Renflexis (infliximab-abda)

Humana

Pharmacy Coverage Policy

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

Description

Renflexis (infliximab-abda) is biosimilar to Remicade (infliximab). Infliximab neutralizes the biological activity of TNF-α by binding to the soluble and transmembrane forms of TNF-α therefore effectively inhibiting the binding of TNF-α with its receptors.

Renflexis (infliximab-abda) is 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

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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 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.

Renflexis (infliximab-abda) is supplied as individually boxed-single use vials as 100mg/20 mL vial for IV injection.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

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- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Renflexis (infliximab-abda) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Rheumatoid Arthritis

- The member must have a diagnosis of moderately to severely active rheumatoid arthritis.
- The member must be at least 18 years of age or older.
- The member has failed to achieve symptom control (e.g. reduced joint pain, reduced joint swelling) or has intolerance with Inflectra.
- The member must be on concomitant treatment with methotrexate during Renflexis therapy, unless contraindicated or intolerant to methotrexate.

Crohn's Disease (Non-Fistulizing)

- The member must have a diagnosis of moderate to severely active Crohn’s disease.
- The member must be at least 6 years of age.
- The member has failed to achieve symptom control (e.g. improved liquid or soft stool, reduced abdominal pain, stable weight) or has intolerance with Inflectra.

Ankylosing Spondylitis

- The member must have a diagnosis of highly persistent, active ankylosing

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spondylitis.
- The member must be at least 18 years of age or older.
- The member has failed to achieve symptom control (e.g. reduced spinal pain, reduced inflammation) or has intolerance with Inflectra.

Psoriatic Arthritis

- The member must have a diagnosis of active psoriatic arthritis.
- The member must be at least 18 years of age or older.
- The member has failed to achieve symptom control (e.g. reduced joint pain or swelling, reduced erythema) or has intolerance with Inflectra.

Plaque Psoriasis

- The member must have a diagnosis of moderate to severe, extensive chronic plaque psoriasis.
- The member must be at least 18 years of age.
- The member has failed to achieve symptom control (e.g. reduction in erythema, reduction of area of skin involved) or has intolerance with Inflectra.

Ulcerative Colitis

- The member must have a diagnosis of moderately to severely active ulcerative colitis.
- The member must be at least 6 years of age.
- The member has failed to achieve symptom control (e.g. reduced stool frequency, reduced rectal bleeding) or has intolerance with Inflectra.

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Fistulizing Crohn's Disease

- The member must have a diagnosis of Crohn's disease with one or more draining fistulas.
- The member must be at least 18 years of age.
- The member has failed to achieve symptom control (e.g. improved liquid or soft stool, reduced abdominal pain, stable weight) or has intolerance with Inflectra.

Renflexis (infliximab-abda) will be approved for plan year durations or as deemed appropriate by clinical review.

Coverage Limitations

Renflexis (infliximab-abda) therapy is not considered medically necessary for members with the following concomitant conditions:

- Combination therapy with other biologics (e.g. Cosentyx, Enbrel, Humira, Kevzara, Remicade).

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Renflexis (infliximab-abda).

Black Box Warnings:

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.

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- Discontinue Renflexis (infliximab-abda) if a patient develops a serious infection.

- Perform test for latent TB; if positive, start treatment for TB prior to starting infliximab products. Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab products.

- Postmarketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported with patients treated with TNF blockers including infliximab products. Almost all had received azathioprine or 6-mercaptopurine concomitantly with a TNF-blocker at or prior to diagnosis. The majority of cases were reported in patients with Crohn's disease or ulcerative colitis, most of whom were adolescent or young adult makes.

Renflexis (infliximab-abda) can cause and/or should not be used in patients with:

- Clinically important active infections
- A history of tuberculosis, positive PPD
- Women who are pregnant or lactating
- Multiple sclerosis or other demyelinating events
- Moderate to severe congestive heart failure
- Undifferentiated cytopenias
- Malignancies
- Neurologic events
- Hematologic Events
- Hepatosplenic T-cell lymphomas
- Hepatitis B Virus reactivation
- Hepatoxicity
- A known hypersensitivity to murine products or other components of the formulation.
- Hepatosplenic T-cell Lymphoma – carefully assess the risk benefit especially if the

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patient has Crohn's disease or ulcerative colitis, is male, and is receiving azathioprine or 6-mercaptopurine treatment
- Demyelinating disease – consider stopping Renflexis (infliximab-abda) if exacerbation or new onset occurs.
- Live vaccines- should not be given with Renflexis (infliximab-abda). Bring pediatric patients up to date with all vaccinations prior to initiating Renflexis (infliximab-abda).
- Cerebrovascular accidents, myocardial infarctions (some fatal), and arrhythmias have been reported during and within 24 hours of initiation of infliximab infusion. Monitor patients during infusion and discontinue if serious reaction occurs.

Renflexis (infliximab-abda) at doses >5 mg/kg should not be administered to patients with moderate to severe heart failure.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Renflexis; infliximab-abda; Rheumatoid Arthritis; Crohn's Disease; Ankylosing Spondylitis; Psoriatic Arthritis; Plaque Psoriasis; Ulcerative Colitis; Intravenous injection; pharmacy

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