

REMICADE / HCP WEBSITE COPY
JANSSEN CAREPATH

Indications for REMICADE® (infliximab)

Crohn's Disease

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

REMICADE® 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

REMICADE® 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 Crohn's disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis

REMICADE® 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 who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis

REMICADE® 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 who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis

REMICADE®, in combination with methotrexate, 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.

Ankylosing Spondylitis

REMICADE® is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

Psoriatic Arthritis

REMICADE® 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.

Plaque Psoriasis

REMICADE® is indicated for the treatment of adult patients with chronic severe (i.e., extensive and/ or

SARAH BELZER

copy + ideation + creative direction

disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. REMICADE® should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

SERIOUS INFECTIONS

Patients treated with REMICADE® (infliximab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue REMICADE® if a patient develops a serious infection or sepsis.

Reported infections include:

- Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before and during treatment with REMICADE®. 1,2 Treatment for latent infection should be initiated prior to treatment with REMICADE®.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients may present with disseminated, rather than localized, disease. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

The risks and benefits of treatment with REMICADE® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with REMICADE®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy, who are on treatment for latent TB, or who were previously treated for TB infection.

Risk of infection may be higher in patients greater than 65 years of age, pediatric patients, patients with co-morbid conditions and/ or patients taking concomitant immunosuppressant therapy. In clinical trials, other serious infections observed in patients treated with REMICADE® included pneumonia, cellulitis, abscess, and skin ulceration.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including REMICADE®. Approximately half of these cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including REMICADE®. These cases have had a very

SARAH BELZER

copy + ideation + creative direction

aggressive disease course and have been fatal. The majority of reported REMICADE® cases have occurred in patients with Crohn's disease or ulcerative colitis and most were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with REMICADE® at or prior to diagnosis. Carefully assess the risks and benefits of treatment with REMICADE®, especially in these patient types.

In clinical trials of all TNF inhibitors, more cases of lymphoma were observed compared with controls and the expected rate in the general population. However, patients with Crohn's disease, rheumatoid arthritis, or plaque psoriasis may be at higher risk for developing lymphoma. In clinical trials of some TNF inhibitors, including REMICADE®, more cases of other malignancies were observed compared with controls. The rate of these malignancies among patients treated with REMICADE® was similar to that expected in the general population whereas the rate in control patients was lower than expected. Cases of acute and chronic leukemia have been reported with postmarketing TNF-blocker use. As the potential role of TNF inhibitors in the development of malignancies is not known, caution should be exercised when considering treatment of patients with a current or a past history of malignancy or other risk factors such as chronic obstructive pulmonary disease (COPD).

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocker therapy, including REMICADE®. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

CONTRAINDICATIONS

REMICADE® is contraindicated in patients with moderate to severe (NYHA Class III/ IV) congestive heart failure (CHF) at doses greater than 5 mg/ kg. Higher mortality rates at the 10 mg/ kg dose and higher rates of cardiovascular events at the 5 mg/ kg dose have been observed in these patients. REMICADE® should be used with caution and only after consideration of other treatment options. Patients should be monitored closely. Discontinue REMICADE® if new or worsening CHF symptoms appear. REMICADE® should not be (re)administered to patients who have experienced a severe hypersensitivity reaction or to patients with hypersensitivity to murine proteins or other components of the product.

HEPATITIS B REACTIVATION

TNF inhibitors, including REMICADE®, have been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases were fatal. Patients should be tested for HBV infection before initiating REMICADE®. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing REMICADE® for patients identified as carriers of HBV and monitor closely for active HBV infection during and following termination of therapy with REMICADE®. Discontinue REMICADE® in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of REMICADE® and monitor patients closely.

HEPATOTOXICITY

Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported rarely in patients receiving REMICADE® postmarketing. Some cases were fatal or required liver transplant. Aminotransferase elevations were not noted prior to discovery of liver injury in many cases.

SARAH BELZER

copy + ideation + creative direction

Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/ or marked liver enzyme elevations (e.g., ≥ 5 times the upper limit of normal) develop, REMICADE® should be discontinued, and a thorough investigation of the abnormality should be undertaken.

HEMATOLOGIC EVENTS

Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported. The causal relationship to REMICADE® therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias or infection. Consider discontinuation of REMICADE® in patients who develop significant hematologic abnormalities.

HYPERSENSITIVITY

REMICADE® has been associated with hypersensitivity reactions that differ in their time of onset. Acute urticaria, dyspnea, and hypotension have occurred in association with infusions of REMICADE®. Serious infusion reactions including anaphylaxis were infrequent. Medications for the treatment of hypersensitivity reactions should be available.

NEUROLOGIC EVENTS

TNF inhibitors, including REMICADE®, have been associated in rare cases with CNS manifestation of systemic vasculitis, seizure, and new onset or exacerbation of CNS demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barré syndrome. Exercise caution when considering REMICADE® in patients with these disorders and consider discontinuation if these disorders develop.

AUTOIMMUNITY

Treatment with REMICADE® may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

ADVERSE REACTIONS

In clinical trials, the most common REMICADE® adverse reactions occurring in $>10\%$ of patients included infections (e.g., upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

USE WITH OTHER DRUGS

Concomitant use of REMICADE® with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as REMICADE® 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/ THERAPEUTIC INFECTIOUS AGENTS

Live vaccines or therapeutic infectious agents should not be given with REMICADE® due to the possibility of clinical infections, including disseminated infections.

Bring pediatric patients up to date with all vaccinations prior to initiating REMICADE®. At least a 6-month waiting period following birth is recommended before the administration of any live vaccine to infants

SARAH BELZER

copy + ideation + creative direction

exposed in utero to REMICADE®.

For more information, please see [full Prescribing Information](#) and [Medication Guide](#) for REMICADE®. Provide the Medication Guide to your patients and encourage discussion.

References:

1. American Thoracic Society, Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. Am J Respir Crit Care Med 2000;161:S221-S247.
2. See latest Centers for Disease Control guidelines and recommendations for tuberculosis testing in immunocompromised patients.
039670-150902

[REMICADE HOME PAGE]

1.0 OVERVIEW (REMICADE Landing Page)

[Image: REMICADE logo]

[Top Navigation]

[OVERVIEW](#) <links to overview page of REMICADE>

[PATIENT COVERAGE](#) [Dropdown listing] <links to overview of Patient Coverage>

[REIMBURSEMENT](#) [Dropdown listing] < links to overview of Reimbursement>

[PATIENT AFFORDABILITY](#) [Dropdown listing] <links to overview of Patient Affordability>

[PATIENT SUPPORT](#) [Dropdown listing] <links to overview of Patient Support>

[Headline]

Welcome to Janssen CarePath

[Subheader]

Everything you need in one place to get your patients started on the right path

[Intro Copy]

Navigating today's healthcare system doesn't have to be so hard. At Janssen CarePath, you'll find the resources you need in a single location so you can get the information you're looking for — fast.

REMICADE® is marketed by Janssen Pharmaceuticals, Inc.

SARAH BELZER

copy + ideation + creative direction

2.0 PATIENT COVERAGE

[Image: REMICADE logo]

[Top Navigation]

[OVERVIEW](#) <links to overview page of REMICADE>

[PATIENT COVERAGE](#) [Dropdown listing] <links to overview of Patient Coverage>

[REIMBURSEMENT](#) [Dropdown listing] < links to overview of Reimbursement>

[PATIENT AFFORDABILITY](#) [Dropdown listing] <links to overview of Patient Affordability>

[PATIENT SUPPORT](#) [Dropdown listing] <links to overview of Patient Support>

[Header]

Patient Coverage

[Subheader]

Easy Access, Great Resources, Fast Answers

[Intro Copy]

Janssen CarePath is working behind the scenes to make it easier for healthcare providers like you to navigate the complex processes so you can focus on running your practice and your patients can focus on getting better.

[Header]

2.1 [Medicaid Fee-for-Service](#)

Payers create resources to provide information for healthcare services. Since information varies by payer, it is important to contact the payer directly or consult its Web site to obtain product-specific coverage.

[Header]

2.2 [Commercial Payer Information](#)

[Headline]

Looking For Payer-Specific Information?

[Subheader]

Let Janssen CarePath connect you

[Intro Copy]

Getting lost in a sea of paperwork? [This section](#) contains information on state-specific Commercial Payer and Medicare Part D prior authorization. You'll find the information you need to get the ball rolling.

[Header]

2.3 Exception & Appeals Process Information

[Subheader]

Isn't It Time It Got Easier?

SARAH BELZER

copy + ideation + creative direction

[Intro Copy]

Each Payer follows a different process when filing exceptions, appeals, and grievances. If you're looking for some general information to start the process, Janssen CarePath's [Exception & Appeals Process Information](#) provides a summary of the process and helpful links where more information may be obtained. It is important to contact the payer directly or consult its website to obtain product-specific information.

[Header]

2.4 [REMICADE® and Medicare](#)

This section provides an overview of the Medicare program with links to more details on the Medicare Web site. It also describes the Medicare coverage for REMICADE®.

[Header]

2.5 [Practice Resources](#)

This section contains forms that may be helpful in tracking your practice's inventory of REMICADE®, policies for key payers you work with, important telephone numbers, and a sample business associate contract.

MEDICAID FEE-FOR-SERVICE

[Header]

2.1.1 Medicaid Fee-for-Service

[Copy]

Medicaid fee-for-service is a state-specific program. Coverage may depend on the indication as well as other factors. As this information varies by state, it is important to contact the state agency directly or consult its Web site to obtain product-specific coverage and other information.

Disclaimer: Clicking on any of the links below will take you to a Web site to which this [Privacy Policy](#) does not apply. We encourage you to read the Privacy Policy of every Web site you visit.

Blank Entry: Not found in the public domain

Brand: A patented drug listed in PDL or supporting documents

Covered: Drug is listed in PDL or supporting documents

Preferred: Refers to the coverage level of a drug

COMMERCIAL PAYER INFORMATION

[Header]

2.2.1 Commercial Payer Information

[Buttons]

[Commercial Payer Information](#)

[Medicaid Fee-for-Service](#)

SARAH BELZER

copy + ideation + creative direction

EXCEPTION AND APPEALS PROCESS INFORMATION

[Header]

2.3.1 Exception & Appeals Process Information

[Copy]

Each Payer follows a different process when filing exceptions, appeals and grievances. If you're looking for some general information to start the process, click on one of our brochures below and take the first step today.

[Exceptions and Appeals for Drug Therapies: A Guide for Healthcare Providers](#)
[How to Request an Exception or Appeal a Decision from Your Prescription Drug Plan](#)

California and Colorado require that certain health plans must use the uniform Prior Authorization (PA) Request Form. In addition, there are new rules regarding the PA process. The rules became effective October 1, 2014 or January 1, 2015, depending on the type of health plan. Click on the PDF below for more information.

[Uniform Prescription Drug Prior Authorization Request Form & Notification Requirements for Health Plans in California](#)
[Uniform Prescription Drug Prior Authorization Request Form & Notification Requirements for Health Plans in Colorado](#)

The information below provides a summary of each payer's general exceptions and appeals process, which may pertain to services as well as to drugs and products. Some payers provide additional and specific exceptions and appeals information in the individual drug formularies. For this information, refer to the specific formulary.

Click on the payer link to be taken to detailed exception and appeals process information.

REMICADE AND MEDICARE

[Header]

2.4 REMICADE® (infliximab) and Medicare

[Copy]

Overview of Medicare

Medicare is a federal program that provides health insurance coverage to the following types of people:

- Individuals over age 65 with a work history
- Individuals with certain disabilities who have been disabled for at least 2 years
- Individuals diagnosed with end-stage renal disease (ESRD)

While Medicare covers many healthcare needs, it may not cover all of the patient's healthcare costs. The patient may have to pay a monthly premium for Medicare and then pay a co-insurance and deductible for many services.

SARAH BELZER

copy + ideation + creative direction

2.8.2 Medicare Coverage of REMICADE®

Medicare covers most physician-administered drugs like REMICADE® under Medicare Part B. There are comprehensive published Part B coverage policies specific to REMICADE®. Copies of coverage policies (for example, local coverage determinations [LCDs]) are available on your regional Medicare Administrative Contractor's (MAC's) website, which can be found in the Billing section of this website.

Medicare typically places few restrictions on REMICADE® coverage. However, some Medicare policies may limit coverage of REMICADE® to certain diagnoses, such as:

- Crohn's disease
- Ulcerative colitis
- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriatic arthritis
- Plaque psoriasis
-

You can check your regional MAC website for coverage policies for REMICADE® or call AccessOne® at 1-888-ACCESS-1 (1-888-222-3771) for more assistance.

The 4 Parts of Medicare

Medicare is divided into 4 parts: A, B, C, and D. Part A covers facility care such as hospitals, and Part B covers physician and other outpatient services. Part C, which is known as the Medicare Advantage program, allows private managed care plans to administer a patient's Medicare benefits.

Medicare Part D offers prescription drug coverage to anyone enrolled in Medicare Parts A or B. Table 1 provides additional detail regarding the 4 parts of the Medicare program.

Table 1. The 4 Parts of Medicare

| | |
|--|---|
| <p>Part A</p> <p>Typically known as the hospital benefit, Part A provides coverage for services such as hospitalizations, hospice care, skilled nursing facility stays, and home health services.</p> | <p>Part B</p> <p>Part B benefits provide reimbursement for physician services, clinical laboratory services, hospital outpatient services, prescription drugs administered "incident to" a physician's services, durable medical equipment, and some home health services.</p> |
| <p>Part C</p> <p>Also known as Medicare Advantage, this benefit provides Medicare Part A, B and often Part D coverage through managed care plans.</p> | <p>Part D</p> <p>Prescription drug coverage for medicines that are usually self-administered or taken orally.</p> |

To learn more about the different parts of Medicare, you can call the Medicare program at 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov.

Updates to Medicare in 2015

Annual updates to the Medicare program may affect providers and patients in 2015. Updates include changes in patient cost-sharing for Medicare coverage and services.

SARAH BELZER

copy + ideation + creative direction

It will be important to monitor the Medicare program in 2015 because additional changes may go into effect throughout the year. The following are updates to some of the patient costs associated with Medicare in 2015.

Part A (Inpatient Hospital, Skilled Nursing Care)¹

Most Medicare beneficiaries do not pay a monthly premium for Part A coverage. However, they may have to pay a deductible for inpatient hospital stays, skilled nursing facility stays, and some home health services. For each benefit period, Medicare pays all covered costs except the Part A deductible.

Medicare Part A cost-shares have increased for calendar year 2015. For each benefit period, the patient pays:

- A total of \$1,260 for a hospital stay of 1-60 days
- For days 61 through 90, the patient is responsible for an additional \$315/ day
- For days 91 through 150, the patient is responsible for an additional \$630/ day
- For days beyond 150, the patient is responsible for all costs

Part B (Physician Services, Outpatient Hospital Services, Certain Home Health Services, Durable Medical Equipment)¹

In 2015, the monthly fee or premium for Medicare Part B is based on your income. Most people will pay the standard monthly Part B premium of \$104.90 (unchanged from 2014). However, some people will pay a higher premium if their modified adjusted gross income is more than \$85,000 for an individual or \$170,000 for a married couple. These amounts change each year. There is also a \$147.00 deductible per year. After patients meet the deductible, they pay 20% of the Medicare-approved amount for services. Medicare Part B covers 80% of all Medicare-approved services.

Part C (Medicare Advantage)

Because these plans offer a variety of coverage, the patient's cost-share (e.g., co-pay or co-insurance, deductibles, and premiums) can vary from plan to plan. If you are enrolled in a Medicare Advantage plan, you should check with the specific plan to find out what the cost-share will be for 2015.

Part D (Prescription Drug Coverage)

In 2015, people with Medicare Part D will pay an average monthly premium of \$33.13.² After a \$320 deductible, patients pay 25% of the next \$2,960 in prescription drug costs.³ Patients will then be in the "donut hole" (also known as the coverage gap), where they will pay 45% of the plan's cost for covered brand medications and 65% of the plan's cost for covered generic medications until they reach \$4,700 in out-of-pocket prescription drug costs. This is known as the catastrophic coverage phase. Patients are responsible for 5% of all additional drug costs after reaching the catastrophic coverage phase.⁴ Except for the average monthly premium and the prescription drug costs before the coverage gap which increased from 2014, patient cost-share under Medicare Part D has decreased in 2015.

Medicare Supplemental Coverage

Most patients who have Medicare also have some type of secondary insurance coverage. This secondary coverage may be an employer-sponsored plan, Medigap plan, or the Medicaid program. These plans offer a wide variety of supplemental coverage to Medicare. For example, Medigap plans may cover some or all of a patient's 20% co-insurance and deductible for administration of REMICADE® provided through Medicare Part B. However, Medigap plans typically do not provide this type of

SARAH BELZER

copy + ideation + creative direction

coverage for REMICADE® if it is provided under the Part D prescription drug benefit. Patients enrolled in a Medicare Advantage plan cannot also enroll in a Medigap plan.

Special Notice for Providers: Coding for Disaster Victim Services

In order to track and facilitate claims processing for disaster victims, CMS established a national modifier and condition code:

CR, Catastrophic/ Disaster Related (modifier)

DR, Disaster Related (condition code)

Any provider may use the modifier. MACs use either the modifier or the condition code. The condition code would identify claims that are or may be impacted by specific payer policies related to a national or regional disaster. The modifier indicates a specific Part B service that may be impacted by a policy related to the disaster.

For additional information regarding disaster victim services, please contact Medicare at 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov or www.cms.gov.

Additional Information About Medicare Coverage

For more details about the costs of Medicare coverage, please call the Medicare program at 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov.

[Smaller print]

¹ Medicare.gov. Medicare costs at a glance. <http://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-a-glance.html>. Accessed October 15, 2014.

² CMS. Medicare prescription drug premiums (Part D). <http://www.medicare.gov/part-d/costs/premiums/drug-plan-premiums.html>. Accessed October 15, 2014.

³ CMS. Medicare & You Handbook, 2015. <http://www.medicare.gov/Pubs/pdf/10050.pdf>. Accessed October 15, 2014.

⁴ CMS. Announcement of calendar year (CY) 2015 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2015.pdf>. Accessed October 30, 2014.

PRACTICE RESOURCES

[Header]

2.5 Practice Resources

[Gastroenterology PEF Support Enrollment Form](#)

This is the Prescription Enrollment Form (PEF) for Gastroenterology.

[Benefits Investigation Form \(BIF\)](#)

Use this form to initiate a request for verification of benefits on a per-patient basis

[eBIF Submission](#)

SARAH BELZER

copy + ideation + creative direction

[Limitation of Services request form](#)

If you prefer your patients not be contacted by Janssen CarePath for explanation of benefits, complete this form.

3.0 REIMBURSEMENT

[Image: REMICADE logo]

[Top Navigation]

[OVERVIEW](#) <links to overview page of REMICADE>

[PATIENT COVERAGE](#) [Dropdown listing] <links to overview of Patient Coverage>

[REIMBURSEMENT](#) [Dropdown listing] < links to overview of Reimbursement>

[PATIENT AFFORDABILITY](#) [Dropdown listing] <links to overview of Patient Affordability>

[PATIENT SUPPORT](#) [Dropdown listing] <links to overview of Patient Support>

[Header]

Reimbursement

[Subheader]

Got Billing and Reimbursement Questions? We've Got the Answers.

[Intro Copy]

At Janssen CarePath, we get that there's a lot that goes into managing billing and reimbursements, so we've put together the information you'll need for REMICADE® in one convenient location.

Coverage policies may vary by insurer or even between plans offered by the same insurer. This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current, the information may not be as current or comprehensive when you view it. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions.

[Headline]

The New ICD-10 Coding For Providers

[Subheader]

Easy access to the information you need.

[Copy]

Remember, if you're a provider, you'll want to get familiar with the new codes and use them from here on out. Everyone covered by the Health Insurance Portability and Accountability Act (HIPAA) will be affected by the usage of the new codes. Learn more in the [ICD-10 Support](#) area.

[Header]

3.4 [Reimbursement Resources](#)

SARAH BELZER

copy + ideation + creative direction

This overview outlines the key points you need to know about reimbursement for REMICADE®. It includes details about coding and coverage for REMICADE® and its administration, important information about documentation of services, and reimbursement support services for REMICADE® for your practice.

ICD-10 SUPPORT

[Header]

3.1.1 ICD-10 Support

[Copy]

Introduction

While sample ICD-9-CM codes have been mapped to the latest ICD-10-CM codes so that coders can become familiar with the new codes prior to the implementation date, the ultimate responsibility for correct coding lies with the provider of services. The codes included in these charts and articles are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use.

ICD-10 Crosswalk Sample

This chart provides a sampling of various codes that reflect the conversion from ICD-9 to ICD-10.

[ICD-10 Crosswalk Sample](#)

Dermatology Crosswalk

The [Dermatology ICD-9 to ICD-10 crosswalk](#) reviews the most common ICD-10 codes for Dermatology diagnoses.

Gastroenterology Crosswalk

The [Gastroenterology ICD-9 to ICD-10 crosswalk](#) reviews the most common ICD-10 codes for Gastroenterology diagnoses.

Rheumatology Crosswalk

The [Rheumatology ICD-9 to ICD-10 crosswalk](#) reviews the most common ICD-10 codes for Rheumatology diagnoses.

ICD-10 SUPPORT

[Header]

3.1.1 ICD-10 Crosswalk Sample

[Copy]

While sample ICD-9-CM codes have been mapped to the latest ICD-10-CM codes so that coders can become familiar with the new codes prior to the implementation date, the ultimate responsibility for correct coding lies with the provider of services. The codes included in this chart are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use. Please refer to the current policy for the latest codes since these codes are subject to change. The codes provided are not intended to be exhaustive. Please consult your ICD-10 code book for additional information.

SARAH BELZER

copy + ideation + creative direction

ICD-9 Conversion to ICD-10

Click on the plus symbol below for an ICD-10 Crosswalk Sample.

[ANAL FISSURE AND FISTULA / FISSURE AND FISTULA OF ANAL AND RECTAL REGIONS](#)

ICD-9

ICD-10

565Anal Fissure and Fistula

K60Fissure and Fistula of Anal and Rectal Regions

565.1Anal fistula

K60.3Anal fistula

K60.4Rectal fistula

K60.5Anorectal fistula

[ANKYLOSING SPONDYLITIS AND OTHER INFLAMMATORY SPONDYLOPATHIES / ANKYLOSING SPONDYLITIS](#)

[OTHER DISORDERS OF INTESTINE / OTHER DISEASES OF INTESTINE](#)

[PSORIASIS AND SIMILAR DISORDERS / PSORIASIS](#)

[REGIONAL ENTERITIS / CROHN'S DISEASE](#)

[RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES / OTHER RHEUMATOID ARTHRITIS](#)

[ULCERATIVE COLITIS](#)

For more information on the transition to ICD-10, visit the [CMS Web site](#).

SOURCES

Optum. "2013 ICD-10-CM: The Complete Official Draft Code Set"

PMIC. "ICD-10-CM 2013: Transition and Training Edition"

REIMBURSEMENT RESOURCES

[Header]

3.4 Reimbursement Resources

[Copy]

Coverage policies may vary by insurer or even between plans offered by the same insurer.

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current, the information may not be as current or comprehensive when you view it. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions.

Overview of Reimbursement for REMICADE® (infliximab)

This overview outlines the key points you need to know about reimbursement for REMICADE®. It includes details about coding and coverage for REMICADE® and its administration, important information about documentation of services, and reimbursement support services for REMICADE® for your practice.

SARAH BELZER

copy + ideation + creative direction

Coding

The product-specific HCPCS code for REMICADE® is J1745, infliximab, 10 mg. It is important to note that this code represents 1/10th of a vial. You should be sure to bill 10 units of J1745 on the claim form when indicating that a single 100-mg vial of REMICADE® was used.

- 1 vial = 10 units
- 2 vials = 20 units
- 3 vials = 30 units

Medicare uses CPT codes 96413 and 96415 to describe the first and subsequent hours, respectively, of the infusion procedure associated with therapy with REMICADE® in the physician office setting. Commercial payers may use these codes or alternate codes 96365 and 96366.

Hospital claims should use CPT codes 96413 and 96415 to describe administration of REMICADE®. The descriptions for the most commonly used codes to describe first and subsequent hours of administration of REMICADE® are:

| | |
|-------|--|
| 96413 | Chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance |
| 96415 | Chemotherapy administration, intravenous infusion technique, each additional hour, single or initial substance (list separately in addition to code 96413 for initial hour of infusion services) |

Non-Medicare payer policies regarding the use of 96413 and 96415 may vary. Alternatively, some may prefer use of CPT codes 96365 (IV infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour) and 96366 (IV infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; each additional hour). (List separately in addition to code for primary procedure.) Please consult your local payer for specific coding policies, or call Janssen CarePath for assistance at 1-877-CAREPATH (1-877-227-3728).

Be sure to consult your payer for specific coding requirements for REMICADE®.

Coverage

You should know that there is a demonstrated history of paid claims for REMICADE® for all payers, including Medicare, Medicaid, and commercial plans. Coverage varies by carrier and individual patient case.

There are comprehensive, published Medicare Part A and Part B coverage policies specific to REMICADE®. Copies of coverage policies are available on your regional Medicare Administrative Contractor (MAC) website, and these can be found in the Billing and Reimbursement section of this website.

You can bill most payers electronically for REMICADE® and its associated services.

Documentation of Services

SARAH BELZER

copy + ideation + creative direction

Keep the following tips in mind to ensure that your documentation is thorough and accurate:

- When billing for evaluation and management (E&M) services in addition to administration of REMICADE®, be sure that the E&M services are separately identifiable and medically necessary and that justification is noted in the patient record
- Correct use of modifiers is important—make sure modifiers are accurate and appropriately reflected in the patient record
- Always verify payer rules for the billing of E&M codes

Reimbursement Support Through Janssen CarePath

Janssen CarePath provides information and assistance regarding coding, coverage, and claim submissions related to REMICADE® (infliximab). In addition, Janssen CarePath can also investigate specialty pharmacy options that may be available to simplify product procurement and billing for healthcare providers. Finally, Janssen CarePath can provide reimbursement information and support directly to patients.

Janssen CarePath is available at 1-877-CAREPATH (1-877-227-3728), Monday-Friday, 8 AM-8 PM ET.

Janssen CarePath can assist you with the following:

Benefits investigation, to determine patient-specific benefits for REMICADE®

Alternate coverage research for patients requiring coverage or additional coverage for REMICADE®

Requirements for prior authorization process

Assistance with the appeal process for administrative denials

Infusion site location assistance through www.2infuse.com

Personalized care coordination including benefits explanation to your patients

Upon patient request:

- Appointment reminder calls and follow-up calls
- Patient education materials, providing disease-state information and infusion education for all approved indications for REMICADE®

Billing Guide for REMICADE®

The [Billing Guide for REMICADE®](#) is intended to help healthcare providers and billing staff understand third-party reimbursement for infusible drugs and the services by which they are administered. Specifically, this guide presents general coverage, coding and payment information relevant to the sites of care in which infusible drugs are administered, and references resources for additional help.

4.0 PATIENT AFFORDABILITY

[Image: REMICADE logo]

SARAH BELZER

copy + ideation + creative direction

[Top Navigation]

[OVERVIEW](#) <links to overview page of REMICADE>

[PATIENT COVERAGE](#) [Dropdown listing] <links to overview of Patient Coverage>

[REIMBURSEMENT](#) [Dropdown listing] <links to overview of Reimbursement>

[PATIENT AFFORDABILITY](#) [Dropdown listing] <links to overview of Patient Affordability>

[PATIENT SUPPORT](#) [Dropdown listing] <links to overview of Patient Support>

[Header]

Patient Savings

[Subheader]

Sometimes we all need a little help from our friends

[Intro Copy]

When patients who have private insurance need help paying for their Janssen prescription, the Janssen CarePath Savings Program may be able to help. Patients without private insurance may find help from the programs and resources available from Janssen Prescription Assistance.

[Janssen Prescription Assistance for REMICADE® \(infliximab\)](#)

This page has information about prescription assistance programs sponsored by relevant Janssen Pharmaceutical Companies as well as up-to-date information about independent foundations that may have available funding to help minimize drug costs for REMICADE®.

[Johnson & Johnson Patient Assistance Foundation](#)

Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF) is committed to providing access to medicines for uninsured individuals who lack the financial resources to pay for them. If your patient needs REMICADE® (infliximab) and is uninsured and unable to pay for their medicine, please have them contact a JJPAF program specialist at 1-800-652-6227 9 AM to 6 PM ET or visit the foundation website at [JJPAF.org](#) to see if they might qualify for assistance.

[Janssen CarePath Savings Program](#)

The Janssen CarePath Savings Program supports your access to REMICADE® (infliximab). Based on your eligibility, the Janssen CarePath Savings Program can provide a rebate for your medication out-of-pocket costs, including deductible, co-payment, and co-insurance. If eligible, you will be responsible for \$5 per infusion and will receive a rebate for the remaining medication out-of-pocket costs, for up to 12 months from the first eligible date of service or a maximum annual benefit of \$10,000, whichever comes first. Eligible patients must be beginning or currently receiving treatment with REMICADE® and must have commercial insurance that covers medication costs for REMICADE®. Patients enrolled in Medicare, Medicaid, or other federally funded programs are not eligible to participate. To enroll, patients should submit a completed [enrollment form \(editable\)](#) to Janssen CarePath. Click to view the [full patient brochure](#) and [Medication Guide](#). For additional information, including eligibility and restrictions, please visit [JanssenCarePath.com/Remicade](#).

[Janssen CarePath Extended Access Program](#)

Janssen CarePath Extended Access is a patient rebate program for Remicade® patients who have

SARAH BELZER

copy + ideation + creative direction

participated in the Janssen CarePath Savings Program and have exhausted the 12 months in the program. In order to be eligible for Extended Access, you must have met the eligibility requirements of the Janssen CarePath Savings Program. If eligible, you will be responsible for \$5 per infusion and will receive a rebate for the remaining medication out-of-pocket costs for up to 12 months from your re-enrollment or a maximum annual benefit of \$10,000, whichever comes first. To enroll, please submit a completed [enrollment form \(editable\)](#) to the Janssen CarePath Extended Access Program. Click to view the [full patient brochure](#) and [Medication Guide](#). For additional information, including eligibility and restrictions, please visit JanssenCarePath.com/Remicade.

5.0 PATIENT SUPPORT

[Image: REMICADE logo]

[Top Navigation]

[OVERVIEW](#) <links to overview page of REMICADE>

[PATIENT COVERAGE](#) [Dropdown listing] <links to overview of Patient Coverage>

[REIMBURSEMENT](#) [Dropdown listing] <links to overview of Reimbursement>

[PATIENT AFFORDABILITY](#) [Dropdown listing] <links to overview of Patient Affordability>

[PATIENT SUPPORT](#) [Dropdown listing] <links to overview of Patient Support>

[Header]

Patient Support

[Subheader]

Helping your patients get the care they need

[Intro Copy]

Janssen CarePath is committed to helping medical practitioners like yourself manage your patients' treatment and the challenges they face from the moment a condition is identified, so you can spend more time on your practice and less time on paperwork.

[Header]

5.1 [Infusion Resources](#)

Here, you will find help with documenting infusion visits as well as a tool to track infusions with REMICADE®.

These are just some of the resources you can use to help your practice manage therapy with REMICADE®. This is not an all-inclusive compilation of resources. You should talk to others within your office, hospital, or specialty association to see if there are additional tools that can help you in managing your practice.

[Header]

5.2 [Specialty Pharmacy Options](#)

Simplify product procurement and billing for in-office infusion.

SARAH BELZER

copy + ideation + creative direction

[Header]

5.3 [Care Coordination](#)

When it comes to convenience, Janssen CarePath is hard at work. We're here to help deliver the support your patients are looking and simplify the process—soup to nuts. We make getting Janssen medications easier, coordinate their care through one of our Care Coordinators, and help assess and explain insurance benefits and any out-of-pocket expenses.

Janssen CarePath Care Coordinators are individually assigned to assist physician, office staff, and patient.

[Header]

5.4 [Helpful Internet Links](#)

This section of the site has a list of other web resources to help your patients and their families understand and manage therapy with REMICADE® and their disease.

INFUSION RESOURCES

[Header]

5.1 Infusion Resources

The following resources may aid your practice in documenting the patient's infusion with REMICADE® (infliximab).

[Header]

[Alternate Site of Care Letter Template](#)

This letter template can be used by the infusing site to establish communication protocols with the prescribing physician to ensure continuity of care. The infusing site may record infusion information then fax it to the prescribing physician for their records.

[Header]

[Infusion Site Locator](#)

Utilize the powerful search capabilities of 2infuse.com to help providers locate convenient infusion sites.

INFUSION RESOURCES

[Header]

5.1.1 Infusion Site Locator

[Copy]

Streamlined infusion site location

An important resource for your practice...

- A powerful service for physicians who decide not to infuse in their office
- Rapidly locates infusion sites convenient for patients using 2infuse.com
- Janssen CarePath specialists search for infusion sites by ZIP code and driving distance
- Detailed search results that include valuable information about infusion sites including hospital affiliations and staff profiles
- Close coordination with you to meet the needs of your patients

Meaningful benefits for your patients...

SARAH BELZER

copy + ideation + creative direction

- Quick, easy access to infusion sites convenient to home or workplace
- Access to infusion therapy for patients when and where they need it

Upon patient request

- Education materials and support
- Assistance with appointment reminders and infusion appointment follow-up

[Click](#) to locate an infusion site

If you have any questions, please call Janssen CarePath at 1-877-CAREPATH (1-877-227-3728), Monday through Friday between 8 AM and 8 PM ET.

The 2infuse.com site offers the user the opportunity to locate and contact an infusion site of care. Inclusion of centers in this database is based on opt-in approval by authorized personnel for those sites listed. This database is compiled for informational purposes only. No fees have been or will be received in exchange for participation in this database. Inclusion of centers in this database does not represent an endorsement, referral or recommendation from Janssen Biotech, Inc. Moreover, the infusion sites of care participating in this search feature do not necessarily endorse the use of REMICADE® (infliximab). Janssen Biotech, Inc. makes no representations as to whether any of the infusion sites of care participating in this search feature are covered by particular healthcare plans or insurers, if at all. Users of this Web site are solely responsible for communications and interactions with any of the listed facilities or physician offices, and any information users send them is not governed by our Legal Notice and Privacy Policy. You are responsible for compliance with state and federal laws regulating physician referrals, such as anti-kickback laws, the Stark law, or state professional practice restrictions.

SPECIALTY PHARMACY OPTIONS]

[Header]

5.2 Specialty Pharmacy Options

[Copy]

Specialty pharmacy options

Allow practice to provide access to therapy with REMICADE® (infliximab), without direct purchase or billing of product...

- Payer investigation of potential third-party assignment of benefits options, both pharmacy and major medical
- Provides listing of third-party pharmacy providers for shipment and billing of REMICADE® on behalf of practice

If you have any questions, please call Janssen CarePath at 1-877-CAREPATH (1-877-227-3728), Monday through Friday between 8 AM and 8 PM ET.

CARE COORDINATION

[Header]

5.3 Care Coordination

SARAH BELZER

copy + ideation + creative direction

[Copy]

Single source support for access to infusion therapy at 1-877-CAREPATH (1-877-227-3728)

Personalized patient support services

An important resource for your practice...

- Assignment of Care Coordinator for both patient and physician/practice
- Personalized one-to-one attention for your patients, widening your circle of care
- Allows you to devote more time to patient care and improve patient access to infusion therapy

Meaningful benefits for your patients...

- Patient counseling with respect to insurance benefits, coverages and co-pays

Upon patient request

- Education materials and support
- Assistance with appointment reminders and infusion appointment follow-up

Physicians may request Janssen CarePath not to call patients concerning insurance benefit investigation. However, patients may request Janssen CarePath services by contacting Janssen CarePath directly.

If you have any questions, please call Janssen CarePath at 1-877-CAREPATH (1-877-227-3728), Monday through Friday between 8 AM and 8 PM ET.

HELPFUL INTERNET LINKS

[Header]

5.4 Helpful Internet Links

[Copy]

There are many useful resources available online to help your patients understand and manage their therapy with REMICADE® (infliximab) and their disease. You may find the Web sites listed here helpful as referrals in educating your patients about their condition.

Remicade.com

remicade.com

This Web site contains information about REMICADE®. On this site, patients can find a specialist, sign up for newsletters, and get helpful information about their condition. See below for approved indications for REMICADE®.

Living with Ulcerative Colitis

livingwithuc.com

This Web site is designed to be an education and information resource for patients, their families, and friends on the subject of Ulcerative colitis (UC). Here, patients will learn about UC, its symptoms and impact, and how gastroenterologists can help. Patients can also read about treatment options and medication choices.

SARAH BELZER

copy + ideation + creative direction

Arthritis Foundation

arthritis.org

This site includes education and online community resources for people with arthritis and their families.

National Psoriasis Foundation

psoriasis.org

The National Psoriasis Foundation is a patient-driven, non-profit organization that is the voice for the 5 million people affected by psoriatic diseases, including Psoriatic arthritis. The Web site's mission is to improve lives through education, advocacy and research.

Crohn's & Colitis Foundation of America

ccfa.org

The Crohn's and Colitis Foundation of America is a non-profit, volunteer-driven organization dedicated to finding the cure for Crohn's disease and Ulcerative colitis. The Web site contains medical information, news, and events about digestive disease.

Spondylitis Association of America

spondylitis.org

The Spondylitis Association of America is the first and largest resource for people affected by spondylitis. The Web site's efforts help to advance education, research and treatment for Ankylosing spondylitis (AS) and related diseases. This site includes information and support for patients with AS and their families.

[Header]

Reimbursement Resources

Coverage policies may vary by insurer or even between plans offered by the same insurer.

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current, the information may not be as current or comprehensive when you view it. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions.

Overview of Reimbursement for REMICADE® (infliximab)

This overview outlines the key points you need to know about reimbursement for REMICADE®. It includes details about coding and coverage for REMICADE® and its administration, important information about documentation of services, and reimbursement support services for REMICADE® for your practice.

Coding

The product-specific HCPCS code for REMICADE® is J1745, infliximab, 10 mg. It is important to note that this code represents 1/10th of a vial. You should be sure to bill 10 units of J1745 on the claim form when indicating that a single 100-mg vial of REMICADE® was used.

SARAH BELZER

copy + ideation + creative direction

1 vial = 10 units

2 vials = 20 units

3 vials = 30 units

Medicare uses CPT codes 96413 and 96415 to describe the first and subsequent hours, respectively, of the infusion procedure associated with therapy with REMICADE® in the physician office setting.

Commercial payers may use these codes or alternate codes 96365 and 96366.

Hospital claims should use CPT codes 96413 and 96415 to describe administration of REMICADE®.

The descriptions for the most commonly used codes to describe first and subsequent hours of administration of REMICADE® are:

| | |
|-------|--|
| 96413 | Chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance |
| 96415 | Chemotherapy administration, intravenous infusion technique, each additional hour, single or initial substance (list separately in addition to code 96413 for initial hour of infusion services) |

Non-Medicare payer policies regarding the use of 96413 and 96415 may vary. Alternatively, some may prefer use of CPT codes 96365 (IV infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour) and 96366 (IV infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; each additional hour). (List separately in addition to code for primary procedure.) Please consult your local payer for specific coding policies, or call AccessOne® for assistance at 1-ACCESS-1 (1-888-222-3771).

Be sure to consult your payer for specific coding requirements for REMICADE®.

Coverage

You should know that there is a demonstrated history of paid claims for REMICADE® for all payers, including Medicare, Medicaid, and commercial plans. Coverage varies by carrier and individual patient case.

There are comprehensive, published Medicare Part A and Part B coverage policies specific to REMICADE®. Copies of coverage policies are available on your regional Medicare Administrative Contractor (MAC) website, and these can be found in the Billing and Reimbursement section of this website.

You can bill most payers electronically for REMICADE® and its associated services.

Documentation of Services

Keep the following tips in mind to ensure that your documentation is thorough and accurate:

- When billing for evaluation and management (E&M) services in addition to administration of REMICADE®, be sure that the E&M services are separately identifiable and medically necessary and that justification is noted in the patient record

SARAH BELZER

copy + ideation + creative direction

- Correct use of modifiers is important—make sure modifiers are accurate and appropriately reflected in the patient record
- Always verify payer rules for the billing of E&M codes

Reimbursement Support Through AccessOne®

AccessOne® provides information and assistance regarding coding, coverage, and claim submissions related to REMICADE® (infliximab). In addition, AccessOne® can also investigate specialty pharmacy options that may be available to simplify product procurement and billing for healthcare providers. Finally, AccessOne® can provide reimbursement information and support directly to patients.

AccessOne® is available at 1-888-ACCESS-1 (1-888-222-3771), Monday-Friday, 8 AM-8 PM ET.

AccessOne® can assist you with the following:

Benefits investigation, to determine patient-specific benefits for REMICADE®

Alternate coverage research for patients requiring coverage or additional coverage for REMICADE®

Requirements for the prior authorization process

Assistance with the appeal process for administrative denials

Infusion site location assistance through www.2infuse.com

Personalized care coordination including benefits explanation to your patients