Sylvant® (Siltuximab)

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Definition
Siltuximab is a human-mouse chimeric monoclonal antibody that binds interleukin-6 (IL-6) and prevents the binding of IL-6 to soluble and membrane-bound IL-6 receptors. IL-6 can induce immunoglobulin secretion, and its overproduction is associated with systemic effects in patients with multicentric Castleman's disease.

Length of Authorization
Coverage will be provided for 6 months and may be renewed.

Dosing Limits
Max Units (per dose and over time) [Medical Benefit]:
- 130 billable units per 21 days

I. INITIAL APPROVAL CRITERIA

Sylvant may be considered medically necessary in the following conditions:

- Patient is human immunodeficiency virus (HIV) negative; **AND**
- Patient is human herpes virus-8 (HHV-8) negative; **AND**
- Patient is currently free of all clinically significant infections; **AND**
- Patient will NOT receive any live vaccines while being treated with Sylvant; **AND**
- Must be used as a single agent; **AND**
- Patient has a diagnosis of Multicentric Castleman's Disease
  - Must be used second-line for relapsed or refractory disease.
Limitations/Exclusions
Adcentris is not considered medically necessary when any of the following selection criteria is met:

1) Dosing exceeds dose limit of Sylvant (Siltuximab).
2) Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

- Patient continues to meet INITIAL APPROVAL CRITERIA.
- Tumor response with disease stabilization or reduction of tumor size and spread.
- Absence of unacceptable toxicity from the drug including: Severe infusion related reactions, GI perforation, etc.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>All indications</td>
<td>– 11 mg/kg intravenously every 21 days</td>
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</tbody>
</table>

Applicable Procedure Codes

- J2860 Injection, siltuximab, 10 mg, 1 billable unit = 10 mg

Applicable NDCs

- 57894-0420-xx Sylvant 100 mg single-use vial
- 57894-0421-xx Sylvant 400 mg single-use vial

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>D36.0</td>
<td>Benign neoplasm of lymph nodes</td>
</tr>
<tr>
<td>D47.22</td>
<td>Castleman disease</td>
</tr>
<tr>
<td>R59.0</td>
<td>Localized enlarged lymph nodes</td>
</tr>
<tr>
<td>R59.1</td>
<td>Generalized enlarged lymph nodes</td>
</tr>
<tr>
<td>R59.9</td>
<td>Enlarged lymph nodes, unspecified</td>
</tr>
</tbody>
</table>

References

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for siltuximab. National Comprehensive Cancer Network, 2019. 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 March 2019.