

Novartis is pleased to announce that, effective April 1, 2020, the Centers for Medicare and Medicaid Services (CMS) has issued a product-specific C-code, C9053 for 100 mg/10 mL (10 mg/mL) solution in a single-dose vial of ADAKVEO® (crizanlizumab-tmca) for IV infusion. The code can be reported in box 44 on the CMS-1450 (UB-04) claim form for the hospital outpatient department.

C-codes are used primarily to report services under the Outpatient Prospective Payment System (OPPS), but may also be recognized by other private and public payer types. Please check with each payer for specific requirements.

**Important billing and coding information:**

ADAKVEO is supplied as a 100 mg/10 mL (10 mg/mL) single dose vial. See below for coding details:

Unique C-Code for ADAKVEO	Description	Units per 10 mL (10 mg/mL) single-dose vial
C9053	Injection, ADAKVEO, 1 mg	100

KVEO

administered April 1 and later. If you have questions or need further clarification, please contact me at 330-338-1141, or ADAKVEO Support at PANO at **1-800-282-7630**.

**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 at

<https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/adakveo.pdf>.