MyNavCare® PATIENT SUPPORT

EPKINLY® (epcoritamab-bysp) Reimbursement & Coding Guide

An overview of coverage, coding, and available patient support services for EPKINLY.

Actor Portrayal

Genmab and AbbVie have prepared this reference guide to assist healthcare providers with obtaining insurance reimbursement for EPKINLY® (epcoritamab-bysp) and its administration. Please note that coverage, coding, and payment may vary significantly by patient, payor, plan, treatment setting, and site of care. Genmab and AbbVie make no representation, warranty, or guarantee that the information provided herein is up to date and/or accurate; will satisfy the requirements of the patient, insurer, or payor; or result in payment. All information included in this guide is provided for informational purposes only, is not intended to provide reimbursement or legal advice, and does not guarantee payment of any claim. It is the sole responsibility of healthcare providers to select the appropriate codes and ensure the accuracy of all claims submitted for reimbursement.

Please see Indications on page 3 and Important Safety Information, including Boxed Warnings for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), on pages 5-6. Please see full Prescribing Information, including Boxed Warnings.

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This guide contains coding and billing information to consider related to EPKINLY. This guide is provided for informational purposes only and is not intended as coverage or coding advice. Individual coding decisions are the responsibility of the provider and should be based upon the diagnosis and treatment of individual patients. These codes are not all-inclusive; appropriate codes can vary by patient, setting of care, and payor. Please check with the payor to verify codes and special billing requirements. Genmab and AbbVie do not make any representation or guarantee concerning reimbursement or coverage for any service or item.

EPKINLY® (epcoritamab-bysp) Select Treatment Information[1]

Indications[1]

DLBCL and High-grade B-cell Lymphoma

- EPKINLY is indicated for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBCL) after 2 or more lines of systemic therapy.

  This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Follicular Lymphoma

- EPKINLY is indicated in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL).
- EPKINLY is indicated as monotherapy for the treatment of adults with relapsed or refractory FL after 2 or more lines of systemic therapy.

Dosage & Administration[1]

- EPKINLY should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).
- Administer EPKINLY to well-hydrated patients. Administer premedications and prophylaxis as recommended.
- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms.
- For patients with DLBCL and FL, assess whether hospitalization or outpatient monitoring for the first 48 mg dose is appropriate based on comorbidities or other situational factors. During outpatient monitoring after the first 48 mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS.
- Administer EPKINLY subcutaneously according to the step-up dosage schedules below to reduce the incidence and severity of CRS. EPKINLY is administered in 28-day cycles until disease progression or unacceptable toxicity.

Diffuse Large B-Cell Lymphoma (DLBCL) and High-Grade B-Cell Lymphoma[1]

Dosing Schedule	Cycle of Treatment	Days	Dose of EPKINLY
Weekly	Cycle 1	1	0.16 mg (Step-up dose 1)
		8	0.8 mg (Step-up dose 2)
		15	48 mg (First full dose)
		22	48 mg
Weekly	Cycles 2 and 3	1, 8, 15 and 22	48 mg
Every two weeks	Cycles 4 to 9	1 and 15	48 mg
Every four weeks	Cycle 10 and beyond	1	48 mg

Drug Wastage Modifiers To Be Denoted Based On The Billing Units[2]

Modifier requirements should be confirmed with the payor. Example of documentation of drug wastage during the “step-up” doses and all full doses for **Diffuse Large B-Cell Lymphoma and High-Grade B-Cell Lymphoma** is as follows:

Dose[1]	Claim Form Line 1[2]	Claim Form Line 2[2]
Step-up dose 1: 0.16 mg	J9321 – 1 billable unit	J9321 – JW modifier appended 24 billable units
Step-up dose 2: 0.8 mg	J9321 – 5 billable units	J9321 – JW modifier appended 20 billable units
Full dose: 48 mg	J9321 – JZ modifier appended 300 billable units	Not applicable

Please see full Prescribing Information, including Boxed Warnings, for guidance on premedication requirements, dosage modifications, and management of adverse reactions, and re-starting EPKINLY after dosage delay. Please see Important Safety Information on pages 5-6.

EPKINLY® (epcoritamab-bysp)
Select Treatment Information *(continued)*[1]

Follicular Lymphoma (FL)[1]

Dosing Schedule	Cycle of Treatment	Days	Dose of EPKINLY
Weekly	Cycle 1	1	0.16 mg (Step-up dose 1)
		8	0.8 mg (Step-up dose 2)
		15	3 mg (Step-up dose 3)
		22	48 mg (First full dose)
Weekly	Cycles 2 and 3	1, 8, 15 and 22	48 mg
Every two weeks	Cycles 4 to 9	1 and 15	48 mg
Every four weeks	Cycle 10 and beyond	1	48 mg

EPKINLY Dosage Schedule in Combination with Lenalidomide and Rituximab for Patients with FL

Indication	Cycle[a]	Day	Dose of EPKINLY	
Follicular Lymphoma	Cycle 1	1	Step-up dose 1	0.16 mg
		8	Step-up dose 2	0.8 mg
		15	Step-up dose 3	3 mg
		22	First full dose	48 mg
	Cycles 2 and 3	1, 8, 15 and 22	48 mg	
	Cycles 4 to 12	1	48 mg	

[a]Cycle = 28 days

Drug Wastage Modifiers To Be Denoted Based On The Billing Units[2]

Modifier requirements should be confirmed with the payor. Example of documentation of drug wastage during the "step-up" doses and all full doses for **Follicular Lymphoma** is as follows:

Dose[1]	Claim Form Line 1[2]	Claim Form Line 2[2]
Step-up dose 1: 0.16 mg	J9321 – 1 billable unit	J9321 – JW modifier appended 24 billable units
Step-up dose 2: 0.8 mg	J9321 – 5 billable units	J9321 – JW modifier appended 20 billable units
Step-up dose 3: 3 mg	J9321 – 19 billable units	J9321 – JW modifier appended 6 billable units
Full dose: 48 mg	J9321 – JZ modifier appended 300 billable units	Not applicable

- Dosages of EPKINLY 0.16 mg and 0.8 mg require dilution prior to administration. See Sections 2.7 through 2.10 of the full Prescribing Information for instructions on preparation and administration.[1]

Please see full Prescribing Information, including Boxed Warnings, for guidance on premedication requirements, dosage modifications, and management of adverse reactions, and re-starting EPKINLY after dosage delay. Please see Important Safety Information on pages 5-6.

EPKINLY® (epcoritamab-bysp) Important Safety Information[1]

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **Immune effector cell–associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.**

CRS

- CRS occurred in 51% (80/157) of patients with large B-cell lymphoma (LBCL) receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (37% Grade 1, 17% Grade 2, and 2.5% Grade 3) and recurred in 31% of patients. Most events (92%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 6% of patients after the 0.16 mg dose (Cycle 1, day 1), 12% after the 0.8 mg dose (Cycle 1, day 8), 43% after the first 48 mg dose (Cycle 1, day 15), and 5% after the next 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 24 hours (range: 0-10 days). The median time to onset after the first full 48 mg dose was 21 hours (range: 0-7 days).
- CRS occurred in 49% (42/86) of patients with FL receiving EPKINLY monotherapy at the recommended dosage schedule in EPCORE NHL-1 (45% Grade 1, 9% Grade 2) and recurred in 48% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 12% of patients after the 0.16 mg dose (Cycle 1, day 1), 6% after the 0.8 mg dose (Cycle 1, day 8), 15% after the 3 mg dose (Cycle 1, day 15), and 37% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 59 hours (range: 0.1-7 days). The median time to onset after the first full 48 mg dose was 61 hours (range: 0.1-7 days).
- CRS occurred in 24% (32/131) of patients with FL receiving EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1 (19% Grade 1, 5% Grade 2, and 12% serious adverse reactions due to CRS) and recurred in 41% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS occurred in 5% of patients after the 0.16 mg dose (Cycle 1, day 1), 3.8% after the 0.8 mg dose (Cycle 1, day 8), 2.3% after the 3 mg dose (Cycle 1, day 15), and 18% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent EPKINLY dose was 78 hours (range: 0.2-12 days). The median time to onset after the first 48 mg dose was 41 hours (range: 0.3-12 days).
- For patients with LBCL and FL, assess whether hospitalization or outpatient monitoring for the first 48 mg dose is appropriate based on comorbidities or other situational factors. During outpatient monitoring after the first 48 mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS.
- In patients who experienced CRS, the signs and symptoms included pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range: <1-27 days). Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients with LBCL, 4.7% of patients with FL receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- Administer pretreatment medications to reduce the risk of CRS.
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

ICANS

- ICANS occurred in 6% (10/157) of patients with LBCL receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (4.5% Grade 1, 1.3% Grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred within Cycle 1 of treatment, with a median time to onset of 16.5 days (range: 8-141 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset was 3 days (range: 1-13 days). The median duration of ICANS was 4 days (range: 0-8 days), with ICANS resolving in 90% of patients with supportive care.
- ICANS occurred in 6% (8/127) of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (3.9% Grade 1, 2.4% Grade 2). The median time to onset was 22 days (range: 14-66 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset of ICANS was 3 days (range: 0.4-7 days). The median duration of ICANS was 2 days (range: 1-7 days), with ICANS resolving in 100% of patients.

Please see additional Important Safety Information on page 6 and full Prescribing Information, including Boxed Warnings.

EPKINLY® (epcoritamab-bysp) Important Safety Information *(continued)*[1]

- Among patients with FL who received EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1, ICANS occurred in 0.8% (1/131, Grade 1).
- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical manifestations of ICANS included, but were not limited to, confusional state, lethargy, tremor, dysgraphia, aphasia, and non-convulsive status epilepticus.
- Monitor patients for potential ICANS. At the first signs or symptoms of ICANS, immediately evaluate patient, provide supportive therapy based on severity, and manage per current practice guidelines.

Infections

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL in EPCORE NHL-1 (most common: 4.5% sepsis, 3.2% pneumonia). Fatal infections occurred in 1.3% of patients (1.3% COVID-19).
- Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving EPKINLY monotherapy, following the 2-step up dosage schedule in EPCORE NHL-1 (most common: 20% COVID-19, 13% pneumonia, 3% urinary tract infections). Fatal infections occurred in 6% of patients (5% COVID-19, 0.8% pneumonia, 0.8% sepsis).
- Among 243 patients with FL who received EPKINLY in combination with lenalidomide and rituximab in EPCORE FL-1, serious infections occurred in 28% of patients. The most common serious infections were pneumonia (15%), COVID-19 (7%), opportunistic infections (5%) and upper respiratory infections (3.3%). The most common opportunistic infections of any grade were cytomegalovirus (CMV) infection (7%) and herpesvirus infection (7%).
- Progressive multifocal leukoencephalopathy (PML), including fatal cases, has occurred in patients treated with EPKINLY. Across a broader clinical trial population, PML was reported in 0.4% (11/3,072) of patients, including in the first-line treatment setting. Of the 11 cases of PML, 6 resulted in fatal outcomes and 1 was unresolved at the time of death.
- Monitor patients for signs and symptoms of infection and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis during treatment with EPKINLY and consider prophylaxis against herpesvirus.

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial of patients with LBCL, Grade 3 or 4 decreased neutrophils occurred in 32% (Grade 4, 14%), decreased hemoglobin in 12% (Grade 4, 0%), and decreased platelets in 12% (Grade 4, 7%) of patients. Febrile neutropenia occurred in 2.5% (Grade 4, 0.6%).
- In the clinical trial of patients with FL who received EPKINLY monotherapy following the 2-step up dosage schedule, Grade 3 or 4 decreased neutrophils occurred in 30% (Grade 4, 17%), decreased hemoglobin in 10% (Grade 4, 0%), and decreased platelets in 8% (Grade 4, 4%) of patients. Febrile neutropenia occurred in 3.1% (Grade 4, 0%).
- In patients with FL who received EPKINLY in combination with lenalidomide and rituximab, Grade 3 or 4 decreased neutrophils occurred in 67% (Grade 4, 41%), decreased lymphocytes in 62% (Grade 4, 13%), decreased hemoglobin in 7%, and decreased platelets in 10% (Grade 4, 4.1%) of patients. Febrile neutropenia occurred in 6% (Grade 4, 2.1%).
- Monitor complete blood counts throughout treatment. Based on severity of cytopenias, temporarily withhold or permanently discontinue EPKINLY. Consider prophylactic granulocyte colony-stimulating factor administration as applicable.

EPKINLY® (epcoritamab-bysp) Important Safety Information *(continued)*[1]

Embryo-Fetal Toxicity

- EPKINLY may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY.

Adverse Reactions

- EPKINLY as monotherapy for LBCL or FL: Most common (≥20%) adverse reactions were CRS, injection site reactions, fatigue, musculoskeletal pain, fever, diarrhea, COVID-19, rash, and abdominal pain. Most common Grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, and decreased platelets.
- EPKINLY in combination with lenalidomide and rituximab for FL: Most common (≥20%) adverse reactions were rash, upper respiratory tract infections, fatigue, injection site reactions, constipation, diarrhea, CRS, pneumonia, COVID-19, and fever. The most common Grade 3 to 4 laboratory abnormalities (≥10%) were decreased neutrophils, decreased lymphocytes, and decreased platelets.

Use in Specific Populations

- **Lactation:** Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.
- **Geriatric Use:** In patients with relapsed or refractory FL who received EPKINLY in EPCORE NHL-1, 52% were ≥65 years old, and 13% were ≥75 years old. A higher rate of fatal adverse reactions, primarily infections, including COVID-19, was observed in patients ≥65 years old compared to younger adult patients. No overall difference in efficacy was observed.

EPKINLY® (epcoritamab-bysp) Coding Overview

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes[3]

The following diagnosis codes may apply for EPKINLY based on the FDA-approved indications. Diagnosis code requirements should be confirmed by the payor.

Diffuse Large B-Cell Lymphoma (DLBCL) and High-Grade B-Cell Lymphoma

ICD-10-CM Code	Description
C83.3	Diffuse large B-cell lymphoma
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.398	Diffuse large B-cell lymphoma of other extranodal and solid organ sites

Follicular Lymphoma

ICD-10-CM Code	Description
C82.00 – C82.09	Follicular lymphoma grade I
C82.10 – C82.19	Follicular lymphoma grade II
C82.20 – C82.29	Follicular lymphoma grade III
C82.30 – C82.39	Follicular lymphoma grade IIIa
C82.50 – C82.59	Diffuse follicle center lymphoma
C82.60 – C82.69	Cutaneous follicle center lymphoma
C82.80 – C82.89	Other types of follicular lymphoma
C82.90 – C82.99	Follicular lymphoma, unspecified

Coding current as of October 2025

Please see Indications on page 3 and Important Safety Information, including Boxed Warnings for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), on pages 5-6. Please see full Prescribing Information, including Boxed Warnings.

EPKINLY® (epcoritamab-bysp) Coding Overview *(Continued)*

Healthcare Common Procedure Coding System (HCPCS) Codes[4]

CMS issued a permanent Healthcare Common Procedure Coding System (HCPCS) J-Code for EPKINLY for use in all treatment settings.

HCPCS Code	Description and Billing Unit*
J9321	Injection, epcoritamab-bysp, 0.16 mg

*As an example, a 48 mg dose is equivalent to 300 billing units.

New Technology Add-On Payment (NTAP) Designation[5]

CMS has assigned an International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) code to denote the administration of EPKINLY during an inpatient administration. This code is effective for dates of service on or after October 1, 2023. When the EPKINLY ICD-10-PCS code is applied to relevant inpatient claim forms, CMS will assess the eligibility for additional payment above the MS-DRG.

ICD-10-PCS Code	Description
XW013S9	Introduction of epcoritamab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 9

National Drug Code (NDC)[6]

Payors may require the NDC number for EPKINLY on medical claims submitted for provider-administered therapy. Specific requirements for NDC reporting may vary; however, the 11-digit format is generally preferred for claim submissions. Some payors may require reporting the 11-digit NDC number, along with an NDC qualifier (N4), basis of measure, and quantity. The various formats are outlined below.

Vial Size/Strength	10-Digit NDC	11-Digit NDC	N4-Appended NDC
4 mg/0.8 mL	82705-002-01	82705-0002-01	N482705000201ML
48 mg/0.8 mL	82705-010-01	82705-0010-01	N482705001001ML

Coding current as of October 2025

EPKINLY® (epcoritamab-bysp) Coding Overview *(Continued)*

Current Procedural Terminology (CPT) Codes[7]

The following CPT code may be applicable for the administration of EPKINLY. Appropriate code requirements may vary by payor and should be confirmed by the provider.

CPT Code	Description
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic

Revenue Codes[8]

When EPKINLY is administered in the hospital outpatient setting, payors and hospitals will have specific policies on what revenue code they require. Providers should confirm the appropriate revenue code assignment per patient. For Medicare claims, the revenue code reflected below should be used to support appropriate claims processing.[9]

Revenue Code	Description
0636	Drugs requiring detailed coding

Documentation of Drug Wastage[2]

Under Medicare's discarded drug policy, hospital outpatient departments and physician offices must use the JW modifier to report the amount of unused drug from a single-use vial that is discarded and must document the amount of discarded drug in the patient's medical record. Medicare will pay for both the amount of drug that is administered and the amount of drug that is discarded, up to the amount that is indicated on the vial or package label.

When a portion of a single-use vial is discarded, the amount of discarded drug should be billed as a separate line item with the JW modifier. Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.

Many commercial insurance plans and other payors have adopted the same or similar guidelines as CMS for billing drug wastage. For all payors, it is best practice to check provider policies for the most current requirements.

Modifier	Description
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

Coding current as of October 2025

EPKINLY® (epcoritamab-bysp) Coding Overview *(Continued)*

340B Pricing Acquisition Modifier[10]

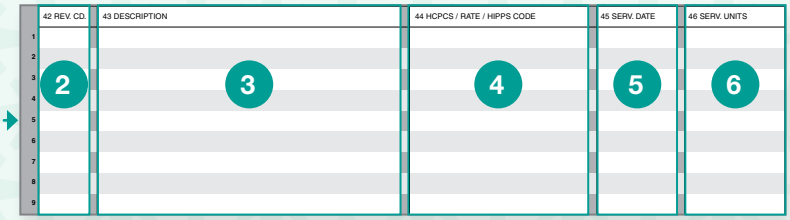
Effective January 1, 2025, the Centers for Medicare & Medicaid Services (CMS) requires 340B entities to append modifier -TB to claims, when appropriate, to identify drug acquired at 340B pricing. Appropriate use of the -TB modifier enables CMS to track the utilization of 340B-acquired drugs and biologicals and to comply with the applicable requirements of the Inflation Reduction Act.

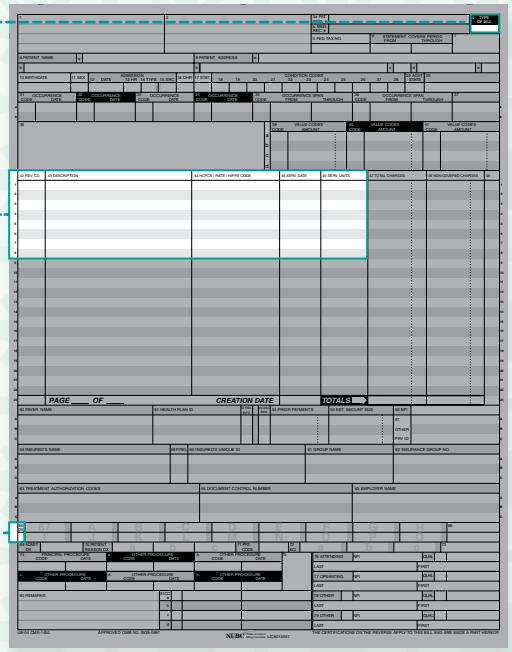
Commercial payors and some Medicaid agencies are also requiring the TB modifier to identify drugs purchased under the 340B program. This modifier must be used on claims to ensure compliance with payer billing rules and 340B program requirements. Providers should confirm this requirement with each payor.[11,12]

Modifier	Description
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

Sample CMS 1450 Claim Form *(Hospital Outpatient)*

This sample form is provided for informational purposes only. The accurate completion of claims documentation is the responsibility of the provider. Genmab and AbbVie do not guarantee reimbursement for any services or product.





1 TYPE OF BILL

Item 4

Enter the appropriate type of bill code (eg, 013X Hospital Outpatient).[13]

2

Item 42

Enter a 4-digit revenue code that aligns with the administration of EPKINLY (epcoritamab-bysp), in accordance with hospital billing policy[13] (e.g., 0636 – Drugs Requiring Detailed Coding).[8]

3

Item 43

Enter the corresponding descriptor for the revenue code listed in Item 42. When required to submit drug data for Medicaid rebate calculations, enter the N4-appended 11-digit EPKINLY NDC, followed by quantity qualifier and quantity administered (eg, N482705000201 mL).[13]

4

Item 44

Enter J9321 for EPKINLY.[4] If applicable, discarded product should be reported on a separate line with the JW modifier.[2] If no drug wastage, append JZ modifier to the HCPCS.[2] On a separate line, enter the drug administration CPT code (96401).[7] Commercial payors may request the dosage administered, or documentation of actual amount administered, and amount discarded.

5

Item 45

Enter date of service.[13]

6

Item 46

Report billing units here.[12] EPKINLY (epcoritamab-bysp) is billed on a per 0.16 mg basis. For the drug administration CPT code 96401, enter a unit of “1”.[7]

7 66 DX

Item 66

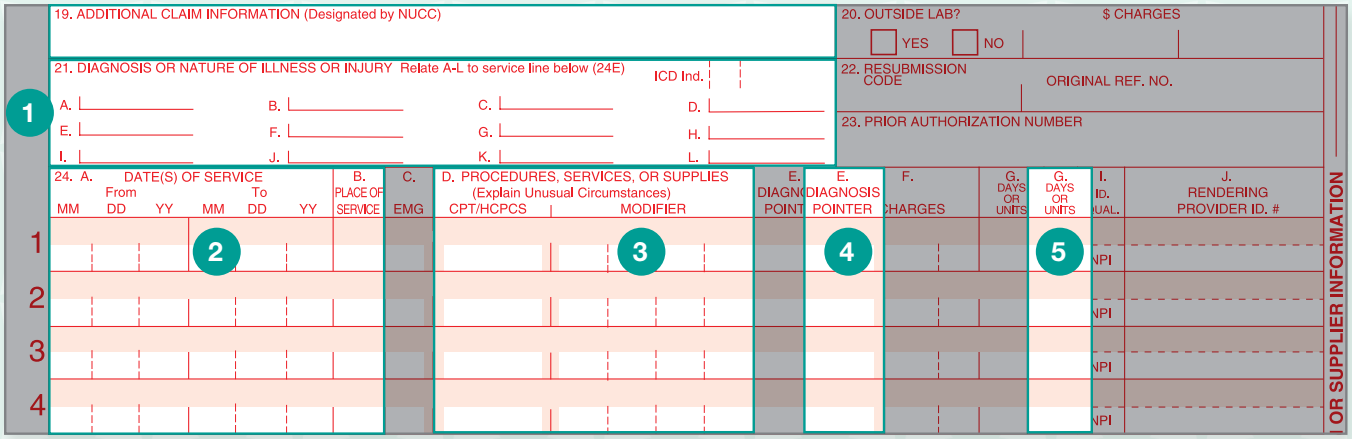
Enter the primary ICD-10-CM diagnosis code specific to the rationale for treating with EPKINLY.[3]

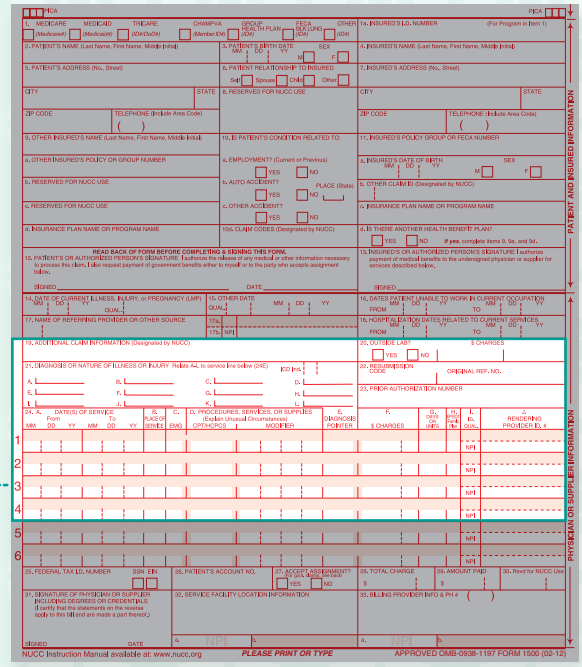
Coding current as of October 2025

Please see Indications on page 3 and Important Safety Information, including Boxed Warnings for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), on pages 5-6. Please see full Prescribing Information, including Boxed Warnings.

Sample CMS 1500 Claim Form *(Physician Office)*

This sample form is provided for informational purposes only. The accurate completion of claims documentation is the responsibility of the provider. Genmab and AbbVie do not guarantee reimbursement for any services or product.





1 Item 21

Enter appropriate ICD-10-CM diagnosis codes based on the patient's documented medical record.[14]

2 Item 24A and 24B

Enter the date of service and the appropriate 2-digit place of service code corresponding to the location where services are rendered (eg, 11 – Physician Office).[14]

3 Item 24D

EPKINLY® (epcoritamab-bysp) should be billed with HCPCS J9321.[4] If applicable, discarded product should be reported on a separate line with the JW modifier.[2] If no drug wastage, append JZ modifier to the HCPCS.[2] On a separate line, enter the appropriate CPT drug administration code (eg, 96401).[7]

4 Item 24E

Enter the diagnosis code reference letter from Item 21 that relates to the product or procedure listed in Item 24D.[14]

5 Item 24G

Report billing units here.[14] EPKINLY is billed on a per 0.16 mg basis. For the drug administration CPT code 96401, enter a unit of "1."[7]

Coding current as of October 2025

Hospital Outpatient Observation Services[15]

In some cases, outpatient observation services may be applicable for patients who are prescribed EPKINLY® (epcoritamab-bysp) during the post-administration period. Each payor may have a different policy regarding eligibility, documentation, and length of observation services.

All services submitted to Medicare must meet Medical Necessity guidelines. The definition of "medically necessary" for Medicare purposes can be found in Section 1862(a)(1)(A) of the Social Security Act – Medical Necessity.[16]

CPT & Revenue Coding for Outpatient Observation Services

When EPKINLY is administered in the hospital outpatient setting, the Medicare coding guidance listed below could apply if the patient meets eligibility for outpatient observation services. Medicare requires that hospitals report observation charges under the following revenue codes and CPT codes.

Revenue Codes

Revenue Code[8]	Description
0760	Specialty Services - General Classification
0762	Specialty Services - Observation Hours

CPT Codes

CPT Code[4]	Description
G0463	Hospital Outpatient Clinic Visit for Assessment and Management of a Patient
G0378	Hospital Observation Service, per Hour

Payment for hospital outpatient observation services may vary by payer based on initiation of the observation service (e.g., direct admit from physician practice vs. transition from a hospital outpatient clinic visit) and/or qualifying criteria. This may result in an incremental add-on to outpatient clinic services payment, or separate payment under a Comprehensive Observation Ambulatory Payment or comparable methodology.

For Medicare outpatient observation services, as of January 2024, physicians would bill one or more of the CPT codes listed below. Use of these codes should be confirmed with other payors.

CPT code[7]	Description
99221-99223	Initial inpatient or observation care, per day (evaluation and management documentation/ level varying by code)
99231-99233	Subsequent hospital inpatient or observation care, per day (evaluation and management documentation/level varying by code)
99238	Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter
99239	Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter

Claims Submission Processes

Claims-approval requirements and processes can differ by health insurance plan. Applying the following practices during claims submission may help reduce claim delays and denials.

Collect accurate demographic and insurance information

Obtain prior authorizations as needed

- Individual payors may establish Prior Authorization requirements based on both the FDA-approved label indications as well as inclusion and exclusion criteria for the clinical trial referenced by the FDA for approval. Medical documentation and clinical history may be necessary for Prior Authorization review. Check with individual payors for specific Prior Authorization requirements.

Apply accurate coding

- Code to the highest level of specificity.
- Clarify with each payor on required claim documentation for EPKINLY® (epcoritamab-bysp).

Ensure that medical documentation supports medical necessity and is readily available if needed to respond to a payor's request

Confirm that payor contract amendments are up to date in the EMR/EHR system and that claims are timely and compliant with those contracts

Need Additional Support?

Contact a *MyNavCare* Support Specialist by calling **1-866-NAV-CAR1** (1-866-628-2271), Monday-Friday, 8 AM-8 PM ET, or visit **MyNavCare.com** to learn more.

Sample Letter of Medical Necessity

The following pages include templates that may be customized to use as a letter of medical necessity or a letter of appeal.

This letter template is a resource for healthcare provider offices to use when corresponding with a patient's health insurance company regarding **medical necessity for prescribing Genmab medications.** This letter should be customized based on your patient's medical history with corresponding personal information.

Use of this letter does not guarantee reimbursement for Genmab medications prescribed, which is at the discretion of the payer, and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare provider. Note that some payers require additional forms, which should be submitted in addition to this letter, as well as any other supporting documentation.

<Today's date>

<Payer name>
ATTN: <Contact Firstname Lastname, TITLE>
<Payer street address>
<City>, <State> <Zip>

Re: Medical necessity of <DRUG NAME>

Patient name: <Firstname Lastname>
Date of birth: <MM/DD/YYYY>
Member ID: <Member ID #>
Policy or group number: <Policy/Group #>
Case ID number: <Case ID #>

To Whom It May Concern:

I am writing on behalf of my patient <Firstname Lastname> to document the medical necessity of <DRUG NAME> for the treatment of <specific diagnosis>. This letter provides information about the patient's medical history and diagnosis and a statement summarizing my treatment rationale.

Patient history and diagnosis

- <ICD-10-CM diagnosis code>
- <Date of diagnosis>
- <First visit date and date of referral>
- <Patient's performance status>
- <Previous treatments including drug names and duration, responses to those treatments, and reason for discontinuation>
- <Patient's disease progression and scan history>
- <Any additional factors impacting [**DRUG NAME**] treatment selection>

Treatment Plan
On <DATE>, the FDA approved <DRUG NAME> for the treatment of <indication>. <Write out plan of treatment for patient, including dosage, frequency, and length of treatment]. Consider including clinical rationale to support use of this treatment.>

Summary
Based on the provided information, I believe <DRUG NAME> is appropriate and medically necessary for <Firstname Lastname>. If you have any questions, please contact me at <physician's phone number> or email me at <physician@domain.com>. Thank you for your time and consideration.

Sincerely,
<Physician name & credentials>

Enclosures: <List any applicable enclosures such as prescribing information, patient medical history, relevant peer-reviewed articles, FDA approval letter, etc.>

This sample letter is for informational purposes only. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional.

Sample Letter of Appeal

This letter template is a resource for healthcare provider offices to use when corresponding with a patient's health insurance company regarding **medical necessity for prescribing Genmab medications.** This letter should be customized based on your patient's medical history with corresponding personal information.

Use of this letter does not guarantee reimbursement for Genmab medications prescribed, which is at the discretion of the payer, and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare provider. Note that some payers require additional forms, which should be submitted in addition to this letter, as well as any other supporting documentation.

<Today's date>

<Payer name>
ATTN: <Contact Firstname Lastname, TITLE>
<Payer street address>
<City>, <State> <Zip>

Re: Appeal for denial of <DRUG NAME>

Patient name: <Firstname Lastname>
Date of birth: <MM/DD/YYYY>
Member ID: <Member ID #>
Policy or group number: <Policy/Group #>
Case ID number: <Case ID #>
Dates of service: <MM/DD/YYYY>, <MM/DD/YYYY>, <MM/DD/YYYY>, etc.

To Whom It May Concern:

I am writing to request that you reconsider your denial of coverage for <DRUG NAME>, which I have prescribed to my patient <Firstname Lastname> for the treatment of <specific diagnosis>.

Your reason(s) for the denial [is/are] <list reason(s) for the denial>. Listed below are the patient's medical history, diagnosis, and treatment plan, which confirm the medical necessity and appropriate treatment with <DRUG NAME>.

Patient history and diagnosis

- <ICD-10-CM diagnosis code>
- <Date of diagnosis>
- <First visit date and date of referral>
- <Patient's performance status>
- <Previous treatments including drug names and duration, responses to those treatments, and reason for discontinuation>
- <Patient's disease progression and scan history>
- <Any additional factors impacting [**DRUG NAME**] treatment selection>

Treatment plan
On <DATE>, the FDA approved <DRUG NAME> for the treatment of <indication>. <Write out plan of treatment for patient, including dosage, frequency, and length of treatment]. Consider including clinical rationale to support use of this treatment.>

In view of the above information and appeal packet provided, I believe the medication for this patient should be covered. If you have any questions, please contact me at <physician's phone number> or email me at <physician@domain.com>. Thank you for your time and consideration.

Sincerely,
<Physician name & credentials>

Enclosures: <List any applicable enclosures such as letter of medical necessity, prescribing information, clinical notes, medical records, diagnostic test results, peer reviewed articles, pathology reports, relevant peer-reviewed articles, FDA approval letter, etc.>

This sample letter is for informational purposes only. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional.

EPKINLY® (epcoritamab-bysp) Distributors & Specialty Pharmacies

EPKINLY is available directly through specialty distributors and can be dispensed through an exclusive network of specialty pharmacies.

Specialty Distributors

Prescribers can purchase EPKINLY from the following specialty distributors in the United States and Puerto Rico.

United States	Phone Number	Email Address
ASD Healthcare, AmerisourceBergen	1-800-746-6273	Service@asdhealthcare.com
BioCare SD (Institutional)	1-800-304-3064	Order@biocaresd.com
BioCare SD (Clinic)	1-800-304-3064	Order@biocaresd.com
Cardinal SPD Acute, Cardinal Health	1-855-855-0708	GMB-spd-csorderentry@cardinalhealth.com
Cardinal SPD Provider, Cardinal Health	1-877-453-3972	SPDOncologyTeam@cardinalhealth.com
McKesson Plasma and Biologics, McKesson	1-877-625-2566	MPBorders@McKesson.com
McKesson Specialty Care Distribution, McKesson	1-800-482-6700	OncologyCustomerSupport@McKesson.com
Morris & Dickson Specialty, Morris & Dickson	1-800-388-3833	CustomerService@morrisdickson.com
Oncology Supply, AmerisourceBergen	1-800-633-7555	Service@oncologysupply.com
Puerto Rico		
Cardinal Health PR	1-787-625-4200	Cuserv@cardinalhealth.com
Cesar Castillo	1-787-641-5082 or 1-787-999-1616, ext. 5082	CCI_SPECIALTY@cesarcastillo.com

Specialty Pharmacies

If you prefer, EPKINLY can also be dispensed through an exclusive network of specialty pharmacies. Please call a *MyNavCare* Support Specialist at 1-866-NAV-CAR1 (1-866-628-2271) to determine if your patient is eligible to access this medication through Genmab's specialty pharmacy partners. Listed below are our specialty pharmacies in Puerto Rico.

Puerto Rico	Intake Phone Number	Intake Fax Number for New Prescriptions
Alivia Specialty Pharmacy	1-888-925-1989	1-787-925-1015 or 1-787-723-6987
Special Care Pharmacy Services	1-888-727-1727	1-787-783-2951

Please see Indications on page 3 and Important Safety Information, including Boxed Warnings for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), on pages 5-6. Please see full Prescribing Information, including Boxed Warnings.

MyNavCare® PATIENT SUPPORT

MyNavCare Patient Support® Services

Helping Patients Access Care

MyNavCare offers resources, services, and support to help patients access EPKINLY® (epcoritamab-bysp) throughout their treatment journey.

- Benefits verification
- Prior authorization support
- Appeals information
- Financial assistance*
- Coverage and claims information
- Patient Engagement Liaison† ongoing support and information

*Based on eligibility requirements and Terms and Conditions.

†*MyNavCare* Patient Engagement Liaisons are part of the *MyNavCare Patient Support*® program and do not provide medical advice or work under the direction of the prescribing healthcare providers. They are trained to direct patients to speak with their healthcare provider about any treatment-related questions.

Ways to Start *MyNavCare* Enrollment

Healthcare providers can start the enrollment process.‡ Once enrollment is complete, a dedicated *MyNavCare* Patient Access Specialist will begin benefits verification for your patient.

Digital Enrollment Pathways

Online

Digitally enroll a patient in *MyNavCare* using DocuSign®.‡

Enroll now at **MyNavCare.com**

OR

HCP Portal

Get patients enrolled and track their coverage status in the *MyNavCare* HCP Portal.

Sign up for the portal by visiting **MyNavCareHCPportal.com**

OR

EHR-Integrated Enrollment

Practices with supported EHR integrations may digitally enroll patients into *MyNavCare*.

Fax

Complete and fax the Enrollment Form to 1-866-628-2276 to get patients started with *MyNavCare*.

Download the form at **MyNavCare.com**

‡A patient or care partner's signature is required to authorize enrollment. You may check benefits verification status and patient prescription on the *MyNavCare* HCP Portal or contact us for assistance.

§All other trademarks are property of their respective owners.

‖AssistPoint is a registered trademark of Annexus Health, Inc.

References

1. EPKINLY® (epcoritamab-bysp) Prescribing Information. Genmab A/S; Revised 3/2026. https://www.genmab-pi.com/prescribing-information/epkinly-pi.pdf
2. Centers for Medicare & Medicaid Services. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Updated December 23, 2025. Accessed February 10, 2026. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf
3. Centers for Medicare & Medicaid Services (CMS). ICD-10 Codes. 2026 ICD-10 CM & PCS Files. Downloads. Open 2026 Code Tables, Tabular and Index (ZIP). Open icd10cmCodesFile Adobe Acrobat Document. Accessed February 10, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes
4. Centers for Medicare & Medicaid Services (CMS). October 2025 n-Numeric HCPCS File (ZIP). Open Zip File. Open HCPC2025_OCT_ANWEB_v4. Accessed February 10, 2026. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
5. Centers for Medicare & Medicaid Services. Inpatient Prospective Payment Systems. FY 2026 IPPS Final Rule Home Page. FY 2026 Final Rule Data and Supplemental Files. FY 2026 MAC Implementation Files. #8 MAC Implementation File 8 (ZIP) – FY 2026 New Technology Add-on Payment. Open MAC Implementation File 8 – FY 2026 (Continued NTAP) Text Document. Accessed February 10, 2025. https://www.cms.gov/files/zip/fy2026-ipps-fr-mac-implementation-file-8.zip
6. UnitedHealthcare. National Drug Code (NDC) Requirement Policy, Professional and Facility. Updated December 14, 2025. Accessed February 10, 2026. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-National-Drug-Code-Requirement-Policy.pdf
7. CPT (Current Procedural Terminology). (2026). CPT® 2026 Professional Edition (2026 ed.). American Medical Association.
8. Noridian Healthcare Solutions. Revenue Codes. Jurisdiction E: Medicare Part A. Updated June 17, 2025. Updated June 17, 2025. Accessed February 10, 2026. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes
9. Centers for Medicare & Medicaid Services. Billing and Coding Article. Billing and Coding: Hospital Outpatient Drugs and Biologicals Under the Outpatient Prospective Payment System (OPPS). A55913. Effective December 26, 2024. Accessed February 10, 2026. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55913
10. Centers for Medicare & Medicaid Services. MLN Fact Sheet. Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier. Updated effective January 1, 2025. Accessed February 10, 2026. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf
11. BlueCrossBlueShield of North Carolina. Reimbursement Policy: Modifier TB requirement. Updated August 29, 2025, effective November 1, 2025. Accessed February 10, 2026. https://www.bluecrossnc.com/providers/provider-news/2025/reimbursement-policy-modifier-tb-requirement
12. Colorado Department of Health Care Policy & Financing. 340B Policy and Procedures Manual. Outpatient Drugs and Physician-Administered Drugs. 340B Policy Statements. Updated October 10, 2025. Accessed September 16, 2025. https://hcpf.colorado.gov/340b-manual
13. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25 - Completing and Processing the Form CMS-1450 Data Set. Rev. 12423, 12-20-23. Accessed February 10, 2026. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf
14. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26 - Completing and Processing Form CMS-1500 Data Set. Rev. 12779, Issued: 08-09-24. Accessed February 10, 2026. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf
15. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS). Rev. 12979; Issued: 11-22-24. Accessed February 10, 2026. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c04.pdf
16. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17 - Drugs and Biologicals. Rev. 13255; Issued: 06-06-25. Accessed February 10, 2026. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf

MyNavCare®
PATIENT SUPPORT

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