

Policy Title:	Infliximab (Remicade, Renflexis, Inflectra)		
Policy Number:	000662	Department:	PHA
Effective Date:	07/01/2019		
Review Date:	02/13/2019		
Revision Date:	09/13/17, 4/19/19		

Purpose: To support appropriate use of Infliximab.

Scope: Medicaid, Exchange, Integrity

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 and Inflectra.

Procedure:

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

Initial Criteria coverage for Medicaid and Exchange:

- If the patient is requesting Remicade, the patient must have failure or intolerable side effects to both Inflectra AND Renflexis;
- If the patient is requesting Renflexis, the patient must have failure or intolerable side effects to Inflectra;
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment;
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment;
- Patient does not have an active infection, including clinically important localized infections;
- Must not be administered concurrently with live vaccines;
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast tofacitinib, baricitinib);
- Dosing and frequency* is within FDA guidelines;
- 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;
- Adult patient (18 years or older);
- Documented moderate to severe disease;
- 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;
- Patient is at least 6 years of age;
- Documented moderate to severe disease;
- 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;
- Adult patient (18 years or older);
- Documented moderate to severe disease;
- 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 Ulcerative Colitis:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology;
- Patient is at least 6 years of age;
- Documented moderate to severe disease;
- 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;
- Adult patient (18 years or older);
- 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).

Rheumatoid Arthritis (RA):

- Must be prescribed by, or in consultation with, a specialist in rheumatology;
- Adult patient (18 years or older);
- Documented moderate to severe disease;
- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, or leflunomide;
- Used in combination with methotrexate (MTX) unless contraindicated.

Psoriatic Arthritis:

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology;
- Adult patient (18 years or older);
- Documented moderate to severe active disease; AND
 - For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
 - For patients with peripheral arthritis, a trial and failure of at least a 3 month trial of ONE 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;
- Adult patient (18 years or older);
- Documented active disease;
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal antiinflammatory agents (NSAIDs), 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);
- 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 due to plaque location (i.e. head and neck, palms, soles or genitalia);

- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues);
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least one systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate);
- 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 or dithranol).

Initial Criteria Coverage for Integrity ONLY:

- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment;
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment;
- Patient does not have an active infection, including clinically important localized infections;
- Must not be administered concurrently with live vaccines;
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast tofacitinib, baricitinib);
- Dosing and frequency* is within FDA guidelines;
- 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;
- Adult patient (18 years or older);
- Documented moderate to severe disease;
- 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;
- Patient is at least 6 years of age;
- Documented moderate to severe disease;
- 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;
- Adult patient (18 years or older);
- Documented moderate to severe disease;

- 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 Ulcerative Colitis:

- Must be prescribed by, or in consultation with, a specialist in gastroenterology;
- Patient is at least 6 years of age;
- Documented moderate to severe disease;
- 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;
- Adult patient (18 years or older);
- 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).

Rheumatoid Arthritis (RA):

- Must be prescribed by, or in consultation with, a specialist in rheumatology;
- Adult patient (18 years or older);
- Documented moderate to severe disease;
- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, or leflunomide;
- Used in combination with methotrexate (MTX) unless contraindicated.

Psoriatic Arthritis:

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology;
- Adult patient (18 years or older);
- Documented moderate to severe active disease; AND

- For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
- For patients with peripheral arthritis, a trial and failure of at least a 3 month trial of ONE 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;
- Adult patient (18 years or older);
- Documented active disease;
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal antiinflammatory agents (NSAIDs), 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);
- 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 due to plaque location (i.e. head and neck, palms, soles or genitalia);
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues);
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least one systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate);
- 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 or dithranol).

Renewal Criteria for Medicaid and Exchange:

- Patient meets all initial criteria, including trials of biosimilar agent(s);
- Patient is tolerating medication;
- 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 HarveyBradshaw 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.]

Renewal Criteria for Integrity ONLY:

- Patient meets all initial criteria;
- Patient is tolerating medication;
- 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 HarveyBradshaw 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 = 6 months

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 weeks	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

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J1745	Injection, infliximab, excludes biosimilar, 10mg (Remicade)
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg

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