Reference number(s)
1700-A

SPECIALTY GUIDELINE MANAGEMENT

ADCETRIS (brentuximab vedotin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Classical Hodgkin Lymphoma (CHL)
   i. Treatment of CHL after failure of autologous hematopoietic stem cell transplantation (auto-HSCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates
   ii. Treatment of CHL at high risk of relapse or progression as post-auto-HSCT consolidation
   iii. Previously untreated Stage III or IV classical Hodgkin lymphoma (CHL), in combination with doxorubicin, vinblastine, and dacarbazine
2. Systemic anaplastic large cell lymphoma (sALCL)
   i. Treatment of systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen
   ii. 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
3. Treatment of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) in patients who have received prior systemic therapy

B. Compendial Uses
1. CD30+ B-Cell Lymphomas
   i. Monomorphic post-transplant lymphoproliferative disorders (B-cell type)
   ii. Monomorphic post-transplant lymphoproliferative disorders (T-cell type)
   iii. Diffuse large B-cell lymphoma
   iv. AIDS-Related B-cell lymphomas (CD30+ AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)
   v. Histologic transformation of follicular lymphoma to CD30+ diffuse large B-cell lymphoma
   vi. Histologic transformation of nodal marginal zone lymphoma to CD30+ diffuse large B-cell lymphoma
   vii. High-grade B-Cell lymphomas
2. CD30+ Primary Cutaneous Lymphomas
   i. Mycosis Fungoides (MF)/Sezary Syndrome (SS)
   ii. Lymphomatoid papulosis (LyP)
3. CD30+ T-Cell Lymphomas
   i. Hepatosplenic T-cell lymphoma
   ii. Adult T-cell leukemia/lymphoma
   iii. Breast implant-associated anaplastic large cell lymphoma (ALCL)
   iv. Peripheral T-cell lymphoma (PTCL)
   v. Extranodal NK/T-cell Lymphoma (nasal type)

vi. Angioimmunoblastic T-cell lymphoma

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Testing or analysis confirming CD30 expression on the surface of the cell (initial requests).

III. CRITERIA FOR INITIAL APPROVAL

A. Classical Hodgkin lymphoma (CHL)

Authorization of 12 months may be granted for treatment of CD30+ CHL when any of the following are met:

1. The requested drug will be used as a single agent, or
2. The requested drug will be used in combination with doxorubicin, vinblastine, and dacarbazine, or
3. The requested drug will be used in combination with bendamustine for subsequent therapy, or
4. The requested drug will be used in combination with dacarbazine, or
5. The requested drug will be used in combination with nivolumab for relapsed or refractory disease, or
6. The requested drug will be used in combination with gemcitabine for subsequent therapy.

B. B-Cell Lymphomas

Authorization of 12 months may be granted for treatment of CD30+ B-cell lymphomas with any of the following subtypes:

1. Monomorphic post-transplant lymphoproliferative disorders (B-cell type) when the requested drug will be used for subsequent therapy.
2. Monomorphic post-transplant lymphoproliferative disorders (T-cell type) when the requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
3. Diffuse large B-cell lymphoma when all of the following are met:
   i. The requested drug will be used as subsequent therapy, and
   ii. The member is not a candidate for transplant.
4. AIDS-Related B-cell lymphomas (AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma) when both of the following are met:
   i. The requested drug will be used for subsequent therapy, and
   ii. The member is not a candidate for transplant.
5. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma when the member has received at least two chemoimmunotherapy regimens.
6. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma when the member has received at least two chemoimmunotherapy regimens.
7. High-grade B-cell lymphomas when both of the following are met:
   i. The requested drug will be used for subsequent therapy, and
   ii. The member is not a candidate for transplant.

C. Primary Cutaneous Lymphomas

Authorization of 12 months may be granted for treatment of CD30+ primary cutaneous lymphomas with any of the following subtypes:

1. Mycosis fungoides (MF)/Sezary syndrome (SS)
2. Lymphomatoid papulosis (LyP) when both of the following are met:
   i. The requested drug will be used as a single agent, and

ii. The disease is relapsed or refractory.

3. Cutaneous anaplastic large cell lymphoma when either of the following are met:
   i. The requested drug will be used as a single agent, or
   ii. The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).

D. T-Cell Lymphomas

Authorization of 12 months may be granted for treatment of CD30+ T-cell lymphomas with any of the following subtypes:

1. Hepatosplenic T-cell lymphoma when either of the following are met:
   i. The requested drug will be used as a single agent after two or more primary treatment regimens, or
   ii. The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
2. Adult T-cell leukemia/lymphoma when either of the following are met:
   i. The requested drug will be used as a single agent for subsequent therapy, or
   ii. The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
3. Breast implant associated anaplastic large cell lymphoma (ALCL) when either of the following are met:
   i. The requested drug will be used as a single agent, or
   ii. The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
4. Peripheral T-cell lymphoma (PTCL) [including the following subtypes: anaplastic large cell lymphoma, peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma] when either of the following are met:
   i. The requested drug will be used a single agent for subsequent or palliative therapy, or
   ii. The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
5. Extranodal NK/T-cell lymphoma (nasal type) when all of the following are met:
   i. The requested drug will be used as a single agent, and
   ii. The member has relapsed or refractory disease, and
   iii. The member has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).
6. Angioimmunoblastic T-cell lymphoma when either of the following are met:
   i. The requested drug will be used as a single agent for subsequent or palliative therapy, or
   ii. The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
7. Systemic anaplastic large cell lymphoma when either of the following are met:
   i. The requested drug will be used as a single agent, or
   ii. The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Adcetris [package insert]. Bothell, WA: Seattle Genetics, Inc; October 2019.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed April 14, 2021.