Mass General Brigham
Health Plan

Avsola (infliximab-qbtx)
Inflectra (infliximab-dyyb)
Infliximab
Remicade (infliximab)
Renflexis (infliximab-abda)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled through a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active Crohn's disease
2. Moderately to severely active Ulcerative colitis
3. Moderately to severely active Rheumatoid arthritis in combination with methotrexate
4. Active Ankylosing spondylitis
5. Active Psoriatic arthritis
6. Chronic severe Plaque psoriasis

Compendial Uses

1. Axial spondyloarthritis
2. Behcet's syndrome
3. Granulomatosis with polyangiitis (Wegener's granulomatosis)
4. Hidradenitis suppurativa
5. Juvenile idiopathic arthritis
6. Pyoderma gangrenosum
7. Sarcoidosis
8. Takayasu's arteritis
9. Uveitis

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all the following diagnosis-specific criteria is met:

Moderately to severely active Crohn's disease (CD)

1. Diagnosis of moderately to severely active Crohn's disease
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
3. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Entyvio and Stelara IV 130mg
4. ONE of the following:
    a. Frequent diarrhea and abdominal pain
    b. At least 10% weight loss
    c. Complications such as obstruction, fever, abdominal mass
    d. Abnormal lab values (e.g., C-reactive protein [CRP])
    e. CD Activity Index (CDAI) greater than 220
5. One of the following:
    a. Member has fistulizing disease.
    b. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Azathioprine
        iii. Corticosteroids (e.g., prednisone)
        iv. methotrexate

Moderately to severely active ulcerative colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
3. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Entyvio and Stelara IV 130mg
4. ONE of the following:
    a. Greater than 6 stools per day
    b. Frequent blood in stools
    c. Frequent urgency
    d. Presence of ulcers
    e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
    f. Dependent on, or refractory to, corticosteroids
5. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine

b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
c. Azathioprine
d. Corticosteroids (e.g., prednisone)

Moderately to severely active rheumatoid arthritis (RA)

1. Diagnosis of moderately to severely active rheumatoid arthritis
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
3. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Simponi Aria
4. The member has a minimum duration of 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    a. Methotrexate
    b. Leflunomide
    c. Sulfasalazine

Active ankylosing spondylitis (AS) and axial spondyloarthritis

1. One of the following diagnoses:
    a. Active ankylosing spondylitis
    b. Axial spondyloarthritis
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
3. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Simponi Aria
4. Member has minimal duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.

Active psoriatic arthritis (PsA)

1. Diagnosis of active psoriatic arthritis
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
3. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Simponi Aria
4. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Chronic severe plaque psoriasis

1. Diagnosis of chronic severe plaque psoriasis

2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
3. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Ilumya
4. Member has at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
5. Member meets ONE of the following criteria:
    a. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
        i. Corticosteroids (e.g., betamethasone, clobetasol)
        ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)
        iii. Tazarotene
        iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        v. Anthralin
        vi. Coal tar
    b. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Behcet's syndrome

1. Diagnosis of refractory Behcet's syndrome
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Granulomatosis with polyangiitis (Wegener's granulomatosis)

1. Diagnosis of granulomatosis with polyangiitis (Wegener's granulomatosis)
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Hidradenitis suppurativa

1. Diagnosis of severe, refractory hidradenitis suppurativa when the documentation of Hurley Stage III HS received
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Juvenile Idiopathic arthritis (JIA)

1. Diagnosis of juvenile idiopathic arthritis (JIA)
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Pyoderma gangrenosum

1. Diagnosis of pyoderma gangrenosum
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Sarcoidosis

1. Diagnosis of sarcoidosis
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Takayasu's arteritis

1. Diagnosis of Takayasu's arteritis
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Uveitis

1. Diagnosis of Uveitis
2. Member has had inadequate response, intolerance or contraindication to a trial of immunosuppressive therapy for uveitis (e.g., methotrexate, azathioprine, or mycophenolate mofetil)
3. For Avsola, Remicade, infliximab, and Renflexis: member has a documented intolerable adverse event with the preferred product, Inflectra, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Continuation of Therapy

Requests for reauthorization will be approved when all the following criteria are met:

1. Initial criteria are met
2. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 24 months
2. The following quantity limits apply:

Remicade, Inflectra, Renflexis, infliximab, and Avsola 100 mg	10 vials per 28 days

References

1. Avsola (infliximab-axxq) [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2019.
2. Baughman RP, Lower EE. Infliximab for refractory sarcoidosis. Sarcoidosis Vasc Diffuse Lung Dis 2001; 18:70
3. Della Rossa A, Tavoni A, Merlini G, et al. Two Takayasu arteritis patients successfully treated with infliximab: a potential disease-modifying agent? Rheumatology (Oxford) 2005; 44:1074
4. 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*. 2016;75(3):499-510.
5. Grant A, Gonzalez T, Montgomery MO, et al. Infliximab therapy for patients with moderate to severe hidradenitis suppurativa: a randomized, double-blind, placebo-controlled crossover trial. J Am Acad Dermatol 2010; 62:205
6. Inflectra (infliximab dyyb) [prescribing information]. New York, NY: Pfizer; November 2017
7. Laharie D, Bourreille A, Branche J, et al. Long-term outcome of patients with steroid-refractory acute severe UC treated with ciclosporin or infliximab. Gut 2017

8. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
9. Meyer A, Rudant J, Drouin J, et al. Effectiveness and Safety of Reference Infliximab and Biosimilar in Crohn Disease: A French Equivalence Study. Ann Intern Med 2019; 170:99.
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11. Park W, Yoo DH, Jaworski J, et al. Comparable long-term efficacy, as assessed by patient-reported outcomes, safety and pharmacokinetics, of CT-P13 and reference infliximab in patients with ankylosing spondylitis: 54-week results from the randomized, parallel-group PLANETAS study. *Arthritis Res Ther*. 2016;18:25.
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13. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc; June 2018.
14. Renflexis (infliximab) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; November 2017.
15. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.
16. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
17. Smolen JS, Landewé R, Billsma 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*;0*:1-18.
18. Tugal-Tutkun I, Mudun A, Urgancioglu M, et al. Efficacy of infliximab in the treatment of uveitis that is resistant to treatment with the combination of azathioprine, cyclosporine, and corticosteroids in Behçet's disease: an open-label trial. Arthritis Rheum 2005; 52:2478
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22. Yoo DH, Racewicz A, Brzezicki J, et al. A phase III randomized study to evaluate the efficacy and safety of CT-P13 compared with reference infliximab in patients with active rheumatoid arthritis: 54-week results from the PLANETRA study. *Arthritis Res Ther*. 2016;18:82.[PubMed 27038608]

Review History

03/21/05 – Reviewed
05/15/05 – Implemented
02/27/06 – Updated
02/25/08 – Updated
02/23/09 – Updated
02/22/10 – Reviewed
02/28/11 – Updated

02/27/12 – Updated
02/25/13 – Updated
02/24/14 – Updated
02/23/15 – Reviewed
02/22/16 – Reviewed
02/27/17 - Added Inflectra; adopted SGM & PDS
02/26/18 – Updated
02/20/19 – Updated
11/20/19 - Added all SGM compendial uses that were previously listed on custom criteria as reviewed on a case-by-case basis and deleted off-label case-by-case reviews statement. Added criteria to compendial diagnosis. Added Skyrizi as required preferred product for PsO. Added Rinvoq as required preferred trial for RA
10/31/2020 – Reviewed; Updated criteria to have preferred agent as Remicade for Comm/Exch strategy. Non-preferred as Avsola, Renflexis, and Inflectra. Updated references. Effective 1/1/21. Avsola addition effective 2/1/21.
11/17/2021 – Reviewed and Updated for Nov P&T; updated preferred agent to Inflectra. Effective 01/01/2022
06/22/2022 – Reviewed and Updated for Jun P&T; added new formulation of unbranded infliximab as a non-preferred agent. Effective 08/01/2022.
11/15/2023 – Reviewed and Updated for Nov P&T; removed TB requirement
12/13/2023 – Reviewed and Updated for Dec P&T; Added additional treatment options for conventional therapies for Rheumatoid arthritis. Added disease involvement for Crohn's and UC. Removed Appendix. Plaque psoriasis – changed from 5% BSA to 3% BSA. Removed appendix with contraindications to methotrexate. Consolidated conventional therapies for plaque psoriasis. Psoriatic arthritis – removed conventional therapy and added disease involvement. Effective: 2/1/2024
11/13/2024 – Reviewed and updated for November P&T. Updated criteria to include diagnoses for each agent. Updated reauthorization criteria to align with other agents. Administrative update-removed Appendix A. Effective 1/1/2025.