

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

Billing & Coding Guide

IMPORTANT SAFETY INFORMATION

RISK OF SERIOUS INFECTIONS:

Patients treated with TYENNE 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.

Reported infections include:

- Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients, except those with COVID-19, should be tested for latent tuberculosis before TYENNE use and during therapy (except patients with COVID-19). 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.



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

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

Topics include billing, coding, coverage, 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 USAGE¹

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) in adult patients.
- Active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- Active systemic juvenile idiopathic arthritis in patients 2 years of age and older.
- Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.
- Coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Important Safety Information (continued)

CONTRAINDICATIONS

Known hypersensitivity to Tocilizumab products.

WARNINGS AND PRECAUTIONS

COVID-19

Monitor for signs and symptoms of new infections during and after treatment with TYENNE in patients with COVID-19. Limited information is available regarding the use of TYENNE in patients with COVID-19 and concomitant serious active infections. The risks and benefits of treatment with TYENNE in patients with COVID-19 and other concurrent infections should be considered.

Gastrointestinal Perforations

Events of gastrointestinal (GI) perforation have been reported in clinical trials, primarily as complications of diverticulitis in RA patients. Use TYENNE with caution in patients who may be at increased risk for GI perforation. Promptly evaluate patients presenting with new-onset abdominal symptoms for early identification of GI perforation.

Hepatotoxicity

Serious cases of hepatic injury have been observed in patients taking intravenous or subcutaneous Tocilizumab. 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

AVAILABLE FORMULATIONS OF TYENNE® (tocilizumab-aazg)

TYENNE[®] is available as vials for infusion and single dose autoinjector and prefilled syringes for subcutaneous injection¹

Vial for intravenous infusion



🖊 Three dosage forms to minimize waste

- 80 mg/4 mL
- 200 mg/10 mL
- 400 mg/20 mL

Different cap colors for easy identification

Coding for single-dose vial for intravenous infusion is included in this billing guide.

Single-dose autoinjector for subcutaneous injection



162 mg/0.9 mL, single-dose (65219-584-01)

Single-dose prefilled syringe for subcutaneous injection



162 mg/0.9 mL, single-dose (65219-586-04)

Important Safety Information (continued)

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.

Patients who are hospitalized with COVID-19 may have elevated AST or ALT levels. Multi-organ failure with involvement of the liver is recognized as a complication of severe COVID-19. The decision to administer TYENNE should balance the potential risks of acute treatment with TYENNE against the potential benefit of treating COVID-19. It is not recommended to initiate TYENNE treatment in COVID-19 patients with elevated ALT or AST above 10x ULN. Monitor ALT and AST during treatment.

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 was associated with a higher incidence of neutropenia. It is not recommended

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

ICD-10 CODES

This coding information may assist you as you complete the payer forms for TYENNE® (tocilizumab-aazg).

Diagnosis: ICD-10-CM ^{*2}		
ICD-10 Codes	Description	
D89.833	Cytokine release syndrome, grade 3	
D89.834	Cytokine release syndrome, grade 4	
D89.835	Cytokine release syndrome, grade 5	
D89.839	Cytokine release syndrome, grade unspecified	
M05.00-M05.09	Felty's syndrome (rheumatoid arthritis with splenomegaly 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	
U07.1	COVID-19	

*Some codes used need to have a greater level of specificity.

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

Healthcare Common Procedure Coding System (HCPCS)

HCPCS Code for TYENNE [®] (tocilizumab-aazg) ³			
HCPCS	Description	Site of service	Billing units
Q5135	Injection, tocilizumab-aazg (TYENNE®), biosimilar, 1 mg	All	1

Payment status indicator

Identifies whether a service represented by a CPT or HCPCS code is payable under the Outpatient Prospective Payment System (OPPS) Ambulatory Payment Classification (APC) or another payment system. Only 1 status indicator is assigned to each CPT or HCPCS code.

Payment status indicator ⁴		
HCPCS Code	Description	Status indicator
Q5135	Injection, tocilizumab-aazg (TYENNE®), biosimilar, 1 mg	G

G Pass-Through Drugs and Biologicals Paid under OPPS; separate APC payment includes pass-through amount.

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

Important Safety Information (continued)

to initiate TYENNE treatment in RA, GCA, PJIA, and SJIA patients with a low neutrophil count i.e., absolute neutrophil count (ANC) less than 2000 per mm³. In patients who develop an ANC less than 500 per mm³ treatment is not recommended.

It is not recommended to initiate TYENNE treatment in COVID-19 patients with an ANC less than 1000 per mm³. Neutrophils should be monitored.

Thrombocytopenia: Treatment with Tocilizumab 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 mm³. In patients who develop a platelet count less than 50000 per mm³, treatment is not recommended. It is not recommended to initiate TYENNE treatment

in COVID-19 patients with a platelet count less than 50000 per mm³. Platelets should be monitored. **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 was associated with increases in lipid parameters such as total cholesterol, triglycerides, LDL cholesterols, and/or HDL cholesterol.

Immunosuppression

The impact of treatment with Tocilizumab on the development of malignancies is not known, but malignancies were observed in clinical studies with Tocilizumab. TYENNE is an immunosuppressant, and treatment with

Modifiers

Summary of Code Modifiers				
Modifier	Description ⁵	Indication and Placement ⁶⁻⁸	CMS-1500 (Item 24D)	CMS-1450 (Box 44)
JA	Administered via intravenous solution	For drugs that have only one HCPCS Level II (J or Q) code but multiple routes of administration, providers should append one of the following modifiers (JA or JB) to describe the given route of administration.	✓ Required by Medicare	✓ Required by Medicare
JB	Administered via subcutaneous injection	For drugs that have only one HCPCS Level II (J or Q) code but multiple routes of administration, providers should append one of the following modifiers (JA or JB) to describe the given route of administration.	√ Required by Medicare	✓ Required by Medicare
WL	Drug amount discarded/ not administered to any patient	Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial.	√ Required by Medicare	√ Required by Medicare
JZ	Zero drug amount discarded/not administered to any patient	To be used for single-dose containers or single- use packages when the entire amount has been administered to the patient (no wastage).	√ Required by Medicare	✓ Required by Medicare
ТВ	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	TB modifier is used to identify drugs or biologicals acquired through the 340B Drug Pricing Program for informational purposes. The TB modifier is required for all 340B covered entities, including hospital-based and non-hospital-based entities, for claims with dates of service beginning on or after January 1, 2025. TB modifier to be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs.	N/A	√ Required by Medicare

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.

Important Safety Information (continued)

immunosuppressants may result in an increased risk of malignancies.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported in association with Tocilizumab and anaphylactic events with a fatal outcome have been reported with intravenous infusion of Tocilizumab. Additionally, serious cutaneous reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported in patients with autoinflammatory conditions treated with 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

NDC Numbers and CPT Codes



What codes do I use to bill for TYENNE® (tocilizumab-aazg)?

• 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)¹

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
	80 mg/4 mL, single-dose vial	65219-590-04	65219-0590-04
IV Infusion	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) Code⁹

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.

Important Safety Information (continued)

other hypersensitivity reaction occurs, stop administration of TYENNE immediately and discontinue TYENNE permanently. Do not administer TYENNE to patients with known hypersensitivity to TYENNE. *Demyelinating Disorders* The impact of treatment with Tocilizumab 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.

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Physician's Office Billing Information¹⁰

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 separate 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 = 1 mg 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)

Vaccinations

Avoid use of live vaccines concurrently with TYENNE. No data are available on the secondary transmission of infection from persons 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 TYENNE may restore CYP450 activities to higher levels than those in the absence of TYENNE leading to increased metabolism of drugs that are CYP450 substrates. Exercise caution when co-administering 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, miscarriage, or other adverse maternal or fetal outcomes. 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. 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).

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

Sample CMS 1500 Claim Form

(physician office site of service)¹⁰

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® (tocilizumab-aazg) claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee TYENNE® coverage or reimbursement.

Image: Provide by National UNIFORM CLAIM COMMITTEE (NUCC) 02/12		
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□ (<i>Medicare#</i>) (<i>Medicaid#</i>) (<i>ID#/DoD#</i>) (<i>Member ID#</i>) (<i>ID#</i>) (<i>ID#</i>) (<i>ID#</i>)	_][
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE SEX 4. INSURED'S NAME (Last Name, First Name, Middle Initial) 1. I M F		
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	NRO	for more information.
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	Ē	CM diagnosis code(s).
d, INSURANCE PLAN NAME OR PROGRAM NAME 10d. CLAIM CODES (Designated by NUCC) d, IS THERE ANOTHER HEALTH BENEFIT PLAN?		
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM. 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE Lauthorize	11	
12. PATIENT'S OR AUTHORIZED PERSONS SIGNATURE I authorize the release of any medical or other information necessary to process his claim. I also request payment of government benefits either to myself or to the party who accepts assignment		
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17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES		(Q5135)/Modifiers and CPT codes.
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Block 19		
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31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # ()	11	
(I certify that the statements on the reverse apply to this bill and are made a part thereof.)		
SIGNED DATE a. NP b. a. NP b.	↓	
NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12	· ·	

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Hospital/Institutional Billing¹¹

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 = 1 mg. Please bill according to the amount of product administered or wasted.		
Administration and Professional Servic	e 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.		

*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.

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

Important Safety Information (continued)

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

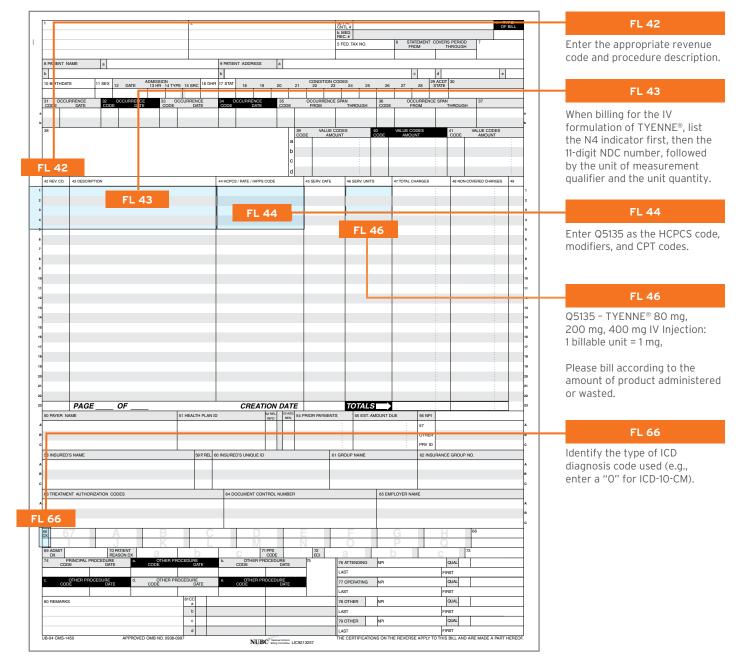
TYENNE is indicated for the treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older.

TYENNE is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older. TYENNE is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Please see additional Important Safety Information in full Prescribing Information, including **BOXED WARNING**.

Sample CMS 1450 (UB-04) Claim Form

(hospital outpatient site of service)¹¹

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® (tocilizumab-aazg) claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee TYENNE® coverage or reimbursement.



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
- Letter of medical necessity (see sample at tyennehcp.com/tyenne-letter-medical-necessity)
- Drug-identifying information (e.g., NDC)
- An invoice
- Letter of appeal (see sample at tyennehcp.com/tyenne-letter-appeal)

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KabiCare Reimbursement and Payment Support

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



Enrollment Support

- **Case Management Support** KabiCare helps your team navigate insurance processes and provides information related to your patient's insurance coverage. After enrollment is complete and insurance is confirmed, your patient will receive a phone call from KabiCare to review their benefits and discuss other KabiCare resources that may be available.
- **Provider Access** Centralized provider portal for submitting enrollments and checking patient status.



Insurance Support

- **Bridge to Therapy** The Bridge to Therapy Program provides commercially insured patients access to treatment without delay while they are waiting for insurance approval. Eligibility criteria apply.*
- **Benefits Investigation** Once your patient is enrolled, KabiCare conducts the benefits investigation on behalf of the patient to confirm insurance coverage details. The information is provided to you, your practice, and your patient to aid in patient access.
- **Prior Authorization Support** If a prior authorization is needed, KabiCare will provide the appropriate forms to the office for completion and will help follow up on the status.
- Billing & Coding Support KabiCare offers reimbursement resources to help you submit claims and understand eligibility for reimbursement.⁺ Visit <u>tyenne.com</u> for the Billing & Coding Guide.
- Claims Appeals Support Should a claim or prior authorization be denied, KabiCare will
 provide the appropriate appeal documentation and the information required to contest the
 denial similar to the prior authorization process. Visit <u>KabiCare.us</u> for a Sample Letter of
 Medical Necessity and Sample Letter of Appeal.

^{*} Eligibility criteria apply. Patients are not eligible for commercial copay support and Bridge to Therapy program if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare programs.

⁺ Terms and conditions apply.

⁺ Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Fresenius Kabi has no control over these programs.

[§] Clinical support provided by KabiCare is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

KabiCare Contact Information



Financial Support

- Commercial Copay Support If your patient has commercial or private insurance, they
 may be eligible* for the copay program that lowers their out-of-pocket costs to as little as
 \$0/month for treatment with an annual maximum.
- Patient Assistance Program If your patient does not have insurance or their plan does not cover their medication, they may be eligible for additional assistance through the Patient Assistance Program or through independent nonprofit assistance programs. Eligibility criteria apply.[‡]



Clinical Support

- Clinical Support KabiCare clinical support can provide medication counseling, offer self-injection training for applicable products, and answer questions your patient may have about their Fresenius Kabi biosimilar.[§]
- **Specialty Pharmacy Support** The Patient Support Guide will coordinate with the specialty pharmacy to ensure proper triage of the prescription with benefit details to facilitate a timely dispense.







Fax 1-833-302-1420



Visit our website at <u>KabiCare.us</u>

To learn more about the KabiCare patient support program, please scan the QR code:



TYENNE® (tocilizumab-aazg) treatment approval process

Benefits verification

Complete a thorough assessment and investigation of benefits before administering TYENNE[®] (tocilizumab-aazg) to determine that the patient's coverage is in effect at the time of injection and to see if any additional information is required to obtain coverage.

Benefits verification checklist

Confirm the following with the patient's insurance plan:

- The patient is actively covered
- Insurance policy effective and termination dates
- Whether the patient has a secondary insurer (in addition to primary)
- Whether the product is covered under medical benefit, pharmacy benefit, or both
- The insurance holder's name and relationship to the patient
- 🗸 In-network or out-of-network coverage
- V HCPCS Q-Code, CPT[®] code for administration, diagnosis code, and number of units covered
- Whether a prior authorization (PA) and supplemental documentation/medical record is required
- The patient's financial responsibility (copay, coinsurance percentage, deductible).
- The policy limits, including exclusions or documentation requirements.
- 🗸 If uninsured, whether the patient may be eligible for the Patient Assistance Program

Please contact KabiCare for assistance





Please see Important Safety Information throughout this brochure and click to see <u>full Prescribing Information</u>, including **Boxed Warning** for 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® Account Manager to connect with a Field Reimbursement Manager who is available to share the latest updates in payer coverage.

References: 1. TYENNE® (tocilizumab-aazg) prescribing information. Lake Zurich, IL: Fresenius Kabi, USA LLC; 2025 2. Centers for Medicare & Medicaid Services. ICD Code Lists: Valid ICD-10 List [excel file]. Page last modified October 29, 2024. https://www.cms.gov/medicare/coordination-benefits-recovery/overview/icd-code-lists. Accessed January 10, 2025. 3. CMS.gov. Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations. 2024 HCPCS Application Summary for quarter 2, 2024. https://www.cms. gov/files/document/2024-hcpcs-application-summary-quarter-2-2024-drugs-and-biologicals.pdf. Accessed. March 11, 2025. 4. cms. gov. October 2024 Update of the Hospital Outpatient Prospective Payment System (OPPS). Page last modified August 29, 2024. https:// www.cms.gov/files/document/r12816cp.pdf. Accessed March 11, 2025. 5. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update: January 2025 Alpha-Numeric HCPCS Files [zip file]. https://www.cms.gov/medicare/coding-billing/healthcare-common-proceduresystem/quarterly-update. Page last modified December 17, 2024. Accessed January 10, 2025. 6. Enhanced claim editor program: Route of administration modifiers JA and JB. April 16, 2024. https://provcomm.ibx.com/pnc-ibc/news/Pages/Enhanced-Claim-Editor-Program-Routeof-Administration-Modifiers-JA-and-JB.aspx. Accessed January 20, 2025. 7. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ clm104c17.pdf. Revised February 15, 2024. Accessed January 10, 2025. 8. Centers for Medicare & Medicaid Services. Medicare Part B inflation rebate guidance: Use of the 340B Modifier. https://www.cms.gov/files/document/mIn4800856-medicare-part-b-inflation-rebate-guidanceuse-340b-modifier.pdf. Accessed January 10, 2025. 9. 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. 10. Centers for Medicaid Services. Medicare Claims Processing Manual, Chapter 26. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ clm104c26pdf.pdf. Accessed May 28, 2024. 11. 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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