POLICY NUMBER UM ONC_1383	SUBJECT Sylvant ™ (siltuximab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 02/12/20	APPROVAL DATE February 12, 2020	EFFECTIVE DATE March 01, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 02/12/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		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 is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. 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**
    b. 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**
    c. 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: http://pathways.newcenturyhealth.com **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Idiopathic Multicentric Castleman's Disease (iMCD)**
    a. The member has active multicentric Castleman's disease that has progressed following conventional/standard treatment for relapsed/refractory disease **AND**
    b. The criteria for active disease include any of the following in *Attachment A* **AND**
    c. The member is human immunodeficiency virus-1 (HIV-1) or human herpes virus-8 (HHV-8) **NEGATIVE AND**
    d. Sylvant (siltuximab)is being used as a single agent (except with corticosteroids not to exceed 1 mg/kg/day of prednisone).

III. EXCLUSION CRITERIA

1. Sylvant (siltuximab) is being used after disease progression with the same regimen.
2. Concurrent use with live vaccines or other anticancer therapies.
3. The member has any of the following conditions:
    i. Unicentric Castleman's disease
    ii. Human immunodeficiency virus-1 (HIV-1) or human herpes birus-8 (HHV-8) **POSITIVE**
    iii. Active infections
    iv. Previous history of lymphoma,
4. Dosing exceeds single dose limit of Sylvant (siltuximab) is 11 mg/kg.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

1. Attachment A: Criteria for Active Disease

VII. REFERENCES

1. Sylvant PI prescribing information. Janssen Biotech, Inc. Horsham, PA 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.

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.