Pharmacy Management Drug Policy

SUBJECT: Remicade® (infliximab), Infliximab, Renflexis® (infliximab-abda)
POLICY NUMBER: PHARMACY-44
EFFECTIVE DATE: 08/2003
LAST REVIEW DATE: 08/24/2023

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:

Remicade®/Infliximab 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.

Inflectra® (infliximab-dyyb) is the first biosimilar monoclonal antibody (mAb) approved by the FDA. Analytical data demonstrates that it is highly similar in structure and function to Remicade. The FDA's decision follows the February 9, 2016 FDA Arthritis Advisory Committee's recommendation to approve proposed biosimilar infliximab across all eligible indications, by a vote of 21-3. Infliximab-dyyb products neutralize the biological activity of TNFα by binding with high affinity to the soluble and transmembrane forms of TNFα and inhibit binding of TNFα with its receptors. Inhibiting the binding of TNFα to its receptors prevents the release of the pro-inflammatory cytokines are involved in the body's immune and inflammatory responses.

Renflexis® (infliximab-abda) is the second biosimilar monoclonal antibody (mAb) approved by the FDA. Analytical data demonstrates that it is highly similar in structure and function to Remicade. Renflexis was approved by the FDA on April 21, 2017 for all eligible indications. Infliximab-abda products neutralize the biological activity of TN TNFα by binding with high affinity to the soluble and transmembrane forms of TNFα and inhibit binding of TNFα with its receptors. Inhibiting the binding of TNFα to its receptors prevents the release of the pro-inflammatory cytokines are involved in the body's immune and inflammatory responses.

Avsola™ (infliximab-axxq) is the third biosimilar monoclonal antibody (mAb) approved by the FDA. Analytical data demonstrates that it is highly similar in structure and function to Remicade. Avsola was approved by the FDA on December 6, 2019 for all eligible indications. Infliximab-abda products neutralize the biological activity of TN TNFα by binding with high affinity to the soluble and transmembrane forms of TNFα and inhibit binding of TNFα with its receptors. Inhibiting the binding of

TNFα to its receptors prevents the release of the pro-inflammatory cytokines are involved in the body's immune and inflammatory responses.

For a biological product to be labeled as a biosimilar, it must be shown that it is 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.

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

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

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:

- For infliximab naïve (new start) patients – Standard induction dosing and two dosing intervals (every 8 weeks, etc.)
- For patients who have previously received infliximab – Two dosing intervals (every 8 weeks, etc.)

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. Member must be followed by, and the drug prescribed a rheumatologist or a recognized expert with treatment in inflammatory back pain **AND**
b. There must be presence of refractory disease defined by failure or at least two NSAIDs at maximum strength for at least 1 month each **AND**
c. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
d. Infliximab dosing will be authorized for ankylosing spondylitis (AS) as 5mg/kg at weeks 0, 2, and 6, and every 6 weeks thereafter

e. Dosing for arthritis associated with gastrointestinal disease may be dosed similar to Rheumatoid Arthritis regimens.
f. Recertification for Remicade, Infliximab, or Renflexis, will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

II. Crohn's Disease

a. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
    i. Moderate to severe disease - Crohn's Disease Activity Index (CDAI) score of 220-450, typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting, or significant anemia **AND**
b. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated **AND**
c. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
d. Authorization Period and Limitations for patients with Crohn's Disease:
    i. **Initial therapy:** A maximum of 4 infusions in a 4-month period may be authorized when criteria are met. The recommended initial dose for adult and pediatric patients aged 6 and older is 5mg/kg administered at weeks 0, 2, and 6 and then every 8 weeks thereafter. Patients who do not respond by week 14 are unlikely to respond to continued dosing and consideration should be given to discontinue infliximab in these patients.
    ii. **Dose Escalation:** For patients who respond and then lose their response, consideration may be given to increase either the dose or the frequency. Requests to increase both the dose and the frequency at the same time will not be authorized. 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.
e. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

III. Plaque Psoriasis

a. The patient must be actively followed by, and the drug prescribed by 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 (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months 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 above-mentioned agents
    i. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
        1. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
        2. PUVA in combination with topical corticosteroids **OR**
        3. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
e. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
f. Infliximab dosing will be authorized for plaque psoriasis as 5 mg/kg at 0, 2, 6 weeks followed by maintenance therapy every 8 weeks.
g. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

IV. Psoriatic Arthritis

a. Member must be actively followed by, and the drug prescribed by a dermatologist or rheumatologist **AND**
b. Member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present **AND**
c. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
d. Infliximab dosing will be authorized at a dose of 5mg/kg at weeks 0, 2, and 6 weeks and then every 8 weeks thereafter. Infliximab can be used with or without methotrexate.
e. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

V. Rheumatoid Arthritis

a. Member must be actively followed by, and the drug prescribed by a rheumatologist **AND**
b. Member must have had failure to methotrexate alone at a minimum dose of 12.5 – 15mg weekly after at least a 12-week period **AND**
c. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola **AND**
d. Member must be receiving concomitant methotrexate therapy (at least 7.5mg to 10mg per week) and will continue methotrexate therapy (at least 7.5mg to 10mg per week) for the duration of infliximab use
    i. **Note**: For patients that have a contraindication to or documented side effects to methotrexate the expectation is that infliximab will NOT be used as monotherapy. Alternative DMARDs (leflunomide, hydroxychloroquine, sulfasalazine, etc.) can be used in place of methotrexate. Each case will be reviewed individually, and the facts and merits of each case will be fully considered.
e. Authorization Period and Limitations for Patients with Rheumatoid Arthritis
    i. **Initial therapy**: A maximum of 5 infusions in a 6-month period may be authorized when criteria are met. Note: The recommended initial dose is 3mg/kg administered at weeks 0, 2, and 6 and then every 8 weeks thereafter.
    ii. **Continued therapy**:
        1. After the initial 6 months of therapy, a maximum of 7 infusions in a 1-year period may be authorized when documentation (including chart notes) indicates that there is disease stability or improvement **OR**
        2. A maximum of 6 infusions in a 6-month period may be considered medically necessary for patients who have had an incomplete response to administration (up to 10 mg/kg) every 8 weeks. NOTE: Available data do NOT support increasing both the dose (to 10 mg/kg) **AND** dosing frequency (to every 4 weeks) at the same time. 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.
f. Low disease activity or remission should be considered treatment targets for members receiving infliximab. Members with moderate or high disease activity >3 months due to lack of or loss of benefit should discontinue infliximab and switch to another biologic agent.
g. Members with high disease activity who fail infliximab therapy due to a serious adverse effect should switch to a non-TNF biologic. Member with moderate or high disease activity who fails infliximab therapy due to non-serious adverse effects should switch to another TNF-blocker or a non-TNF biologic agent.
h. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

VI. Ulcerative Colitis

a. Member must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
b. Member must have failure or intolerance to at least ONE of the following conventional therapies for at least 3 months:
    i. Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
    ii. 5-Aminosalicylates: Sulfasalazine, Mesalamine (asacol, colazol), Olsalazine
    iii. Cyclosporine
    iv. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required **AND**
c. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
d. Infliximab dosing will be authorized for UC as 5 mg/kg at 0, 2, and 6 weeks and every 8 weeks thereafter.
e. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

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

VII. Behcet's disease

a. Member must have a confirmed diagnosis of Behcet's disease with ocular involvement (uveitis) **AND**
b. Member must be actively followed by, and the drug prescribed by a rheumatologist **AND**
c. Member must be refractory to corticosteroids and at least one immunosuppressive agent **AND**
d. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
e. Initial dosing will be authorized at 5mg/kg. The typical schedule of weeks 0, 2, and 6 and then every 8 weeks thereafter is common regimen associated with this disease state.
f. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

VIII. Hidradenitis Suppurativa

a. Member must be actively followed by, and the drug prescribed by 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 **AND**

d. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
e. Initial approval will be for 6 months - 5 infusions of 5mg/kg week 0, week 2 and week 6: then maintenance doses at week 14 and week 22. Recertification will require progress notes showing a therapeutic response to initial dosing, and if approvable, will be authorized for 5 years per MSD guidelines.
f. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

IX. Noninfectious Uveitis

a. Member must be actively followed by, and the drug prescribed by 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 **AND**
c. Member must have documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
d. Initial approval will be for 6 months – 5mg/kg IV infusion at weeks 0, 2, 6 – then a maintenance dose of 5 mg/kg IV infusion every 8 weeks thereafter. Recertification will require progress notes showing a therapeutic response to initial dosing, and if approvable, will be authorized for 5 years per MSD guidelines.
e. Recertification for Remicade, Infliximab, or Renflexis will require documentation of serious side effects or drug failure after adequate trials of Inflectra AND Avsola
    - This requirement is not applicable to Medicare Advantage requests
    - Please see policy guidelines #3 for exceptions to this requirement for applicable Commercial contracts
    - Provider must provide clear rationale as to why Inflectra and Avsola are not appropriate

APPROVAL TIME PERIODS:

Line of Business	Medical Initial approval (IV)	Medical Recertification (IV)
Commercial, Exchange, and Safety Net (Medicaid, HARP, CHP, Essential Plan)	All sites of service: 1 year	All sites of service: 1 year
Medicare Part B	All sites of service: 2 years	All sites of service: 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. The drugs in this policy may apply to all other lines of business including Medicare Part B
4. For members with Medicare Part B, 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.

4. The patient has no contraindications to the use of infliximab, including:
    a. Class III or IV CHF, or in subjects with an ejection fraction less than 50%
    b. Patient must be free of clinically important active infection.
    c. Infliximab should not be administered to patients with known hypersensitivity to any murine proteins or other components of the product.
5. Infliximab carries a Black Box Warning for risk of infection. Tuberculosis, invasive fungal infections, and other opportunistic infections have been observed in patients receiving infliximab.
6. All patients should be evaluated for latent tuberculosis with a tuberculin skin test. Treatment of latent tuberculosis infection should be initiated prior to therapy with Infliximab. Annual testing is recommended for patients who live, travel, or work in situations where tuberculosis exposure is likely.
7. Caution should be exercised in patients with a clinically important chronic infection or a history of recurrent infection.
8. Rare post-marketing cases of hepatosplenic T-cell lymphoma have been reported in adolescent and young adults with Crohn's disease treated with Infliximab. All these cases have occurred in patients on concomitant treatment with azathioprine or mercaptopurine.
9. Severe hepatic reactions including acute liver failure, jaundice, hepatitis, and cholestasis have been reported in post marketing data. This has occurred between 2 weeks to more than 1 year after initiation of therapy. Patients with signs or symptoms of liver dysfunction should be evaluated for liver injury if jaundice and/ or marked liver enzyme elevations (≥ 5 x upper limit of normal) develops. Infliximab should be discontinued, and a thorough investigation of the abnormality should be undertaken.
10. Infliximab has been associated with the reactivation of chronic hepatitis B in patients who are chronic carriers of the virus. Chronic carriers should be appropriately evaluated and monitored prior to the initiation of therapy. Patients with psoriasis who are candidates for anti-TNF therapy should undergo hepatitis B screening prior to initiating therapy. Patients who are seropositive for hepatitis B surface antigen with inactive disease should undergo a course of antiviral therapy 2 – 4 weeks prior to initiation of anti-TNF therapy.
11. Safety and efficacy of Infliximab products in juvenile rheumatoid arthritis has not been established. The merits of each case will be evaluated individually.
12. Involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis all help to distinguish psoriatic arthritis from other inflammatory arthritis, including RA.
13. 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.)
14. **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 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.
15. Patients should not receive live attenuated herpes zoster vaccine while receiving anti-TNF therapy.
16. 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.)
17. 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
18. 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.
19. 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.

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).

HCPCS:

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

UPDATES:

Date	Revision
08/24/2023	P&T Committee Approval
03/15/2023	Revised
01/01/2023	Revised
11/2022	P&T Committee Approval
9/2022	P&T Committee Approval

02/2022	Revised
12/2021	Revised
09/2021	Reviewed/P&T Committee Approval
02/2021	Revised
01/2021	Revised
10/2020	Revised
9/16/2020	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
12/2013	Revised
10/2013	Revised
08/2013	Revised
02/2013	Reviewed
11/2011	Revised
10/2010	Revised
06/2010	Revised
07/2009	Revised
05/2009	Revised

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