CareSource

PHARMACY POLICY STATEMENT **Ohio 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/Non-hospital outpatient facility
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel and Humira 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has had back pain for 3 months or more that began before the age of 50; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
   a) Arthritis;
   b) Elevated serum C-reactive protein;
   c) Inflammation at the tendon, ligament or joint capsule insertions;
   d) Positive HLA-B27 test;
   e) Limited chest expansion;
   f) Morning stiffness for 1 hour or more; AND
7. Member meets at least **one** of the following scenarios:
   a) Member has Axial (spinal) disease;
   b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response;
   c) Member has tried and failed to respond to treatment with at least **two** prescription 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 **both** of the following: Enbrel and Humira. Treatment failure requires at least for 12 weeks of therapy with each drug without an adequate response.
9. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. 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. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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.

CROHN'S DISEASE (CD)

For **initial** authorization:
1. Member is 6-17 years of age with moderately to severely active CD as defined by Pediatric Crohn's Disease Activity Index (PCDAI) greater than 30 OR member is 18 years of age or older with moderately to severely active non-fistulizing CD as defined by Crohn's Disease Activity Index (CDAI) greater than 220 and less than 400; AND
2. Member has had a trial and inadequate response to at least **one** of the following:
   a) 6-mercaptopurine;
   b) Azathioprine;
   c) Methotrexate;
   d) Corticosteroid(s); OR
3. Member is 18 years of age or older with fistulizing CD; AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Medication must be prescribed by a gastroenterologist; AND
6. Member has documented trial and failure of or contraindication to Humira. Treatment failure requires at least 12 weeks of therapy without an adequate response.
7. **Dosage allowed:** 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter. If no response by week 14, consider discontinuing therapy.

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

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
4. Documented member's PCDAI or CDAI score improvement.

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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a dermatologist or rheumatologist; AND
4. Member has PsO for 6 months or longer; AND
5. Member is not going to receive systemic therapy or phototherapy while on Remicade; AND

6. Member's plaque psoriasis involving 10% or more of the body surface area (BSA) or 5% or more of BSA if psoriasis involves sensitive areas (hands, feet, face, or genitals); AND
7. Member's Psoriasis Area and Severity Index (PASI) greater than or equal to 12; AND
8. 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 (tanning beds emit mostly UVA light and therefore would not meet this criteria)).
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
9. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
10. Member has tried and failed treatment with **both** of the following: Enbrel and Humira. Treatment failure requires at least for 12 weeks of therapy with each drug without an adequate response.
11. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. 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. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member meets at least **one** of the following scenarios:
   a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) and has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response;
   c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine); AND
5. Member must have tried and failed treatment with **both** of the following: Enbrel and Humira. Treatment failure requires at least for 12 weeks of therapy with each drug without an adequate response.

6. **Dosage allowed:** 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. 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. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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 moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Medication must be used in combination with methotrexate, or if intolerant to methotrexate, another immunosuppressant (i.e., azathioprine, hydroxychloroquine, cyclosporine, etc.); AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDS OR must have a contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks (non-biologic DMARDs include: methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide); AND
6. Member has tried and failed treatment with **both** of the following: Enbrel and Humira. Treatment failure requires at least for 12 weeks of therapy with each drug without an adequate response.
7. **Dosage allowed:** 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. 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. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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.

ULCERATIVE COLITIS (UC)

For **initial** authorization:

1. Member is 6-17 years of age with moderate to severe active UC as defined by Pediatric Ulcerative Colitis Activity Index (PUCAI) of 35 or greater OR member is 18 years of age or older with moderately to severely active UC as defined by Mayo score of 6 or greater with an endoscopy subscore of 2 or 3; AND
2. Medication must be prescribed by a gastroenterologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member must have tried and failed treatment with at least with **one** or more of the following:
   a) 6-mercaptopurine;

b) Azathioprine;
c) Methotrexate;
d) Oral corticosteroids;
e) Salicylates; AND

5. Member has documented trial and failure of or contraindication to Humira (only for members 18 years of age or older). Treatment failure requires at least 12 weeks of therapy without an adequate response.
6. **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. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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.

CareSource considers Renflexis (infliximab-abda) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Amyloid angiopathy
- Asthma
- Behcet's disease
- Birdshot retinochoroidopathy
- Bronchiolitis obliterans
- Central nervous system amyloidosis
- Chemotherapy induced enterocolitis (not due to Yervoy or Opdivo)
- Chronic immune-mediated myelitis
- Chronic obstructive pulmonary disease
- Cogan's syndrome
- Corneal ulcer
- Cranial nerve palsy
- Cystoid macular degeneration
- Disc herniation-induced sciatica
- Discoid lupus erythematosus
- Eczema
- Eosinophilic fasciitis
- Graft-versus-host-disease
- Granuloma annulare
- Granulomatous angiitis
- Granulomatous mastitis
- Hepatitis C genotype 1
- IgG4-related disease
- Infectious uveitis

- Iritis
- Juvenile idiopathic arthritis
- Kawasaki syndrome
- Localized scleroderma/morphea
- Membranous glomerulopathy
- Microscopic colitis
- Multifocal osteomyelitis (e.g., (chronic recurrent multifocal osteomyelitis (CRMO))
- Neurosarcoidosis
- Nodular scleritis
- Panniculitis
- Polyarteritis nodosa
- Polymyositis
- Prevention of post-operative recurrence of Crohn's disease
- Rejection following small bowel transplantation
- Relapsing polychondritis
- Scleroderma
- Sjogren's syndrome
- Still's disease
- Systemic lupus erythematosus
- Takayasu arteritis
- Tolosa-Hunt syndrome
- Tubulo-interstitial nephritis with uveitis (TINU) syndrome
- Wegener's granulomatosis/Wegener's peripheral neuropathy

DATE	ACTION/DESCRIPTION
10/03/2019	New policy for Renflexis created.

References:

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13. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Use of Thiopurines, Methotrexate, and Anti–TNF-a Biologic Drugs for the Induction and Maintenance of Remission in Inflammatory Crohn's Disease. Gastroenterology 2013; 145:1459-1463.
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18. Academy of Managed Care Pharmacy (AMCP) v4.0 Formulary Submission Dossier. RENFLEXIS® (infliximab). October, 2019.

Effective date: 04/01/2020
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