Tofidence™
tocilizumab-bavi

Access and Reimbursement Guide

Helpful Resources for Your Practice

Information on How to Navigate the Access and Reimbursement Process

TOFIDENCE™ (tocilizumab-bavi) injection, for IV use, is an FDA-approved biosimilar to Actemra® (tocilizumab).[1*†]

*A biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.[1]
†Actemra is a registered trademark of Chugai Seiyaku Kabushiki Kaisha Corp., a member of the Roche Group.

FDA=US Food and Drug Administration; IV=intravenous.

TOFIDENCE™ (tocilizumab-bavi) injection, for intravenous use

INDICATIONS

Rheumatoid Arthritis (RA)

TOFIDENCE™ (tocilizumab-bavi) 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)

TOFIDENCE™ (tocilizumab-bavi) is indicated for the treatment of giant cell arteritis in adult patients.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

TOFIDENCE™ (tocilizumab-bavi) is indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

Systemic Juvenile Idiopathic Arthritis (SJIA)

TOFIDENCE™ (tocilizumab-bavi) is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Coronavirus Disease 2019 (COVID-19)

TOFIDENCE™ (tocilizumab-bavi) 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).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS INFECTIONS

Patients treated with tocilizumab products including TOFIDENCE are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate (MTX) or corticosteroids.

If a serious infection develops, interrupt TOFIDENCE 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 TOFIDENCE use and during therapy. Treatment for latent infection should be initiated prior to TOFIDENCE 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 TOFIDENCE 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 TOFIDENCE, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

CONTRAINDICATIONS

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

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Contents

Steps to Access

Before Administration

Benefits Investigation

Complete a benefits investigation to determine if a prior authorization (PA) is required and identify the following components:

- Coverage requirements, including PA and/or medical documentation, referral restrictions, and observation stay rules
- Patient out-of-pocket (OOP) costs, such as annual deductible vs amount met to date, coinsurance and/or copay, and annual OOP maximum vs amount met to date
- Billing guidelines, such as documentation requirements when submitting a claim and Healthcare Common Procedure Coding System (HCPCS) reporting requirements

PA

- To obtain a PA, contact the patient's payer(s) directly to submit necessary documentation such as PA, letters of medical necessity, out-of-state and/or out-of-network exception requests, and related documentation
- If an authorization or exception request has been denied, the appeal process and timeline will likely be stated in the denial letter. The healthcare provider may wish to contact the payer for instructions if the next steps in the process are not documented

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

Serious Infections: see Boxed Warning

Gastrointestinal Perforations

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

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Steps to Access (cont'd)

After Administration

Submit a claim for reimbursement, track payer remittance, and evaluate responsiveness in addressing reimbursement issues

Did the claim go through? Monitor payer remittance for the submitted claim(s)

- Submit appeal with required documentation within filing timelines if the claim is denied
- Submit eligible OOP expenses to copay assistance or charitable funding programs, if applicable
- Verify patient benefits before the next appointment

Refer to the recommended dosing during the patient's next appointment

For RA, PJIA, and SJIA, TOFIDENCE may be used alone or in combination with methotrexate; and in RA, other DMARDs may be used. Avoid using TOFIDENCE with biological DMARDs.[1]

Indication[1]	Dose	Dosing Schedule
Moderately to severely active RA in adult patients with inadequate response to one or more DMARDs	Starting at 4 mg/kg followed by an increase to 8 mg/kg based on clinical response*	Every 4 weeks
GCA Adult patients	6 mg/kg	Every 4 weeks, in combination with a tapering course of glucocorticoids†
PJIA (active) Patients 2 years of age and older	Patients weighing <30 kg: 10 mg/kg	Every 4 weeks
	Patients weighing ≥30 kg: 8 mg/kg	Every 4 weeks
SJIA (active) Patients 2 years of age and older	Patients weighing <30 kg: 12 mg/kg	Every 2 weeks
	Patients weighing ≥30 kg: 8 mg/kg	Every 2 weeks
Hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO	8 mg/kg	Single dose, one additional dose after 8 hours if needed‡

*When used in combination with DMARDs or as monotherapy.
†TOFIDENCE can be used alone following discontinuation of glucocorticoids.
‡If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of TOFIDENCE may be administered at least 8 hours after the initial infusion.
DMARDs=disease-modifying anti-rheumatic drugs; ECMO=extracorporeal membrane oxygenation.

Laboratory monitoring and dose reduction is recommended for management of certain dose-related laboratory changes, including elevated liver enzymes, neutropenia, and thrombocytopenia (see Prescribing Information).

IMPORTANT SAFETY INFORMATION (Cont'd)
WARNINGS AND PRECAUTIONS (Cont'd)
Hepatotoxicity
Serious cases of hepatic injury have been observed in patients taking intravenous 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 with tocilizumab products. While most cases presented with marked elevations of transaminases (>5 times upper limit of normal [ULN]), some cases presented with signs or symptoms of liver dysfunction and only mildly elevated transaminases.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Coverage, Coding, and Reimbursement

Biosimilar Reimbursement

TOFIDENCE is reimbursed using the buy-and-bill method, in which providers purchase the drug and bill to insurers after the patient receives the medication (as opposed to the patient receiving drugs directly from the pharmacy). Biosimilars are generally reimbursed under Medicare Part B at average sales price (ASP) +6% of the reference product's ASP.[2,3] As of October 1, 2022, the Centers for Medicare & Medicaid Services (CMS) has put in place a temporary increase whereby qualifying* biosimilars will be reimbursed at ASP +8% of its reference product's ASP for a period of 5 years.[3] If the ASP is not available, then the biosimilar will be reimbursed at the wholesale acquisition cost (WAC) plus 3%.[4†] Actemra is the reference product for TOFIDENCE.[1]

*Qualifying biosimilars are those that have an ASP that is not more than the ASP of the associated reference biological product. Other biosimilars will continue to be paid a rate of ASP plus 6% of its reference biological product's ASP.[3]

†Medicare Part B reimbursement is subject to sequestration. In practice, the sequestration payments result in an approximately 1.6% reduction in the Medicare Part B reimbursement (2.0% x 80% of the reimbursement to the provider).[5,13] If the ASP is not available, then the biosimilar will be reimbursed at the WAC plus 3%.[4]

Relevant Codes for TOFIDENCE

When a patient has received TOFIDENCE, your practice or facility may submit a claim to the patient's insurance plan. Page 6 reviews the codes that may be commonly associated with the administration of TOFIDENCE.

IMPORTANT SAFETY INFORMATION (Cont'd)
WARNINGS AND PRECAUTIONS (Cont'd)
Hepatotoxicity (cont'd)
During randomized controlled studies, treatment with tocilizumab was associated with a higher incidence of transaminase elevations. Increased frequency and magnitude of these elevations was observed when potentially hepatotoxic drugs (e.g., MTX) were used in combination with tocilizumab.

It is not recommended to initiate TOFIDENCE 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 TOFIDENCE.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Coverage, Coding, and Reimbursement (cont'd)

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.

Example Coding for TOFIDENCE IV Infusion[6]

Rheumatoid Arthritis (RA)

DESCRIPTION	ICD-10-CM CODE
Rheumatoid lung disease with rheumatoid arthritis	M05.10–M05.19
Rheumatoid vasculitis with rheumatoid arthritis	M05.20–M05.29
Rheumatoid heart disease with rheumatoid arthritis	M05.30–M05.39
Rheumatoid myopathy with rheumatoid arthritis	M05.40–M05.49
Rheumatoid polyneuropathy with rheumatoid arthritis	M05.50–M05.59
Rheumatoid arthritis with involvement of other organs and systems	M05.60–M05.69
Rheumatoid arthritis with rheumatoid factor without organ or systems involvement	M05.70–M05.79
Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement	M05.7A
Other rheumatoid arthritis with rheumatoid factor	M05.80–M05.8A
Rheumatoid arthritis with rheumatoid factor, unspecified	M05.9
Rheumatoid arthritis without rheumatoid factor	M06.00–M06.09
Rheumatoid arthritis without rheumatoid factor, other specified site	M06.0A
Other specified rheumatoid arthritis	M06.80–M06.8A
Rheumatoid arthritis, unspecified	M06.9

Giant Cell Arteritis (GCA)

DESCRIPTION	ICD-10-CM CODE
Giant cell arteritis with polymyalgia rheumatica	M31.5
Other giant cell arteritis	M31.6

Biogen 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.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Hepatotoxicity (cont'd)

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

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

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Coverage, Coding, and Reimbursement (cont'd)

Example Coding for TOFIDENCE IV Infusion[6]

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

DESCRIPTION	ICD-10-CM CODE
Unspecified juvenile rheumatoid arthritis of unspecified site	M08.00
Juvenile rheumatoid polyarthritis (seronegative)	M08.3
Other juvenile arthritis, unspecified site	M08.80
Juvenile arthritis, unspecified, unspecified site	M08.90

Systemic Juvenile Idiopathic Arthritis (SJIA)

DESCRIPTION	ICD-10-CM CODE
Juvenile rheumatoid arthritis with systemic onset, unspecified site	M08.20
Juvenile rheumatoid arthritis with systemic onset	M08.21–M08.29
Juvenile rheumatoid arthritis with systemic onset, other specified site	M08.2A
Other juvenile arthritis, unspecified site	M08.80
Juvenile arthritis, unspecified, unspecified site	M08.90

Coronavirus Disease 2019 (COVID-19)

DESCRIPTION	ICD-10-CM CODE
COVID-19	U07.1

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Changes in 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 TOFIDENCE 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 absolute neutrophil count less than 500 per mm^3 treatment is not recommended.

It is not recommended to initiate TOFIDENCE treatment in COVID-19 patients with an ANC less than 1000 per mm^3.

Coverage, Coding, and Reimbursement (cont'd)

HCPCS II Codes for TOFIDENCE[7]

Coding System	Code	Description
HCPCS II Code	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg

One billable unit of TOFIDENCE is equivalent to 1 mg[7]

TOFIDENCE is currently available as[1]:

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

All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

HCPCS=Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Changes in Laboratory Parameters (cont'd)

Thrombocytopenia

Treatment with tocilizumab products was associated with a reduction in platelet counts. It is not recommended to initiate TOFIDENCE treatment 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.

In COVID-19 patients with a platelet count less than 50,000 per mm^3, treatment is not recommended.

Elevated Liver Enzymes

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

It is not recommended to initiate TOFIDENCE treatment in COVID-19 patients with elevated ALT or AST >10x ULN.

Lipid Abnormalities

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

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Coverage, Coding, and Reimbursement (cont'd)

Claim submission follows strict rules—the impacts below highlight specific considerations by site of care and form type.

Drug Reimbursement Modifiers[8-10]

Modifier Code	Notes	Form Type	Section	SOC
JW	Drug amount discarded/ not administered to any patient	1500 1450	24D on 1500 44 on 1450	Clinical and facility (hospital)
JZ	Zero drug amount discarded/ not administered to any patient	1500 1450	24D on 1500 44 on 1450	Clinical and facility (hospital)
TB	Informational only, used to inform 340B drug pricing for IRA exclusion of CPI-U penalty	1450	44	Select 340B (short list to be refreshed as needed/HRSA)
JG	Informational only, historically used to inform payment reduction (unnecessary and sunset in 2025)	1450	44	Select 340B

Administration Reimbursement Modifiers[11,12]

Modifier Code	Notes	Form Type	Section	SOC
96365	Simple infusion	1500 1450	24D on 1500 44 on 1450	Clinical and facility (hospital)
96413	Complex infusion, MACs scrutinizing use, need to support with notes in medical record	1500 1450	24D on 1500 44 on 1450	Clinical and facility (hospital)

CPI-U=Consumer Price Index for All Urban Consumers; HRSA=Health Resources and Services Administration; IRA=Inflation Reduction Act; MAC=Medicare Administrative Contractors.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Immunosuppression

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

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Coverage, Coding, and Reimbursement (cont'd)

Use of JZ Modifier for Zero Drug/Biosimilar Amount Discarded/Not Administered to Any Patient[8]

- The JZ modifier is available for use as of **January 1, 2023**
- Starting **July 1, 2023**, healthcare providers (HCPs) are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts. For more information on the JZ modifier, visit CMS.gov

JZ Modifier Example:

Use is applicable for both CMS-1500 (clinic) and CMS-1450 (hospital outpatient department) settings.

- A provider treats a 75-kg patient by infusing a 200 mg and 400 mg vial of TOFIDENCE with no waste **(1 mg of TOFIDENCE = 1 unit)**
- There are no discarded amounts, so the provider must use the JZ modifier.
- The provider files a claim with one line for the drug. The claim line should include Q5133 followed by the JZ modifier (attesting that there were no discarded amounts), and the number of units (600 mg) administered in the units field

K	L				
D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	
Q5133	JZ			600	

Use of JW Modifier for Drug/Biosimilar Amount Discarded/Not Administered to Any Patient[8]

- Healthcare providers are required to report the JW modifier on Part B drug claims to indicate the amount of discarded product
- The discarded amount is defined as what remains from a single-use vial or other single-use packaging after administering a dose or quantity of drug to a Medicare patient

JW Modifier Example:

The following is for sites other than hospital outpatient departments that use the CMS-1500 form:

- A provider treats a 72-kg patient by infusing 576 mg from a 200 mg and 400 mg vial
- The provider lists the product on 2 lines of the claim; both lines start with Q5133
- The first line represents the 576 mg that were administered to the patient
- The second line represents the 24 mg that were discarded, so those 24 units are recorded and "JW" is added to Q5133. This is known as the JW modifier

K	L				
D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	
Q5133				576	
Q5133	JW			24	

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Hypersensitivity Reactions, Including Anaphylaxis

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. In addition, serious cutaneous reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported in patients with autoinflammatory conditions treated with tocilizumab products. TOFIDENCE for intravenous use should only be infused by a healthcare professional with appropriate medical support to manage anaphylaxis. If a hypersensitivity reaction occurs, immediately discontinue TOFIDENCE; treat promptly and monitor until signs and symptoms resolve.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Coverage, Coding, and Reimbursement (cont'd)

NDC Codes for TOFIDENCE[1]

Coding System	Code	Description
NDC	10-digit code: 64406-024-01 11-digit code: 64406-0024-01*	80 mg/4 mL single-dose vial
	10-digit code: 64406-022-01 11-digit code: 64406-0022-01*	200 mg/10 mL single-dose vial
	10-digit code: 64406-023-01 11-digit code: 64406-0023-01*	400 mg/20 mL single-dose vial

*Please note that although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. The 10-digit TOFIDENCE format is converted to an 11-digit code by adding a zero (0) in front of the second group of numbers, eg, 64406-0024-01. It is important to communicate with your payers to determine the appropriate NDC format requirements.

Administration Codes for TOFIDENCE[11]

Type	Code	Description
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

All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

CPT=Current Procedural Terminology; NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Hypersensitivity Reactions, Including Anaphylaxis (cont'd)

Anaphylaxis and other hypersensitivity reactions that required treatment discontinuation were reported in 0.1% (3 out of 2644) of patients in the 6-month controlled trials of intravenous tocilizumab and 0.2% (8 out of 4009) of patients in the intravenous all-exposure RA population. In the SJIA controlled trial with intravenous tocilizumab, 1 out of 112 patients (0.9%) experienced hypersensitivity reactions that required treatment discontinuation. In the PJIA controlled trial with intravenous tocilizumab 0 out of 188 patients (0%) in the tocilizumab all-exposure population experienced hypersensitivity reactions that required treatment discontinuation.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Sample CMS-1500 Claim Form

Physician Office Setting

Field 17b: Indicate the appropriate National Provider Identifier (NPI).

Field 21: Indicate the most medically appropriate diagnosis code.

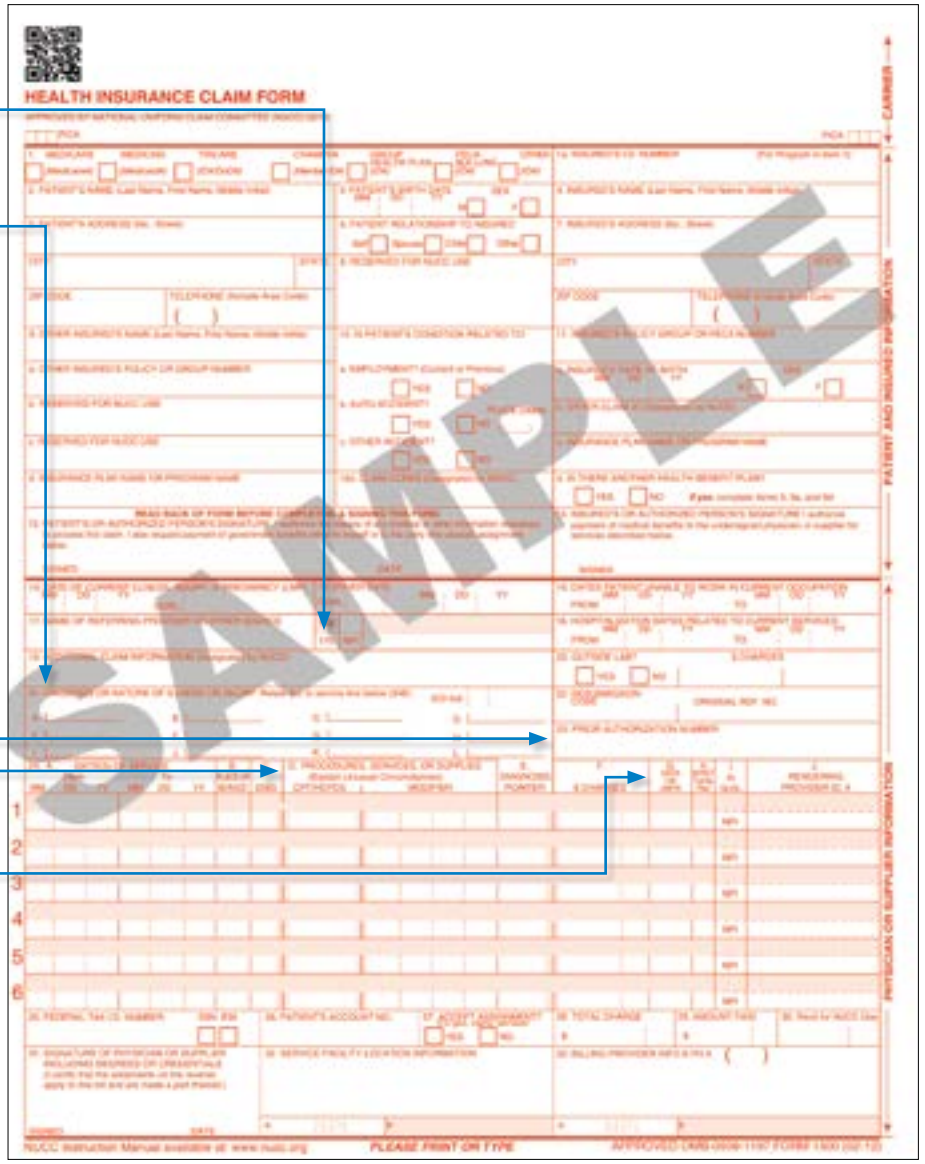
Field 23: If required, report PA number here.

Field 24D:

1. Indicate the appropriate HCPCS code (Q5133).
2. Indicate the appropriate CPT code (96365 or 96413) to report drug administration procedures.
3. Record JZ in the modifier column to indicate that no amount of product was discarded.

Field 24G: Indicate the appropriate HCPCS and/or CPT code units.

*One billable unit of TOFIDENCE is equivalent to 1 mg.



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
- PA number
- Drug-identifying information (eg, NDC)

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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 RA clinical studies. Monitor patients for signs and symptoms potentially indicative of demyelinating disorders. Prescribers should exercise caution in considering the use of TOFIDENCE in patients with preexisting or recent onset demyelinating disorders.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Ordering Process

TOFIDENCE Product Information

How supplied and packaged[1]	TOFIDENCE (tocilizumab-bavi) injection is a preservative-free, sterile, clear to opalescent, colorless to light yellow solution. TOFIDENCE is supplied as 80 mg/4 mL (NDC 64406-024-01), 200 mg/10 mL (NDC 64406-022-01), and 400 mg/20 mL (NDC 64406-023-01) individually packaged 20 mg/mL single-dose vials for further dilution prior to intravenous infusion.	
Carton dimensions	**Assembled: 58 mm (L) X 62 mm (W) X 80 mm (H)**	
WAC*	TOFIDENCE (tocilizumab-bavi) 80 mg/4 mL (20 mg/mL) single-dose vial – NDC 64406-024-01	$444
	TOFIDENCE (tocilizumab-bavi) 200 mg/10 mL (20 mg/mL) single-dose vial – NDC 64406-022-01	$1,110
	TOFIDENCE (tocilizumab-bavi) 400 mg/20 mL (20 mg/mL) single-dose vial – NDC 64406-023-01	$2,220
Storage and Handling[1]	Do not use beyond expiration date on the container or package. TOFIDENCE must be refrigerated at 36 °F to 46 °F (2 °C to 8 °C). Do not freeze. Protect the vials from light by storage in the original package until time of use.	

Not actual size.

*Price effective **May 1, 2024**.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Active Hepatic Disease and Hepatic Impairment

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

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Ordering Process (cont'd)

5% Off-Invoice Discount (OID) for TOFIDENCE is available through select specialty distributors

TOFIDENCE can be acquired in 1 of 2 ways:

1 Buy-and-bill through select specialty distributors

Specialty Distributor*	Phone Number	Fax Number	Website
McKesson Plasma and Biologics	877-625-2566	888-752-7626	https://connect.mckesson.com
McKesson Specialty Care Distribution	855-477-9800	855-824-9489	https://mscs.mckesson.com/
CuraScriptSD	877-599-7748	800-862-6208	https://www.curascriptsd.com/
Besse Medical	800-543-2111	800-543-8695	https://www.besse.com/contact-us
Oncology Supply	800-633-7555	800-248-8205	https://www.oncologysupply.com/contact-us
ASD Healthcare	800-746-6273	800-547-9413	https://www.asdhealthcare.com/contact-us
Cardinal Health SPD	855-855-0708	N/A	https://orderexpress.cardinalhealth.com/ https://specialtyonline.cardinalhealth.com/
Metro Medical	800-768-2002 615-329-2002	N/A	https://www.metromedicalorder.com/

2 TOFIDENCE is also accessible via an open specialty pharmacy network.

*Specialty distributor and contact information are current as of **January 1, 2024**, and are subject to change.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Vaccinations

Avoid use of live vaccines concurrently with TOFIDENCE as clinical safety has not been established. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving tocilizumab products or on the effectiveness of vaccination in patients receiving tocilizumab products. Patients should be brought up to date on all recommended vaccinations prior to initiation of TOFIDENCE therapy, if possible.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Ordering Requirements by Type of Coverage

Payer Reimbursement for Drugs and Services

If your patient is covered by:

Medicare Part B

For biosimilars, Medicare Part B reimburses physician services, including drug administration services, based on the Medicare Physician Fee Schedule (MPFS) at ASP plus 8% of the reference product, as published quarterly by CMS.[3]* If the ASP is not available, then the biosimilar will be reimbursed at the WAC plus 3%.[4] Medicare Part B pays for 80% of the allowed charges for TOFIDENCE and its administration, with the beneficiary responsible for the remaining 20% coinsurance. Medicare Part B patients could have a secondary, or supplemental, plan (eg, Medigap) to help cover the Part B 20% coinsurance.[13]

Medicaid and Private Payers

Some payers may require PA for TOFIDENCE, or they may have other requirements.

Medicaid: Reimbursement for TOFIDENCE and its administration services varies by state. Medicaid rates are updated quarterly and can be found on the Medicaid.gov website.

Private Payers: Reimbursement for TOFIDENCE and its administration services will vary by payer, depending on the specific provisions outlined in a healthcare provider's contract.

Medicare, commercial (private) payers, and Medicaid each have different reimbursement policies. Being familiar with these differences may help to minimize potential challenges when seeking reimbursement.

*Medicare Part B reimbursement is subject to sequestration, which reduces the portion of the payment paid by Medicare by 2%. As a result, the payment rate is effectively ASP + 4.3%.[5,13] If the ASP is not available, then the biosimilar will be reimbursed at the WAC plus 3%.[4]

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS

Rheumatoid Arthritis

The most common serious adverse reactions were serious infections. The most common serious infections included pneumonia, urinary tract infection, cellulitis, herpes zoster, gastroenteritis, diverticulitis, sepsis and bacterial arthritis. In the tocilizumab-IV monotherapy clinical study, the rate of serious infections was 3.6 per 100 patient years in the tocilizumab group and 1.5 per 100 patient years in the methotrexate group. The rate of serious infections in the 4 mg per kg and 8 mg per kg tocilizumab plus DMARD group was 4.4 and 5.3 events per 100 patient years, respectively, compared to 3.9 events per 100 patient years in the placebo plus DMARD group.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Ordering Considerations

To help ensure a site of care's chosen distributor or pharmacy has enough inventory of the drug to meet the site of care's anticipated needs, the site may wish to review the following information:

- **Weekly** purchase amount (units)
- Weekly **purchase amount by contract**—Wholesale Acquisition Cost, Group Purchasing Organization, 340B
- Anticipated **TOFIDENCE** adoption
- Anticipated date for **large orders**

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS (Cont'd)

Rheumatoid Arthritis (cont'd)

The tocilizumab-IV data in rheumatoid arthritis (RA) includes 5 double-blind, controlled, multicenter studies. In these studies, patients received doses of tocilizumab-IV 8 mg per kg monotherapy (288 patients), tocilizumab-IV 8 mg per kg in combination with DMARDs (including methotrexate) (1582 patients), or tocilizumab-IV 4 mg per kg in combination with methotrexate (774 patients).

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Patient Services Overview:
Biogen Biosimilar Support Services

Help support your patients with financial and insurance assistance

Benefits investigation and PA support

Biogen Biosimilar Support Services can help patients determine coverage options for TOFIDENCE.

Patient financial assistance

Biogen Biosimilar Support Services aims to support patients regardless of insurance coverage.

To learn more information or to enroll your patient in Biogen Biosimilar Support Services, please visit https://biogenbiosimilarsupportservices-tofidence.com.

For more information about these services, contact Biogen Biosimilar Support Services at 1-877-422-8360, Monday through Friday, 8:30 AM – 8 PM ET.

IMPORTANT SAFETY INFORMATION (Cont'd)
ADVERSE REACTIONS (Cont'd)
Rheumatoid Arthritis (cont'd)

In the 5 Phase III clinical trials, the most common adverse reactions (≥5% of patients treated with tocilizumab-IV) in the 24-week Phase 3 Controlled Study Population were:

	Tocilizumab 8 mg per kg MONOTHERAPY	Methotrexate	Tocilizumab 4 mg per kg +DMARDs	Tocilizumab 8 mg per kg +DMARDs	Placebo +DMARDs
	N = 288 %	N = 284 %	N = 774 %	N = 1582 %	N = 1170 %
Upper Respiratory Tract Infection	7	5	6	8	6
Nasopharyngitis	7	6	4	6	4
Headache	7	2	6	5	3
Hypertension	6	2	4	4	3
ALT increased	6	4	3	3	1

TOFIDENCE™ (tocilizumab-bavi) injection, for intravenous use

INDICATIONS

Rheumatoid Arthritis (RA)

TOFIDENCE™ (tocilizumab-bavi) 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)

TOFIDENCE™ (tocilizumab-bavi) is indicated for the treatment of giant cell arteritis in adult patients.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

TOFIDENCE™ (tocilizumab-bavi) is indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

Systemic Juvenile Idiopathic Arthritis (SJIA)

TOFIDENCE™ (tocilizumab-bavi) is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Coronavirus Disease 2019 (COVID-19)

TOFIDENCE™ (tocilizumab-bavi) 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).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS INFECTIONS

Patients treated with tocilizumab products including TOFIDENCE are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate (MTX) or corticosteroids.

If a serious infection develops, interrupt TOFIDENCE 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 TOFIDENCE use and during therapy. Treatment for latent infection should be initiated prior to TOFIDENCE 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 TOFIDENCE 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 TOFIDENCE, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Serious Infections: see Boxed Warning

Gastrointestinal Perforations

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

Hepatotoxicity

Serious cases of hepatic injury have been observed in patients taking intravenous 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 with tocilizumab products. While most cases presented with marked elevations of transaminases (>5 times upper limit of normal [ULN]), some cases presented with signs or symptoms of liver dysfunction and only mildly elevated transaminases.

During randomized controlled studies, treatment with tocilizumab was associated with a higher incidence of transaminase elevations. Increased frequency and magnitude of these elevations was observed when potentially hepatotoxic drugs (e.g., MTX) were used in combination with tocilizumab.

It is not recommended to initiate TOFIDENCE 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 TOFIDENCE.

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

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

Changes in 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 TOFIDENCE 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 absolute neutrophil count less than 500 per mm^3 treatment is not recommended.

It is not recommended to initiate TOFIDENCE treatment in COVID-19 patients with an ANC less than 1000 per mm^3.

Thrombocytopenia

Treatment with tocilizumab products was associated with a reduction in platelet counts. It is not recommended to initiate TOFIDENCE treatment 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.

In COVID-19 patients with a platelet count less than 50,000 per mm^3, treatment is not recommended.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Changes in Laboratory Parameters (cont'd)

Elevated Liver Enzymes

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

It is not recommended to initiate TOFIDENCE treatment in COVID-19 patients with elevated ALT or AST >10x ULN.

Lipid Abnormalities

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

Immunosuppression

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

Hypersensitivity Reactions, Including Anaphylaxis

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. In addition, serious cutaneous reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported in patients with autoinflammatory conditions treated with tocilizumab products. TOFIDENCE for intravenous use should only be infused by a healthcare professional with appropriate medical support to manage anaphylaxis. If a hypersensitivity reaction occurs, immediately discontinue TOFIDENCE; treat promptly and monitor until signs and symptoms resolve.

Anaphylaxis and other hypersensitivity reactions that required treatment discontinuation were reported in 0.1% (3 out of 2644) of patients in the 6-month controlled trials of intravenous tocilizumab and 0.2% (8 out of 4009) of patients in the intravenous all-exposure RA population. In the SJIA controlled trial with intravenous tocilizumab, 1 out of 112 patients (0.9%) experienced hypersensitivity reactions that required treatment discontinuation. In the PJIA controlled trial with intravenous tocilizumab 0 out of 188 patients (0%) in the tocilizumab all-exposure population experienced hypersensitivity reactions that required treatment discontinuation.

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 RA clinical studies. Monitor patients for signs and symptoms potentially indicative of demyelinating disorders. Prescribers should exercise caution in considering the use of TOFIDENCE in patients with preexisting or recent onset demyelinating disorders.

Active Hepatic Disease and Hepatic Impairment

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

Vaccinations

Avoid use of live vaccines concurrently with TOFIDENCE as clinical safety has not been established. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving tocilizumab products or on the effectiveness of vaccination in patients receiving tocilizumab products. Patients should be brought up to date on all recommended vaccinations prior to initiation of TOFIDENCE therapy, if possible.

ADVERSE REACTIONS

Rheumatoid Arthritis

The most common serious adverse reactions were serious infections. The most common serious infections included pneumonia, urinary tract infection, cellulitis, herpes zoster, gastroenteritis, diverticulitis, sepsis and bacterial arthritis. In the tocilizumab-IV monotherapy clinical study, the rate of serious infections was 3.6 per 100 patient years in the tocilizumab group and 1.5 per 100 patient years in the methotrexate group. The rate of serious infections in the 4 mg per kg and 8 mg per kg tocilizumab plus DMARD group was 4.4 and 5.3 events per 100 patient years, respectively, compared to 3.9 events per 100 patient years in the placebo plus DMARD group.

The tocilizumab-IV data in rheumatoid arthritis (RA) includes 5 double-blind, controlled, multicenter studies. In these studies, patients received doses of tocilizumab-IV 8 mg per kg monotherapy (288 patients), tocilizumab-IV 8 mg per kg in combination with DMARDs (including methotrexate) (1582 patients), or tocilizumab-IV 4 mg per kg in combination with methotrexate (774 patients).

In the 5 Phase III clinical trials, the most common adverse reactions (≥5% of patients treated with tocilizumab-IV) in the 24-week Phase 3 Controlled Study Population were:

	Tocilizumab 8 mg per kg MONOTHERAPY	Methotrexate	Tocilizumab 4 mg per kg +DMARDs	Tocilizumab 8 mg per kg +DMARDs	Placebo +DMARDs
	N = 288 %	N = 284 %	N = 774 %	N = 1582 %	N = 1170 %
Upper Respiratory Tract Infection	7	5	6	8	6
Nasopharyngitis	7	6	4	6	4
Headache	7	2	6	5	3
Hypertension	6	2	4	4	3
ALT increased	6	4	3	3	1

Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay.

Giant Cell Arteritis

The overall safety profile observed for tocilizumab administered intravenously in GCA patients was generally consistent with the known safety profile of tocilizumab.

Polyarticular Juvenile Idiopathic Arthritis

Infections

The rate of infections in the tocilizumab-IV all exposure population was 163.7 per 100 patient years. The most common events observed were nasopharyngitis and upper respiratory tract infections. The rate of serious infections was numerically higher in patients weighing less than 30 kg treated with 10 mg/kg tocilizumab-IV (12.2 per 100 patient years) compared to patients weighing at or above 30 kg, treated with 8 mg/kg tocilizumab-IV (4.0 per 100 patient years). The incidence of infections leading to dose interruptions was also numerically higher in patients weighing less than 30 kg treated with 10 mg/kg tocilizumab-IV (21%) compared to patients weighing at or above 30 kg, treated with 8 mg/kg tocilizumab-IV (8%).

IMPORTANT SAFETY INFORMATION (Cont'd)

Polyarticular Juvenile Idiopathic Arthritis (cont'd)

Infusion Reactions

In PJIA patients, infusion-related reactions are defined as all events occurring during or within 24 hours of an infusion. In the tocilizumab-IV all exposure population, 11 patients (6%) experienced an event during the infusion, and 38 patients (20.2%) experienced an event within 24 hours of an infusion. The most common events occurring during infusion were headache, nausea and hypotension, and occurring within 24 hours of infusion were dizziness and hypotension. In general, the adverse drug reactions observed during or within 24 hours of an infusion were similar in nature to those seen in RA and SJIA patients.

Systemic Juvenile Idiopathic Arthritis

The most common adverse events (at least 5%) seen in tocilizumab-IV treated patients in the 12 week controlled portion of the study were: upper respiratory tract infection, headache, nasopharyngitis and diarrhea.

Infections

In the 12 week controlled phase, the rate of all infections in the tocilizumab-IV group was 345 per 100 patient years and 287 per 100 patient years in the placebo group. In the open label extension over an average duration of 73 weeks of treatment, the overall rate of infections was 304 per 100 patient years.

In the 12 week controlled phase, the rate of serious infections in the tocilizumab-IV group was 11.5 per 100 patient years. In the open label extension over an average duration of 73 weeks of treatment, the overall rate of serious infections was 11.4 per 100 patient years. The most commonly reported serious infections included pneumonia, gastroenteritis, varicella, and otitis media.

Macrophage Activation Syndrome

In the 12 week controlled study, no patient in any treatment group experienced macrophage activation syndrome (MAS) while on assigned treatment; 3 per 112 (3%) developed MAS during open-label treatment with tocilizumab-IV. One patient in the placebo group escaped to tocilizumab-IV 12 mg per kg at Week 2 due to severe disease activity, and ultimately developed MAS at Day 70. Two additional patients developed MAS during the long-term extension. All 3 patients had tocilizumab-IV dose interrupted (2 patients) or discontinued (1 patient) for the MAS event, received treatment, and the MAS resolved without sequelae. Based on a limited number of cases, the incidence of MAS does not appear to be elevated in the tocilizumab-IV SJIA clinical development experience; however no definitive conclusions can be made.

Infusion Reactions

In the 12 week controlled phase, 4% of tocilizumab-IV and 0% of placebo treated patients experienced events occurring during infusion. One event (angioedema) was considered serious and life-threatening, and the patient was discontinued from study treatment.

Within 24 hours after infusion, 16% of patients in the tocilizumab-IV treatment group and 5% of patients in the placebo group experienced an event. In the tocilizumab-IV group the events included rash, urticaria, diarrhea, epigastric discomfort, arthralgia, and headache. One of these events, urticaria, was considered serious.

Anaphylaxis

Anaphylaxis was reported in 1 out of 112 patients (less than 1%) treated with tocilizumab-IV during the controlled and open label extension study.

Coronavirus Disease 2019 (COVID-19)

The safety of tocilizumab in hospitalized COVID-19 patients was evaluated in a pooled safety population that includes patients enrolled in EMPACTA, COVACTA, AND REMDACTA.

The analysis of adverse reactions included a total of 974 patients exposed to tocilizumab.

Adverse Reaction	Tocilizumab 8 mg per kg N = 974 (%)	Placebo N = 483 (%)
Hepatic Transaminases increased	10%	8%
Constipation	9%	8%
Urinary tract infection	5%	4%
Hypertension	4%	1%
Hypokalaemia	4%	3%
Anxiety	4%	2%
Diarrhea	4%	2%
Insomnia	4%	3%
Nausea	3%	2%

In the pooled safety population, the rates of infection/serious infection events were 30%/19% in patients receiving tocilizumab versus 32%/23% receiving placebo.

Laboratory Abnormalities

In the pooled safety population of EMPACTA, COVACTA, and REMDACTA, neutrophil counts <1000 cells/mcl occurred in 3.4% of patients who received tocilizumab and 0.5% of patients who received placebo. Platelet counts <50,000 cells/mcl occurred in 3.2% of patients who received tocilizumab and 1.5% of patients who received placebo. ALT or AST at or above 5x ULN occurred in 11.7% of patients who received tocilizumab and 9.9% of patients who received placebo.

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 TOFIDENCE with CYP3A4 substrate drugs where decrease in effectiveness is undesirable, e.g., oral contraceptives, lovastatin, atorvastatin, etc.

USE IN PREGNANCY

Based on animal data, there may be a potential risk to the fetus. 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 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Biogen MA Inc. at 1-877-422-8360.

Tofidence™
tocilizumab-bavi

References: 1. TOFIDENCE Prescribing Information, Cambridge, MA: Biogen. **2.** Yang J, Carioto J, Pyenson B, et al. Greater uptake, an alternative reimbursement methodology needed to realize cost-saving potential of oncology biosimilars in the United States. *J Manag Care Spec Pharm.* 2021;27(12):1642-1651. doi:10.18553/jmcp.2021.21202. **3.** Frequently asked questions. Inflation Reduction Act. Biosimilars temporary payment increase. Centers for Medicare and Medicaid Services. https://www.cms.gov/files/document/biosimilar-faqs.pdf. Accessed September 6, 2024. **4.** Final policy, payment, and quality provisions changes to the Medicare physician fee schedule for calendar year 2019. Centers for Medicare and Medicaid Services. November 1, 2018. https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year. Accessed September 6, 2024. **5.** 2% payment adjustment (sequestration) changes. 2021-12-16-MLNC. Centers for Medicare and Medicaid Services. December 16, 2021. https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-12-16-mlnc#_Toc90391082. Accessed September 6, 2024. **6.** ICD-10-CM tabular list of diseases and injuries. FY 2025 ICD-10-CM coding guidelines. 2025 ICD-10-CM. Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare/coding-billing/icd-10-codes. Accessed September 6, 2024. **7.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations. Fourth quarter, 2023 HCPCS coding cycle. Centers for Medicare and Medicaid Services. Department of Health and Human Services. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-4-2023-drugs-and-biologicals-posted-01/26/2024-updated-03/04.pdf. Accessed September 6, 2024. **8.** Medicare program. Discarded drugs and biologicals – JW modifier and JZ modifier policy frequently asked questions. Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. Accessed September 6, 2024. **9.** Seshamani M. *Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier.* Centers for Medicare and Medicaid Services. Department of Health and Human Services. December 14, 2023. https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf. Accessed September 6, 2024. **10.** Seshamani M. *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act*. Centers for Medicare and Medicaid Services. Department of Health and Human Services. December 14, 2023. https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf. Accessed September 6, 2024. **11.** Smith AL. CPT coding for drug administration. American Academy of Professional Coders. February 1, 2013. https://www.aapc.com/blog/23016-infuse-yourself-with-coding-knowledge/. Accessed September 6, 2024. **12.** Infusion services. WPS Government Health Administrators. October 6, 2021. https://med.wpsgha.com/guides-resources/. Accessed September 6, 2024. **13.** Medicare Part B drugs: trends in spending and utilization, 2008-2021. Assistant Secretary for Planning and Evaluation, Office of Health Policy. June 9, 2023. https://aspe.hhs.gov/sites/default/files/documents/06338d34b766b2853741150acaacfd0e/aspe-medicare-part-b-drug-pricing_508c.pdf. Accessed October 3, 2024.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including **Boxed Warning**.

Biogen

225 Binney Street, Cambridge, MA 02142