Effective Date: 12/01/2018
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Policy Number: C15428-A

Adcetris (brentuximab vedotin)

PRODUCTS AFFECTED

Adcetris (brentuximab vedotin)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
see FDA uses
NOTE: Patient's must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories1 or 2A only).
(NOTE: a category 2B therapy/regimen may be authorized on an exception basis with documented Molina Healthcare medical director or Molina Healthcare oncologist consultation)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. CLASSICAL HODGKIN LYMPHOMA:

Drug and Biologic Coverage Criteria

1. Diagnosis of classical Hodgkin lymphoma (cHL)
   AND
2. Documentation member meets ANY of the following conditions:
   (a) Previous failure of autologous hematopoietic stem cell transplant (auto-HSCT) for treatment of cHL
   OR
   (b) Relapsed disease after failure of at least two (2) prior multi-agent chemotherapy regimens in member who is not an auto-HSCT candidate
   OR
   (c) consolidation therapy following an autologous hematopoietic stem cell transplant in patients at high risk for relapse or progression AND ONE (1) of the following conditions defining high risk: (i) Disease was refractory to primary therapy, (ii) Disease relapsed in less than 12 monthsof primary therapy OR (iii) Disease with extra nodal involvement prior to auto- HSCT
   OR
   (d) Second-line therapy prior to HDT/ASCR to minimize the use of more intensive chemotherapy
   OR
   (e) Palliative therapy as a single agent for relapsed or refractory disease in older adults (age >60)
   OR
   (f) For previously untreated Stage III or IV cHL, in combination with chemotherapy [doxorubicin, vinblastine, and dacarbazine]
   AND ONE OF THE FOLLOWING
   i. Prescriber attests that member has no known neuropathy AND Member has an International Prognostic Score (IPS) $\geq$ 4
      OR
   ii. Member has a labeled medical contraindication to bleomycin-based therapy (ABVD)
      OR
   iii. Brentuximab is considered medically necessary to reduce the risk of bleomycin pulmonary toxicity in cycles 3-6: after 4 doses/2 cycles with bleomycin, and a PET/CT showing Deauville4-5requiring escalation in therapy, and on a case-by-case basis, for individuals for whom there is expressed concern for the development of bleomycin pulmonary toxicity with further treatment (i.e., Medical reasons for why the recommended alternative Escalated BEACOPP cannot be used).

(NOTE: the proper succession for these criteria can be found within compendia monographs, FDA label or NCCN guidelines; IF compendia monographs, FDA label or NCCN guidelines have a formulary/preferred product at therapeutic parity with requested agent a formulary/preferred product should be used first where state regulations allow) Molina reviewers and delegates will comply with all regulations and requirements applicable to the review of the request, providing exception to our standard criteria as may be required under state regulations and requirements.

B. ALL OTHER LABELED INDICATIONS:

1. (a) Prescribed as a SINGLE agent for relapsed or refractory disease for ONE (1) of the following diagnosis: Systemic Anaplastic Large Cell Lymphoma (sALCL), CD30+ Peripheral T-Cell Lymphoma (PTCL), CD30+ angioimmunoblastic T-cell lymphoma (ATCL)
   AND
   (b) Documentation of failure of at least one (1) prior multi-agent chemotherapy regimen
   OR
2. (a)Prescribed for CD30+ adult T-cell leukemia/lymphoma
   AND
   (b) Failure of at least one prior multi-agent chemotherapy regimen OR Subsequent therapy after high-dose therapy and autologous stem cell rescue (HDT/ASCR)
   OR
3. (a) Prescribed as adjuvant systemic therapy for localized disease to capsule/implant/breast AND Member had incomplete excision or partial capsulectomy with residual disease
   OR

(b) Member has extended disease (stage II-IV)
OR

4. Diagnosis of one of CD30-expressing mycosis fungoides† or Sezary syndrome
   OR
5. Prescribed as a single agent for ONE (1) of the following diagnosis: CD 30+ primary cutaneous anaplastic large cell lymphoma (pcALCL), OR Cutaneous anaplastic large cell lymphoma (ALCL) with regional nodes (excludes sALCL) OR Lymphomatoid papulosis (LyP) with extensive lesions if refractory to all primary treatment options
   OR
6. Prescribed as second line therapy for diffuse large B cell lymphoma for CD30+
   OR
7. Prescribed for previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30- expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone

C. OFF-LABEL USE: Refer to the 'Off-Label Use of Drugs and Biologic Agents' MCP-162 if diagnosis is NOT specifically listed above.

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Current chart notes detailing response and adherence to therapy
   AND
2. Documented clinically significant improvements in the disease state, stability on the medication, or lack of disease progression
   AND
3. Documentation that member is not having intolerable or unacceptable toxicity

DURATION OF APPROVAL:

Initial authorization: 3 months, Continuation of therapy: 6 months or maximum duration per FDA label or NCCN guideline, whichever is shorter

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified hematologist/oncologist. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age or older

QUANTITY:

Hodgkin lymphoma, advanced (Stage III or IV), previously untreated: 1.2 mg/kg (maximum dose:120 mg) every 2 weeks until a maximum of 12 doses
Hodgkin lymphoma relapsed or refractory: 1.8 mg/kg (maximum dose: 180 mg) every 3 weeks Hodgkin lymphoma, consolidation therapy after autologous hematopoietic stem cell transplantation (HSCT): 1.8 mg/kg (maximum dose: 180 mg) every 3 weeks, continue until a maximum of 16 cycles (Moskowitz 2015).
Mycosis fungoides (CD-30 expressing): 1.8 mg/kg (maximum dose: 180 mg) every 3 weeks, continue until a maximum of 16 cycles
Primary cutaneous anaplastic large cell lymphoma, relapsed (pcALCL): 1.8 mg/kg (maximum dose:180 mg) every 3 weeks, continue until a maximum of 16 cycles
Peripheral T-cell lymphoma (CD30-expressing), previously untreated: IV: 1.8 mg/kg (maximum dose:180mg) every 3 weeks for 6 to 8 doses (in combination with cyclophosphamide, doxorubicin, and prednisone). Administer primary prophylaxis with G-CSF (filgrastim) beginning with cycle 1.

Systemic anaplastic large cell lymphoma, relapsed: IV: 1.8 mg/kg (maximum dose: 180 mg) every 3 weeks, continue until disease progression or unacceptable toxicities

Maximum Quantity Limits – << based on FDA label>>

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Antineoplastic Antibody-Drug Complexes

FDA-APPROVED USES:

- Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine
- Classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation
- Classical Hodgkin lymphoma (cHL) after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates
- Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30- expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone
- Systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multiagent chemotherapy regimen
- Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Lymphoma is a general term for a group of cancers that originate in the lymphatic system. There are two major subgroups of lymphoma, Hodgkin lymphoma (HL) and non-Hodgkin lymphoma; both express CD30. NHL is divided into two major subgroups, based on the appearance and immunophenotype of the tumor cells: Nodular lymphocyte predominant HL and Classic HL. Classical HL is a type of Hodgkin lymphoma characterized by an abnormal type of B lymphocyte called Reed Sternberg cells. It accounts for 90 to 95 percent of Hodgkin lymphoma. The National Cancer Institute estimates that there will be 8,500 new cases of Hodgkin lymphoma and an estimated 1,050deaths in 2018. The treatment of patients with Hodgkin lymphoma is primarily guided by the clinical stage of disease. Brentuximab combines the action of an antibody with chemotherapy (an antibody-drug conjugate). An antibody-drug conjugate designed to target tumor cells expressing CD30, a tumor necrosis factor(TNF) receptor. The antibody-drug conjugate binds with the CD30, and a small

molecule chemotherapeutic agent (monomethyl auristatin [MMAE]) is released. The MMAE causes cell cycle arrest and cell death. Indicated for the treatment of patients with:

1) Classical Hodgkin lymphoma (HL) after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates,
2) Classical HL at high risk of relapse or progression as post-auto-HSCT consolidation,
3) Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy, and
4) Systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen.

CLASSICAL HODGKIN LYMPHOMA

Previously Untreated Stage III or IV Classical Hodgkin Lymphoma (HL)

The ECHELON-1 open-label, multicenter international pivotal randomized phase 3 trial, randomized a total of 1334 patients, from November 2012 through January 2016; 670 treatment-naive participants with stage III or IV Hodgkin's to standard therapy and assigned 664 others to brentuximab vedotin, doxorubicin, vinblastine, and dacarbazine (A+AVD).

Patients with previously untreated stage III or IV classic Hodgkin's lymphoma in patients were assigned to receive brentuximab vedotin, doxorubicin, vinblastine, and dacarbazine (A+AVD) (n =664) and standard-of-care ABVD (n = 670) doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD)

Efficacy was established based on modified progression-free survival (mPFS), defined as progression, death, or receipt of additional anticancer therapy for patients who are not in a complete response after completion of frontline therapy.

The primary outcome was the rate of modified progression-free survival at 2 years, defined as a composite risk of progression, death, or noncomplete response and the use of a different anticancer therapy.

All secondary efficacy endpoints, including development of neutropenia and peripheral neuropathy, also favored A+AVD.

At median follow-up of 2.9 years, this measurement reached 82.1% in the A+AVD group and77.2% in the ABVD group.

Brentuximab vedotin, doxorubicin, vinblastine, and dacarbazine (A+AVD) compared with doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) significantly improved the 2-year progression-free survival rate in the randomized ECHELON-1 trial in patients with previously untreated stage III or IV classic Hodgkin's lymphoma

The results of this Phase III study demonstrate the superior efficacy of A+AVD compared with ABVD as the first-line treatment for patients with advanced Hodgkin's lymphoma. [NCT01712490]

Classical Hodgkin Lymphoma Post-Autologous Hematopoietic Stem-Cell Transplantation (Auto-HSCT) Consolidation

A randomized, double-blind, placebo-controlled, phase 3 trial was conducted at 78 sites across North America and Europe in patients with unfavorable-risk relapsed or primary refractory classic HL who had undergone auto-HSCT (Moskowitz et al.)

Patients were randomly assigned, by fixed-block randomization with a computer-generated random number sequence, to receive 16 cycles of 1.8 mg/kg brentuximab vedotin or placebo intravenously every 3 weeks, starting 30–45 days after transplantation.

Randomization was stratified by best clinical response after completion of salvage chemotherapy (complete response vs partial response vs stable disease) and primary refractory HL versus relapsed disease less than 12 months after completion of frontline therapy versus relapse 12 months or more after treatment completion.

Patients and study investigators were masked to treatment assignment. The primary endpoint was progression-free survival by independent review, defined as the time from randomization to the first documentation of tumor progression or death. Analysis was by intention to treat.

Between April 6, 2010, and Sept 21, 2012, 329 patients were randomly assigned to the brentuximab vedotin group (n=165) or the placebo group (n=164). Progression-free survival by independent review was significantly improved in patients in the brentuximab vedotin group compared with those in the placebo group (hazard ratio [HR] 0.57, 95% CI 0.40–0.81; p=0.0013). Median progression- free survival by independent review was 42.9 months (95% CI 30•4–42•9) for patients in the brentuximab vedotin group compared with 24.1 months (11.5–not estimable) for those in the placebogroup. There was consistent benefit (HR <1) of brentuximab vedotin consolidation recorded across subgroups. The most frequent adverse events in the brentuximab vedotin group were peripheral sensory neuropathy (94 [56%] of 167 patient's vs 25 [16%] of 160 patients in the placebo group) and neutropenia (58 [35%] vs 19 [12%] patients). At time of analysis,28 (17%) of 167 patients had died in the brentuximab vedotin group compared with 25 (16%) of 160 patients in the placebo group.

Early consolidation with brentuximab vedotin after autologous stem-cell transplantation improved progression-free survival in patients with HL with risk factors for relapse or progression after transplantation. This treatment provides an important therapeutic option for patients undergoing autologous stem-cell transplantation. [NCT01100502]

Classical Hodgkin Lymphoma, Relapsed

A multinational, open-label, phase II study the efficacy and safety of brentuximab vedotin were evaluated in 102 patients with relapsed or refractory Hodgkin lymphoma after autologous stem cell transplant. (Younes A, et al.)

Patients had histologically documented CD30-positive Hodgkin lymphoma by central pathology review. Brentuximab vedotin was administered 1.8 mg/kg every 3 weeks as a 30-minute outpatient IV infusion for up to 16 cycles. Median age was 31 years (age range, 15 to 77 years) and 53% of patients were women.

The median number of prior cancer-related systemic therapies was 3.5 (range, 1 to 13); 71% had primary refractory disease and 42% had not responded to their most recent prior therapy. The median number of cycles received was 9 (range, 1 to 16), with a median duration of treatment of 27 weeks (range, 3 to 54).

An objective response (greater than 50% tumor shrinkage) was achieved in 75% (76/102) of patients, and 34% (35 patients) achieved complete remission. Tumor size was reduced in 95% (97 patients). Symptoms resolved in 83% (29/35) of patients with symptoms at baseline. Among patients achieving complete remission, the median duration of response was not reached at the time initial results were reported, with a median follow-up of 1 year.

Overall progression-free survival (PFS) was 25 weeks by independent review and 39 weeks by investigator assessment; however, at the time initial results were reported, PFS was not reached in patients who achieved complete remission. [NCT00848926]

The most common treatment-related adverse events were peripheral sensory neuropathy, nausea, fatigue, neutropenia, and diarrhea. The ADC brentuximab vedotin was associated with manageable toxicity and induced objective responses in 75% of patients with relapsed or refractory HL after auto-SCT. Durable CRs approaching 2 years were observed, supporting study in earlier lines of therapy.

Systemic Anaplastic Large-Cell Lymphoma (sALCL), Relapsed

A Phase 2 Study of SGN-35 in Treatment of Patients with Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma (sALCL)

This is a single-arm, open-label, multicenter, clinical trial to evaluate the efficacy and safety of

brentuximab vedotin (SGN-35) as a single agent in patients with relapsed or refractory ALCL Patients with systemic ALCL and recurrent disease after at least one prior therapy received brentuximab vedotin 1.8 mg/kg intravenously every 3 weeks over 30 minutes as an outpatient infusion.

The primary end point of the study was overall objective response rate as assessed by independent central review.

Of 58 patients treated in the study, 50 patients (86%) achieved an objective response, 33 patients(57%) achieved a complete remission (CR), and 17 patients (29%) achieved a partial remission.

The median durations of overall response and CR were 12.6 and 13.2 months, respectively. Grade3 or 4 adverse events in ≥ 10% of patients were neutropenia (21%), thrombocytopenia (14%), and peripheral sensory neuropathy (12%). Brentuximab vedotin induced objective responses in the majority of patients and CRs in more than half of patients with sALCL. Approval is based on overall response rates of 86%, with a median duration of response of
12.6 months [NCT00866047]

Primary Cutaneous Anaplastic Large-Cell Lymphoma and CD30-expressing Mycosis Fungoides

A Phase 3 Trial of Brentuximab Vedotin versus Physician's Choice (Methotrexate or Bexarotene) in CD30-Positive Cutaneous T-Cell Lymphoma (ALCANZA)

An international, open-label, randomized, phase 3, multicenter trial in adult patients with CD30- positive mycosis fungoides or primary cutaneous anaplastic large-cell lymphoma who had been previously treated (Prince et al.) was conducted across 52 centers in 13 countries.

Patients were randomly assigned (1:1) to receive intravenous brentuximab vedotin 1.8 mg/kg once every 3 weeks, for up to 16 3-week cycles, or physician's choice (oral methotrexate 5- 50mg once per week or oral bexarotene 300 mg/m2 once per day) for up to 48 weeks.

The primary endpoint was the proportion of patients in the intention-to-treat population achieving an objective global response lasting at least 4 months per independent review facility. Safety analyses were done in all patients who received at least one dose of study drug. Between Aug 13, 2012, and July 31, 2015, 131 patients were enrolled and randomly assigned to a group (66 to brentuximab vedotin and 65 to physician's choice), with 128 analyzed in the intention-to-treat population (64 in each group).

At a median follow-up of 22.9 months (95% CI 18.4-26.1), the proportion of patients achieving an objective global response lasting at least 4 months was 56.3% (36 of 64 patients) with brentuximab vedotin versus 12.5% (eight of 64) with physician's choice, resulting in a between- group difference of43.8% (95% CI 29.1-58.4; p<0.0001).

Grade 3-4 adverse events were reported in 27 (41%) of 66 patients in the brentuximab vedotin group and 29 (47%) of 62 patients in the physician's choice group. Peripheral neuropathy was seen in 44 (67%) of 66 patients in the brentuximab vedotin group (n=21 grade 2, n=6 grade 3) and four (6%) of 62 patients in the physician's choice group. One of the four on-treatment deaths was deemed by the investigator to be treatment-related in the brentuximab vedotin group; no on- treatment deaths were reported in the physician's choice group. Significant improvement in objective response lasting at least 4 months was seen with brentuximab vedotin versus physician's choice of methotrexate or bexarotene. [NCT01578499]

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Adcetris (brentuximab vedotin) that are not an FDA-approved indication or not included in this policy are considered not medically necessary. This is subject to change based on research and medical literature, or at the discretion of Molina Healthcare.

Black Box Warning: PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)

JC virus infection resulting in PML and death can occur in patients receiving Adcetris(brentuximab vedotin)

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J9042	injection, brentuximab vedotin, 1mg

AVAILABLE DOSAGE FORMS:

Adcetris SOLR 50MG (Single dose vial)

REFERENCES

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12. National Cancer Institute. Surveillance, Epidemiology, and End Results (SEER) Program. Cancer Stat Facts: Hodgkin Lymphoma. Available at:https://seer.cancer.gov/statfacts/html/hodg.html