Seagen Secure®
Patient Assistance Program

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

ADCETRIS® (brentuximab vedotin) for Injection
Prior Authorization Request Guide

Drafting a Prior Authorization Request 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 855-4-SECURE (855-473-2873).

Most health plans require a prior authorization request and supporting documentation to process and cover a claim for biologic treatments. A request allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

Plans often have specific Prior Authorization Request Forms that must be used for requests. These forms may be downloaded from each plan's website. Follow the plan's requirements when requesting ADCETRIS® (brentuximab vedotin) for injection; otherwise, treatment may be delayed.

Prior Authorization Requests: Guidance and Recommendations

1. Your Seagen Secure Oncology Access Advocate may be able to provide you with prior authorization requirements for specific plans and pharmacy benefit managers. Benefit verifications performed by the Seagen Secure and/or specialty pharmacies can assist with identifying prior authorization criteria, including any previous therapies and other plan-specific requirements
2. All Prior Authorization Request Forms should be completed and submitted to the plan by the office of the healthcare provider (HCP)
3. Fax the completed Prior Authorization Request Form to the health plan
4. Fax the Seagen Secure Enrollment Form to Seagen Secure at 855-557-2480
5. If a prior authorization is denied and the HCP wishes to submit an appeal, the Seagen Secure Oncology Access Advocate can identify which payer appeal form may be required. Seagen Secure can track appeals with a payer once submitted
6. Plans will usually allow up to 3 levels of appeal for prior authorization denials. The third appeal may include a review by an external review board or hearing. Refer to the Seagen Secure Preparing a Prior Authorization Appeals Letter document

Prior Authorization Considerations

- ✔ Verify and record that all of the prior authorization requirements for the plan have been met
- ✔ If applicable, provide evidence that all plan-specified prerequisites have been met. For exception requests, when medically appropriate, explain why a particular requirement is not medically appropriate for the patient
- ✔ Review the attached sample letter as an example
- ✔ If required, use the health plan's Prior Authorization Request Form that can be found on the plan's website. Your Seagen Secure Oncology Access Advocate may also be able to assist you in locating the plan-specific form

Please see Indications and Important Safety Information on pages 3-4.
Click here for full Prescribing Information, including BOXED WARNING, for ADCETRIS.

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Sample Prior Authorization Request Letter

Most health plans require a prior authorization request and supporting documentation to cover a claim for ADCETRIS® (brentuximab vedotin) for injection. This resource, Drafting a Prior Authorization Request Letter, provides general information to HCPs when drafting the necessary 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:

This letter serves as a prior authorization request for ADCETRIS® (brentuximab vedotin) for [patient's name, plan identification number, and group number] for the treatment of [diagnosis and ICD code].

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

ADCETRIS is indicated for the treatment of:

- Adults with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine.
- Pediatric patients 2 years and older 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.
- Adults with classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.
- Adults with 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.
- Adults 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.
- Adults with systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen.
- Adults with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30- expressing mycosis fungoides (MF) who have received prior systemic therapy.

If this is a prior authorization renewal for continuation of therapy, please indicate if the patient has experienced disease progression or unacceptable toxic effects:

[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.]

Physician contact information:

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #] or mailed to [physician office mailing address]. Please send a copy of the prior authorization determination decision to [patient's name, street address, state, ZIP].

Sincerely,

_____

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

Encl: Medical records, supporting documentation, photo(s), clinical references.

Reauthorization of ADCETRIS

If the prior authorization request 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 patient diagnosis 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.]

Please see Indications and Important Safety Information on pages 3-4.
Click here for full Prescribing Information, including BOXED WARNING, for ADCETRIS.

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Indications and Important Safety Information

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 multi-agent 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.

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.

Please see continuing Important Safety Information on page 4.
Click here for full Prescribing Information, including BOXED WARNING, for ADCETRIS.

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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 use effective contraception during ADCETRIS treatment and for 2 months after the last dose of ADCETRIS. Advise male patients with female partners of reproductive potential to use effective contraception during ADCETRIS treatment and for 4 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.

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

Reference: ADCETRIS Prescribing Information. Bothell, WA: Seagen Inc.; 2023.

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