SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™ Coding Guide*

The coding information is for your reference only and is subject to change. Please be sure to consult your organization for coding guidance. Note, these codes are relevant for SARCLISA ESCENA with or without CirCLIQ.

National Drug Code (NDC)[1]

10-digit NDC	11-digit NDC†	Description
0024-0674-01	00024-0674-01	1,400 mg/10 mL single-dose vial

*These codes are not intended to encourage or suggest a use of the drug that is inconsistent with FDA-approved use. The codes are not intended to be exhaustive, and additional codes may apply. Payer policies for coding vary. Consult your payers for guidance.
†Payer requirements for 10- or 11-digit NDC use and format may vary. Please verify requirements prior to use.

HCPCS code[2]

Code	Description	HCPCS code dosage (billing units)	Example
J3590	Unclassified biologics	10 mg = 1 unit	1,400-mg vial = 140 units

Sanofi anticipates the permanent HCPCS code to be available in April 2027.

ICD-10-CM diagnosis codes[3]

Code	Description
C90.0X	Multiple myeloma
→ C90.00	Multiple myeloma not having achieved remission
→ C90.01	Multiple myeloma in remission
→ C90.02	Multiple myeloma in relapse

CPT® code[4]

Code	Description
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

Revenue codes (for hospital outpatient departments)[5]

Code	Description
0331	Chemotherapy administration—injection
0636	Drugs requiring detailed coding

Place of service codes[6]

Code	Name	Description
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus—Outpatient Hospital	A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization (Effective January 1, 2016).
22	On Campus—Outpatient Hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization (Description change effective January 1, 2016).

CPT, Current Procedural Terminology; FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

The above codes may be used to communicate services rendered when filing claims for SARCLISA ESCENA with or without CirCLIQ. These codes are being provided for informational purposes only and should be verified, as codes may change. The provision of billing codes does not constitute reimbursement or legal advice. Providers are solely responsible for ensuring the accuracy of billing submissions to any payer.

INDICATIONS

SARCLISA ESCENA (isatuximab-irfc) is indicated:

- In combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT)
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy
- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including lenalidomide and a proteasome inhibitor

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SARCLISA ESCENA is contraindicated in patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients.

Please see additional Important Safety Information on the next page and accompanying full Prescribing Information.

SARCLISA ESCENA™ (isatuximab-irfc) Injection for subcutaneous use 1,400 mg/10 mL FOR USE WITH CirCLIQ™ On-Body Delivery System

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

SARCLISA ESCENA can cause both systemic administration reactions (SARs), including severe or life-threatening reactions, and local injection-site reactions (ISRs).

Systemic Administration Reactions

In a pooled safety population of 411 patients with multiple myeloma who received SARCLISA ESCENA in combination with pomalidomide and dexamethasone (Pd); carfilzomib and dexamethasone (Kd); and bortezomib, lenalidomide, and dexamethasone (VRd) (IRAKLIA, IZALCO, and IsaSocut, respectively, N=411), SARs occurred in 3.2% (Grade 1: 2.2%, Grade 2: 0.7%, Grade 3: 0.2%) of patients. SARs occurred at the first administration in 1.9% of patients and at subsequent administrations in 1.5% of patients. The median time to onset was 4 hours (range: 12 minutes to 3 days). The most frequently reported symptoms of SARs (all below 1%) were pyrexia and dyspnea, and the most frequently reported Grade ≥3 symptom was dyspnea (not collected in IsaSocut study). In multiple myeloma clinical trials with intravenous isatuximab-irfc, anaphylactic reactions occurred in <1% of patients.

To decrease the risk and severity of SARs, premedicate patients prior to SARCLISA ESCENA administration with leukotriene receptor antagonists (at cycle 1 only), acetaminophen, diphenhydramine or equivalent, and dexamethasone.

In case of grade 2 SAR during SARCLISA ESCENA administration, stop current administration and do not complete it. Administer additional premedication, as needed, for subsequent SARCLISA ESCENA administration. In case of grade 3 SAR during SARCLISA ESCENA administration, stop current administration and do not complete it. SARCLISA ESCENA administration may be resumed at the next planned administration. In case of a third occurrence of a grade 3 SAR, permanently discontinue SARCLISA ESCENA treatment. In case of grade 4 SAR, permanently discontinue SARCLISA ESCENA treatment.

Injection Site Reactions

In clinical trials of SARCLISA ESCENA in combination with Pd, Kd, or VRd (IRAKLIA, IZALCO, and IsaSocut, respectively, N=411), injection site reactions (ISRs) with SARCLISA ESCENA administration were reported in 9% (8% Grade 1 and 1.5% Grade 2) of patients and in 0.86% of injections. Among the SARCLISA ESCENA injections with ISRs , 82% occurred the day of the administration and 4.2% were delayed by at least 3 days. With SARCLISA ESCENA + Pd and SARCLISA ESCENA + Kd, 5% of patients experienced symptoms of ISR (not collected in IsaSocut study). The most frequent (≥1%) symptoms of ISR were injection site erythema (3.3%), injection site swelling (2.1%), and injection site pain (1.5%).

In case of grade 2 ISR during administration of SARCLISA ESCENA, interrupt it and resume it only after recovery to grade ≤1 with pauses during the administration (if using OBDS) or a slower administration (if manual injection). If the Grade 2 ISR occurs after the administration, continue SARCLISA ESCENA treatment after recovery to grade ≤1. In case of grade 3 or 4 ISR, permanently discontinue SARCLISA ESCENA treatment.

In case SARCLISA ESCENA administration using CirCLIQ OBDS needs to be paused, refer to the OBDS Instructions for Use.

Neutropenia

Neutropenia was reported in patients receiving SARCLISA ESCENA subcutaneously in combination with Pd, Kd, or VRd. In clinical trials of SARCLISA ESCENA (IRAKLIA, IZALCO, and IsaSocut, N=411), neutropenia occurred in 86% of patients based on laboratory value. Grade 3-4 neutropenia occurred in 66% of patients based on laboratory value. Febrile neutropenia was reported in 3.4% and neutropenic infections occurred in 13% of patients.

Monitor complete blood cell counts periodically during treatment. Monitor patients with neutropenia for signs of infection. In case of grade 4 neutropenia, delay or omit SARCLISA ESCENA dose until neutrophil count recovery to at least 1×10^9/L, and provide supportive care with growth factors, according to institutional guidelines.

Infections

SARCLISA ESCENA can cause severe, life-threatening, or fatal infections. In patients who received SARCLISA ESCENA subcutaneously in combination with Pd, Kd, or VRd (IRAKLIA, IZALCO, and IsaSocut, respectively, N=411), fatal infections occurred in 2.9% of patients, serious infections occurred in 29% of patients, and Grade ≥3 infections occurred in 29% of patients. The most commonly reported infections (≥10%) were pneumonia (21%), upper respiratory tract infection (19%), and COVID-19 (12%). The most frequent serious infection (≥5%) was pneumonia (17%).

Patients receiving SARCLISA ESCENA should be closely monitored for signs of infection and appropriate standard therapy instituted.

Antibacterial and antiviral prophylaxis (such as herpes zoster prophylaxis) should be considered during treatment.

Second Primary Malignancies

Second primary malignancies were reported in 3.9% of patients in clinical trials with SARCLISA ESCENA in combination with Pd, Kd, and VRd (IRAKLIA, IZALCO, and IsaSocut, respectively, N=411).

Monitor patients for the development of second primary malignancies and initiate treatment as indicated.

Laboratory Test Interference

Interference with Serological Testing (Indirect Antiglobulin Test)

Isatuximab-irfc binds to CD38 on red blood cells (RBCs) and may result in a false-positive indirect antiglobulin test (indirect Coombs test). This interference with the indirect Coombs test may persist for at least 6 months after the last administration of intravenous isatuximab-irfc. The indirect antiglobulin test was positive during intravenous isatuximab-irfc + Pd treatment in 68% of the tested patients, and during intravenous isatuximab-irfc + Kd treatment in 63% of patients. In patients with a positive indirect antiglobulin test, blood transfusions were administered without evidence of hemolysis. ABO/RhD typing was not affected by intravenous isatuximab-irfc treatment.

Before the first isatuximab-irfc administration, conduct blood type and screen tests on isatuximab-treated patients. Consider phenotyping prior to starting isatuximab-irfc treatment. If treatment with isatuximab-irfc has already started, inform the blood bank that the patient is receiving isatuximab-irfc, and isatuximab-irfc interference with blood compatibility testing can be resolved using dithiothreitol-treated RBCs. If an emergency transfusion is required, non–cross-matched ABO/RhD-compatible RBCs can be given as per local blood bank practices.

Interference with Serum Protein Electrophoresis and Immunofixation Tests

Isatuximab-irfc is an IgG kappa monoclonal antibody that can be incidentally detected on both serum protein electrophoresis and immunofixation assays (IFE) used for the clinical monitoring of endogenous M-protein. In patients with persistent very good partial response, where interference is suspected, consider using a validated isatuximab-specific IFE assay (Sebia Hydrashift) to remove isatuximab-irfc interference and specifically visualize any remaining serum M-protein, to facilitate determination of complete response.

Embryo-Fetal Toxicity

Based on its mechanism of action, isatuximab-irfc can cause fetal harm when administered to a pregnant woman. Isatuximab-irfc may cause fetal immune cell depletion and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with isatuximab-irfc and for 7 months after the last dose. The combination of isatuximab-irfc with pomalidomide or lenalidomide is contraindicated in pregnant women because pomalidomide or lenalidomide may cause birth defects and death of the unborn child. Refer to the pomalidomide or lenalidomide prescribing information on use during pregnancy.

ADVERSE REACTIONS

In combination with pomalidomide and dexamethasone: The most common adverse reactions (≥20%) are upper respiratory tract infection, fatigue, pneumonia, musculoskeletal pain, and diarrhea.

In combination with carfilzomib and dexamethasone: The most common adverse reactions (≥20%) are upper respiratory tract infection and musculoskeletal pain.

In combination with bortezomib, lenalidomide, and dexamethasone: The most common adverse reactions (≥20%) are peripheral neuropathy, constipation, diarrhea, fatigue, musculoskeletal pain, upper respiratory tract infections, injection site reaction, insomnia, edema, rash, and erythema.

The most common hematology laboratory abnormalities (≥40%) with SARCLISA ESCENA combination therapies are decreased neutrophils, decreased platelets, decreased hemoglobin, decreased leukocytes, and decreased lymphocytes.

Serious adverse reactions occurred in 53% of patients receiving SARCLISA ESCENA + Pd. Serious adverse reactions in ≥5% of patients who received SARCLISA ESCENA + Pd included pneumonia (20.5%). Fatal adverse reactions occurred in 4.9% of patients who received SARCLISA ESCENA + Pd, including pneumonia (1.5%), sepsis/septic shock (1.5%), death (0.8%), COVID-19, lower respiratory tract infection, hemorrhagic stroke, and sudden death (0.4% each).

Serious adverse reactions occurred in 41% of patients receiving SARCLISA ESCENA + Kd. Serious adverse reactions in ≥5% of patients included pneumonia (11%). Fatal adverse reactions occurred in 5.4% of patients who received SARCLISA ESCENA + Kd, including meningitis (1.4%), acute pulmonary edema (1.4%), acute respiratory distress syndrome (1.4%), and death from unknown cause (1.4%).

Serious adverse reactions occurred in 45% of patients who received SARCLISA ESCENA + VRd. Serious adverse reactions in >5% of patients included pneumonia (8%). Fatal adverse reactions occurred in 2.7% of patients who received SARCLISA ESCENA + VRd, including cardio-respiratory arrest (1.4%) and myocardial infarction (1.4%).

USE IN SPECIAL POPULATIONS

Based on its mechanism of action, SARCLISA ESCENA can cause fetal harm when administered to a pregnant woman. There are no available data on SARCLISA ESCENA use in pregnant women to evaluate for a drug-associated risk.

The combination of SARCLISA ESCENA and pomalidomide or lenalidomide is contraindicated in pregnant women because pomalidomide and lenalidomide may cause birth defects and death of the unborn child. Refer to the pomalidomide or lenalidomide prescribing information on use during pregnancy. Pomalidomide and lenalidomide are only available through a REMS program.

Because of the potential for serious adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with SARCLISA ESCENA and for 7 months after the last dose.

Please see full Prescribing Information.

References: 1. SARCLISA ESCENA [prescribing information]. Morristown, NJ: sanofi-aventis U.S. LLC. **2.** SEER. Accessed March 13, 2026. seer.cancer.gov/oncologytoolbox/canmed/hcpcs/1271/ **3.** Centers for Medicare & Medicaid Services. Accessed March 13, 2026. https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment/2026-model-software-icd-10-mappings **4.** American Medical Association. CPT® 2021 Professional Edition (Current Procedural Terminology). Chicago, IL: American Medical Association; 2020. **5.** Noridian Healthcare Solutions. Accessed March 17, 2026. https://med.noridianmedicare.com/web/jea/topics/claim-submission/ revenue-codes **6.** Centers for Medicare & Medicaid Services. Accessed March 13, 2026. www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets.

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