Mass General Brigham
Health Plan

Inflectra (infliximab-dyyb)
Remicade (infliximab)
Renflexis (infliximab-abda)
Avsola (infliximab-qbtx)
infliximab
Effective 02/01/2024

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

Moderately to severely active Crohn's disease (CD)
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for treatment of moderately to severely active CD when the following criteria are met:

1. 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.
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Entyvio and Stelara IV 130mg
3. 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) great than 220
4. 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for treatment of moderately to severely active CD when the following criteria are met:

1. 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.
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Entyvio and Stelara IV 130mg
3. 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

4. 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for treatment of moderately to severely active RA when one of the following criteria is met:

1. 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.
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Simponi Aria
3. 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
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when the following criteria is met:

1. 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.
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Simponi Aria
3. 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR

Authorization may be granted for treatment of active psoriatic arthritis (PsA) when the following criteria is met:

1. 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.
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Simponi Aria
3. 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

Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola, Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for treatment of chronic severe plaque psoriasis when all the following criteria are met:

1. 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.
2. For Avsola, Remicade, infliximab, and Renflexis: member has a documented inadequate response or intolerable adverse event with Ilumya
3. 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
4. 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

Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment 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
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment of granulomatosis with 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment 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
Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment 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

Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola, Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment of sarciodosis
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

Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola, Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment 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

Authorization may be granted for members new to the plan who are currently receiving treatment with Remicade, Avsola, Inflectra, infliximab, or Renflexis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria are met:

1. Diagnosis of treatment 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

Authorization may be granted for members who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Remicade, Inflectra, Avsola, infliximab, or Renflexis 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

Appendices

Appendix A

Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine
2. Mild to moderate disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternatives: methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
    a. Methotrexate IM
4. Moderate to severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – maintenance of remission
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM

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2. Renflexis (infliximab) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; November 2017.
3. Inflectra (infliximab dyyb) [prescribing information]. New York, NY: Pfizer; November 2017
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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