RX.PA.016.CCH INFLIXIMAB PRODUCTS (REMICADE, INFLECTRA, RENFLEXIS, AVSOLA)

PURPOSE

The purpose of this policy is to define the prior authorization process for Remicade® (infliximab), Inflectra® (infliximab-dyyb), Renflexis® (infliximab-abda), and Avsola™ (infliximab-axxq).

Remicade® (infliximab), Inflectra® (infliximab-dyyb), Renflexis® (infliximab-abda), and Avsola™ (infliximab-axxq) are indicated for the following:

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Infliximab is indicated only in combination with methotrexate.
- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.
- Reducing signs and symptoms in patients with active ankylosing spondylitis
- 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. Infliximab should only be administered to patients who are closely monitored and have regular follow-up visits with a physician.
- Reducing signs and symptoms and inducing and maintaining a clinical remission in adult and pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy AND for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.
- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy AND for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older (Remicade only) with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications.

This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity and approval by the Medical Policy Committee.

The drugs, Remicade® (infliximab), Inflectra® (infliximab-dyyb), Renflexis® (infliximab-abda) and Avsola™ (infliximab-axxq) are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Avsola™ are subject to the preferred medical drug list program. This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. Coverage for non-preferred products may be provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products
Preferred	• Inflectra® (infliximab-dyyb) • Remicade® (infliximab) • Renflexis® (infliximab-abda)
Non-preferred	• Avsola™ (infliximab-axxq)

Requests for a non-preferred drug on the Medical Benefit must meet one of the following exception criteria in addition to clinical criteria:

II. *EXCEPTION CRITERIA (Use for Non-Preferred Requests Only)*

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product(s) (as applicable).

Coverage for a non-preferred product is provided when ANY of the following criteria are met:

- Member has a documented intolerable adverse event with the preferred products and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests on the Medical Benefit)*

Must meet all of the criteria listed under the respective diagnosis:

For All Diagnoses:

- Requests for non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products
- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.*TB* test (T-Spot)]
- Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with the Infliximab product
- Must have no evidence of infection
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling

1. Rheumatoid Arthritis:

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
    - Members with significant side effects/toxicity or who have a contraindication to methotrexate must have an adequate trial (of at least 3 months) of leflunomide, hydroxychloroquine, or sulfasalazine with an inadequate response, significant side effect/toxicity, or have a contraindication to these therapies

2. Psoriatic Arthritis:

- Must be prescribed by a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis
- For peripheral disease and dactylitis:
    - Must have an adequate trial (of at least 4 weeks) with a non-steroidal anti-inflammatory drugs (NSAIDs) at an anti-inflammatory target dose, with an inadequate response, significant side effects/toxicity, or have a contraindication to these therapies.
    - Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (methotrexate, sulfasalazine, or leflunomide) with an

inadequate response, significant side effects/toxicity, or have a contraindication to these therapies

- For axial disease and enthesitis:
  - Must have an adequate trial (of at least 4 weeks each) with TWO NSAIDs at anti-inflammatory doses with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
- For skin or nail psoriatic arthritis
  - Must have an adequate trial of topical treatments, phototherapy, or photochemotherapy with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
  - Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (methotrexate, cyclosporine, or acitretin) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

3. Ankylosing Spondylitis:

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of ankylosing spondylitis
- Must have an adequate trial (of at least 4 weeks) with **TWO** NSAIDs at anti-inflammatory dose, with an inadequate response, significant side effects/toxicity, or have a contraindication to these therapies

4. Plaque Psoriasis:

- Must be prescribed by a dermatologist
- Must be age 18 years or older
- Must have a diagnosis of severe chronic plaque psoriasis
- Must have a minimum body surface area involvement of > 5% (Members with plaque psoriasis of palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement)
- Must have an adequate trial of topical treatments, phototherapy, or photochemotherapy with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (methotrexate, cyclosporine, or acitretin) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

5. Crohn's Disease:

- Must be prescribed by a gastroenterologist
- Must be age 6 years or older
- Must have a diagnosis of moderate to severely active Crohn's disease or fistulizing Crohn's disease

- Must have an adequate trial of conventional therapy including corticosteroids **OR** at least 3 months of immunosuppressants (e.g., azathioprine, 6-mercaptopurine) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

6. Ulcerative Colitis:

- Must be prescribed by a gastroenterologist
- Must be age 6 years or older
- Must have a diagnosis of moderate to severely active Ulcerative Colitis
- Must have an adequate trial of conventional therapy including corticosteroids, at least 3 months of 5-ASA agents (e.g., sulfasalazine, mesalamine), **OR** at least 3 months of immunosuppressants (azathioprine, 6-mercaptopurine) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

Code	Brand	Description
J1745	Remicade	INJ, INFLIXIMAB, EXCLUDES BIOSIMILAR, 10 MG
Q5103	Inflectra	INJ INFLIXIMAB-DYYB BIOSIMILR 10 MG
Q5104	Renflexis	INJ INFLIXIMAB-ABDA BIOSIMILR 10 MG
Q5121	Avsola	INJ INFLIXIMAB-AXXQ BIOSIMILR 10 MG

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial review	3/22