POLICY NUMBER UM ONC_1203	SUBJECT Adcetris™ (brentuximab vedotin)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
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	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	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, 10/09/19, 12/11/19, 04/08/20	
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 All	

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 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. **NOTE: The preferred regimen for first line therapy in stage III and IV, and high risk stage I and II Hodgkin 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).**
3. **Classical Hodgkin Lymphoma**
    a. Adcetris (brentuximab vedotin) is being used in member with classical Hodgkin Lymphoma that is CD30 positive and the following:

i. 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**

ii. Upon disease progression after ASCT (autologous stem cell transplant) **OR**

iii. After failure of at least two prior multi-agent chemotherapy regimens in members who are not ASCT candidates OR

iv. As consolidation therapy in members who have not received prior brentuximab vedotin following HSCT (Hematopoietic Stem Cell Transplant) for primary refractory or relapsed disease **OR**

v. Weight calculation, for dosage, not to exceed 100kg which translates to no more than 180mg per dose (as monotherapy) or 120 mg per dose (in combination with chemotherapy).

4. Non-Hodgkin Lymphoma

a. Adcetris (brentuximab vedotin) is being used in members with Systemic Anaplastic Large Cell Lymphoma (sALCL) that is CD30 positive and affter failure of at least one prior multiagent chemotherapy regimen **OR**

b. Therapy for primary cutaneous anaplastic large cell lymphoma (pcALCL) as a single agent or in combination with chemotherapy for primary therapy or for therapy of relapsed/refractory disease.

5. Peripheral T-Cell Lymphomas (PTCL)

a. Adcetris (brentuximab vedotin) is being used for PTCL that is CD30 positive and any of the following:

i. First line therapy as a single agent or as a component of brentuximab vedotin + CHP (cyclophosphamide, doxorubicin, prednisone) **OR**

ii. Second line or subsequent therapy as a single agent or in combination with chemotherapy for relapsed/refractory disease.

6. Breast Implant Associated Anaplastic Lymphoma

a. Disease is documented to be CD-30 positive **AND**

b. Adcetris (brentuximab vedotin) is being used as adjuvant therapy for localized disease to the capsule/implant/breast following incomplete excision or partial capsulectomy with residual disease **AND**

c. If node positive or radiation therapy is not feasible **OR**

d. For extended disease (stage II - IV) either as a single agent **OR**

e. As a component of brentuximab vedotin + CHP (cyclophosphamide, doxorubicin, prednisone).

III. EXCLUSION CRITERIA

1. Disease progression while on Adcetris (brentuximab vedotin).
2. Dosing exceeds single dose limit of Adcetris (brentuximab vedotin) 180 mg (1.8 mg/kg/dose) or 120 mg (1.2 mg/kg/dose).
3. 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 PTCL .

4. 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.

Requests for Adcetris (brentuximab vedotin) shall be reviewed for appropriateness per FDA approved product.

V. APPROVAL AUTHORITY

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

VI. ATTACHMENTS

None

VII. REFERENCES

1. Adcetris prescribing information. Bothell, WA: Seattle Genetics Inc. 2018.
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.