SmartHealth Ascension

# Infliximab

## (Remicade® or unbranded) J1745

### Covered with prior authorization

**Infliximab (Remicade® or unbranded) may be authorized when the following criteria are met:**

- Diagnosis of Crohn's disease (CD); **AND**
- Individual is 6 year of age or older with moderate to severe CD; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants); **OR**
- Individual is 6 years of age of older with fistulizing CD; **AND**
- Dosing is age-appropriate:
    - Adult: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response;
    - Pediatric: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

**OR**

- Diagnosis of ulcerative colitis (UC); **AND**
- Individual is 6 years of age or older with moderate to severe UC; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants); **AND**
- Dosing is age-appropriate:
    - Adult: Dosing: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
    - Pediatric: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

**OR**

- Diagnosis of rheumatoid arthritis (RA); **AND**
- Individual is 18 years of age or older with moderate to severe RA; **AND**
- Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose; **OR**
- If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **AND**
- Dosing: (In conjunction with methotrexate) 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.

**OR**

- Diagnosis of ankylosing spondylitis (AS); **AND**
- Individual is 18 years of age or older with moderate to severe AS; **AND**

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or non biologic disease modifying antirheumatoid drugs (DMARDs) (such as sulfasalazine)]; **AND**
- Dosing is 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks.

**OR**

- Diagnosis of psoriatic arthritis (PsA); **AND**
- Individual is 18 years of age or older with moderate to severe PsA; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying antirheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)]; **AND**
- Dosing 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

**OR**

- Diagnosis of plaque psoriasis (Ps) (Psoriasis vulgaris); **AND**
- Individual is 18 years of age or older with chronic moderate to severe plaque Ps with either of the following:
    - Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) body surface area (BSA); **OR**
    - Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapies (such as acitretin, cyclosporine, or methotrexate); **AND**
- Dosing is 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

**Exclusion criteria:**

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- In combination with other TNF antagonists, apremilast, JAK inhibitors, or other biologic drugs (such as, abatacept, anakinra, IL-17 inhibitors, IL-23 inhibitors, rituximab, ustekinumab, tocilizumab, or vedolizumab);
- Tuberculosis, other active serious infections, or a history of recurrent infections;
- If initiating therapy, individual has not had a tuberculin skin test (TST), or a Center for Disease Control (CDC-) and Prevention -recommended equivalent, to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors);
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

**Step/Alternative Therapies:**

| Preferred Product(s) [No PA Required] | Non-Preferred Product(s) [PA Required] |
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|---|---|
| infliximab-dyyb, biosimilar, (inflectra) [Q5103] | infliximab (infliximab) |
| infliximab-abda, biosimilar, (renflexis) [Q5104] | infliximab (REMICADE)® |
| infliximab-qbtx, biosimilar, (ixifi) [Q5109] (not on market) | |
| infliximab-axxq, biosimilar, (avsola) [Q5121] | |

**Initial authorization for approved indications is up to 12 months.**

**Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.Clinical documentation provided must be from within the most recent 12 months.**

**Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.**

**U.S. Food and Drug Administration:**
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Remicade® is a tumor necrosis factor (TNF) blocker indicated for:

- Crohn's Disease:
  - reducing signs and symptoms 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.
- Pediatric Crohn's Disease:
  - reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Ulcerative Colitis:
  - reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Pediatric Ulcerative Colitis:
  - reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Rheumatoid Arthritis in combination with methotrexate:
  - reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.
- Ankylosing Spondylitis:
  - reducing signs and symptoms in patients with active disease.
- Psoriatic Arthritis:
  - reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.

- Plaque Psoriasis:
    - 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 appropriate.

**References**:

Fraenkel, L., Bathon, J. M., England, B. R., & et al. (2021, June 8). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*, *73*(7), 924 - 939. Wiley Online Library. 10.1002/acr.24596

*INFLIXIMAB (infliximab) label*. (2021, October). Accessdata.fda.gov. Retrieved April 25, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103772s5401lbl.pdf

Menter, A., & et al. (2019, April). Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *Journal of the American Academy of Dermatology*, *80*(4), 1029-1072. 10.1016/j.jaad.2018.11.057

*Remicade® (infliximab) Label*. (2013, November). Accessdata.fda.gov. Retrieved April 25, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103772s5359lbl.pdf

**Criteria History/ Revision Information**:

| Date | Summary of Changes |
|---|---|
| April 2022 | Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team |
| May 2022 | Criteria for use summary approved by Ascension Therapeutic Affinity Group |

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.