



BILLING AND CODING GUIDE

INDICATIONS

AVTOZMA® is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

- **Rheumatoid Arthritis (RA):** Adult patients with moderately to severely active RA who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
- **Giant Cell Arteritis (GCA):** Adult patients with GCA.
- **Polyarticular Juvenile Idiopathic Arthritis (PJIA):** Patients 2+ years old with active PJIA.
- **Systemic Juvenile Idiopathic Arthritis (SJIA):** Patients 2+ years old with active SJIA.
- **Cytokine Release Syndrome (CRS):** Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.
- **Coronavirus Disease 2019 (COVID-19):** Hospitalized adult patients with COVID-19 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 AVTOZMA 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 or corticosteroids.

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

Introduction to AVTOZMA® (tocilizumab-anoh)¹

AVTOZMA injection for intravenous or subcutaneous use is an interleukin-6 (IL-6) receptor antagonist biosimilar to ACTEMRA® (tocilizumab).

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. Biosimilarity of AVTOZMA has been demonstrated for the condition(s) of use (eg, indication[s], dosing regimen[s]), strength(s), dosage form(s), and route(s) of administration described in its full Prescribing Information.

This guide is provided for informational purposes only. Correct coding is the responsibility of the provider who is submitting the claim for the item or service. Please check with the payer to verify codes and specific billing requirements. Celltrion does not make any representation or guarantees concerning reimbursement or coverage for any service or item, nor does Celltrion guarantee patient assistance to the limits described.

AVTOZMA Formulation¹

FOR INTRAVENOUS INFUSION



80 mg/4 mL (20 mg/mL)
Carton of 1 vial*
NDC: 72606-042-01

FOR INTRAVENOUS INFUSION



200 mg/10 mL (20 mg/mL)
Carton of 1 vial*
NDC: 72606-043-01

FOR INTRAVENOUS INFUSION



400 mg/20 mL (20 mg/mL)
Carton of 1 vial*
NDC: 72606-044-01

*Please note that the above images may differ from the actual product images
FDA, US Food and Drug Administration; NDC, National Drug Code.

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- Bacterial, viral and other infections due to opportunistic pathogens.

Indications¹

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Dosage and Administration¹

General Administration and Dosing Information

- **RA, GCA, PJIA, and SJIA** – It is recommended that AVTOZMA not be initiated in patients with an absolute neutrophil count (ANC) below 2000 per mm³, platelet count below 100,000 per mm³, or ALT or AST above 1.5 times the upper limit of normal (ULN).
- **COVID-19** – It is recommended that AVTOZMA not be initiated in patients with an ANC below 1000 per mm³, platelet count below 50,000 mm³, or ALT or AST above 10 times the ULN.
- In **RA, CRS, or COVID-19** patients, AVTOZMA doses exceeding 800 mg per infusion are not recommended.
- In **GCA patients**, AVTOZMA doses exceeding 600 mg per infusion are not recommended.

Indication	Recommended Dosing
Rheumatoid Arthritis (RA)	Recommended Adult Intravenous Dosage: • When used in combination with nonbiologic DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks, followed by an increase to 8 mg per kg every 4 weeks based on clinical response
Giant Cell Arteritis (GCA)	Recommended Adult Intravenous Dosage: • The recommended dose is 6 mg per kg every 4 weeks in combination with a tapering course of glucocorticoids. AVTOZMA can be used alone following discontinuation of glucocorticoids
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	Recommended Intravenous PJIA Dosage Every 4 Weeks: • Patients less than 30 kg weight: 10 mg per kg • Patients at or above 30 kg weight: 8 mg per kg
Systemic Juvenile Idiopathic Arthritis (SJIA)	Recommended Intravenous SJIA Dosage Every 2 Weeks: • Patients less than 30 kg weight: 12 mg per kg • Patients at or above 30 kg weight: 8 mg per kg
Cytokine Release Syndrome (CRS)	Recommended Intravenous CRS Dosage: • Patients less than 30 kg weight: 12 mg per kg • Patients at or above 30 kg weight: 8 mg per kg • Alone or in combination with corticosteroids
Coronavirus Disease 2019 (COVID-19)	The recommended dosage of AVTOZMA for adult patients with COVID-19 is 8 mg per kg administered by a 60-minute intravenous infusion

ALT, alanine transaminase; AST, aspartate transaminase; ANC, absolute neutrophil count.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNING: RISK OF SERIOUS INFECTIONS (CONTINUED)

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

Sample Coding

This section serves as an educational reference for coding that may be appropriate for reporting AVTOZMA and related services. Medical record documentation must support the codes reported on the claim. These codes may be appropriate when AVTOZMA is administered to patients in the physician's office or a hospital setting.

Diagnosis Codes (ICD-10-CM Codes)²

This list is for informational purposes only. One or more codes may be appropriate on a claim. Please review payer policy requirements for guidance on diagnosis codes.

Code	Description
Rheumatoid Arthritis (RA)	
M05.00-M05.09	Felty's syndrome (rheumatoid arthritis with splenadenomegaly 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
Giant Cell Arteritis (GCA)	
M31.5	Giant cell arteritis with polymyalgia rheumatica
M31.6	Other giant cell arteritis
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.80	Other juvenile arthritis, unspecified site
M08.90	Juvenile arthritis, unspecified, unspecified site
Systemic Juvenile Idiopathic Arthritis (SJIA)	
M08.20-M08.29	Juvenile rheumatoid arthritis with systemic onset
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site
Cytokine Release Syndrome	
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
Coronavirus Disease 2019 (COVID-19)	
J12.82	Pneumonia due to coronavirus disease 2019
U07.1	COVID-19

Note: Allowable diagnosis codes may vary by payer.

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNING: RISK OF SERIOUS INFECTIONS (CONTINUED)

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

National Drug Code^{1,3}

The National Drug Code (NDC) is required on the claim form. While 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 NDC unit of measure, qualifier and quantity may also be required. Check payer-specific reporting requirements.

AVTOZMA	Carton Size	10-Digit NDC	11-Digit NDC
80 mg/4 mL (20 mg/mL)	Carton of 1 vial	72606-042-01	72606-0042-01
200 mg/10 mL (20 mg/mL)	Carton of 1 vial	72606-043-01	72606-0043-01
400 mg/20 mL (20 mg/mL)	Carton of 1 vial	72606-044-01	72606-0044-01

Administration and Billing Codes

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form (or the electronic equivalent).

CPT® Code⁴⁻⁶

Drug administration services are reported on claims forms in both the physician office and hospital outpatient sites of care using the Current Procedural Terminology (CPT®) coding system.

Code Set	Code and Description	Location on CMS-1500 Form	Location on CMS-1450 (UB-04) Form
CPT®	96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	Field 24D	Field 44
CPT®	96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	Field 24D	Field 44

IMPORTANT SAFETY INFORMATION (CONTINUED)

Contraindications: Known hypersensitivity to tocilizumab products.

Serious Infections. Serious and sometimes fatal infections, including bacterial, mycobacterial, invasive fungal, viral, and opportunistic infections, have been reported with tocilizumab products, including AVTOZMA. Common serious infections include pneumonia, urinary tract infections, cellulitis, herpes zoster, and sepsis, while opportunistic infections such as tuberculosis and cryptococcus have also occurred. Patients with chronic or recurrent infections, tuberculosis exposure, or underlying conditions predisposing to infections should have the risks and benefits of AVTOZMA carefully evaluated. Monitor patients closely during and after treatment for signs of infection, and discontinue AVTOZMA if a serious infection develops, initiating appropriate antimicrobial therapy as needed.

Gastrointestinal (GI) Perforation. Gastrointestinal perforation events, primarily associated with diverticulitis, have been reported in clinical trials of tocilizumab. Use AVTOZMA cautiously in patients at increased risk for gastrointestinal perforation. Promptly evaluate any patient experiencing new abdominal symptoms to ensure early detection and management of this condition.

Hepatotoxicity. Serious hepatic injury, including cases of liver transplant and death, has occurred with tocilizumab products, with onset ranging from months to years. Some cases involved marked transaminase elevations ($>5\times$ ULN), while others presented with mild elevations and symptoms of liver dysfunction. Risk is higher with hepatotoxic drugs like methotrexate. Baseline and regular liver tests are required for RA, GCA, PJIA, and SJIA patients, with specific monitoring intervals based on the condition. Do not initiate AVTOZMA if ALT or AST $>1.5\times$ ULN (RA/GCA) or $>10\times$ ULN (COVID-19), and discontinue if ALT or AST $>5\times$ ULN. Evaluate symptoms of liver injury promptly, and only restart treatment if liver test abnormalities are resolved and attributed to another cause.

Changes in Laboratory Parameters. Treatment with tocilizumab products, including AVTOZMA, has been associated with neutropenia, thrombocytopenia, elevated liver enzymes, and lipid abnormalities. Infections are uncommon with treatment-related neutropenia, but AVTOZMA should not be initiated in RA or GCA patients with ANC $<2000/\text{mm}^3$ or platelet counts $<100,000/\text{mm}^3$, and treatment is not recommended if ANC drops below $500/\text{mm}^3$ or platelets below $50,000/\text{mm}^3$. For COVID-19 patients, AVTOZMA is not recommended with ANC $<1000/\text{mm}^3$ or platelets $<50,000/\text{mm}^3$. Monitor neutrophils, platelets, and liver enzymes 4–8 weeks after starting therapy and every 3 months thereafter, adjusting treatment as needed. Lipid levels, including cholesterol and triglycerides, may increase and should be assessed 4–8 weeks after initiation, with management per clinical guidelines. A similar pattern is observed in PJIA and SJIA, requiring specific monitoring intervals for these populations. Refer to Dosage and Administration for modifications based on test results.

HCPCS Level II Codes⁵⁻⁷

Drugs are typically reported using product-specific Healthcare Common Procedure Coding System (HCPCS) codes, which are assigned by CMS. Effective October 1, 2025, providers may use HCPCS code Q5156 [Injection, tocilizumabanoh (AVTOZMA), biosimilar, 1 mg] to report AVTOZMA on claims. Effective January 24, 2025, providers may report HCPCS Q0237, M0237 or M0238 for use in patient with COVID-19, as appropriate. Note that providers should not report the HCPCS code for the reference product when billing for a biosimilar.

Code Set	Code and Description ⁸	Location on CMS-1500 Form ⁵	Location on CMS-1450 (UB-04) Form ⁶
HCPCS	Q5156 Injection, tocilizumabanoh (AVTOZMA), biosimilar, 1 mg	Field 24D	Field 44

Modifiers^{5,6,8,9}

Modifier	Description ^{8,9}	Location on CMS-1500 Form ⁵	Location on CMS-1450 (UB-04) Form ⁶
JZ	No amount of drug was discarded from a single-vial/dose drug and not administered to any patient	Field 24D	Field 44
JW	Amount of drug discarded/not administered to any patient	Field 24D	Field 44
TB	Drug or biological acquired with 340B drug pricing program discount, reported for tracking purposes	Field 24D	Field 44

Note on product and administration coding:

If you order AVTOZMA through a specialty pharmacy or the Celltrion CONNECT® Patient Assistance Program (PAP), you should not seek reimbursement for the product; however, your patient's health plan may still require that you include the HCPCS code on the claim with a zero or nominal charge in order for them to reimburse the drug administration procedure.

Remember to submit a claim for reimbursement for services associated with AVTOZMA.

CMS, Centers for Medicare & Medicaid Services.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Immunosuppression. The effect of tocilizumab products on malignancy development is unknown, though malignancies were observed in clinical studies. As an immunosuppressant, AVTOZMA may increase the risk of malignancies.

Hypersensitivity Reactions, Including Anaphylaxis. Hypersensitivity reactions, including anaphylaxis and fatal events, have been reported with tocilizumab products. Anaphylaxis requiring discontinuation occurred in 0.1% to 0.7% of trial patients, with postmarketing cases reported at various doses, with or without premedication, and as early as the first infusion. AVTOZMA intravenous infusions must be administered by healthcare professionals equipped to manage anaphylaxis. For subcutaneous use, patients must seek immediate medical attention if hypersensitivity symptoms occur. Discontinue AVTOZMA permanently if anaphylaxis or other hypersensitivity reaction occurs. Do not use in patients with known hypersensitivity to tocilizumab products.

Demyelinating Disorders. The impact of tocilizumab on demyelinating disorders is unknown, but rare cases like multiple sclerosis and polyneuropathy were reported in RA studies. Monitor for symptoms and use caution in patients with preexisting or recent demyelinating disorders.

Active Hepatic Disease and Hepatic Impairment. Treatment with AVTOZMA is not recommended.

Live Vaccines. Avoid concurrent use of live vaccines with AVTOZMA, as clinical safety and secondary transmission risk are unknown. Follow guidelines on timing between live vaccines and AVTOZMA.

Adverse Reactions reported in ≥5% of tocilizumab-treated patients include upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased ALT, and injection site reactions.

Sample CMS-1500 Claim Form—Physician Office⁵

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE ☐ **MEDICAID** ☒ **TRICARE** ☐ **CHAMPVA** ☐ **GROUP HEALTH PLAN** ☐ **FECA BLK LUNG** ☐ **OTHER** ☐
(Medicare#) (Medicaid#) (ID#(DoD#)) (Member ID#) (ID#) (ID#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S.

3. PATIENT'S BIRTH DATE MM DD YY
02 12 70

4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S.

5. PATIENT'S ADDRESS (No., Street)
123 Main Street

6. PATIENT RELATIONSHIP TO INSURED
Self ☒ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)
123 Main Street

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits due to myself or to the party who accepts assignment below.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) MM DD YY
QUAL: 10 01 25

15. OTHER DATE MM DD YY
QUAL: 10 01 25

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
John Smith, MD

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
AVTOZMA 80 MG IV NDC: 72606-0042-01

20. OUTSIDE LAB? YES ☐ NO ☒ **\$ CHARGES**

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)
A. M81.0 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
1	N472606003701																													
2	10 01 25	10 01 25																												
3																														
4																														
5																														
6																														

25. FEDERAL TAX ID NUMBER SSN EIN ☐ ☐

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? YES ☐ NO ☒

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Rev'd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH #

34. SIGNATURE OF PHYSICIAN OR SUPPLIER

35. DATE

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Field 19: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC.

Note: Some payers may also request the wholesale acquisition cost (WAC) price to be included.

Field 21: Indicate the most medically appropriate diagnosis code (ICD-10-CM).

Field 23: If required, report the prior authorization number here.

Field 24A: If line item NDC information is required, it will be entered in the shaded portion of item 24A. NDCs must be billed with the N4 qualifier before the NDC.

Field 24D: Indicate appropriate HCPCS as required by the payer (eg, Q5156). Include the appropriate CPT® code (eg, 96365 or 96413) to report the administration procedure.

Field 24E: Enter the diagnosis code reference letter as shown in box 21. Enter only 1 diagnosis pointer.

Field 24G: Enter the number of HCPCS units.

CMS-1450 (UB-04) Claim Form—Hospital Outpatient Departments⁶

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

1 Facility Name Street Address City, State, Zip Phone		2 Pay-to name Street Address City, State, Zip		3a PAY. CNTL. # b. NPI c. REG. # 5 FED. TAX NO.		4 TYPE OF BILL	
8 PATIENT NAME a Jane S. Doe		9 PATIENT ADDRESS a 123 Main Street		c AZ d 12333		e US	
10 BIRTHDAY 03/23/1970		11 SEX F		12 DATE		13 HPI	
14 TYPE		15 SRC		16 DHR		17 STAT	
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22		23		24		25	
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- Prior authorization (PA) assistance
- Appeal support
- Co-pay Assistance Program (Celltrion CARES) for your commercially insured patients
- Financial support for qualified eligible patients



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- Sample Letters of Medical Exception and Appeal
- Downloadable brochures
- Downloadable Enrollment Form
- Downloadable Billing and Coding Guide

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IMPORTANT SAFETY INFORMATION**WARNING: RISK OF SERIOUS INFECTIONS**

Patients treated with tocilizumab products including AVTOZMA 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 or corticosteroids.

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

Contraindications: Known hypersensitivity to tocilizumab products.

Serious Infections. Serious and sometimes fatal infections, including bacterial, mycobacterial, invasive fungal, viral, and opportunistic infections, have been reported with tocilizumab products, including AVTOZMA. Common serious infections include pneumonia, urinary tract infections, cellulitis, herpes zoster, and sepsis, while opportunistic infections such as tuberculosis and cryptococcus have also occurred. Patients with chronic or recurrent infections, tuberculosis exposure, or underlying conditions predisposing to infections should have the risks and benefits of AVTOZMA carefully evaluated. Monitor patients closely during and after treatment for signs of infection, and discontinue AVTOZMA if a serious infection develops, initiating appropriate antimicrobial therapy as needed.

Gastrointestinal (GI) Perforation. Gastrointestinal perforation events, primarily associated with diverticulitis, have been reported in clinical trials of tocilizumab. Use AVTOZMA cautiously in patients at increased risk for gastrointestinal perforation. Promptly evaluate any patient experiencing new abdominal symptoms to ensure early detection and management of this condition.

Hepatotoxicity. Serious hepatic injury, including cases of liver transplant and death, has occurred with tocilizumab products, with onset ranging from months to years. Some cases involved marked transaminase elevations ($>5\times$ ULN), while others presented with mild elevations and symptoms of liver dysfunction. Risk is higher with hepatotoxic drugs like methotrexate. Baseline and regular liver tests are required for RA, GCA, PJIA, and SJIA patients, with specific monitoring

intervals based on the condition. Do not initiate AVTOZMA if ALT or AST $>1.5\times$ ULN (RA/GCA) or $>10\times$ ULN (COVID-19), and discontinue if ALT or AST $>5\times$ ULN. Evaluate symptoms of liver injury promptly, and only restart treatment if liver test abnormalities are resolved and attributed to another cause.

Changes in Laboratory Parameters. Treatment with tocilizumab products, including AVTOZMA, has been associated with neutropenia, thrombocytopenia, elevated liver enzymes, and lipid abnormalities. Infections are uncommon with treatment-related neutropenia, but AVTOZMA should not be initiated in RA or GCA patients with ANC $<2000/\text{mm}^3$ or platelet counts $<100,000/\text{mm}^3$, and treatment is not recommended if ANC drops below $500/\text{mm}^3$ or platelets below $50,000/\text{mm}^3$. For COVID-19 patients, AVTOZMA is not recommended with ANC $<1000/\text{mm}^3$ or platelets $<50,000/\text{mm}^3$. Monitor neutrophils, platelets, and liver enzymes 4–8 weeks after starting therapy and every 3 months thereafter, adjusting treatment as needed. Lipid levels, including cholesterol and triglycerides, may increase and should be assessed 4–8 weeks after initiation, with management per clinical guidelines. A similar pattern is observed in PJIA and SJIA, requiring specific monitoring intervals for these populations. Refer to Dosage and Administration for modifications based on test results.

Immunosuppression. The effect of tocilizumab products on malignancy development is unknown, though malignancies were observed in clinical studies. As an immunosuppressant, AVTOZMA may increase the risk of malignancies.

Hypersensitivity Reactions, Including Anaphylaxis.

Hypersensitivity reactions, including anaphylaxis and fatal events, have been reported with tocilizumab products. Anaphylaxis requiring discontinuation occurred in 0.1% to 0.7% of trial patients, with postmarketing cases reported at various doses, with or without premedication, and as early as the first infusion. AVTOZMA intravenous infusions must be administered by healthcare professionals equipped to manage anaphylaxis. For subcutaneous use, patients must seek immediate medical attention if hypersensitivity symptoms occur. Discontinue AVTOZMA permanently if anaphylaxis or other hypersensitivity reaction occurs. Do not use in patients with known hypersensitivity to tocilizumab products.

Demyelinating Disorders. The impact of tocilizumab on demyelinating disorders is unknown, but rare cases like multiple sclerosis and polyneuropathy were reported in RA studies. Monitor for symptoms and use caution in patients with preexisting or recent demyelinating disorders.

Active Hepatic Disease and Hepatic Impairment. Treatment with AVTOZMA is not recommended.

Live Vaccines. Avoid concurrent use of live vaccines with AVTOZMA, as clinical safety and secondary transmission risk are unknown. Follow guidelines on timing between live vaccines and AVTOZMA.

Adverse Reactions reported in $\geq 5\%$ of tocilizumab-treated patients include upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased ALT, and injection site reactions.

For more information about AVTOZMA, please see full Prescribing Information.

References

1. AVTOZMA [prescribing information]. Celltrion USA, Inc.; 2025. 2. AAPC. ICD-10-CM 2025: *The Complete Official Codebook*. Salt Lake City, UT: AAPC; 2025. 3. National Drug Codes explained. Drugs.com. Updated March 20, 2025. Accessed June 12, 2025. <https://www.drugs.com/ndc.html> 4. American Medical Association. CPT 2025 Professional Edition. Chicago, IL: American Medical Association; 2025. 5. CMS.gov. CMS-1500. Accessed June 12, 2025. <https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms1188854> 6. CMS.gov. CMS-1450. Accessed June 12, 2025. <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pa-listing-items/cms-1450> 7. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations. Second Quarter, 2025 HCPCS Coding Cycle. Centers for Medicare & Medicaid Services. Accessed July 24, 2025. <https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-2-2025-drugs-and-biologicals-posted-07/7/2025.pdf> 8. American Academy of Ophthalmology. Fact Sheet: JW and JZ Modifiers. Published June 5, 2023. Accessed June 12, 2025. <https://www.aao.org/Assets/a82e22ae-3045-4abd-8a28-f653f6d61597/638212325906530000/modifiers-jw-jz-fs-pdf?inline=1#:~:text=Report%20JZ%20modifier%20when%20the,up%20to%20the%20nearest%20unit> 9. Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier. Centers for Medicare and Medicaid Services. MLN4800856 November 2024. Accessed July 16, 2025. <https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf>

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