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 August 2022 and is subject to change.

Please see Important Safety Information on pages 14 and 15 and accompanying full Prescribing Information.

sanofi

Introduction

This guide provides billing, coding, and reimbursement information for SARCLISA. This guide 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

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 on pages 14 and 15 and accompanying full Prescribing Information.

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Billing and coding[a]

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[b]	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

NDC=National Drug Code.

[a]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.

[b]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[3c,d]

Effective October 1, 2020, the new SARCLISA HCPCS Level II code J9227 should be used for professional and institutional claims[c]

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

HCPCS=Healthcare Common Procedure Coding System.

[c]The HCPCS Level II code J9227 is effective for Medicare Part B patients starting on October 1, 2020. Please check with commercial and Medicaid resources for the effective date.

[d]The fact that a HCPCS code exists does not imply coverage, only that the product may be reimbursed if covered.

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)

CPT=Current Procedural Terminology.

Revenue codes (for hospital outpatient departments)[5]

Code	Description
0260	IV therapy
0636	Drugs requiring detailed coding

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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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 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[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)
X				X			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 [X]	Doe, John
5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., Street)
123 Main St.	Self [X] 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 MM DD YY
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a. / 17b. NPI	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY
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.		22. RESUBMISSION CODE / ORIGINAL REF. NO.
A. C90.02 B. C. D. / E. F. G. H. / I. J. K. L.		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. #
00024065401										
1 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.

PATIENT AND INSURED INFORMATION — PHYSICIAN OR SUPPLIER INFORMATION

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

Sample

Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions (cont'd)

Based on ICARIA-MM, IRRs occurred in 38% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd). All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases.

In IKEMA, infusion-related reactions occurred in 46% of patients treated with SARCLISA, carfilzomib, and dexamethasone (Isa-Kd). In the Isa-Kd arm, the infusion-related reactions occurred on the infusion day in 99% of episodes. In patients treated with Isa-Kd, 95% of those experiencing an infusion-related reaction experienced it during the first cycle of treatment. All infusion-related reactions resolved: within the same day in 74% of episodes, and the day after in 24% of episodes.

Please see additional Important Safety Information on pages 14 and 15 and accompanying full Prescribing Information.

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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)

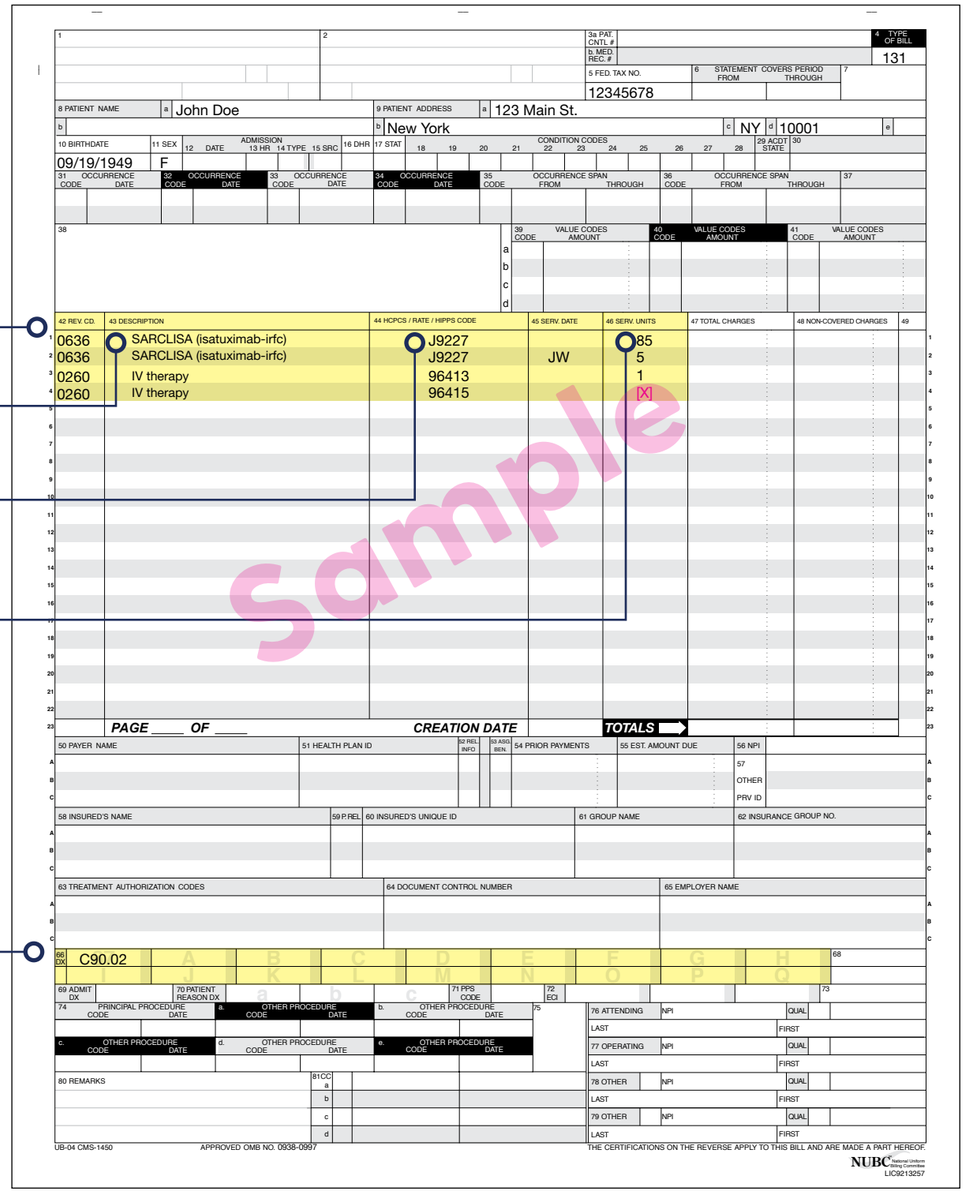
FL 44
Enter J code J9227 and appropriate CPT codes

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 multiple myeloma being treated

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



Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions (cont'd)

The most common symptoms (≥5%) of an infusion-related reaction in ICARIA-MM and IKEMA (N=329) included dyspnea, cough, nasal congestion, and nausea. Anaphylactic reactions occurred in less than 1% of patients. 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 on pages 14 and 15 and accompanying full Prescribing Information.

Dose and infusion times for SARCLISA

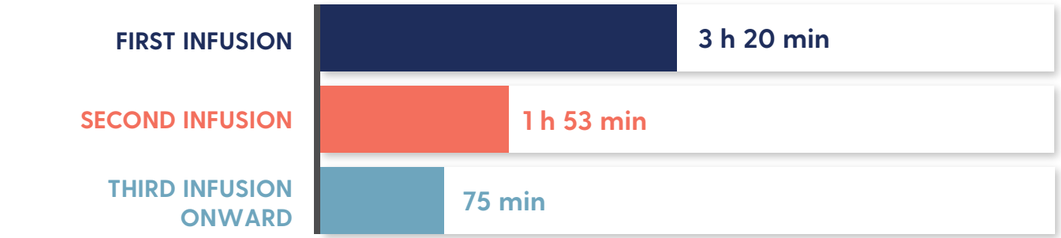
Recommended dose[1]

- 10 mg/kg actual body weight administered as an IV infusion in combination with carfilzomib and dexamethasone or in combination with pomalidomide and dexamethasone
- 250-mL fixed infusion volume
- Premedication should be administered 15 to 60 minutes prior to infusion of SARCLISA
- Treatment is repeated until disease progression or unacceptable toxicity

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

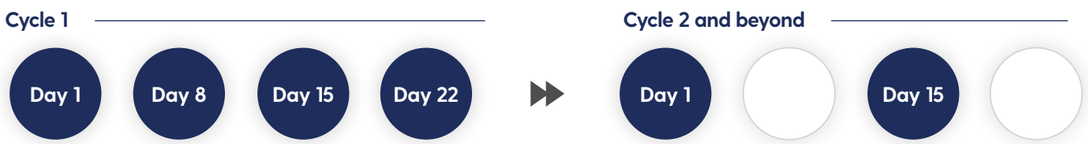
Calculated infusion times

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



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.

Administration of SARCLISA

Premedication[1]

Administer the following premedications prior to SARCLISA infusion to reduce the risk and severity of 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)
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 of the backbone treatment, before SARCLISA and carfilzomib or SARCLISA and pomalidomide administration.

Administer the recommended premedication agents 15 to 60 minutes prior to starting a SARCLISA infusion.

Infusion rates of SARCLISA administration[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 one 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.

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.

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Ordering SARCLISA® (isatuximab-irfc)

Specialty distributors

SARCLISA is available from the following authorized specialty distributors:

ASD Healthcare
Phone: **1.800.746.6273**
Web: **asdhealthcare.com**

Oncology Supply
Phone: **1.800.633.7555**
Web: **oncologysupply.com**

Cardinal Health Specialty Distribution
Phone: **1.866.677.4844**
Web: **specialtyonline.cardinalhealth.com**

McKesson Plasma and Biologics
Phone: **1.877.625.2566**
Web: **connect.mckesson.com**

McKesson Specialty Health
Phone: **1.800.482.6700**
Web: **oncology.mckessonspecialtyhealth.com**

Specialty pharmacies

SARCLISA is available for the dispensing process from the following authorized specialty pharmacies:

Biologics
Phone: **1.800.850.4306**
Fax: **1.800.823.4506**
Web: **biologicsinc.com**

CVS Specialty
Phone: **1.800.799.0251**
Fax: **1.855.296.0210**
Web: **cvsspecialty.com**

Product returns

For information about product returns or to file a product complaint, please contact CareASSIST.

For questions regarding SARCLISA distribution and acquisition or product returns, please contact CareASSIST by phone at 1-833-WE+CARE (1-833-930-2273), Monday through Friday, 9 AM to 8 PM ET or by fax at 1-855-411-9689.

Please see additional Important Safety Information on pages 14 and 15 and accompanying full Prescribing Information.

CareASSIST by Sanofi for SARCLISA

We are committed to helping remove barriers for eligible patients and caregivers as they navigate their treatment journey

Access and Reimbursement
Assistance navigating the insurance process, including benefits investigations, claims assistance, and information about prior authorizations and appeals.

Financial Assistance
CareASSIST offers programs and services that can help eligible patients with the cost of SARCLISA.

Resource Support
Information on independent support services for patients and caregivers, as well as product ordering and replacement information.

If your patients have commercial insurance, they may qualify for the CareASSIST Copay Program[a]

[a]IMPORTANT NOTICE: Not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, TRICARE, or similar federal or state programs including any state pharmaceutical assistance programs. Not valid where prohibited by law. Sanofi reserves the right to modify or discontinue the programs at any time. All program details provided upon registration. Please visit sarclisahcp.com for more information.

Call **1-833-WE+CARE (1-833-930-2273)**, Mon – Fri, 9 AM – 8 PM ET, or visit **SanofiCareASSIST.com/hcp/Sarclisa** to learn more.

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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

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.

Based on ICARIA-MM, IRRs occurred in 38% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd). All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases.

In IKEMA, infusion-related reactions occurred in 46% of patients treated with SARCLISA, carfilzomib, and dexamethasone (Isa-Kd). In the Isa-Kd arm, the infusion-related reactions occurred on the infusion day in 99% of episodes. In patients treated with Isa-Kd, 95% of those experiencing an infusion-related reaction experienced it during the first cycle of treatment. All infusion-related reactions resolved: within the same day in 74% of episodes, and the day after in 24% of episodes.

The most common symptoms (≥5%) of an infusion-related reaction in ICARIA-MM and IKEMA (N=329) included dyspnea, cough, nasal congestion, and nausea. Anaphylactic reactions occurred in less than 1% of patients. 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.

Neutropenia

SARCLISA may cause neutropenia.

In patients treated with Isa-Pd, neutropenia occurred in 96% of patients and grade 3-4 neutropenia occurred in 85% of patients. Neutropenic complications occurred in 30% of patients, including febrile neutropenia (12%) and neutropenic infections (25%), defined as infection with concurrent grade ≥3 neutropenia. The most frequent neutropenic infections included infections of the upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%).

In patients treated with Isa-Kd, neutropenia occurred in 55% of patients, with grade 3-4 neutropenia in 19% of patients (grade 3 in 18% and grade 4 in 1.7%). Neutropenic complications occurred in 2.8% of patients, including febrile neutropenia (1.1%) and neutropenic infections (1.7%).

Monitor complete blood cell counts periodically during treatment. Consider the use of antibiotics 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 1.0 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 is increased in patients treated with SARCLISA-containing regimens. The overall incidence of second primary malignancies in all the SARCLISA-exposed patients was 3.6%.

In ICARIA-MM, second primary malignancies occurred in 3.9% of patients in the Isa-Pd arm and in 0.7% of patients in the Pd arm.

In IKEMA, second primary malignancies occurred in 7% of patients in the Isa-Kd arm and in 4.9% of patients in the Kd arm.

The most common (≥1%) second primary malignancies in ICARIA-MM and IKEMA (N=329) included skin cancers (4% with SARCLISA-containing regimens and 1.5% with comparative regimens) and solid tumors other than skin cancer (1.8% with SARCLISA-containing regimens and 1.5% with comparative regimens). All patients with skin cancer continued treatment after resection of the skin cancer.

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). 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 is contraindicated in pregnant women because pomalidomide may cause birth defects and death of the unborn child. Refer to the pomalidomide 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.

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).

USE IN SPECIAL POPULATIONS

Because of the potential for serious adverse reactions in the breastfed child from isatuximab-irfc administered in combination with Pd, 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

CareASSIST®
Patient Support by Sanofi

We are committed to helping remove barriers for eligible patients and caregivers as they navigate their treatment journey.

For more information, please visit **www.SanofiCareASSIST.com/hcp/Sarclisa** or call **1-833-WE+CARE (1-833-930-2273)**, Monday through Friday, 9 AM to 8 PM ET.

Please see Important Safety Information on pages 14 and 15 and accompanying full Prescribing Information.

References: 1. SARCLISA [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC. **2.** Centers for Medicare & Medicaid Services. 2021 ICD-10-CM. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm. Accessed March 30, 2021. **3.** Centers for Medicare & Medicaid Services. HCPCS Release & Code Sets: 2021. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed March 30, 2021. **4.** American Medical Association (AMA). *CPT® 2020 Professional Edition (Current Procedural Terminology)*. Chicago, IL: American Medical Association; 2020. **5.** Noridian Healthcare Solutions. Revenue codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Accessed March 30, 2021. **6.** Centers for Medicare & Medicaid Services. CMS-1500 form. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf. Accessed March 30, 2021. **7.** Centers for Medicare & Medicaid Services CMS-1450 form. https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450. Accessed March 30, 2021.

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