

NEW J-CODE (J0791)¹ For ADAKVEO® (crizanlizumab-tmca) 1 unit = 5 mg Effective July 1, 2020



Miscellaneous coding and billing reference sheet

Physician office setting

Sample CMS-1500 claim form² for ADAKVEO® (crizanlizumab-tmca) - Physician office administration

Although this sheet provides information that should facilitate the claims process, all coding information is for reference purposes only. Novartis does not guarantee payment.

The health care billing environment is constantly evolving to keep pace with scientific advances and financial constraints. Information specific to billing and coding is subject to change and should be verified for each patient prior to treatment. A provider should contact patients' payers directly for any revised or additional requirements, information, or guidance.

This sample claim form assumes a 70-kg patient who received a dose of 5 mg/kg or 350 mg via a 30-minute infusion on July 1, 2020. In this example, **due to the patient's weight, there will be wastage**.

- Box 19:** This area may be used to list the drug name, the route of administration, and the amount administered.
- Box 21:** Enter the appropriate ICD-10-CM diagnosis code (eg, D571 for sickle-cell disease without crisis). Code to the highest level of specificity.³
- Box 24A:** In the nonshaded area, list the date of service. In the shaded area, provide a detailed drug description. The N4 indicator is listed first, the 11-digit National Drug Code number is listed second, the unit of measurement qualifier is listed third (eg, ML for milliliters), and the unit quantity is listed at the end. Example: N400078088361ML35 (Note: Some payers may request the 11-digit NDC number be listed in box 19).
- Box 24D:** Enter the appropriate HCPCS code for ADAKVEO: J0791, Injection, crizanlizumab-tmca, 5 mg.¹ The JW modifier must be used to report the amount of drug in single-dose or single-use packaging that is discarded and eligible for payment.⁴ Include the appropriate CPT code to report the administration procedure (eg, 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour).⁵
- Box 24F:** Enter the charge for each listed service and the product.
- Box 24G:** Report the appropriate number of units for the procedure and the appropriate number of units for ADAKVEO. 1 unit = 5 mg.
- Box 32A:** Enter required National Provider Identifier of the facility where the services were rendered.
- Box 33A:** Enter the billing provider's National Provider Identifier.
- Box 33B:** **Please note:** Some payers may require a taxonomy code to be reported. The taxonomy code characterizes type, classification, and/or specialization based on the primary services rendered.

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

19 ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
injection, crizanlizumab-tmca, 350mg

21 DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service the below (date)) ICD-9-CM
D57.1

24A DATE(S) OF SERVICE From To
7 1 20 7 1 20

24D PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)
J0791

24F CHARGES
70

24G UNITS
1

24H UNITS
10

24I UNITS
1

24J UNITS
10

24K UNITS
1

24L UNITS
10

24M UNITS
1

24N UNITS
10

24O UNITS
1

24P UNITS
10

24Q UNITS
1

24R UNITS
10

24S UNITS
1

24T UNITS
10

24U UNITS
1

24V UNITS
10

24W UNITS
1

24X UNITS
10

24Y UNITS
1

24Z UNITS
10

25 FEDERAL TAX I.D. NUMBER
SSN EIN

26 PATIENT'S ACCOUNT NO.

27 ACCEPT ASSIGNMENT? (Explain Unusual Circumstances)
YES NO

28 TOTAL CHARGE
\$

29 AMOUNT PAID
\$

30 REVENUE FOR NUCC USE

31 SIGNATURE OF PHYSICIAN OR SUPPLIER (INCLUDING DEGREE 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

33A BILLING PROVIDER INFO & PH #

33B TAXONOMY CODE

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

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate health care setting, and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist health care providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider.

INDICATION

ADAKVEO® (crizanlizumab-tmca) is indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients, aged 16 years and older, with sickle cell disease.

Important Safety Information

Infusion-Related Reactions

In the SUSTAIN clinical trial, infusion-related reactions (defined as occurring within 24 hours of infusion) were observed in 2 (3%) patients treated with ADAKVEO 5 mg/kg. Monitor patients for signs and symptoms of infusion-related reactions, which may include fever, chills, nausea, vomiting, fatigue, dizziness, pruritus, urticaria, sweating, or shortness of breath or wheezing. Discontinue ADAKVEO infusion for severe reactions and institute appropriate medical care.

Laboratory Test Interference: Platelet Counts

Interference with automated platelet counts (platelet clumping) has been observed following administration of ADAKVEO, in particular, when blood samples were collected in tubes containing EDTA.

Run blood samples within 4 hours of blood collection or collect blood samples in tubes containing citrate. When needed, estimate platelet count via peripheral blood smear.

Pregnancy

Based on animal data ADAKVEO has the potential to cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. ADAKVEO should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the fetus.

Most Common Adverse Reactions

The most frequently reported adverse reactions ($\geq 10\%$) in patients treated with ADAKVEO were nausea (18%), arthralgia (18%), back pain (15%), and pyrexia (11%).

Other Clinically Important Adverse Reactions

Clinically relevant adverse reactions (all grades) that were reported in $< 10\%$ of patients treated with ADAKVEO included: oropharyngeal pain, abdominal pain (abdominal pain, upper abdominal pain, lower abdominal pain, abdominal discomfort, and abdominal tenderness), diarrhea, vomiting, pruritus (pruritus and vulvovaginal pruritus), musculoskeletal chest pain, myalgia, infusion-site reaction (infusion-site extravasation, infusion-site pain, and infusion-site swelling), and infusion-related reaction.

Please see full Prescribing Information [here](#).

References: 1. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions. <https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-1-2020-drugs-and-biologicals-updated-04142020.pdf>. Accessed April 21, 2020. 2. Centers for Medicare & Medicaid Services. CMS Manual System. Details for title: CMS 1500. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS1188854>. Accessed May 28, 2020. 3. Centers for Medicare and Medicaid Services. 2020 ICD-10-CM. <https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM>. Accessed May 28, 2020. 4. Centers for Medicare & Medicaid Services. Medicare Program JW Modifier: Drug/Biological Amount Discarded/Not Administered to Any Patient Frequently Asked Questions. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>. Accessed May 13, 2020. 5. Find-A-Code: 96365 - CPT® Code in category: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug). InnovatiHealth Systems, Inc. <https://www.findacode.com/code.php?set=CPT&c=96365>. Updated 2018. Accessed May 26, 2020.



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6/20

CZB-1231216

