FOR INJECTION

Inflectra®

infliximab-dyyb

Billing and Coding Guide for INFLECTRA®

INFLECTRA is a registered trademark of Pfizer Inc.

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

Pfizer Inc. has developed this reference guide to assist healthcare providers (HCPs) with understanding coding for INFLECTRA® (infliximab-dyyb) for Injection, the first infliximab biosimilar to be approved in the United States (US).

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for INFLECTRA. Coding and coverage policies change periodically and often without notice. The HCP is solely responsible for determining coverage and reimbursement parameters and appropriate coding for treatment of his/her patients. The information provided should not be considered a guarantee of coverage or reimbursement for INFLECTRA.

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with infliximab products 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 INFLECTRA® (infliximab-dyyb) 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 INFLECTRA®. Treatment for latent infection should be initiated prior to treatment with INFLECTRA®.**
- **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 INFLECTRA® 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 INFLECTRA®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

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

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRAApi.com.

Pfizer enCompass®

Pfizer enCompass offers resources and co-pay support for eligible patients prescribed INFLECTRA.

For assistance, call or visit:

1-844-722-6672, Monday–Friday, 8 AM–8 PM ET

https://www.pfizercopay.com/

www.pfizerencompass.com

IMPORTANT SAFETY INFORMATION (Continued)

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including infliximab products. 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 infliximab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported 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 a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treatment with INFLECTRA®, especially in these patient types.

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Coverage for INFLECTRA

Coverage for INFLECTRA may vary across commercial payers, Medicare, and Medicaid and by treatment site of care. HCPs should confirm payer policies prior to treating patients with INFLECTRA.

Coding Overview

The physician office and hospital outpatient department (HOPD) sites of care, payers typically recognize the following codes for reporting INFLECTRA on claim forms:

Claim Information	Type of Code	Code and Descriptor	Relevant Site of Care
INFLECTRA	HCPCS code[1]	**Q5103** Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	Physician office, HOPD
	HCPCS modifier[1]	**JZ**[a] Zero drug amount discarded/not administered to any patient	
		JW[a] Drug amount discarded/not administered to any patient	
		TB Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes	340B covered entities
	NDC[2]	**10-digit** 0069-0809-01 one single-dose 100 mg vial **11-digit**[b] **0**0069-0809-01 one single-dose 100 mg vial	Physician office, HOPD
	Revenue code[3]	**0636** Drugs requiring detailed coding	HOPD

[a]Required by Medicare, other payer reporting requirements may vary.

[b]For claims-reporting purposes, the Health Insurance Portability and Accountability Act (HIPAA) requires conversion of the 10-digit NDC to an 11-digit NDC by adding a leading zero, where appropriate, to create a 5-4-2 configuration. For INFLECTRA claims, the zero is added in front of the first segment of numbers in the 10-digit format as listed in the prescribing information. See placement of the red zero in the table above. Check payer reporting requirements for NDC unit of measure and quantity.

HCPCS – Healthcare Common Procedure Coding System; HOPD – hospital outpatient department; NDC – National Drug Code.

IMPORTANT SAFETY INFORMATION (Continued)

MALIGNANCIES (Continued)

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 infliximab products, more cases of other malignancies were observed compared with controls. The rate of these malignancies among infliximab-treated patients 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 blocker therapy 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).

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRAapi.com.

Coding for INFLECTRA Administration and Physician Services

Current Procedural Terminology (CPT®) codes define specific medical procedures performed by physicians.[6] The following codes may be used to report the administration of INFLECTRA.

Claim Information	Type of Code	Code and Descriptor	Relevant Sites of Services
Procedures, services, and supplies	CPT codes[4]*	**96365** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour **96366** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure) **96413** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug **96415** Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)	Physician office, HOPD
	Revenue codes[3]	**0260** IV therapy, general **0500** Outpatient services, general **0510** Clinic, general	HOPD

CPT – Current Procedural Terminology; HOPD – hospital outpatient department; IV – intravenous.

*Payer polices may vary in coding for the administration of INFLECTRA, individual payer policies should be reviewed for reporting requirements. Billing highly complex administration codes (9641x) requires medical record documentation of the complexity involved beyond what is required for therapeutic infusions (9636x).

IMPORTANT SAFETY INFORMATION (Continued)

MALIGNANCIES (Continued)

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF blocker therapy, including infliximab products. 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 infliximab compared to biologics-naïve patients or the general population, particularly those over 60 years of age. A causal relationship between infliximab products and cervical cancer cannot be excluded. Periodic screening should continue in women treated with INFLECTRA®.

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

FDA-Approved Indications for INFLECTRA

INFLECTRA is a tumor necrosis factor (TNF) blocker indicated for:

Crohn's Disease:
- reducing signs and symptoms, and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

Pediatric Crohn's Disease:
- reducing signs and symptoms, and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis:
- reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis:
- reducing signs and symptoms, inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis in Combination With Methotrexate:
- reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease.

Ankylosing Spondylitis:
- reducing signs and symptoms in adult patients with active disease.

Psoriatic Arthritis:
- reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients.

Plaque Psoriasis:
- treatment of adult patients with chronic severe (ie, extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

IMPORTANT SAFETY INFORMATION (Continued)

CONTRAINDICATIONS

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

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

Diagnosis Coding for INFLECTRA

Based on FDA approval, the following International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes may be appropriate when submitting a claim for INFLECTRA. HCPs are responsible for determining appropriate codes based upon actual patient circumstances.

Claim Information	Indication	Code and Descriptor
Diagnosis[5]	Crohn's disease	K50.00–K50.919: Crohn's disease
	Ulcerative colitis	K51.00–K51.919: Ulcerative colitis
	Rheumatoid arthritis	M06.00–M06.9: Other rheumatoid arthritis
	Ankylosing spondylitis	M45.0–M45.9: Ankylosing spondylitis
	Psoriatic arthritis	L40.50–L40.53, L40.59: Arthropathic psoriasis
	Plaque psoriasis	L40.0: Psoriasis vulgaris

See full indications for INFLECTRA on prior page.

IMPORTANT SAFETY INFORMATION (Continued)

HEPATITIS B REACTIVATION

TNF blockers, including infliximab products, 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 INFLECTRA®. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing INFLECTRA® for patients identified as carriers of HBV, and monitor closely for active HBV infection during and following termination of therapy with INFLECTRA®. Discontinue INFLECTRA® in patients who develop HBV reactivation, and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of INFLECTRA®, and monitor patients closely.

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

Buy-and-Bill: HCP Purchases INFLECTRA and Submits a Claim for Reimbursement for INFLECTRA and the Administration Service

Physician Office Sample Claim Form: CMS-1500

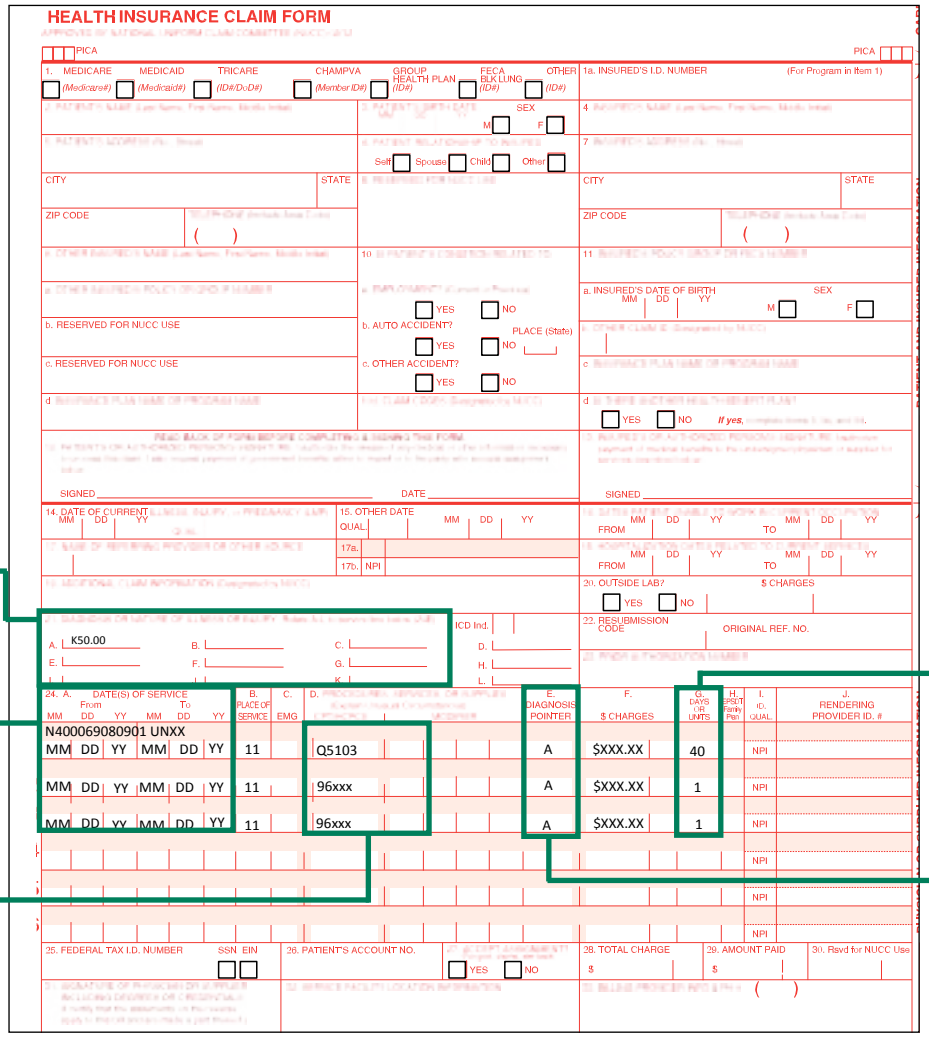
DISCLAIMER: This sample form is intended as a reference for the coding and billing of INFLECTRA. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

Item Number 21 Diagnosis: Enter the appropriate diagnosis code; eg, ICD-10-CM. Final code depends on medical record documentation

Item Number 24A Date(s) of Service: Enter the NDC in the shaded area above the month, day, and year. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character unit of measure qualifier and quantity. *Check payer requirements and format for reporting NDC and unit of measure (UoM)*

Item Number 24D Procedures/Services/ Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,

- Drug: Q5103 for INFLECTRA
- Administration: 96xxx for drug administration
- Add appropriate modifier as applicable



Item Number 24G Units: Enter the appropriate number of billing units for each line item; eg,

- For Q5103, 1 billing unit represents 10 mg of INFLECTRA

Item Number 24E Diagnosis Pointer: Enter the letter (A-L) that corresponds to the diagnosis in Item Number 21

IMPORTANT SAFETY INFORMATION (Continued)

HEPATOTOXICITY

Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported in patients receiving infliximab products 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, INFLECTRA® should be discontinued, and a thorough investigation of the abnormality should be undertaken.

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Buy-and-Bill: HCP Purchases INFLECTRA and Submits a Claim for Reimbursement for INFLECTRA and the Administration Service

Hospital Outpatient Sample Claim Form: UB-04

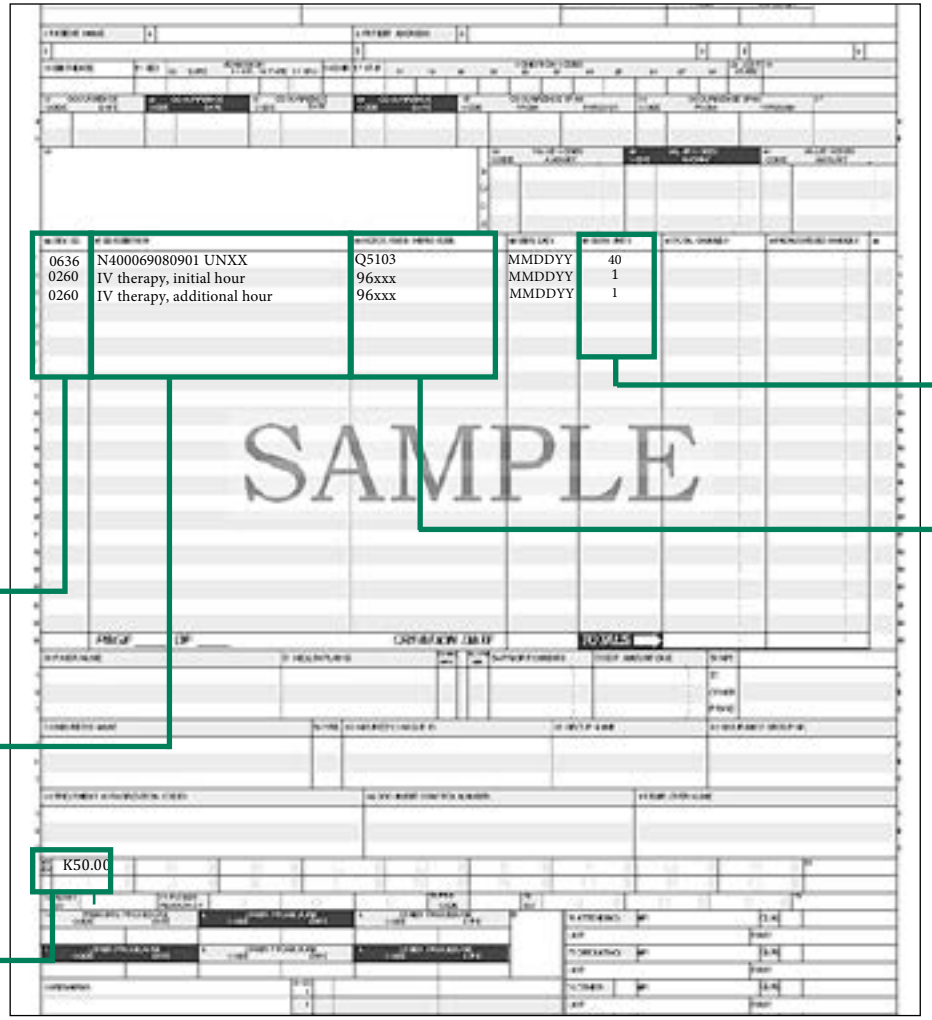
DISCLAIMER: This sample form is intended as a reference for the coding and billing of INFLECTRA. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

FL 42 Revenue Code: Enter the appropriate revenue code; eg,
- 0636 for INFLECTRA
- 0260 for IV infusion

Other revenue codes may apply

FL 43 Revenue Description: Enter the NDC. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UoM qualifier and quantity.
Check payer requirements and format for reporting NDC and UoM

FL 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code. *Final code depends on medical record documentation*



FL 46 Units of Service: Enter the appropriate number of billing units for each line item; eg,
- For Q5103, 1 billing unit represents 10 mg of INFLECTRA

FL 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
- Drug: Q5103 for INFLECTRA
- Add appropriate modifier as applicable
- Administration: 96xxx for drug administration

IMPORTANT SAFETY INFORMATION (Continued)

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 INFLECTRA® (≤5 mg/kg) or patients with mild heart failure should be closely monitored, and treatment should be discontinued if new or worsening symptoms appear.

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

Acquisition of INFLECTRA Through a Specialty Pharmacy: HCP Acquires INFLECTRA Through a Specialty Pharmacy and Submits a Claim for Reimbursement Only for the Administration of INFLECTRA

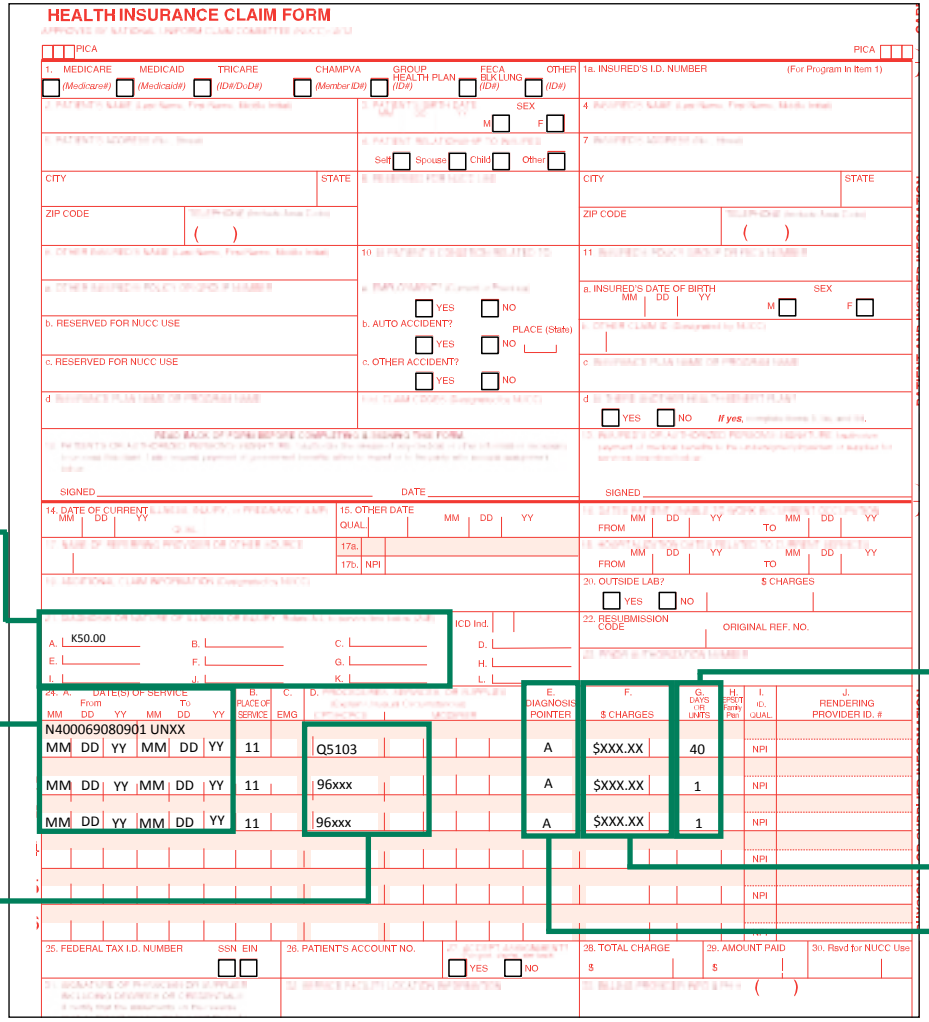
Physician Office Sample Claim Form: CMS-1500

DISCLAIMER: This sample form is intended as a reference for the coding and billing of INFLECTRA. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

Item Number 21 Diagnosis: Enter the appropriate diagnosis code; eg, ICD-10-CM. Final code depends on medical record documentation

Item Number 24A Date(s) of Service: Enter the NDC in the shaded area above the month, day, and year. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UoM qualifier and quantity. *Check payer requirements and format for reporting NDC and UoM*

Item Number 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
- Drug: Q5103 for INFLECTRA
- Administration: 96xxx for drug administration
- Add appropriate modifier as applicable


HEALTH INSURANCE CLAIM FORM

PICA

1. MEDICARE (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)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE SEX M F

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

5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

8. RESERVED FOR NUCC USE

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

a. OTHER INSURED'S POLICY OR GROUP NUMBER

b. RESERVED FOR NUCC USE

c. RESERVED FOR NUCC USE

d. INSURANCE PLAN NAME OR PROGRAM NAME

10. IS PATIENT'S CONDITION RELATED TO:
a. EMPLOYMENT? YES NO
b. AUTO ACCIDENT? YES NO PLACE (State)
c. OTHER ACCIDENT? YES NO

11. INSURED'S POLICY GROUP OR FECA NUMBER

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

b. OTHER CLAIM ID (Designated by NUCC)

c. INSURANCE PLAN NAME OR PROGRAM NAME

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

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: MM DD YY
15. OTHER DATE QUAL MM DD YY
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a.
17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO
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. K50.00 B. C. D. E. F. G. H. I. J. K. L.
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 CPT/HCPCS MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
N400069080901 UNXX										
MM DD YY	MM DD YY	11		Q5103	A	$XXX.XX	40		NPI	
MM DD YY	MM DD YY	11		96xxx	A	$XXX.XX	1		NPI	
MM DD YY	MM DD YY	11		96xxx	A	$XXX.XX	1		NPI	
									NPI	
									NPI	
									NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN
26. PATIENT'S ACCOUNT NO.
27. ACCEPT ASSIGNMENT? YES NO
28. TOTAL CHARGE $
29. AMOUNT PAID $
30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS
32. SERVICE FACILITY LOCATION INFORMATION
33. BILLING PROVIDER INFO & PH # ( )

Item Number 24G Units: Enter the appropriate number of billing units for each line item; eg,
- For Q5103, 1 billing unit represents 10 mg of INFLECTRA

Item 24F: Enter charges for the administration of INFLECTRA; enter $00.00 charges for INFLECTRA since this was purchased by the specialty pharmacy

Item Number 24E Diagnosis Pointer: Enter the letter (A-L) that corresponds to the diagnosis in Item Number 21

IMPORTANT SAFETY INFORMATION (Continued)

HEMATOLOGIC EVENTS

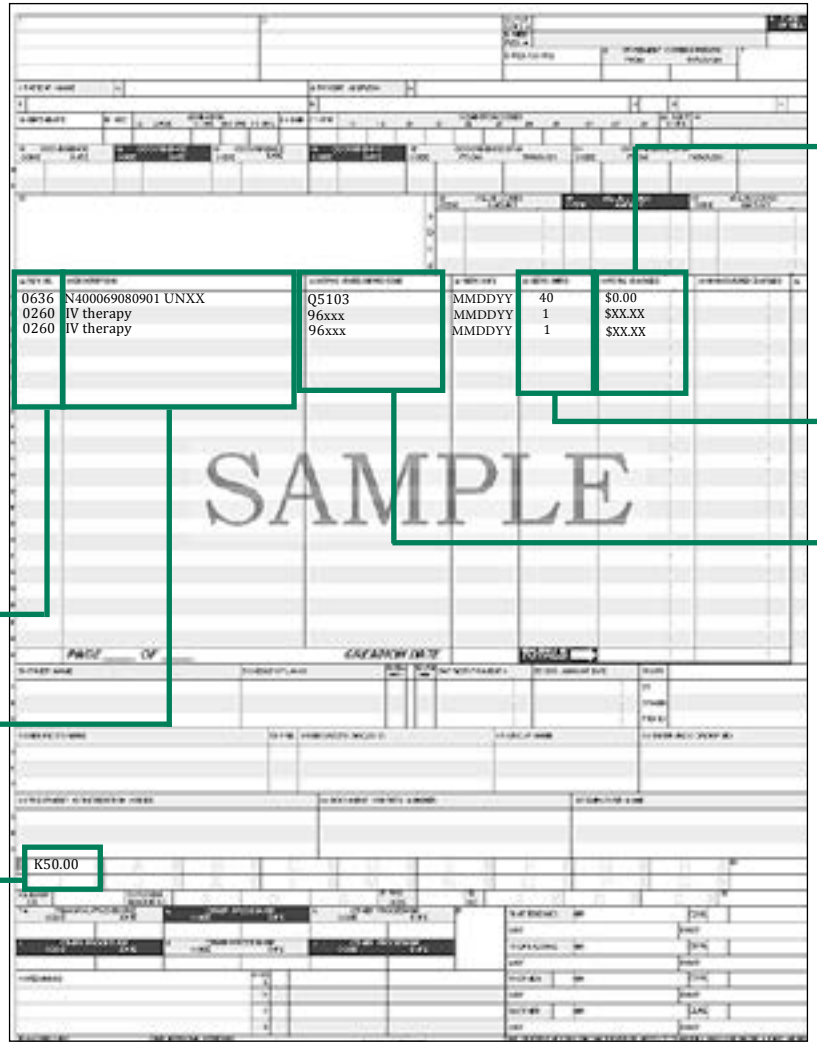
Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported. The causal relationship to infliximab-product therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate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

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

Acquisition of INFLECTRA Through a Specialty Pharmacy: HCP Acquires INFLECTRA Through a Specialty Pharmacy and Submits a Claim for Reimbursement Only for the Administration of INFLECTRA

Hospital Outpatient Sample Claim Form: UB-04

DISCLAIMER: This sample form is intended as a reference for the coding and billing of INFLECTRA. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.



FL 42 Revenue Code: Enter the appropriate revenue code; eg,
- 0636 for INFLECTRA
- 0260 for IV infusion

Other revenue codes may apply

FL 43 Revenue Description: Enter the NDC. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UoM qualifier and quantity. *Check payer requirements and format for reporting NDC and UoM*

FL 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code. *Final code depends on medical record documentation*

FL 47: Enter charges for the administration of INFLECTRA; enter $00.00 charges for INFLECTRA since this was purchased by the specialty pharmacy

FL 46 Units of Service: Enter the appropriate number of billing units for each line item; eg,
- For Q5103, 1 billing unit represents 10 mg of INFLECTRA.

FL 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
- Drug: Q5103 for INFLECTRA
- Add appropriate modifier as applicable
- Administration: 96xxx for drug administration

IMPORTANT SAFETY INFORMATION (Continued)
HYPERSENSITIVITY

Infliximab products 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 infliximab products. Medications for the treatment of hypersensitivity reactions should be available.

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

INFLECTRA Coding for Home Infusion

Home infusion providers should confirm appropriate coding with the patient's payer prior to submitting a claim for INFLECTRA.

Claim Information	Type of Code	Code and Descriptor	Billing Considerations
INFLECTRA	HCPCS code[1]	**Q5103** Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	Codes identifying INFLECTRA
	NDC[2]	**10-digit** 0069-0809-01 one single-dose 100 mg vial **11-digit**[a] **0**0069-0809-01 one single-dose 100 mg vial	
Procedures, services, and supplies	CPT codes[4]	**99601** Home infusion/specialty drug administration, per visit (up to 2 hours) **99602** Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (list separately in addition to code for primary procedure)	Home nursing CPT codes
	HCPCS codes[1]	**S9359** Home infusion therapy, anti-tumor necrosis factor intravenous therapy; (eg, infliximab); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	May be appropriate when submitting a claim for per diem specialty therapy services

[a]For claims-reporting purposes, the Health Insurance Portability and Accountability Act (HIPAA) requires conversion of the 10-digit NDC to an 11-digit NDC by adding a leading zero, where appropriate, to create a 5-4-2 configuration. For INFLECTRA claims, the zero is added in front of the first segment of numbers in the 10-digit format as listed in the prescribing information. See placement of the red zero in the table above. Check payer reporting requirements for NDC unit of measure and quantity.

CPT – Current Procedural Terminology; HCPCS – Healthcare Common Procedure Coding System; NDC – National Drug Code.

IMPORTANT SAFETY INFORMATION (Continued)

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 infliximab product infusion. Cases of transient visual loss have been reported during or within 2 hours of infliximab product infusion. Monitor patients during infusion, and if a serious reaction occurs, discontinue infusion. Manage reactions according to signs and symptoms.

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRAApi.com.

IMPORTANT SAFETY INFORMATION (Continued)

NEUROLOGIC EVENTS

Infliximab products and agents that inhibit TNF 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 INFLECTRA® in patients with these disorders and consider discontinuation if these disorders develop.

CONCURRENT ADMINISTRATION WITH OTHER BIOLOGICS

Concurrent use of infliximab products with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as INFLECTRA® 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 infliximab products may result in the formation of autoantibodies and in the development of a lupus-like syndrome. Discontinue INFLECTRA® treatment if symptoms of a lupus-like syndrome develop.

VACCINATIONS AND USE OF LIVE VACCINES/THERAPEUTIC INFECTIOUS AGENTS

Prior to initiating INFLECTRA®, update vaccinations in accordance with current vaccination guidelines. Live vaccines or therapeutic infectious agents should not be given with INFLECTRA® 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 INFLECTRA®.

ADVERSE REACTIONS

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

INDICATIONS

INFLECTRA® is indicated for:

Crohn's Disease

- 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

- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active CD who have had an inadequate response to conventional therapy

Ulcerative Colitis

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy

Pediatric Ulcerative Colitis

- 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

- 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) in combination with methotrexate (MTX)

Ankylosing Spondylitis

- Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)

Psoriatic Arthritis

- 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

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

Please see Important Safety Information throughout, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRApi.com.

References

1. Centers for Medicare & Medicaid Services. January 2026 alpha-numeric HCPCS file. Accessed December 1, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
2. INFLECTRA package insert. Pfizer Inc.; 2025.
3. Noridian Healthcare Solutions. Revenue codes. Accessed December 1, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes
4. American Medical Association. CPT 2026 Professional Edition. AMA; 2025. All rights reserved. CPT® is a registered trademark of the American Medical Association.
5. Centers for Medicare & Medicaid Services. 2026 ICD-10-CM. Accessed December 1, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes#

Please see Important Safety Information throughout, Indications on page 13, and click for full Prescribing Information, including BOXED WARNING and Medication Guide, also available at INFLECTRAApi.com.

FOR INJECTION

Inflectra®

infliximab-dyyb

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