RENFLEXIS®
(infliximab-abda) for injection, for intravenous use 100 mg

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Billing Codes for RENFLEXIS

Included are lists of codes that may be relevant for RENFLEXIS and its administration. This information is current as of October 2022. The information provided here is compiled from sources believed to be accurate, but Organon makes no representation that it is accurate. Information about Healthcare Common Procedure Coding System (HCPCS) codes is based on guidance issued by the Centers for Medicare & Medicaid Services (CMS) applicable to Medicare Part B and may not apply to other public or private payers. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of a particular code and for information on additional codes. This information is subject to change. Organon cautions that payer coding requirements vary and can frequently change, so it is important to regularly check with each payer or, where applicable, the Medicare Administrative Contractor, as to payer-specific requirements.

You are solely responsible for determining the appropriate codes and for any action you take in billing. The information provided here is not intended to be definitive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. Organon and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs. Diagnosis codes should be selected only by a health care professional.

SELECTED SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with infliximab products.

Serious Infections:

Infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens (eg, tuberculosis [TB], histoplasmosis) have been reported. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Patients may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Discontinue RENFLEXIS if a patient develops a serious infection or sepsis. Patients should be tested for latent TB before RENFLEXIS use and during therapy. Treatment for latent TB should be initiated prior to RENFLEXIS use. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with RENFLEXIS.

Malignancies:

Lymphoma, including cases of fatal hepatosplenic T-cell lymphoma (HSTCL), and other malignancies have been reported, including in children and young adult patients. Cases of HSTCL have had a very aggressive disease course and have been fatal. Due to the risk of HSTCL, mostly reported in Crohn's disease and ulcerative colitis, assess the risk/benefit, especially if the patient is male and is receiving azathioprine or 6-mercaptopurine treatment.

Please see Selected Safety Information continued on pages 2, 3, and 4.

Have billing and coding questions?

Visit organonaccessprogram-renflexis.com OR Call 866-847-3539

Monday through Friday, 8 AM to 8 PM ET

Before prescribing RENFLEXIS, please read the accompanying Prescribing Information, including the Boxed Warning about serious infections and malignancies. The Medication Guide also is available.

BILLING CODES

Following are codes that might be relevant when submitting a claim for RENFLEXIS® (infliximab-abda). Please consult with the applicable payer to understand the payer's specific billing requirements.

NDC AND PACKAGING INFORMATION

RENFLEXIS (infliximab-abda) for injection, for intravenous use 100 mg

100-mg vial individually packaged in a carton

Vial NDC: 78206-162-01 – 1 VIAL in 1 CARTON

Carton NDC: 78206-162-99 – 1 INJECTION, POWDER, LYOPHILIZED FOR SOLUTION in 1 VIAL

NDC, National Drug Code.

HCPCS CODE[1]

CMS previously required that Part B–covered biosimilars with a common reference product be coded using a shared HCPCS code in conjunction with a 2-character manufacturer-identifying modifier. Under this policy, RENFLEXIS was billed using the shared HCPCS code Q5102 (injection, infliximab, biosimilar, 10 mg) in conjunction with the modifier ZC (Merck/Samsung Bioepis).[2] In the second-quarter 2018 HCPCS update, CMS announced that the product-specific HCPCS code for RENFLEXIS will be Q5104 (injection, infliximab-abda, biosimilar [RENFLEXIS], 10 mg).[1] This new code was effective in the HCPCS code set on April 1, 2018. Q5104 replaces the previous shared code, Q5102, which was discontinued on April 1, 2018. The code Q5102, along with the accompanying modifier, is applicable to dates of service prior to April 1, 2018.[2]

Q5104	Injection, infliximab-abda, biosimilar (RENFLEXIS), 10 mg

For questions on billing if a portion of a package is wasted, consult the applicable payer's policy regarding wastage. Record the amount of drug administered and the amount wasted in the patient's medical record. Medicare requires the use of the JW modifier (Drug Amount Discarded/Not Administered to Any Patient) on all claims that include wasted product.

REVENUE CODE FOR USE IN THE HOSPITAL SETTING[3]

0636	Drugs requiring detailed coding

SELECTED SAFETY INFORMATION (*continued*)

Contraindications:

Patients with severe hypersensitivity reactions to infliximab products and patients with moderate to severe congestive heart failure.

Please see Selected Safety Information continued on pages 3 and 4.

BILLING CODES (*continued*)

Following are codes that might be relevant when submitting a claim for RENFLEXIS® (infliximab-abda). Please consult with the applicable payer to understand the payer's specific billing requirements.

CPT CODES FOR ADMINISTRATION[4–7]

96413	(Some payers may use 96365. Check with the applicable payer.) Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	(Some payers may use 96366. Check with the applicable payer.) Each additional hour (use 96415 in conjunction with 96413; report 96415 for infusion intervals of greater than 30 minutes beyond 1-hour increments)

CPT, Current Procedural Terminology.

DIAGNOSIS CODES

Health care professionals are solely responsible for selecting codes that appropriately reflect the patient's diagnosis, the services rendered, and the applicable payer's guidelines. Please use the appropriate ICD-10-CM code(s) for the patient's condition.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

SELECTED SAFETY INFORMATION (*continued*)

Other Warnings and Precautions:

Melanoma and Merkel cell carcinoma, invasive cervical cancer, hepatitis B reactivation, hepatotoxicity, hematological events, neurological events, and lupus-like syndrome have been reported. Hypersensitivity reactions, some severe and requiring hospitalization, have been reported. Most reactions have occurred during or within 2 hours of infusion. RENFLEXIS should be discontinued for severe hypersensitivity reactions. Serious cerebrovascular accidents, myocardial ischemia/infarction (some fatal), hypotension, hypertension, and arrhythmias have been reported during and within 24 hours of initiation of infusion of infliximab. Transient visual loss has been reported during or within 2 hours of initiation of infusion of infliximab. Discontinue infusion if serious reaction occurs. Concomitant use of RENFLEXIS with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as RENFLEXIS is not recommended because of the possibility of an increased risk of infection. Care should be taken when switching from one biologic to another, since overlapping biological activity may further increase the risk of infection. Live vaccines or therapeutic infectious agents should not be given with RENFLEXIS due to the possibility of clinical infections, including disseminated infections. Bring pediatric patients up to date with all vaccinations prior to initiating RENFLEXIS. At least a 6-month waiting period following birth is recommended before the administration of any live vaccine to infants exposed *in utero* to infliximab products.

Please see Selected Safety Information continued on page 4.

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INDICATIONS AND USAGE

Crohn's Disease

RENFLEXIS is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy

RENFLEXIS is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease

Pediatric Crohn's Disease

RENFLEXIS is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy

Ulcerative Colitis

RENFLEXIS is indicated for 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 (UC) who have had an inadequate response to conventional therapy

Pediatric Ulcerative Colitis

RENFLEXIS is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy

Rheumatoid Arthritis

RENFLEXIS is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)

Psoriatic Arthritis

RENFLEXIS is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis (PsA)

Ankylosing Spondylitis

RENFLEXIS is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS)

Plaque Psoriasis

RENFLEXIS is indicated for the treatment of adult patients with chronic severe (ie, extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. RENFLEXIS should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician

SELECTED SAFETY INFORMATION (*continued*)

Common Adverse Reactions (AEs):

The most common AEs (>10%) in clinical trials with infliximab products included infections (eg, upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

Before prescribing RENFLEXIS, please read the accompanying Prescribing Information, including the Boxed Warning about serious infections and malignancies. The Medication Guide also is available.

References: 1. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update April 2018. Updated September 27, 2022. Accessed September 27, 2022. https://www. cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update **2.** Centers for Medicare & Medicaid Services. Part B Biosimilar Biological Product Payment and Required Modifiers. Published April 2, 2018. Accessed September 27, 2022. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html **3.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 18 – Preventive and Screening Services. Revised April 22, 2022. Accessed September 27, 2022. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c18pdf.pdf **4.** American Medical Association. CPT Code/Relative Value Search - 96413. Accessed October 13, 2022. https://apps.ama-assn.org/CptSearch/user/search/cptSearchSubmit.do?locality=1&keyword=96413 **5.** American Medical Association. CPT Code/Relative Value Search - 96365. Accessed October 13, 2022. https://apps.ama-assn.org/CptSearch/user/search/cptSearchSubmit.do?locality=1&keyword=96365 **6.** American Medical Association. CPT Code/Relative Value Search - 96415. Accessed October 13, 2022. https://apps.ama-assn.org/CptSearch/user/search/cptSearchSubmit.do?locality=1&keyword=96415 **7.** American Medical Association. CPT Code/Relative Value Search - 96366. Accessed October 13, 2022. https://apps.ama-assn.org/CptSearch/user/search/cptSearchSubmit.do?locality=1&keyword=96366

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