Tyenne®
tocilizumab-aazg

Billing & Coding Guide

Information to Support the Access & Reimbursement Process for TYENNE®

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

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

TYENNE® (tocilizumab) 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) 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
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologics (Applies only to CMS Form 1450 - Medicare Hospital Outpatient Prospective Payment System (OPPS))
HCPCS Modifier*	
JW **(IV ONLY)**	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient
TB*	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 separately payable drugs under Medicare Part B.[3]

* **Beginning January 1, 2018, Medicare requires hospitals to identify certain separately payable drugs or biologics that are acquired through the 340B program and furnished to a Medicare beneficiary. Use of the modifier 'TB' may vary based on the type of outpatient hospital and payment status indicator of the drug. Providers should verify the appropriate modifier to use when billing for a drug under the 340B program.**

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.

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. To convert a 10-digit NDC to an 11-digit NDC, a leading zero is added to the middle sequence of numbers (in the case of TYENNE®, a 0 is added in front of 590 to create 0590, in front of 592 to create 0592, and in front of 594 to create 0594). Check with the payer to confirm the correct code required when billing to TYENNE®.

NDC Number (PK)		10-digit NDC Code	11-digit NDC Code
IV	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

Current Procedural Terminology (CPT) Code[5]

The CPT code is used to report the IV injection of TYENNE® by a healthcare professional in a physician's office or hospital outpatient clinic.

Administration Procedures	Code
Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); initial, up to 1 hour	96365
Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	96413

Important Safety Information (continued)

CONTRAINDICATION

TYENNE is contraindicated in patients with known hypersensitivity to tocilizumab products.

WARNINGS AND PRECAUTIONS

Gastrointestinal Perforations

Events of gastrointestinal (GI) perforation have been reported in clinical trials, primarily as complications of diverticulitis in patients treated with tocilizumab. 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 products. 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

Physician's Office Billing Information

TYENNE® (tocilizumab-aazg) Coding Information*	
Coding information in **Block 19**: (Electronic Form: Loop 2400)	Enter a concise summary of information, including: • The National Drug Code (NDC) • Total quantity of the drug administered, expressed in the unit of measure (mg) • The date the drug was administered
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Enter appropriate HCPCS/Modifiers and CPT codes. Enter the HCPCS code without a narrative description, (enter narrative description in block 19).
Number of Units in **Block 24G**: (Electronic Form: Loop 2400, SV1, 04 [03=UN])	Providers should enter "1" in the quantity billed/number of services field and enter the total amount of the drug or biological actually administered (mg) in block 19 or the electronic equivalent field.
Administration and Professional Service Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	The following code 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: • 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)[5]
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.

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.

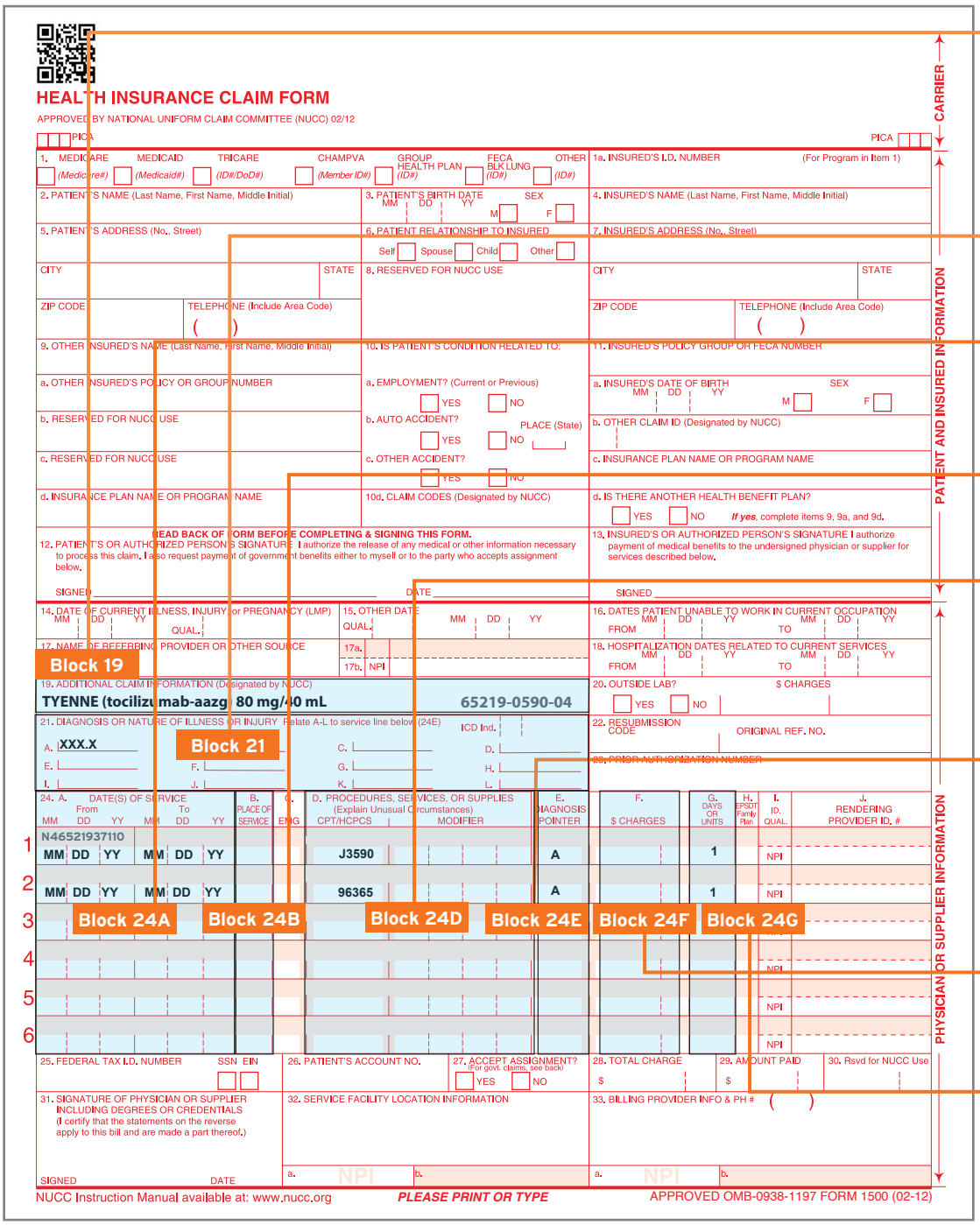
Laboratory Parameters

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 2000 per mm^3. In patients who develop an ANC less than 500 per

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

Tyenne® tocilizumab-aazg



Block 19: Additional Information

Enter the appropriate drug-identifying information as required by payer (e.g., brand/generic drug name, NDC 11-digit format, dose administered, route of administration, etc.).

Block 21: Diagnosis

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

Block 24A: Date(s) of Service

If line item NDC information is required, enter it in the shaded portion of item 24a.

Block 24B: Place of Service

Enter Place of Service Code such as 11 for physician office.

Block 24D:Drug Code

Enter appropriate HCPCS/Modifiers and CPT codes. For example:

– Drug: HCPCS Code (e.g., either J3590 or J3490).

Block 24E: Diagnosis Pointer

Refer to the diagnosis for this service from line 21, enter only 1 diagnosis pointer per line.

Block 24F: $ Charges

Typically, enter average wholesale price, (AWP) invoice price or whichever price method is stated in your contract with the payer.

Block 24G: Units

Enter the billing units. The number of units for TYENNE® will always be 1 unit since it uses a miscellaneous code.

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.

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Hospital/Institutional Billing

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 appropriate HCPCS/Modifiers and CPT codes. Enter the HCPCS code without a narrative description, (enter narrative description in FL 19)
Service Units in **FL 46**: (Electronic Form: Loop 2400, SV205)	Providers should enter "1" in the quantity billed/number of services field and enter the total amount of the drug or biological actually administered (in mg) in FL 19 or the electronic equivalent field.
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)	Indicate drug name and unit of measure, for example TYENNE® (80 mg/4 mL single-dose vial) IV/Infusion.
Coding Information in **FL 44**: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Enter appropriate HCPCS and CPT codes and modifiers. • 96365, Administration for intravenous administration
Diagnosis Code Information*	
ICD-10-CM Code in **FL 66**: (Electronic Form: Loop 2300, HI01-2 [HI01-1=BK])	Appropriate ICD-10-CM code(s) for patient condition. Sequencing of codes may vary based on patient's condition and payer's policy.
	The following primary ICD-10-CM diagnosis code may be appropriate to describe patients: • M05.09 - Rheumatoid arthritis with rheumatoid factor, unspecified
Additional remarks in **FL 80**: (Electronic Form: Loop 2400)	Enter a concise summary of information, including: • The National Drug Code (NDC), • Total quantity of the drug administered, expressed in the unit of measure (mg) • The date the drug was administered.

* 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 EVENITY™. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

mm^3 treatment is not recommended.

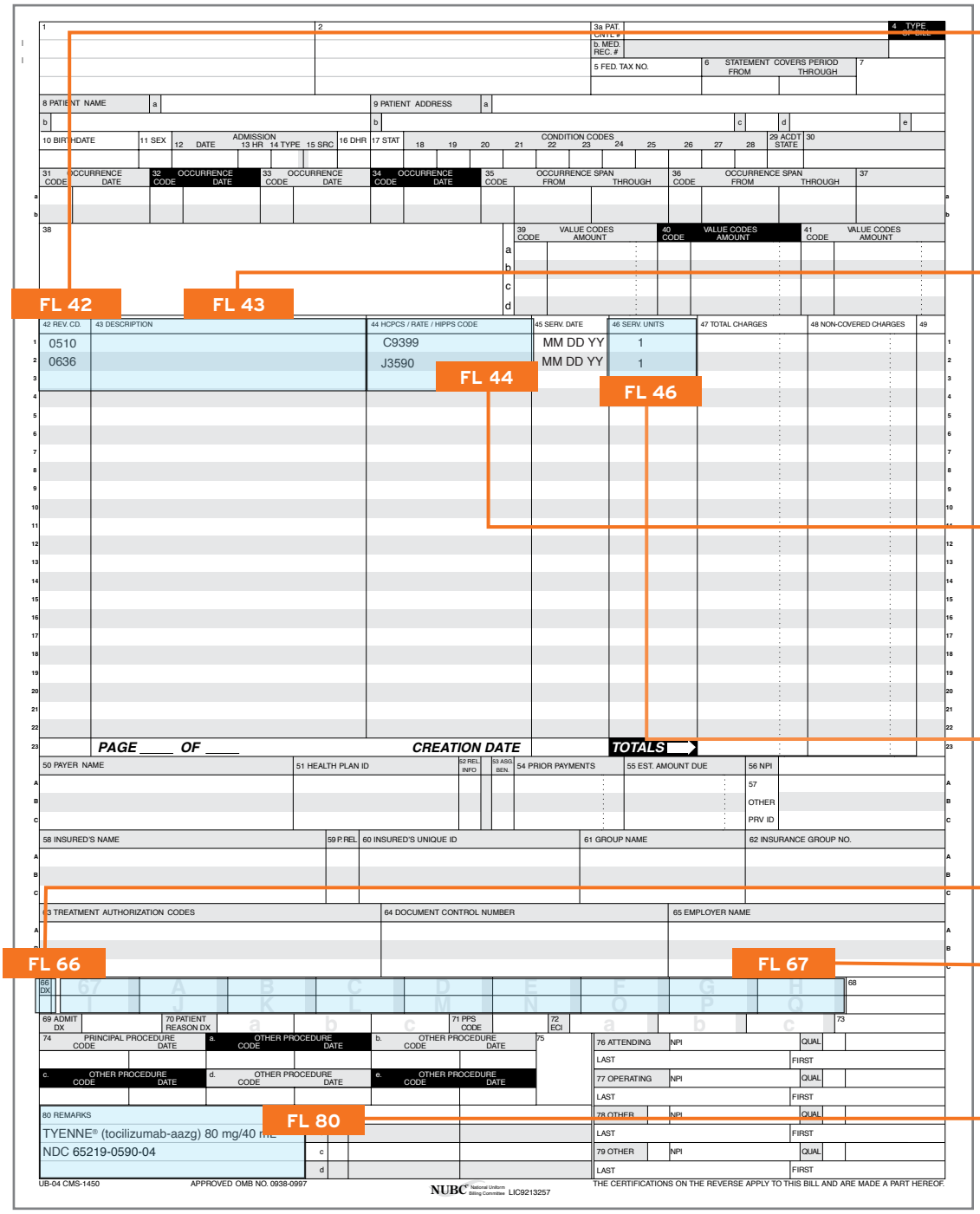
Thrombocytopenia: Treatment with tocilizumab products was associated with a reduction in platelet counts. It is not recommended to initiate TYENNE in RA, GCA, PJIA, and SJIA patients with a platelet count below 100,000 per mm^3. In patients who develop a platelet count less than 50,000 per mm^3, treatment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

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

Tyenne® tocilizumab-aazg



FL 42

Enter the appropriate revenue code and procedure description. For example:
- 0510: clinic–general classification
- 0636: drugs requiring detailed coding

FL 43

Enter narrative description of corresponding revenue code (e.g., clinic, lab, general). If line item NDC information is required, enter it in the unshaded portions of Locator Box 43. Payer requirements for NDC entries may vary.

FL 44

Enter appropriate HCPCS/ Modifiers and CPT codes. For example:
- Drug: HCPCS Code – J3590/ J3490/C9399
- Administration: CPT Code - 96365 for intravenous infusion

FL 46

Enter the billing units. The number of units for TYENNE® will always be 1 unit since it uses a miscellaneous code.

FL 66

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

FL 67

Indicate the diagnosis using the ICD10-CM code that supports the medical justification for your patient's condition.

FL 80

Additional details you may want to include are the drug name, drug strength, unit of measure, number of units administered/ discarded, total dosage, route of administration, and 11 digit NDC. Commercial plans may require a prior authorization.

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
- Letter of medical necessity (see sample at **tyennehcp.com/tyenne-letter-medical-necessity**)
- PA number
- Drug-identifying information (eg, NDC)
- Letter of appeal (see sample at **tyennehcp.com/tyenne-letter-appeal**)
- May require an invoice

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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†

PERSONAL SUPPORT
including nurse educators and field reimbursement managers‡

DEDICATED SUPPORT
to address access challenges

CENTRALIZED PATIENT SUPPORT PORTAL
with real-time status updates

*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.

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

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.

Please see additional Important Safety Information in full Prescribing Information, including Boxed Warning.

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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.

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