Amneal PATHways Patient Access To Health

PEMRYDI RTU™ (pemetrexed injection)

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Coding and Billing Guide for PEMRYDI RTU™ (pemetrexed injection)

Overview and Disclaimer

Amneal developed this guide to support healthcare professionals (HCPs) treating patients with PEMRYDI RTU in physician offices and hospital outpatient departments (HOPDs). The content in this guide is provided for informational purposes. This information is not legal advice and it does not guarantee reimbursement for any product or service. Payer guidance changes frequently and varies by health insurance plan. Contact the Amneal PATHways® Patient Support Program or payers directly to confirm the latest coding, billing, and coverage guidance. HCPs should ensure that information reported to payers reflects services that were rendered and documented in the patient's medical record. The information here is current as of April 2024.

Indications[1]

PEMRYDI RTU is a folate analog metabolic inhibitor indicated:

- in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
- in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous NSCLC.
- as a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy.
- as a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy.
  Limitations of Use: Pemetrexed Injection is not indicated for treatment of squamous cell non-small cell lung cancer.
- initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

Reporting Diagnosis

The following International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes may be appropriate to report the patient's medical condition. Please note the list is not all-inclusive; other codes could apply.

ICD-10-CM Code[2]	Description	Appropriate Use
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung	Report the appropriate ICD-10-CM diagnosis code based on HCP medical record documentation
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung	
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung	
C34.2	Malignant neoplasm of middle lobe, bronchus or lung	
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung	
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung	
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung	
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung	
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung	
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung	
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung	
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung	
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung	
C45.0	Mesothelioma of pleura	
Z51.11	Encounter for antineoplastic chemotherapy	Check payer policies for reporting requirements as guidelines vary. Some guidance recommends listing Z51.11 first when the reason for the encounter is chemotherapy and reporting the underlying diagnosis as secondary[3]

Key: HCP – healthcare provider; ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification.

Reporting Use of PEMRYDI RTU and Its Administration

Product-Specific Billing Code

PEMRYDI RTU can be reported on outpatient medical claims with an appropriate Healthcare Common Procedure Coding System (HCPCS) code.

HCPCS[4]	Description	Site(s) of Care	Appropriate Use
J9324	Injection, pemetrexed (pemrydi rtu), 10 mg	Physician office, HOPD	Use for dates of service on and after January 1, 2024

Key: HCPCS – Healthcare Common Procedure Coding System; HOPD – hospital outpatient department.

When billing PEMRYDI RTU using J9324, 1 billing unit is equal to 10 milligrams

HCPCS Modifiers

Payers may require one or more HCPCS modifiers to be reported along with J9324 on outpatient claims to provide additional information about the services provided.

HCPCS[4]	Description	Site(s) of Care	Appropriate Use
JZ[5]	Zero drug amount discarded/not administered to any patient	Physician office, HOPD	Attach modifier "-JZ" to J9324 when all of the drug in a single-use vial is administered to a patient and none is discarded
JW[5]	Drug amount discarded/not administered to any patient		Attach modifier "-JW" to J9324 when some of the drug in a single-use vial is discarded. This requires 2 separate claim lines: • Claim line 1: Report the amount of drug administered with the appropriate number of billing units for the HCPCS code and no modifier • Claim line 2: Report modifier "-JW" with the HCPCS code and the appropriate number of billing units for any amount of discarded drug
JG[6]	Drug or biological acquired with a 340B Drug Pricing Program discount, reported for informational purposes	340B-covered entities	340B-covered entities may append to J9324 with either modifier "-JG" or "-TB," as appropriate, for claims with dates of service through December 31, 2024
TB[6]	Drug or biological acquired with a 340B Drug Pricing Program discount, reported for informational purposes for select entities		

Key: HCPCS – Healthcare Common Procedure Coding System; HOPD – hospital outpatient department.

National Drug Codes (NDCs)

Payers commonly require that HCPs report the NDC, in combination with the appropriate HCPCS code, on medical claims to help identify PEMRYDI RTU.[7] For claims-reporting purposes, convert the 10-digit NDC listed in the prescribing information to an 11-digit NDC by adding a leading "0" (zero), where appropriate, to create a 5-4-2 configuration.[8]

11-digit NDC[1]	NDC Descriptor[1]	Site(s) of Care	Appropriate Use
70121-2453-01	100 mg/10 mL (10 mg/mL) 1 SDV in a carton	Physician office, HOPD	The NDC is typically preceded with NDC qualifier "N4": eg, N470121245301. Report without dashes or other punctuation When required by payers, report "ML" as the unit of measure with the appropriate NDC quantity
70121-2461-01	500 mg/50 mL (10 mg/mL) 1 SDV in a carton		

Key: HOPD – hospital outpatient department; NDC – National Drug Code; SDV – single-dose vial.

Current Procedural Terminology (CPT®[a]) Codes[9]

The following codes may be used to report the intravenous (IV) administration of PEMRYDI RTU:

CPT Code(s)	Description	Site(s) of Care	Appropriate Use
96409[b]	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	Physician office, HOPD	Drug administration codes may vary and are dependent on other therapies administered on the same day as PEMRYDI RTU Codes may also vary by payer and site of care Per CPT guidelines, an IV push code should be used for an infusion lasting 15 minutes or less[a]
96411[b]	Chemotherapy administration; intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure)		
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug		
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (list separately in addition to code for primary procedure)		

Key: CPT – Current Procedural Terminology; HOPD – hospital outpatient department; IV – intravenous.
[a] CPT Copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
[b] Check individual payer policy and medical record documentation. Billing highly complex administration codes (964xx) may require documentation in the medical record that supports the complexity beyond what is required for a therapeutic administration (963xx).

Revenue Codes[10]

The following revenue codes may be appropriate to report the use of PEMRYDI RTU and its administration in the hospital outpatient settings to some payers:

Used For	Revenue Code	Description	Site(s) of Care
PEMRYDI RTU	0636	Drugs requiring detailed coding	HOPD
Drug administration procedure	0260[a]	IV therapy – general	
	0510[a]	Clinic – general	

Key: HOPD – hospital outpatient department; IV – intravenous.
[a] Other revenue codes may apply.

Contact the Amneal PATHways® Patient Support Program

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Portal:
https://www.pathwaysproviderportal.com/
(First-time users must register)

Sample Claim Forms

CMS-1500 Sample Claim Form (Physician Office)

Services rendered in physician offices are reported using the CMS-1500 claim form (electronic claim file 837P). In this example, an adult patient with a BSA of 1.85 m^2 received 925 mg of PEMRYDI RTU (500 mg/m^2) for non-squamous NSCLC administered as an IV infusion over 10 minutes.

Item Number 21 Diagnosis: Enter the appropriate diagnosis code based on HCP documentation.

- ICD-10-CM: C34.XX for malignant neoplasm of bronchus and lung

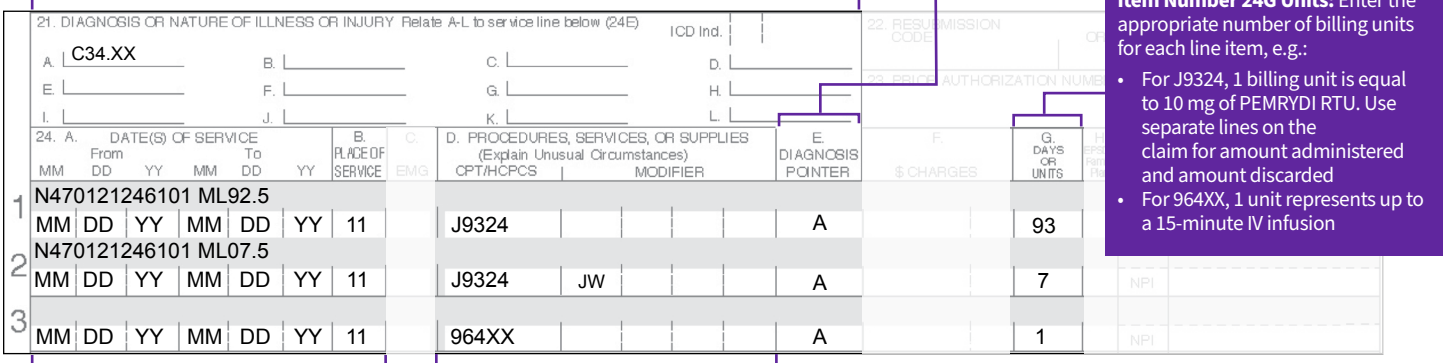
An "X" indicates that additional characters are required. Final code depends on medical record documentation and payer requirements

Item Number 24E Diagnosis Pointer:

Enter the letter (A-L) that corresponds to the diagnosis in Item Number 21

Item Number 24G Units: Enter the appropriate number of billing units for each line item, e.g.:

- For J9324, 1 billing unit is equal to 10 mg of PEMRYDI RTU. Use separate lines on the claim for amount administered and amount discarded
- For 964XX, 1 unit represents up to a 15-minute IV infusion



Item Number 24A Date(s) of Service: Enter the NDC number in the shaded area above the month, day, and year. The "N4" qualifier is required before the NDC; do not include dashes. Follow with one space, then the two-character unit of measure qualifier and quantity.

Check payer requirements and format for reporting NDC

Item Number 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and Modifiers, e.g.:

- Drug: J9324 for PEMRYDI RTU
- Modifier: -JW to show that some amount of drug was discarded
- Administration: 964XX for IV infusion

An "X" indicates that additional characters are required. Final code depends on medical record documentation

CMS-1450 (UB-04) Sample Claim Form (Hospital Outpatient)

Services rendered in outpatient facilities, including HOPDs, are reported using the CMS-1450 institutional claim form (electronic claim file 837I). In this example, an adult patient with a BSA of 1.85 m^2 received 925 mg of PEMRYDI RTU (500 mg/m^2) for non-squamous NSCLC administered as an IV infusion over 10 minutes. PEMRYDI RTU was acquired through the 340B Drug Pricing Program.

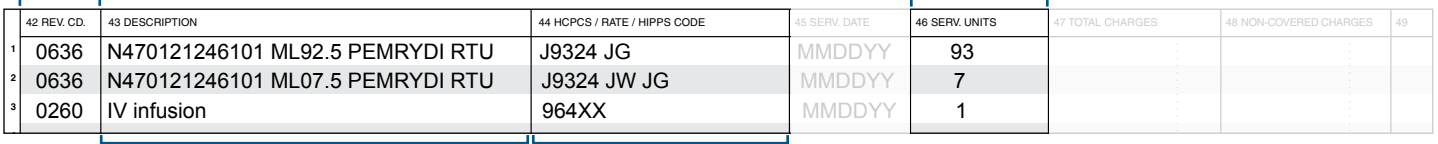
FL 42 Revenue Code: Enter the appropriate revenue code, e.g.:

- 0636 for PEMRYDI RTU
- 0260 for IV infusion

Other revenue codes may apply

FL 46 Units of Service: Enter the appropriate number of billing units for each line item, e.g.:

- For J9324, 1 billing unit is equal to 10 mg of PEMRYDI RTU. Use separate lines on the claim for amount administered and amount discarded
- For 964XX, 1 unit represents up to a 15-minute IV infusion



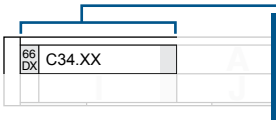
FL 43 Revenue Description: Enter the NDC number. The "N4" qualifier is required before the NDC; do not include dashes. Follow with one space, then the two-character unit of measure qualifier and quantity.

Check payer requirements and format for reporting NDC

FL 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, e.g.:

- Drug: J9324 for PEMRYDI RTU
- Modifier: -JG to show the product was acquired through 340B
- Modifier: -JW to show the amount of discarded PEMRYDI RTU
- Administration: 964XX for IV infusion

An "X" indicates that additional characters are required. Final code depends on medical record documentation



FL 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes:
Enter the appropriate diagnosis code based on HCP documentation.

- ICD-10-CM: C34.XX for malignant neoplasm of bronchus and lung

An "X" indicates that additional characters are required. Final code depends on medical record documentation and payer requirements

Key: BSA – body surface area; FL – Form Locator; HCPCS – Healthcare Common Procedure Coding System; ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification; IV – intravenous; NDC – National Drug Code; NSCLC – non-small cell lung cancer.

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Important Safety Information

Contraindication

Pemetrexed Injection is contraindicated in patients with hypersensitivity reaction to Pemetrexed.

Warnings and Precautions

- **Myelosuppression:** May cause severe bone marrow suppression resulting in cytopenia and an increased risk of infection. Do not administer when the absolute neutrophil count is less than 1500 cells/mm^3 and platelets are less than 1,000,000 cells/mm^3. The risk of myelosuppression is increased in patients who do not receive supplemental vitamins of folic acid and vitamin B12 prior to and throughout PEMRYDI RTU plus cisplatin treatment.
- **Renal Failure:** May cause severe and sometimes fatal renal failure. Do not administer when creatinine clearance is less than 45 mL/min.
- **Bullous and Exfoliative Skin Toxicity:** Permanently discontinue for severe and life-threatening bullous, blistering, or exfoliating skin toxicity.
- **Interstitial Pneumonitis:** Withhold PEMRYDI RTU for acute onset of new or progressive unexplained pulmonary symptoms such as dyspnea, cough, or fever pending diagnostic evaluation. If pneumonitis is confirmed, permanently discontinue PEMRYDI RTU.
- **Radiation Recall:** May occur in patients who received radiation weeks to years previously; permanently discontinue for signs of radiation recall.

Adverse Reactions

- Common adverse reactions (incidence ≥20% or 1 in 5 patients) when administered as a single agent are fatigue, nausea, and anorexia.
- Common adverse reactions (incidence ≥20% or 1 in 5 patients) when administered with cisplatin are vomiting, neutropenia, anemia, stomatitis/pharyngitis, thrombocytopenia, and constipation.
- Common adverse reactions (incidence ≥20% or 1 in 5 patients) when administered with pembrolizumab and platinum chemotherapy are fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, and pyrexia.

Drug Interactions

- Modify the ibuprofen dosage for patients with a creatinine clearance between 45 mL/min and 79 mL/min, as ibuprofen increases the risk of Pemetrexed Injection toxicity in patients with mild to moderate renal impairment.

Use in Specific Populations

- **Pregnancy:** Can cause fetal harm. Advise females of reproductive potential to use effective contraception during treatment.
- **Lactation:** Advise not to breastfeed.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Biosciences, a division of Amneal Pharmaceuticals LLC, at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References

1. PEMRYDI RTU. Prescribing information. Amneal Pharmaceuticals LLC; 2023. **2.** CMS. 2024 International Classification of Diseases, 10th Revision, Clinical Modification ICD-10-CM tabular list of diseases and injuries. Updated February 1, 2024. Accessed March 4. 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm **3.** CMS. ICD-10-CM official guidelines for coding and reporting FY2024 – Updated April 1, 2024 (April 1, 2024 – September 30, 2024). Accessed March 4, 2025. https://www.cms.gov/files/document/fy-2024-icd-10-cm-coding-guidelines-updated-02/01/2024.pdf **4.** CMS. HCPCS quarterly update. April 2024 alpha-numeric HCPCS file. Updated March 7, 2024. Accessed March 18, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **5.** CMS. FAQs discarded drugs and biologicals – JW modifier and JZ modifier policy. Updated December 4, 2023. Accessed March 4, 2024. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **6.** CMS. MLN4800856 – Medicare Part B inflation rebate guidance: Use of the 340B modifier. December 2023. Accessed March 4, 2024. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf **7.** CMS. Medicare claims processing manual. Chapter 26. Completing and processing the form CMS-1500 data set. §10.4. Pub 100-04. Updated December 14, 2023. Accessed March 4, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **8.** FDA.gov. Format of the National Drug Code. September 28, 2023. Accessed March 5, 2024. https://www.fda.gov/media/173715/download **9.** Current Procedural Terminology (CPT®) 2024. American Medical Association. **10.** Noridian Healthcare Solutions. Revenue codes. Accessed March 4, 2024. https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes