BILLING GUIDE FOR
REMICADE® (infliximab) AND Infliximab

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with REMICADE® and Infliximab. Infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens (eg, TB, histoplasmosis) have been reported. Lymphoma, including cases of fatal hepatosplenic T-cell lymphoma (HSTCL), and other malignancies have been reported, including in children and young adult patients. 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. REMICADE® and Infliximab are contraindicated at doses >5 mg/kg in patients with moderate or severe heart failure and in patients with severe hypersensitivity reactions to REMICADE® and Infliximab. Other serious side effects reported include melanoma, Merkel cell carcinoma, invasive cervical cancer, hepatitis B reactivation, hepatotoxicity, hematological events, hypersensitivity, cardiovascular and cerebrovascular reactions during and after infusion, neurological events, and lupus-like syndrome. Please see related and other Important Safety Information on pages 22-23 for REMICADE® and Infliximab.

Remicade® INFLIXIMAB | Infliximab

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Johnson & Johnson is committed to providing reimbursement information for REMICADE® (infliximab) and Infliximab to you. This billing guide has been developed to provide you with information regarding:

- Essential coding considerations
- Sample claim forms
- Important product information
- Reimbursement support resources

For information and assistance about REMICADE® and Infliximab access and reimbursement support resources, contact J&J withMe at 877-227-3728 or visit JNJwithMe.com.

Disclaimer

Please note this information is provided for your background education and is not intended to serve as guidance for specific coding, billing, and claims submissions. Decisions on which codes best describe the services provided must be made by individual providers based on their clinical judgment, payer-specific guidance, and other requirements.

Please see Important Safety Information for REMICADE® and Infliximab on pages 22-23.

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REMICADE® (infliximab) AND Infliximab

Infliximab IS AN UNBRANDED BIOLOGIC FROM THE MAKERS OF REMICADE®

Unbranded Infliximab from Johnson & Johnson is REMICADE® without the brand name[1-3]

Produced from the **same** cell line and at the **same** manufacturing sites as REMICADE®

Approved for all the **same** indications as REMICADE® with the **same** safety and efficacy profile

Available in the **same** strength, **same** dosage form, and **same** route of administration as REMICADE®

Offering the **same** affordability and patient support programs as REMICADE®

UNDERSTANDING UNBRANDED BIOLOGICS

An unbranded biologic is NOT a biosimilar[4]

BRAND-NAME BIOLOGIC[5,6]*	UNBRANDED BIOLOGIC[4]	BIOSIMILAR[5,6]
Approved based on a full complement of safety and effectiveness data	The **same** as the brand-name biologic*	**Highly similar** to brand-name biologic* with no clinically meaningful differences
Produced through biotechnology in a living system (ie, a "cell line")	Produced using the **same** cell line as the brand-name biologic*	Produced using a **different** cell line

*"Brand-name biologic" refers to the reference biologic.

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INDICATIONS[1,2]

Crohn's Disease

REMICADE® and Infliximab are 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.
- reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing CD.

Pediatric Crohn's Disease

REMICADE® and Infliximab are 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 CD who have had an inadequate response to conventional therapy.

Ulcerative Colitis

REMICADE® and Infliximab are 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

REMICADE® and Infliximab are 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 UC who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis

REMICADE® or Infliximab, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA).

Ankylosing Spondylitis

REMICADE® and Infliximab are indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS).

Psoriatic Arthritis

REMICADE® and Infliximab are indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis (PsA).

Plaque Psoriasis

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

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DOSING AND ADMINISTRATION[1,2]

REMICADE® and Infliximab dosing is weight based and indication specific. Infusions are administered every 8 weeks (or 6 weeks for those with active Ankylosing Spondylitis) after 3 induction doses. Both induction and maintenance doses are administered by intravenous infusion over a period of not less than 2 hours.

Table 1a. Recommended Dosage and Intervals for REMICADE® and Infliximab in Adult Patients[1,2]

Indication	Induction	Maintenance
Moderately to Severely Active Crohn's Disease* *Patients who do not respond by Week 14 are unlikely to respond with continued dosing and consideration should be given to discontinuing REMICADE® or Infliximab in these patients.	5 mg/kg 0, 2, and 6 weeks	5 mg/kg† every 8 weeks †For adult patients who respond and then lose their response, consideration may be given to treatment with 10 mg/kg every 8 weeks.
Moderately to Severely Active Ulcerative Colitis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks
Moderately to Severely Active Rheumatoid Arthritis‡ ‡In conjunction with methotrexate.	3 mg/kg 0, 2, and 6 weeks	3 mg/kg§ every 8 weeks §For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks bearing in mind that risk of serious infections is increased at higher doses per infusion or more frequent dosing.
Active Ankylosing Spondylitis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 6 weeks
Active Psoriatic Arthritis‖ ‖Can be used with or without methotrexate.	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks
Chronic Severe Plaque Psoriasis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks

Table 1b. Recommended Dosage and Intervals for REMICADE® and Infliximab in Pediatric Patients (≥6 Years)[1,2]

Indication	Induction	Maintenance
Moderately to Severely Active Crohn's Disease	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks
Moderately to Severely Active Ulcerative Colitis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks

SELECTED IMPORTANT SAFETY INFORMATION

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DOSING AND ADMINISTRATION[1,2] (cont'd)

Reconstitution, Dilution, and Administration Instructions for REMICADE® or Infliximab[1]

REMICADE® or Infliximab is intended for use under the guidance and supervision of a healthcare provider. The supplied lyophilized powder must be reconstituted and diluted prior to administration. The infusion solution should be prepared and administered by a trained medical professional using aseptic technique by the following procedure:

1. Calculate the dose, total volume of reconstituted REMICADE® or Infliximab solution required and the number of REMICADE® or Infliximab vials needed. More than one vial may be needed for a full dose.
2. Reconstitute each 100 mg REMICADE® or Infliximab vial with 10 mL of Sterile Water for Injection, USP, to obtain a concentration of 10 mg/mL, using a syringe equipped with a 21-gauge or smaller needle as follows:
   - Remove the flip-top from the vial and wipe the top with an alcohol swab.
   - Insert the syringe needle into the vial through the center of the rubber stopper and direct the stream of Sterile Water for Injection, USP, to the glass wall of the vial. Gently swirl the solution by rotating the vial to dissolve the lyophilized powder, which has a cake-like appearance. Avoid prolonged or vigorous agitation. DO NOT SHAKE. Foaming of the solution on reconstitution is not unusual.
   - Allow the reconstituted solution to stand for 5 minutes. Visually inspect the reconstituted solution for particulate matter and discoloration. The reconstituted solution should be colorless to light yellow and opalescent, and the solution may develop a few translucent particles as infliximab is a protein. Do not use if the lyophilized powder has not fully dissolved or if opaque particles, discoloration, or other foreign particles are present. Do not store unused reconstituted REMICADE® or Infliximab solution.
3. Dilute the total volume of the reconstituted REMICADE® or Infliximab solution to 250 mL* with sterile 0.9% Sodium Chloride Injection, USP, (do not dilute with any other diluent) as follows:
   - Withdraw a volume from the 0.9% Sodium Chloride Injection, USP, 250 mL bottle or bag equal to the total volume of reconstituted REMICADE® or Infliximab required for a dose. Slowly add the total volume of reconstituted REMICADE® or Infliximab solution from the vial(s) to the 250 mL infusion bottle or bag.
   - Discard any unused portion of the reconstituted REMICADE® or Infliximab solution remaining in the vial(s).
   - Gently invert the bag to mix the solution. The resulting infusion concentration should range between 0.4 mg/mL (minimum recommended concentration) and 4 mg/mL (maximum recommended concentration) of infliximab.
4. The REMICADE® or Infliximab infusion should begin within 3 hours of reconstitution and dilution. The infusion must be administered intravenously for at least 2 hours with an infusion set with an in-line, sterile, non-pyrogenic, low-protein-binding filter (pore size of 1.2 µm or less).
5. Given that the vials do not contain antibacterial preservatives, discard any unused portion of the infusion solution (do not store for reuse).

   No physical biochemical compatibility studies have been conducted to evaluate the co-administration of REMICADE® or Infliximab with other agents. REMICADE® or Infliximab should not be infused concomitantly in the same intravenous line with other agents.

Please refer to the Dosage and Administration section of the full Prescribing Information for REMICADE® or full Prescribing Information for Infliximab for complete information on how to prepare and administer REMICADE® or Infliximab.

*For volumes greater than 250 mL, either use a larger infusion bag (e.g. 500 mL) or multiple 250 mL infusion bags to ensure that the concentration of the infusion solution does not exceed 4 mg/mL.

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CODING

ICD-10-CM Diagnosis Codes

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve the greatest level of specificity. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A 3-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the 7th character, if applicable.[7]

Table 2. ICD-10-CM Codes[8] for Consideration*

Crohn's Disease	
K50.00	Crohn's disease of small intestine without complications
K50.10	Crohn's disease of large intestine without complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.90	Crohn's disease, unspecified, without complications
Fistula (Use in Addition to Codes for Crohn's Disease)	
K60.3	Anal fistula
K60.4	Rectal fistula
Ulcerative Colitis	
K51.80	Other ulcerative colitis without complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.50	Left-sided colitis without complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.90	Ulcerative colitis, unspecified, without complications
Rheumatoid Arthritis	
M06.00	Rheumatoid arthritis w/o rheumatoid factor, unspecified site
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
Ankylosing Spondylitis	
M45.9	Ankylosing spondylitis of unspecified sites in spine
Psoriatic Arthritis	
L40.50	Arthropathic psoriasis, unspecified
Plaque Psoriasis	
L40.0	Psoriasis vulgaris

*These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with US Food and Drug Administration-approved use. The codes provided are not exhaustive and additional codes may apply. Listed codes may require a higher level of specificity when reporting for individual patients.

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CODING (cont'd)

National Drug Code (NDC)

The National Drug Code (NDC) is a unique number that identifies a drug's labeler, product, and trade package size. The NDC has typically been reserved for pharmacy billing, including drugs provided for home infusion. However, Medicaid fee-for-service programs, Medicare crossover claims for dual-eligible beneficiaries and some private payers now also require the NDC for billing instead of, or in addition to, the HCPCS code, for physician claims and those of other service providers. Although the FDA uses a 10-digit format when registering NDCs, payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires use of the 11-digit NDC. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below. In some cases, you may be required to include the NDC number on a claim form.[9]

Table 3. NDC for REMICADE® and Infliximab[1,2]

	10-digit NDC	11-digit NDC	Description
REMICADE®	**57894-030-01**	**57894-0030-01**	**Single-use vial containing 100 mg of infliximab, reconstituted with 10 mL of Sterile Water for Injection, USP, for final concentration of 10 mg/mL**
Infliximab	**57894-160-01**	**57894-0160-01**	

NDC Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and mL (milliliters) applies to drugs supplied in vials in liquid form.[9] NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here is an example for a 400-mg dose:

Table 4. NDC Units

	Dose to Be Billed	NDC (11-digit)	Packaging	NDC Unit of Measure	NDC Units
REMICADE®	**400 mg**	**57894-0030-01**	**100-mg vial (powder)**	**UN**	**4**
Infliximab	**400 mg**	**57894-0160-01**	**100-mg vial (powder)**	**UN**	**4**

In this example the drug is supplied in 100-mg vials, in powder form for reconstitution. The NDC is specific to the packaging, thus one 100-mg vial equals 1 NDC unit. The total dose to be billed is 400 mg (400 divided by 100), or 4 NDC units. The drug is packaged in powder form so the unit of measure is "UN." Accurate NDC coding typically requires the following components[9]:

- Reporting the NDC with 11 digits in a 5-4-2 configuration; this may require converting a 10-digit NDC to an 11-digit NDC
- Reporting the correct NDC unit of measure (ie, UN, mL)
- Reporting the number of NDC units dispensed
- Reporting the qualifier, N4, in front of the NDC

For REMICADE®, using the same 400-mg example, this format would appear as: **N457894003001 UN4**

For Infliximab, using the same 400-mg example, this format would appear as: **N457894016001 UN4**

Payer requirements for NDC use and format may vary. Please contact your payers for specific coding policies and more information on correct billing and claims submission. For additional support, you may contact J&J withMe at 877-227-3728 or visit **JNJwithMe.com**.

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CODING (cont'd)

Healthcare Common Procedure Code System (HCPCS) Level II Codes (eg, J codes)

Drugs are typically reported using product-specific HCPCS codes **(eg, J codes)** assigned by the Centers for Medicare & Medicaid Services (CMS). HCPCS units are determined by the specific HCPCS descriptor. The descriptor is not necessarily the same as the package or therapeutic dose, so the dose must be converted to billable HCPCS units to accurately complete a claim. The HCPCS code for REMICADE® and Infliximab is:

J1745 - Injection, infliximab, excludes biosimilar, 10 mg[10]

Each 100-mg vial of drug represents 10 units of J1745, thus each 10-mg dose of REMICADE® or Infliximab equals one billing unit, or 1/10th of a vial. When coding for J1745, report the total number of 10-mg increments administered. Table 5 illustrates the correlation between vials, milligrams, and billing units for REMICADE® and Infliximab.

Table 5. Billing Units for REMICADE® and Infliximab

Number of 100-mg Vials	Total Milligrams (mg)	Number of Billing Units Based on J1745 (10 mg Per Unit)
1	100	10
2	200	20
3	300	30
4	400	40

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CODING FOR DRUG ADMINISTRATION

Coding for Drug Administration Services

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form. Please note that HCPs are responsible for selecting appropriate codes for any particular claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements. It is advisable to contact your local payer with regard to local payment policies.

Codes for Drug Administration

Drug administration services are reported on claims forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. The CPT® codes most commonly associated with the administration of REMICADE® or Infliximab are:

- **96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug,[11] and
- **96415** - Each additional hour[11] (Use 96415 in conjunction with 96413; report 96415 for infusion intervals of greater than 30 minutes beyond 1-hour increments.)

These codes, often referred to as "complex" codes, apply to the parenteral administration of chemotherapy and also antineoplastic agents provided for treatment of noncancer diagnoses, or to substances such as certain monoclonal antibodies and other biologic response modifiers. Complex drug administration services also require special considerations to prepare, dose, or dispose and typically entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions.[11]

Alternatively, some payers may require the use of these CPT® codes:

- **96365** - Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour,[11] and
- **96366** - Each additional hour (List separately in addition to code for primary procedure; report 96366 for infusion intervals of greater than 30 minutes beyond 1-hour increments.)[11]

These codes, often referred to as "therapeutic" codes, typically require special considerations to prepare, dose, or dispose of the drug/biologic and necessitate special training and competency for the staff who administer it. These services generally require periodic patient assessment during and/or after the procedure.[11]

Payer policies for codes used to describe infusion services may vary. Consult your payers for policies regarding use of 96413 and 96415 or 96365 and 96366. For additional support, you may contact J&J withMe at 877-227-3728 or visit **JNJwithMe.com**.

Partial Additional Hours of Infusion Time[12]

CMS has a policy for reporting the add-on infusion codes when less than a full hour of service is provided. Providers may report the add-on infusion code for "each additional hour" only if the infusion interval is greater than 30 minutes beyond the 1-hour increment. For example, if the patient receives an infusion of a single drug that lasts 2 hours, the provider would report the "initial" code up to 1 hour and the add-on code for the additional 60 minutes. If the incremental amount of infusion time is 30 minutes or less, the time is not to be billed separately. Note that some payers may require reporting the actual number of minutes on the claim.

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OTHER CODING CONSIDERATIONS

Place of Service Codes

The Place of Service (POS) code set provides setting information necessary to appropriately pay professional service claims. The place of service is the location of the provider's face-to-face encounter with the beneficiary. POS codes are required on all claims for professional services (billed on the CMS-1500). Under the Physician Fee Schedule (PFS), some procedures have separate rates for professional services when provided in facility and nonfacility settings; therefore, it is important to accurately designate the POS to ensure appropriate payment. The physician practice location is considered "nonfacility" (NF), allowing for the practice expenses to be included in the payment under the PFS. When professional services are performed in a facility (eg, hospital outpatient department), the practice does not incur the same expense (eg, overhead, staff, equipment and supplies), thus payment under the PFS is generally lower for facility-based services than for NF services.

The physician practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus provider-based departments, CMS created a new POS code (POS 19) and revised the POS code description for outpatient hospital (POS 22). Professional services delivered in outpatient hospital settings must now specifically include the off-campus or on-campus POS on the claim form.

Table 6. Place of Service Codes[13]

POS Code	POS Name	POS Descriptor
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus – Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)
22	On Campus – Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016)

Revenue Codes

Many payers require use of American Hospital Association (AHA) revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by three other digits and are used on claims forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors. The following revenue codes may be applicable to CMS-1450 claims for drugs and their administration:

- 0260 IV Therapy, General[14]
- 0510 Clinic, General[14]
- 0636 Pharmacy, drugs requiring detailed coding[14]

OTHER CODING CONSIDERATIONS (cont'd)

HCPCS and CPT® Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. They provide additional information about a service or procedure and help to eliminate the appearance of duplicate billing and unbundling. This could include using modifiers to designate a specific site of service or to document an interrupted procedure, wasted product, same-day procedure, etc. Appropriately used, modifiers improve coding and reimbursement accuracy.

Table 7 summarizes modifiers that may be applicable to the provision of REMICADE® or Infliximab in physician offices and hospital outpatient departments.

Table 7. Summary of Code Modifiers

Modifier	Description	Indication and Placement	CMS-1500 (Item 24D)	CMS-1450 (Box 44)
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified HCP on the same day of the procedure or other service[11]	• Patient requires distinct E/M service in addition to the infusion procedure[11] • Must be substantiated by documentation that supports the relevant criteria for the reported E/M code[11] • Append the modifier to the appropriate E/M code[11]	✓ Required by Medicare	✓ Required by Medicare
JW	Drug amount discarded/not administered to any patient[10]	• Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial[15] • Append the modifier to the drug code on a line separate from that reporting the administered dose[15]	✓ Required by Medicare	✓ Required by Medicare
JZ	Zero drug amount discarded/not administered to any patient[10]	• To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage)[16] • Append the modifier to the drug code line[16]	✓ Required by Medicare	✓ Required by Medicare
PO*	Excepted services provided at an off-campus, outpatient provider-based department of a hospital[10]	• To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim[17]	N/A	✓ Required by Medicare
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[10]	• To be reported on each claim line for non-excepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim[17]	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes[10]	• Must be reported by hospitals (except for rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes only[17] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[17]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities[10]	• Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes[17] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[17]	N/A	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations or satellite facilities of a hospital, or a provider-based department that is "on campus."[17]

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Remicade® INFLIXIMAB | Infliximab

OTHER CODING CONSIDERATIONS (cont'd)

Same-Day Evaluation and Management Services

It may be necessary to provide E/M services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate, distinct from the drug administration procedure, and documented appropriately are generally covered.

Please note that CMS has a specific policy regarding use of CPT® code 99211 (level 1 medical visit for an established patient) in the physician office. The policy states:

CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or nonchemotherapy drug administration code.[12]

Thus, CPT® code 99211 cannot be paid on the same day as an office-based infusion of REMICADE® or Infliximab. If a therapeutic or complex drug administration service and a significantly identifiable, distinct E/M service are provided on the same day, a different diagnosis is not required.[12]

CMS Discarded Drug Policy[15]

When a physician, hospital, or other provider or supplier must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug or biologic to a Medicare patient, the program provides payment for the amount of drug or biologic discarded as well as the dose administered, up to the amount of the drug or biologic as indicated on the vial or package label.

Medicare contractors require the modifier JW to identify unused drugs or biologics from single-use vials or single-use packages that are appropriately discarded. This modifier, billed on a separate claim line, supports payment for the amount of discarded drug or biologic.

For example, a single-use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units is billed on another line accompanied by the JW modifier. Both line items will be processed for payment. Providers must record the discarded amounts of drugs and biologics in the patient's medical record.

JW Modifier Summary

- Payment for discarded amounts of drug/biologic applies only to single-use vials or packages
- Multiuse vials are not subject to payment for discarded amounts
- Discarded amounts of drugs/biologics must be recorded in the patient's medical record
- Medicare contractors require the JW modifier; other payer policies may vary

CMS Policy for Reporting of No Drug Wastage

Effective July 1, 2023, Medicare will require the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts. This policy applies to all providers and suppliers who buy and bill separately payable drugs under Medicare Part B. The provider or supplier must file a claim with one line for the drug.

For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the Units field.[16]

Drugs Supplied at No Cost to the Provider

Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider ("white bagging"). When the drug is supplied by a third party, at no cost to the provider, it should NOT be billed to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it. When reporting drug administration services for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "0.01" charges.[18] Payer policies may vary.

Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

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SAMPLE CLAIMS FORMS

Physician Office Claims (CMS-1500)

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and non-institutional providers who qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf

The 837P (Professional) is the standard format used by HCPs and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

Hospital Outpatient Claims (CMS-1450)

The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including hospital outpatient departments (HOPDs). Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The ANSI ASC X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

For more information on electronic claims, please see the CMS website at:

https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html

Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

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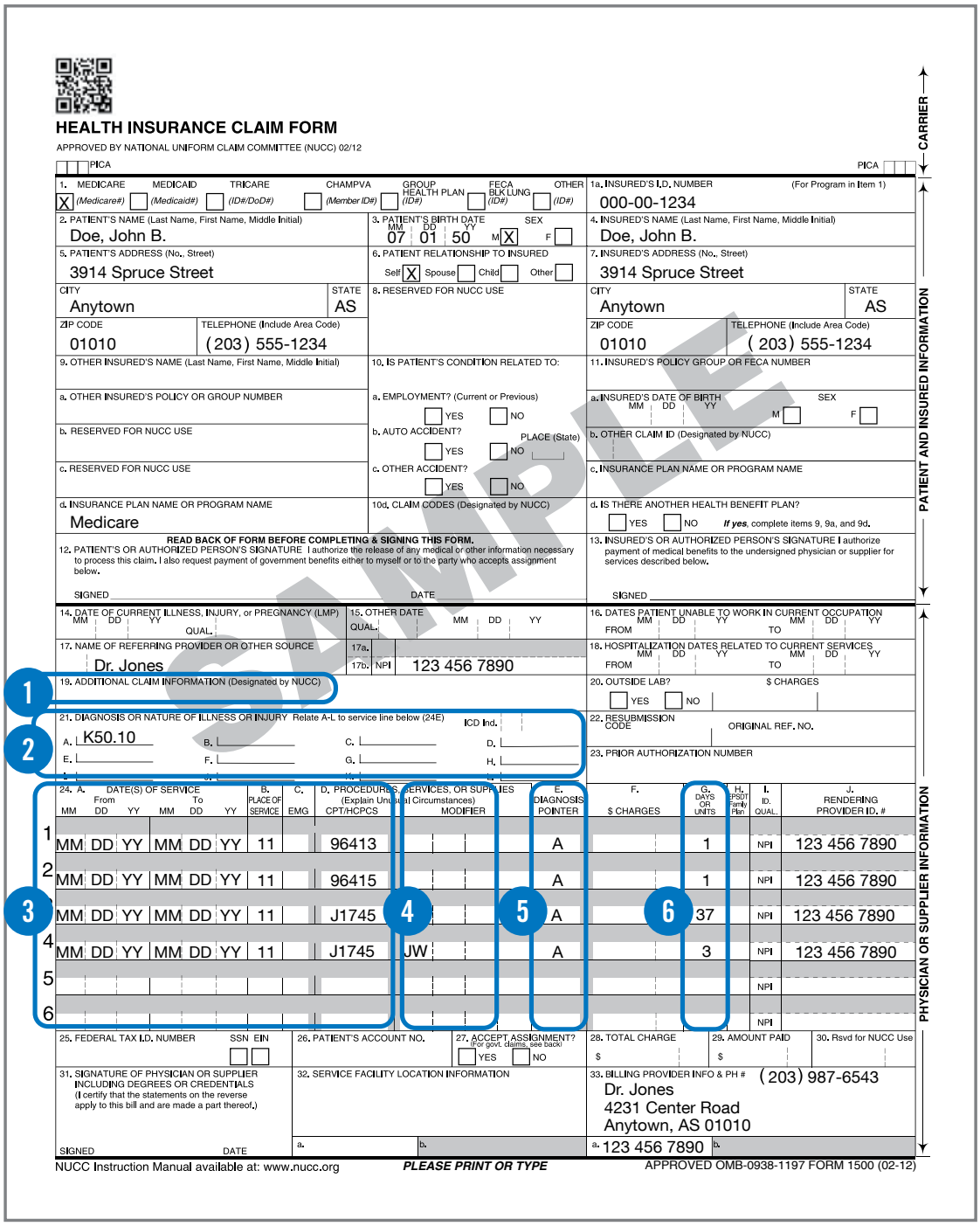
SAMPLE CLAIMS FORMS (cont'd)

Physician Office Sample Claim Form: CMS-1500



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE [X] (Medicare#) MEDICAID [ ] (Medicaid#) TRICARE [ ] (ID#/DoD#) CHAMPVA [ ] (Member ID#) GROUP HEALTH PLAN [ ] (ID#) FECA BLK LUNG [ ] (ID#) OTHER [ ] (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 000-00-1234

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John B.

3. PATIENT'S BIRTH DATE MM DD YY: 07 01 50 SEX M [X] F [ ]

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John B.

5. PATIENT'S ADDRESS (No., Street): 3914 Spruce Street

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 3914 Spruce Street

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

CITY: Anytown STATE: AS

ZIP CODE: 01010 TELEPHONE (Include Area Code): (203) 555-1234

ZIP CODE: 01010 TELEPHONE (Include Area Code): (203) 555-1234

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) [ ] YES [ ] NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? [ ] YES [ ] NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? [ ] YES [ ] NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [ ] YES [ ] NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones

17a.

17b. NPI 123 456 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? [ ] YES [ ] NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. K50.10 B. C. D.

E. F. G. H.

I. J. K.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY	MM DD YY	11		96413		A		1		NPI	123 456 7890
2 MM DD YY	MM DD YY	11		96415		A		1		NPI	123 456 7890
3 MM DD YY	MM DD YY	11		J1745	4	A	6	37		NPI	123 456 7890
4 MM DD YY	MM DD YY	11		J1745	JW	A		3		NPI	123 456 7890
5										NPI	
6										NPI	

5

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) [ ] YES [ ] NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. b.

33. BILLING PROVIDER INFO & PH # (203) 987-6543

Dr. Jones
4231 Center Road
Anytown, AS 01010

a. 123 456 7890 b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* APPROVED OMB-0938-1197 FORM 1500 (02-12)

SAMPLE

Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

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Remicade® INFLIXIMAB | Infliximab

SAMPLE CLAIMS FORMS (cont'd)

Physician Office Sample Claim Form: CMS-1500

1 **Item 19**—Some payers may require additional information (eg, a statement that the patient is on concomitant methotrexate) or additional codes such as the NDC. Payer requirements may vary.*

2 **Item 21**—Indicate diagnosis/diagnoses using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

3 **Item 24D**—Indicate appropriate CPT® and HCPCS codes and modifiers if required.

REMICADE® or Infliximab
J1745 - Injection, infliximab, excludes biosimilar, 10 mg

If line item NDC information is required, it will be entered in the shaded portion of Item 24A.[13] For example:

	24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	N457894003001 UN3.7										
	MM DD YY MM DD YY			J1745		A		37		NPI	123 456 7890
2										NPI	

ER INFORMATION

Payer requirements for NDC entries may vary.*

Infusion Services*
96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour
96415 - Each additional hour

4 When it is necessary to discard the remainder of a single-use vial after administering a dose of drug/biologic to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.[15] Other payer policies may vary.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.[16]

	24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	N457894003001 UN4										
	MM DD YY MM DD YY			J1745	JZ	A		40		NPI	123 456 7890
2										NPI	

ER INFORMATION

5 **Item 24E**—Refer to the diagnosis for this service (see Item 21). Enter only one diagnosis pointer.

6 **Item 24G**—Enter the number of HCPCS units: 10 mg = 1 unit (100-mg vial = 10 units).

*For information and assistance, you may contact J&J withMe at 877-227-3728 or visit **JNJwithMe.com**.

Please see Important Safety Information for REMICADE® and Infliximab
on pages 22 and 23.

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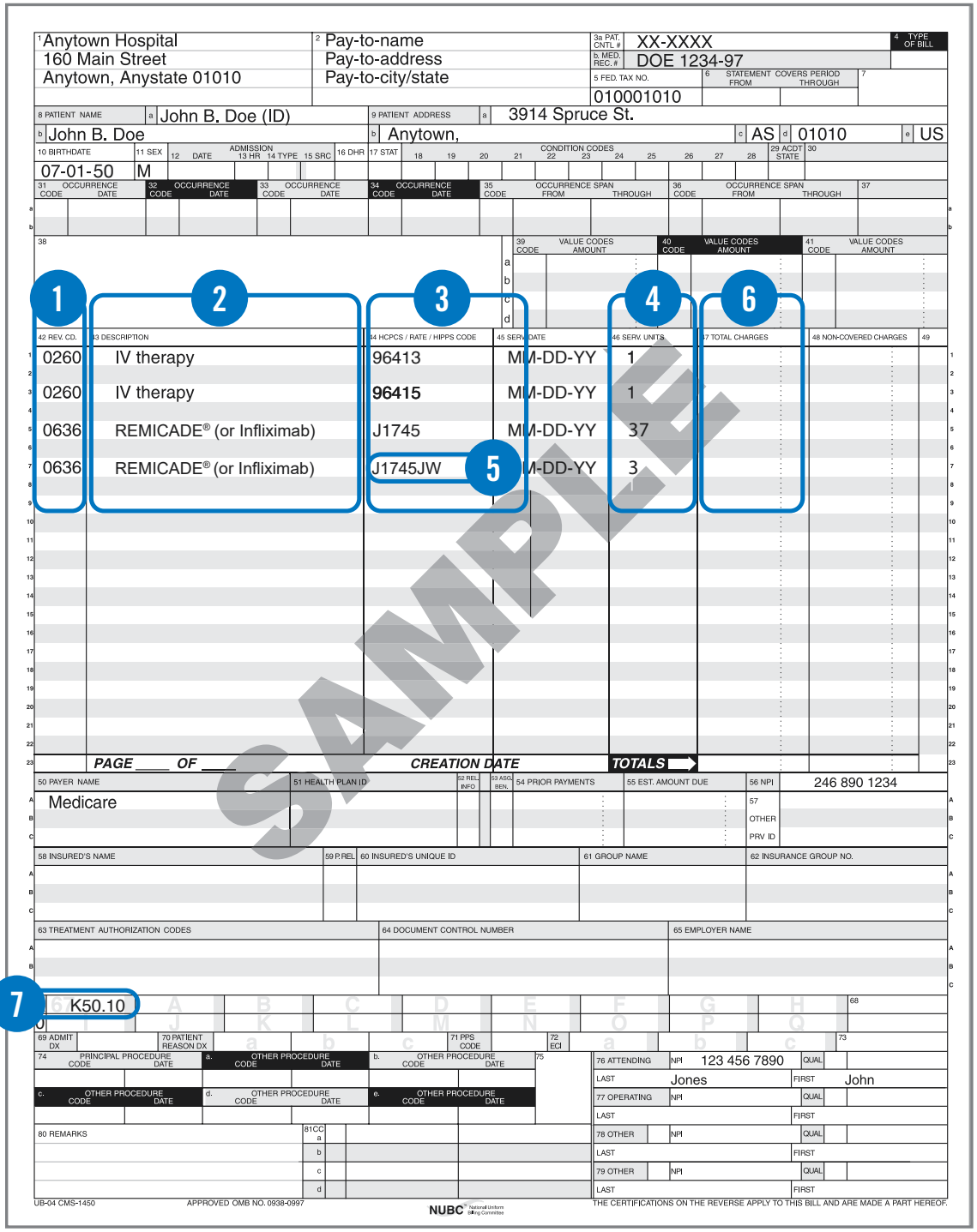
Remicade® INFLIXIMAB | Infliximab

SAMPLE CLAIMS FORMS (cont'd)

HOPD Sample Claim Form: CMS-1450 (UB-04)



1	2	3	4	6
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	46 SERV. UNITS	48 NON-COVERED CHARGES
0260	IV therapy	96413	1	
0260	IV therapy	96415	1	
0636	REMICADE® (or Infliximab)	J1745	37	
0636	REMICADE® (or Infliximab)	J1745JW (5)	3	

1 Anytown Hospital
160 Main Street
Anytown, Anystate 01010

2 Pay-to-name
Pay-to-address
Pay-to-city/state

3a PAT. CNTL. # XX-XXXX
b. MED. REC. # DOE 1234-97

4 TYPE OF BILL

5 FED. TAX NO. 010001010

6 STATEMENT COVERS PERIOD FROM THROUGH

8 PATIENT NAME a John B. Doe (ID)
b John B. Doe

9 PATIENT ADDRESS a 3914 Spruce St.
b Anytown, c AS d 01010 e US

10 BIRTHDATE 07-01-50

11 SEX M

50 PAYER NAME: Medicare

56 NPI: 246 890 1234

7 K50.10

76 ATTENDING NPI 123 456 7890 LAST Jones FIRST John

SAMPLE

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC

THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

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Remicade® INFLIXIMAB | Infliximab

SAMPLE CLAIMS FORMS (cont'd)

HOPD Sample Claim Form: CMS-1450 (UB-04)

1. **Locator Box 42**—List revenue codes in ascending order.

2. **Locator Box 43**—Enter narrative description for corresponding revenue code (eg, IV therapy, drug). If line item NDC information is required, it will be entered in the unshaded portions of Locator Box 43.[19] Payer requirements for NDC entries may vary.*

3. **Locator Box 44**—Indicate appropriate CPT® and HCPCS codes and modifiers as required by payer.

REMICADE® or Infliximab
J1745 - Injection, infliximab, excludes biosimilar, 10 mg

Infusion Services*
96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour
96415 - Each additional hour

Modifiers

*PO or PN modifiers must be reported by all off-campus HOPDs. The PO modifier is to be reported with every HCPCS code for all items and services furnished in an *excepted*, off-campus PBD of a hospital. The PN modifier is to be reported on each claim line for all items and services furnished in a *non-excepted*, off-campus PBD of a hospital.[17]

*For informational purposes, JG and TB modifiers must be reported for all 340B-acquired drugs. **Hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) report TB. All others report JG.**[17]

4. **Locator Box 46**—Enter the number of HCPCS units: 10 mg = 1 unit (100-mg vial = 10 units).

5. When it is necessary to discard the remainder of a single-use vial after administering a dose of drug/biologic to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.[15] Other payer policies may vary.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the drug code line, immediately after the drug code with no spaces.[16]

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0260	IV therapy	96413	MM-DD-YY	1				1
2									2
3	0260	IV therapy	96415	MM-DD-YY	1				3
4									4
5	0636	REMICADE®	J1745JZ	MM-DD-YY	40				5

6. **Locator Box 47**—Indicate total charges.

7. **Locator Box 67**—Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

*For information and assistance, you may contact J&J withMe at 877-227-3728 or visit **JNJwithMe.com**.

Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

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COVERAGE CONSIDERATIONS

Factors That Influence Coverage

Third-party payers (eg, commercial insurers, Medicare, Medicaid) will generally cover parenteral drugs for their approved U.S. Food and Drug Administration indications and the associated professional administration services. However, benefits may vary depending upon the payer and the specific plan ("insurance product") in which a patient is enrolled.

Medical Necessity

When third-party payers review infusible drug claims, they will first determine if the type of service provided is covered under their policies. Next, payers will look for evidence supporting the medical necessity of the therapy. This evidence may include:

- Information about the patient's medical condition and history
- A physician's statement or Letter of Medical Necessity
- Supporting literature (eg, peer-reviewed studies and compendia monographs)
- Full Prescribing Information
- Availability of other treatment alternatives

Medical necessity refers to a decision by a health plan that a treatment, test, or procedure is necessary for health or to treat a diagnosed medical problem. Health insurance companies provide coverage only for health-related services that they define or determine to be medically necessary. Medicare National Coverage Determinations (NCDs) and Medicare Administrative Contractors (MACs) Local Coverage Determinations (LCDs) define medical necessity requirements for Medicare coverage. These documents contain guidance on covered diagnoses, required documentation, and limitations of coverage for specific services in accordance with medical necessity.

Administrative Considerations

Other considerations may be involved in a payer's decision to cover a product or service:

- **Does the payer's contract specifically indicate the sites of care that may bill for infusion services or infused drugs?**

  A small portion of payers have exclusive contracts with designated preferred providers for infusion services. This may include certain clinics or specialty pharmacies that deliver drugs to HCPs or other infusion centers.

- **Does the payer cover the therapy only when provided through a specific treatment site?**

  Payers may have site-specific coverage rules that restrict provision of infused therapies. For example, currently Medicare does not cover infusions when they are billed by Medicare-certified ambulatory surgery centers. Payers also may restrict coverage for certain infused drugs in the home or hospital outpatient setting.

- **Is the billing provider a "participating" member of, or "in-network" provider for, that particular plan?**

  Payers contract with providers to deliver services to the plan's members. Providers are thus "participating" or within that plan's network, requiring them to abide by the contract charge structure when providing care for that plan's members.

- **Is the plan willing to grant in-network status when a service is otherwise out of network?**

  In some cases (eg, when there are no available in-network providers), health plans may grant in-network status for a provider and related services. In such cases, the provider accepts the in-network rate and the patient will be able to access in-network cost-sharing. It may be helpful to contact a payer to ask for a service to be converted to in-network status.

- **If required by the plan, has the appropriate referral or prior authorization (PA) been obtained?**

  Many plans require that nonemergency services be preapproved or that a primary care physician make the referral for specialty care. Failing to obtain appropriate referrals or preauthorization can result in nonpayment by the plan.

Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

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Once the clinical decision has been made to prescribe a J&J medicine, Johnson & Johnson has resources to help you support your patients.

J&J withMe Is Your Single Source for Access, Affordability, and Treatment Support for Your Patients

Access support to help navigate payer processes

J&J withMe helps verify insurance coverage for your patients taking REMICADE® or Infliximab and provides reimbursement information.

Online benefits investigation and prior authorization support at **Portal.JNJwithMe.com**

Affordability support to help your patients start and stay on the treatment you prescribe

J&J withMe can help you find out what affordability assistance may be available for your patients taking REMICADE® or Infliximab.

Comprehensive Provider Portal to enroll eligible patients in the J&J withMe Savings Program and more at **Portal.JNJwithMe.com**

Treatment support to help your patients get informed and stay on REMICADE® or Infliximab

J&J withMe provides additional support to your patients, including patient education, web-based resources, and personalized reminders.

J&J withMe Savings Program

The J&J withMe Savings Program for REMICADE® covers Infliximab.

Add REMICADE® or Infliximab to the patient account from your patient dashboard on the Provider Portal.

Request a benefits investigation for REMICADE® or Infliximab and follow the steps to initiate the BI process.

Eligible patients who have been prescribed Infliximab are automatically enrolled in the J&J withMe Savings Program for REMICADE® and Infliximab and can use their Savings Program card for program benefits for Infliximab. The patient will NOT need to obtain a replacement card for the combined Savings Program.

J&J withMe Savings Program details for REMICADE® are the same for Infliximab:

- Eligible patients using commercial insurance pay as little as $5 per infusion for their REMICADE® or Infliximab medicine
- Maximum program benefit per calendar year shall apply. Savings may apply to co-pay, co-insurance, or deductible. Offer subject to change or end without notice. Program does not cover the cost to give patients their infusion. Patients may participate without sharing their income information. See program requirements at **Infliximab.JNJwithMeSavings.com**.

The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe a J&J medicine.

Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

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IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with either REMICADE® or 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 either REMICADE® or Infliximab 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 either REMICADE® or Infliximab.[1,2] Treatment for latent infection should be initiated prior to treatment with either REMICADE® or Infliximab.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, pneumocystosis, and cryptococcosis. 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, Listeria, and Salmonella.**

The risks and benefits of treatment with either REMICADE® or Infliximab 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 either REMICADE® or Infliximab, 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 either REMICADE® or Infliximab 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 either REMICADE® or Infliximab. 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 either REMICADE® or Infliximab. These cases have had a very aggressive disease course and have been fatal. The majority of reported REMICADE® and Infliximab 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 either REMICADE® or Infliximab at or prior to diagnosis. Carefully assess the risks and benefits of treatment with either REMICADE® or Infliximab, especially in these patient types.

In clinical trials of all TNF blockers, 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 blockers, including either REMICADE® or Infliximab, more cases of other malignancies were observed compared with controls. The rate of these malignancies among patients treated with either REMICADE® or Infliximab 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 blockers 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 therapies, including either REMICADE® or Infliximab. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

A population-based retrospective cohort study found a 2- to 3-fold increase in the incidence of invasive cervical cancer in women with rheumatoid arthritis treated with either REMICADE® or Infliximab compared to biologics-naïve patients or the general population, particularly those over 60 years of age. A causal relationship between either REMICADE® or Infliximab and cervical cancer cannot be excluded. Periodic screening should continue in women treated with either REMICADE® or Infliximab.

CONTRAINDICATIONS

The use of either REMICADE® or Infliximab at doses >5 mg/kg is contraindicated in patients with moderate or severe heart failure. REMICADE® and Infliximab are contraindicated in patients with a previous severe hypersensitivity reaction to infliximab or any of the inactive ingredients of REMICADE® and Infliximab or any murine proteins (severe hypersensitivity reactions have included anaphylaxis, hypotension, and serum sickness).

HEPATITIS B REACTIVATION

TNF blockers, including REMICADE® and Infliximab, 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 either REMICADE® or Infliximab. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing either REMICADE® or Infliximab for patients identified as carriers of HBV and monitor closely for active HBV infection

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IMPORTANT SAFETY INFORMATION (cont'd)

HEPATITIS B REACTIVATION (CONT'D)

during and following termination of therapy with either REMICADE® or Infliximab. Discontinue either REMICADE® or Infliximab in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of either REMICADE® or Infliximab and monitor patients closely.

HEPATOTOXICITY

Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported in patients receiving either REMICADE® or Infliximab postmarketing. Some cases were fatal or required liver transplant. Aminotransferase elevations were not noted prior to discovery of liver injury in many cases. Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or marked liver enzyme elevations (eg, ≥5 times the upper limit of normal) develop, either REMICADE® or Infliximab should be discontinued, and a thorough investigation of the abnormality should be undertaken.

HEART FAILURE

In a randomized, placebo-controlled study in patients with moderate or severe heart failure (NYHA Functional Class III/IV), higher mortality rates and a higher risk of hospitalization were observed at Week 28 at a dose of 10 mg/kg and higher rates of cardiovascular events were observed at both 5 mg/kg and 10 mg/kg. There have been postmarketing reports of new onset and worsening heart failure, with and without identifiable precipitating factors. Patients with moderate or severe heart failure taking either REMICADE® or Infliximab (≤5 mg/kg) or patients with mild heart failure should be closely monitored and treatment should be discontinued if new or worsening symptoms appear.

HEMATOLOGIC EVENTS

Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported. The causal relationship to REMICADE® and Infliximab 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 either REMICADE® or Infliximab in patients who develop significant hematologic abnormalities.

HYPERSENSITIVITY

REMICADE® and Infliximab have been associated with hypersensitivity reactions that differ in their time of onset. Anaphylaxis, acute urticaria, dyspnea, and hypotension have occurred in association with infusions of either REMICADE® or Infliximab. Medications for the treatment of hypersensitivity reactions should be available.

CARDIOVASCULAR AND CEREBROVASCULAR REACTIONS DURING AND AFTER INFUSION

Serious cerebrovascular accidents, myocardial ischemia/infarction (some fatal), hypotension, hypertension, and arrhythmias have been reported during and within 24 hours of initiation of either REMICADE® or Infliximab infusions. Cases of transient visual loss have been reported during or within 2 hours of either REMICADE® or Infliximab infusions. Monitor patients during infusion and if a serious reaction occurs, discontinue infusion. Manage reactions according to signs and symptoms.

NEUROLOGIC EVENTS

TNF blockers, including REMICADE® and Infliximab, have been associated 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 either REMICADE® or Infliximab in patients with these disorders and consider discontinuation if these disorders develop.

CONCURRENT ADMINISTRATION WITH OTHER BIOLOGICS

Concurrent use of either REMICADE® or Infliximab with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as REMICADE® and Infliximab 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.

AUTOIMMUNITY

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

VACCINATIONS AND USE OF LIVE VACCINES/ THERAPEUTIC INFECTIOUS AGENTS

Prior to initiating either REMICADE® or Infliximab, update vaccinations in accordance with current vaccination guidelines. Live vaccines or therapeutic infectious agents should not be given with either REMICADE® or Infliximab due to the possibility of clinical infections, including disseminated infections.

At least a 6-month waiting period following birth is recommended before the administration of any live vaccine to infants exposed *in utero* to either REMICADE® or Infliximab.

ADVERSE REACTIONS

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

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For more information, please see the full Prescribing Information, including Boxed Warning and Medication Guide for REMICADE® and full Prescribing Information, including Boxed Warning and Medication Guide for Infliximab. Provide the Medication Guides 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.

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Please see Important Safety Information for REMICADE® and Infliximab on pages 22 and 23.

References: 1. Infliximab [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** REMICADE® (infliximab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **3.** Data on file. Janssen Biotech, Inc. **4.** US Food and Drug Administration. FAQs - Purple Book. Accessed May 12, 2025. https://purplebooksearch.fda.gov/faqs **5.** US Food and Drug Administration. Biosimilar and Interchangeable Biologics: More Treatment Choices. Revised August 17, 2023. Accessed May 12, 2025. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices **6.** Declerck P, Farouk-Rezk M, Rudd PM. Biosimilarity versus manufacturing change: two distinct concepts. *Pharm Res*. 2016;33(2):261-268. **7.** Centers for Medicare & Medicaid Services. ICD-10-CM official guidelines for coding and reporting FY 2025 (October 1, 2024-September 30, 2025). Revised October 1, 2024. Accessed May 12, 2025. https://www.cms.gov/files/document/fy-2025-icd-10-cm-coding-guidelines.pdf **8.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Accessed May 12, 2025. https://www.cms.gov/medicare/coding/icd10/downloads/6_i10tab2010.pdf **9.** Cigna. Coding guidelines for drug-related medical claims. Accessed May 12, 2025. https://static.cigna.com/assets/chcp/resourceLibrary/medicalResourcesList/medicalDoingBusinessWithCigna/codingGuidelinesForDrugRelatedMedicalClaims.html **10**. Centers for Medicare & Medicaid Services. April 2025 Alpha-numeric HCPCS file. Updated February 28, 2025. Accessed May 12, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **11.** American Medical Association. Current Procedural Terminology: CPT® 2025: Professional Edition. Chicago, IL: AMA Press; 2024. **12.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 12: Physicians/Non-Physician Practitioners. Revised December 19, 2024. Accessed May 12, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf **13.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26: Completing and Processing the Form CMS-1500 Data Set. Revised August 9, 2024. Accessed May 12, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf **14.** Noridian Healthcare Solutions. Revenue Codes. Updated March 18, 2024. Accessed May 12, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **15.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. Revised February 15, 2024. Accessed May 12, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf **16.** Centers for Medicare & Medicaid Services. Medicare Program Discarded drugs and biologicals – JW modifier and JZ modifier policy: frequently asked questions. Modified January 14, 2025. Accessed May 12, 2025. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf **17.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 4: Part B Hospital. Revised November 22, 2024. Accessed May 12, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf **18.** Centers for Medicare & Medicaid Services. Billing and Coding: Patients Supplied Donated or Free-of-Charge Drug. Revised November 22, 2023. Accessed May 12, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55045 **19.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25: Completing and Processing the Form CMS-1450 Data Set. Revised December 20, 2023. Accessed May 12, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf

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