Infliximab (Remicade®, Inflectra®, Renflexis®)

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Remicade, Inflectra, and Renflexis require prior authorization from HealthPartners Pharmacy Administration. The setting of drug administration will be reviewed as part of the prior authorization.

Note:
For all inquiries, transfer to the Medical Injectable Line (ext 26135).

A quantity limit of 120 units (1200 mg) will be applied to all claims. Claims for greater than 120 units (1200 mg) will not be covered without prior authorization for the higher dose. Claims for greater amounts will be reviewed for billing accuracy, accurate weight-based dosing, and an inadequate response to standard dosing.

Coverage

Remicade is generally approved for use in patients diagnosed with moderate to severe rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, ulcerative colitis and moderate to severe Crohn’s disease when all the following criteria are met:

Initial authorizations

1. Prescribed and followed by Rheumatology, Dermatology or Gastroenterology.
2. Patient has had a trial and failure of an appropriate regimen of first-line therapy based on the indication for treatment:

A. Moderate to Severe Rheumatoid Arthritis - DMARD therapy including concurrent use of two or three of the regimens below for at least 3 months or intolerance or a contraindication to use:
   i. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
   ii. Hydroxychloroquine titrated to 200-400mg daily
   iii. Sulfasalazine titrated to 2,000mg-3,000mg daily
   iv. Leflunomide 10-20mg daily

B. Psoriatic Arthritis – First line therapy including concurrent use of the regimens below for at least 1 month:
   i. Continuous treatment with a NSAID at therapeutic doses; and,
   ii. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)

C. Plaque psoriasis – First-line therapy including concurrent use of two of the regimens below for at least 3 months or intolerance or a contraindication to use:
   i. Topical corticosteroid therapy
   ii. Phototherapy: at least 20-30 treatments given 2-3 times weekly Note: Home units are supported in certain situations (See the Home Phototherapy medical policy)
   iii. Methotrexate 5mg-15mg weekly (GI intolerance requires trial of SC/IM methotrexate at 5mg-15mg weekly) in combination with folic acid supplementation
   iv. Cyclosporine at a dose of at least 2.5 – 5 mg/kg/day until disease control achieved
   v. Acitretin at a dose of at least 25 mg daily

D. Ankylosing Spondylitis – Use of first-line therapy including all of the regimens below:
   i. Continuous treatment with a NSAID at therapeutic doses for one month; and,
   ii. For patients with only peripheral disease, local corticosteroid injections when the disease process permits; and,
   iii. For patients with only peripheral disease, methotrexate 20mg for at least 3 months or Sulfasalazine titrated to 2000mg to 3000mg daily for at least 3 months.

E. Ulcerative Colitis – Use of at least two of the systemic regimens below for at least 12 weeks:
   i. Sulfasalazine 4-6 gram daily
   ii. Mesalamine 2-4.8 gram daily
   iii. Balsalazide 6.75 grams
   iv. Corticosteroid regimens:
Moderate to Severe Crohn’s Disease – Use of first-line therapy including one of the following:

1. Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated:
   a) Prednisone 40-60 mg daily
   b) Oral budesonide 9 mg daily
   c) Budesonide rectal; or
   d) Azathioprine 1.5-2.5 mg/kg daily
   e) 6-mercaptopurine 1-1.5 mg/kg daily

2. Breakthrough disease while stabilized for at least 3 months on one of the following therapies:
   a) Azathioprine 2-3 mg/kg daily
   b) 6-mercaptopurine 1-1.5 mg/kg daily
   c) Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)

3. For commercial products only (does not apply to Medicare or Minnesota Health Care Programs products), medication administration must occur at a clinic office or home-infusion setting unless medical necessity is met based on the criteria below, supported by medical documentation:
   A. The patient has experienced a severe or life-threatening reaction with previous infusions of the same or similar products; or,
   B. The patient has a medical condition that renders him or her unstable, exceptionally complex, immunocompromised or otherwise high-risk such that continued oversight in the current facility is required; or,
   C. There are no alternative settings available to the patient as a result of both of the following:
      i. The patient is unable to use home-infusion services as documented by the physician, social worker, or infusion provider; and,
      ii. The patient is unable to access alternative settings due to unreasonable distance (>30 miles) or other extenuating circumstances.

4. The prescribed regimen is within the FDA-approved dosing regimen. A current patient weight is required for all requests.

5. No other biologic agent will be used concurrently to treat this indication.

Authorizations will be provided for one year.

Reauthorizations for biologic regimens of up to FDA-approved doses and frequencies

Renewals will be provided annually with provider attestation that they have seen the patient within the last fourteen months and the patient is benefiting from use of the medication.

Inflectra (infliximab-dyyb) and Renflexis (infliximab-abda) – Coverage may be authorized when all of the following are met:

1. Medical necessity has been demonstrated based on all Remicade coverage criteria above, and
2. Patient has tried and failed the following preferred anti-TNF agents:
   A. Remicade, Enbrel, and Humira for Rheumatoid Arthritis, Psoriatic Arthritis, Plaque Psoriasis, or Ankylosing Spondylitis
   B. Remicade and Humira for Crohn’s Disease or Ulcerative Colitis, and
3. Provider has documented a statement of medical necessity including rationale suggesting improved outcomes with Inflectra that could not be achieved with a preferred product.

Definitions

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

1. **Rheumatoid arthritis (RA)** - Infliximab in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.
2. **Ankylosing Spondylitis** - Infliximab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.
3. **Psoriatic Arthritis** - Infliximab is indicated for reducing signs and symptoms of active arthritis,
inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.

4. **Crohn’s disease** (also known as regional enteritis) - Infliximab is indicated for
   A. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
   B. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

5. **Pediatric Crohn’s Disease** – Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

6. **Ulcerative Colitis** – Infliximab is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

7. **Pediatric Ulcerative Colitis** – Infliximab is indicated for reducing signs and symptoms, inducing and maintaining clinical remission in pediatric patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

8. **Plaque Psoriasis** - Infliximab is indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Inflectra (infliximab-dyyb) and Renflexis (infliximab-abda) are biosimilars of Remicade (infliximab). Inflectra and Renflexis share the same mechanism of action and indications as Remicade except for Pediatric Ulcerative Colitis, for which the biosimilar drugs are not indicated.

**Setting**: The type of physical site where the drug is provided. Settings include inpatient hospital, outpatient hospital, clinic office, or home-infusion.

- **Outpatient Hospital sites** have physicians and practitioners on-site and are the appropriate site to manage unstable patients and patients experiencing certain moderate to severe adverse events. Hospital settings are typically the highest-cost, most-intensive, and are the highest level settings.
- **Clinic offices** are lower level settings which are not outpatient hospital settings that can manage some unstable patients and patients experiencing adverse events. Physicians may or may not be readily available.
- **Home-infusion** is a lower level setting, and is performed by a licensed nurse supported by a licensed pharmacy who have expertise in administering complex medications in a patient’s home. Home infusion providers regularly manage mild to moderate adverse events, and are prepared to manage severe adverse events if needed.

**Codes**

*If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.*

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**Products**

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan
has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria may not apply to Medicare Products if Medicare requires different coverage. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7979 or 1-800-233-9645.


References

8. Remicade Full Prescribing Information-Janssen Biotech, Inc. Horsham, PA;October 2017
9. Inflectra Full Prescribing Information-Pfizer Labs, New York, NY;November 2017
10. Renflexis Full Prescribing Information – Merck & Co., Inc, Kenilworth, NJ; April 2017