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

SARCLISA® (isatuximab-irfc) Billing and Coding Guide

Your guide to access and reimbursement

The information provided in this reimbursement guide is valid as of September 2024 and is subject to change.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

sanofi

Introduction

This guide provides billing, coding, and reimbursement information for SARCLISA. 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, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. 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 payer. Sanofi provides no guarantee that codes will be appropriate or that reimbursement will be made. Please consult the payer organization for reimbursement, billing, and coding guidance

Indication

SARCLISA (isatuximab-irfc) 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
- 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 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)

Important Safety Information

CONTRAINDICATIONS

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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

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Billing and coding*

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[1]

10-digit NDC	11-digit NDC[0]	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 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

FDA, US Food and Drug Administration; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

HCPCS code[3]

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[4]

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

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; IV, intravenous.

Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Serious infusion-related reactions (IRRs), including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

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SARCLISA® (isatuximab-irfc)
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CMS sample forms

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

Important Safety Information

WARNINGS AND PRECAUTIONS

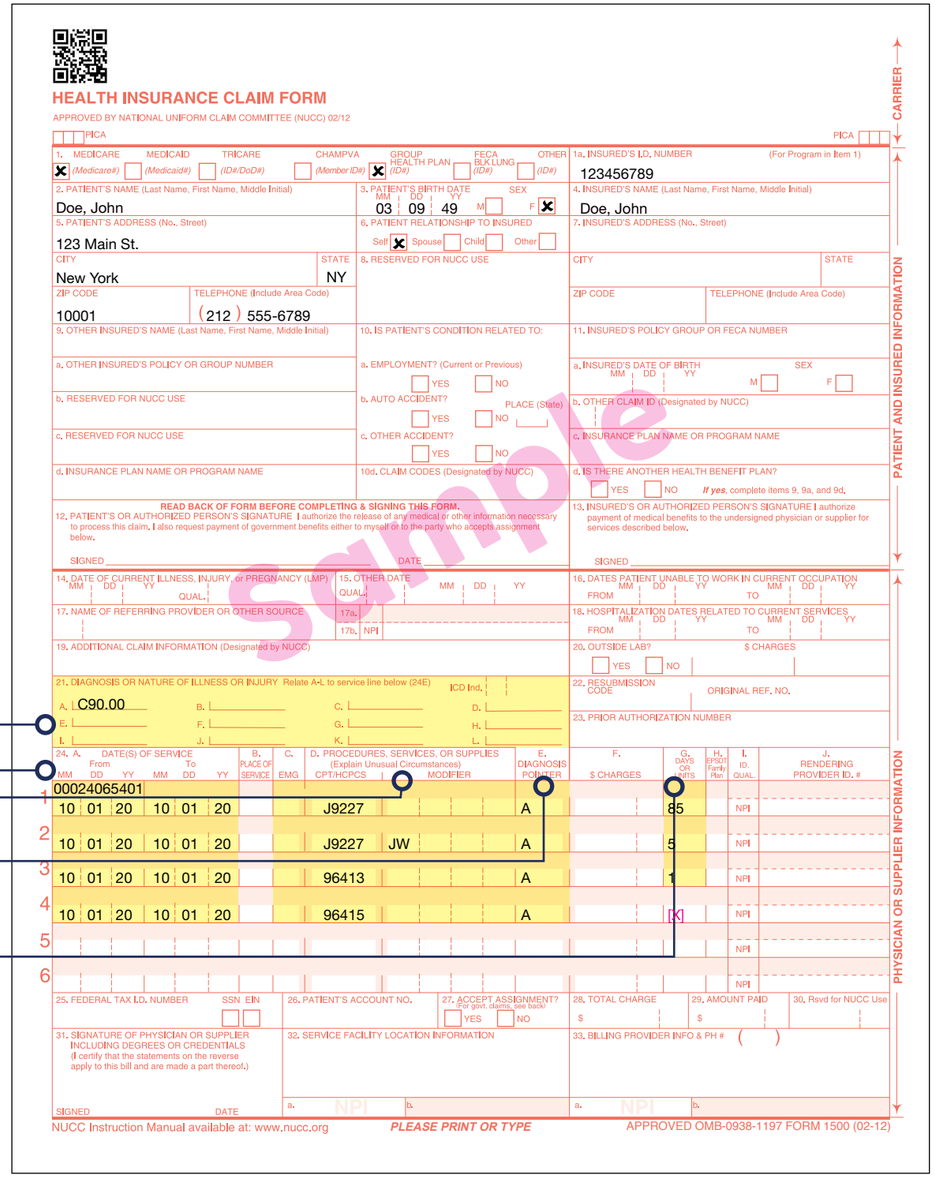
Infusion-Related Reactions (cont'd)

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 additional Important Safety Information throughout and accompanying full Prescribing Information.

CMS-1500 sample[6]
Physician office form



HEALTH INSURANCE CLAIM FORM

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

PICA — PICA — CARRIER

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

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 123456789

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE (MM DD YY)	SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Doe, John	03 09 49	M ☐ F ☒	Doe, John

5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., Street)
123 Main St.	Self ☒ Spouse ☐ Child ☐ Other ☐	

CITY	STATE	8. RESERVED FOR NUCC USE	CITY	STATE
New York	NY			

ZIP CODE	TELEPHONE (Include Area Code)	ZIP CODE	TELEPHONE (Include Area Code)
10001	(212) 555-6789		

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
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) YES ☐ NO ☐	a. INSURED'S DATE OF BIRTH (MM DD YY) SEX M ☐ F ☐
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? YES ☐ NO ☐ PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? YES ☐ NO ☐	c. INSURANCE PLAN NAME OR PROGRAM NAME
d. INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES ☐ NO ☐ *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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 either to myself or to the party who accepts assignment below. SIGNED ____ DATE ____

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

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) (MM DD YY) QUAL.	15. OTHER DATE QUAL. (MM DD YY)	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (MM DD YY) FROM TO
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a. 17b. NPI	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (MM DD YY) FROM TO
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? YES ☐ NO ☐ $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. A. C90.00 B. C. D. E. F. G. H. I. J. K. L.		22. RESUBMISSION CODE ORIGINAL REF. NO.
		23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From (MM DD YY) To (MM DD YY)	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 00024065401										
10 01 20 10 01 20			J9227		A		85		NPI	
2 10 01 20 10 01 20			J9227	JW	A		5		NPI	
3 10 01 20 10 01 20			96413		A		1		NPI	
4 10 01 20 10 01 20			96415		A		[X]		NPI	
5									NPI	
6									NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN	26. PATIENT'S ACCOUNT NO.	27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES ☐ NO ☐	28. TOTAL CHARGE $	29. AMOUNT PAID $	30. Rsvd 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.) SIGNED DATE	32. SERVICE FACILITY LOCATION INFORMATION a. NPI b.		33. BILLING PROVIDER INFO & PH # ( ) a. NPI b.		

PHYSICIAN OR SUPPLIER INFORMATION — PATIENT AND INSURED INFORMATION

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

Sample

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 IV use | 500 mg/25 mL, 100 mg/5 mL

CMS sample forms (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

Important Safety Information

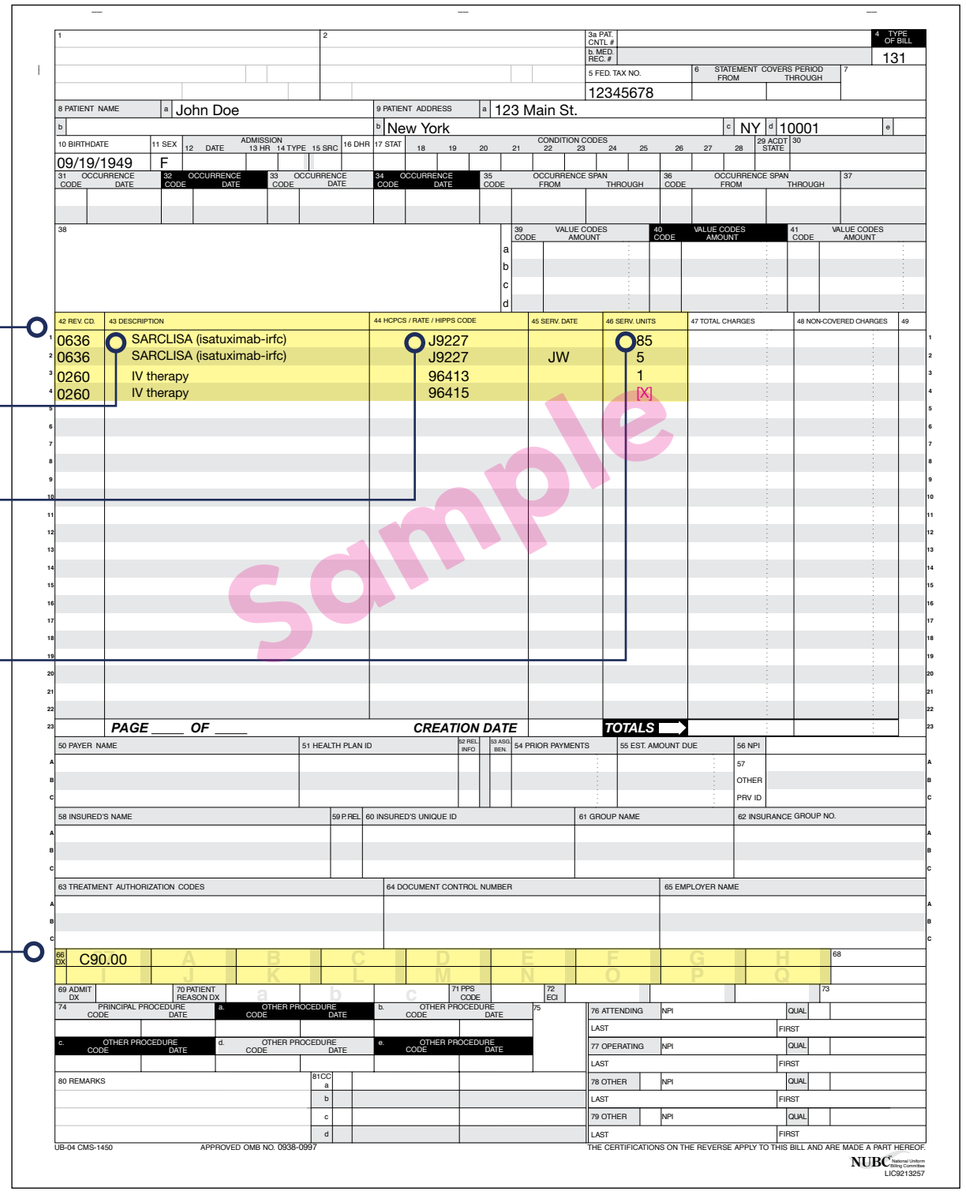
WARNINGS AND PRECAUTIONS

Infusion-Related Reactions (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 additional Important Safety Information throughout and accompanying full Prescribing Information.

CMS-1450 (UB-04) sample[7]
Hospital outpatient form



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.

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Dose and infusion times for SARCLISA

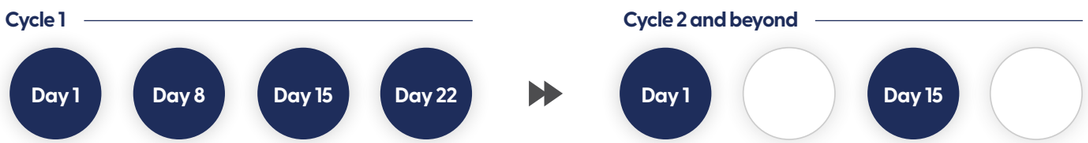
Recommended dose[1]

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

Dosing Schedule[1]

RRMM schedule:

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

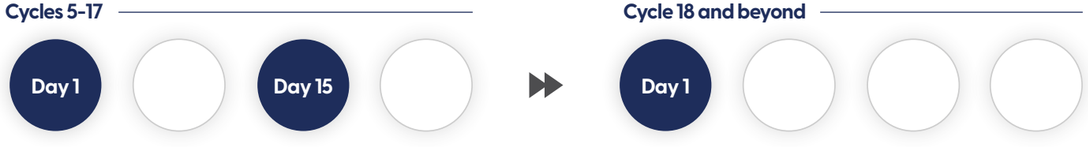


On days where both SARCLISA and carfilzomib are administered, administer dexamethasone first, followed by SARCLISA infusion, then followed by carfilzomib infusion. For dosing instructions for combination agents administered with SARCLISA, refer to the study design descriptions in the SARCLISA Prescribing Information and the respective manufacturer's Prescribing Information.

NDMM schedule:

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

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.

Administration of SARCLISA

Premedication[1]

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, orally on day 22 in cycle 2 and beyond, and orally on day 23 in all cycles) When administered in combination with SARCLISA and pomalidomide: 40 mg orally or IV (or 20 mg orally 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, orally on the other days)
Acetaminophen	650 mg to 1,000 mg orally (or equivalent)
H_2 antagonists	Institution-preferred agent
Diphenhydramine	25 mg to 50 mg orally or IV (or equivalent). The IV route is preferred for at least the first 4 infusions

The above recommended dose of dexamethasone (orally 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.

Infusion rates of SARCLISA administration[1]

Infusion times decrease to 75 minutes after the second infusion in the absence of IRRs[1]

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; Rd, lenalidomide, dexamethasone.

Important Safety Information

WARNINGS AND PRECAUTIONS

Infections

SARCLISA 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%).

Monitor patients for signs and symptoms of infection prior to and during treatment with SARCLISA and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

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Ordering SARCLISA® (isatuximab-irfc)

Specialty distributors

SARCLISA is 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 is 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 Sanofi U.S. Trade Customer Support at 1-800-372-6634.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

careASSIST®
Patient Support by Sanofi

Partnering to provide support and resources for your patients

Enroll your patients prescribed SARCLISA in CareASSIST, the comprehensive support program from Sanofi

Each patient will be matched with a Case Manager for individualized support.

Case Managers provide:

Ways to lower out-of-pocket costs for SARCLISA

Access and reimbursement support

Lifestyle and logistical support

Tap the button to activate personalized support from **CareASSIST**

Enroll your patient

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(isatuximab-irfc)
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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

SARCLISA (isatuximab-irfc) 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
- 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 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)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Serious infusion-related reactions (IRRs), including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. 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.

Infections

SARCLISA 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%).

Monitor patients for signs and symptoms of infection prior to and during treatment with SARCLISA and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

Neutropenia

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%.

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 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 of SARCLISA are recommended.

Second Primary Malignancies

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. Monitor patients for the development of second primary malignancies.

Laboratory Test Interference

Interference with Serological Testing (Indirect Antiglobulin Test)

SARCLISA 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 approximately 6 months after the last infusion of SARCLISA. The indirect antiglobulin test was positive during Isa-Pd treatment in 68% of the tested patients, and during Isa-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 SARCLISA treatment.

Before the first SARCLISA infusion, conduct blood type and screen tests on SARCLISA-treated patients. Consider phenotyping prior to starting SARCLISA treatment. If treatment with SARCLISA has already started, inform the blood bank that the patient is receiving SARCLISA and that SARCLISA 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

SARCLISA is an IgG kappa monoclonal antibody that can be incidentally detected on both serum protein electrophoresis and immunofixation assays 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.

Embryo-Fetal Toxicity

Based on the mechanism of action, SARCLISA can cause fetal harm when administered to a pregnant woman. SARCLISA may cause fetal immune cell depletion and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use an effective method of contraception during treatment with SARCLISA and for 5 months after the last dose. The combination of SARCLISA 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%) 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-Pd. Serious adverse reactions in >5% of patients who received Isa-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-Kd. The most frequent serious adverse reactions in >5% of patients who received Isa-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-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-VRd. The serious adverse reaction in >5% of patients who received Isa-VRd was pneumonia (30%). Fatal adverse reactions occurred in 11% of patients with Isa-VRd (those occurring in more than 1% of patients were pneumonia [5%]).

USE IN SPECIAL POPULATIONS

Because of the potential for serious adverse reactions in the breastfed child from isatuximab-irfc administered in combination with pomalidomide or lenalidomide and dexamethasone, advise lactating women not to breastfeed during treatment with SARCLISA.

Please see full Prescribing Information.

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

Please see Important Safety Information throughout and accompanying full Prescribing Information.

References: 1. SARCLISA [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. Accessed September 20, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm **3.** Centers for Medicare & Medicaid Services. CMS HCPCS Application Summaries and Coding Decisions: Second Quarter, 2020 HCPCS Coding Cycle for Drug and Biological Products. Accessed September 20, 2024. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf **4.** American Medical Association. *CPT® 2021 Professional Edition (Current Procedural Terminology).* Chicago, IL: American Medical Association; 2020. **5.** Noridian Healthcare Solutions. Revenue codes. Accessed September 20, 2024. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **6.** Centers for Medicare & Medicaid Services. CMS-1500 form. Accessed September 20, 2024. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf **7.** Centers for Medicare & Medicaid Services. CMS-1450 form. Accessed September 20, 2024. https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450

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