Genentech
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Sample Billing and Coding

for ACTEMRA® (tocilizumab) and Rituxan® (rituximab)

Considerations for claims submission

ACTEMRA Indication

ACTEMRA is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

BOXED WARNING

RISK OF SERIOUS INFECTIONS:

Patients treated with ACTEMRA are at increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, or other opportunistic infections. If a serious infection develops, interrupt ACTEMRA until the infection is controlled.

Reported infections include:

- Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before ACTEMRA use and during therapy. Treatment for latent infection should be initiated prior to ACTEMRA use.
- Invasive fungal infections, including candidiasis, aspergillosis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
- Bacterial, viral and other infections due to opportunistic pathogens.

The risks and benefits of treatment with ACTEMRA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with ACTEMRA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Rituxan Indication

Rituxan® (rituximab), in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more TNF antagonist therapies.

BOXED WARNINGS

- Infusion-Related Reactions: Rituxan administration can result in serious, including fatal infusion-related reactions. Deaths within 24 hours of Rituxan infusion have occurred. Approximately 80% of fatal infusion reactions occurred in association with the first infusion. Monitor patients closely. Discontinue Rituxan infusion for severe reactions and provide medical treatment for Grade 3 or 4 infusion-related reactions.
- Severe Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions can occur in patients receiving Rituxan.
- Hepatitis B Virus (HBV) Reactivation: HBV reactivation can occur in patients treated with Rituxan, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with Rituxan. Discontinue Rituxan and concomitant medications in the event of HBV reactivation.
- Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving Rituxan.

ACTEMRA® tocilizumab | Rituxan® Rituximab

Please see the full Prescribing Information for **ACTEMRA** and **Rituxan**, including **BOXED WARNINGS.**

Sample Coding for ACTEMRA for Adults With RA: IV Infusion and SC Injection

This coding information may assist you as you complete the payer forms for ACTEMRA

TYPE	CODE	DESCRIPTION	
Diagnosis: ICD-10-CM	M05.00–M05.09	Felty's syndrome (rheumatoid arthritis with splenoadenomegaly and leukopenia)	
	M05.10–M05.19	Rheumatoid lung disease with rheumatoid arthritis of unspecified site	
	M05.20–M05.29	Rheumatoid vasculitis with rheumatoid arthritis	
	M05.30–M05.39	Rheumatoid heart disease with rheumatoid arthritis	
	M05.40–M05.49	Rheumatoid myopathy with rheumatoid arthritis	
	M05.50–M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis	
	M05.60–M05.69	Rheumatoid arthritis with involvement of other organs and systems	
	M05.70–M05.79	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement	
	M05.7A	Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement	
	M05.80–M05.8A	Other rheumatoid arthritis with rheumatoid factor	
	M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified	
	M06.00–M06.09	Rheumatoid arthritis without rheumatoid factor	
	M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified site	
	M06.80–M06.8A	Other specified rheumatoid arthritis	
	M06.9	Rheumatoid arthritis, unspecified	
Drug: HCPCS	J3262	Injection, tocilizumab, 1 mg	
HCPCS: Modifier* **Note:** Beginning July 1, 2023, CMS requires the use of the JZ modifier to indicate there were no units of a drug discarded.	JW	Drug amount discarded/not administered to any patient	IV only
	JZ	Zero drug amount discarded/not administered to any patient	

TYPE	CODE		DESCRIPTION	
	10-digit	11-digit		
Drug: NDC **Note:** Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	50242-135-01	50242-0135-01	80 mg (4 mL) single-use vial	
	50242-136-01	50242-0136-01	200 mg (10 mL) single-use vial	
	50242-137-01	50242-0137-01	400 mg (20 mL) single-use vial	
	50242-138-01	50242-0138-01	Prefilled syringe providing 162 mg per 0.9 mL	SC only
	50242-143-01	50242-0143-01	162 mg per 0.9 mL autoinjector (ACTPen®)	SC only
Administration procedures: CPT	96365		Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); initial, up to 1 hour	
	96413		Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	
	96372		Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	SC only

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; IV=intravenous; NDC=National Drug Code; RA=rheumatoid arthritis; SC=subcutaneous.

*The JW modifier will be required on claims for all single-dose containers or single-use drugs when an amount is discarded. The JZ modifier is required on claims for all single-dose containers or single-use drugs when no drug is discarded/administered to any patient as of July 1, 2023. For more information on the JZ modifier, visit CMS.gov.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any item or service.

Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

When submitting claims, be sure to:

- Keep complete, legible and easily accessible records
- Communicate with appropriate payer contacts to determine plan-specific requirements
- Monitor the first few claims submitted to each plan to learn about the plan's requirements so you can apply the knowledge to future claims

Sample Coding for Rituxan for Adults With RA

TYPE	CODE		DESCRIPTION
Diagnosis: ICD-10-CM	M05.00–M05.09		Felty's syndrome (rheumatoid arthritis with splenoadenomegaly and leukopenia)
	M05.10–M05.19		Rheumatoid lung disease with rheumatoid arthritis
	M05.20–M05.29		Rheumatoid vasculitis with rheumatoid arthritis
	M05.30–M05.39		Rheumatoid heart disease with rheumatoid arthritis
	M05.40–M05.49		Rheumatoid myopathy with rheumatoid arthritis
	M05.50–M05.59		Rheumatoid polyneuropathy with rheumatoid arthritis
	M05.60–M05.69		Rheumatoid arthritis with involvement of other organs and systems
	M05.70–M05.79		Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
	M05.7A		Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
	M05.80–M05.8A		Other rheumatoid arthritis with rheumatoid factor
	M05.9		Rheumatoid arthritis with rheumatoid factor, unspecified
	M06.00–M06.09		Rheumatoid arthritis without rheumatoid factor
	M06.0A		Rheumatoid arthritis without rheumatoid factor, other specified site
	M06.80–M06.8A		Other specified rheumatoid arthritis
	M06.9		Rheumatoid arthritis, unspecified
	J9312		Injection, rituximab, 10 mg
Drug: HCPCS	Other drugs: for ancillary premedications and supplies as appropriate	J1100	Injection, dexamethasone sodium phosphate, 1 mg
		J1200	Injection, diphenhydramine HCL, up to 50 mg
		J2920	Injection, methylprednisolone sodium succinate, up to 40 mg
		J2930	Injection, methylprednisolone sodium succinate, up to 125 mg
		J7030	Infusion, normal saline solution, 1000 cc
		J7040	Infusion, normal saline solution, sterile (500 mL = 1 unit)
		J7050	Infusion, normal saline solution, 250 cc

TYPE	CODE		DESCRIPTION
HCPCS: Modifier* **Note:** Beginning July 1, 2023, CMS requires the use of the JZ modifier to indicate there were no units of a drug discarded.	JW		Drug amount discarded/not administered to any patient
	JZ		Zero drug amount discarded/not administered to any patient
Drug: NDC **Note:** Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	**10-digit**	**11-digit**	
	50242-051-21	50242-0051-21	100 mg/10 mL single-dose vial
	50242-053-06	50242-0053-06	500 mg/50 mL single-dose vial
Administration procedures: CPT	**ADMINISTRATION CODES FOR RITUXAN**		
	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)
	ADMINISTRATION CODES FOR SUPPORTIVE MEDICINES		
	96367		Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (List separately in addition to code for primary procedure) (Report 96367 in conjunction with 96365, 96374, 96409, 96413 if provided as a secondary or subsequent service after a different initial service is administered through the same IV access. Report 96367 only once per sequential infusion of same infusate mix)
	96375		Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure) (Use 96375 in conjunction with 96365, 96374, 96409, 96413) (Report 96375 to identify intravenous push of a new substance/drug if provided as a secondary or subsequent service after a different initial service is administered through the same IV access)

*The JW modifier will be required on claims for all single-dose containers or single-use drugs when an amount is discarded. The JZ modifier is required on claims for all single-dose containers or single-use drugs when no drug is discarded/administered to any patient as of July 1, 2023. For more information on the JZ modifier, visit CMS.gov.

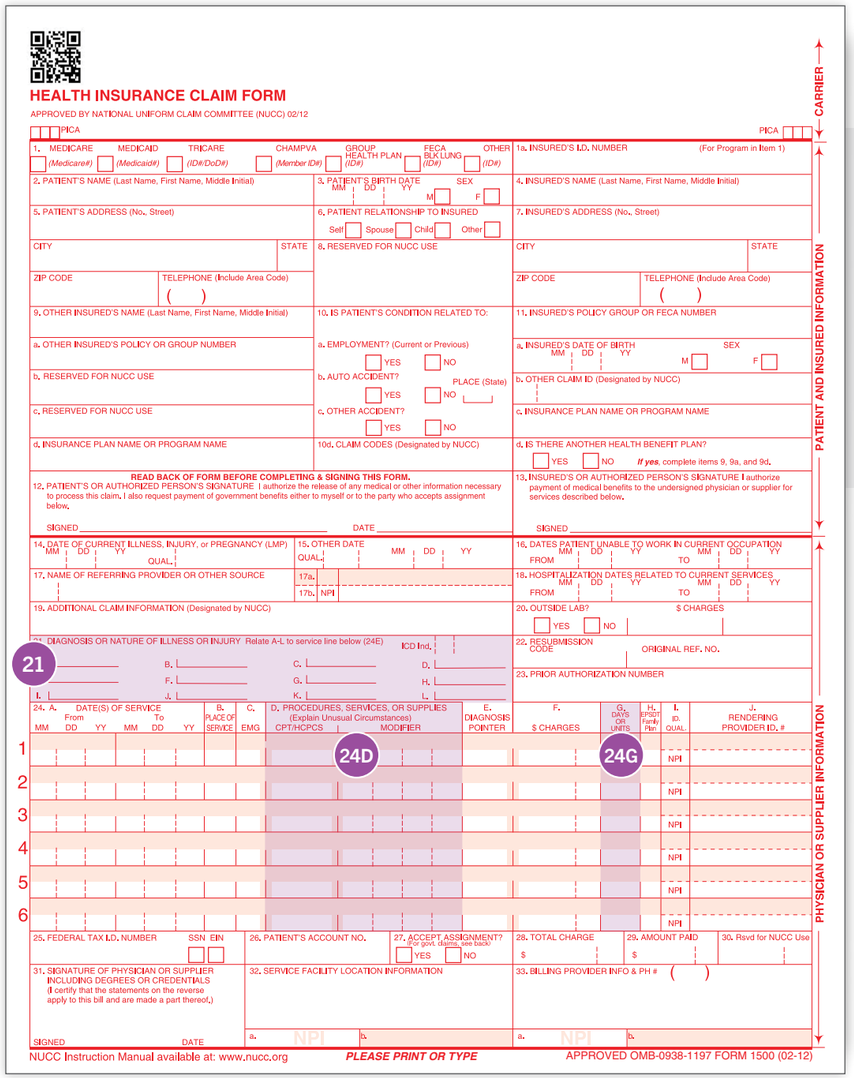
These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech and Biogen do not make any representation or guarantee concerning reimbursement or coverage for any item or service.

Please see the full Prescribing Information for **ACTEMRA** and **Rituxan**, including **BOXED WARNINGS.**

ACTEMRA® tocilizumab | Rituxan® Rituximab

CMS-1500 Example Claim Form

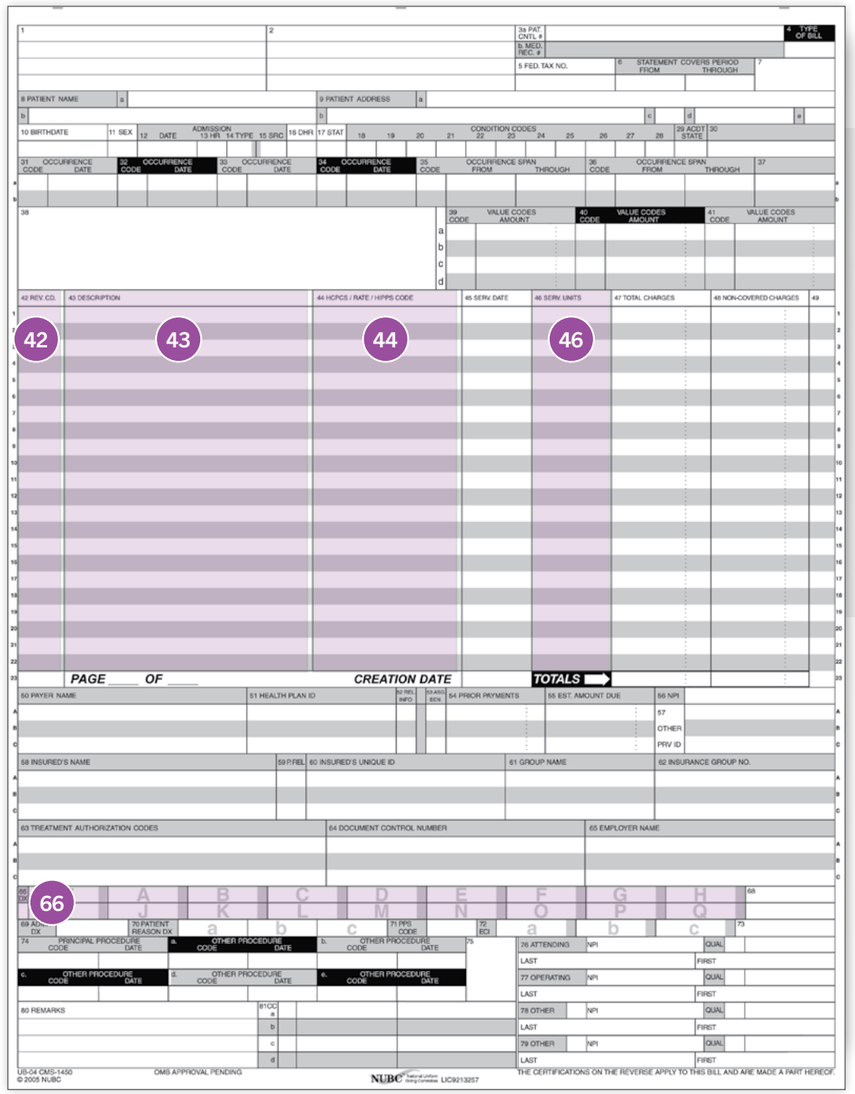
The CMS-1500 claim form is used by some payers to bill for services provided in the **noninstitutional (physician office) setting.**



- **21** Input diagnosis code(s) here
- **24D** Input HCPCS code, NDC and appropriate CPT administration code(s) and required modifier(s) on separate lines
- **24G** Input number of units for each line item

CMS-1450/UB-04 Example Claim Form

The CMS-1450 /UB-04 claim form is used by some payers to bill for services provided in the **institutional (hospital) setting.**



- **42** Input revenue code
- **43** Input NDC
- **44** Input HCPCS code on one line and appropriate CPT administration code(s) and required modifier(s) on a separate line
- **46** Number of units for each line item
- **66** Input diagnosis code(s) here

Please see the full Prescribing Information for **ACTEMRA** and **Rituxan**, including **BOXED WARNINGS.**

ACTEMRA® tocilizumab | Rituxan® Rituximab

Your Direct Connection to Genentech

To learn more about our programs and services:

Visit **Genentech-Access.com/ACTEMRA** or **Genentech-Access.com/Rituxan-RA**

Get support from your **Genentech representative**

Call our **Specialists** at **(866) 681-3261** Monday through Friday, 6 a.m. to 5 p.m. PT

BOXED WARNING and Additional Important Safety Information (cont)

ACTEMRA is contraindicated in patients with known hypersensitivity to ACTEMRA.

Other serious or potentially life-threatening adverse reactions that have been reported in clinical trials with ACTEMRA include gastrointestinal perforations. Use ACTEMRA with caution in patients who may be at risk for GI perforations.

Monitor patients for signs and symptoms of hepatic injury. Modify or discontinue ACTEMRA if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Laboratory monitoring is recommended due to potential consequences of treatment-related laboratory abnormalities in neutrophils, platelets, lipids, and liver function tests.

Hypersensitivity reactions, including anaphylaxis and death, have occurred.

- If anaphylaxis or other hypersensitivity reaction occurs, stop administration of ACTEMRA immediately and discontinue ACTEMRA permanently.

Avoid use of live vaccines concurrently with ACTEMRA, as clinical safety has not been established.

Other potential risks of ACTEMRA include demyelinating disorders and malignancies. Treatment with ACTEMRA is not recommended in patients with active hepatic disease or hepatic impairment.

Most common adverse reactions (≥ 5%) include upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased ALT, injection site reactions (SC only).

You may report side effects to the FDA at (800) FDA-1088 or **www.fda.gov/medwatch**. You may also report side effects to Genentech at (888) 835-2555.

Please see additional Important Safety Information in accompanying full Prescribing Information, including **BOXED WARNING**.

BOXED WARNINGS and Additional Important Safety Information (cont)

Rituxan administration can also result in additional serious, including fatal, adverse reactions including:

- Tumor lysis syndrome (TLS): Administer aggressive intravenous hydration, anti-hyperuricemic agents, monitor renal function
- Infections: Withhold Rituxan and institute appropriate anti-infective therapy. Rituxan is not recommended for use in patients with severe, active infections
- Cardiovascular adverse reactions: Discontinue infusions in case of serious or life-threatening events
- Renal toxicity: Discontinue in patients with rising serum creatinine or oliguria
- Bowel obstruction and perforation: Consider and evaluate for abdominal pain, vomiting, or related symptoms
- Immunizations: Live virus vaccinations prior to or during Rituxan treatment are not recommended
- Embryo-Fetal toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception
- Patients with RA should be closely observed for signs of infection if biologic agents and/or DMARDs other than methotrexate are used concomitantly
- The use of Rituxan in patients with RA who have not had prior inadequate response to one or more TNF antagonists is not recommended
- Most common adverse reactions in patients with RA were upper respiratory tract infection, nasopharyngitis, urinary tract infection, and bronchitis. Other important adverse reactions include infusion-related reactions, serious infections, and cardiovascular events

For additional Important Safety Information, please see the Rituxan full Prescribing Information, including **BOXED WARNINGS**.

Attention Healthcare Provider: Provide Medication Guide to patient prior to Rituxan infusion.

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