CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Renflexis (infliximab-abda)
BILLING CODE	Q5104 (1 unit = 10 mg or 1 x 100 mg vial = 10 units)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Actemra, Cimzia, Cosentyx, Enbrel, Kevzara, Olumiant, Otezla, Siliq, and Xeljanz QUANTITY LIMIT— 1200 mg (120 units per dose)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Renflexis (infliximab-abda) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active ankylosing spondylitis (AS); AND
4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
7. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
8. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, or Cosentyx. Treatment failure requires at least 12 weeks of therapy with each drug.
9. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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CROHN'S DISEASE (CD)

For **initial** authorization:

1. Member is 6 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least **one** of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate; OR
5. Member has severe disease that requires immediate use of a biologic agent, as indicated by **one** of the following:
   a) Extensive small bowel disease involving more than 100 cm;
   b) History of bowel or colon resection and is at high risk for CD recurrence (e.g., smoker, <30 years old, 2 or more resections, penetrating/fistulizing disease, etc.);
   c) Fistulizing disease.
6. **Dosage allowed:** 5mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
7. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla, or Siliq. Treatment failure requires at least 12 weeks of therapy with each drug.
8. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **one** of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are not required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
6. Member has tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla, or Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
7. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:
1. Member must be 18 years of age or older with moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND
   Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
5. Medication is being given in combination with methotrexate or with another non-biologic DMARD if unable to tolerate methotrexate; AND

6. Member has tried and failed treatment with at least **two** of the following: Actemra, Cimzia, Enbrel, Kevzara, Olumiant, or Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
7. **Dosage allowed:** 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks thereafter. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

ULCERATIVE COLITIS (UC)

For **initial** authorization:
1. Member is 6 years of age or older with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member must have a documented trial and inadequate response with **one** of the following:
   a) 3 months of 6-mercaptopurine or azathioprine;
   b) 30 days of corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).
5. **Dosage allowed:** 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of UC (defined as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Renflexis (infliximab-abda) not medically necessary for the treatment of the following disease that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/03/2019	New policy for Renflexis created.
05/03/2021	Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. Updated list of preferred agents and drug trials to match Remicade. AS: Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. CD: Removed PCDAI and CDAI score requirements. Specified length of trials for conventional therapies, previously not specified. Those with severe disease can skip the drug trial. Changed initial approval to 6 months to observe efficacy.

	PsA: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). PsO: Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. RA: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. UC: Removed PUCAI and Mayo score requirements. Specified the length of trials for conventional therapies (previously not specified).

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