

## Sarclisa® (isatuximab-irfc) (Intravenous)

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### I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- Cycle 1, every week x 4 doses, followed by Cycle 2, and beyond, every 2 weeks
  - Sarclisa 100 mg/5 mL single-dose vial for injection: 4 vials per dose
  - Sarclisa 500 mg/25 mL single dose vial for injection: 2 vials per dose

#### B. Max Units (per dose and over time) [HCPCS Unit]:

- Cycle 1 every week x 4 doses, followed by Cycle 2, and beyond, every 2 weeks
  - 110 billable units per dose

### III. Initial Approval Criteria <sup>1,3,4</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient is not refractory to previous treatment with anti-CD38 therapy (i.e., daratumumab, etc.) *[Note: refractory is defined as progression on or within 60 days after the end of prior anti-CD38 treatment OR failure to achieve at least minimum response to treatment]; AND*

#### Multiple Myeloma † Φ <sup>1-4</sup>

- Patient has relapsed, refractory, or progressive disease; **AND**
  - Used in combination with pomalidomide and dexamethasone after at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.); **OR**
  - Used in combination with carfilzomib and dexamethasone in patients who have received 1 to 3 prior lines therapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, neutropenia, secondary primary malignancies, etc.

#### V. Dosage/Administration <sup>1</sup>

| Indication       | Dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Multiple Myeloma | <p>Combination therapy with pomalidomide and dexamethasone OR carfilzomib and dexamethasone:</p> <ul style="list-style-type: none"><li>▪ 10 mg/kg of actual body weight given as an intravenous infusion:<ul style="list-style-type: none"><li>– Weekly Cycle 1 (four doses total; Days 1, 8, 15, &amp; 22)</li><li>– Every two weeks Cycle 2 and beyond (two doses per cycle; Days 1 &amp; 15)</li></ul></li></ul> <p><i>*Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.</i></p> |

#### VI. Billing Code/Availability Information

HCPCS Code:

- J9227 – Injection, isatuximab-irfc, 10 mg; 1 billable unit = 10 mg

NDC(s):

- Sarclisa 100 mg/5 mL single-dose vial: 00024-0654-xx
- Sarclisa 500 mg/25 mL single-dose vial: 00024-0656-xx

#### VII. References

1. Sarclisa [package insert]. Bridgewater, NJ; Sanofi-Aventis US, LLC; March 2021. Accessed January 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for isatuximab-irfc. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2022.

3. Attal M, Richardson PG, Rajkumar SV, et al. ICARIA-MM study group. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. *Lancet*. 2019 Dec 7;394(10214):2096-2107. doi: 10.1016/S0140-6736(19)32556-5. Epub 2019 Nov 14. Erratum in: *Lancet*. 2019 Dec 7;394(10214):2072.
4. Moreau P, Dimopoulos M, Yong K, et al. Isatuximab plus carfilzomib/dexamethasone versus carfilzomib/dexamethasone in patients with relapsed/refractory multiple myeloma: IKEMA Phase III study design. *Future Oncol*. 2020 Jan;16(2):4347-4358. doi: 10.2217/fo-2019-0431. Epub 2019 Dec 13.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description                                                                           |
|--------|----------------------------------------------------------------------------------------------|
| C90.00 | Multiple myeloma not having achieved remission                                               |
| C90.02 | Multiple myeloma, in relapse                                                                 |
| C90.10 | Plasma cell leukemia not having achieved remission                                           |
| C90.12 | Plasma cell leukemia in relapse                                                              |
| C90.20 | Extramedullary plasmacytoma not having achieved remission                                    |
| C90.22 | Extramedullary plasmacytoma in relapse                                                       |
| C90.30 | Solitary plasmacytoma not having achieved remission                                          |
| C90.32 | Solitary plasmacytoma in relapse                                                             |
| Z85.79 | Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                        |                                                   |
|---------------------------------------------------------------|----------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory          | Contractor                                        |
| E (1)                                                         | CA, HI, NV, AS, GU, CNMI               | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)                                                     | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC                |
| 5                                                             | KS, NE, IA, MO                         | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6                                                             | MN, WI, IL                             | National Government Services, Inc. (NGS)          |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                                                                             |                                                   |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory                                                               | Contractor                                        |
| H (4 & 7)                                                     | LA, AR, MS, TX, OK, CO, NM                                                                  | Novitas Solutions, Inc.                           |
| 8                                                             | MI, IN                                                                                      | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)                                                         | FL, PR, VI                                                                                  | First Coast Service Options, Inc.                 |
| J (10)                                                        | TN, GA, AL                                                                                  | Palmetto GBA, LLC                                 |
| M (11)                                                        | NC, SC, WV, VA (excluding below)                                                            | Palmetto GBA, LLC                                 |
| L (12)                                                        | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)                                                   | NY, CT, MA, RI, VT, ME, NH                                                                  | National Government Services, Inc. (NGS)          |
| 15                                                            | KY, OH                                                                                      | CGS Administrators, LLC                           |

# Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator  
Aspirus Health Plan, Inc.  
PO Box 1890  
Southampton, PA 18966-9998  
Phone: 1-866-631-5404 (TTY: 711)  
Fax: 763-847-4010  
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: [https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim\\_Lang-Assist-Notice.pdf](https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf).

## Language Assistance Services

**Albanian:** KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

**Arabic:** تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

**French:** ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

**German:** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

**Hindi:** यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

**Hmong:** LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

**Korean:** 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

**Polish:** UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

**Russian:** ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

**Spanish:** ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

**Tagalog:** PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

**Traditional Chinese:** 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

**Vietnamese:** CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

**Pennsylvania Dutch:** Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

**Lao:** ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).