



Coding and Billing Guide

For ADCETRIS[®] (brentuximab vedotin) for Injection

SeagenSecure.com

1-855-4SECURE (855-473-2873)

Monday-Friday, 8 AM-8 PM ET

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Please click [here](#) for Indications and Important Safety Information.
Click [here](#) for full Prescribing Information, including **BOXED WARNING**, for ADCETRIS.

Introduction

Accurate and appropriate completion of coding and billing requirements can reduce delays or inaccurate denials in claims processing and facilitate timely reimbursement.

This guide is intended to be an educational reference, providing general coding and billing information to facilitate medically appropriate patient access to ADCETRIS (brentuximab vedotin) for injection. It is offered for informational purposes only and is not intended to provide reimbursement or legal advice.

Each healthcare provider (HCP) is responsible for determining the appropriate codes, coverage, and payment for individual patients. Seagen does not guarantee third-party coverage or payment or reimbursement for denied claims.

Because insurance coverage, coding, claims filing, and reimbursement vary by setting of care as well as by payer type, the information included in this guide is general. HCPs should always verify coverage prior to initiating therapy and determine the appropriate codes on a case-by-case basis.

While Seagen has made every effort to be current as of the publication of this guide, the information may not be as current when you view it. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only. This information does not represent any statement, promise, or guarantee by Seagen about coverage, levels of reimbursement, payment, or charge. Additional information may exist, and actual coverage and reimbursement decisions are made by individual payers. Providers should contact the applicable third-party payers for specific information on coding and billing requirements.

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims conforming to the requirements of the relevant payer for those products and services rendered. Pharmacies (or any other provider submitting a claim) should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials provided by Seagen Secure are to assist providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider, and information provided by Seagen should in no way be considered a guarantee of coverage or reimbursement for any product or service.

Navigating Claim Delays and Denials

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.

Understanding the reasons why insurers may deny medical claims can help limit the number of denials. Common causes of delayed or denied claims may include:

- ✘ Inaccurate or missing codes (eg, J-codes [HCPCS Codes], CPT codes, ICD-10-CM codes)
- ✘ Incorrect product information
- ✘ Missing or incorrect NDC, prior authorization number, National Provider Identifier
- ✘ Incorrect patient identifier information (eg, insurance identification number, date of birth)
- ✘ Failure to follow payer-specific requirements

Call or visit [SeagenSecure.com](https://www.seagensecure.com) for resources and information about benefit and reimbursement assistance.

Please click [here](#) for Indications and Important Safety Information.
Click [here](#) for full Prescribing Information, including BOXED WARNING, for ADCETRIS.

Considerations When

Requesting Prior Authorizations

- ✓ Determine if ADCETRIS (brentuximab vedotin) is covered as a medical or pharmacy benefit prior to infusion
- ✓ Verify and record that all of the prior authorization requirements for the plan have been met
- ✓ Ensure medical records include full and proper documentation of the patient's history including diagnosis codes, prior therapy, and rationale for treatment to justify coding
 - For exception requests, when medically appropriate, explain why a particular requirement is not medically appropriate for the patient
- ✓ If required, include a Letter of Medical Necessity that provides the patient's medical history and rationale for the therapy
- ✓ Verify that all identification numbers and names are correct

➤ [Click here](#) for a sample prior authorization request letter

➤ [Click here](#) for a sample letter of medical necessity

Submitting a Claim

- ✓ Specify the correct number of billing units on the health insurance claim form (CMS-1500) or on the UB-04/CMS-1450 Claim Form.¹ Dosing for ADCETRIS is weight-based. Therefore, ensure the actual dose administered to the patient is reflected in the billing units (see [pages 10-13](#) for instructions on filling out claim forms)
- ✓ Use the correct ICD-10-CM, CPT, and HCPCS codes, including modifiers if applicable
- ✓ Verify the proper use of billing codes
- ✓ For the hospital outpatient setting, confirm that the correct revenue code is used with the appropriate supporting HCPCS code
- ✓ Submit the claim within the timeframe specified by the payer
- ✓ Track clearinghouse claims to ensure successful transmission

Relevant Billing Codes for ADCETRIS (brentuximab vedotin)

The billing codes listed below may be appropriate when billing for ADCETRIS and its administration for the treatment of FDA-approved indications.

It is the HCP's responsibility to determine the appropriate codes and to submit accurate claims for products and services provided. Seagen does not guarantee coverage and/or reimbursement for ADCETRIS. Coverage, coding, and reimbursement policies vary significantly by payer, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. HCPs should verify coverage, coding, and reimbursement guidelines on a case-by-case basis.

Healthcare Common Procedure Coding System (HCPCS)

The HCPCS is used to identify products, supplies, and services that are billed to private and government payers by hospitals, physicians, and other HCPs.²

HCPCS Code ³	Description	Billing Unit
J9042	Injection, brentuximab vedotin, 1 mg	1 mg = 1 billing unit

One billing unit of J9042 equals 1 mg of brentuximab vedotin.³ As a result, 50 units equals 1 single-dose 50-mg vial.¹ Actual units reported will vary by dosage required for each individual patient.

National Drug Code (NDC)

You may be required to include an NDC for ADCETRIS on a claim form. The 10-digit NDC for ADCETRIS is listed below.

NDC Code ¹	Description
51144-050-01	50 mg brentuximab vedotin

Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary.

FDA=US Food and Drug Administration.

Current Procedural Terminology (CPT®) Codes for Drug Administration Service

Five-digit codes that describe the procedures and services performed by physicians and other HCPs.

CPT Code ⁴	Description
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique, each additional hour

HCPs should consult the current CPT® manual and always select the code that accurately describes the administration service performed for the patient. HCPs should also contact the payer for additional coding information required.

Please click [here](#) for Indications and Important Safety Information.
 Click [here](#) for full Prescribing Information, including **BOXED WARNING**, for ADCETRIS.

Relevant Billing Codes for ADCETRIS (brentuximab vedotin) (cont'd)

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)

ICD-10-CM codes are used to identify a patient's diagnosis. At least 1 ICD-10-CM diagnosis code must be included in all hospital and physician office claims to describe the patient's diagnosis.

The ICD-10-CM diagnosis codes listed are provided only as examples of potentially relevant codes. Providers should consult a current ICD-10-CM manual and select the most appropriate diagnosis code(s) to accurately describe a patient's condition. All diagnosis codes should be supported with adequate documentation.

Digits 1-4: Diagnosis Code

Hodgkin Lymphoma⁵

Code	Description
C81.1	Nodular sclerosis classical Hodgkin lymphoma
C81.2	Mixed cellularity classical Hodgkin lymphoma
C81.3	Lymphocyte-depleted classical Hodgkin lymphoma
C81.4	Lymphocyte-rich classical Hodgkin lymphoma
C81.7	Other classical Hodgkin lymphoma
C81.9	Hodgkin lymphoma, unspecified

Cutaneous T-cell Lymphoma⁵

Code	Description
C84.0	Mycosis fungoides
C86.6	Primary cutaneous CD30-positive T-cell proliferations (includes primary cutaneous anaplastic large-cell lymphoma)

Peripheral T-cell Lymphoma⁵

Code	Description
C84.4	Peripheral T-cell lymphoma, not classified
C84.6	Anaplastic large-cell lymphoma, anaplastic lymphoma kinase-positive
C84.7	Anaplastic large-cell lymphoma, anaplastic lymphoma kinase-negative
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C91.5	Adult T-cell leukemia/lymphoma (human T-cell lymphotropic virus type 1 associated)

Digit 5: Site (always bill to the 5th digit)

Subcodes for Hodgkin Lymphoma; Peripheral T-cell Lymphoma, Not Otherwise Specified; Anaplastic Large-cell Lymphoma; and Mycosis Fungoides⁵

Code	Description
0	Unspecified site
1	Lymph nodes of head, face, and neck
2	Intrathoracic lymph nodes
3	Intra-abdominal lymph nodes
4	Lymph nodes of the axilla and upper limb
5	Lymph nodes of the inguinal region and lower limb
6	Intrapelvic lymph nodes
7	Spleen
8	Lymph nodes of multiple sites
9	Extranodal and solid organ sites

Subcodes* for Adult T-cell Leukemia/Lymphoma⁵

Code	Description
0	Not having achieved remission
1	In remission
2	In relapse

*Applies to C91.5.

Did you know?



Dedicated Field Reimbursement Managers are able to share certain coverage and on-label coding information to support patient access inquires. Contact your local Seagen representative to learn more.

Please click [here](#) for Indications and Important Safety Information. Click [here](#) for full Prescribing Information, including **BOXED WARNING**, for ADCETRIS.

Sample Claim Forms

Health Insurance Claim Form (CMS-1500)⁶

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (TRICARE#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA (FECA#) OTHER (Other#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE (MM DD YY) SEX (M) (F)

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED (Self) (Spouse) (Child) (Other)

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.)

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) (MM DD YY) QUAL. ()

15. OTHER DATE (MM DD YY)

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM) (TO)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE (17a. () 17b. NPI ())

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM) (TO)

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? (YES) (NO) \$ CHARGES ()

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) (ICD 10-Code)

22. RESUBMISSION CODE ORIGINAL REF. NO. ()

23. PRIOR AUTHORIZATION NUMBER ()

24. A. DATE(S) OF SERVICE (From) (To) B. PLACE OF SERVICE (EMG) C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) (CPT/HCPCS) (MODIFIER) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSON Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #

25. FEDERAL TAX ID. NUMBER () SSN () EIN ()

26. PATIENT'S ACCOUNT NO. ()

27. ACCEPT ASSIGNMENT? (For gov't claims, see back) (YES) (NO)

28. TOTAL CHARGE (\$) 29. AMOUNT PAID (\$) 30. Rev'd for NUCC Use ()

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION (a. NPI () b. ())

33. BILLING PROVIDER INFO & PH # ()

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE (17a. () 17b. NPI ())

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM) (TO)

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? (YES) (NO) \$ CHARGES ()

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) (ICD 10-Code)

22. RESUBMISSION CODE ORIGINAL REF. NO. ()

23. PRIOR AUTHORIZATION NUMBER ()

24. A. DATE(S) OF SERVICE (From) (To) B. PLACE OF SERVICE (EMG) C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) (CPT/HCPCS) (MODIFIER) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSON Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #

1
2
3
4
5

A B C D E F

- A Item 19**
Some payers may require drug name, total dosage, and method of administration to be provided in Item 19.⁷
- B Item 21**
Enter appropriate site-specific ICD-10-CM diagnosis code(s) based on the patient's documented medical record.⁸
- C Item 24A and 24B**
Enter the date of service and the appropriate place of service code.⁸
- D Item 24D**
Enter the appropriate HCPCS code for ADCETRIS (brentuximab vedotin): J9042.³ Enter the appropriate CPT code for the administration service.⁸ If applicable, discarded product should be reported on a separate line with the JW modifier.⁹
- E Item 24E**
Enter the diagnosis code reference letter or number from Item 21 that relates to the product or procedure listed in Item 24D.⁸
- F Item 24G**
Report billing units here. 1 mg = 1 billing unit.³ Actual units reported will vary by dosage required for each individual patient.

This sample form is provided for informational purposes only. The accurate completion of claims documentation is the responsibility of the HCP. Seagen does not guarantee reimbursement for any services or product.

Please click [here](#) for Indications and Important Safety Information. Click [here](#) for full Prescribing Information, including **BOXED WARNING**, for ADCETRIS.

Sample Claim Forms (cont'd)

Outpatient Hospital Claim Form (CMS-1450 [UB-04])¹⁰

42 REV CD	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 NON COVERED CHARGES	49
1							1
2							2
3							3
4							4
5							5

- A Item 42**
Enter a 4-digit revenue code that best describes the service provided, in accordance with the hospital billing policy.¹¹
- B Item 43**
Enter the corresponding description for the revenue code listed in Item 42. When required to submit drug rebate data for Medicaid rebates, enter the NDC qualifier "N4" followed by the 11-digit NDC, the quantity qualifier, and the quantity administered.¹¹
- C Item 44**
Enter the appropriate HCPCS code for ADCETRIS (brentuximab vedotin): J9042.^{3,11} If applicable, discarded product should be reported on a separate line with the HCPCS code and JW modifier.⁹
- D Item 45**
Enter the date of service.¹¹
- E Item 46**
Report billing units here. 1 mg = 1 billing unit.³ Actual units reported will vary by dosage required for each individual patient.

66 DX	67 A	B	C	D	E	F	G	H	68
1	A	B	C	D	E	F	G	H	1
2	J	K	L	M	N	O	P	Q	2

- F Item 66**
Enter the appropriate diagnosis code(s).¹¹
- G Item 67A-67Q**
Enter the site-specific ICD-10-CM diagnosis codes for the malignancy being treated as documented in the patient's medical records.¹¹

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Seagen Secure

Support Throughout the Prior Authorization and Coverage Process

Coverage support is a key way in which Seagen Secure helps patients access their prescribed therapies. Seagen Secure is available to assist patients throughout the patient journey.

Seagen Secure may be able to help:



When initiating a benefit investigation for patients who will receive ADCETRIS (brentuximab vedotin) through the network specialty distributor of the provider's choice



When an HCP needs to order ADCETRIS for eligible patients enrolled in the Patient Assistance Program (PAP)

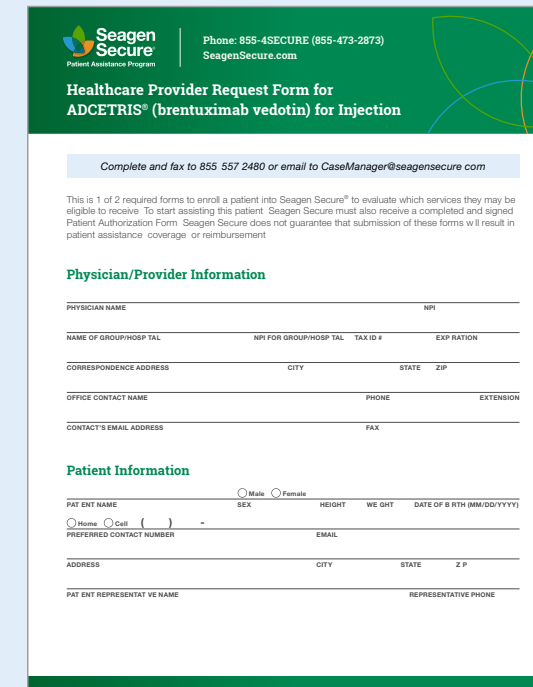


When an HCP has a question about billing the patient's insurance for ADCETRIS

Enrolling in Seagen Secure

There are 2 required forms to enroll a patient in Seagen Secure.

Whenever possible, submit these forms together to ensure efficient processing.



Seagen Secure Patient Assistance Program Phone: 855-4SECURE (855-473-2873) SeagenSecure.com

Healthcare Provider Request Form for ADCETRIS® (brentuximab vedotin) for Injection

Complete and fax to 855 557 2480 or email to CaseManager@seagensecure.com

This is 1 of 2 required forms to enroll a patient into Seagen Secure® to evaluate which services they may be eligible to receive. To start assisting this patient, Seagen Secure must also receive a completed and signed Patient Authorization Form. Seagen Secure does not guarantee that submission of these forms will result in patient assistance coverage or reimbursement.

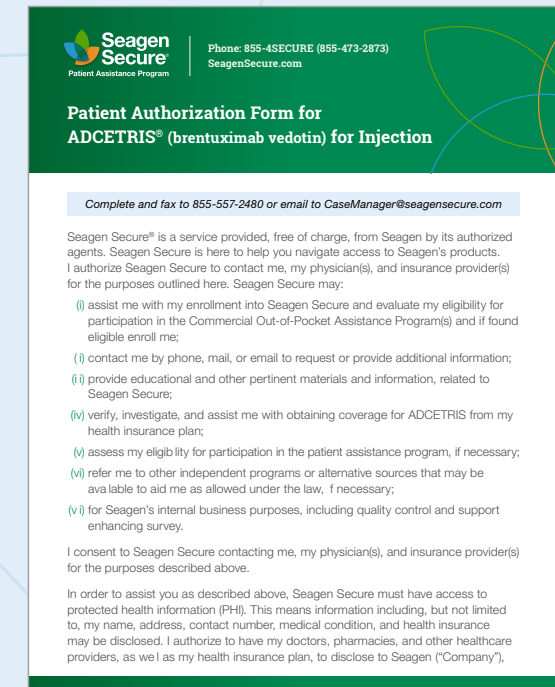
Physician/Provider Information

PHYSICIAN NAME _____ NPI _____
NAME OF GROUP/HOSP TAL _____ NPI FOR GROUP/HOSP TAL _____ TAX ID # _____ EXP RATION _____
CORRESPONDENCE ADDRESS _____ CITY _____ STATE _____ ZIP _____
OFFICE CONTACT NAME _____ PHONE _____ EXTENSION _____
CONTACT'S EMAIL ADDRESS _____ FAX _____

Patient Information

PAT ENT NAME _____ SEX Male Female HEIGHT _____ WT GHT _____ DATE OF BIRTH (MM/DD/YYYY) _____
 Home Cell () - _____
PREFERRED CONTACT NUMBER _____ EMAIL _____
ADDRESS _____ CITY _____ STATE _____ ZIP _____
PAT ENT REPRESENTATIVE NAME _____ REPRESENTATIVE PHONE _____

Click to access the
HCP Request Form



Seagen Secure Patient Assistance Program Phone: 855-4SECURE (855-473-2873) SeagenSecure.com

Patient Authorization Form for ADCETRIS® (brentuximab vedotin) for Injection

Complete and fax to 855-557-2480 or email to CaseManager@seagensecure.com

Seagen Secure® is a service provided, free of charge, from Seagen by its authorized agents. Seagen Secure is here to help you navigate access to Seagen's products. I authorize Seagen Secure to contact me, my physician(s), and insurance provider(s) for the purposes outlined here. Seagen Secure may:

- (i) assist me with my enrollment into Seagen Secure and evaluate my eligibility for participation in the Commercial Out-of-Pocket Assistance Program(s) and if found eligible enroll me;
- (ii) contact me by phone, mail, or email to request or provide additional information;
- (iii) provide educational and other pertinent materials and information, related to Seagen Secure;
- (iv) verify, investigate, and assist me with obtaining coverage for ADCETRIS from my health insurance plan;
- (v) assess my eligibility for participation in the patient assistance program, if necessary;
- (vi) refer me to other independent programs or alternative sources that may be available to aid me as allowed under the law, if necessary;
- (vii) for Seagen's internal business purposes, including quality control and support enhancing survey.

I consent to Seagen Secure contacting me, my physician(s), and insurance provider(s) for the purposes described above.

In order to assist you as described above, Seagen Secure must have access to protected health information (PHI). This means information including, but not limited to, my name, address, contact number, medical condition, and health insurance may be disclosed. I authorize to have my doctors, pharmacies, and other healthcare providers, as well as my health insurance plan, to disclose to Seagen ("Company").

Click to access the
Patient Authorization Form

Please click [here](#) for Indications and Important Safety Information.
Click [here](#) for full Prescribing Information, including **BOXED WARNING**, for ADCETRIS.

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.

Click [here](#) for full Prescribing Information, including **BOXED WARNING**, for ADCETRIS.

Important Safety Information (cont'd)

Increased toxicity in the presence of severe renal impairment: The frequency of \geq 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 \geq 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 (\geq 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.

Contact Seagen Secure

Seagen Secure is a dynamic and comprehensive suite of solutions to help patients access their prescribed Seagen therapy.

There are 3 ways to contact Seagen Secure for assistance:



Call

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



Go online

SeagenSecure.com or email
casemanager@seagensecure.com




Fax

855-557-2480

For more information on Seagen Secure, please contact your Field Reimbursement Manager.

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