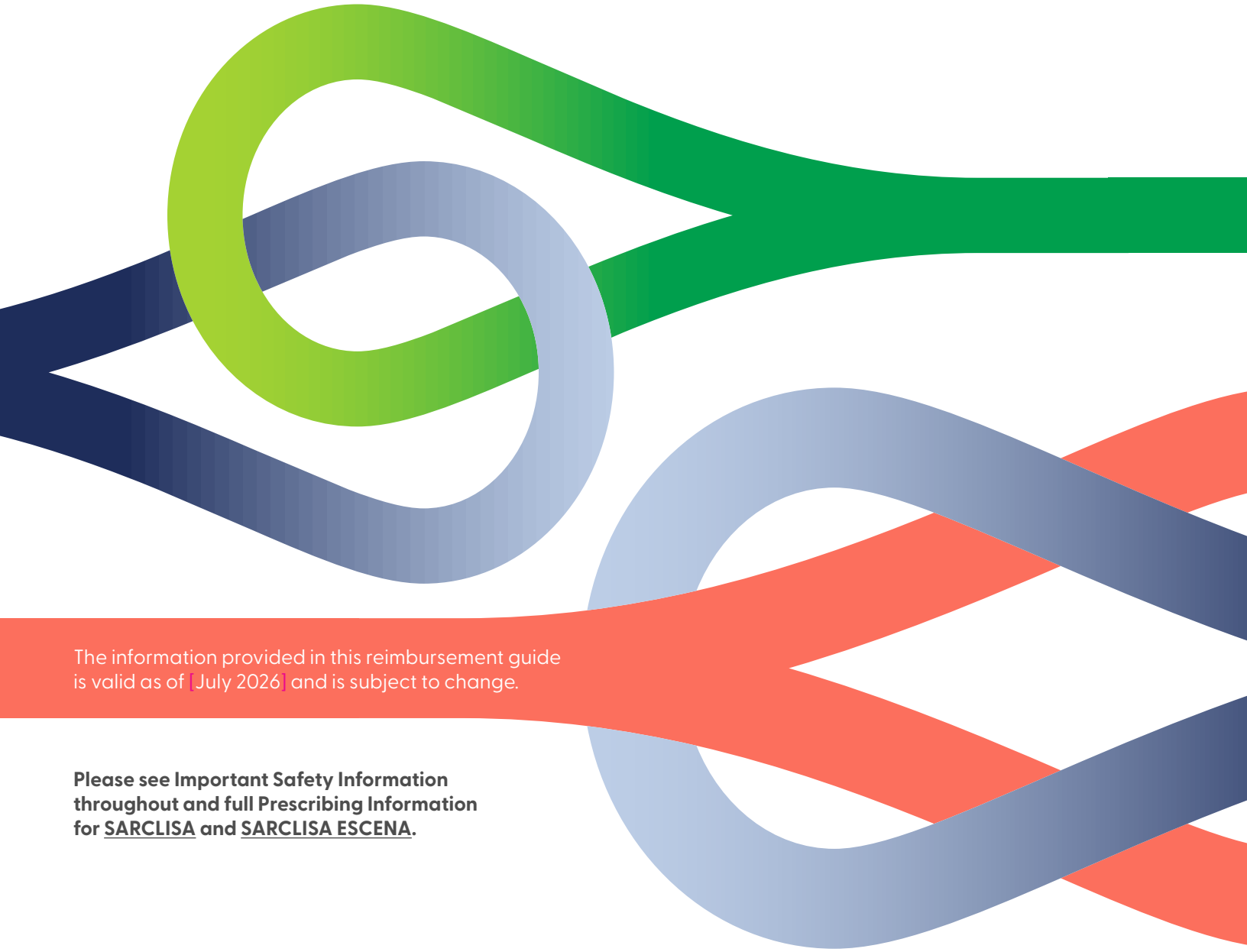
SARCLISA®
(isatuximab-irfc)
Injection for intravenous use
500 mg/25 mL, 100 mg/5 mL

SARCLISA ESCENA™
(isatuximab-irfc)
Injection for subcutaneous use
1,400 mg/10 mL

FOR USE WITH CirCLIQ™ On-Body Delivery System

SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™ and SARCLISA® (isatuximab-irfc) Billing and Coding Guide

Your guide to access and reimbursement



The information provided in this reimbursement guide is valid as of [July 2026] and is subject to change.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

Introduction

This guide provides billing, coding, and reimbursement information for SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™ and SARCLISA (isatuximab-irfc). It also includes sample forms, a list of specialty distributors and wholesalers, and information about patient support and reimbursement.

Please note:

- While the information in this guide is current as of the date of publication, it is subject to change without notice
- This guide is provided for informational purposes only and does not constitute legal or reimbursement advice. It is not intended to substitute for the physician's independent diagnosis or treatment of each patient. The information contained herein is gathered from various resources and is subject to change. Providers are solely responsible for the accuracy of all coding and claims submitted for reimbursement to any third-party payor

Indications for SARCLISA (isatuximab-irfc) and SARCLISA ESCENA (isatuximab-irfc)

- SARCLISA and SARCLISA ESCENA are 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)
- SARCLISA and SARCLISA ESCENA are indicated 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
- SARCLISA is indicated in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- SARCLISA ESCENA is indicated 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 for SARCLISA and SARCLISA ESCENA

CONTRAINDICATIONS—SARCLISA and SARCLISA ESCENA

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

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

Table of contents

SARCLISA® (isatuximab-irfc)
Injection for intravenous use
500 mg/25 mL, 100 mg/5 mL

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

Billing and coding for SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™*

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

NDC numbers[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 billing and 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.

ICD-10-CM diagnosis codes[2]

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

HCPCS code[3]

HCPCS 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 [January 2027.]

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; NDC, National Drug Code.

Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA

Infusion-Related Reactions—SARCLISA

SARCLISA can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening and fatal outcomes have been reported. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

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

CMS sample forms for SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™

This CMS sample form is provided as an example. This CMS-1500 form is commonly used for billing for prescribed medications administered in healthcare provider (physician) offices.

The notes below provide information about how to populate the essential fields that health plans require for reimbursement. **(For medication administered in hospital outpatient settings, please see pages 8 and 9.)**

This sample claim form is intended for use only as a reference. Reimbursement codes are subject to continual change. Please confirm the accuracy of the codes you use to bill for the prescribed medications with each payer.

Item 21
Enter the appropriate ICD-10-CM diagnosis codes for multiple myeloma

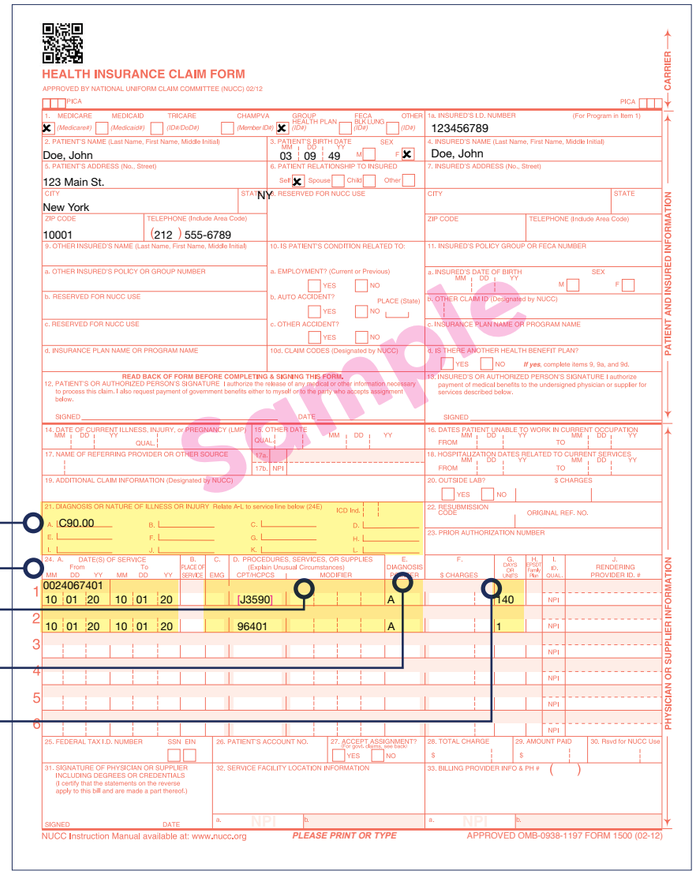
Item 24A
Enter the date of service for each procedure, service, or supply. Include NDC information, if required, in the shaded areas above each date

Item 24D
Enter J-code [J3590] and appropriate CPT codes and modifiers for procedures, services, and supplies. Enter the specific procedure code without a description. If you need to report an "unlisted procedure" code or a "not otherwise classified" (NOC) code, include a detailed description in Box 19

Item 24E
Enter the diagnosis code reference letter or number from Box 21 that relates to the date of service and the services or procedures performed that are entered on that same line under 24D

Item 24G
Enter the appropriate number of billing units based on the HCPCS code dosage of 1,400 mg. For example, 1,400 mg = 140 billing units

CMS-1500 sample[7]
Physician office form



Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

Infusion-Related Reactions—SARCLISA (cont'd)

In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), infusion-related reactions occurred in 206 patients (35%). Among these 206 patients, 92% experienced infusion-related reactions during the first infusion and 12% after the first cycle.

The most common symptoms (≥5%) of an infusion-related reaction included dyspnea and cough. Grade 1 infusion-related reactions were reported in 6% of patients, grade 2 in 28%, and grade 3 or 4 in 1.2%. Anaphylactic reactions occurred in less than 1% of patients. The total incidence of SARCLISA infusion interruptions was less than 1% and the incidence of patients with at least one SARCLISA infusion interruption due to infusion-related reactions was 26%. The median time to first SARCLISA infusion interruption was 61 minutes (range 4 to 240 minutes). SARCLISA was discontinued in 1% of patients due to infusion-related reactions. To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, H_2 antagonists, diphenhydramine or equivalent, and dexamethasone.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

CMS sample forms for SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™ (cont'd)

The CMS UB-04 form is used for billing for prescribed medications administered in hospital outpatient settings. The notes below provide information about how to populate the essential fields that health plans require for reimbursement.

This sample claim form is intended for use only as a reference. Reimbursement codes are subject to continual change. Please confirm the accuracy of the codes you use to bill for the prescribed medications with each payer.

Form Locator (FL) 42
Enter the 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy

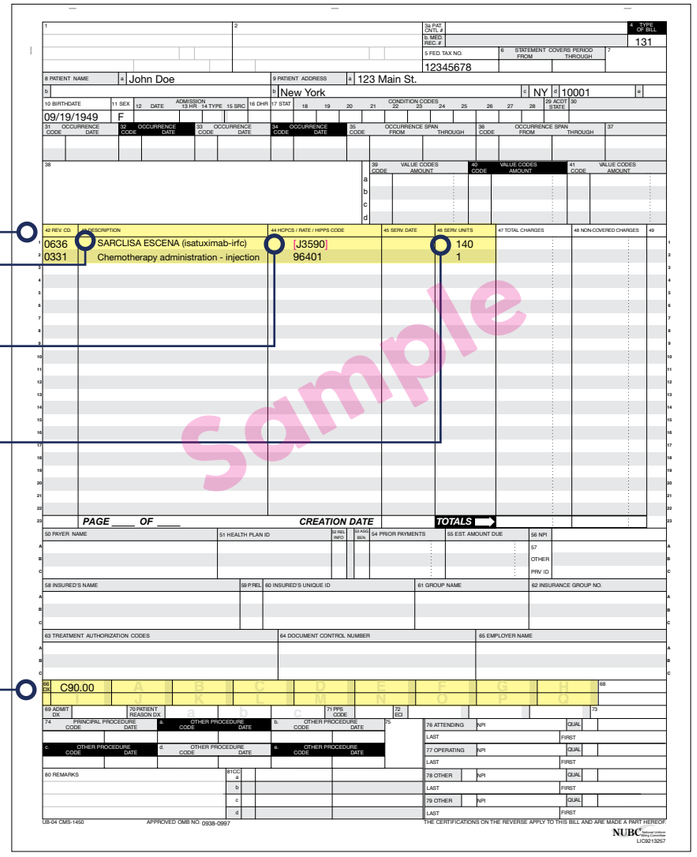
FL 43
Enter the description of service (eg, SC therapy)

FL 44
Enter J-code [J3590] and appropriate CPT codes

FL 46
Enter the appropriate number of service based on the HCPCS code dosage of 1,400 mg. For example, 1,400 mg = 140 billing units

FL 66
Enter the appropriate ICD-10-CM diagnosis codes for MM being treated

CMS-1450 (UB-04) sample[8]
Hospital outpatient form



Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

Infusion-Related Reactions—SARCLISA (cont'd)

Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade ≥2 reactions, interrupt SARCLISA infusion and provide appropriate medical management. For patients with grade 2 or grade 3 reactions, if symptoms improve to grade ≤1, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients. If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally. In case symptoms do not improve to grade ≤1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medications, or require hospitalization, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if an anaphylactic reaction or life-threatening (grade 4) IRR occurs and institute appropriate management.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; MM, multiple myeloma.

Dosing for SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™[1]

Recommended Dosage

- **Relapsed or refractory multiple myeloma (RRMM):** 1,400 mg administered as an SC injection with the CirCLIQ OBDS or with a syringe and infusion set for manual administration, in combination with Kd or Pd
- **Newly diagnosed multiple myeloma (NDMM):** 1,400 mg administered as an SC injection with the CirCLIQ OBDS or with a syringe and infusion set for manual administration, in combination with VRd
- Treatment is repeated until disease progression or unacceptable toxicity

Dosing Schedule

RRMM schedule:

Weekly dosing transitions to every other week after the first cycle. Treatment is administered in 28-day cycles.

On the days when both SARCLISA ESCENA and carfilzomib are administered, administer dexamethasone first, followed by SARCLISA ESCENA administration, then followed by carfilzomib infusion.

NDMM schedule*:

Weekly dosing transitions to every other week after the first cycle and then to once monthly (every 4 weeks) at Cycle 13. After Cycle 13, bortezomib is stopped and patients receive triplet therapy with SARCLISA ESCENA + Rd.

Induction treatment period: 12 induction cycles, 4 weeks per cycle†

Continuous treatment period: 4 weeks per cycle†

For dosing instructions for combination agents administered with SARCLISA ESCENA, refer to the study design descriptions in the SARCLISA ESCENA Prescribing Information and the respective manufacturer's Prescribing Information.

*Pattern reflects: weekly in Cycle 1 → q2w in Cycles 2–12 → q4w (Day 1 only) from Cycle 13 onward with SARCLISA ESCENA + Rd.

†Induction phase and continuous phase cycles=28 days each.

Administration of SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™[1]

Premedication

Administer the following premedications prior to SARCLISA ESCENA administration to reduce the risk and severity of systemic administration reactions (SARs).

Dexamethasone	When administered in combination with SARCLISA ESCENA and carfilzomib: 20 mg PO or IV When administered in combination with SARCLISA ESCENA and pomalidomide: 40 mg PO or IV (or 20 mg PO or IV for patients ≥75 years of age) When administered in combination with SARCLISA ESCENA, bortezomib, and lenalidomide: 20 mg PO
Acetaminophen	650 mg to 1,000 mg PO
Leukotriene receptor antagonists	Cycle 1 only (Days 1, 8, 15, and 22)
Diphenhydramine	25 mg to 50 mg PO or IV (or equivalent). The IV route is preferred for at least the first 4 administrations

The above recommended dose of dexamethasone (PO or IV) corresponds to the total dose to be administered before SARCLISA ESCENA administration as part of the premedication and part of the backbone treatment.

Administer the recommended premedication agents 15 to 60 minutes prior to starting a SARCLISA ESCENA administration. If no SAR occurs during Cycle 1, assess patient-specific factors and consider omitting subsequent premedication during future treatment cycles.

Preparing SARCLISA ESCENA

- SARCLISA ESCENA is a clear to slightly opalescent, colorless to slightly yellow solution that may contain a few translucent to white particles. SARCLISA ESCENA should not be used if the solution is cloudy or discolored, or if particles other than those described above are present. Inspect the vials for particulate matter and discoloration prior to administration whenever solution and container permit
- To prevent medication errors, check the SARCLISA ESCENA vial label to ensure it is the correct medication for SC use (vial with green cap)
- Prior to use, allow SARCLISA ESCENA to reach ambient temperature between 64 °F and 82 °F (18 °C and 28 °C) for approximately 20 minutes. Keep the unpunctured vial in the original carton prior to use to protect from light. Do not heat. Do not shake
- Once the vial is taken out of the refrigerator, it must not be returned to the refrigerator. Unpunctured vials may be stored at ambient temperature between 64 °F and 82 °F (18 °C and 28 °C) for a single period of up to 24 hours
- No dose reduction of SARCLISA ESCENA is recommended. Dose delay or omission may be required

Administering SARCLISA ESCENA

SARCLISA ESCENA with **CirCLIQ**

SARCLISA ESCENA with **manual administration**

- SARCLISA ESCENA is for abdominal SC administration by a healthcare provider only
- Do not administer SARCLISA ESCENA intravenously
- Change (rotate) the site of each SC administration at least 1 inch (2.5 cm) from previous injection site with every injection to avoid accumulation of fatty tissue
- Do not inject other medications in the area where SARCLISA ESCENA is injected
- Do not inject into areas where the skin is injured, tender, red, hot, has scars, or is excessively hairy
- Administer within 4 hours (including injection time) at room temperature. Discard after 4 hours if not used

IV, intravenous; Kd, carfilzomib and dexamethasone; OBDS, on-body delivery system; Pd, pomalidomide and dexamethasone; PO, by mouth; q2w, every 2 weeks; q4w, every 4 weeks; Rd, lenalidomide and dexamethasone; SC, subcutaneous; VRd, bortezomib, lenalidomide, and dexamethasone.

Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

Hypersensitivity and Other Administration Reactions—SARCLISA ESCENA

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

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

SARCLISA ESCENA™ (isatuximab-irfc) FOR USE WITH CirCLIQ™ On-Body Delivery System

Injection for subcutaneous use

1,400 mg/10 mL

Billing and coding for **SARCLISA** (isatuximab-irfc)*

The billing and coding information is for your reference only and is subject to change. Please be sure to consult your organization for reimbursement, billing, and coding guidance.

NDC numbers[9]

10-digit NDC	11-digit NDC†	Description
0024-0654-01	00024-0654-01	 100 mg/5 mL single-dose vial
0024-0656-01	00024-0656-01	 500 mg/25 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 billing and 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.

ICD-10-CM diagnosis codes[10]

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

HCPCS code[11]

HCPCS code	Description	HCPCS code dosage (billing units)	Example
J9227	Injection, isatuximab-irfc, 10 mg	10 mg = 1 unit	100-mg vial = 10 units
			500-mg vial = 50 units

JW modifier: Providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records.

CPT® codes[12,13]

Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)

Revenue codes (for hospital outpatient departments)[5]

Code	Description
0260	IV therapy
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; IV, intravenous; NDC, National Drug Code.

Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

Hypersensitivity and Other Administration Reactions—SARCLISA ESCENA (cont'd)

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.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

SARCLISA® (isatuximab-irfc) Injection for intravenous use 500 mg/25 mL, 100 mg/5 mL

CMS sample forms for **SARCLISA** (isatuximab-irfc)

This Centers for Medicare & Medicaid Services (CMS) sample form is provided as an example. This CMS-1500 form is commonly used for billing for prescribed medications administered in healthcare provider (physician) offices.

The notes below provide information about how to populate the essential fields that health plans require for reimbursement. **(For medication administered in hospital outpatient settings, please see pages 8 and 9.)**

This sample claim form is intended for use only as a reference. Reimbursement codes are subject to continual change. Please confirm the accuracy of the codes you use to bill for the prescribed medications with each payer.

Item 21
Enter the appropriate ICD-10-CM diagnosis codes for multiple myeloma

Item 24A
Enter the date of service for each procedure, service, or supply. Include NDC information, if required, in the shaded areas above each date

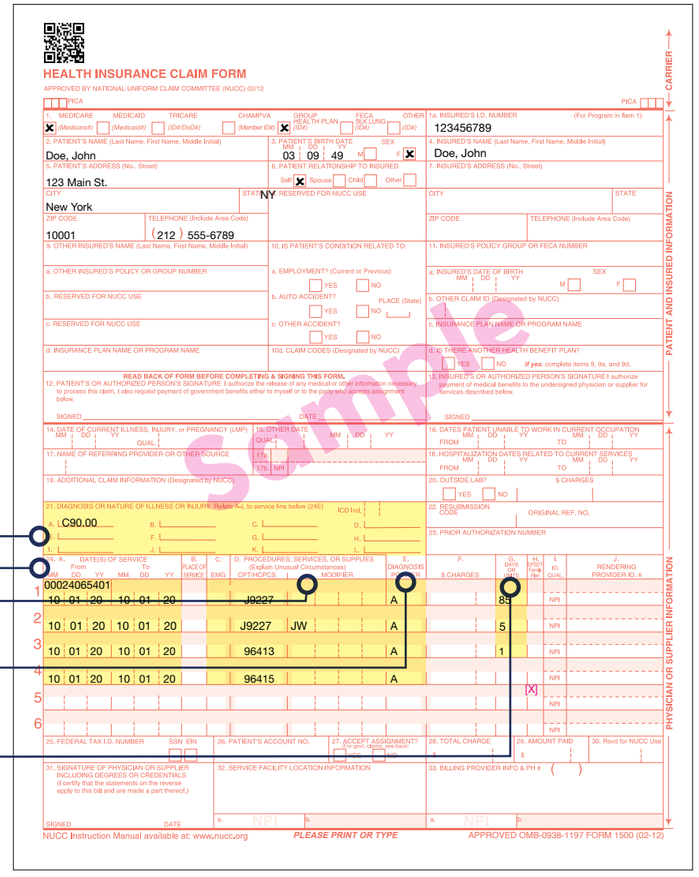
Item 24D
Enter J-code J9227 and appropriate CPT codes and modifiers for procedures, services, and supplies. Enter the specific procedure code without a description. If you need to report an "unlisted procedure" code or a "not otherwise classified" (NOC) code, include a detailed description in Box 19

Item 24E
Enter the diagnosis code reference letter or number from Box 21 that relates to the date of service and the services or procedures performed that are entered on that same line under 24D

Item 24G
Enter the appropriate number of billing units based on the HCPCS code dosage of 10 mg. For example, 10 mg = 1 billing unit; so for a patient with multiple myeloma (MM) weighing 85 kg, the dose would be 850 mg → 85 units

JW modifier: 850 mg dose would require one 500-mg and four 100-mg vials, for a total of 900 mg, resulting in 50 mg wastage. 50 mg = 5 billing units

CMS-1500 sample[7]
Physician office form



Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

Hypersensitivity and Other Administration Reactions—SARCLISA ESCENA (cont'd)

Systemic Administration Reactions (cont'd)

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.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

SARCLISA® (isatuximab-irfc) Injection for intravenous use 500 mg/25 mL, 100 mg/5 mL

CMS sample forms for **SARCLISA** (isatuximab-irfc) (cont'd)

The CMS UB-04 form is used for billing for prescribed medications administered in hospital outpatient settings. The notes below provide information about how to populate the essential fields that health plans require for reimbursement.

This sample claim form is intended for use only as a reference. Reimbursement codes are subject to continual change. Please confirm the accuracy of the codes you use to bill for the prescribed medications with each payer.

Form Locator (FL) 42
Enter the 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy

FL 43
Enter the description of service (eg, IV therapy)

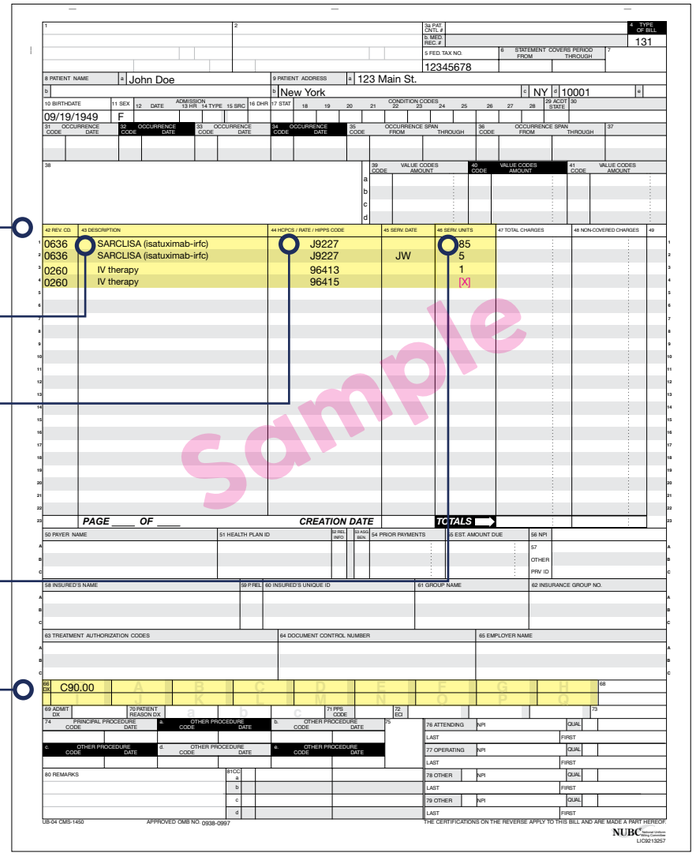
FL 44
Enter J-code J9227 and appropriate CPT codes

FL 46
Enter the appropriate number of service based on the HCPCS code dosage of 10 mg. For example, 10 mg = 1 billing unit; for a patient with MM weighing 85 kg, the dose would be 850 mg → 85 units

JW modifier: 850-mg dose would require one 500-mg and four 100-mg vials, for a total of 900 mg, resulting in 50-mg wastage. 50 mg = 5 billing units

FL 66
Enter the appropriate ICD-10-CM diagnosis codes for MM being treated

CMS-1450 (UB-04) sample[8]
Hospital outpatient form



Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

Hypersensitivity and Other Administration Reactions—SARCLISA ESCENA (cont'd)

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%).

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

Your partners in navigating patient access and reimbursement

Our Case Managers are experts in navigating the oncology space. They'll provide the information you need to get your patients started on SARCLISA ESCENA and SARCLISA IV as quickly as possible.

SARCLISA (isatuximab-irfc) Injection for intravenous use 500 mg/25 mL, 100 mg/5 mL

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

careASSIST Sanofi Support

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IV, intravenous; MM, multiple myeloma.

SARCLISA® (isatuximab-irfc) Injection for intravenous use 500 mg/25 mL, 100 mg/5 mL

Dose and infusion times for **SARCLISA** (isatuximab-irfc)[9]

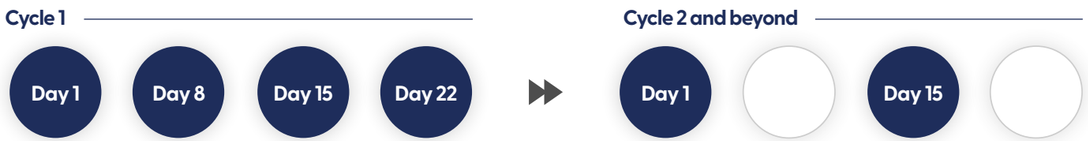
Recommended Dosage

- **Relapsed or refractory multiple myeloma (RRMM):** 10 mg/kg actual body weight administered as an IV infusion in combination with Kd or Pd
- **Newly diagnosed multiple myeloma (NDMM):** 10 mg/kg actual body weight administered as an IV infusion in combination with VRd
- 250 mL fixed infusion volume
- Treatment is repeated until disease progression or unacceptable toxicity

Dosing Schedule

RRMM schedule:

Weekly dosing transitions to every other week after the first cycle. Treatment is administered in 28-day cycles.



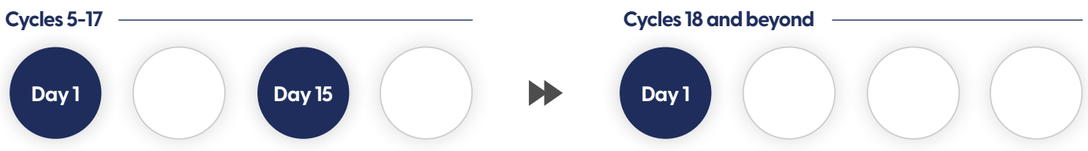
On days when both SARCLISA and carfilzomib are administered, administer dexamethasone first, followed by SARCLISA infusion, then followed by carfilzomib infusion.

NDMM schedule:

Weekly dosing transitions to every other week after the first cycle and then to once monthly (every 4 weeks) at Cycle 18. After Cycle 4, bortezomib is stopped and patients receive triplet therapy with SARCLISA + Rd.

Induction treatment period: 4 induction cycles, 6 weeks per cycle*

Continuous treatment period: 4 weeks per cycle†



For dosing instructions for combination agents administered with SARCLISA, refer to the study design descriptions in the SARCLISA Prescribing Information and the respective manufacturer's Prescribing Information.

*Induction phase cycles=42 days each.
†Continuous phase cycles=28 days each.

Administration of **SARCLISA** (isatuximab-irfc)[9]

Premedication

Administer the following premedications prior to SARCLISA infusion to reduce the risk and severity of infusion-related reactions (IRRs).

Dexamethasone	When administered in combination with SARCLISA and carfilzomib: 20 mg (IV on the days of SARCLISA and/or carfilzomib infusions, PO on Day 22 in Cycle 2 and beyond, and PO on Day 23 in all cycles) When administered in combination with SARCLISA and pomalidomide: 40 mg PO or IV (or 20 mg PO or IV for patients ≥75 years of age) When administered in combination with SARCLISA, bortezomib, and lenalidomide: 20 mg (IV on the days of SARCLISA infusions, PO on the other days)
Acetaminophen	650 mg to 1,000 mg PO (or equivalent)
H_2 antagonists	Institution-preferred agent
Diphenhydramine	25 mg to 50 mg PO or IV (or equivalent). The IV route is preferred for at least the first 4 infusions

The above recommended dose of dexamethasone (PO or IV) corresponds to the total dose to be administered only once before infusion as part of the premedication and part of the backbone treatment. Administer dexamethasone before SARCLISA and pomalidomide, before SARCLISA and carfilzomib, and before SARCLISA, bortezomib, and lenalidomide administration.

Administer the recommended premedication agents 15 to 60 minutes prior to starting a SARCLISA infusion. No post-infusion medications are required for SARCLISA.

Infusion rates of SARCLISA administration

Infusion times decrease to 75 minutes after the second infusion in the absence of IRRs

Calculate the dose (mg) of required SARCLISA based on actual patient weight (measured prior to each cycle to have the administered dose adjusted accordingly). Note that more than 1 SARCLISA vial may be necessary to obtain the required dose for the patient.

Incremental escalation of the infusion rate should be considered only in the absence of IRRs.

	Dilution volume	Initial rate	Absence of IRR	Rate increment	Maximum rate	Total time (if no rate adjustments)
First infusion	250 mL	25 mL/h	For 60 min	25 mL/h every 30 min	150 mL/h	**3 h 20 min**
Second infusion	250 mL	50 mL/h	For 30 min	50 mL/h for 30 min, then increase by 100 mL/h	200 mL/h	**1 h 53 min**
Subsequent infusions	250 mL	200 mL/h	–	–	200 mL/h	**75 min**

SARCLISA should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage IRRs if they occur.

IV, intravenous; Kd, carfilzomib and dexamethasone; PO, by mouth; Rd, lenalidomide and dexamethasone; VRd, bortezomib, lenalidomide, and dexamethasone.

Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

Hypersensitivity and Other Administration Reactions—SARCLISA ESCENA (cont'd)

Injection Site Reactions (cont'd)

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.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

SARCLISA®
(isatuximab-irfc)
Injection for intravenous use
500 mg/25 mL, 100 mg/5 mL

Ordering SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™ and SARCLISA (isatuximab-irfc)

Specialty distributors

SARCLISA ESCENA with CirCLIQ and SARCLISA are available from the following authorized specialty distributors:

ASD Healthcare
1.800.746.6273
asdhealthcare.com
Part of AmerisourceBergen Specialty Distribution

Cardinal Health Specialty Distribution
1.866.677.4844
specialtyonline.cardinalhealth.com

McKesson Plasma and Biologics
1.877.625.2566
connect.mckesson.com

McKesson Specialty Health
1.800.482.6700
mckesson.com/specialty/oncology

Morris & Dickson
1.800.388.3833
morrisdickson.com

Oncology Supply
1.800.633.7555
oncologysupply.com
Part of AmerisourceBergen Specialty Distribution

Specialty pharmacies

SARCLISA ESCENA with CirCLIQ and SARCLISA are available for the dispensing process from the following authorized specialty pharmacies:

Biologics
1.800.850.4306
1.800.823.4506
biologics.mckesson.com

CVS Specialty
1.800.799.0251
1.855.296.0210
cvsspecialty.com

For additional details or product return inquiries, please contact your Sanofi Key Account Manager.

Please see Important Safety Information throughout and full Prescribing Information for SARCLISA and SARCLISA ESCENA.

SARCLISA ESCENA™ (isatuximab-irfc) with CirCLIQ™ and SARCLISA® (isatuximab-irfc) patient support

Together, we can help patients at every step of their treatment journey

CareASSIST® is Sanofi's support program for patients prescribed SARCLISA ESCENA and SARCLISA. Once the patient is enrolled in **CareASSIST**, they're matched with a dedicated Case Manager. Case Managers are experts in the oncology access space and are deeply knowledgeable about the types of resources available to patients. They'll work with patients one-on-one to provide a tailored, personalized support experience.

Once enrolled in **CareASSIST**, patients will be paired with a Case Manager who will provide individualized guidance. Case Managers are trained to assist across the full spectrum of nonclinical support.

They will work closely with the patient to:

- Guide patients through the insurance process and their benefits
- Connect patients with resources that provide emotional, logistical, and health-related support
- Help eligible patients with commercial insurance **pay as little as $0*** out of pocket through the **CareASSIST Copay Program**
- Support eligible patients who are uninsured or lack coverage receive their medication at no cost† through the **CareASSIST Patient Assistance Program**
- Identify other financial assistance programs that may be able to help with treatment costs

Want more information or additional resources?

Give one of our Case Managers a call at **1-833-WE+CARE (1-833-930-2273)**, Monday through Friday, 9 am to 6 pm ET.

You can also visit **SanofiCareASSIST.com** to learn more.

***Important Notice:** Prescription must be for an approved indication. Not valid for prescriptions covered by or submitted for reimbursement, in whole or in part, under Medicare, Medicaid, VA, DoD, TRICARE®, or similar federal or state programs including any state pharmaceutical assistance programs. Not valid where prohibited by law. This offer is nontransferable, limited to one per person, and cannot be combined with any other offer or discount. Any savings provided by the program may vary depending on patients' out-of-pocket costs. Sanofi reserves the right to modify or discontinue the program at any time without notice. All program details provided upon registration.

†Free product is provided by Sanofi Cares North America (SCNA), a charitable organization of Sanofi under Section 501(c)(3) of the IRC.

DoD, US Department of Defense; VA, US Department of Veteran's Affairs.

Enroll your patient — Tap the button to activate personalized support from **CareASSIST**

SARCLISA® (isatuximab-irfc) Injection for intravenous use 500 mg/25 mL, 100 mg/5 mL

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

careASSIST® Sanofi Support

Indications for SARCLISA (isatuximab-irfc) and SARCLISA ESCENA (isatuximab-irfc)

- SARCLISA and SARCLISA ESCENA are 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)
- SARCLISA and SARCLISA ESCENA are indicated 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
- SARCLISA is indicated in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- SARCLISA ESCENA is indicated 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 for SARCLISA and SARCLISA ESCENA

CONTRAINDICATIONS—SARCLISA and SARCLISA ESCENA

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

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA

Infusion-Related Reactions—SARCLISA

SARCLISA can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening and fatal outcomes have been reported. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), infusion-related reactions occurred in 206 patients (35%). Among these 206 patients, 92% experienced infusion-related reactions during the first infusion and 12% after the first cycle.

The most common symptoms (≥5%) of an infusion-related reaction included dyspnea and cough. Grade 1 infusion-related reactions were reported in 6% of patients, grade 2 in 28%, and grade 3 or 4 in 1.2%. Anaphylactic reactions occurred in less than 1% of patients. The total incidence of SARCLISA infusion interruptions was less than 1% and the incidence of patients with at least one SARCLISA infusion interruption due to infusion-related reactions was 26%. The median time to first SARCLISA infusion interruption was 61 minutes (range 4 to 240 minutes). SARCLISA was discontinued in 1% of patients due to infusion-related reactions. To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, H_2 antagonists, diphenhydramine or equivalent, and dexamethasone.

Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade ≥2 reactions, interrupt SARCLISA infusion and provide appropriate medical management. For patients with grade 2 or grade 3 reactions, if symptoms improve to grade ≤1, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients. If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally. In case symptoms do not improve to grade ≤1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medications, or require hospitalization, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if an anaphylactic reaction or life-threatening (grade 4) IRR occurs and institute appropriate management.

Hypersensitivity and Other Administration Reactions—SARCLISA ESCENA

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.

Infections—SARCLISA and SARCLISA ESCENA

SARCLISA and SARCLISA ESCENA can cause severe, life-threatening, or fatal infections.

In patients who received SARCLISA at the recommended dose in ICARIA-MM, IKEMA, and IMROZ (N=592), serious infections, including opportunistic infections, occurred in 46%, grade 3 or 4 infections occurred in 43%, and fatal infections occurred in 4.7%. The most common serious infection reported was pneumonia (32%).

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 or SARCLISA ESCENA should be closely monitored for signs and symptoms of infection prior to and during treatment and appropriate standard therapy instituted. Administer prophylactic antimicrobials according to guidelines. Antibacterial and antiviral prophylaxis (such as herpes zoster prophylaxis) should be considered during treatment.

Neutropenia—SARCLISA and SARCLISA ESCENA

SARCLISA may cause neutropenia.

In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), neutropenia based on laboratory values occurred in 81%, with grade 3 or 4 occurring in 52%. Neutropenic infections occurred in 12% of patients, with grade 3 or 4 in 4.9%, and febrile neutropenia in 4%.

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. If needed, use antibacterial and antiviral prophylaxis during treatment. Monitor patients with neutropenia for signs of infection. In case of grade 4 neutropenia, delay SARCLISA or delay or omit SARCLISA ESCENA dose until neutrophil count recovery to at least 1 x 10^9/L, and provide supportive care with growth factors, according to institutional guidelines. No dose reductions are recommended.

Second Primary Malignancies—SARCLISA and SARCLISA ESCENA

The incidence of second primary malignancies, during treatment and post-treatment, is increased in patients treated with SARCLISA-containing regimens. In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), second primary malignancies occurred in 71 patients (12%).

In ICARIA-MM, at a median follow-up time of 52 months, second primary malignancies occurred in 7% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa + Pd) and in 2% of patients treated with Pd.

In IKEMA study, at a median follow-up time of 57 months, second primary malignancies occurred in 10% of patients treated with SARCLISA, carfilzomib, and dexamethasone (Isa + Kd) and in 8% of patients treated with Kd.

In IMROZ study, at a median follow-up time of 60 months, second primary malignancies occurred in 16% of patients treated with SARCLISA, bortezomib, lenalidomide, and dexamethasone (Isa + VRd) and in 9% of patients treated with VRd.

The most common (≥1%) second primary malignancies in ICARIA-MM, IKEMA, and IMROZ (N=592) included skin cancers (7% with SARCLISA-containing regimens and 3.1% with comparative regimens) and solid tumors other than skin cancer (4.6% with SARCLISA-containing regimens and 2.9% with comparative regimens). Patients with non-melanoma skin cancer continued treatment after resection of the skin cancer, except 2 patients in the Isa + VRd arm and 1 patient in the VRd arm of the IMROZ study.

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.

SARCLISA® (isatuximab-irfc)
Injection for intravenous use
500 mg/25 mL, 100 mg/5 mL

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

Important Safety Information for SARCLISA and SARCLISA ESCENA (cont'd)

WARNINGS AND PRECAUTIONS—SARCLISA and SARCLISA ESCENA (cont'd)

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. This interference can impact the accuracy of the determination of complete response in some patients with IgG kappa myeloma 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—SARCLISA and SARCLISA ESCENA

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—SARCLISA

In combination with pomalidomide and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infection, infusion-related reactions, pneumonia, and diarrhea. The most common hematology laboratory abnormalities (≥80%) were decreased hemoglobin, decreased neutrophils, decreased lymphocytes, and decreased platelets.

In combination with carfilzomib and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infection, infusion-related reactions, fatigue, hypertension, diarrhea, pneumonia, dyspnea, insomnia, bronchitis, cough, and back pain. The most common hematology laboratory abnormalities (≥80%) were decreased hemoglobin, decreased lymphocytes, and decreased platelets.

In combination with bortezomib, lenalidomide, and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infections, diarrhea, fatigue, peripheral sensory neuropathy, pneumonia, musculoskeletal pain, cataract, constipation, peripheral edema, rash, infusion-related reaction, insomnia, and COVID-19. The most common hematologic laboratory abnormalities (≥80%) were decreased hemoglobin, decreased leukocytes, decreased lymphocytes, decreased platelets, and decreased neutrophils.

Serious adverse reactions occurred in 62% of patients receiving Isa-IV + Pd. Serious adverse reactions in >5% of patients who received Isa-IV + Pd included pneumonia (26%), upper respiratory tract infections (7%), and febrile neutropenia (7%). Fatal adverse reactions occurred in 11% of patients (those that occurred in more than 1% of patients were pneumonia and other infections [3%]).

Serious adverse reactions occurred in 59% of patients receiving Isa-IV + Kd. The most frequent serious adverse reactions in >5% of patients who received Isa-IV + Kd were pneumonia (25%) and upper respiratory tract infections (9%). Adverse reactions with a fatal outcome during treatment were reported in 3.4% of patients in the Isa-IV + Kd group (those occurring in more than 1% of patients were pneumonia occurring in 1.7% and cardiac failure in 1.1% of patients).

Serious adverse reactions occurred in 71% of patients receiving Isa-IV + VRd. The serious adverse reaction in >5% of patients who received Isa-IV + VRd was pneumonia (30%). Fatal adverse reactions occurred in 11% of patients with Isa-IV + VRd (those occurring in more than 1% of patients were pneumonia [5%]).

ADVERSE REACTIONS—SARCLISA ESCENA

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—SARCLISA and SARCLISA ESCENA

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

The combination of SARCLISA or 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 and for 7 months after the last dose.

Please see accompanying full Prescribing Information for SARCLISA and SARCLISA ESCENA.

SARCLISA® (isatuximab-irfc)
Injection for intravenous use
500 mg/25 mL, 100 mg/5 mL

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

References: 1. SARCLISA ESCENA [prescribing information]. Morristown, NJ: sanofi-aventis U.S. LLC. **2.** 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 **3.** SEER. Accessed March 13, 2026. seer.cancer.gov/oncologytoolbox/canmed/hcpcs/1271/ **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 **7.** Centers for Medicare & Medicaid Services. Accessed January 13, 2026. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf **8.** Centers for Medicare & Medicaid Services. Accessed January 13, 2026. https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450 **9.** SARCLISA [prescribing information]. Morristown, NJ: sanofi-aventis U.S. LLC. **10.** Centers for Disease Control and Prevention. June 7, 2024. Accessed January 2, 2026. https://www.cdc.gov/nchs/icd/icd-10-cm/index.html **11.** Centers for Medicare & Medicaid Services. July 31, 2020. Accessed January 2, 2026. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf **12.** Codify by AAPC. Accessed January 20, 2026. https://www.aapc.com/codes/cpt-codes/96413 **13.** Codify by AAPC. Accessed January 20, 2026. https://www.aapc.com/codes/cpt-codes/96415

sanofi

SARCLISA®
(isatuximab-irfc)
Injection for intravenous use
500 mg/25 mL, 100 mg/5 mL

SARCLISA ESCENA™
(isatuximab-irfc)
Injection for subcutaneous use
1,400 mg/10 mL

FOR USE WITH CirCLIQ™ On-Body Delivery System