Drug Policy:

Sylvant™ (siltuximab)

POLICY NUMBER UM ONC_1383	**SUBJECT** Sylvant™ (siltuximab)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 02/12/20, 12/09/20, 11/10/21	**APPROVAL DATE** November 10, 2021	**EFFECTIVE DATE** November 29, 2021	**COMMITTEE APPROVAL DATES** 02/12/20, 12/09/20, 11/10/21	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Sylvant (siltuximab) 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. Idiopathic Multicentric Castleman's Disease (iMCD)

1. The member has active multicentric Castleman's disease and is human immunodeficiency virus-1 (HIV-1) and human herpes virus-8 (HHV-8) NEGATIVE AND Sylvant (siltuximab) will be used as monotherapy.

III. EXCLUSION CRITERIA

A. Sylvant (siltuximab) is being used after disease progression with the same regimen or another interleukin-6 receptor targeted therapy [i.e., Actemra (tocilizumab)].

B. Concurrent use with live vaccines or other anticancer therapies.

C. Dosing exceeds single dose limit of Sylvant (siltuximab) is 11 mg/kg.

D. Investigational use of Sylvant (siltuximab) 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. Attachment A: Criteria for Active Disease

VII. REFERENCES

A. Sylvant prescribing information. EUSA Pharma (UK), Ltd.Hemel Hempstead, Hertfordshire, U.K. 2020.

B. Clinical Pharmacology Elsevier Gold Standard 2021.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.

F. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

G. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

Attachment A: Criteria for Active Disease

CRITERIA FOR ACTIVE DISEASE[a]

- Fever
- Increased serum C-reactive protein level >20 mg/L in the absence of any other etiology
- At least three of the following other MCD-related symptoms:
  - Peripheral lymphadenopathy
  - Enlarged spleen
  - Edema
  - Pleural effusion
  - Ascites
  - Cough
  - Nasal obstruction
  - Xerostomia
  - Rash
  - Central neurologic symptoms
  - Jaundice
  - Autoimmune hemolytic anemia

[a] Gérard L, Bérezné A, Galicier L, et al. Prospective study of rituximab in chemotherapy-dependent human immunodeficiency virus-associated multicentric Castleman's disease: ANRS 117 CastlemaB Trial. J Clin Oncol 2007;25:3350-3356.