Tyenne®
tocilizumab-aazg

TYENNE® (tocilizumab-aazg)
Intravenous (IV) Infusion and Subcutaneous (SC) Injection

Billing & Coding Guide

INDICATIONS

TYENNE 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).
- Giant cell arteritis (GCA) in adult patients.
- Active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older.
- Active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older.

Important Safety Information

RISK OF SERIOUS INFECTIONS:

Patients treated with TYENNE® (tocilizumab-aazg) 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 TYENNE until the infection is controlled.

Please see Important Safety Information throughout this brochure and click to see full Prescribing Information, including **Boxed Warning** for TYENNE® (tocilizumab-aazg).

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The TYENNE® Coding and Billing Guide provides general reimbursement information for healthcare providers.

Topics include coding, coverage, billing, and reimbursement for treatment with TYENNE®.

The content provided in this guide is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure TYENNE® claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee that payers will consider all codes appropriate for all encountered scenarios and Fresenius Kabi does not guarantee TYENNE® coverage or reimbursement.

INDICATIONS AND USAGE

Rheumatoid Arthritis (RA)

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

Giant Cell Arteritis (GCA)

TYENNE® (tocilizumab-aazg) is indicated for the treatment of giant cell arteritis (GCA) in adult patients.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

TYENNE® (tocilizumab-aazg) is indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

Systemic Juvenile Idiopathic Arthritis (SJIA)

TYENNE® (tocilizumab-aazg) is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Important Safety Information (continued)

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before TYENNE use and during therapy. Treatment for latent infection should be initiated prior to TYENNE 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 TYENNE 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 TYENNE, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

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ICD-10 CODES

Tyenne® tocilizumab-aazg

This coding information may assist you as you complete the payer forms for TYENNE®.

Diagnosis: ICD-10-CM[1]	
ICD-10 Codes	Description
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
M08.20-M08.29	Juvenile rheumatoid arthritis with systemic onset
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M31.5	Giant cell arteritis with polymyalgia rheumatica
M31.6	Other giant cell arteritis

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. Fresenius Kabi 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.

HCPCS/Modifiers

Healthcare Common Procedure Coding System (HCPCS)[2]	
HCPCS	Description
Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
HCPCS Modifier	
JW **(IV ONLY)**	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient
TB	Drug or biological acquired with 340B drug pricing program discount; reported for informational purposes

IMPORTANT NOTICE: As of October 1, 2023, CMS rejects "single dose" drug claims without modifier JZ or JW may be returned unprocessable until claims are properly submitted including waste modifiers—per Discarded Drugs and Biologicals. The JW and JZ modifier policy applies to all providers and suppliers who buy and bill single use vials drugs under Medicare Part B.[3] Some commercial payers may require a waste modifier.

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. Fresenius Kabi 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.

Contact your TYENNE® Immunology Sales Specialist to connect with a Field Reimbursement Manager who is available to share the latest updates in payer coverage.

Please see Important Safety Information throughout this brochure and click to see full Prescribing Information, including **Boxed Warning** for TYENNE® (tocilizumab-aazg).

NDC Numbers and CPT Codes

Tyenne® tocilizumab-aazg

What codes do I use to bill for TYENNE®?

- A new prescription is required for TYENNE®.
- To ensure your patient will receive TYENNE®, please select the appropriate dosing from the Enrollment and Prescription Form or when prescribing electronically.

National Drug Code (NDC)[4]

Electronic data exchange standards usually require the use of an 11-digit NDC.

Dosage Form	NDC Number	10-digit NDC Code	11-digit NDC Code
IV Infusion	80 mg/4 mL, single-dose vial	65219-590-04	65219-0590-04
	200 mg/10 mL, single-dose vial	65219-592-10	65219-0592-10
	400 mg/20 mL, single-dose vial	65219-594-20	65219-0594-20
SC Injection	162 mg/0.9 mL, single-dose prefilled autoinjector	65219-584-01	65219-0584-01
	162 mg/0.9 mL, single-dose prefilled syringe	65219-586-04	65219-0586-04

Current Procedural Terminology (CPT) Code[5]

The CPT code is used to report the injection of TYENNE® by a healthcare professional.

Dosage Form	Administration Procedures	CPT Code
IV Infusion – Simple	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	96XXX
IV Infusion – Complex*	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	96XXX
SC Injection	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	96372

*All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement. Medicare requires detailed documentation to support a complex infusion code claim.

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Physician's Office Billing Information[6]

TYENNE® (tocilizumab-aazg) Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Input HPCS code 5135, NDC, and an appropriate CPT administration code, and required modifiers on seperate lines.
Number of Units in **Block 24G**: (Electronic Form: Loop 2400, SV1, 04 [03=UN])	Input number of units for each line item: 1 billable unit = 1mg Please bill according to the amount of product administered or wasted.
Administration and Professional Service Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	The following codes may be available to report administration of TYENNE®. Other codes may be appropriate on a payer-specific basis. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes.
Diagnosis Code Information*	
ICD-10-CM Code in **Block 21**: (Electronic Form: Loop 2300, HI, 01-2)	A primary ICD-10-CM diagnosis code may be appropriate to describe patients.
	A primary diagnosis code may be appropriate to describe patients.

* The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for TYENNE®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Important Safety Information (continued)

Some of these cases have resulted in liver transplant or death.

Time to onset for cases ranged from months to years after treatment initiation. Most cases presented with marked elevations of transaminases (>5 times ULN), and some cases presented with signs or symptoms of liver dysfunction and only mildly elevated transaminases.

Treatment with tocilizumab was associated with a higher incidence of transaminase elevations; increased frequency and magnitude of these elevations were observed when tocilizumab was used in combination with potentially hepatotoxic drugs (e.g., methotrexate).

It is not recommended to initiate TYENNE treatment in RA, GCA, PJIA, and SJIA patients with elevated transaminases ALT or AST greater than 1.5x ULN. In patients who develop elevated ALT or AST greater than 5x ULN discontinue TYENNE.

Measure liver tests promptly in patients who report symptoms that may indicate liver injury. If the patient is found to have abnormal liver tests, TYENNE treatment should be interrupted. TYENNE should only be restarted in patients with another explanation for the liver test abnormalities after normalization of the liver tests.

Laboratory Parameters

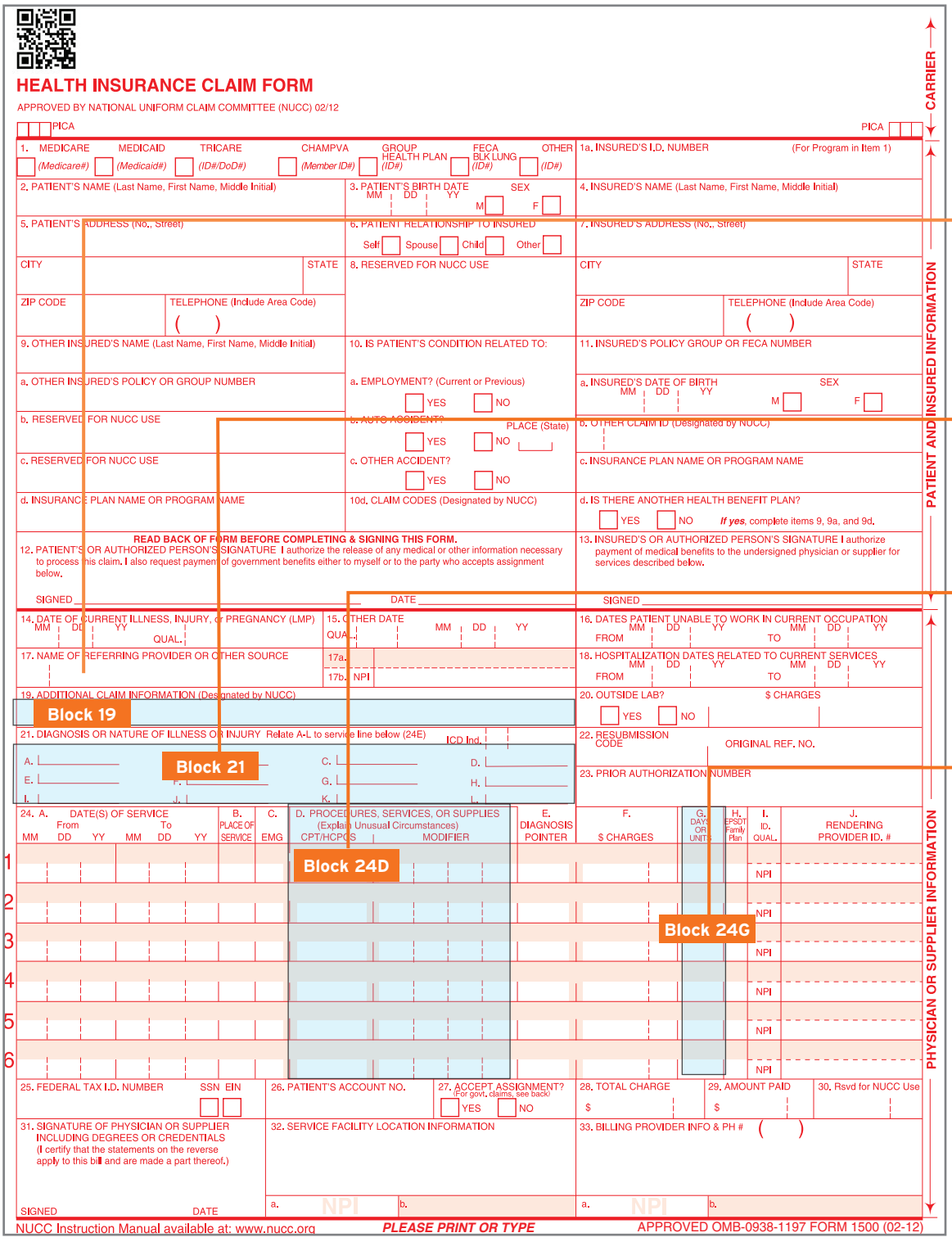
Laboratory monitoring is recommended due to potential consequences of treatment-related laboratory abnormalities in neutrophils, platelets, lipids, and liver function tests. Dosage modifications may be required.

Neutropenia: Treatment with tocilizumab products was associated with a higher incidence of neutropenia. It is not recommended to initiate TYENNE treatment in RA, GCA, PJIA, and SJIA patients with a low neutrophil count i.e., absolute neutrophil count (ANC) less than 2,000 per mm^3. In patients who develop an ANC less than 500 per mm^3, treatment is not recommended.

Sample CMS 1500 Claim Form
(physician office site of service)[6]

Tyenne® tocilizumab-aazg

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure TYENNE® claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee TYENNE® coverage or reimbursement.



Block 19: Additional Information

Medicare requires reporting additional NDC codes in box 19. Refer to your MAC for more information.

Block 21: Diagnosis

Enter appropriate ICD-10-CM diagnosis code(s).

Block 24D: Drug Code

Enter appropriate HCPCS (Q5135)/Modifiers and CPT codes.

Block 24G: Units

Enter the billing units:
1 billing unit = 1mg.

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Hospital/Institutional Billing[7]

TYENNE® (tocilizumab-aazg) Coding Information*	
Revenue Code in **Form Location (FL) 42**: (Electronic Form: Loop 2400, SV201)	Use the most appropriate revenue code for cost center, e.g., 636 Drugs that require detail coding.
Coding Information in **FL 44**: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Enter Q5135 as the HCPCS code, appropriate modifiers and CPT codes.
Service Units in **FL 46**: (Electronic Form: Loop 2400, SV205)	Q5135 – TYENNE® 80 mg, 200 mg, 400 mg IV Injection: 1 billable unit = 1mg. Please bill according to the amount of product administered or wasted.
Administration and Professional Service Coding Information*	
Revenue Code in **FL 42**: (Electronic Form: Loop 2400, SV201)	Appropriate revenue code for the cost center in which the service is performed.
Description in **FL 43**: (Not required by Medicare)	When billing for the IV formulation of TYENNE®, list the N4 indicator first, then the 11-digit NDC number, followed by the unit of measurement qualifier and the unit quantity.
Coding Information in **FL 44**: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Enter Q5135 as the HCPCS code, appropriate modifiers and CPT codes.
Diagnosis Code Information*	
ICD-10-CM Code in **FL 66**: (Electronic Form: Loop 2300, HI01-2 [HI01-1=BK])	Input diagnosis code, ICD-10-CM code(s) for patient condition.

Sequencing of codes may vary based on patient's condition and payer's policy.

* The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for TYENNE®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Important Safety Information (continued)

Thrombocytopenia: Treatment with tocilizumab products was associated with a reduction in platelet counts. It is not recommended to initiate TYENNE in RA, GCA, PJIA, and SJIA patients with a platelet count below 100,000 per mm^3. In patients who develop a platelet count less than 50,000 per mm^3, treatment is not recommended.

Elevated Liver Enzymes: It is not recommended to initiate TYENNE treatment in patients with elevated transaminases ALT or AST >1.5x ULN. In patients who develop elevated ALT or AST >5x ULN, treatment is not recommended.

Lipid Abnormalities: Treatment with tocilizumab products was associated with increases in lipid parameters such as total cholesterol, triglycerides, LDL cholesterols, and/or HDL cholesterol.

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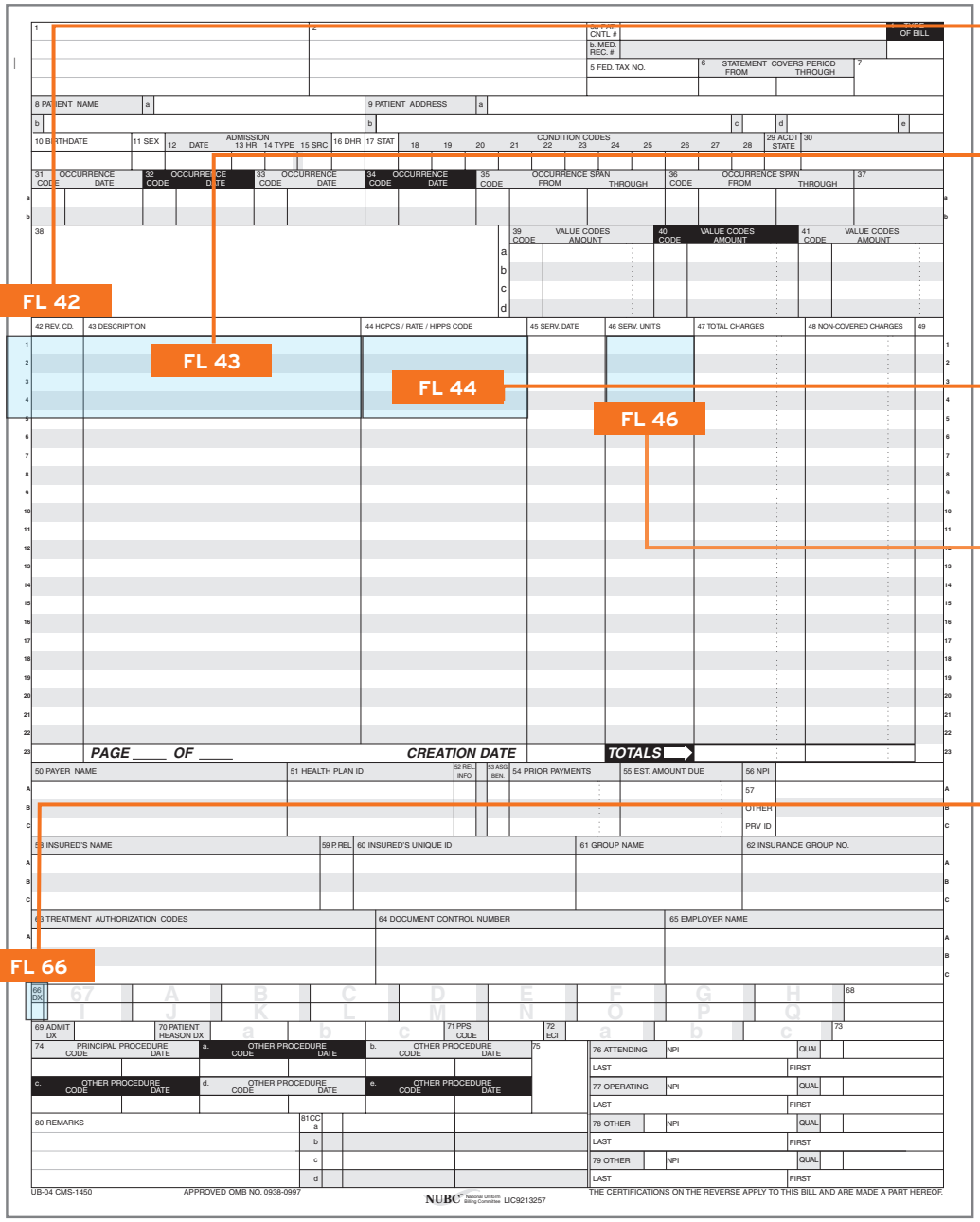
Sample CMS 1450 (UB-04) Claim Form
(hospital outpatient site of service)[7]

Tyenne® tocilizumab-aazg

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure TYENNE® claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee TYENNE® coverage or reimbursement.



FL 42

Enter the appropriate revenue code and procedure description.

FL 43

When billing for the IV formulation of TYENNE®, list the N4 indicator first, then the 11-digit NDC number, followed by the unit of measurement qualifier and the unit quantity.

FL 44

Enter Q5135 as the HCPCS code, modifiers and CPT codes.

FL 46

Q5135 – TYENNE® 80 mg, 200 mg, 400 mg IV Injection:
1 billable unit = 1mg,

Please bill according to the amount of product administered or wasted.

FL 66

Identify the type of ICD diagnosis code used (e.g., enter a "0" for ICD-10-CM).

Additional documentation for filing your claim

In addition to the CMS 1500 or CMS 1450 (UB-04) claim form, the payer may request the following:

- Patient medical history
- Physician clinical notes
- PA number
- May require an invoice
- Letter of medical necessity (see sample at **tyennehcp.com/tyenne-letter-medical-necessity**)
- Drug-identifying information (e.g., NDC)
- Letter of appeal (see sample at **tyennehcp.com/tyenne-letter-appeal**)

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KabiCare Reimbursement and Payment Support

Comprehensive support to enable patient access

KabiCare provides comprehensive access and support resources for patients including but not limited to:

FINANCIAL SUPPORT
programs, including copay assistance for eligible patients with out-of-pocket costs as little as $0/month*

BRIDGE TO THERAPY
program to avoid treatment delay while waiting for insurance approval†

CLINICAL INSIGHTS PROGRAM
provides a Therapeutic Drug Monitoring program to help commercially insured patients monitor their treatment journey at no cost to the patient§||

DEDICATED SUPPORT
to address access challenges

CENTRALIZED PATIENT SUPPORT PORTAL
with real-time status updates

PERSONAL SUPPORT
including nurse educators and field reimbursement managers‡

* Terms and conditions apply.
† Eligibility criteria apply. Patients are not eligible for Bridge to Therapy if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare program.
‡ Nurse support provided by KabiCare is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.
§ Patients must be 18 years or older and prescribed TYENNE® for an on-label indication. Patients are not eligible for the Clinical Insights Program if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare program.
|| The Clinical Insights Anser Tests were developed and validated by Prometheus Laboratories, Inc., a partner of Fresenius Kabi. Test results are provided via Prometheus Laboratories Inc. to physicians. Prescribing physicians are decision makers and are ultimately responsible for the exercise of independent clinical judgment in the best interest of patients.

Important Safety Information (continued)

Immunosuppression

The impact of treatment with tocilizumab products on the development of malignancies is not known, but malignancies were observed in clinical studies with tocilizumab. TYENNE is an immunosuppressant, and treatment with immunosuppressants may result in an increased risk of malignancies.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported in association with tocilizumab products and anaphylactic events with a fatal outcome have been reported with intravenous infusion of tocilizumab products. TYENNE for intravenous use should only be infused by a healthcare professional with appropriate medical support to manage anaphylaxis. For TYENNE subcutaneous injection, advise patients to seek immediate medical attention if they experience any symptoms of a hypersensitivity reaction. If anaphylaxis or other hypersensitivity reaction occurs, stop administration of TYENNE immediately and discontinue TYENNE permanently. Do not administer TYENNE to patients with known hypersensitivity to tocilizumab products.

Demyelinating Disorders

The impact of treatment with tocilizumab products on demyelinating disorders is not known, but multiple sclerosis and chronic inflammatory demyelinating polyneuropathy were reported rarely in clinical studies. Monitor patients for signs and symptoms of demyelinating disorders. Prescribers should exercise caution in considering the use of TYENNE in patients with preexisting or recent-onset demyelinating disorders.

Active Hepatic Disease and Hepatic Impairment

Treatment with TYENNE is not recommended in patients with active hepatic disease or hepatic impairment.

Vaccinations

Avoid use of live vaccines concurrently with TYENNE. No data are available on the secondary transmission of infection from persons

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KabiCare Contact Information

Tyenne® tocilizumab-aazg

KabiCare
Patient support from Fresenius Kabi

Call 1-833-KABICARE
(1-833-522-4227)
Monday through Friday
8 a.m. to 8 p.m. ET
(excluding holidays)

Fax 1-833-302-1420

Visit our website
at **KabiCare.us**

TYENNE® offers additional educational tools and resources, including:

- Sampling
- Educational resources
- Video resources
- Demo kits

Important Safety Information (continued)

receiving live vaccines to patients receiving TYENNE or on the effectiveness of vaccination in patients receiving TYENNE. Patients should be brought up to date on all recommended vaccinations prior to initiation of TYENNE therapy, if possible.

ADVERSE REACTIONS

Most common adverse reactions (incidence of at least 5%): upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased ALT, injection site reactions.

DRUG INTERACTIONS

In GCA patients, no effect of concomitant corticosteroid on tocilizumab exposure was observed.

Cytochrome P450s in the liver are down-regulated by infection and inflammation stimuli including cytokines such as IL-6. Inhibition of IL-6 signaling in RA patients treated with tocilizumab products may restore CYP450 activities to higher levels than those in the absence of tocilizumab products leading to increased metabolism of drugs that are CYP450 substrates.

Exercise caution when coadministering TYENNE with CYP3A4 substrate drugs where decrease in effectiveness is undesirable, e.g., oral contraceptives, lovastatin, atorvastatin, etc.

USE IN PREGNANCY

The limited available data with tocilizumab products in pregnant women are not sufficient to determine whether there is a drug-associated risk for major birth defects and miscarriage.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Fresenius Kabi at (800) 551-7176.

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Tyenne®
tocilizumab-aazg

TYENNE® (tocilizumab-aazg) offers resources to help your patients start and stay on prescribed therapy

We are dedicated to providing your patients with ongoing support to help them access Fresenius Kabi medications as prescribed.

Contact your TYENNE® Immunology Sales Specialist to connect with a Field Reimbursement Manager who is available to share the latest updates in payer coverage.

References: 1. Centers for Medicare & Medicaid Services. ICD Code Lists: Valid ICD-10 List [excel file]. https://www.cms.gov/medicare/coordination-benefits-recovery/overview/icd-code-lists. Page last modified October 17, 2023. Accessed Feb 15, 2024. **2.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update: January 2024 Alpha-Numeric HCPCS Files [zip file]. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. Page last modified December 7, 2023. Accessed February 15, 2024. **3.** Medicare Program Discarded Drugs and Biologicals - JW Modifier and JZ Modifier Policy Frequently Asked Questions. cms.gov. Accessed February 15, 2024. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. **4.** TYENNE® (tocilizumab-aazg) prescribing information. Lake Zurich, IL: Fresenius Kabi, USA LLC; 2024. **5.** CPT coding for Drug Administration - AAPC Knowledge Center. aapc.com. https://www.aapc.com/blog/23016-infuse-yourself-with-coding-knowledge/. Accessed February 15, 2024. **6.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual, Chapter 26. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf. Accessed May 28, 2024. **7.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual, Chapter 25. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf. Accessed May 28, 2024.

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