Drug Policy:

**Adcetris™ (brentuximab vedotin)**

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<th>POLICY NUMBER</th>
<th>SUBJECT</th>
<th>DEPT/PROGRAM</th>
<th>PAGE</th>
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<tr>
<td>UM OMC_1203</td>
<td>Adcetris™ (brentuximab vedotin)</td>
<td>UM Dept</td>
<td>1 OF 4</td>
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**DATES COMMITTEE REVIEWED**

02/08/12, 10/13/13, 12/04/14, 07/26/16, 08/10/17, 08/08/18, 07/10/19, 10/09/19, 12/11/19, 04/08/20, 12/09/20, 02/10/21

**APPROVAL DATE**

February 10, 2021

**EFFECTIVE DATE**

February 26, 2021

**COMMITTEE APPROVAL DATES**

(latest version listed last)

02/08/12, 10/13/13, 12/04/14, 07/26/16, 08/10/17, 08/08/18, 07/10/19, 12/11/19, 04/08/20, 12/09/20, 02/10/21

**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 Adcetris (brentuximab vedotin) 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 available, generic alternatives are preferred over brand-name drugs.

B. Classical Hodgkin Lymphoma

1. NOTE: The preferred regimen for first line therapy in stage III and IV classical Hodgkin’s Lymphoma, per NCH Policies and NCH Pathways, is ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) except in members with contraindications or intolerance to Bleomycin (e.g. lung disease, prior smoking history) AND IPS- International Prognostic Score of 2-7 (see below).

2. Adcetris (brentuximab vedotin) is being used in member with classical Hodgkin Lymphoma that is CD30 positive and the following:
   a. Primary treatment in combination with AVD (doxorubicin, vinblastine, dacarbazine) for unfavorable stage I-II or stage III-IV disease in members who have a contraindication to the use of Bleomycin OR
   b. As a single agent for subsequent lines of therapy
   c. As consolidation therapy in members who have not received prior brentuximab vedotin following HSCT (Hematopoietic Stem Cell Transplant).

### International Prognostic Score in Hodgkin Lymphoma

- Serum Albumin <4 g/dL (1 point)
- Hemoglobin <10.5 g/dL (1 point)
- Male Sex (1 point)
- Stage IV Disease by Ann Arbor Classification (1 point)
- Age ≥45 Years (1 point)
- White Cell Count ≥15,000/mm3 (1 point)
- Lymphocyte Count <600/mm3 or <8% of White Cell Count (1 point)
IPS Score: 5 year Freedom From Progression (FFP) and Overall Survival (OS)

<table>
<thead>
<tr>
<th>Points</th>
<th>Description</th>
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<tbody>
<tr>
<td>0 Points</td>
<td>84% Freedom from progression and 89% overall survival</td>
</tr>
<tr>
<td>1 Point</td>
<td>77% Freedom from progression and 90% overall survival</td>
</tr>
<tr>
<td>2 Points</td>
<td>67% Freedom from progression and 81% overall survival</td>
</tr>
<tr>
<td>3 Points</td>
<td>60% Freedom from progression and 78% overall survival</td>
</tr>
<tr>
<td>4 Points</td>
<td>51% Freedom from progression and 61% overall survival</td>
</tr>
<tr>
<td>5 to 7 Points</td>
<td>42% Freedom from progression and 56% overall survival</td>
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C. **CD30 Positive T-Cell Lymphomas**
   1. Adcetris (brentuximab vedotin) is being used for T-Cell Lymphomas (including anaplastic large cell lymphomas) that are CD30 positive and any of the following:
      a. First line therapy as a single agent or as a component of brentuximab vedotin + CHP (cyclophosphamide, doxorubicin, prednisone) OR
      b. Second line or subsequent therapy as a single agent for relapsed/refractory disease.

III. **EXCLUSION CRITERIA**
   A. Disease progression while on Adcetris (brentuximab vedotin).
   B. Dosing exceeds single dose limit of Adcetris (brentuximab vedotin) 180 mg (1.8 mg/kg/dose) or 120 mg (1.2 mg/kg/dose).
   C. Treatment with Adcetris (brentuximab vedotin) exceeds the maximum duration limit of 6 month cycles as a part of AAVD (12 doses for first line treatment of Hodgkin’s Disease) OR exceeds 16 cycles for refractory/relapsed disease/consolidation treatment after HSCT OR exceeds 8 doses for previously untreated CD-30 + T Cell Lymphoma.
   D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. **MEDICATION MANAGEMENT**
   A. Please refer to the FDA label/package insert for details regarding these topics.
   B. Requests for Adcetris (brentuximab vedotin) shall be reviewed for appropriateness per FDA approved product.

V. **APPROVAL AUTHORITY**
   A. Review – Utilization Management Department
   B. Final Approval – Utilization Management Committee
VI. ATTACHMENTS
   A. None

VII. REFERENCES
