I. PURPOSE

To define and describe the accepted indications for Sarclisa (isatuximab-irfc) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Multiple Myeloma (MM)

1. NOTE: The preferred anti-CD38 agent, per NCH Policies, is Darzalex (daratumumab). This recommendation is based on a lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior patient outcomes with Sarclissa (isatuximab-irfc) vs Darzalex (daratumumab). Please see UM ONC_1280 Darzalex and Darzalex Faspro (daratumumab) policy.

2. NOTE: Sarclissa (isatuximab-irfc) use is NOT supported by NCH Policy for members with myeloma/plasma cell dyscrasia, who have experienced disease progression on prior therapy with Darzalex/Darzalex Faspro (daratumumab).

3. Sarclisa (isatuximab-irfc) may be used for members with relapsed or refractory MM who have an intolerance or contraindication to Darzalex (daratumumab) and any of the following:
   a. Sarclisa (isatuximab-irfc) is being used in combination with Pomalyst (pomalidomide) and steroid AND the member has received prior therapy with a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), and an immunomodulatory agent (e.g., lenalidomide, thalidomide) other than Pomalyst (pomalidomide) OR
   b. Sarclisa (isatuximab-irfc) is being used in combination with Kyprolis (carfilzomib) and steroid following 1 prior line of therapy other than Kyprolis (carfilzomib).

III. EXCLUSION CRITERIA

A. Sarclisa (isatuximab-irfc) is being used after disease progression with the same regimen or after disease progression on a daratumumab-based regimen.

B. Dosing exceeds single dose limit of Sarclisa (isatuximab-irfc) 10 mg/kg.

C. Investigational use of Sarclisa (isatuximab-irfc) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
   1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
   2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
   3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
   4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.

6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT
   A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY
   A. Review – Utilization Management Department
   B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS
   A. None

VII. REFERENCES