# Medical Policy Bulletin

**Title:**
Intravenous Infliximab and Related Biosimilars
**Policy #:**
MA08.019q

**The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.**

**When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.**

**This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.**

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## Policy

**Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.**

**The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.**

**In the absence of coverage criteria from applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals, or other Medicare coverage documents, this policy uses internal coverage criteria developed by the Company in consideration of peer-reviewed medical literature, clinical practice guidelines, and/or regulatory status.**

**INDEX OF MEDICALLY NECESSARY INDICATIONS**
*This policy addresses numerous medically necessary indications for the use of intravenous infliximab (Remicade) and related biosimilars (e.g., unbranded infliximab, infliximab-abda [Renflexis], infliximab-axxq [Avsola], infliximab-dyyb [Inflectra], infliximab-qbtx [Ixifi]) (listed in order of appearance within the Policy section). Please see below for the specific medical necessity criteria. (NOTE: Experimental/Investigational section below must also be reviewed).*

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| **RHEUMATOLOGIC CONDITIONS** | Ankylosing spondylitis and nonradiographic axial spondyloarthritis<br>Autoimmune collagen vascular disease<br>Behçet syndrome<br>Inflammatory bowel disease arthritis<br>Polyarticular juvenile idiopathic arthritis (JIA)<br>Psoriatic arthritis<br>Reactive arthritis (Reiter disease)<br>Rheumatoid arthritis (RA)<br>Sarcoidosis<br>Uveitis, noninfectious, due to Behçet syndrome<br>Uveitis, noninfectious, not due to Behçet syndrome |
| **GASTROINTESTINAL INDICATIONS** | Crohn disease: non-fistulizing |

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| | Crohn disease: fistulizing<br>Ulcerative colitis |
| **DERMATOLOGIC INDICATIONS** | Hidradenitis suppurativa<br>Plaque psoriasis<br>Pyoderma gangrenosum |
| **HEMATOPOIETIC CELL TRANSPLANTATION** | Acute graft-versus-host disease (aGVHD) |
| **IMMUNOTHERAPY-RELATED TOXICITY INDICATIONS** | Cardiac toxicities<br>Diarrhea or colitis<br>Elevated serum creatinine/acute renal failure inflammatory arthritis<br>Pneumonitis<br>Uveitis |

**MEDICALLY NECESSARY**

Intravenous infliximab (Remicade) and related biosimilars (e.g., unbranded infliximab, infliximab-abda [Renflexis], infliximab-axxq [Avsola], infliximab-dyyb [Inflectra], infliximab-qbtx [Ixifi]) are considered medically necessary and, therefore, covered when the individual meets all of the requirements in the following sections:

- Dosing and frequency requirements listed in Dosing Chart
- Indications and all the criteria are met

**RHEUMATOLOGIC CONDITIONS**

- Ankylosing spondylitis and nonradiographic axial spondyloarthritis
    - When all of the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increasing inflammation, pain, disability, and decreased function)
        - Documentation of an adequate therapeutic trial* of at least two nonsteroidal anti-inflammatory drugs (NSAIDs) that have failed to control symptoms

*An adequate therapeutic trial is defined as: Treatment with NSAIDS for at least 3 months at maximum recommended or tolerated anti-inflammatory dose unless treatment is discontinued due to lack of response, intolerance, toxicity, or contraindication

    - If the above criteria are not met, there must be documentation both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform activities of daily [ADLs], or severe impact on quality of life)
- Autoimmune collagen vascular disease
    - Consideration may be given for individuals with an autoimmune collagen vascular disease that is refractory to conventional therapies.
- Behçet syndrome
    - Documented failure, contraindication, or intolerance to conventional therapy, such as: corticosteroids, colchicine, or disease-modifying antirheumatic drugs (DMARDs) (e.g., azathioprine, cyclosporine, other tumor necrosis factor [TNF] inhibitors)
- Inflammatory bowel disease arthritis
    - When all of the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)
        - Documented failure, contraindication or intolerance to a 3-month trial of any of the DMARDs (e.g., sulfasalazine, azathioprine, methotrexate, other anti-TNF agents)
    - If the above criteria are not met, there must be documentation of very severe disease and the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact to quality of life)
- Polyarticular juvenile idiopathic arthritis (JIA)
    - When all of the following criteria are met:
        - Individual is 4 years of age and older with moderate-to-severe polyarticular JIA with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)

        - Documented failure, contraindication, or intolerance to a 3-month trial of any of the nonbiologic DMARDs (e.g., methotrexate, sulfasalazine, leflunomide)
        - Documented failure, contraindication, or intolerance to a 3-month trial of any of the US Food and Drug Administration (FDA)-approved biologic DMARDs for JIA (e.g., anti-TNF agents, T-cell costimulation modulators)
        - Infliximab or related biosimilars will be used in combination with methotrexate, or as a monotherapy when the individual is intolerant of, or has a contraindication to, methotrexate
    - If the above criteria are not met, there must be documentation of both very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact on quality of life)
- Psoriatic arthritis
    - When all the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)
        - Documented failure, contraindication, or intolerance to a 3-month trial of any of the DMARDs (e.g., sulfasalazine, azathioprine, cyclosporine, methotrexate, other anti-TNF agents)
    - If the above criteria are not met, there must be documentation both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact to quality of life)
- Reactive arthritis (Reiter disease)
    - When all the following criteria are met:
        - Individual is over 18 years of age with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)
        - Documented failure, contraindication, or intolerance to a 3-month trial of any of the DMARDs (e.g., sulfasalazine, methotrexate, other anti-TNF agents)
    - If the above criteria are not met, there must be documentation of very severe disease and the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact to quality of life)
- Rheumatoid arthritis (RA)
    - When all the following criteria are met:
        - Individual is over 18 years of age with moderate-to-severe RA with evidence of active disease (increased disease activity evidenced by increasing inflammation, pain, disability, and decreased function)
        - Documented failure, contraindication or intolerance to a 3-month trial of any of the DMARDs (e.g., hydroxychloroquine, leflunomide, sulfasalazine, methotrexate, other anti-TNF agents or non-TNF biologics [abatacept, rituximab, tocilizumab])
        - Infliximab or related biosimilars will be used in combination with methotrexate, or as a monotherapy when the individual is intolerant of, or has a contraindication to, methotrexate
    - If the above criteria are not met, there must be documentation both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform ADLs, or severe impact on quality of life)
- Sarcoidosis
    - When both criteria are met:
        - Individual at least 18 years of age
        - Documentation of failure, contraindication, or intolerance to a 3-month trial of a standard regimen of corticosteroids and DMARDs (e.g., methotrexate, azathioprine)
    - If the above criteria are not met, there must be documentation both of very severe disease and that the professional provider considers infliximab or related biosimilars to the best initial drug of choice with appropriate justification (disability, and inability to perform ADLs, or severe impact on quality of life)
- Uveitis, noninfectious, due to Behçet syndrome
    - Documented diagnosis of Behçet disease with vision-threatening uveitis
- Uveitis, noninfectious, not due to Behçet syndrome

- Documented failure, contraindication, or intolerance to corticosteroids and at least one DMARD (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus, or other TNF inhibitors**)**

**GASTROINTESTINAL INDICATIONS**

- Crohn disease (CD): nonfistulizing
  - Presence of moderate-to-severe active CD in adults or pediatric individuals 6 years of age or older when all the following criteria are met:
    - The individual has active CD as indicated by any of the following signs or symptoms: gastrointestinal bleeding, weight loss, diarrhea, perianal disease, internal fistula(ae), intestinal obstruction, megacolon or extraintestinal manifestations, such as arthritis or spondylitis
    - The individual has had an inadequate response to conventional therapy (unless intolerant or contraindicated) that include, but are not limited to: antibiotics, 5-aminosalicylates (e.g., mesalamine), DMARDs (e.g., 6-MP [6-MP], azathioprine, corticosteroids)
  - Presence of severe inflammatory disease involving the distal small bowel and/or large bowel in an individual who is having symptoms of gastrointestinal bleeding, diarrhea, profound anemia, and poor nutritional intake associated with weight loss and abdominal pain.
- Crohn disease: fistulizing
  - When both criteria are met:
    - An adult or pediatric individual 6 years of age or older whose presentation of CD involves the formation of a fistula(ae)
    - An adult or pediatric individual 6 years of age or older with diffuse inflammatory disease involving the distal small bowel and/or large bowel who is having symptoms of profound anemia, gastrointestinal bleeding, poor nutritional intake associated with weight loss, and abdominal pain
- Ulcerative colitis: adults
  - When all the following criteria are met:
    - In individuals 18 years of age or older with moderate-to-severe active ulcerative colitis who have had an inadequate response to conventional therapy, including a documented failure, contraindication, or intolerance to at least two of the following:
      - Aminosalicylates: (e.g., mesalamine [Apriso, Asacol, Canasa, Lialda, Pentasa, Rowasa], sulfasalazine [Azulfidine], olsalazine [Dipentum])
      - Systemic corticosteroids: (e.g., prednisone, prednisolone)
      - DMARDs (e.g., 6-MP, azathioprine [Imuran], or cyclosporine [e.g., Neoral, Gengraf])

OR

  - When either of the following criteria are met:
    - In individuals 18 years of age or older, when there is a clinical presentation that requires an intervention with a more immediate effect to resolve the colitis; examples include:
      - Symptoms of profound anemia, poor nutritional intake associated with weight loss, and abdominal pain
      - Individuals who have the potential for adverse events to the other, more common treatment regimens or who have contraindication to the use of these treatment regimens (e.g., individuals with underlying diabetes may have worsening control with the addition of prednisone)
  - If the above criteria are not met, there must be documentation of the individual's rapidly worsening disease as indicated by increasing disability, poorly controlled symptoms, and increasing quality of life concerns (cannot perform ADLs without great difficulty) and there is inadequate response to more conventional agents.
- Ulcerative colitis: children
  - When all of the following criteria are met:
    - Child is at least 6 years of age
    - Has moderate-to-severe active ulcerative colitis (see Policy Guidelines section)
    - Has had an inadequate response to conventional therapy (e.g., aminosalicylates, azathioprine [AZA, Imuran], 6-MP, or corticosteroids)

**DERMATOLOGIC INDICATIONS**

- Hidradenitis suppurativa
  - When all of the following criteria are met:

        - The individual is 18 years of age or older with documentation of moderate-to-severe hidradenitis suppurativa with recurrent abscesses/inflammatory nodules and scar formation.
        - Documentation of failure, contraindication, or intolerance to at least 3 months of antibiotics (e.g., doxycycline, clindamycin, rifampin).
        - Documentation of failure, contraindication, or intolerance to a 3-month trial of any of the FDA-approved biologic DMARDs for hidradenitis suppurativa (e.g., anti-TNF agents, T-cell costimulation modulators).
- Plaque psoriasis
    - When all the following criteria are met:
        - The individual is 18 years of age or older with chronic, severe psoriasis who is a candidate for systemic therapy but other systemic therapies are less medically appropriate (e.g., presence of other factors such as hypertension, alcohol consumption, the condition of pregnancy, nonmelanoma skin cancers).
        - Individual is affected with plaque psoriasis covering more than 10% of body surface area (BSA) or a lesser percentage if psoriasis affects sensitive body areas, such as hands, feet, face, or genitals.
        - Documentation of failure, contraindication, or intolerance to a trial of at least 3 months with at least one of the following:
            - Phototherapy: either UVB, PUVA
            - Methotrexate (e.g., Trexall, Rheumatrex)
            - Retinoids (e.g., acitretin [Soriatane])
            - Cyclosporine (e.g., Neoral, Gengraf)
    - If the above criteria are not met, there must be documentation of severe psoriasis (>10 percent BSA) or a lesser percentage if psoriasis affects sensitive body areas, such as hands, feet, face, or genitals and is very symptomatic (e.g., pain, pruritus, burning, scaling), the symptoms significantly hinder the quality of life, and the use of other systemic therapy is not appropriate due to other factors (e.g., history of hypertension, alcohol consumption, the condition of pregnancy, nonmelanoma skin cancers).
- Pyoderma gangrenosum
    - In individuals 18 years of age or older with documentation of pyoderma gangrenosum that is refractory to a 3-month trial of conventional treatments, such as local steroid injections, topical tacrolimus, systemic corticosteroids, dapsone, DMARDs (e.g., cyclosporine), and conservative wound care, including oral antibiotics
    - If the above criterion is not met, there must be documentation of rapidly worsening disease process as indicated by increasing disability, poorly controlled symptoms, and increasing quality of life concerns (cannot perform ADLs without great difficulty) and who is not adequately responding to more conventional agents.

**HEMATOPOIETIC CELL TRANSPLANTATION**

- Acute Graft-Versus Host Disease (aGVHD)
    - Acute GVHD in those who have undergone hematopoietic cell transplantation, as additional therapy in conjunction with systemic corticosteroids and in combination with original immunosuppressive agent (i.e tacrolimus, cyclosporine, methotrexate) following no response (steroid-refractory disease) to first-line therapy options

**IMMUNOTHERAPY-RELATED TOXICITY INDICATIONS**

- Treatment of any of the following immunotherapy-related toxicities as additional immunosuppression
    - Cardiac toxicities
        - In individuals with myocarditis if no improvement within 24 to 48 hours of starting pulse-dose methylprednisolone
    - Esophagitis
        - In individuals with moderate-to-severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or bude
        - sonide
    - Diarrhea or colitis
        - In individuals with mild (Grade 1) diarrhea and colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin

        - In individuals with moderate (Grade 2) or severe (Grades 3–4) diarrhea or colitis if colonoscopy or flexible sigmoidoscopy shows significant ulceration or extensive nonulcerative inflammation
    - Anemia
        - In individuals with G4 hemolytic anemia with hemolysis if no response to corticosteroids and rituximab
    - Elevated serum creatinine/acute renal injury
        - In individuals with severe (Stage 3) (creatinine >3 times baseline or >4 mg/dL) elevated serum creatinine/acute kidney injury toxicity remains greater than Stage 2 after 4 to 6 weeks of corticosteroids or if creatinine increases during steroid taper (or once off corticosteroids)
    - Inflammatory arthritis
        - In individuals with moderate or severe inflammatory arthritis unable to taper corticosteroids after one week
    - Pneumonitis
        - In individuals with moderate (G2) pneumonitis if no improvement after 48 to 72 hours of corticosteroids or severe (Grades 3–4) pneumonitis who show no improvement after 48 hours methylprednisolone).
    - Uveitis
        - In individuals with G1-4 uveitis that is refractory to high-dose systemic corticosteroids (treatment guided by ophthalmology)

**EXPERIMENTAL/INVESTIGATIONAL**

All other uses for intravenous infliximab and related biosimilars, including use in IgG4-related diseases, are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the medical policy on off-label coverage for prescription drugs and biologics.

**DOSING AND FREQUENCY REQUIREMENTS**

Refer to Dosing Chart for dosing and frequency requirements for intravenous infliximab and related biosimilars.

The Company reserves the right to modify the dosing and frequency requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of infliximab and related biosimilars. Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the FDA; Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of infliximab and related biosimilars outside of the dosing and frequency requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the precertification process. The Company reserves the right to conduct postpayment review and audit procedures for any claims submitted for infliximab and related biosimilars**.**

| **Indication** | **Dosage and Frequency** |
|---|---|
| Acute graft-versus-host disease (aGVHD) | Infliximab 10 mg/kg IV weekly for a maximum of 9 doses |
| Anklyosing spondylitis and Nonradiographic Axial Spondyloarthritis | Induction: 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5 mg/kg IV every 6 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Behcet's Syndrome | Induction: 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5 mg/kg IV every 6-8 weeks (up to a maximum of 10 mg/kg IV every 8 weeks) |
| Crohn's disease (moderate to severe) or fistulizing Crohn's disease | Adults:<br>Induction: 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5 mg/kg IV every 8 weeks. For adults who respond and then |

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| | lose their response, consideration may be given to treatment with 10 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)<br><br>Children:<br>Induction: 5 mg/kg IV at weeks 0, 2, 6<br>Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)<br><br>• For children who are steroid-refractory or have severe extensive or fistulizing disease, especially with hypoalbuminemia, consideration may be given for a higher induction dose of 10 mg/kg and/or decreasing the interval between infusions to 4-6 weeks. |
| Hidradenitis Suppurativa | Induction: 5-10 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5-10 mg/kg IV every 4 weeks, and with decreasing dosage as tolerated. |
| Toxicities Related to Immune Checkpoint Inhibitors | Infliximab 5 mg/kg IV at weeks 0, 2, and 6 |
| Inflammatory bowel disease arthritis (enteropathic arthritis) | Induction: 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Plaque Psoriasis, severe | Induction: 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Polyarticular Juvenile Idiopathic Arthritis (JIA) | Induction: 3 to 6 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 3 to 6 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Psoriatic arthritis | Induction: 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Reactive arthritis (Reiter's disease) | Induction: 3 to 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 3 to 5 mg/kg IV every 6-8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Rheumatoid arthritis | Induction: 3 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 3 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Pyoderma gangrenosum | Induction: 5 mg/kg IV at week 0. Repeat at week 2 if needed.<br>Maintenance: 5 mg/kg IV every 4-12 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Sarcoidosis | Induction: 3 to 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 3 to 5 mg/kg IV every 4 to 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks) |
| Ulcerative colitis (adult and pediatric) | Induction: 5 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 5 mg/kg IV every 8 weeks (up to a maximum of 10 mg/kg IV every 4 weeks)<br><br>• For children who are steroid-refractory or have severe extensive or fistulizing disease, especially with hypoalbuminemia, consideration may be given for a higher induction dose of 10 mg/kg and/or decreasing the interval between infusions to 4-6 weeks. |
| Uveitis, non-infectious | Induction: 3 to 10 mg/kg IV at weeks 0, 2, and 6<br>Maintenance: 3 to 10 mg/kg IV every 4 to 8 weeks |

**REQUIRED DOCUMENTATION**

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

When coverage of infliximab and related biosimilars are requested outside of the dosing and frequency requirements listed in this Policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

**BILLING REQUIREMENTS**

For drugs that have more than one method of administration, application of the JA modifier is required to indicate the route of administration. To report the intravenous route of administration, append the following modifier: JA Administered Intravenously.

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

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## Guidelines

**BLACK BOX WARNINGS**

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings.

**THE PEDIATRIC ULCERATIVE COLITIS ACTIVITY INDEX (PUCAI)**

The Pediatric Ulcerative Colitis Activity Index, published in 2007 in *Gastroenterology,* analyzes data that has been obtained from the child through noninvasive means during the previous 48 hours. Elements of this data assessment include the presence of abdominal pain, rectal bleeding, stool consistency, number of stools in 24 hours, presence or absence of nocturnal stools, and the child's activity level.

| **The Pediatric Ulcerative Colitis Activity Index (PUCAI)**<br>**Maximum score is 85** | |
|---|---|
| Remission | <10 |
| Mild-to-moderate disease | 11 to 30 |
| Moderate-to-severe disease | 30 to 65 |
| Severe | >65 |

Turner D, Otley AR, Mack D, et al. Development, Validation, and Evaluation of a Pediatric Ulcerative Colitis Activity Index: A Prospective Multicenter Study. *Gastroenterology.* 2007;133(2):423-432.

For complete information on the parameters evaluated in the PUCAI and how it is scored, please see the following table: http://download.lww.com/wolterskluwer_vitalstream_com/PermaLink/MPG/A/MPG_2011_04_25_LEE_201708_SDC1.pdf.

**BENEFIT APPLICATION**

There is no Medicare coverage determination addressing intravenous infliximab and related biosimilars; therefore, the Company policy is applicable.

Subject to the applicable Evidence of Coverage, intravenous infliximab and related biosimilars are covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria and dosing and frequency requirements listed in this medical policy are met.

However, services that are identified in this policy as experimental/investigational are not eligible for coverage or reimbursement by the Company.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when infliximab (Remicade®) is covered under a member's medical benefit (Part B benefit). It does not address instances when infliximab (Remicade®) is covered under a member's pharmacy benefit (Part D benefit).

INFORMATION FROM THE MANUFACTURER AND THE FDA LABELING

PEDIATRIC USE
Intravenous infliximab and related biosimilars have not been studied in children with Crohn disease or ulcerative colitis younger than 6 years of age. The long-term (duration >1 year) safety and effectiveness of infliximab and related biosimilars in the treatment of Crohn disease or ulcerative colitis for the pediatric population have not been established in clinical trials.

CONTRAINDICATIONS
Intravenous infliximab and related biosimilars at doses greater than 5 mg/kg should not be administered to individuals with moderate to severe heart failure. In a randomized study evaluating infliximab and related biosimilars in individuals with moderate to severe heart failure (New York Heart Association [NYHA] Functional Class III/IV), treatment at 10 mg/kg was associated with an increased incidence of death and hospitalization due to worsening heart failure.

USE WITH ANAKINRA (KINERET®) OR ABATACEPT (ORENCIA®)
The combination of infliximab or related biosimilars with anakinra (Kineret), abatacept (Orencia) and other biological products used to treat the same condition as infliximab or related biosimilars is not recommended.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

The FDA initially approved infliximab (Remicade®) on August 24, 1998. Supplemental approvals have since been issued. The FDA has issued subsequent approvals for biosimilar products.

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## Description

Infliximab (Remicade) was initially approved by the US Food and Drug Administration (FDA) on August 24, 1998, for rheumatoid arthritis (RA) and Crohn disease (CD). Supplemental approvals have since been issued. The FDA has issued subsequent approvals for biosimilar products. According to the FDA, "a biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products." NOTE: Unbranded Infliximab for Injection, made by Janssen, is an unbranded biologic that is the same product as the brand-name product infliximab (Remicade). It is NOT considered a biosimilar.

Infliximab and related biosimilars are chimeric immunoglobulin monoclonal antibodies that bind to and neutralize the effects of tumor necrosis factor-alpha (TNF-α), a naturally occurring cytokine that plays a role in inflammatory and immune responses. Increased concentrations of TNF-α have been found in the affected tissues of individuals with certain anti-inflammatory disease, such as RA, CD, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. Infliximab and related biosimilars are supplied as a sterile, white, lyophilized powder for intravenous (IV) infusion, which is prepared and administered by a professional provider.

Infliximab and related biosimilars is available in two forms: injection for intravenous use and injection for subcutaneous use.

Infliximab and related biosimilars contain anti-TNF-α antibodies that reduce infiltration of inflammatory cells and TNF-α production in affected areas (e.g., the inflamed joints in RA, the inflamed intestines in CD). Infliximab and related biosimilars also initiate healing in areas of erosion and inflammation caused by diseases such as ulcerative colitis and CD. Decreased concentrations of TNF-α may be associated with decreased disease activity; however, the full mechanism of action of infliximab is not thoroughly understood.

Several categories of drugs are used to treat some rheumatic joint diseases that produce chronic inflammation. For many rheumatologic conditions, treatment typically begins with over-the-counter (OTC) drugs referred to as nonsteroidal anti-inflammatory drugs (NSAIDs); these drugs are analgesic, antipyretic, relieve pain without impairing consciousness, and, when given in higher doses, have anti-inflammatory effects. The term "non-steroidal" distinguishes these agents from those that contain steroids whose action is also anti-inflammatory. NSAIDs include, but are not limited to, aspirin, ibuprofen, and naproxen, which are available without a prescription at local retail pharmacies.

Disease-modifying antirheumatic drugs (DMARDs) act to slow down disease progression, and some act with mild chemotherapeutic action, causing immunosuppression. Furthermore, DMARDs can be subdivided into drugs that are the traditional small molecular mass, chemically synthesized nonbiologic DMARDs, such as, but not limited to, methotrexate, sulfasalazine, azathioprine, leflunomide, hydroxychloroquine sulfate, cyclosporine, and biologic DMARDs. Examples of biologic DMARDs include, but are not limited to, etanercept (Enbrel), adalimumab (Humira), anakinra (Kineret), abatacept (Orencia), rituximab (Rituxan), and infliximab (Remicade).

For gastrointestinal or dermatologic manifestations of inflammatory disease, other types of initial treatments are indicated, depending on severity of symptom presentation and degree of disability.

**OFF-LABEL INDICATIONS**

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of professional clinical guidelines issued by leading professional organizations and government entities.

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## Coding

**Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.**

**The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.**

**In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.**

**The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.**

### CPT Procedure Code Number(s)
N/A

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### ICD - 10 Procedure Code Number(s)
N/A

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### ICD - 10 Diagnosis Code Number(s)

**ICD-10-CM Codes and Narratives**

**This is not an all inclusive list**

**INFLIXIMAB AND RELATED BIOSIMILARS IS CONSIDERED MEDICALLY NECESSARY WHEN REPORTED WITH ANY OF THE FOLLOWING DIAGNOSIS CODES:**

Report the most appropriate diagnosis code for toxicities related to immune checkpoint inhibitors.

D59.0 Drug-induced autoimmune hemolytic anemia

D59.2 Drug-induced nonautoimmune hemolytic anemia

D86.0 Sarcoidosis of lung

D86.2 Sarcoidosis of lung with sarcoidosis of lymph nodes

D86.83 Sarcoid iridocyclitis

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

H20.9 Unspecified iridocyclitis

H44.111 Panuveitis, right eye

H44.112 Panuveitis, left eye

H44.113 Panuveitis, bilateral

H44.131 Sympathetic uveitis, right eye

H44.132 Sympathetic uveitis, left eye

H44.133 Sympathetic uveitis, bilateral

I30.0 Acute nonspecific idiopathic pericarditis

I30.8 Other forms of acute pericarditis

I40.8 Other acute myocarditis

I40.9 Acute myocarditis, unspecified

I49.9 Cardiac arrhythmia, unspecified

I77.82 Antineutrophilic cytoplasmic antibody (ANCA) vasculitis

J70.2 Acute drug-induced interstitial lung disorders

J70.4 Drug-induced interstitial lung disorders, unspecified

K20.0 Eosinophilic esophagitis

K20.80 Other esophagitis without bleeding

K20.81 Other esophagitis with bleeding

K20.90 Esophagitis, unspecified without bleeding

K20.91 Esophagitis, unspecified with bleeding

K29.00 Acute gastritis without bleeding

K29.01 Acute gastritis with bleeding

K29.30 Chronic superficial gastritis without bleeding

K29.31 Chronic superficial gastritis with bleeding
K29.40 Chronic atrophic gastritis without bleeding
K29.41 Chronic atrophic gastritis with bleeding
K29.50 Unspecified chronic gastritis without bleeding
K29.51 Unspecified chronic gastritis with bleeding
K29.60 Other gastritis without bleeding
K29.61 Other gastritis with bleeding
K29.70 Gastritis, unspecified, without bleeding
K29.71 Gastritis, unspecified, with bleeding
K29.80 Duodenitis without bleeding
K29.81 Duodenitis with bleeding
K29.90 Gastroduodenitis, unspecified, without bleeding
K29.91 Gastroduodenitis, unspecified, with bleeding
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
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

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

L40.0 Psoriasis vulgaris

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

L73.2 Hidradenitis suppurativa

L88 Pyoderma gangrenosum

M02.30 Reiter's disease, unspecified site

M02.311 Reiter's disease, right shoulder

M02.312 Reiter's disease, left shoulder

M02.321 Reiter's disease, right elbow

M02.322 Reiter's disease, left elbow

M02.331 Reiter's disease, right wrist

M02.332 Reiter's disease, left wrist

M02.341 Reiter's disease, right hand

M02.342 Reiter's disease, left hand

M02.351 Reiter's disease, right hip

M02.352 Reiter's disease, left hip

M02.361 Reiter's disease, right knee

M02.362 Reiter's disease, left knee

M02.371 Reiter's disease, right ankle and foot

M02.372 Reiter's disease, left ankle and foot

M02.38 Reiter's disease, vertebrae

M02.39 Reiter's disease, multiple sites

M05.7A Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement

M05.8A Other rheumatoid arthritis with rheumatoid factor of other specified site

M05.00 Felty's syndrome, unspecified site

M05.011 Felty's syndrome, right shoulder

M05.012 Felty's syndrome, left shoulder

M05.021 Felty's syndrome, right elbow

M05.022 Felty's syndrome, left elbow

M05.031 Felty's syndrome, right wrist

M05.032 Felty's syndrome, left wrist

M05.041 Felty's syndrome, right hand

M05.042 Felty's syndrome, left hand

M05.051 Felty's syndrome, right hip

M05.052 Felty's syndrome, left hip

M05.061 Felty's syndrome, right knee

M05.062 Felty's syndrome, left knee

M05.071 Felty's syndrome, right ankle and foot

M05.072 Felty's syndrome, left ankle and foot

M05.09 Felty's syndrome, multiple sites

M05.10 Rheumatoid lung disease with rheumatoid arthritis of unspecified site

M05.111 Rheumatoid lung disease with rheumatoid arthritis of right shoulder

M05.112 Rheumatoid lung disease with rheumatoid arthritis of left shoulder

M05.121 Rheumatoid lung disease with rheumatoid arthritis of right elbow

M05.122 Rheumatoid lung disease with rheumatoid arthritis of left elbow

M05.131 Rheumatoid lung disease with rheumatoid arthritis of right wrist

M05.132 Rheumatoid lung disease with rheumatoid arthritis of left wrist

M05.141 Rheumatoid lung disease with rheumatoid arthritis of right hand

M05.142 Rheumatoid lung disease with rheumatoid arthritis of left hand

M05.151 Rheumatoid lung disease with rheumatoid arthritis of right hip

M05.152 Rheumatoid lung disease with rheumatoid arthritis of left hip

M05.161 Rheumatoid lung disease with rheumatoid arthritis of right knee

M05.162 Rheumatoid lung disease with rheumatoid arthritis of left knee

M05.171 Rheumatoid lung disease with rheumatoid arthritis of right ankle and foot
M05.172 Rheumatoid lung disease with rheumatoid arthritis of left ankle and foot
M05.19 Rheumatoid lung disease with rheumatoid arthritis of 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
M05.221 Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222 Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.231 Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232 Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.241 Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242 Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.251 Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252 Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.261 Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262 Rheumatoid vasculitis with rheumatoid arthritis of left 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
M05.29 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
M05.321 Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322 Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.331 Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332 Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.341 Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342 Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.351 Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352 Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.361 Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362 Rheumatoid heart disease with rheumatoid arthritis of left 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
M05.39 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
M05.421 Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422 Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.431 Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432 Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.441 Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442 Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.451 Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452 Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.461 Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462 Rheumatoid myopathy with rheumatoid arthritis of left 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
M05.49 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
M05.521 Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522 Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.531 Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532 Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.541 Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542 Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.551 Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552 Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.561 Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562 Rheumatoid polyneuropathy with rheumatoid arthritis of left 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
M05.59 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
M05.621 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
M05.631 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

M05.641 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
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
M05.661 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
M05.671 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
M05.69 Rheumatoid arthritis of multiple sites with involvement of other organs and systems
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
M05.721 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
M05.731 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
M05.741 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
M05.751 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
M05.761 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
M05.771 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
M05.79 Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.80 Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811 Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812 Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.821 Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822 Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.831 Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832 Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.841 Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842 Other rheumatoid arthritis with rheumatoid factor of left hand
M05.851 Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852 Other rheumatoid arthritis with rheumatoid factor of left hip
M05.861 Other rheumatoid arthritis with rheumatoid factor of right knee

M05.862 Other rheumatoid arthritis with rheumatoid factor of left 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
M05.89 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
M06.8A Other specified rheumatoid arthritis, 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
M06.021 Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022 Rheumatoid arthritis without rheumatoid factor, left elbow
M06.031 Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032 Rheumatoid arthritis without rheumatoid factor, left wrist
M06.041 Rheumatoid arthritis without rheumatoid factor, right hand
M06.042 Rheumatoid arthritis without rheumatoid factor, left hand
M06.051 Rheumatoid arthritis without rheumatoid factor, right hip
M06.052 Rheumatoid arthritis without rheumatoid factor, left hip
M06.061 Rheumatoid arthritis without rheumatoid factor, right knee
M06.062 Rheumatoid arthritis without rheumatoid factor, left knee
M06.071 Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072 Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.08 Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09 Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.4 Inflammatory polyarthropathy
M06.80 Other specified rheumatoid arthritis, unspecified site
M06.811 Other specified rheumatoid arthritis, right shoulder
M06.812 Other specified rheumatoid arthritis, left shoulder
M06.821 Other specified rheumatoid arthritis, right elbow
M06.822 Other specified rheumatoid arthritis, left elbow
M06.831 Other specified rheumatoid arthritis, right wrist
M06.832 Other specified rheumatoid arthritis, left wrist
M06.841 Other specified rheumatoid arthritis, right hand
M06.842 Other specified rheumatoid arthritis, left hand
M06.851 Other specified rheumatoid arthritis, right hip
M06.852 Other specified rheumatoid arthritis, left hip

M06.861 Other specified rheumatoid arthritis, right knee
M06.862 Other specified rheumatoid arthritis, left knee
M06.871 Other specified rheumatoid arthritis, right ankle and foot
M06.872 Other specified rheumatoid arthritis, left ankle and foot
M06.88 Other specified rheumatoid arthritis, vertebrae
M06.89 Other specified rheumatoid arthritis, multiple sites
M06.9 Rheumatoid arthritis, unspecified
M07.60 Enteropathic arthropathies, unspecified site
M07.611 Enteropathic arthropathies, right shoulder
M07.612 Enteropathic arthropathies, left shoulder
M07.621 Enteropathic arthropathies, right elbow
M07.622 Enteropathic arthropathies, left elbow
M07.631 Enteropathic arthropathies, right wrist
M07.632 Enteropathic arthropathies, left wrist
M07.641 Enteropathic arthropathies, right hand
M07.642 Enteropathic arthropathies, left hand
M07.651 Enteropathic arthropathies, right hip
M07.652 Enteropathic arthropathies, left hip
M07.661 Enteropathic arthropathies, right knee
M07.662 Enteropathic arthropathies, left knee
M07.671 Enteropathic arthropathies, right ankle and foot
M07.672 Enteropathic arthropathies, left ankle and foot
M07.68 Enteropathic arthropathies, vertebrae
M07.69 Enteropathic arthropathies, multiple sites
M08.09 Unspecified juvenile rheumatoid arthritis, multiple sites
M08.1 Juvenile ankylosing spondylitis
M08.3 Juvenile rheumatoid polyarthritis (seronegative)
M08.89 Other juvenile arthritis, multiple sites
M08.99 Juvenile arthritis, unspecified, multiple sites
M35.2 Behcet's disease
M35.9 Systemic involvement of connective tissue, unspecified
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

M45.9 Ankylosing spondylitis of unspecified sites in spine

M45.A0 Non-radiographic axial spondyloarthritis of unspecified sites in spine

M45.A1 Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region

M45.A2 Non-radiographic axial spondyloarthritis of cervical region

M45.A3 Non-radiographic axial spondyloarthritis of cervicothoracic region

M45.A4 Non-radiographic axial spondyloarthritis of thoracic region

M45.A5 Non-radiographic axial spondyloarthritis of thoracolumbar region

M45.A6 Non-radiographic axial spondyloarthritis of lumbar region

M45.A7 Non-radiographic axial spondyloarthritis of lumbosacral region

M45.A8 Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region

M45.AB Non-radiographic axial spondyloarthritis of multiple sites in spine

N17.0 Acute kidney failure with tubular necrosis

N17.1 Acute kidney failure with acute cortical necrosis

N17.2 Acute kidney failure with medullary necrosis

N17.8 Other acute kidney failure

N17.9 Acute kidney failure, unspecified

INFLIXIMAB AND RELATED BIOSIMILARS ARE CONSIDERED EXPERIMENTAL/INVESTIGATIONAL WHEN REPORTED WITH THE FOLLOWING DIAGNOSIS CODE:

D89.84 IgG4-related disease

## HCPCS Level II Code Number(s)

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

## Revenue Code Number(s)

N/A

Modifiers

THE FOLLOWING MODIFIER IS USED WHEN REPORTING

Intravenous Infliximab And Related Biosimilars For Intravenous Use

JA - Administered Intravenously

Modifiers

THE FOLLOWING MODIFIER IS USED WHEN REPORTING
Intravenous Infliximab and Related Biosimilars for Intravenous Use

JA - Administered Intravenously

## Coding And Billing Requirements

For drugs that have more than one method of administration, application of the JA modifier is required to indicate the route of administration.

- To report the intravenous route of administration, append the following modifier: JA Administered Intravenously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

## Policy History

**Revisions From MA08.019q:**

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|---|---|
| 03/20/2026 | This version of the policy will become effective 03/20/2026.<br><br>The following HCPCS codes has been deleted from this policy:<br>Q5109 Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg |

**Revisions From MA08.019p:**

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|---|---|
| 12/15/2025 | This version of the policy will become effective 12/15/2025.<br><br>The following ICD-10 CM codes have been added to this policy:<br>M05.A Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis |

**Revisions From MA08.019o:**

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|---|---|
| 04/21/2025 | This version of the policy will become effective 04/21/2025.<br><br>This policy has been updated to communicate the Company's coverage positions for Intravenous Infliximab and Related Biosimilars.<br><br>The criteria for immunotherapy-related toxicities has been updated, in alignment with National Comprehensive Cancer Network (NCCN) recommendations.<br><br>The following ICD-10 CM codes have been added to this policy as Medically Necessary:<br>D59.0 Drug-induced autoimmune hemolytic anemia<br>D59.2 Drug-induced nonautoimmune hemolytic anemia<br>K20.0 Eosinophilic esophagitis<br>K20.80 Other esophagitis without bleeding<br>K20.81 Other esophagitis with bleeding<br>K20.90 Esophagitis, unspecified without bleeding<br>K20.91 Esophagitis, unspecified with bleeding<br>K29.00 Acute gastritis without bleeding<br>K29.01 Acute gastritis with bleeding<br>K29.30 Chronic superficial gastritis without bleeding<br>K29.31 Chronic superficial gastritis with bleeding<br>K29.40 Chronic atrophic gastritis without bleeding<br>K29.41 Chronic atrophic gastritis with bleeding<br>K29.50 Unspecified chronic gastritis without bleeding<br>K29.51 Unspecified chronic gastritis with bleeding |

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| | K29.60 Other gastritis without bleeding<br>K29.61 Other gastritis with bleeding<br>K29.70 Gastritis, unspecified, without bleeding<br>K29.71 Gastritis, unspecified, with bleeding<br>K29.80 Duodenitis without bleeding<br>K29.81 Duodenitis with bleeding<br>K29.90 Gastroduodenitis, unspecified, without bleeding<br>K29.91 Gastroduodenitis, unspecified, with bleeding |

**Revisions From MA08.019n:**

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|---|---|
| 01/01/2025 | This version of the policy will become effective 01/01/2025.<br><br>The following ICD-10 CM code has been added to this policy as Experimental/Investigational:<br>D89.84 IgG4-related disease<br><br>The following ICD-10 CM code has been removed from this policy:<br>D89.89 Other specified disorders involving the immune mechanism, not elsewhere classified |

**Revisions From MA08.019m:**

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| 05/07/2024 | This version of the policy will become effective 05/07/2024.<br><br>This policy has been updated to communicate the Company's coverage positions for Intravenous Infliximab and Related Biosimilars.<br><br>Ankylosing spondylitis indication has been expanded to include nonradiographic axial spondyloarthritis.<br><br>The criteria for acute graft-versus host disease and immunotherapy-related toxicities have been updated, in alignment with National Comprehensive Cancer Network (NCCN) recommendations.<br><br>A Billing Requirement was added to this policy regarding the Coding Modifier: JA Intravenous administration.<br><br>The following ICD-10 CM codes have been **added** to this policy as Medically Necessary:<br><br>I30.8 Other forms of acute pericarditis<br>J70.4 Drug-induced interstitial lung disorders, unspecified<br>M06.4 Inflammatory polyarthropathy<br>M45.A0 Non-radiographic axial spondyloarthritis of unspecified sites in spine<br>M45.A1 Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region<br>M45.A2 Non-radiographic axial spondyloarthritis of cervical region<br>M45.A3 Non-radiographic axial spondyloarthritis of cervicothoracic region<br>M45.A4 Non-radiographic axial spondyloarthritis of thoracic region<br>M45.A5 Non-radiographic axial spondyloarthritis of thoracolumbar region<br>M45.A6 Non-radiographic axial spondyloarthritis of lumbar region<br>M45.A7 Non-radiographic axial spondyloarthritis of lumbosacral region<br>M45.A8 Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region<br>M45.AB Non-radiographic axial spondyloarthritis of multiple sites in spine |

**Revisions From MA08.019l:**

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| 01/02/2023 | This version of the policy will become effective 01/02/2023.<br><br>This policy has been updated to communicate the Company's coverage positions for |

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| | Intravenous Infliximab and Related Biosimilars.<br><br>Sarcoidosis indication has been expanded to include types other than just pulmonary.<br><br>The criteria for immunotherapy-related toxicities have been updated, in alignment with National Comprehensive Cancer Network (NCCN) recommendations.<br><br>Granulomatosis with polyangiitis (Wegener's granulomatosis) off-label indication has been removed from this policy due to paucity of evidence; other drugs are FDA-approved for this indication.<br><br>The following ICD-10 CM codes have been **added** to this policy as Medically Necessary:<br>D86.86 Sarcoid arthropathy<br>D86.87 Sarcoid myositis<br>D86.89 Sarcoidosis of other sites<br>D86.9 Sarcoidosis, unspecified<br>H44.111 Panuveitis, right eye<br>H44.112 Panuveitis, left eye<br>H44.113 Panuveitis, bilateral<br>I40.9 Acute myocarditis, unspecified<br><br>The following ICD-10 CM codes have been **removed** from this policy:<br>M31.30 Wegener's granulomatosis without renal involvement<br>M31.31 Wegener's granulomatosis with renal involvement<br><br>The following ICD-10 CM codes have been **removed** from this policy, due to laterality/specificity of codes:<br>H20.049, H44.139,<br>M02.319, M02.329, M02.339, M02.349, M02.359, M02.369, M02.379,<br>M05.019, M05.029, M05.039, M05.049, M05.059, M05.069, M05.079,<br>M05.119, M05.129, M05.139, M05.149, M05.159, M05.169, M05.179,<br>M05.219, M05.229, M05.239, M05.249, M05.259, M05.269, M05.279,<br>M05.319, M05.329, M05.339, M05.349, M05.359, M05.369, M05.379,<br>M05.419, M05.429, M05.439, M05.449, M05.459, M05.469, M05.479,<br>M05.519, M05.529, M05.539, M05.549, M05.559, M05.569, M05.579,<br>M05.619, M05.629, M05.639, M05.649, M05.659, M05.669, M06.679,<br>M05.719, M05.729, M05.739, M05.749, M05.759, M05.769, M05.779,<br>M05.819, M05.829, M05.839, M05.849, M05.859, M05.869, M05.879,<br>M06.019, M06.029, M06.039, M06.049, M06.059, M06.069, M06.079,<br>M06.819, M06.829, M06.839, M06.849, M06.859, M06.869, M06.879,<br>M07.619, M07.629, M07.639, M07.649, M07.659, M07.669, M07.679 |

**Revisions From MA08.019k:**

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| 10/01/2022 | This version of the policy will become effective 10/01/2022.<br><br>The following ICD-10 code has been **added** to this policy:<br>I77.82 Antineutrophilic cytoplasmic antibody [ANCA] vasculitis |

**Revisions From MA08.019i:**

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| 12/20/2021 | This version of the policy will become effective 12/20/2021.<br><br>This policy has been updated to communicate the Company's coverage positions for the following indications, in alignment with peer-reviewed literature and National Comprehensive Cancer Network (NCCN):<br><br>• **Behcet's syndrome:** Medically Necessary<br>• **Acute graft-versus-host disease (GVHD) in those who have undergone hematopoietic cell transplantation:** Medically Necessary<br>• **IgG4-related disease**: Experimental/Investigational |

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| | Revisions have been made to the following Medically Necessary indications:<br>• **Granulomatosis with polyangiitis (Wegener's granulomatosis)**: rituximab has been added as an example of prior therapy<br>• **Inflammatory bowel disease arthritis**: methotrexate has been added and cyclophosphamide has been removed, as examples of prior therapy<br>• **Reactive arthritis (Reiter's disease):** azathioprine, cyclophosphamide, cyclosporine have been removed as examples of prior therapies<br>• **Crohn's disease, non-fistualizing**: removed the timeframe of "at least 3 months" as a requirement of the prior therapies<br>• **Ulcerative colitis, adults:** removed the timeframe of "at least 3 months" as a requirement of the prior therapies. Removed methotrexate as an example of prior therapy<br>• **Ulcerative colitis, children:** aminosalicylates have been added as an example of prior therapies. Removed methotrexate as an example of prior therapy<br>• **Pyoderma gangrenosum:** systemic corticosteroids, dapsone, DMARDs (e.g., cyclosporine) have been added as example a of prior therapy<br>• **Immunotherapy-related toxicity indications:** updated indications and Dosing & Frequency, per National Comprehensive Cancer Network (NCCN)<br><br>The following ICD-10 CM codes have been **added** to this policy as Medically Necessary:<br>D89.810 Acute graft-versus-host disease<br>M35.2 Behcet's disease<br><br>The following ICD-10 CM code has been **added** to this policy as Experimental/Investigational:<br>D89.89 Other specified disorders involving the immune mechanism, not elsewhere classified<br><br>The following ICD-10 CM code has been **removed** from this policy:<br>M06.1 Adult-onset Still's disease |

**Revisions From MA08.019h:**

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|---|---|
| 10/01/2020 | This policy has been identified for the ICD-10 CM code update, effective 10/01/2020.<br><br>The following ICD-10 CM codes have been **added** to this policy:<br>M05.7A Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement<br><br>M05.8A Other rheumatoid arthritis with rheumatoid factor of other specified site<br><br>M06.0A Rheumatoid arthritis without rheumatoid factor, other specified site<br><br>M06.8A Other specified rheumatoid arthritis, other specified site |

**Revisions From MA08.019g:**

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| 07/01/2020 | This policy has been identified for the HCPCS code update, effective 07/01/2020.<br><br>The following HCPCS code has been **added** to this policy to represent infliximab-axxq (Avsola™):<br>Q5121 Injection, infliximab-axxq, biosimilar, (avsola), 10 mg |

**Revisions From MA08.019f:**

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|---|---|
| 04/22/2019 | This version of the policy will become effective 04/22/2019. The following indications have been **added** to this policy and Dosing Chart:<br>• Medical Necessity criteria and dosing and frequency information for the coverage of toxicities related to immune checkpoint inhibitors: (Cardiac Toxicities, Diarrhea or Colitis, Elevated Serum Creatinine/Acute Renal Failure, Inflammatory Arthritis, Pneumonitis) in consideration of National Comprehensive Cancer Network-Clinical Practice Guidelines in Management of Immune Checkpoint Inhibitor-Related Toxicities.<br>• Medical necessity criteria and dosing and frequency information for the coverage of Hidradenitis suppurativa. |

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| | • High induction dosing and frequency information was added to Dosing Chart for moderate to severe pediatric ulcerative colitis and Crohn's disease.<br><br>**ICD Section:**<br>The following ICD-10 CM codes have been **added** to ICD Section of this policy:<br>I30.0 Acute nonspecific idiopathic pericarditis<br>I40.8 Other acute myocarditis<br>I49.9 Cardiac arrhythmia, unspecified<br>J70.2 Acute drug-induced interstitial lung disorders<br>K52.1 Toxic gastroenteritis and colitis<br>L73.2 Hidradenitis suppurativa<br>N17.0 Acute kidney failure with tubular necrosis<br>N17.1 Acute kidney failure with acute cortical necrosis<br>N17.2 Acute kidney failure with medullary necrosis<br>N17.8 Other acute kidney failure<br>N17.9 Acute kidney failure, unspecified<br><br>The following statement was **added** to ICD Section of this policy:<br><br>Report the most appropriate diagnosis code for toxicities related to immune checkpoint inhibitors. |

**Revisions From MA08.019e:**

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|---|---|
| 01/01/2019 | This policy has been identified for the HCPCS code update, effective 01/01/2019.<br><br>The following HCPCS codes have been **added** to this policy:<br>Q5109 Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg |

**Revisions From MA08.019d:**

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|---|---|
| 04/01/2018 | This policy has been identified for the HCPCS code update, effective 04/01/2018.<br><br>The following HCPCS code has been **deleted** from this policy:<br>Q5102 Injection, infliximab, biosimilar, 10 mg<br><br>The following HCPCS codes have been **added** to this policy:<br>Q5103 Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg<br>Q5104 Injection, infliximab-abda, biosimilar, (renflexis), 10 mg |

**Revisions From MA08.019c:**

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| 12/27/2017 | This Policy has undergone a routine review, and the medical necessity criteria have been revised as follows:<br>o New Biosimilars: infliximab-abda (Renflexis™) and infliximab-qbtx (Ixifi™)<br>o Medical Necessity criteria and Dosing and Frequency Information for the coverage of non-infectious uveitis<br>o Minor updates to the following indications due to updates to Standards of Care.<br>▪ Inflammatory bowel disease arthritis<br>▪ Psoriatic arthritis<br>▪ Rheumatoid arthritis (RA)<br>▪ Crohn's disease: non-fistualizing<br>▪ Plaque psoriasis |

**Revisions From MA08.019b:**

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| 03/08/2017 | This policy was updated to reflect the indications for the newly FDA-approved biosimilar, infliximab-dyyb (Inflectra).<br><br>The following ICD-10 codes have been removed from this policy, since other codes are more appropriate:<br>K60.3, K60.4, K60.5, K63.2, M01.x11, M01.x12, M01.x21, M01.x22, M01.x31, M01.x32, M01.x41, M01.x42, M01.x51, M01.x52 M01.x61, M01.x62, M01.x71, M01.x72, M01.x8, M01.x9, M06.211, M06.212, M06.221, M06.222, M06.231, M06.232, M06.241, M06.242, M06.251, M06.252, M06.261, M06.262, M06.271, M06.272, M06.28, M06.29, M06.311, M06.312, M06.321, M06.322, |

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| | M06.331, M06.332, M06.341, M06.342, M06.351, M06.352, M06.361, M06.362, M06.371, M06.372, M06.38, M06.39, M06.4, M08.011, M08.012, M08.021, M08.022, M08.031, M08.032, M08.041, M08.042, M08.051, M08.052, M08.061, M08.062, M08.071, M08.072, M08.08, M08.211, M08.212, M08.221, M08.222, M08.231, M08.232, M08.241, M08.242, M08.251, M08.252, M08.261, M08.262, M08.271, M08.272, M08.28, M08.29, M08.811, M08.812, M08.821, M08.822, M08.831, M08.832, M08.841, M08.842, M08.851, M08.852, M08.861, M08.862, M08.871, M08.872, M08.88, M08.89, M08.911, M08.912, M08.921, M08.922, M08.931, M08.932, M08.941, M08.942, M08.951, M08.952, M08.961, M08.962, M08.971, M08.972, M08.98, M36.8, M48.8x1, M48.8x2, M48.8x3, M48.8x4, M48.8x5, M48.8x6, M48.8x7, M48.8x8, N82.0, N82.2, N82.3, N82.4, N82.8. |

**Revisions From MA08.019a:**

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| 01/01/2017 | This policy has been identified for the HCPCS code update, effective 01/01/2017.<br>The following HCPCS narrative has been **revised** in this policy:<br><br>**FROM:** J1745 Injection, infliximab, 10 mg<br>**TO:** J1745 Injection, infliximab, excludes biosimilar, 10 mg |

**Revisions From MA08.019:**

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| 12/09/2015 | This version of the policy will become effective 12/09/2015.<br><br>The policy has been reviewed and reissued to communicate the Company's continuing position on infliximab (Remicade®). |
| 01/01/2015 | This is a new policy. |

Version Effective Date:
03/20/2026
Version Issued Date:
03/20/2026
Version Reissued Date:
N/A