Pharmacy Management Drug Policy

SUBJECT: Remicade® (infliximab), Infliximab, Renflexis® (infliximab-abda), Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb)
POLICY NUMBER: PHARMACY-44
EFFECTIVE DATE: 08/2003
LAST REVIEW DATE: 11/12/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Infliximab (Remicade®/Inflectra®/Avsola®/Renflexis®) is a chimeric (murine-human) IgG1k monoclonal antibody produced by recombinant DNA technology by continuous perfusion and is purified by a series of steps that includes measures to inactivate and remove viruses. Remicade neutralizes the biological activity of tumor necrosis alpha (TNFα) by high-affinity binding and inhibits binding of TNFα with its receptors. Inhibiting the binding of TNFα to its receptors prevents the release of the pro-inflammatory cytokines that are involved in the body's immune and inflammatory responses.

A biosimilar is a biological product shown to be highly similar and has no differences from an existing FDA approved reference product (i.e., Remicade) by extensively analyzing the structure, purity, chemical identity, and bioactivity. It has been concluded that there are no clinically meaningful differences demonstrated through human pharmacokinetic / exposure and pharmacodynamic / responses, and assessment of immunogenicity. Biosimilars may be approved for all or a subset of the same indications as the reference product, depending on patent exclusivity. Biosimilars differ from generics in complexity, manufacturing processes, and in the data needed to demonstrate similarity for approval.

Table 1. FDA approved indications:

	Remicade/Infliximab	Inflectra	Renflexis	Avsola
AS	✓	✓	✓	✓
CD	✓	✓	✓	✓
Pediatric CD (6 years and older)	✓	✓	✓	✓
PS	✓	✓	✓	✓
PsA	✓	✓	✓	✓
RA	✓	✓	✓	✓
UC	✓	✓	✓	✓
Pediatric UC (6 years and older)	✓	✓	✓	✓

AS – Ankylosing Spondylitis; CD – Crohn's Disease; PS – Psoriasis; PsA – Psoriatic Arthritis; RA – Rheumatoid Arthritis; UC – Ulcerative Colitis

Table 2. Approved dosing

FDA Approved Indications and dosing	Induction	Maintenance
Ankylosing Spondylitis (≥18 years and older)	5 mg/kg at 0, 2 and 6 weeks followed by maintenance dosing	5 mg/kg every 6 weeks thereafter
Crohn's Disease* (≥ 6 years and older) **Ulcerative Colitis** (≥ 6 years and older) **Psoriatic Arthritis** (≥18 years and older) **Plaque Psoriasis** (≥18 years and older)		5 mg/kg every 8 weeks thereafter
Rheumatoid Arthritis+ (≥18 years and older)	3 mg/kg at 0, 2 and 6 weeks followed by maintenance dosing	3mg/kg every 8 weeks thereafter
Compendial supported indications and dosing		
Behcet's disease	5 mg/kg at 0, 2 and 6 weeks followed by maintenance dosing	5 mg/kg every 8 weeks thereafter
Hidradenitis Suppurativa	5mg/kg at 0, 2 and 6 weeks followed by ***2*** maintenance doses	5 mg/kg at week 14 and week 22
Noninfectious Uveitis	5mg/kg at 0, 2 and 6 weeks followed by maintenance dosing	5 mg/kg every 8 weeks thereafter

* For patients with Crohn's Disease who respond and then lose their response, consider treatment with 10 mg/kg IV every 8 weeks.
\+ For patients who have incomplete responses, consider adjusting the dose up to 10 mg/kg IV every 8 weeks OR treating as often as every 4 weeks.

Inflectra and Avsola are the preferred infliximab products and will be covered under the medical benefit without prior authorization for all lines of business.

Zymfentra (infliximab-dyyb) subcutaneous injection criteria: refer to Inflammatory Conditions CRPA.

Approval of Remicade, Infliximab, and Renflexis for new start and continuation use for existing users will require documentation of serious side effects or drug failure after adequate trials of Inflectra **AND** Avsola.

A. An adequate trial is defined as the following based on FDA approved dosing on Table 2:
   a. For infliximab naïve (new start) patients – Standard induction dosing and two dosing intervals (every 8 weeks, etc.)
   b. For existing infliximab users– Two dosing intervals (every 8 weeks, etc.)
B. This requirement applies to Medicare Advantage new start requests only
C. Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
D. Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate
E. Approved dosing referred to Table 2 as appropriate for the patient
F. Requested dosing must be consistent with FDA-approved or off-label/guideline-supported dosing recommendations
   a. A dosing regimen of greater than 10mg/kg at any frequency interval will not be authorized. A dosing regimen of less than every 4 weeks at any strength will not be authorized. Requests to increase both the dose and the frequency at the same time will not be authorized.

REMICADE (infliximab), INFLIXIMAB, RENFLEXIS (infliximab-abda) POLICY:

Based upon our assessment and review of the peer-reviewed literature infliximab has been medically proven to be effective and therefore, medically necessary for any of the following indications if all the following criteria are met:

I. Ankylosing Spondylitis
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**

b. Must be at least 18 years old **AND**
c. Must have a diagnosis of Ankylosing Spondylitis **AND**
d. Must have refractory disease defined by failure or at least two NSAIDs at maximum strength for at least 1 month each

II. Crohn's Disease

a. Must be prescribed by or in consultation with a Gastroenterologist **AND**
b. Must be at least 18 years old **AND**
c. Must have a diagnosis of moderately to severely active Crohn's Disease
d. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
   i. Treatment with a biologic medication as first-line therapy will be assessed on a case-by-case basis through a letter of medical necessity and clinical progress notes based on severity of the disease (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ilecolonic resection)

III. Plaque Psoriasis

a. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
b. The patient must be at least 18 years of age **AND**
c. The patient must have moderate to severe chronic plaque psoriasis that involves at least 10% of their body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
d. The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**i or ii**)
   i. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the aforementioned agents **OR**
   ii. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure).

IV. Psoriatic Arthritis

a. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist **AND**
b. Must be at least 18 years old **AND**
c. Must have a diagnosis of active Psoriatic Arthritis **AND**
d. Infliximab can be used with or without methotrexate.

V. Rheumatoid Arthritis

a. Must be prescribed by or in consultation with a Rheumatologist **AND**
b. Must be at least 18 years old **AND**
c. Must have a diagnosis of moderately to severely active Rheumatoid Arthritis **AND**
d. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
e. Must be used in combination with methotrexate. Consideration for the use without concurrent methotrexate may be given to patients who have a previous intolerance or contraindication to methotrexate therapy

VI. Ulcerative Colitis

a. Must be prescribed by or in consultation with a Gastroenterologist **AND**
b. Must have a diagnosis of moderately to severely active Ulcerative Colitis **AND**
c. Must be at least 6 years old **AND**
d. Must meet for ONE of the following (i or ii):
   i. Member must have failure or intolerance to at least ONE of the following conventional therapies for at least 3 months:
      a) Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
      b) 5-Aminosalicylates: Sulfasalazine, Mesalamine (asacol, colazol), Olsalazine
      c) IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
   ii. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema

The following are **non-FDA approved indications** which **may be considered medically appropriate:**

VII. Behcet's disease

a. Must be prescribed by or in consultation with a Rheumatologist **AND**
b. Member must have a confirmed diagnosis of Behcet's disease with ocular involvement (uveitis) **AND**
c. Member must be refractory to corticosteroids and at least one immunosuppressive agent

VIII. Hidradenitis Suppurativa

a. Must be prescribed by or in consultation with a Dermatologist **AND**
b. Member must have a diagnosis of stage II, stage III, or severe refractory hidradenitis suppurativa with recurrent abscesses **AND**
c. Member must have had a minimum of a three-month trial of systemic antibiotics (such as minocycline, doxycycline, clindamycin, or rifampin) which failed to provide clinical improvement

IX. Noninfectious Uveitis

a. Must be prescribed by or in consultation with a Rheumatologist or Ophthalmologist **AND**
b. Member must have a previous trial of ALL the following:
   i. A topical or injected ophthalmic steroid (unless contraindications are present)
   ii. An oral systemic steroid
   iii. An adequate trial of an immunosuppressive agent, such as but not limited to, azathioprine, mycophenolate, or methotrexate

APPROVAL TIME PERIODS:

Line of Business	Medical Initial approval (IV)	Medical Recertification (IV)
Commercial, Exchange, and Safety Net (Medicaid, HARP, CHP, Essential Plan)	1 year	1 year
Medicare Advantage	2 years	2 years

POLICY GUIDELINES:

1. Prior-authorization is contract dependent.
2. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.

4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
6. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required. The provider must make their intent to override a trial of the preferred drugs clear and must provide rationale and supporting documentation for one of the following:
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
7. A diagnosis of Irritable Bowel Disease associated arthritis will be evaluated using criteria for Ankylosing Spondylitis. Recent data suggest following dosing regimens developed for patients with Rheumatoid Arthritis. (Allowing dose increases above 5mg/kg.)
8. **Concurrent use of Inflammatory Agents**

   a. Remicade, Infliximab, Inflectra, Renflexis, or Avsola as well as other immunomodulating therapies or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) (Enbrel, Stelara, Cimzia, biosimilars, etc.) should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to the added risk of immunosuppression, potential for a higher rate of adverse effects, and lack of evidence for additive therapy. NOTE: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with biologics and targeted synthetic DMARDs.
   b. Requests for the concurrent use of inflammatory agents will be evaluated for safety and efficacy and subject to off-label review.
   c. Otezla/XR in combination with biologic DMARD therapy (such as adalimumab, Enbrel, Cosentyx, etc.) is not FDA approved or supported with a high level of clinically valid medical evidence for the treatment of plaque psoriasis or psoriatic arthritis. Therefore, these requests are considered combination therapy and are considered not medically necessary.

9. For New Starts, approval of Remicade, Infliximab, and Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola. An adequate trial is defined as:
   a. For infliximab naïve (new start) patients – Standard induction dosing and two dosing intervals (every 8 weeks, etc.)
   b. For patients who have previously received infliximab – Two dosing intervals (every 8 weeks, etc.)
10. Recertification for Remicade, Infliximab, and Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola (as described in #16).
   a. This requirement pertains to all FDA approved, compendia supported, and off-label indications
   b. This requirement **does not** apply to Medicare Advantage requests
11. All off-label uses of infliximab will be evaluated based on off-label policy criteria. If clinical criteria are met, then Inflectra and Avsola will be the required products.
12. For Medicare Advantage plans, the preferred product requirement only applies to patients who are new to therapy and will not affect patients who are currently established on therapy with non-preferred products.
13. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
14. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
15. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
16. The requested site of care may impact approval timeframe and subject to review.
17. Approval timeframes may be extended to align authorization periods for drugs administered as part of a multidrug regimen, including when regimen components are administered across different

benefits. This provision does not apply when the approval timeframe reflects a drug-specific limitation on duration of therapy.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. Codes may not be covered under all circumstances. Please read the policy and guideline statements carefully. Codes may not all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I). Not medically necessary/appropriate = (NMN).
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HCPCS:

Number	Description
J1745	Remicade/Infliximab
Q5103	Inflectra
Q5104	Renflexis
Q5121	Avsola

UPDATES:

Date	Revision
11/12/2026	Reviewed / P&T Committee Approval
09/14/2026	Revised
08/13/2026	Reviewed / P&T Committee Approval
06/01/2026	Revised
05/14/2026	Reviewed / P&T Committee Approval
02/12/2026	Reviewed / P&T Committee Approval
01/23/2026	Revised
11/19/2025	Revised
05/08/2025	Reviewed / P&T Committee Approval
04/01/2025	Revised
03/06/2025	Revised
02/17/2025	Revised
01/09/2025	Revised
01/01/2025	Revised
08/15/2024	Reviewed / P&T Committee Approval
06/28/2024	Revised
06/20/2024	Revised
06/04/2024	Revised
08/24/2023	P&T Committee Approval
03/15/2023	Revised
01/01/2023	Revised
11/2022	P&T Committee Approval
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02/2022	Revised
12/2021	Revised
09/2021	Reviewed/P&T Committee Approval
02/2021	Revised
01/2021	Revised
10/2020	Revised

09/16/2020	P&T Approval
08/2020	Revised
06/2020	Revised
01/2020	Revised
07/2019	Revised
06/2019	Annual Review
02/2019	Revised
09/2018	Revised
03/2018	Revised
01/2018	Revised
12/2017	Revised
08/2017	Revised
05/2017	P&T Approval
12/2016	Revised
05/2016	Revised
10/2015	Revised
12/2014	Revised
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10/2013	Revised
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07/2009	Revised
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