilateral
H20.829	Vogt-Koyanagi syndrome, unspecified eye
H30.001	Unspecified focal chorioretinal inflammation, right eye
H30.002	Unspecified focal chorioretinal inflammation, left eye
H30.003	Unspecified focal chorioretinal inflammation, bilateral
H30.009	Unspecified focal chorioretinal inflammation, unspecified eye
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral

Diagnosis Code	Description
H30.019	Focal chorioretinal inflammation, juxtapapillary, unspecified eye
H30.021	Focal chorioretinal inflammation of posterior pole, right eye
H30.022	Focal chorioretinal inflammation of posterior pole, left eye
H30.023	Focal chorioretinal inflammation of posterior pole, bilateral
H30.029	Focal chorioretinal inflammation of posterior pole, unspecified eye
H30.031	Focal chorioretinal inflammation, peripheral, right eye
H30.032	Focal chorioretinal inflammation, peripheral, left eye
H30.033	Focal chorioretinal inflammation, peripheral, bilateral
H30.039	Focal chorioretinal inflammation, peripheral, unspecified eye
H30.041	Focal chorioretinal inflammation, macular or paramacular, right eye
H30.042	Focal chorioretinal inflammation, macular or paramacular, left eye
H30.043	Focal chorioretinal inflammation, macular or paramacular, bilateral
H30.049	Focal chorioretinal inflammation, macular or paramacular, unspecified eye
H30.101	Unspecified disseminated chorioretinal inflammation (chorioretinitis/choroiditis), right eye
H30.102	Unspecified disseminated chorioretinal inflammation (chorioretinitis/choroiditis), left eye
H30.103	Unspecified disseminated chorioretinal inflammation (chorioretinitis/choroiditis), bilateral
H30.109	Unspecified disseminated chorioretinal inflammation (chorioretinitis/choroiditis), unspecified eye
H30.111	Disseminated chorioretinal inflammation (choroiditis/chorioretinitis) posterior pole, right eye
H30.112	Disseminated chorioretinal inflammation (choroiditis/chorioretinitis) posterior pole, left eye
H30.113	Disseminated chorioretinal inflammation (choroiditis/chorioretinitis) posterior pole, bilateral
H30.119	Disseminated chorioretinal inflammation (choroiditis/chorioretinitis) posterior pole, unspecified eye
H30.121	Disseminated chorioretinal inflammation (chorioretinitis/choroiditis) peripheral, right eye
H30.122	Disseminated chorioretinal inflammation (chorioretinitis/choroiditis) peripheral, left eye
H30.123	Disseminated chorioretinal inflammation (chorioretinitis/choroiditis) peripheral, bilateral
H30.129	Disseminated chorioretinal inflammation (chorioretinitis/choroiditis) peripheral, unspecified eye
H30.131	Disseminated chorioretinal inflammation, generalized, right eye
H30.132	Disseminated chorioretinal inflammation, generalized, left eye
H30.133	Disseminated chorioretinal inflammation, generalized, bilateral
H30.139	Disseminated chorioretinal inflammation, generalized, unspecified eye
H30.20	Posterior cyclitis, unspecified eye
H30.21	Posterior cyclitis, right eye
H30.22	Posterior cyclitis, left eye
H30.23	Posterior cyclitis, bilateral
H30.811	Harada's disease, right eye
H30.812	Harada's disease, left eye
H30.813	Harada's disease, bilateral
H30.819	Harada's disease, unspecified eye
H30.891	Other chorioretinal inflammations, right eye
H30.892	Other chorioretinal inflammations, left eye
H30.893	Other chorioretinal inflammations, bilateral
H30.899	Other chorioretinal inflammations, unspecified eye
H30.90	Unspecified chorioretinal inflammation, unspecified eye
H30.91	Unspecified chorioretinal inflammation, right eye
H30.92	Unspecified chorioretinal inflammation, left eye
H30.93	Unspecified chorioretinal inflammation, bilateral

Diagnosis Code	Description
H35.021	Exudative retinopathy, right eye
H35.022	Exudative retinopathy, left eye
H35.023	Exudative retinopathy, bilateral
H35.029	Exudative retinopathy, unspecified eye
H35.061	Retinal vasculitis, right eye
H35.062	Retinal vasculitis, left eye
H35.063	Retinal vasculitis, bilateral
H35.069	Retinal vasculitis, unspecified eye
H44.111	Panuveitis, right eye
H44.112	Panuveitis, left eye
H44.113	Panuveitis, bilateral
H44.119	Panuveitis, unspecified eye
H44.131	Sympathetic uveitis, right eye
H44.132	Sympathetic uveitis, left eye
H44.133	Sympathetic uveitis, bilateral
H44.139	Sympathetic uveitis, unspecified eye
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified
I40.8	Other acute myocarditis
I40.9	Acute myocarditis, unspecified
I50.9	Heart failure, unspecified
J70.2	Acute drug-induced interstitial lung disorders
J70.4	Drug-induced interstitial lung disorders, unspecified
K31.6	Fistula of stomach and duodenum
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications

Diagnosis Code	Description
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction

Diagnosis Code	Description
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis
K60.30	Anal fistula, unspecified
K60.311	Anal fistula, simple, initial
K60.312	Anal fistula, simple, persistent
K60.313	Anal fistula, simple, recurrent
K60.319	Anal fistula, simple, unspecified
K60.321	Anal fistula, complex, initial
K60.322	Anal fistula, complex, persistent
K60.323	Anal fistula, complex, recurrent
K60.329	Anal fistula, complex, unspecified
K60.40	Rectal fistula, unspecified
K60.411	Rectal fistula, simple, initial
K60.412	Rectal fistula, simple, persistent
K60.413	Rectal fistula, simple, recurrent
K60.419	Rectal fistula, simple, unspecified
K60.421	Rectal fistula, complex, initial
K60.422	Rectal fistula, complex, persistent
K60.423	Rectal fistula, complex, recurrent
K60.429	Rectal fistula, complex, unspecified
K60.50	Anorectal fistula, unspecified
K60.511	Anorectal fistula, simple, initial
K60.512	Anorectal fistula, simple, persistent
K60.513	Anorectal fistula, simple, recurrent
K60.519	Anorectal fistula, simple, unspecified
K60.521	Anorectal fistula, complex, initial
K60.522	Anorectal fistula, complex, persistent
K60.523	Anorectal fistula, complex, recurrent
K60.529	Anorectal fistula, complex, unspecified
K63.2	Fistula of intestine
L40.0	Psoriasis vulgaris
L40.1	Generalized pustular psoriasis
L40.2	Acrodermatitis continua
L40.3	Pustulosis palmaris et plantaris
L40.4	Guttate psoriasis

Diagnosis Code	Description
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
L40.8	Other psoriasis
L40.9	Psoriasis, unspecified
M05.00	Felty's syndrome, unspecified site
M05.011	Felty's syndrome, right shoulder
M05.012	Felty's syndrome, left shoulder
M05.019	Felty's syndrome, unspecified shoulder
M05.021	Felty's syndrome, right elbow
M05.022	Felty's syndrome, left elbow
M05.029	Felty's syndrome, unspecified elbow
M05.031	Felty's syndrome, right wrist
M05.032	Felty's syndrome, left wrist
M05.039	Felty's syndrome, unspecified wrist
M05.041	Felty's syndrome, right hand
M05.042	Felty's syndrome, left hand
M05.049	Felty's syndrome, unspecified hand
M05.051	Felty's syndrome, right hip
M05.052	Felty's syndrome, left hip
M05.059	Felty's syndrome, unspecified hip
M05.061	Felty's syndrome, right knee
M05.062	Felty's syndrome, left knee
M05.069	Felty's syndrome, unspecified knee
M05.071	Felty's syndrome, right ankle and foot
M05.072	Felty's syndrome, left ankle and foot
M05.079	Felty's syndrome, unspecified ankle and foot
M05.09	Felty's syndrome, multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip

Diagnosis Code	Description
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand

Diagnosis Code	Description
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems

Diagnosis Code	Description
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.7A	Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.8A	Other rheumatoid arthritis with rheumatoid factor of other specified site
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site

Diagnosis Code	Description
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M05.A	Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis
M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified site
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot

Diagnosis Code	Description
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.1	Adult-onset Still's disease
M06.20	Rheumatoid bursitis, unspecified site
M06.211	Rheumatoid bursitis, right shoulder
M06.212	Rheumatoid bursitis, left shoulder
M06.219	Rheumatoid bursitis, unspecified shoulder
M06.221	Rheumatoid bursitis, right elbow
M06.222	Rheumatoid bursitis, left elbow
M06.229	Rheumatoid bursitis, unspecified elbow
M06.231	Rheumatoid bursitis, right wrist
M06.232	Rheumatoid bursitis, left wrist
M06.239	Rheumatoid bursitis, unspecified wrist
M06.241	Rheumatoid bursitis, right hand
M06.242	Rheumatoid bursitis, left hand
M06.249	Rheumatoid bursitis, unspecified hand
M06.251	Rheumatoid bursitis, right hip
M06.252	Rheumatoid bursitis, left hip
M06.259	Rheumatoid bursitis, unspecified hip
M06.261	Rheumatoid bursitis, right knee
M06.262	Rheumatoid bursitis, left knee
M06.269	Rheumatoid bursitis, unspecified knee
M06.271	Rheumatoid bursitis, right ankle and foot
M06.272	Rheumatoid bursitis, left ankle and foot
M06.279	Rheumatoid bursitis, unspecified ankle and foot
M06.28	Rheumatoid bursitis, vertebrae
M06.29	Rheumatoid bursitis, multiple sites
M06.30	Rheumatoid nodule, unspecified site
M06.311	Rheumatoid nodule, right shoulder
M06.312	Rheumatoid nodule, left shoulder
M06.319	Rheumatoid nodule, unspecified shoulder
M06.321	Rheumatoid nodule, right elbow
M06.322	Rheumatoid nodule, left elbow
M06.329	Rheumatoid nodule, unspecified elbow
M06.331	Rheumatoid nodule, right wrist
M06.332	Rheumatoid nodule, left wrist
M06.339	Rheumatoid nodule, unspecified wrist
M06.341	Rheumatoid nodule, right hand
M06.342	Rheumatoid nodule, left hand
M06.349	Rheumatoid nodule, unspecified hand
M06.351	Rheumatoid nodule, right hip
M06.352	Rheumatoid nodule, left hip
M06.359	Rheumatoid nodule, unspecified hip

Diagnosis Code	Description
M06.361	Rheumatoid nodule, right knee
M06.362	Rheumatoid nodule, left knee
M06.369	Rheumatoid nodule, unspecified knee
M06.371	Rheumatoid nodule, right ankle and foot
M06.372	Rheumatoid nodule, left ankle and foot
M06.379	Rheumatoid nodule, unspecified ankle and foot
M06.38	Rheumatoid nodule, vertebrae
M06.39	Rheumatoid nodule, multiple sites
M06.4	Inflammatory polyarthropathy
M06.8A	Other specified rheumatoid arthritis, other specified site
M06.80	Other specified rheumatoid arthritis, unspecified site
M06.811	Other specified rheumatoid arthritis, right shoulder
M06.812	Other specified rheumatoid arthritis, left shoulder
M06.819	Other specified rheumatoid arthritis, unspecified shoulder
M06.821	Other specified rheumatoid arthritis, right elbow
M06.822	Other specified rheumatoid arthritis, left elbow
M06.829	Other specified rheumatoid arthritis, unspecified elbow
M06.831	Other specified rheumatoid arthritis, right wrist
M06.832	Other specified rheumatoid arthritis, left wrist
M06.839	Other specified rheumatoid arthritis, unspecified wrist
M06.841	Other specified rheumatoid arthritis, right hand
M06.842	Other specified rheumatoid arthritis, left hand
M06.849	Other specified rheumatoid arthritis, unspecified hand
M06.851	Other specified rheumatoid arthritis, right hip
M06.852	Other specified rheumatoid arthritis, left hip
M06.859	Other specified rheumatoid arthritis, unspecified hip
M06.861	Other specified rheumatoid arthritis, right knee
M06.862	Other specified rheumatoid arthritis, left knee
M06.869	Other specified rheumatoid arthritis, unspecified knee
M06.871	Other specified rheumatoid arthritis, right ankle and foot
M06.872	Other specified rheumatoid arthritis, left ankle and foot
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot
M06.88	Other specified rheumatoid arthritis, vertebrae
M06.89	Other specified rheumatoid arthritis, multiple sites
M06.9	Rheumatoid arthritis, unspecified
M08.1	Juvenile ankylosing spondylitis
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region

Diagnosis Code	Description
M45.9	Ankylosing spondylitis of unspecified sites in spine
M48.8X1	Other specified spondylopathies, occipito-atlanto-axial region
M48.8X2	Other specified spondylopathies, cervical region
M48.8X3	Other specified spondylopathies, cervicothoracic region
M48.8X4	Other specified spondylopathies, thoracic region
M48.8X5	Other specified spondylopathies, thoracolumbar region
M48.8X6	Other specified spondylopathies, lumbar region
M48.8X7	Other specified spondylopathies, lumbosacral region
M48.8X8	Other specified spondylopathies, sacral and sacrococcygeal region
M48.8X9	Other specified spondylopathies, site unspecified
N17.8	Other acute kidney failure
N17.9	Acute kidney failure, unspecified
N82.2	Fistula of vagina to small intestine
N82.3	Fistula of vagina to large intestine
N82.4	Other female intestinal-genital tract fistulae
R19.7	Diarrhea, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela

## Background

Infliximab is a genetically engineered chimeric human/mouse monoclonal antibody (cA2) against tumor necrosis factor alfa (TNF-alfa), a key mediator of mucosal inflammation. Increased levels of TNF-alfa are found in the intestinal mucosa and stool of patients with active Crohn's disease and in the joints of rheumatoid arthritis patients. Elevated TNF-alfa concentrations are also involved in ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. TNF-alfa activity is neutralized by cA2 antibody binding to the soluble and transmembrane forms which blocks the binding of TNF-alfa with its receptors. Activities inhibited by anti-TNF-alfa antibodies include induction of interleukins, enhancement of leukocyte migration, and expression of adhesion molecules. In vitro studies have demonstrated that cells expressing transmembrane TNF-alfa bound by infliximab are lysed by complement or effector cells. In animal models, antibodies to TNF-alfa were shown to prevent or reduce inflammation.<sup>1</sup>

## Clinical Evidence

### Proven

Infliximab is proven for:

- **Crohn's disease:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
  - Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.
- **Pediatric Crohn's disease:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy.
- **Ulcerative colitis:**
  - Reducing signs and symptoms, inducing, and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

- **Pediatric ulcerative colitis:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy.
- **Rheumatoid arthritis in combination with methotrexate:**
  - Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease.
- **Plaque psoriasis:**
  - Treatment of adult patients with chronic severe (i.e., extensive and /or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.
- **Psoriatic arthritis:**
  - Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis.
- **Ankylosing spondylitis:**
  - Reducing signs and symptoms in adult patients with active disease.

## ***Sarcoidosis***

The use of infliximab in patients with chronic pulmonary sarcoidosis was assessed in a multicenter, randomized, double-blind, placebo-controlled study. Patients must have been treated with at least 10 mg/d of prednisone or equivalent or one or more immunosuppressants for  $\geq 3$  months before screening. They received infliximab 3 mg/kg (n = 46), 5 mg/kg (n = 47), or placebo (n = 45) at weeks 0, 2, 6, 12, 18, and 24. They were followed through 52 weeks. The primary endpoint was the change at week 24 from baseline in percent of predicted forced vital capacity (FVC). Patients receiving infliximab 3 or 5 mg/kg had a mean increase of 2.5% compared with no change for those receiving placebo (p = 0.038).

Infliximab has also been studied for use in sarcoidosis in small clinical trials, small published studies and reports that also conclude that clinical evidence supports the use of infliximab for treatment-resistant sarcoidosis.

## ***Noninfectious Uveitis***

Long-term safety and efficacy of treatment with infliximab in uveitis for more than one year in patients (n = 164) with Behçet's disease (BD) was evaluated via questionnaire in a retrospective multicenter study. Primary outcome measures assessed were best-corrected VA (BCVA) determined by the Landolt ring, proportion of subjects without relapse of uveitis, frequency of ocular inflammatory attacks per year, and adverse effects of the therapy. The mean age at initiation of infliximab treatment was  $42.6 \pm 11.7$  years, and the mean treatment duration was  $32.9 \pm 14.4$  months. Data before and at the last visit during infliximab treatment were analyzed in 4 groups divided by duration of treatment: group A (n = 43, 12- < 24 months), group B (n = 62, 24- < 36 months), group C (n = 42, 36- < 48 months), and group D (n = 17,  $\geq 48$  months). The frequency of ocular attacks decreased in all groups (from  $5.3 \pm 3.0$  to  $1.0 \pm 0.3$  in group A,  $4.8 \pm 4.6$  to  $1.4 \pm 0.3$  in group B,  $4.1 \pm 2.9$  to  $0.9 \pm 0.3$  in group C, and  $9.5 \pm 5.8$  to  $1.6 \pm 0.5$  in group D; all p < 0.05). The BCVA was improved in approximately 55% of the eyes after treatment. Mean BCVA was improved after treatment with infliximab in groups A to C (from  $0.79 \pm 1.04$  to  $0.59 \pm 0.94$  in group A,  $0.59 \pm 1.07$  to  $0.41 \pm 1.04$  in group B, and  $1.15 \pm 1.77$  to  $0.92 \pm 1.73$  in group C; all p < 0.05) but not in group D. Uveitis relapsed in 59.1% of all patients after infliximab treatment, and no difference in duration until relapse was observed between individual groups. Approximately 80% of relapses occurred within one year after the initiation of infliximab treatment in all groups, 90% of which were controlled by increasing doses of topical corticosteroids and shortening the interval of infliximab infusion. Adverse effects were observed in 65 cases or 35% of all subjects. Infliximab treatment was continued in 85% of the patients, but 15% of the patients discontinued infliximab treatment because of adverse effects or insufficient efficacy. Researchers concluded that this study demonstrated that infliximab reduced the frequency of ocular attacks and improved VA in patients with BD-related uveitis refractory to conventional therapies and was generally well tolerated, with few serious adverse events.

Kruh et al. conducted a retrospective, interventional, non-comparative cohort study which evaluated the safety and efficacy of infliximab for the treatment of refractory noninfectious uveitis. Patients (n = 88) with chronic, recalcitrant uveitis treated with infliximab were identified through an electronic medical record database. All charts were reviewed for sex, diagnosis, location of inflammation, presence of vasculitis, prior immunomodulatory treatments, duration of infliximab treatment, dose received, secondary side effects, and other medications continued while receiving treatment with infliximab. The primary outcome measures assessed were the rate of remission, time to remission, relapse rate, failure rate, and patient tolerance. Additional analysis was aimed to identify risk factors that would predict a higher success rate of infliximab to treat various types of noninfectious uveitis. Of the 72 patients (81.8%) who achieved clinical remission while being treated with infliximab, 42 (58.3%) required additional immunomodulatory medications. At 7, 18.1, and 44.7 weeks, 25%, 50%, and 75% of patients, respectively, achieved clinical remission off all corticosteroids. Thirty-two patients (36.4%) experienced at least one side effect while on infliximab therapy, and 17 patients (19.3%) discontinued treatment

secondary to one or more intolerable side effects. The most common adverse effects were skin rash (9.1%) and fatigue (8%). Factors associated with a higher chance to achieve clinical remission were non-idiopathic uveitis ( $p < 0.001$ ), intermediate or panuveitis ( $p < 0.001$ ), absence of vasculitis ( $p < 0.001$ ), and a starting dose  $\geq 5$  mg/kg ( $p < 0.011$ ). Researchers concluded that infliximab treatment induced a high rate of complete clinical remission in recalcitrant uveitis and is well tolerated by most patients.

### ***NCCN Recommended Uses***

According to the NCCN Drugs & Biologics Compendium, NCCN recommends (2A) infliximab for the treatment of:

- Acute graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options:
  - Therapy for steroid-refractory acute GVHD is often used in conjunction with the original immunosuppressive agent
- Immune checkpoint inhibitor-related toxicities – consider adding infliximab for the management of immunotherapy-related:
  - Myocarditis as additional immunosuppression if no improvement within 24–48 hours of starting high-dose methylprednisolone
  - Moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide
  - Mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin
  - Moderate (G2) and strongly consider for severe (G3–4) diarrhea or colitis if colonoscopy or flexible sigmoidoscopy shows significant ulceration or extensive non-ulcerative inflammation\*
  - G4 hemolytic anemia with hemolysis if no response to corticosteroids and rituximab
  - Moderate or severe inflammatory arthritis if unable to taper corticosteroids after 1 week
  - G1–4 uveitis that is refractory to high-dose systemic corticosteroids (treatment guided by ophthalmology)
  - Moderate (G2) pneumonitis if no improvement after 48–72 hours of corticosteroids or severe (G3–4) pneumonitis if no improvement after 48 hours of methylprednisolone
  - Stage 3 acute kidney injury/elevated serum creatinine if toxicity remains > stage 2 after 4–6 weeks of corticosteroids or if creatinine increases during steroid taper (or once off corticosteroids)

\*For patients with severe colitis, higher rates of refractory response to corticosteroids have been reported. Early introduction of infliximab can be considered to reduce recurrence.

### **Unproven**

#### ***Juvenile Idiopathic Arthritis (Juvenile Rheumatoid Arthritis)***

In an international, multicenter, randomized, placebo-controlled, double-blind study, 122 children with polyarticular juvenile rheumatoid arthritis (JRA) and persistent symptoms despite at least 3 months prior MTX were randomized to receive infliximab 3 mg/kg + MTX or placebo + MTX at weeks 0, 2, and 6. At week 14, the placebo group was switched to infliximab 6 mg/kg + placebo. Responses were measured according to American College of Rheumatology Pediatric 30 (Pedi 30) criteria. Although a higher percentage of patients in the 3 mg/kg group achieved responses at week 14 (63.8% vs. 49.2% in placebo group), the study failed to show the efficacy of infliximab for JRA as the difference was not statistically significant. By week 16, similar percentage response was achieved in both groups. At week 52, the percentages reaching ACR Pedi 50 and ACR Pedi 70 were 69.6% and 51.8%, respectively. The safety profile of infliximab 3 mg/kg was generally less favorable than that of infliximab 6 mg/kg, with more serious adverse events, infusion reactions, antibodies to infliximab, and newly induced antinuclear antibodies and antibodies to double-stranded DNA. Patients who completed the study also continued to receive open-label treatment for up to 2 years.

Infliximab has also been studied for use in JIA in smaller, open-label trials. Further large scale studies are required to characterize the efficacy and safety of infliximab in JIA.

### ***Miscellaneous***

The medical literature contains a number of small open-label studies and case reports of infliximab therapy for the treatment of adult-onset Still's disease, Sjögren's syndrome, myelodysplastic syndromes, undifferentiated spondyloarthropathy, Reiter's syndrome, hidradenitis suppurativa, and Wegener's granulomatosis. While these studies and reports showed infliximab to have a positive effect on the manifestations of these diseases, the use of infliximab for these conditions has not been evaluated in large, controlled trials.

## **U.S. Food and Drug Administration (FDA)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Remicade is a tumor necrosis factor (TNF) blocker indicated for:

- **Crohn's disease:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
  - Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
- **Pediatric Crohn's disease:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
- **Ulcerative colitis:**
  - Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- **Pediatric ulcerative colitis:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
- **Rheumatoid arthritis in combination with methotrexate:**
  - Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease
- **Plaque psoriasis:**
  - Treatment of adult patients with chronic severe (i.e., extensive and /or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate
- **Psoriatic arthritis:**
  - Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis
- **Ankylosing spondylitis:**
  - Reducing signs and symptoms in adult patients with active disease

Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), and Renflexis (infliximab-abda) are biosimilar\* to Remicade (infliximab). Avsola, Inflectra and Renflexis are a tumor necrosis factor (TNF) blocker indicated for:

- **Crohn's disease:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
  - Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
- **Pediatric Crohn's disease:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
- **Ulcerative colitis:**
  - Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- **Pediatric ulcerative colitis:**
  - Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
- **Rheumatoid arthritis in combination with methotrexate:**
  - Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease
- **Ankylosing spondylitis:**
  - Reducing signs and symptoms in adult patients with active disease
- **Psoriatic arthritis:**
  - Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis

- **Plaque psoriasis:**

- Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

\*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

Reference Product	Biosimilar Product
Remicade	Avsola, Inflectra, Renflexis, Zymfentra

The FDA issued an alert dated September 7, 2011, to inform healthcare professionals that the Boxed Warning for the entire class of tumor necrosis factor- $\alpha$  (TNF $\alpha$ ) blockers has been updated to include the risk of infection from two bacterial pathogens, *Legionella* and *Listeria*. In addition, the Boxed Warning and Warnings and Precautions sections of the labels for all of the TNF $\alpha$  blockers have been revised so that they contain consistent information about the risk for serious infections and the associated disease-causing pathogens.

The FDA issued an update on November 3, 2011, regarding their ongoing safety review of tumor necrosis factor (TNF) blockers and malignancy in children, adolescents, and young adults (30 years of age or younger). This issue was previously communicated in June 2008, August 2009, and April 2011. The FDA is requiring the manufacturers of TNF blockers to perform enhanced safety surveillance for these products. The manufacturers will also provide FDA with annual summaries and assessments of malignancies and TNF blocker utilization data. Healthcare professionals should remain vigilant for cases of malignancy in patients treated with TNF blockers.

## References

1. Remicade [prescribing information]. Horsham, PA: Janssen Biotech Inc.; February 2025.
2. Yee AM, Pochapin MB. Treatment of complicated sarcoidosis with infliximab anti-tumor necrosis factor- $\alpha$  therapy. *Ann Intern Med.* 2001;135(1):27-31.
3. U.S. Food and Drug Administration Information for Patients and Providers: Tumor Necrosis Factor (TNF) Blockers (marketed as Remicade, Enbrel, Humira, Cimzia, and Simponi). <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-tumor-necrosis-factor-tnf-blockers-marketed-remicade-enbrel-humira-cimzia-and-simponi>. Accessed July 2, 2021.
4. U.S. Food and Drug Administration Drug Safety Communication: UPDATE on Tumor Necrosis Factor (TNF) blockers and risk for pediatric malignancy. <http://www.fda.gov/Drugs/DrugSafety/ucm278267.htm>. Accessed July 2, 2021.
5. U.S. Food and Drug Administration Drug Safety Communication: Drug labels for the Tumor Necrosis Factor- $\alpha$  (TNF $\alpha$ ) blockers now include warnings about infection with Legionella and Listeria bacteria. <http://www.fda.gov/Drugs/DrugSafety/ucm270849.htm>. Accessed July 2, 2021.
6. Takeuchi M, Kezuka T, Sugita S, et al. Evaluation of the long-term efficacy and safety of infliximab treatment for uveitis in Behçet's disease: a multicenter study. *Ophthalmology.* 2014 Oct;121(10):1877-84.
7. Kruh JN, Yang P, Suelves AM, et al. Infliximab for the treatment of refractory noninfectious Uveitis: a study of 88 patients with long-term follow-up. *Ophthalmology.* 2014 Jan;121(1):358-64.
8. Levy-Clark G, Jabs DA, Read RW, et al. Expert panel recommendations for the use of anti-tumor necrosis factor biologic agents in patients with ocular inflammatory disorders. *Ophthalmology.* 2014 Mar;121(3):785-96.
9. Lee FF, Foster CS. Pharmacology of uveitis. *Expert Opin Pharmacother.* 2010;11(7):1135-1146.
10. Murphy CC, Ayliffe WH, Booth A, et al. Tumor necrosis factor alpha blockade with infliximab for refractory uveitis and scleritis. *Ophthalmology.* 2004;111(2):352-356.
11. Sullivan TP, Welsh E, Kerdel FA, et al. Infliximab for hidradenitis suppurativa. *Br J Dermatol.* 2003;149(5):1046-1049.
12. Mariette X, Ravaud P, Steinfeld S, et al. Inefficacy of infliximab in primary Sjögren's syndrome: results of the randomized, controlled Trial of Remicade in Primary Sjögren's Syndrome (TRIPSS). *Arthritis Rheum.* 2004;50(4):1270-1276.
13. Ruperto N, Lovell DJ, Cuttica R, et al. A randomized, placebo-controlled trial of infliximab plus methotrexate for the treatment of polyarticular-course juvenile rheumatoid arthritis. *Arthritis Rheum.* 2007;56(9):3096-106.

14. Russo RA, Katsicas MM. Clinical remission in patients with systemic juvenile idiopathic arthritis treated with anti-tumor necrosis factor agents. *J Rheumatol.* 2009;36(5):1078-82.
15. Baughman RP, Lower EE. Infliximab for refractory sarcoidosis. *Sarcoidosis Vasc Diffuse Lung Dis.* 2001;18(1):70-74.
16. Kraetsch HG, Antoni C, Kalden JR, Manger B. Successful treatment of a small cohort of patients with adult onset Still's Disease with infliximab: first experiences. *Ann Rheum Dis.* 2001;60(suppl 3):iii55-57.
17. Cavagna L, Caporali R, Epis O, et al. Infliximab in the treatment of adult Still's Disease refractory to conventional therapy. *Clin Exp Rheumatol.* 2001;19(3):329-332.
18. Steinfeld SD, Demols P, Salmon I, et al. Infliximab in patients with primary Sjögren's Syndrome: a pilot study. *Arthritis Rheum.* 2001;44(10):2371-2375.
19. Kobbe G, Schneider P, Rohr U, et al. Treatment of severe steroid refractory acute graft-vs-host disease with infliximab, a chimeric human/mouse antiTNFalpha antibody. *Bone Marrow Transplant.* 2001;28(1):47-49.
20. Rivkina AM, Stump LS. Infliximab in graft-versus-host disease. *Am J Health-Syst Pharm.* 2002;59(13):1271-1275.
21. Tynjälä P, Vähäsalo P, Tarkiainen M, et al. Aggressive Combination Drug Therapy in Very Early Polyarticular Juvenile Idiopathic Arthritis (ACUTE-JIA): a multicentre randomised open-label clinical trial. *Ann Rheum Dis.* 2011 Sep;70(9):1605-12.
22. Lamot L, Bukovac LT, Vidovic M, et al. The 'head-to-head' comparison of etanercept and infliximab in treating children with juvenile idiopathic arthritis. *Clin Exp Rheumatol.* 2011 Jan-Feb;29(1):131-9.
23. Ruperto N, Lovell DJ, Cuttica R, et al. Long-term efficacy and safety of infliximab plus methotrexate for the treatment of polyarticular-course juvenile rheumatoid arthritis: findings from an open-label treatment extension. *Ann Rheum Dis.* 2010 Apr;69(4):718-22.
24. Brandt J, Haibel H, Reddig J, et al. Successful short-term treatment of severe undifferentiated spondyloarthritis with anti-tumor necrosis factor- monoclonal antibody infliximab. *J Rheumatol.* 2002;29(1):118-122.
25. De Marco G, Gerloni V, Pontikaki I, et al. Long-term evaluation of infliximab in the treatment of persistently active juvenile idiopathic arthritis refractory to conventional therapy. *Reumatismo.* 2007;59(1):50-6.
26. Stasi R, Amadori S. Infliximab chimaeric anti-tumour necrosis factor alpha monoclonal antibody treatment for patients with myelodysplastic syndromes. *Br J Haematol.* 2002;116(2):334-337.
27. Lamprecht P, Voswinkel J, Lilienthal T, et al. Effectiveness of TNF-alpha blockade with infliximab in refractory Wegener's granulomatosis. *Rheumatology.* 2002;41(11):1303-1307.
28. Doty JD, Mazur JE, Judson MA. Treatment of sarcoidosis with infliximab. *Chest.* 2005;127(3):1064-71.
29. Ulbricht KU, Stoll M, Bierwirth J, et al. Successful tumor necrosis factor alpha blockade treatment in therapy-resistant sarcoidosis. *Arthritis Rheum.* 2003; 48(12):3542-3.
30. Katsicas MM, Russo RA. Use of infliximab in patients with systemic juvenile idiopathic arthritis refractory to etanercept. *Clin Exp Rheumatol.* 2005;23(4):545-8.
31. Gerloni V, Pontikaki I, Gattinara M, et al. Efficacy of repeated intravenous infusions of an anti-tumor necrosis factor alpha monoclonal antibody, infliximab, in persistently active, refractory juvenile idiopathic arthritis: results of an open-label prospective study. *Arthritis Rheum.* 2005;52(2):548-53.
32. Lahdenne P, Vahasalo P, Honkanen V. Infliximab or etanercept in the treatment of children with refractory juvenile idiopathic arthritis: an open label study. *Ann Rheum Dis.* 2003;62(3):245-7.
33. Doherty CB, Rosen T. Evidence-based therapy for cutaneous sarcoidosis. *Drugs.* 2008;68(10):1361-83.
34. Bartolucci P, Ramanoelina J, Cohen P, et al. Efficacy of the anti-TNF-alpha antibody infliximab against refractory systemic vasculitides: an open pilot study on 10 patients. *Rheumatology (Oxford).* 2002;41(10):1126-32.
35. Kleinert J, Lorenz M, Kostler W, et al. Refractory Wegener's granulomatosis responds to tumor necrosis factor blockade. *Win Klin Wochenschr.* 2004;116(9-10):334-8.
36. Roussomoustakaki M, Dimoulios P, Chatzicostas C, et al. Hidradentis suppurativa associated with Crohn's disease and spondyloarthritis: response to anti-TNF therapy. *J Gastroenterol.* 2003;38(10):1000-4.
37. Rosi YL, Lowe L, Kang S. Treatment of hidradentis suppurativa with infliximab in a patient with Crohn's disease. *J Dermatolog Treat.* 2005;16(1):58-61.
38. Fardet L, Dupuy A, Kerob D, et al. Infliximab for severe hidradentis suppurativa: transient clinical efficacy in 7 consecutive patients. *J Am Acad Dermatol.* 2007;56(4):624-8.

39. Baughman RP, Drent M, Kavuru M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement. *Am J Respir Crit Care Med*. 2006;174(7):795-802.
40. Inflectra [prescribing information]. New York, NY: Pfizer Labs; September 2025.
41. Yoo DH, Hrycaj P, Miranda P, et al. A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when co-administered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study. *Ann Rheum Dis*. 2013 Oct;72(10):1613-20.
42. Park W, Hrycaj P, Jeka S, et al. A randomised, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study. *Ann Rheum Dis*. 2013 Oct;72(10):1605-12.
43. Gecse KB, Lovász BD, Farkas K et al. Efficacy and Safety of the Biosimilar Infliximab CT-P13 Treatment in Inflammatory Bowel Diseases: A Prospective, Multicentre, Nationwide Cohort. *J Crohn's Colitis*. 2016 Feb;10(2):133-40.
44. Ruiz-Argüello MB, Maguregui A, Ruiz Del Agua A, et al. Antibodies to infliximab in Remicade-treated rheumatic patients show identical reactivity towards biosimilars. *Ann Rheum Dis*. 2016 Sep;75(9):1693-6.
45. Renflexis [prescribing information]. Jersey City, NJ: Organon & Co.; December 2023.
46. Choe JY, Prodanovic N, Niebrzydowski J, et al. A randomised, double-blind, phase III study comparing SB2, an infliximab biosimilar, to the infliximab reference product Remicade in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy. *Ann Rheum Dis*. 2017 Jan;76(1):58-64.
47. Ringold S, Weiss PF, Beukelman T, DeWitt EM et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum*. 2013 Oct;65(10):2499-512.
48. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immunotherapy-Related Toxicities. Version 1.2020. Available at [www.nccn.org](http://www.nccn.org). Accessed July 2, 2021.
49. Avsola [prescribing information]. Thousand Oaks, CA: Amgen Inc.; September 2025.
50. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Hematopoietic Cell Transplantation (HCT): Pre-Transplant Recipient Evaluation and Management of Graft-Versus-Host Disease. Version 1.2020. Available at [www.nccn.org](http://www.nccn.org). Accessed November 30, 2022.
51. The NCCN Drugs & Biologics Compendium® (NCCN Compendium®). Available at [www.nccn.org](http://www.nccn.org). Accessed November 30, 2022.
52. Sbidian E, Chaimani A, Afach S, et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. *Cochrane Database Syst Rev*. 2020 Jan 9;1:CD011535.

## Policy History/Revision Information

Date	Summary of Changes
04/01/2026	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>• Removed content/language pertaining to the state of Louisiana</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>• Archived previous policy version CS2026D0004AY</li> </ul>

## Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection

with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.