



Coding and Billing Guide

For ADCETRIS[®] (brentuximab vedotin) for Injection

SeagenSecure.com

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Monday-Friday, 8 AM-8 PM ET

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

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.

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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. 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.¹

HCPCS Code ²	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.² As a result, 50 units equals one single-dose 50-mg vial.³ 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 ³	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.

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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 Access and 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.

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Sample Claim Forms

Health Insurance Claim Form (CMS-1500)⁶

- 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): J9042.² 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.² 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.

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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.^{2,11} 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.² 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										1
2										2
3										3
4										4
5										5

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

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.

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

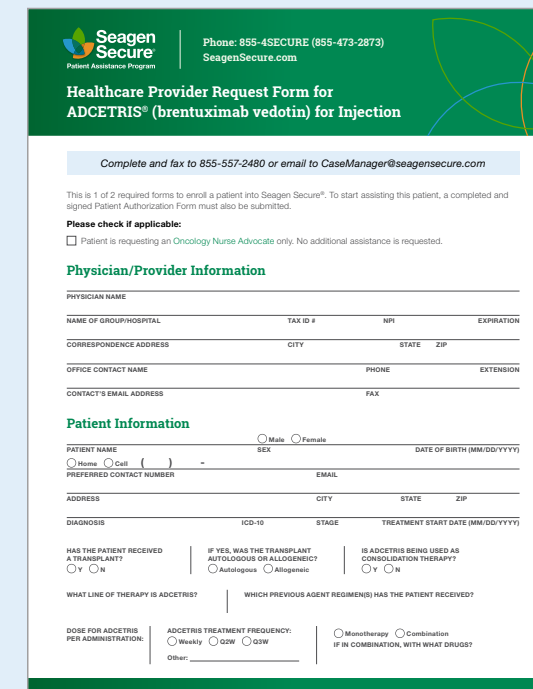


When the HCP has a question about billing the patient's insurance for ADCETRIS

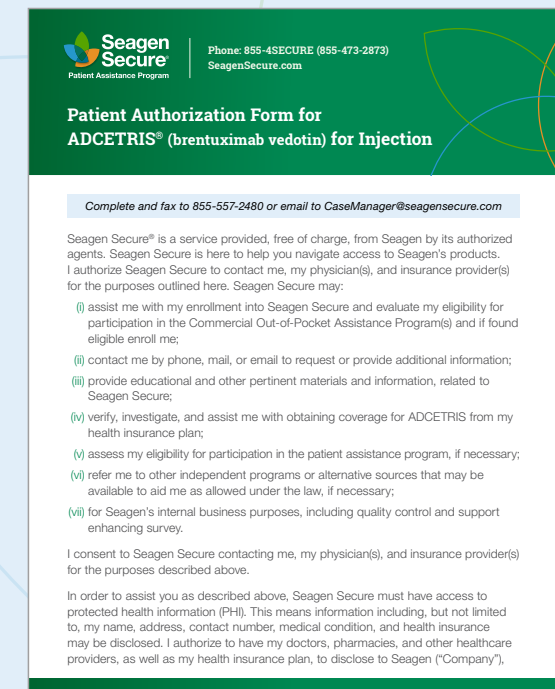
Enrolling in Seagen Secure

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

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



Click to access the
HCP Request Form



Click to access the
Patient Authorization Form

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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.

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

ADCETRIS concomitant with 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. Institute dose modifications accordingly.
- **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 patients who receive ADCETRIS in combination with chemotherapy for previously untreated Stage III/IV cHL or previously untreated PTCL.

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 bacterial, fungal, or viral infections.
- **Tumor lysis syndrome:** Closely monitor patients with rapidly proliferating tumor and high tumor burden.
- **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 compared to patients with normal renal function. Avoid use in patients with severe renal impairment.

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Important Safety Information (cont'd)

- **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 compared to patients with normal hepatic function. 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 antihyperglycemic 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 the potential risk to the fetus, and to avoid pregnancy during ADCETRIS treatment and for at least 6 months after the final dose of ADCETRIS.

Most Common (\geq 20% in any study) Adverse Reactions

Peripheral neuropathy, fatigue, nausea, diarrhea, neutropenia, upper respiratory tract infection, pyrexia, constipation, vomiting, alopecia, decreased weight, abdominal pain, anemia, stomatitis, lymphopenia, and mucositis.

Drug Interactions

Concomitant use of strong CYP3A4 inhibitors or inducers has the potential to affect the exposure to monomethyl auristatin E (MMAE).

Use in Specific Populations

Moderate or severe hepatic impairment or severe renal impairment: MMAE exposure and adverse reactions are increased. Avoid use.

Advise males with female sexual partners of reproductive potential to use effective contraception during ADCETRIS treatment and for at least 6 months after the final dose of ADCETRIS.

Advise patients to report pregnancy immediately and avoid breastfeeding while receiving ADCETRIS.

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

Contact Seagen Secure

Seagen Secure is a dynamic and comprehensive suite of solutions to help patients access Seagen therapies.

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 access and reimbursement manager.

References: 1. Centers for Medicare & Medicaid Services. HCPCS – general information (last modified 10-19-2020). <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>. Accessed October 23, 2020. 2. Centers for Medicare & Medicaid Services. 2020 alpha-numeric HCPCS file. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File>. Accessed October 23, 2020. 3. ADCETRIS [Prescribing Information]. Bothell, WA: Seagen Inc. October 2019. 4. Centers for Medicare & Medicaid Services. Physician fee schedule search: 96413, 96415 <https://www.cms.gov/apps/physician-fee-schedule/search/search-results.aspx?Y=0&T=0&HT=1&CT=3&H1=96413&H2=96415&M=5>. Accessed March 12, 2020. 5. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries (2019). <https://www.cms.gov/files/zip/2021-code-tables-and-index.zip>. File name: icd10cm_tabular_2019.pdf. Accessed January 5, 2020. 6. Centers for Medicare & Medicaid Services. Health Insurance Claim Form (approved February 2012). <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf>. Accessed October 23, 2020. 7. Centers for Medicare & Medicaid Services. Billing and coding guidelines for drugs and biologics (non-chemotherapy) (revised April 1, 2018). https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/34741_55/BCG_L34741.pdf. Accessed October 23, 2020. 8. Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 26 – completing and processing form CMS-1500 data set (revised May 8, 2020). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf>. Accessed October 23, 2020. 9. Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 17 – drugs and biologics. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>. Accessed October 23, 2020. 10. Centers for Medicare & Medicaid Services. CMS-1450. <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/Downloads/CMS-1450.zip>. File name: CMS-1450 UB04-front.pdf. Accessed October 23, 2020. 11. Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 25 – completing and processing the form CMS-1450 data set (revised January 11, 2019). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>. Accessed October 23, 2020.



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