

# Infliximab (Remicade®, Inflectra®, Renflexis®, Avsola™)

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

Remicade, Inflectra, Renflexis, and Avsola must be given by home infusion, at a clinic office, or dispensed by a specialty pharmacy if provided in an outpatient hospital site, as described by the criteria below.

### Note:

For all Commercial and Marketplace inquiries, transfer to the Medical Injectable Line (ext 26135).

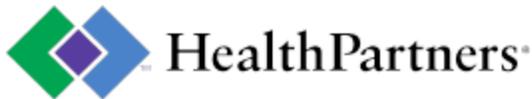
Quantity and frequency limits will be applied to all claims in accordance with FDA-approved indications.

## Coverage

Inflectra and Renflexis are 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; **and**,
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 (This requirement will be waived for patients presenting with high disease activity and features of poor prognosis (per the ACR guidelines)):
    - 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 (This requirement will be waived for patients presenting with fistulizing and severe disease (as defined by the ACG guidelines)):

- i. Sulfasalazine 4-6 gram daily
- ii. Mesalamine 2-4.8 gram daily
- iii. Balsalazide 6.75 grams
- iv. Corticosteroid regimens:
  - a) Prednisone 40-60 mg daily
  - b) Oral budesonide 9 mg daily
  - c) Budesonide rectal; **or**
- v. Azathioprine 1.5-2.5 mg/kg daily
- vi. 6-mercaptopurine 1-1.5 mg/kg daily

F. **Moderate to Severe Crohn's Disease** – Use of first-line therapy including **one** of the following (This requirement will be waived for patients presenting with fistulizing and severe disease (as defined by the ACG guidelines)):

- i. 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**
- ii. Inability to taper off one of the corticosteroid regimens above; **or**
- iii. 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); **and**,

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, or dispensed by a specialty pharmacy if provided in an outpatient hospital 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; **and**,

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

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.

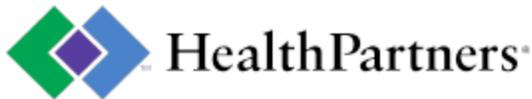
#### Requests for non-preferred infliximab products are generally not covered.

Patients currently treated with a non-preferred infliximab product must switch to a preferred product, Inflectra (infliximab-dyyb) or Renflexis (infliximab-abda).

Coverage for a non-preferred product may be authorized when all of the following are met:

- 1. Medical necessity has been demonstrated based on all coverage criteria above, **and**,
- 2. Member is stable on a non-preferred product without allergic reaction, and has a history of a documented allergic reaction to another infliximab product (note – infusion-related reactions and other side effects are common and not considered documented allergic reactions); **or**
- 3. Patient has used multiple infliximab products in the past, and a change to the preferred product would require a second switch (i.e., use of a third product).

Preferred	Non-Preferred
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Inflectra (infliximab-dyyb)	Remicade (infliximab)
Renflexis (infliximab-abda)	Avsola (infliximab-axxq)

## Definitions

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

Crohn's Disease:

- 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.
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

Pediatric Crohn's Disease:

- 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.

Ulcerative Colitis:

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis:

- 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.

Rheumatoid Arthritis in combination with methotrexate:

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.

Ankylosing Spondylitis:

- Reducing signs and symptoms in patients with active disease.

Psoriatic Arthritis:

- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.

Plaque Psoriasis:

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

Crohn's Disease:

- 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.
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

Pediatric Crohn's Disease:

- 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.

Ulcerative Colitis:

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis:

- 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.

Rheumatoid Arthritis in combination with methotrexate:

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.

Ankylosing Spondylitis:

- Reducing signs and symptoms in patients with active disease.

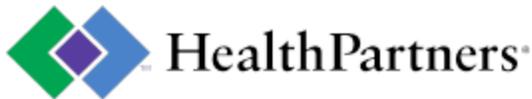
Psoriatic Arthritis:

- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.

Plaque Psoriasis:

- 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.

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



**Crohn's Disease:**

- 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.
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

**Pediatric Crohn's Disease:**

- 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.

**Ulcerative Colitis:**

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

**Pediatric Ulcerative Colitis:**

- 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.

**Rheumatoid Arthritis in combination with methotrexate:**

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.

**Ankylosing Spondylitis:**

- Reducing signs and symptoms in patients with active disease.

**Psoriatic Arthritis:**

- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.

**Plaque Psoriasis:**

- 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.

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

**Crohn's Disease:**

- 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.
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

**Pediatric Crohn's Disease:**

- 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.

**Ulcerative Colitis:**

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

**Pediatric Ulcerative Colitis:**

- 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.

**Rheumatoid Arthritis in combination with methotrexate:**

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.

**Ankylosing Spondylitis:**

- Reducing signs and symptoms in patients with active disease.

**Psoriatic Arthritis:**

- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage,



and improving physical function.

**Plaque Psoriasis:**

- 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.

**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.*

**HCPCS code**

Codes	Description
J1745	Injection, infliximab, excludes biosimilar, 10 mg (Remicade)
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg

**NDC code**

Codes	Description
57894003001	Remicade 100 MG Solution Reconstituted
00069080901	Inflectra 100 MG Solution Reconstituted
00006430501	Renflexis 100 MG Solution Reconstituted
00006430502	Renflexis 100 MG Solution Reconstituted
55513067001	Avsola 100 MG Solution Reconstituted

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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.

Approved by Pharmacy & Therapeutics Committee 12/1/2003; Revised 9/20/2005, 7/5/2006, 10/24/2006, 1/25/2007, 12/5/2008, 4/21/2009, 5/25/2011, 2/24/2012, 8/17/2015, 10/1/2016, 12/15/2016, 2/6/2017, 8/14/2017, 5/7/2018, 1/13/2020, 1/18/2021, 8/8/22; Annual Review 1/25/2007, 12/5/2008, 4/21/2009, 5/17/2010, 5/1/2011, 2/1/2012, 2/1/2013, 2/1/2014, 2/1/2015, 8/1/2015, 8/1/2016, 8/1/2017, 8/1/2018, 7/1/2019, 7/1/2020, 7/1/2021, 7/1/2023

**References**

1. Remicade Prescribing Information. Janssen Biotech, Inc. Horsham, PA; October 2017
2. Inflectra Prescribing Information. Pfizer Labs, New York, NY; June 2019
3. Renflexis Prescribing Information. Merck & Co., Inc, Kenilworth, NJ; June 2019
4. Avsola Prescribing Information. Amgen, Inc. One Amgen Center Drive, Thousand Oaks, CA 91320-1799. December 2019.