Inflectra® (infliximab-dyyb)
Remicade® (infliximab)
Renflexis® (infliximab-abda)
Effective 02/20/19

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active Crohn's disease
2. Moderately to severely active Ulcerative colitis
3. Moderately to severely active Rheumatoid arthritis in combination with methotrexate
4. Active Ankylosing spondylitis
5. Active Psoriatic arthritis
6. Chronic severe Plaque psoriasis

Compendial Uses

1. Axial spondyloarthritis
2. Behcet's syndrome
3. Granulomatosis with polyangiitis (Wegener's granulomatosis)
4. Hidradenitis suppurativa
5. Juvenile idiopathic arthritis
6. Pyoderma gangrenosum
7. Sarcoidosis
8. Takayasu's arteritis
9. Uveitis

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Rheumatoid arthritis (RA), Ankylosing spondylitis (AS), or Psoriatic arthritis (PsA)
Authorization may be granted for members with a diagnosis of RA, AS, or PsA when ALL the following criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following*:
    a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication
    c. Note: *DMARD trial is not required in members with active Ankylosing spondylitis or Psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs.
2. Dosing is appropriate (see appendix A).
3. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira (i.e., member has had an inadequate response, adverse reaction, or contraindication to Enbrel **AND** Humira).

Moderate-severe plaque psoriasis
Authorization may be granted for members with a diagnosis of moderate-severe plaque psoriasis when ALL the following criteria are met, and documentation is provided:

1. Member is ≥18 years of age.
2. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
        i. 1 topical agent + 1 systemic agent
        ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
        iii. 1 systemic agent + 1 phototherapy
        iv. 2 systemic agents
    b. Contraindication to ALL conventional therapies
        i. Topical agents
        ii. Phototherapy
        iii. Systemic agents
    c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis
3. Dosing is appropriate (see appendix A).
4. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira (i.e., member has had an inadequate response, adverse reaction, or contraindication to Enbrel **AND** Humira)

Crohn's disease
Authorization may be granted for members with a diagnosis of Crohn's disease when ALL the following criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following:

a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
    i. Aminosalicylate
    ii. Antibiotic
    iii. Corticosteroid
    iv. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
        1. Note: * If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.
b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

2. Dosing is appropriate (see appendix A).
3. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira (i.e., has had an inadequate response, adverse reaction, or contraindication to Enbrel AND Humira).

Fistulizing Crohn's disease
Authorization may be granted for members with a diagnosis of fistulizing Crohn's disease when ALL the following criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction or contraindication to ONE immunomodulator (e.g., azathioprine or 6-mercaptopurine)
    b. Clinical rationale for use over oral immunomodulator (e.g., medical necessity for a faster-acting agent such as severe/refractory perianal disease, recent or planned surgical resection)
    c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for Crohn's disease
2. Dosing is appropriate (see appendix A).

Ulcerative colitis
Authorization may be granted for members with a diagnosis of ulcerative colitis when ALL the following criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
        i. Aminosalicylate
        ii. Corticosteroid
        iii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
            1. Note: * If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication
2. Dosing is appropriate (see appendix A for dosing).
3. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira (i.e., member has had an inadequate response, adverse reaction, or contraindication to Enbrel AND Humira).

Continuation of Therapy
Reauthorization requires physician documentation indicating a positive response to therapy.

Limitations

1. Initial approvals will be varied based on the treatment:
    a. **For RA, AS/PsA, CD, UC,** approvals will be for 6 months.
    b. **For plaque psoriasis,** approvals will be for 3 months.
2. Reauthorizations will be for 12 months

Appendices

Appendix A: Dosing

	Pediatric Dosing	Other Dosing
Remicade® (infliximab)	**Crohn's Disease (moderate-severe) in patients with inadequate response to conventional therapy (≥ 6 years old):** 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks **Ulcerative colitis (≥ 6 years old):** 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks	**Ankylosing spondylitis:** 5 mg/kg IV at weeks 0, 2, and 6, then every 6 weeks **Crohn's disease-fistulizing or moderate-severe not responding to conventional treatment:** 5 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks Loss of response: 10 mg/kg IV every 8 weeks **Plaque psoriasis-chronic, severe:** 5 mg/kg IV at weeks 0, 2, and 6; then, every 8 weeks **Psoriatic arthritis:** 5 mg/kg IV at weeks 0, 2, and 6 then every 8 weeks; with or without methotrexate **Rheumatoid arthritis (moderate-severe)-in combination with methotrexate:** 3 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks Incomplete response: 10 mg/kg IV every 8 weeks or 3 mg/kg IV every 4 weeks **Ulcerative colitis-in patients with inadequate response to conventional therapy:** 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks

	Pediatric Dosing	Other Dosing
Renflexis® (infliximab-abda)	**Crohn's Disease (moderate-severe) in patients with inadequate response to conventional therapy (≥ 6 years old):** 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks	**Ankylosing spondylitis:** 5 mg/kg IV at weeks 0, 2, and 6, then every 6 weeks **Crohn's disease-fistulizing or moderate-severe not responding to conventional treatment:** 5 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks Loss of response: 10 mg/kg IV every 8 weeks **Plaque psoriasis-chronic, severe:** 5 mg/kg IV at weeks 0, 2, and 6; then, every 8 weeks **Psoriatic arthritis:**

		5 mg/kg IV at weeks 0, 2, and 6 then every 8 weeks; with or without methotrexate **Rheumatoid arthritis (moderate-severe)-in combination with methotrexate:** 3 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks Incomplete response: 10 mg/kg IV every 8 weeks or 3 mg/kg IV every 4 weeks **Ulcerative colitis-in patients with inadequate response to conventional therapy:** 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks

	Pediatric Dosing	Other Dosing
Inflectra® (infliximab-dyyb)	**Crohn's Disease (moderate-severe) in patients with inadequate response to conventional therapy (≥ 6 years old):** 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks	**Ankylosing spondylitis:** 5 mg/kg IV at weeks 0, 2, and 6, then every 6 weeks **Crohn's disease-fistulizing or moderate-severe not responding to conventional treatment:** 5 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks Loss of response: 10 mg/kg IV every 8 weeks **Plaque psoriasis-chronic, severe:** 5 mg/kg IV at weeks 0, 2, and 6; then, every 8weeks **Psoriatic arthritis:** 5 mg/kg IV at weeks 0, 2, and 6 then every 8 weeks; with or without methotrexate **Rheumatoid arthritis (moderate-severe)-in combination with methotrexate:** 3 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks Incomplete response: 10 mg/kg IV every 8 weeks or 3 mg/kg IV every 4 weeks **Ulcerative colitis-in patients with inadequate response to conventional therapy:** 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks

References

1. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc; June 2018.
2. Renflexis (infliximab) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; November 2017.
3. Inflectra (infliximab dyyb) [prescribing information]. New York, NY: Pfizer; November 2017
4. Yoo DH, Racewicz A, Brzezicki J, et al. A phase III randomized study to evaluate the efficacy and safety of CT-P13 compared with reference infliximab in patients with active rheumatoid arthritis: 54-week results from the PLANETRA study. *Arthritis Res Ther*. 2016;18:82.[PubMed 27038608]

5. Park W, Yoo DH, Jaworski J, et al. Comparable long-term efficacy, as assessed by patient-reported outcomes, safety and pharmacokinetics, of CT-P13 and reference infliximab in patients with ankylosing spondylitis: 54-week results from the randomized, parallel-group PLANETAS study. *Arthritis Res Ther*. 2016;18:25.[PubMed 26795209]
6. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;0:1-14.
7. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
8. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.
9. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017*;0*:1-18.
10. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
11. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
12. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
13. Peluso R, Lervolino S, Vitiello M, et al. Extra-articular manifestations in psoriatic arthritis patients. Clin Rheumatol. 2014 May 8. [Epub ahead of print].
14. S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism.* 2013;65:2499-2512.
15. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2015: 10.1002/art.39298. [Epub ahead of print].

Review History

03/21/05 – Reviewed
05/15/05 – Effective
02/27/06 – Reviewed and revised
02/25/08 – Reviewed and revised
02/23/09 – Reviewed and revised
02/22/10 – Reviewed
02/28/11 – Reviewed and revised
02/27/12 – Reviewed and revised
02/25/13 – Reviewed and revised
02/24/14 – Reviewed and revised
02/23/15 – Reviewed

02/22/16 – Reviewed
02/27/17 – Reviewed and revised (added Inflectra; adopted SGM &ST) in P&T Meeting
03/01/18 – Reviewed and revised
02/20/19 – Reviewed in P&T Meeting

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