Seagen Secure®
Patient Assistance Program

855-4SECURE (855-473-2873)
Monday-Friday, 8 AM-8 PM ET

# ADCETRIS® (brentuximab vedotin) for Injection
# Appeals Request Guide

## Preparing a Prior Authorization Appeal Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their prior authorization policies. For more information, call Seagen Secure at 855-4SECURE (855-473-2873).

If the patient's initial claim or Prior Authorization Request Letter is denied by the patient's health plan, the payer may require a Prior Authorization Appeal Letter. Depending on the plan, there may be varying levels of appeals.

Follow the patient's plan requirements when requesting ADCETRIS® (brentuximab vedotin) for injection; otherwise treatment may be delayed.

A **Prior Authorization Appeal Letter** originates from the prescribing healthcare provider (HCP).* It should be submitted with 2 additional items—the patient's medical records and a Letter of Medical Necessity (LMN).

### Prior Authorization: Appeal Considerations

- ✔ Include the patient's full name, plan identification number, and date of birth
- ✔ Add the prescribing HCP's National Provider Identifier (NPI) number and specialty
- ✔ Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with the case identification number from the initial denial letter
- ✔ Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis and International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
  - Indicate the severity of the patient's condition, if applicable
- ✔ Document prior treatments and the duration of each
  - Describe the rationale for why each treatment was discontinued
- ✔ Provide the clinical rationale for treatment; this information may be found in the ADCETRIS Prescribing Information and/or clinical peer-reviewed literature
- ✔ Summarize your recommendation at the end of the letter
- ✔ Include an LMN

*For Medicare beneficiaries, specific requirements must be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/partdmanualchapter18.pdf.

**Please see Indications and Important Safety Information on pages 4-5.**
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# Sample Appeal Letter

If the Prior Authorization Request Letter is denied by the patient's health plan, a HCP may elect to submit an Appeal Letter.*

[Date]
[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]

To whom it may concern:

I have reviewed and recognized your guidelines for the responsible management of medications within this class. I am requesting that you reassess your recent denial of ADCETRIS® (brentuximab vedotin) prior authorization for [patient name]. I understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, I believe that ADCETRIS [dose, frequency] is the appropriate treatment for this patient. In support of my recommendation for ADCETRIS treatment, I have provided an overview of the patient's relevant clinical history below.

Additional language from page 3 of this document can be placed after this paragraph to support the following scenarios:

- Current user of ADCETRIS
- Previous therapy requirement
- Multiple levels of appeal

**Indicate the patient's diagnosis and affirm conditions for use:**

ADCETRIS is indicated for the treatment of adult patients with:

- 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 multi-agent chemotherapy regimen.
- Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30- expressing mycosis fungoides (MF) who have received prior systemic therapy.

ADCETRIS is indicated for the treatment of pediatric patients with:

- Previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide for pediatric patients 2 years and older.

[Insert rationale for prescribing ADCETRIS here, including your professional opinion of the patient's likely prognosis without ADCETRIS treatment.]

**Provide supporting references for your recommendation:**

[Provide clinical rationale for treatment; this information may be found in the ADCETRIS Prescribing Information and/or clinical peer-reviewed literature.]

Please feel free to contact me, [HCP name], at [office phone number] or [patient's name] at [phone number] for any additional information you may require. I look forward to receiving your timely response and approval of this claim.

Sincerely,

_____

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

Encl: Medical records, supporting documentation, and clinical references, if applicable.

*Some plans may require an LMN to accompany the Appeal Letter.

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## Additional language to support a variety of scenarios can be added to the Appeal Letter

**Current User of ADCETRIS**

If this Appeal Letter is for a patient who is currently taking ADCETRIS, which may be due to a change in payer coverage, sample copy may include the following:

[Describe the diagnosis and symptoms of the disease at the time when the patient was first prescribed ADCETRIS. In addition, include a summary of the patient's clinical response to ADCETRIS. It may be necessary to review past medical records to gather this information.]

**Previous Therapy Requirement**

If this Appeal Letter is intended to appeal a plan's requirement that a patient receive a certain number of lines of therapy, sample copy may include the following:

[Please provide statement(s) indicating why this requirement is inappropriate for this patient. Include documentation of previous courses of therapy and the patient's clinical response or intolerance to those treatments.]

**Multiple Levels of Appeal**

If this is the second or later appeal, sample copy may include the following:

[This is my **(add level of request)** prior authorization appeal. A copy of the most recent denial letter is attached for reference. The patient's medical records are also included in response to the denial.]

# Indications

ADCETRIS® (brentuximab vedotin) is indicated for the treatment of:

**Previously untreated Stage III/IV cHL**

- Adult patients with previously untreated Stage III/IV classical Hodgkin lymphoma (cHL) in combination with doxorubicin, vinblastine, and dacarbazine.

**Previously untreated high risk cHL**

- Pediatric patients 2 years and older with previously untreated high risk cHL, in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide.

**cHL post-auto-HSCT consolidation**

- Adult patients with cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.

**Relapsed cHL**

- Adult patients with cHL after failure of auto-HSCT or after failure of at least two prior multiagent chemotherapy regimens in patients who are not auto-HSCT candidates.

**Previously untreated sALCL or other CD30-expressing PTCL**

- Adult patients with 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.

**Relapsed sALCL**

- Adult patients with sALCL after failure of at least one prior multi-agent chemotherapy regimen.

**Relapsed pcALCL or CD30-expressing MF**

- Adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.

# Important Safety Information

**BOXED WARNING**

**PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML): JC virus infection resulting in PML and death can occur in ADCETRIS-treated patients.**

**CONTRAINDICATION**

Contraindicated with concomitant bleomycin due to pulmonary toxicity (e.g., interstitial infiltration and/or inflammation).

**WARNINGS AND PRECAUTIONS**

**Peripheral neuropathy (PN):** ADCETRIS causes PN that is predominantly sensory. Cases of motor PN have also been reported. ADCETRIS-induced PN is cumulative. Monitor for symptoms such as hypoesthesia, hyperesthesia, paresthesia, discomfort, a burning sensation, neuropathic pain, or weakness. Patients experiencing new or worsening PN may require a delay, change in dose, or discontinuation of ADCETRIS.

**Anaphylaxis and infusion reactions:** Infusion-related reactions (IRR), including anaphylaxis, have occurred with ADCETRIS. Monitor patients during infusion. If an IRR occurs, interrupt the infusion and institute appropriate medical management. If anaphylaxis occurs, immediately and permanently discontinue the infusion and administer appropriate medical therapy. Premedicate patients with a prior IRR before subsequent infusions. Premedication may include acetaminophen, an antihistamine, and a corticosteroid.

**Hematologic toxicities:** Fatal and serious cases of febrile neutropenia have been reported with ADCETRIS. Prolonged (≥1 week) severe neutropenia and Grade 3 or 4 thrombocytopenia or anemia can occur with ADCETRIS.

Administer G-CSF primary prophylaxis beginning with Cycle 1 for adult patients who receive ADCETRIS in combination with chemotherapy for previously untreated Stage III/IV cHL or previously untreated PTCL, and pediatric patients who receive ADCETRIS in combination with chemotherapy for previously untreated high risk cHL.

Monitor complete blood counts prior to each ADCETRIS dose. Monitor more frequently for patients with Grade 3 or 4 neutropenia. Monitor patients for fever. If Grade 3 or 4 neutropenia develops, consider dose delays, reductions, discontinuation, or G-CSF prophylaxis with subsequent doses.

**Serious infections and opportunistic infections:** Infections such as pneumonia, bacteremia, and sepsis or septic shock (including fatal outcomes) have been reported in ADCETRIS-treated patients. Closely monitor patients during treatment for infections.

**Tumor lysis syndrome:** Patients with rapidly proliferating tumor and high tumor burden may be at increased risk. Monitor closely and take appropriate measures.

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# Important Safety Information (cont'd)

**Increased toxicity in the presence of severe renal impairment:** The frequency of ≥Grade 3 adverse reactions and deaths was greater in patients with severe renal impairment. Avoid use in patients with severe renal impairment.

**Increased toxicity in the presence of moderate or severe hepatic impairment:** The frequency of ≥Grade 3 adverse reactions and deaths was greater in patients with moderate or severe hepatic impairment. Avoid use in patients with moderate or severe hepatic impairment.

**Hepatotoxicity:** Fatal and serious cases have occurred in ADCETRIS-treated patients. Cases were consistent with hepatocellular injury, including elevations of transaminases and/or bilirubin, and occurred after the first ADCETRIS dose or rechallenge. Preexisting liver disease, elevated baseline liver enzymes, and concomitant medications may increase the risk. Monitor liver enzymes and bilirubin. Patients with new, worsening, or recurrent hepatotoxicity may require a delay, change in dose, or discontinuation of ADCETRIS.

**PML:** Fatal cases of JC virus infection resulting in PML have been reported in ADCETRIS-treated patients. First onset of symptoms occurred at various times from initiation of ADCETRIS, with some cases occurring within 3 months of initial exposure. In addition to ADCETRIS therapy, other possible contributory factors include prior therapies and underlying disease that may cause immunosuppression. Consider PML diagnosis in patients with new-onset signs and symptoms of central nervous system abnormalities. Hold ADCETRIS if PML is suspected and discontinue ADCETRIS if PML is confirmed.

**Pulmonary toxicity:** Fatal and serious events of noninfectious pulmonary toxicity, including pneumonitis, interstitial lung disease, and acute respiratory distress syndrome, have been reported. Monitor patients for signs and symptoms, including cough and dyspnea. In the event of new or worsening pulmonary symptoms, hold ADCETRIS dosing during evaluation and until symptomatic improvement.

**Serious dermatologic reactions:** Fatal and serious cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with ADCETRIS. If SJS or TEN occurs, discontinue ADCETRIS and administer appropriate medical therapy.

**Gastrointestinal (GI) complications:** Fatal and serious cases of acute pancreatitis have been reported. Other fatal and serious GI complications include perforation, hemorrhage, erosion, ulcer, intestinal obstruction, enterocolitis, neutropenic colitis, and ileus. Lymphoma with preexisting GI involvement may increase the risk of perforation. In the event of new or worsening GI symptoms, including severe abdominal pain, perform a prompt diagnostic evaluation and treat appropriately.

**Hyperglycemia:** Serious cases, such as new-onset hyperglycemia, exacerbation of preexisting diabetes mellitus, and ketoacidosis (including fatal outcomes) have been reported with ADCETRIS. Hyperglycemia occurred more frequently in patients with high body mass index or diabetes. Monitor serum glucose and if hyperglycemia develops, administer anti-hyperglycemic medications as clinically indicated.

**Embryo-fetal toxicity:** Based on the mechanism of action and animal studies, ADCETRIS can cause fetal harm. Advise females of reproductive potential of this potential risk, and to avoid pregnancy during ADCETRIS treatment and for 6 months after the last dose of ADCETRIS.

### ADVERSE REACTIONS

The most common adverse reactions (≥20% in any study) are peripheral neuropathy, fatigue, nausea, diarrhea, neutropenia, upper respiratory tract infection, pyrexia, constipation, vomiting, alopecia, decreased weight, abdominal pain, anemia, stomatitis, lymphopenia, mucositis, thrombocytopenia, and febrile neutropenia.

### DRUG INTERACTIONS

Concomitant use of strong CYP3A4 inhibitors has the potential to affect the exposure to monomethyl auristatin E (MMAE). Closely monitor adverse reactions.

### USE IN SPECIAL POPULATIONS

**Lactation:** Breastfeeding is not recommended during ADCETRIS treatment.

**Females and Males of Reproductive Potential:** Advise females to report pregnancy immediately and advise males with female sexual partners of reproductive potential to use effective contraception during ADCETRIS treatment and for 6 months after the last dose of ADCETRIS.

**Click here for full Prescribing Information, including BOXED WARNING, for ADCETRIS.**

**Reference:** ADCETRIS [package insert]. Bothell, WA: Seagen Inc. 2022.

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