Policy Title:	Infliximab IV Products: Remicade, Renflexis, Infliximab (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	09/18/2019, 12/20/2019, 1/22/2020, 8/5/2021, 1/20/2022, 2/10/2022, 3/02/2023, 8/10/23, 12/7/2023, 01/04/2024, 02/14/2014, 05/08/2024, 1/22/2025, 08/17/2026		

Purpose: To support safe, effective, and appropriate use of Infliximab.

Scope: Medicaid*, Commercial, Medicare
*(Intravenous infliximab products only available on the Medical Benefit)

Policy Statement:

Infliximab is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process. This policy applies to Infliximab therapies including, but not limited to, the following: Remicade, and Renflexis. Please see Appendix A for Neighborhood's Site of Care Policy as it relates to Remicade and Renflexis. The Site of Care Policy will be effective as of February 1, 2022.

Procedure:

Coverage of (Infliximab) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

The safety and efficacy of Remicade, and Renflexis was based on clinical trial data from Infliximab. Infliximab is a tumor necrosis factor (TNF) blocker indicated for reducing signs and symptoms of Crohn's disease 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, reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy, reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active UC disease who have had an inadequate response to conventional therapy, reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active UC disease who have had an inadequate response to conventional therapy, reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active Rheumatoid Arthritis, reducing signs and symptoms in patients with active Ankylosing Spondylitis, reducing signs and symptoms of active Psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function and 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

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appropriate. The safety and efficacy of Infliximab for treating various forms of inflammatory bowel diseases (IBD) were assessed through multiple clinical studies. For Crohn's Disease, studies showed that Infliximab (5 mg/kg) significantly improved clinical response and remission compared to placebo. In the multidose trial (ACCENT I), 5 mg/kg and 10 mg/kg Infliximab maintenance groups showed sustained remission and longer response durations compared to placebo. Similarly, for fistulizing Crohn's Disease, Infliximab resulted in higher rates of fistula response and closure compared to placebo, with longer durations of response observed in maintenance groups. In pediatric Crohn's disease, Infliximab also demonstrated substantial clinical response and remission, with better outcomes for patients receiving maintenance doses every 8 weeks.

For ulcerative colitis (UC), Infliximab (5 or 10 mg/kg) was more effective than placebo in achieving clinical response, remission, and mucosal healing, with significant benefits in patients who were on corticosteroids at baseline. In pediatric UC patients, Infliximab showed promising results in reducing symptoms and inducing clinical remission. The safety and efficacy of Infliximab (Infliximab) have also been evaluated in several randomized, multicenter, double-blind, placebo-controlled studies across different conditions, including rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic arthritis (PsA), and plaque psoriasis. In rheumatoid arthritis, the ATTRACT and ASPIRE studies demonstrated that Infliximab, when used in combination with methotrexate (MTX), led to significant improvements in signs and symptoms as measured by the American College of Rheumatology (ACR) response criteria (ACR 20, 50, and 70), with patients achieving better clinical responses compared to placebo.

In ankylosing spondylitis, a study involving 279 patients demonstrated that Infliximab (5 mg/kg) significantly improved disease activity, as measured by the ASAS 20 response, with 60% of patients showing improvement compared to 18% in the placebo group.

For psoriatic arthritis, a study of 200 patients with active disease despite DMARD or NSAID therapy revealed that Infliximab (5 mg/kg) resulted in significant clinical improvements, with higher ACR response rates (ACR 20, 50, and 70) compared to placebo. Additionally, Infliximab treatment resulted in significant reductions in dactylitis, enthesopathy, and radiographic progression, with fewer patients showing structural damage.

In plaque psoriasis, Infliximab was tested in three studies involving patients with chronic, stable disease. In the EXPRESS study, 85% of patients on 5 mg/kg Infliximab achieved PASI 75 at Week 10 compared to only 4% of those receiving placebo. Similar results were observed in the EXPRESS II and SPIRIT studies, with significant PASI improvements observed at Week 10 in patients treated with Infliximab, particularly in those with more extensive disease. Common adverse events include infections (e.g. upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

Initial Criteria:

- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Only one formulation of infliximab will be used (intravenous or subcutaneous); AND
- If the member is requesting J1745 (Remicade or infliximab unbranded), the member must have failure or intolerable side effects to Inflectra or Avsola AND Renflexis; AND

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- If the member is requesting Renflexis, the patient must have failure or intolerable side effects to Inflectra or Avsola; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND
- Member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Infliximab will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g. Hadlima), Enbrel (etanercept), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek), Icotyde (icotrokinra), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.)

Crohn's disease (CD):

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member is 18 years of age or older; AND
- Member has documented moderate to severe disease

Pediatric Crohn's disease (CD):

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member is at least 6 years of age; AND
- Member has documented moderate to severe disease

Ulcerative Colitis (UC):

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member 18 years of age or older; AND
- Member has documented moderate to severe disease

Pediatric Ulcerative Colitis (UC):

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member is at least 6 years of age; AND
- Member has documented moderate to severe disease

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Fistulizing Crohn's Disease:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member is 18 years of age or older; AND
- Member has at least one or more draining fistulas (i.e., enterovesical, enterocutaneous, enteroenteric, or enterovaginal fistulas) for at least 3 months

Rheumatoid Arthritis (RA):

- Must be prescribed by, or in consultation with, a specialist in rheumatology; AND
- Member is 18 years of age or older AND
- Member has documented moderate to severe active disease; AND
- Documentation has been submitted of one of the following criteria:
    - Member has been tested for either of the following biomarkers and the test was positive:
        - Rheumatoid factor (RF)
        - Anti-cyclic citrullinated peptide (anti-CCP); OR
    - Member has been tested for ALL of the following biomarkers:
        - RF
        - Anti-CCP
        - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR); AND
- Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of methotrexate or any other conventional synthetic DMARD despite adequate dosing; AND
- Prescribed in in combination with methotrexate (MTX) unless contraindicated.

Psoriatic Arthritis (PsA):

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- Member is 18 years of age or older; AND
- Documentation has been submitted indicating one of the following criteria:
    - Member has mild to moderate disease and meets one of the following criteria:
        - Member has had an inadequate response, intolerance, or contraindication to methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.) despite adequate dosing; OR
        - Member has enthesitis or predominantly axial disease; OR
    - Member has severe disease.

Ankylosing Spondylitis (AS):

- Must be prescribed by, or in consultation with, a specialist in rheumatology; AND
- Member is 18 years of age or older; AND
- Member has documented active disease; AND

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- Documentation has been submitted that the member had an inadequate response, intolerance, or contraindication to at least TWO (2) NSAIDs

Plaque Psoriasis (PsO):

- Must be prescribed by, or in consultation with, a specialist in dermatology;
- Member is 18 years of age or older; AND
- Member has documented moderate to severe plaque psoriasis with at least one of the following:
    - BSA affected is at least 10%; OR
    - Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
    - Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene); AND
- Documentation has been submitted that the member meets any of the following criteria:
    - Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine, or acitretin); OR
    - Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
    - Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy.

Management of Immune Checkpoint Inhibitor related diarrhea/colitis

- Member is 18 years of age or older; AND
- Prescribed by, or in consultation with, a specialist in gastroenterology, hematology, or oncology; AND
- Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, tremelimumab, dostarlimab, retifanlimab, etc.); AND
    - Member has mild (G1) diarrhea or colitis related to their immunotherapy with persistent or progressive symptoms and a positive lactoferrin/calprotectin; OR
    - Member has moderate (G2) to severe (G3-4) diarrhea or colitis related to their immunotherapy; AND
- Member has had an inadequate response, intolerance, or contraindication to systemic corticosteroids

Continuation of Therapy Criteria:

- Member meets all initial criteria, including trials of biosimilar agent(s); AND
- Member is tolerating medication; AND

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- Crohn's Disease: Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra-intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].
- Pediatric Crohn's Disease: Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra-intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Pediatric Crohn's Disease Activity Index (PCDAI) score or the Harvey-Bradshaw Index score].
- Ulcerative Colitis: Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].
- Pediatric Ulcerative Colitis: Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Pediatric Ulcerative Colitis Activity Index (PUCAI) score or the Mayo Score].
- Fistulizing Crohn's Disease: Disease response as indicated by improvement in signs and symptoms compared to baseline such as a reduction in number of enterocutaneous fistulas draining upon gentle compression, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].
- Psoriatic Arthritis: Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g., defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria].
- Rheumatoid Arthritis: Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g., an improvement on a composite scoring index such as Disease

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Activity Score-28 (DAS28) of 1.2 points or more or a ≥20% improvement on the American College of Rheumatology-20 (ACR20) criteria].

- Ankylosing Spondylitis: Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, morning stiffness, and/or an improvement on a disease activity-scoring tool [e.g., ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)].
- Plaque Psoriasis: Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement ≤1%), and/or an improvement on a disease activity scoring tool [e.g., a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and a four-point reduction in the DLQI from when treatment started.]
- Management of Immune Checkpoint Inhibitor related diarrhea/colitis: May not be renewed.

Coverage Duration:

- Initial coverage criteria = 6 months
- Continuation of therapy = 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Remicade and Renflexis were reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Remicade or Renflexis according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

APPENDIX A

Appendix A: Site of Care Policy

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Purpose: This policy will specify member and drug inclusion and exclusion criteria for the Site of Care program.
Policy Statement: The Site of Care program allows members to obtain certain provider-administered medications at a location outside of the hospital outpatient facility when clinically appropriate. Evidence-based guidelines support the administration of injectable medications in alternative sites of care including in the home (via a home infusion provider). Administration of the injectable medications subject to this policy at alternate sites of care is based upon the professional judgment of the provider and Neighborhood takes into account the clinical appropriateness for each individual patient. Requests for drugs listed in this policy will be assessed for meeting medical necessity based on the clinical documentation provided by the requesting practitioner.

Procedure: Medications identified in this policy are subject to meeting medical necessity standards. This policy applies to those 18 years of age and older. Once it is determined that medical necessity standards are met for the medication, Neighborhood will assess for appropriateness of Site of Care administration. Each case will be addressed on an individual basis. Hospital outpatient facility administration may be considered medically necessary if ANY of the following criteria are present to indicate the patient is medically unstable for infusions in settings other than an outpatient facility setting:

- Member's home is considered unsuitable for care by the home infusion provider; or
- Member's medical status requires enhanced monitoring beyond that which would be routinely required for infusion therapy or able to be provided by a home infusion provider; or
- Previous severe adverse reaction (including but not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) during or following administration of prescribed medication despite standard pre-medication AND must be provided in written documentation; OR
- Member is receiving other medications that require close monitoring with a higher level of care (e.g., cytotoxic chemotherapy or blood products); OR
- Member is at high risk for complications due to medication administration (e.g., at risk for post-transplant complications, increased risk of infusion reactions due to presence of circulating antibodies, unstable vascular access, cardiopulmonary condition at risk for severe adverse reactions, unstable renal function with inability to safely tolerate IV volume loads, etc.); OR
- Member is initiating therapy or re-initiating therapy after a period of at least 6 months with no therapy; OR
- Physically AND/OR cognitively impaired AND a home caregiver is not available to comply with the required treatment regimen and schedule.

If it is determined that the patient is not suited for medication administration in the home, Neighborhood reserves the right to have the medication purchased through a Specialty Pharmacy which will directly deliver the medication to the hospital pharmacy/facility that is administering the medication. In this scenario, the Specialty Pharmacy will bill Neighborhood for the cost of the medication, not the facility.

If initial infusions of a medication were administered in an outpatient facility, subsequent maintenance doses will be authorized in the home setting through a home infusion provider. ***

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***The timeframe of administration allowed at the outpatient facility is subject to change as recommended by the member's provider in consultation with Neighborhood's Pharmacy Department.

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Dosing and Maximum units:

Indication	Loading doses	Maximum units for loading dose	Maintenance dosing	Maximum units for maintenance dosing	Maximum dose and frequency
Rheumatoid Arthritis	3 mg/kg at weeks 0, 2, & 6	40 billable units at weeks 0, 2, 6	3 mg/kg every 8 weeks thereafter	100 billable units every 4 week	Up to 10 mg/kg every 4 weeks
Ankylosing Spondylitis	5 mg/kg at weeks 0, 2, & 6	60 billable units at weeks 0, 2, 6	5 mg/kg every 6 weeks thereafter	60 billable units every 6 weeks	5 mg/kg every 6 weeks
Crohn's Disease	5 mg/kg at weeks 0, 2, & 6	60 billable units at weeks 0, 2, 6	5 mg/kg every 8 weeks thereafter	100 billable units every 8 weeks	Up to 10 mg/kg every 8 weeks
Ulcerative Colitis	5 mg/kg at weeks 0, 2, & 6	60 billable units at weeks 0, 2, 6	5 mg/kg every 8 weeks thereafter	100 billable units every 8 weeks	Up to 10 mg/kg every 8 weeks
Psoriatic Arthritis	5 mg/kg at weeks 0, 2, & 6	60 billable units at weeks 0, 2, 6	5 mg/kg every 8 weeks thereafter	60 billable units every 8 weeks	5 mg/kg every 8 weeks
Plaque Psoriasis	5 mg/kg at weeks 0, 2, & 6	60 billable units at weeks 0, 2, 6	5 mg/kg every 8 weeks thereafter	60 billable units every 8 weeks	5 mg/kg every 8 weeks

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The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J1745	Injection, infliximab, excludes biosimilar, 10mg (Remicade, includes unbranded biologic)
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10mg

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