Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Sylvant (siltuximab)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2014 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Sylvant (siltuximab).

Sylvant (Siltuximab) is indicated for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Limitation of use: siltuximab (Sylvant) was not studied in patients with MCD who are HIV positive or HHV-8 positive because siltuximab (Sylvant) did not bind to virally produced IL-6 in a nonclinical study.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes

appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Sylvant (Siltuximab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by an oncologist or a hematologist
- Must be age 18 years or older
- Must have a diagnosis of multicentric Castleman's disease. Chart documentation demonstrating a history of both of the following is required:
    - Lymphadenopathy in >1 lymph node site
    - Constitutional symptoms such as fever, night sweats, significant weight loss, fatigue, weakness, anorexia, anemia
- Must not be HIV positive or HHV-8 positive
- Must have no evidence of infection

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber showing that the member has benefited from therapy as evidenced by documentation of at least one of the following:

- A reduction in the size or number of lymphadenopathy sites from baseline
- A reduction in constitutional symptoms from baseline

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Same as initial OR Up to <time frame>

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Sylvant [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; 2014
2. Van Rhee F, Casper C, Voorhees P, et al. An open-label, phase 2, multicenter study of the safety of long-term treatment with siltuximab (an anti-interleukin-6 monoclonal antibody) in patients with multicentric Castleman's diease [poster]. Presented at: The 55th American Society of Hematology (ASH) Annual Meeting; December 7-10, 2013a; New Orleans, LA
3. Van Rhee F, Fayad L, Voorhees P, et al. Siltuximab, a novel anti-interleukin-6 monoclonal antibody, for Castleman's Disease. *J Clin Oncol* 2010;28:3701-3708
4. Kurzrock R, Voorhees PM, Casper C, et al. A phase I, open-label study of siltximab, an anti-IL-6 monoclonal antibody, in patients with B-cell non-hodgkin lymphoma, multiple myeloma, or Castleman disease. *Clin Cancer Res* 2013;19:3659-3670
5. Muzes G, Sipos F, Csomor J, et al. Multicentric Castleman's disease: a challenging diagnosis. *Pathol Oncol Res* 2013;19:345-351
6. Nishimoto M, Kanakura Y, Aozasa K, et al. Humanized anti-interleukin-6 receptor antibody treatment of multicentric Castleman disease. *Blood* 2005;106:2627-2632
7. Matsuyama M, Suzuki T, Tsuboi H, et al. Anti-interleukin-6 receptor antibody (tocilizumab) treatment of multicentric Castleman's disease. DOI: 10.2169/internalmedicine.46.6262
8. Beck JT, Hsu S, Wijdenes J, et al. Brief report: alleviation of systemic manifestations of Castleman's disease by monoclonal anti-interleukin-6 antibody. *N Engl J Med* 1994;333(9):602- 605
9. Song SJ, Tomosugi N, Kawabata H, et al. Down-regulation of hepcidin resulting from long-term treatment with an anti-IL-6 receptor antibody (tocilizumab) improves anemia of inflammation inmulticentric Castleman's disease. Blood 2010;116:3627-3624

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*