

Policy Title:	Infliximab Products: Remicade, Renflexis, Inflectra, Avsola, 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		

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

Scope: Medicaid*, Commercial, Medicare-Medicaid Plan (MMP)

*(Medication 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, Renflexis, Avsola and Inflectra. Please see Appendix A for Neighborhood’s Site of Care Policy as it relates to Infliximab products. 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.

Initial Criteria:

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements;OR
- If the patient is requesting J1745 (Remicade or infliximab unbranded), the patient must have failure or intolerable side effects to Inflectra or Avsola AND Renflexis; AND
- If the patient is requesting Renflexis, the patient must have failure or intolerable side effects to Inflectra or Avsola; AND
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; AND
- Patient does not have an active infection, including clinically important localized infections; AND
- Must not be administered concurrently with live vaccines; AND
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib); AND
- Dosing and frequency is within FDA guidelines; AND

- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND

Crohn's disease:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Adult patient (18 years or older); AND
- Documented moderate to severe disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate).

Pediatric Crohn's disease:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Patient is at least 6 years of age; AND
- Documented moderate to severe disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, etc.).

Ulcerative Colitis:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Adult patient (18 years or older); AND
- Documented moderate to severe disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate).

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- Patient is at least 6 years of age; AND
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- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, etc.).

Fistulizing Crohn's Disease:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Adult patient (18 years or older); AND

- Patient 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
- Patient is 18 years of age or older AND
- Documented moderate to severe active disease; AND
- Patient has had at least a 3-month trial and failed previous therapy with ONE formulary oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine hydroxychloroquine, sulfasalazine, leflunomide, etc; AND
- Prescribed in combination with methotrexate (MTX) unless contraindicated.

Psoriatic Arthritis:

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- Patient is 18 years of age or older; AND
- Documented moderate to severe active disease; AND
 - For patients with predominantly axial disease OR active enthesitis, a trial and failure of at least a 4 week trial of ONE (1) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
 - For patients with peripheral arthritis or dactylitis, a trial and failure of at least a 3-month trial of ONE formulary oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine.

Ankylosing Spondylitis:

- Must be prescribed by, or in consultation with, a specialist in rheumatology; AND
- Patient is 18 years of age or older; AND
- Documented active disease; AND
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs) over 4 weeks (in total) unless use is contraindicated.

Plaque Psoriasis:

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology;
- Adult patient (18 years or older); AND
- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
 - Involvement of at least 10% of body surface area (BSA); OR

- Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR
- Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritus” AND
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least one non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); OR
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of phototherapy [i.e., psoralens with UVA light (PUVA) or UVB with coal tar].

Continuation of therapy Criteria:

- Patient meets all initial criteria, including trials of biosimilar agent(s); AND
- Patient is tolerating medication; AND
- 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 Activity Score-28 (DAS28) of 1.2 points or more or a $\geq 20\%$ 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 $\leq 1\%$), 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.]

Coverage duration:

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

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

APPENDIX A

Appendix A: Site of Care Policy

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, and 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:

- Patient's home is considered unsuitable for care by the home infusion provider; or
- Patient'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
- Patient is receiving other medications that require close monitoring with a higher level of care (e.g., cytotoxic chemotherapy or blood products); or
- Patient 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
- Patient 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. ***

***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	5 mg/kg every 8 weeks thereafter	100 billable units every 8 weeks	Up to 10 mg/kg every 8 weeks

		weeks 0, 2, 6			
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

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J1745	Injection, infliximab, excludes biosimilar, 10mg (Remicade, includes unbranded biologic)
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10mg

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