

Infliximab:

Remicade®; Inflectra®; Renflexis™; Avsola®; Infliximab* (Intravenous)

Document Number: IC-0104

Last Review Date: 10/03/2023

Date of Origin: 07/20/2010

Dates Reviewed: 09/2010, 12/2012, 2/2011, 03/2011, 06/2011, 09/2011, 10/2011, 12/2011, 03/2012, 06/2012, 09/2012, 11/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 09/2017, 12/2017, 03/2018, 06/2018, 10/2018, 04/2019, 07/2019, 07/2020, 08/2021, 02/2022, 10/2022, 10/2023

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed unless otherwise specified.

- Therapy for the Management of Immune-Checkpoint Inhibitor Related Toxicity and GVHD may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Loading Dose:

- Remicade/Infliximab 100 mg single-dose vial: 6 vials at weeks 0, 2, 6 (18 vials total)
- Inflectra 100 mg single-dose vial: 6 vials at weeks 0, 2, 6 (18 vials total)
- Renflexis 100 mg single-dose vial: 6 vials at weeks 0, 2, 6 (18 vials total)
- Avsola 100 mg single-dose vial: 6 vials at weeks 0, 2, 6 (18 vials total)

Maintenance Dose:

- Remicade/Infliximab 100 mg single-dose vial: 11 vials every 4 weeks
- Inflectra 100 mg single-dose vial: 11 vials every 4 weeks
- Renflexis 100 mg single-dose vial: 11 vials every 4 weeks
- Avsola 100 mg single-dose vial: 11 vials every 4 weeks

B. Max Units (per dose and over time) [HPCS Unit]:

- **Rheumatoid Arthritis:** 40 billing units at weeks 0, 2, 6, then 120 billing units every 28 days
- **Ankylosing Spondylitis:** 60 billing units at weeks 0, 2, 6, then 60 billing units every 42 days

- **Crohn's Disease & Ulcerative Colitis:** 60 billing units at weeks 0, 2, 6 then 120 billing units every 56 days
- **Psoriatic Arthritis, Plaque Psoriasis, Behcet's Uveitis:** 60 billing units at weeks 0, 2, 6 then 60 billing units every 56 days
- **Management of Immune Checkpoint Inhibitor Related Toxicity:** 60 billing units at weeks 0 & 2; no maintenance dosing
- **Acute GVHD:** 120 billing units at weeks 0, 1, 2, 3; no maintenance dosing

III. Initial Approval Criteria ¹⁻⁴

Coverage is provided in the following conditions:

- | |
|---|
| <ul style="list-style-type: none"> • Patient must try and have an inadequate response, contraindication, or intolerance to Remicade/Unbranded Infliximab AND Inflectra; OR • Patient is continuing treatment with a different infliximab product |
|---|
- Patient has been evaluated and screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating treatment; **AND**
 - Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
 - Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria ¹⁻⁴

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines or therapeutic infectious agents (i.e., BCG bladder instillation for bladder cancer, etc.); **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, IL-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib, etc.); **AND**
- Will not be used in patients with moderate or severe heart failure (i.e., New York Heart Association [NYHA] Functional Class III/IV) [Note: Only applies when doses >5mg/kg are used]; **AND**

Crohn's Disease † Φ ^{1-4,11,13,23,38,75-78}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe disease; **AND**

- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate)

Pediatric Crohn's Disease † Φ^{1-4,80}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient is at least 6 years of age; **AND**
- Documented moderate to severe active disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, etc.)

Ulcerative Colitis †^{1-4,20,81-83, 91,93}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
- Documented failure or ineffective response to a minimum (3) month trial of conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate)] at maximum tolerated doses, unless there is a contraindication or intolerance to use

Pediatric Ulcerative Colitis † Φ^{1-4,84}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient is at least 6 years of age; **AND**
- Documented moderate to severe active disease; **AND**
- Documented failure or ineffective response to a minimum (3) month trial of conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate)] at maximum tolerated doses, unless there is a contraindication or intolerance to use

Fistulizing Crohn's Disease †^{38,76}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient has at least one draining fistula (i.e., enterovesical, enterocutaneous, enteroenteric, or enterovaginal fistulas) for at least 3 months

Rheumatoid Arthritis (RA) †^{1-4,74,85, 91}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**

- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.; **AND**
- Used in combination with methotrexate (MTX) unless contraindicated

Psoriatic Arthritis (PsA) †^{1-4,39,41,71}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
 - For patients with predominantly axial disease, a trial and failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**
 - For patients with peripheral arthritis, dactylitis OR active enthesitis, a trial and failure of at least a 3 month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc.

Ankylosing Spondylitis (AS) †^{1-4,19,73}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented active disease; **AND**
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs) over 4 weeks (in total), unless use is contraindicated

Plaque Psoriasis (PsO) †^{1-4,67-69,79,88,89}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe chronic disease for at least 6 months with at least one of the following:
 - Involvement of at least 3% of body surface area (BSA); **OR**
 - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
 - Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
- Patient did not respond adequately (or is not a candidate) to a 4 week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, tapinarof, roflumilast, retinoic acid derivatives, and/or vitamin D analogues); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least one non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
- Patient did not respond adequately (or is not a candidate**) to a 3 month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

Uveitis Associated with Behçet's Syndrome ‡ 8-10,21,22,34,35, 93

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient's disease is refractory to immunosuppressive therapy (e.g., corticosteroids, cyclosporine, azathioprine, etc.); **AND**
- Patient had an inadequate response to a self-administered biologic therapy (e.g., adalimumab)

Graft Versus Host Disease (GVHD) ‡ 43,65,66

- Patient has received a hematopoietic stem cell transplant; **AND**
- Used for steroid-refractory acute GVHD; **AND**
- Used in combination with systemic corticosteroids as additional therapy following no response to first-line therapies

Management of Immune Checkpoint Inhibitor Related Toxicity ‡ 36,37,43,86

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab, tremelimumab, retifanlimab, etc.); **AND**
- Patient has one of the following toxicities related to their immunotherapy:
 - Myocarditis if no improvement within 24-48 hours of starting high-dose methylprednisolone; **OR**
 - Mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin; **OR**
 - Moderate (G2) to severe (G3-4) diarrhea or colitis; **OR**
 - Moderate (G 2) pneumonitis if no improvement after 48-72 hours of corticosteroids; **OR**
 - Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone; **OR**
 - Stage 3 acute kidney injury/elevated serum creatinine if toxicity remains >grade 2 after 4-6 weeks of corticosteroids or if creatinine increases during or after steroid taper; **OR**
 - Uveitis (G1-4) that is refractory to high-dose systemic corticosteroids; **OR**
 - Moderate to severe inflammatory arthritis; **AND**
 - Used as additional disease-modifying antirheumatic drug (DMARD) therapy; **AND**
 - Patient's symptoms have not improved after holding immunotherapy **AND** one of the following:
 - Patient has not responded to oral corticosteroids; **OR**
 - Patient is unable to taper corticosteroids; **OR**

- Patient has not had response to conventional synthetic (cs) DMARDs (i.e., methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine)

****Examples of contraindications to phototherapy (PUVA or UVB) include the following:** ^{67,68}

- Xeroderma pigmentosum
- Other rare photosensitive genodermatoses (e.g., trichothiodystrophy, Cockayne syndrome, Bloom syndrome, Rothmund-Thomson syndrome) (*UVB only*)
- Genetic disorders associated with increased risk of skin cancer (e.g., Gorlin syndrome, oculocutaneous albinism) (*UVB only*)
- Pregnancy or lactation (*PUVA only*)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (*PUVA only*), treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (*UVB only*)
- Photosensitizing medications (*PUVA only*)
- Severe liver, renal, or cardiac disease (*PUVA only*)
- Young age < 12 years old (*PUVA only*)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ☐ Orphan Drug

IV. Renewal Criteria ¹⁻⁴

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, malignancy (e.g., lymphoma including hepatosplenic T-cell lymphoma, skin cancers, cervical cancer, etc.), significant hematologic abnormalities (e.g., leukopenia, neutropenia, thrombocytopenia, pancytopenia), serious infections (e.g., TB, serious fungal infections, HBV reactivation, etc.), cardiovascular and cerebrovascular accidents, heart failure, neurotoxicity/ demyelinating disorders, hepatotoxicity, lupus-like syndrome, etc.; **AND**

Crohn's Disease ²³

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra-intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

Pediatric Crohn's Disease ²³

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra-intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Pediatric Crohn's Disease Activity Index (PCDAI) score or the Harvey-Bradshaw Index score].

Ulcerative Colitis ²⁴⁻²⁷

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

Pediatric Ulcerative Colitis ²⁴⁻²⁶

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Pediatric Ulcerative Colitis Activity Index (PUCAI) score or the Mayo Score].

Fistulizing Crohn's Disease ²³

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as a reduction in number of enterocutaneous fistulas draining upon gentle compression, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

Psoriatic Arthritis ^{28,72}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria].

Rheumatoid Arthritis ^{29-31, 91}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity

Score-28 (DAS28) of 1.2 points or more or a $\geq 20\%$ improvement on the American College of Rheumatology-20 (ACR20) criteria].

Ankylosing Spondylitis ^{19,87}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, morning stiffness, and/or an improvement on a disease activity scoring tool [e.g. ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)].

Plaque Psoriasis (PsO) ^{33,69,79,88,90}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement $\leq 1\%$), and/or an improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and a four-point reduction in the DLQI from when treatment started].

Uveitis Associated with Behçet's Syndrome ³⁴⁻³⁵

- Disease response as indicated by an improvement in signs and symptoms compared to baseline [e.g. reduction in inflammation and/or lesions, dose reduction of oral glucocorticoids and/or immunosuppressive agents, improvement in vitreous haze, improvement in best corrected visual acuity (BCVA), disease stability and/or reduced rate of decline].

Acute GVHD ‡ ^{65,66}

- May not be renewed (*Note: Requests for continued therapy beyond four doses will be reviewed on a case-by-case basis.*)

Management of Immune Checkpoint Inhibitor related Toxicity ‡ ⁸⁶

- May not be renewed.

V. Dosage/Administration ^{1-4,36,37,42,66,86}

Indication	Loading Doses	Maintenance Dosing	Maximum Dose & Frequency
Rheumatoid Arthritis	3 mg/kg at weeks 0, 2, & 6	3 mg/kg every 8 weeks thereafter	Up to 10 mg/kg every 4 weeks
Ankylosing Spondylitis	5 mg/kg at weeks 0, 2, & 6	5 mg/kg every 6 weeks thereafter	5 mg/kg every 6 weeks
Crohn's Disease & Ulcerative Colitis	5 mg/kg at weeks 0, 2, & 6	5 mg/kg every 8 weeks thereafter	Up to 10 mg/kg every 8 weeks

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

Psoriatic Arthritis, Plaque Psoriasis, Behçet's Uveitis	5 mg/kg at weeks 0, 2, & 6	5 mg/kg every 8 weeks thereafter	5 mg/kg every 8 weeks
Management of Immune Checkpoint Inhibitor Related Toxicity	5 mg/kg at weeks 0,2	N/A	N/A
Acute GVHD	10 mg/kg at week 0,1,2 & 3	N/A	N/A
- Dose escalation (up to the maximum dose and frequency specified above) may occur upon clinical review on a case by case basis provided that the patient has: - Shown an initial response to therapy; AND - Received the three loading doses at the dose <u>AND</u> interval specified above; AND - Received a minimum of one maintenance dose at the dose <u>AND</u> interval specified above; AND - Responded to therapy (by treatment week 16) with subsequent loss of response; AND - Dose escalation may either increase the dose <u>OR</u> decrease the interval provided it does not exceed the following limits: - Dose increase by no more than 2.5 mg/kg; OR - Interval decrease by no more than 2 weeks <u>Note:</u> - Prior to escalating doses a patient's neutralizing IFX-antibodies should be assessed and addition of a DMARD (e.g., thiopurine or MTX), if not already on such therapy, should be considered. - Criteria for disease-specific response to therapy are noted in section IV. Patients with moderate to severe heart failure (NYHA Functional Class III/IV; LVEF $\leq 35\%$) should not receive doses in excess of 5 mg/kg.			

VI. Billing Code/Availability Information

HCPCS Code:

- J1745 – Injection, infliximab, excludes biosimilar, 10 mg; 1 billable unit = 10 mg (*Includes unbranded biologic*)
- Q5103 – Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg; 1 billable unit = 10 mg
- Q5104 – Injection, infliximab-abda, biosimilar, (renflexis), 10 mg; 1 billable unit = 10 mg
- Q5121 – Injection, infliximab-axxq, biosimilar, (avsola), 10 mg; 1 billable unit=10 mg

NDC:

- Remicade 100 mg single-dose vial for injection: 57894-0030-xx
- Infliximab 100 mg single-dose vial for injection: 57894-0160-xx (*Unbranded biologic**)
- Inflectra 100 mg single-dose vial: 00069-0809-xx
- Renflexis 100 mg single-dose vial: 78206-0162-xx
- Avsola 100 mg single-dose vial for injection: 55513-0670-xx

**An unbranded biologic is the same as the brand biologic, Remicade, using the same cell-line as the brand-name reference biologic.*

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

VII. References

1. Remicade/Infliximab [package insert]. Horsham, PA; Janssen Biotech, Inc; October 2021. Accessed September 2023.
2. Inflectra [package insert]. Yeonsu-gu, Incheon, Republic of Korea; CELLTRION, Inc; April 2023. Accessed September 2023.
3. Renflexis [package insert]. Yeonsu-gu, Incheon, Republic of Korea; Samsung Bioepis Co., Ltd; January 2022. Accessed September 2023.
4. Avsola [package insert]. Thousand Oaks, CA; Amgen, Inc; September 2021. Accessed September 2023.
5. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res (Hoboken)*. 2015 Nov 6. doi: 10.1002/acr.22783.
6. Ward MM, Deodhar, A, Akl, EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2015 Sep 24. doi: 10.1002/art.39298.
7. Menter A, Feldman SR, Weinstein GD, et al. A randomized comparison of continuous vs. intermittent infliximab maintenance regimens over 1 year in the treatment of moderate-to-severe plaque psoriasis. *J Am Acad Dermatol* 2007;56:31e1-15.
8. Niccoli L, Nannini C, Benucci M, et al. Long-term efficacy of infliximab in refractory posterior uveitis of Behcet's disease: a 24-month follow-up study. *Rheumatology (Oxford)*. 2007 Jul;46(7):1161-4. Epub 2007 May 3.
9. Giardina A, Ferrante A, Ciccia F, et al. One year study of efficacy and safety of infliximab in the treatment of patients with ocular and neurological Behcet's disease refractory to standard immunosuppressive drugs. *Rheumatol Int* 2011;31:33–37.
10. Okada A, Goto H, Ohno S, et al. Multicenter study of infliximab for refractory uveoretinitis in Behcet disease. *Arch Ophthalmol* 2012;130(5):592-598.
11. Lichtenstein GR, Loftus EV, Isaacs KL, et al. American College of Gastroenterology. Clinical Guideline: Management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113:481-517.
12. Kornbluth, A, Sachar, DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010 Mar;105(3):501-23.
13. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF- α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology*. 2013 Dec;145(6):1459-63. doi: 10.1053/j.gastro.2013.10.047.
14. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012 Jan;148(1):95-102.
15. Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JY, Van Voorhees AS, Elmets CA, Leonardi CL, Beutner KR, Bhushan R, Menter A. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and

INFLIXIMAB

(Remicade®/Infliximab *, Inflectra®, Renflexis™; Avsola®)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

- guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008 May;58(5):851-64.
16. National Institute for Health and Clinical Excellence (NICE). Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor. London (UK): National Institute for Health and Clinical Excellence (NICE); 2010 Aug. 73 p. (Technology appraisal guidance; no. 195)
 17. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2015 Dec 7. pii: annrheumdis-2015-208337. doi: 10.1136/annrheumdis-2015-208337.
 18. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis*. 2017 Mar 6. pii: annrheumdis-2016-210715.
 19. Van Der Heijde D, Ramiro S, Landewe R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis* doi:10.1136/annrheumdis-2016-210770.
 20. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. *J Crohns Colitis*. 2017 Jan 28. doi: 10.1093/ecco-jcc/jjx009.
 21. Jabs DA, Rosenbaum JT, Foster CS, et al. Guidelines for the use of immunosuppressive drugs in patients with ocular inflammatory disorders: recommendations of an expert panel. *Am J Ophthalmol*. 2000 Oct;130(4):492-513.
 22. Levy-Clarke 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.e3. doi: 10.1016/j.optha.2013.09.048.
 23. National Institute for Health and Care Excellence. NICE 2019. Crohn's disease: management. Published 03 May 2019. NICE guideline [NG129]. <https://www.nice.org.uk/guidance/ng129>. Accessed September 2023.
 24. Lewis JD, Chuai S, Nessel L, et al. Use of the Non-invasive Components of the Mayo Score to Assess Clinical Response in Ulcerative Colitis. *Inflamm Bowel Dis*. 2008 Dec; 14(12): 1660–1666. doi: 10.1002/ibd.20520
 25. Paine ER. Colonoscopic evaluation in ulcerative colitis. *Gastroenterol Rep (Oxf)*. 2014 Aug; 2(3): 161–168.
 26. Walsh AJ, Bryant RV, Travis SPL. Current best practice for disease activity assessment in IBD. *Nature Reviews Gastroenterology & Hepatology* 13, 567–579 (2016) doi:10.1038/nrgastro.2016.128
 27. Kornbluth, A, Sachar, DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010 Mar;105(3):501-23.
 28. National Institute for Health and Care Excellence. NICE 2017. Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs. Published 24 May 2017. Technology Appraisal Guidance [TA445].

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

- <https://www.nice.org.uk/guidance/TA445/chapter/1-Recommendations>. Accessed September 2023.
29. National Institute for Health and Care Excellence. NICE 2009. Rheumatoid Arthritis in Adults: Management. Published 25 February 2009. Clinical Guideline [CG79]. <https://www.nice.org.uk/guidance/cg79/resources/rheumatoid-arthritis-in-adults-management-pdf-975636823525>.
 30. National Institute for Health and Care Excellence. NICE 2010. Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after failure of a TNF inhibitor. Published 10 October 2012. Clinical Guideline [TA195]. <https://www.nice.org.uk/guidance/ta195/resources/adalimumab-etanercept-infliximab-rituximab-and-abatacept-for-the-treatment-of-rheumatoid-arthritis-after-the-failure-of-a-tnf-inhibitor-pdf-82598558287813>.
 31. Ward MM, Guthrie LC, Alba MI. Rheumatoid Arthritis Response Criteria And Patient-Reported Improvement in Arthritis Activity: Is an ACR20 Response Meaningful to Patients”. *Arthritis Rheumatol*. 2014 Sep; 66(9): 2339–2343. doi: 10.1002/art.38705
 32. National Institute for Health and Care Excellence. NICE 2008. Infliximab for the treatment of adults with psoriasis. Published 23 January 2008. Technology Appraisal Guidance [TA134]. <https://www.nice.org.uk/guidance/ta134/resources/infliximab-for-the-treatment-of-adults-with-psoriasis-pdf-82598193811141>.
 33. Smith CH, Jabbar-Lopez ZK, Yiu ZK, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. *Br J Dermatol*. 2017 Sep;177(3):628-636. doi: 10.1111/bjd.15665.
 34. Jabs DA, Rosenbaum JT, Foster CS, et al. Guidelines for the use of immunosuppressive drugs in patients with ocular inflammatory disorders: recommendations of an expert panel. *Am J Ophthalmol*. 2000 Oct;130(4):492-513.
 35. Levy-Clarke 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.e3. doi: 10.1016/j.ophtha.2013.09.048.
 36. Minor DR, Chin K, Sashani-Sabet M, et al. Infliximab in the treatment of anti-CTLA4 antibody (Ipilimumab) induced immune-related colitis. *Cancer Biotherapy & Radiopharmaceuticals*. 2009 June; 24 (3). <https://doi.org/10.1089/cbr.2008.0607>
 37. Villadolid J, Amin A. Immune checkpoint inhibitors in clinical practice: update on management of immune-related toxicities. *Translational Lung Cancer Research*. 2015;4(5):560-575. doi:10.3978/j.issn.2218-6751.2015.06.06. Appendix 1 – Covered Diagnosis Codes
 38. Lichtenstein GR, Loftus EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn’s Disease in Adults. *Am J Gastroenterol* 2018; 113:481–517; doi: 10.1038/ajg.2018.27
 39. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology*. Vol. 0, No. 0, Month 2018, pp 1–28 DOI 10.1002/art.40726
 40. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019 Feb 13. pii: S0190-9622(18)33001-9. <https://doi.org/10.1016/j.jaad.2018.11.057>.

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

41. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011 Jul;65(1):137-74.
42. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. *J Oncol Pract*. 2018 Mar;14(3):e130-e136.
43. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Infliximab. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2023.
44. Strik AS, van de Vrie W, Bloemsaat-Minekus JPJ, et al. Serum concentrations after switching from originator infliximab to the biosimilar CT-P13 in patients with quiescent inflammatory bowel disease (SECURE): an open-label, multicentre, phase 4 non-inferiority trial. *Lancet Gastroenterol Hepatol*. 2018 Jun;3(6):404-412.
45. Milassin A, Fabian A, Molnar T. Switching from infliximab to biosimilar in inflammatory bowel disease: overview of the literature and perspective. *Therap Adv Gastroenterol*. 2019; 12: 1756284819842748.
46. Glintborg B, Sørensen IJ, Loft AG, et al. A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry. *Ann Rheum Dis*. 2017 Aug;76(8):1426-1431.
47. Yoo DH, Prodanovic N, Jaworski J, et al. Efficacy and safety of CT-P13 (biosimilar infliximab) in patients with rheumatoid arthritis: comparison between switching from reference infliximab to CT-P13 and continuing CT-P13 in the PLANETRA extension study. *Ann Rheum Dis*. 2017 Feb;76(2):355-363.
48. Park W, Yoo DH, Miranda P, et al. Efficacy and safety of switching from reference infliximab to CT-P13 compared with maintenance of CT-P13 in ankylosing spondylitis: 102-week data from the PLANETAS extension study. *Ann Rheum Dis*. 2017 Feb;76(2):346-354.
49. Jorgensen KK, Olcen IC, Goll GL, et al. Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. *Lancet*. 2017 Jun 10;389(10086):2304-2316.
50. Goll GL, Jørgensen KK, Sexton J, et al. Long-term efficacy and safety of biosimilar infliximab (CT-P13) after switching from originator infliximab: open-label extension of the NOR-SWITCH trial. *J Intern Med*. 2019 Jun;285(6):653-669.

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

51. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. *J Oncol Pract*. 2018 Mar;14(3):e130-e136.
52. Celltrion. CT-P13 (infliximab biosimilar). Briefing document for the US FDA Arthritis Advisory Committee.
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/125544Orig1s000MedR.pdf
53. Milassin A, Fabian A, Molnar T. Switching from infliximab to biosimilar in inflammatory bowel disease: overview of the literature and perspective. *Therap Adv Gastroenterol*. 2019; 12: 1756284819842748.
54. Strik AS, van de Vrie W, Bloemsaat-Minekus JPJ, et al. Serum concentrations after switching from originator infliximab to the biosimilar CT-P13 in patients with quiescent inflammatory bowel disease (SECURE): an open-label, multicentre, phase 4 non-inferiority trial. *Lancet Gastroenterol Hepatol*. 2018 Jun;3(6):404-412.
55. Glintborg B, Sørensen IJ, Loft AG, et al. A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry. *Ann Rheum Dis*. 2017 Aug;76(8):1426-1431.
56. Yoo DH, Prodanovic N, Jaworski J, et al. Efficacy and safety of CT-P13 (biosimilar infliximab) in patients with rheumatoid arthritis: comparison between switching from reference infliximab to CT-P13 and continuing CT-P13 in the PLANETRA extension study. *Ann Rheum Dis*. 2017 Feb;76(2):355-363.
57. Park W, Yoo DH, Miranda P, et al. Efficacy and safety of switching from reference infliximab to CT-P13 compared with maintenance of CT-P13 in ankylosing spondylitis: 102-week data from the PLANETAS extension study. *Ann Rheum Dis*. 2017 Feb;76(2):346-354.
58. Goll GL, Jørgensen KK, Sexton J, et al. Long-term efficacy and safety of biosimilar infliximab (CT-P13) after switching from originator infliximab: open-label extension of the NOR-SWITCH trial. *J Intern Med*. 2019 Jun;285(6):653-669.
59. 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.
60. Smolen JS, Choe JY, Prodanovic N, et al. Comparing biosimilar SB2 with reference infliximab after 54 weeks of a double-blind trial: clinical, structural and safety results. *Rheumatology (Oxford)*. 2017 Oct; 56(10): 1771–1779.
61. Choe J, Prodanovic N, Niebrzydowski J, Staykov I, Dokoupilova E, Baranauskaite A, 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;76:58–64.
62. Smolen JS, Choe JY, Prodanovic N, Niebrzydowski J, Staykov I, Dokoupilova E, et al. Safety, immunogenicity and efficacy after switching from reference infliximab to biosimilar

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

SB2 compared with continuing reference infliximab and SB2 in patients with rheumatoid arthritis: results of a randomised, double-blind, phase III transition study. *Ann Rheum Dis* 2017. E-pub ahead of print.

63. Chow V, Oh M, Gessner M, Fanjiang G. Pharmacokinetic similarity of ABP 710, a proposed biosimilar to infliximab: results from a randomized, single-blind, single-dose, parallel-group study in healthy subjects. *Clin Pharmacol Drug Dev*. 2019. doi:10.1002/cpdd.738
64. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Cell Transplantation Version 1.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2023.
65. Couriel D, Saliba R, Hicks K, et al. Tumor necrosis factor- α blockade for the treatment of acute GVHD. *Blood* 2004;104:649-65
66. Richard EG. (2021). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmetts CA, Corona R (Eds.), *UptoDate*. Last updated: December 1, 2022. Accessed on August 29, 2023. Available from [https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20\(PUVA\)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1](https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20(PUVA)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1).
67. Honigsman H. (2020). UVB therapy (broadband and narrowband). In Elmetts CA, Corona R (Eds.), *UptoDate*. Last updated: January 18, 2023. Accessed on August 29, 2023. Available from [https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20\(broadband%20and%20narrowband\).%20&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1](https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20(broadband%20and%20narrowband).%20&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1).
68. Smith CH, Yiu ZZN, Bale T, et al; British Association of Dermatologists' Clinical Standards Unit. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update. *Br J Dermatol*. 2020 Oct;183(4):628-637. doi: 10.1111/bjd.19039.
69. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020 Jan;82(1):161-201. doi: 10.1016/j.jaad.2019.08.049.
70. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020 Jun;79(6):700-712. doi: 10.1136/annrheumdis-2020-217159.
71. Mease PJ. Measures of psoriatic arthritis: Tender and Swollen Joint Assessment, Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Modified Nail Psoriasis Severity Index (mNAPSI), Mander/Newcastle Enthesitis Index (MEI), Leeds Enthesitis Index (LEI), Spondyloarthritis Research Consortium of Canada (SPARCC), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Leeds Dactylitis Index (LDI), Patient Global for Psoriatic Arthritis, Dermatology Life Quality Index (DLQI), Psoriatic Arthritis Quality of Life (PsAQOL), Functional Assessment of Chronic Illness Therapy-

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

- Fatigue (FACIT-F), Psoriatic Arthritis Response Criteria (PsARC), Psoriatic Arthritis Joint Activity Index (PsAJAI), Disease Activity in Psoriatic Arthritis (DAPSA), and Composite Psoriatic Disease Activity Index (CPDAI). *Arthritis Care Res (Hoboken)*. 2011 Nov;63 Suppl 11:S64-85. doi: 10.1002/acr.20577.
72. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2019 Oct;71(10):1599-1613. doi: 10.1002/art.41042.
 73. Fraenkel L, Bartholomew JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research* Vol. 0, No. 0, Month 2021, pp 1–16 DOI 10.1002/acr.24596
 74. Torres J, Bonovas S, Doherty G, et al. European Crohn's and Colitis Organisation [ECCO] Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *Journal of Crohn's and Colitis*, 2020, 4–22 doi:10.1093/ecco-jcc/jjz180.
 75. Feurstein JD, Ho EY, Shmidt E, et al. American Gastroenterological Association Institute – AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology* 2021;160:2496–2508.
 76. Lamb CA, Kennedy NA, Raine T, et al. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. *Gut* 2019;0:1–106. doi:10.1136/gutjnl-2019-318484.
 77. Panaccione R, Steinhart AH, Bressler B, et al. Canadian Association of Gastroenterology Clinical Practice Guideline for the Management of Luminal Crohn's Disease. *Journal of the Canadian Association of Gastroenterology*, 2019, 2(3), e1–e34 doi: 10.1093/jcag/gwz019.
 78. National Institute for Health and Care Excellence. NICE 2013. Psoriasis. Published 06 August 2013. Quality standard [QS40]. <https://www.nice.org.uk/guidance/qs40>. Accessed September 2023.
 79. Van Rheenen PF, Aloï M, Assa A, et al. The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update. *J Crohns Colitis*. 2020 Oct 7;jjaa161. doi: 10.1093/ecco-jcc/jjaa161.
 80. National Institute for Health and Care Excellence. NICE 2015. Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy. Published 25 February 2015. Technology appraisal guidance [TA329]. <https://www.nice.org.uk/guidance/ta329>. Accessed September 2023.
 81. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2019;114:384–413. <https://doi.org/10.14309/ajg.0000000000000152>; published online February 22, 2019.
 82. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158(5):1450–1461. doi:10.1053/j.gastro.2020.01.006.
 83. Turner D, Ruemmele FM, Orlanski-Meyer E, et al. Management of Paediatric Ulcerative Colitis, Part 1: Ambulatory Care-An Evidence-based Guideline From European Crohn's and

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

- Colitis Organization and European Society of Paediatric Gastroenterology, Hepatology and Nutrition. *J Pediatr Gastroenterol Nutr*. 2018 Aug;67(2):257-291.
84. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Annals of the Rheumatic Diseases* 2020;79:685-699.
85. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Management of Immunotherapy-Related Toxicities Version 2.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2023.
86. National Institute for Health and Care Excellence (NICE). Spondyloarthritis. Quality standard [QS170]. Published: 28 June 2018
<https://www.nice.org.uk/guidance/qs170/chapter/Quality-statements>. Accessed September 2023.
87. National Institute for Health and Care Excellence. NICE 2017. Psoriasis: assessment and management. Published 24 October 2012. Clinical guideline [CG153].
<https://www.nice.org.uk/guidance/CG153>. Accessed September 2023.
88. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol*. 2019 Sep;81(3):775-804. Doi:10.1016/j.jaad.2019.04.042.
89. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. *J Am Acad Dermatol*. 2017 Feb; 76(2):290-298. doi: 10.1016/j.jaad.2016.10.017.
90. National Institute for Health and Care Excellence. NICE 2018. Rheumatoid Arthritis in Adults: Management. Published 11 July 2018. Reference number [NG100]. Last updated 12 October 2020. <https://www.nice.org.uk/guidance/ng100/resources/rheumatoid-arthritis-in-adults-management-pdf-66141531233989>
91. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on therapeutics in ulcerative colitis: medical treatment. *J Crohns Colitis*. 2022 Jan 28. 16 (1):2-17. Doi: 10.1093/ecco-jcc/jjab178
92. Hatemi G, Christensen R, Dongsik B, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. *Annals of the Rheumatic Diseases* 2018;77:808-818.
93. National Government Services, Inc. Local Coverage Article: Billing and Coding: INFLIXIMAB and biosimilars (A52423). Centers for Medicare & Medicaid Services, Inc. Updated on 06/21/2023 with effective date 07/01/2023. Accessed September 2023.
94. Palmetto GBA. Local Coverage Article: Billing and Coding: INFLIXIMAB (A56432). Centers for Medicare & Medicaid Services, Inc. Updated on 09/06/2023 with effective date 09/01/2023. Accessed September 2023.

Appendix 1 – Covered Diagnosis Codes

INFLIXIMAB
(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
D89.810	Acute graft-versus host disease
D89.812	Acute on chronic graft-versus-host-disease
D89.813	Graft-versus-host disease unspecified
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
H44.111	Panuveitis, right eye
H44.112	Panuveitis, left eye
H44.113	Panuveitis, bilateral
H44.119	Panuveitis, unspecified eye
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified
I40.8	Other acute myocarditis
I40.9	Acute myocarditis, unspecified
J70.2	Acute drug-induced interstitial lung disorders
J70.4	Drug-induced interstitial lung disorders, unspecified
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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis 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
L40.59	Other psoriatic arthropathy
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
M05.119	Rheumatoid lung disease with rheumatoid arthritis of unspecified shoulder

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
M05.121	Rheumatoid lung disease with rheumatoid arthritis of right elbow
M05.122	Rheumatoid lung disease with rheumatoid arthritis of left elbow
M05.129	Rheumatoid lung disease with rheumatoid arthritis of unspecified elbow
M05.131	Rheumatoid lung disease with rheumatoid arthritis of right wrist
M05.132	Rheumatoid lung disease with rheumatoid arthritis of left wrist
M05.139	Rheumatoid lung disease with rheumatoid arthritis of unspecified wrist
M05.141	Rheumatoid lung disease with rheumatoid arthritis of right hand
M05.142	Rheumatoid lung disease with rheumatoid arthritis of left hand
M05.149	Rheumatoid lung disease with rheumatoid arthritis of unspecified hand
M05.151	Rheumatoid lung disease with rheumatoid arthritis of right hip
M05.152	Rheumatoid lung disease with rheumatoid arthritis of left hip
M05.159	Rheumatoid lung disease with rheumatoid arthritis of unspecified hip
M05.161	Rheumatoid lung disease with rheumatoid arthritis of right knee
M05.162	Rheumatoid lung disease with rheumatoid arthritis of left knee
M05.169	Rheumatoid lung disease with rheumatoid arthritis of unspecified 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
M05.179	Rheumatoid lung disease with rheumatoid arthritis of unspecified 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
M05.219	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
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
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
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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
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
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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
M05.8A	Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
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
M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified 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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
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
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
M06.4	Inflammatory polyarthropathy
M06.8A	Other specified rheumatoid arthritis, other specified 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

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
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
M35.2	Behçet's disease
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
M79.10	Myalgia, unspecified
M79.11	Myalgia of mastication muscle
M79.12	Myalgia of auxiliary muscles, head and neck
M79.18	Myalgia, other site
N17.8	Other acute kidney failure
N17.9	Acute kidney failure, unspecified
R19.7	Diarrhea, unspecified
T86.09	Other complications of bone marrow transplant
Z94.81	Bone marrow transplant status

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): J,M	NCD/LCD/LCA Document (s): A56432
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56432&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 6,K	NCD/LCD/LCA Document (s): A52423
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52423&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

INFLIXIMAB

(Remicade®/Infliximab *; Inflectra®; Renflexis™; Avsola®)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaaajila gargaarsa afaanij, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚገኙት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግኝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ፡ 1.800.940.5049 (መለስማት ለተሳናቸው፡ 763.847.4013)፡

ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျဉ်လၢၣ်စၢၤ နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013) .

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).