

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

<input type="checkbox"/> Initial Request		<input type="checkbox"/> Renewal		<input type="checkbox"/> Appeal/Redetermination¹	
<input type="checkbox"/> Urgent²		<input type="checkbox"/> Non-Urgent			
Requested Drug Name: Adcetris (brentuximab vedotin) - MEDICARE Part B					
Patient Information:			Prescribing Provider Information:		
Patient Name:			Prescriber Name:		
Member/Subscriber Number:			Prescriber Fax:		
Policy/Group Number:			Prescriber Phone:		
Patient Date of Birth (MM/DD/YYYY):			Prescriber Pager:		
Patient Address:			Prescriber Address:		
Patient Phone:			Prescriber Office Contact:		
Patient Email Address:			Prescriber NPI:		
			Prescriber DEA:		
Prescription Date:			Prescriber Tax ID:		
			Specialty/Facility Name (If applicable):		
			Prescriber Email Address:		
Prior Authorization Request for Drug Benefit					
Patient Diagnosis and ICD Diagnostic Code(s):					
Drug(s) Requested (with J-Code, if applicable):					
Strength/Route/Frequency:					
Unit/Volume of Named Drug(s):					
Start Date and Length of Therapy:					
Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:					
Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:					
Adcetris (brentuximab vedotin)					
Diagnosis (documentation supportive of diagnosis is required)					
<input type="checkbox"/> Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) <u>or</u> after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates (<i>documentation required</i>).					
<input type="checkbox"/> Anaplastic large T-cell systemic malignant lymphoma after failure of at least one prior multi-agent chemotherapy regimen (<i>documentation required</i>).					
<input type="checkbox"/> OTHER (please state): _____					

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Adcetris® (brentuximab)

CLASSIFICATION

- Antineoplastic Agent
- Mitotic Inhibitor
- Monoclonal Antibody

DESCRIPTION

- Brentuximab vedotin is FDA-approved for the treatment of Hodgkin lymphoma in patients who have failed autologous stem-cell transplant (ASCT), or who are not ASCT candidates and have failed at least 2 prior multi-agent chemotherapy regimens. Approval is based on overall response rates of 73%, with a median duration of response of 6.7 months in a phase II, open-label, single-arm, multicenter trial (n=102).
- Brentuximab vedotin is FDA-approved for the treatment of systemic anaplastic large cell lymphoma in patients who have failed at least 1 prior multi-agent chemotherapy regimen. Approval is based on overall response rates of 86%, with a median duration of response of 12.6 months in a phase II, open-label, single-arm, multicenter trial (n=58).
- Orphan status has been granted for both FDA approved indications.
- FDA approved indications are based on response rate. There is no data available demonstrating improvement in patient reported outcomes or survival with Adcetris®.
- Brentuximab vedotin is a CD30-directed antibody-drug conjugate (ADC) consisting of 3 components: 1) the chimeric IgG1 antibody cAC10 which is specific for human CD30; 2) the microtubule disrupting agent MMAE; and 3) a protease-cleavable linker that covalently attaches MMAE to cAC10.
- The anticancer activity of brentuximab vedotin, is presumed to be due to the binding of the ADC to CD30-expressing cells, followed by internalization of the ADC-CD30 complex and the release of MMAE via proteolytic cleavage. The microtubule disrupting agent MMAE binds to tubulin, disrupting the microtubule network which leads to cell cycle arrest and apoptotic death of the cells.
- Hodgkin's lymphoma (HL) and anaplastic large-cell lymphoma (ALCL) are the two most common tumors expressing CD30.
- The most common adverse reactions ($\geq 20\%$) include neutropenia, peripheral sensory neuropathy, fatigue, nausea, anemia, upper respiratory tract infection, diarrhea, pyrexia, rash, thrombocytopenia, cough and vomiting.

FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Tier 6

Commercial Formulary: Tier 6

Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Adcetris® (brentuximab) meets the definition of **medical necessity** for the following:

- Hodgkin's disease after failure of autologous stem cell transplant (ASCT) (*documentation required*).
- Hodgkin's disease after failure of at least 2 or more multi-agent chemotherapy regimens in patients not candidates for ASCT (*documentation of failed therapies required*).

- Per NCCN guidelines, brentuximab is an option for patients with progressive disease after high dose therapy/autologous stem cell rescue (HDT/ASCR) or at least 2 prior chemotherapy regimens for all patients regardless of their eligibility for HDT/ASCR
- Prior therapies may include ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine), Stanford V (mechlorethamine, doxorubicin, vinblastine, vincristine, bleomycin and prednisone), involved field radiation therapy (IFRT), or BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone).
- Anaplastic large T-cell systemic malignant lymphoma after failure of at least one prior multi-agent chemotherapy regimen (*documentation of failed therapies required*).
 - Prior therapies may include CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) +RT, ICE (ifosfamide, carboplatin, and etoposide), or ASCT (autologous stem-cell transplant).
 - NCCN suggests brentuximab as a second-line therapy for nodal ALCL only (excluding cutaneous ALCL) regardless of transplant eligibility.

**Note: There is no data available demonstrating improvement in patient reported outcomes or survival with Adcetris®*

**If coverage criteria are met, initial approval will be given for 4 cycles (equals 4 doses). Continued coverage, up to a maximum of 16 cycles, will be approved with documentation indicating no progression of disease.*

Adcetris® (brentuximab) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined in children or in adults that are ≥ 65 years old):

- *Hodgkin's disease:* 1.8mg/kg administered as an IV infusion over 30 minutes every 3 weeks for a maximum of 16 cycles or until disease progression or unacceptable toxicity. For patients weighing more than 100 kg, calculate the dose at 100 kg.
- *Anaplastic large T-cell systemic malignant lymphoma:* 1.8 mg/kg administered as an IV infusion over 30 minutes every 3 weeks for a maximum of 16 cycles or until disease progression or unacceptable toxicity. For patients weighing more than 100 kg, calculate the dose at 100 kg.
- See product information for dose adjustments with neutropenia and peripheral neuropathy.
- Preparation:
 - Calculate the number of 50 mg brentuximab vedotin vials required for the dose. Reconstitute each 50 mg vial with 10.5 mL of Sterile Water for Injection (SWFI) for a 5 mg/mL solution. Gently swirl, but do not shake, the vial. Dilute into an infusion bag or store the solution at 2 to 8 degrees C (36 to 46 degrees F) and use within 24 hours of reconstitution (do not freeze).
 - Withdraw the required volume of 5 mg/mL reconstituted solution from the vials and add the reconstituted solution to an infusion bag with a minimum volume of 100 mL of NS, D5W, or LR, to achieve a final concentration of 0.4 mg/mL to 1.8 mg/mL. Infuse immediately or store the solution at 2 to 8 degrees C (36 to 46 degrees F) and use within 24 hours of reconstitution (do not freeze). Do not mix or infuse with other medications.

PRECAUTIONS

- **Black Box Warning:** Increased risk of progressive multifocal leukoencephalopathy (PML)
- Concomitant use with bleomycin is contraindicated due to increased risk of pulmonary toxicity.
- High tumor burden; potential increased risk of tumor lysis syndrome; monitoring recommended
- Infusion-related reactions including anaphylaxis have been reported. Permanently discontinue therapy if anaphylaxis occurs. If an infusion reaction occurs, interrupt administration. Premedication is recommended with subsequent infusions.
- Prolonged and severe neutropenia may occur; monitoring is recommended. If grade 3 or 4 neutropenia develops, manage by dose delays, reductions, or discontinuation.
- Peripheral neuropathy, predominantly sensory, has been reported; monitoring is recommended. Drug interruption, dose adjustment, or discontinuation may be necessary.
- Progressive multifocal leukoencephalopathy (PML) has been reported in one patient who had received 4 chemotherapy regimens prior to Adcetris and resulted in fatality. Two additional cases have been reported. FDA has added a black box warning (1/13/12).
- Rapidly proliferating tumor; potential increased risk of tumor lysis syndrome; monitoring recommended
- Stevens-Johnson syndrome (SJS) has been reported. Discontinue therapy if SJS occurs.

Billing/Coding information

CPT Coding:

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HCPCS Coding:

C9042	Injection, brentuximab vedotin, 1mg (effective 1/1/2013)
C9287	Injection, brentuximab vedotin, 1mg (for billing prior to 1/1/12 use J9999 or C9399)

COST

- AWP (January 2012): Adcetris 50mg/vial (1): \$5400.00
- AWP (February 2014): Adcetris 50mg/vial (1): \$6270.00

COMMITTEE APPROVAL

- March 2012

GUIDELINE UPDATE INFORMATION

January 2012	Medical Policy created
June 2014	Medical Policy updated

REFERENCES

- DRUGDEX®, accessed 01/13/12, 3/13/12, 6/29/14.
- Product Information: Adcetris® (brentuximab vedotin), for IV injection. Seattle Genetics, Inc., Bothell, WA, Aug 2011.

- NCCN Guidelines for Hodgkin Lymphoma (Version 3.2011, 09/16/11).
http://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf (Accessed 01/13/12).
- NCCN Guidelines for Non-Hodgkin's Lymphoma (version4.2011, 08/24/11).
http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf (Accessed 01/13/12).
- Younes A, Barlett NL, Leonard JP, et al. Brentuximab vedotin (SGN-35) for relapsed CD30-positive lymphomas. N Eng J Med 2010; 363:1812-21.