The information provided in this reimbursement guide is valid as of April 2020 and is subject to change.

Please see Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.
**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 for informational purposes only and is not intended to provide reimbursement or legal advice. Please consult your 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 two prior therapies including lenalidomide and a proteasome inhibitor.

**CONTRAINDICATIONS**

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

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Please see additional Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.
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 codes

<table>
<thead>
<tr>
<th>10-digit NDC</th>
<th>11-digit NDC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0024-0654-01</td>
<td>00024-0654-01</td>
<td>100 mg/5 mL single-dose vial</td>
</tr>
<tr>
<td>0024-0656-01</td>
<td>00024-0656-01</td>
<td>500 mg/25 mL single-dose vial</td>
</tr>
</tbody>
</table>

NDC=National Drug Code

*Payer requirements for 10- or 11-digit NDC code use and format may vary. Please verify requirements prior to use.

### HCPCS codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
<tr>
<td>J9999</td>
<td>Not otherwise classified, antineoplastic drugs (chemotherapy drug)</td>
</tr>
</tbody>
</table>

HCPCS=Healthcare Common Procedure Coding System.

These HCPCS codes are temporary and will be replaced by permanent J-codes as soon as they are available.

**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

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


### ICD-10-CM diagnosis codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C90.0X</td>
<td>Multiple myeloma</td>
</tr>
<tr>
<td>C90.00</td>
<td>Multiple myeloma not having achieved remission</td>
</tr>
<tr>
<td>C90.01</td>
<td>Multiple myeloma in remission</td>
</tr>
<tr>
<td>C90.02</td>
<td>Multiple myeloma in relapse</td>
</tr>
</tbody>
</table>

Important Safety Information

**WARNINGS AND PRECAUTIONS**

**Infusion-Related Reactions**

Infusion-related reactions (IRRs) have been observed in 39% of patients treated with SARCLISA. All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases. The most common symptoms of an IRR included dyspnea, cough, chills, and nausea. The most common severe signs and symptoms included hypertension and dyspnea.

Please see additional Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.
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 19
Provide any required detailed information such as drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement (attach separately if needed)

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 the relevant HCPCS (J-code) and 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 billing units using the conversion of 1 mg = 1 billing unit

Important Safety Information
WARNINGS AND PRECAUTIONS
Infusion-Related Reactions (cont’d)
To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, H2 antagonists, diphenhydramine or equivalent, and dexamethasone. Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade 1 or 2 reactions, interrupt SARCLISA infusion and provide appropriate medical support. If symptoms improve, restart SARCLISA infusion at half of the initial 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 or recur after interruption, permanently discontinue SARCLISA and institute appropriate emergency medical management. Permanently discontinue SARCLISA if a grade 3 or higher IRR occurs and institute appropriate emergency medical management.

Please see additional Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.
Frequent neutropenic infections included those of upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%).

The most frequent neutropenic infections included those of upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%). The most frequent neutropenic infections included those of upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%).

Please see additional Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.
Dosing information

**Recommended dose and schedule**

Administer pre-infusion medications. The recommended dose of SARCLISA is 10 mg/kg actual body weight administered as an IV infusion in combination with Pd. SARCLISA is given as a 250-mL fixed-volume infusion. No dose reduction of SARCLISA is recommended.

**Weekly dosing for first cycle, followed by every other week for subsequent cycles**

<table>
<thead>
<tr>
<th>First cycle</th>
<th>Subsequent cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Day 1</td>
</tr>
<tr>
<td>Day 8</td>
<td>Day 15</td>
</tr>
<tr>
<td>Day 15</td>
<td>Day 1</td>
</tr>
</tbody>
</table>

- In the clinical trial, pomalidomide 4 mg was taken orally once daily from day 1 to day 21 of each 28-day cycle. Low-dose dexamethasone (orally or IV) 40 mg (20 mg for patients ≥75 years of age) was given on days 1, 8, 15, and 22 for each 28-day cycle
- Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.
- If a planned dose of SARCLISA is missed, administer the dose as soon as possible and adjust the treatment schedule accordingly, maintaining the treatment interval

**Pre-infusion medications**

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

- Dexamethasone 40 mg orally or IV (or 20 mg for patients ≥75 years of age)
- Acetaminophen 650 mg to 1000 mg orally (or equivalent)
- H₂ antagonists
- 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 pomalidomide administration. Administer the recommended premedication agents 15 to 60 minutes prior to starting a SARCLISA infusion.

<table>
<thead>
<tr>
<th>Infusion rates</th>
<th>Dilution Volume</th>
<th>Initial Rate</th>
<th>Absence of IR</th>
<th>Rate Increment</th>
<th>Maximum Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Infusion</td>
<td>250 mL</td>
<td>25 mL/hour</td>
<td>For 60 min</td>
<td>25 mL/hour every 30 min</td>
<td>150 mL/hour</td>
</tr>
<tr>
<td>Second Infusion</td>
<td>250 mL</td>
<td>50 mL/hour</td>
<td>For 30 min</td>
<td>50 mL/hour for 30 min then increase by 100 mL/hour every 30 min</td>
<td>200 mL/hour</td>
</tr>
<tr>
<td>Subsequent Infusion</td>
<td>250 mL</td>
<td>200 mL/hour</td>
<td>–</td>
<td>–</td>
<td>200 mL/hour</td>
</tr>
</tbody>
</table>

Infusion time of 3 hours and 20 minutes decreases to 1 hour and 53 minutes for second infusion and 75 minutes for subsequent infusions in the absence of IRRs or rate adjustments.

**Dose modifications**

No dose reduction of SARCLISA is recommended. Dose delay may be required to allow recovery of blood counts in the event of hematological toxicity. For information concerning drugs given in combination with SARCLISA, see manufacturer’s Prescribing Information.

For other medicinal products that are administered with SARCLISA, refer to the respective current Prescribing Information.

**Important Safety Information**

**WARNINGS AND PRECAUTIONS**

**Neutropenia (cont’d)**

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 10⁹/L, and provide supportive care with growth factors, according to institutional guidelines.

No dose reductions of SARCLISA are recommended.

Please see additional Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.
Ordering SARCLISA® (isatuximab-irfc)

SARCLISA is available from the following authorized specialty distributors:

<table>
<thead>
<tr>
<th>Specialty distributors</th>
<th>Phone</th>
<th>Web</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASD Healthcare</td>
<td>1.800.746.6273</td>
<td>asdhealthcare.com</td>
</tr>
<tr>
<td>Oncology Supply</td>
<td>1.800.633.7555</td>
<td>oncolgyupply.com</td>
</tr>
<tr>
<td>Cardinal Health Specialty Distribution</td>
<td>1.866.677.4844</td>
<td>specialtyonline.cardinalhealth.com</td>
</tr>
<tr>
<td>McKesson Plasma and Biologics</td>
<td>1.877.625.2566</td>
<td>connect.mckesson.com</td>
</tr>
<tr>
<td>McKesson Specialty Health</td>
<td>1.800.482.6700</td>
<td>oncology.mckessonspecialtyhealth.com</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Specialty pharmacies</th>
<th>Phone</th>
<th>Web</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics</td>
<td>1.800.856.1984</td>
<td>biologicsinc.com</td>
</tr>
<tr>
<td>CVS Specialty</td>
<td>1.847.559.4700</td>
<td>cvsspecialty.com</td>
</tr>
<tr>
<td>ASD Healthcare</td>
<td>1.800.746.6273</td>
<td>asdhealthcare.com</td>
</tr>
<tr>
<td>Oncology Supply</td>
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</tr>
<tr>
<td>McKesson Specialty Health</td>
<td>1.800.482.6700</td>
<td>oncology.mckessonspecialtyhealth.com</td>
</tr>
</tbody>
</table>

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, 9:00 AM to 8:00 PM ET or by fax at 1-855-411-9689.

CareASSIST by Sanofi Genzyme for SARCLISA

Resources and support for your eligible patients

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*

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.

*Restrictions may apply. Please visit SanofiCareAssist.com/hcp/Sarclisa for full program details.

Please see Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.
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 two prior therapies including lenalidomide and a proteasome inhibitor.

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
Infusion-related reactions (IRRs) have been observed in 39% of patients treated with SARCLISA. All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases. The most common symptoms of an IRR included dyspnea, cough, chills, and nausea. The most common severe signs and symptoms included hypertension and dyspnea.

To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, H₂ antagonists, diphenhydramine or equivalent, and dexamethasone. Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade 1 or 2 reactions, interrupt SARCLISA infusion and provide appropriate medical support. If symptoms improve, restart SARCLISA infusion at half of the initial 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 or recur after interruption, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if a grade 3 or higher IRR occurs and institute appropriate emergency medical management.

Neutropenia
SARCLISA may cause neutropenia. Neutropenia (reported as laboratory abnormality) occurred in 96% of patients and grade 3-4 neutropenia occurred in 85% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd). Febrile neutropenia occurred in 12% of patients and neutropenic infections, defined as infection with concurrent grade ≥3 neutropenia, occurred in 25% of patients treated with Isa-Pd. The most frequent neutropenic infections included those of upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%).

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 10 x 10⁹/L, and provide supportive care with growth factors, according to institutional guidelines. No dose reductions of SARCLISA are recommended.

Second Primary Malignancies
Second primary malignancies were reported in 3% of patients in the SARCLISA, pomalidomide, and dexamethasone (Isa-Pd) arm and in 0.7% of patients in the pomalidomide and dexamethasone (Pd) arm, and consisted of skin squamous cell carcinoma (2.6% of patients in the Isa-Pd arm and in 0.7% of patients in the Pd arm), breast angiosarcoma (0.7% of patients in the Isa-Pd arm), and myelodysplastic syndrome (0.7% of patients in the Isa-Pd arm). With the exception of the patient with myelodysplastic syndrome, patients were able to continue SARCLISA treatment. Monitor patients for the development of second primary malignancies.

Laboratory Test Interference
Infusion 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). In ICARIA-multiple myeloma (MM), the indirect antiglobulin test was positive during SARCLISA treatment in 67.7% of the tested 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 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 at least 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
The most common adverse reactions (≥20%) were neutropenia (laboratory abnormality, 96% Isa-Pd vs 92% Pd), infusion-related reactions (38% Isa-Pd vs 0% Pd), pneumonia (31% Isa-Pd vs 23% Pd), upper respiratory tract infection (57% Isa-Pd vs 42% Pd), and diarrhea (26% with Isa-Pd vs 19% Pd). Serious adverse reactions occurred in 62% of patients receiving SARCLISA. 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.

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 click here for full Prescribing Information.
The CareASSIST Patient Support Program offers access support for eligible patients prescribed SARCLISA.

For more information, please visit www.sanoficareassist.com/hcp/Sarclisa or call 1-833-WECARE (1-833-930-2273), Monday through Friday, 9:00 AM to 8:00 PM ET.

Please see Important Safety Information on pages 14 and 15 and click here for full Prescribing Information.

References

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