



PEMFEXY[®] **(PEMETREXED INJECTION)**

500 mg/20 mL (25 mg/mL)

BILLING AND CODING GUIDE

Information in this guide was obtained from third-party sources and is made available for illustrative purposes only; it is non-exhaustive, subject to change, and does not constitute coding or legal advice regarding the selection of codes to describe a particular service. Health care professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, appropriately reflect a service or diagnosis. It is the health care professional's responsibility to determine medical necessity, supported by adequate documentation. Eagle Pharmaceuticals, Inc. makes no guarantee of coverage or payment for items or services. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel. CPT[®] Copyright 2022 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Table of Contents

3	Indication and Important Safety Information
4	PEMFEXY® Ordering Information
4	PEMFEXY® Packaging Specifications
5	PEMFEXY® Billing and Coding Information
5	ICD Diagnosis Codes
6	HCPCS Code
6	POS Codes
6	PEMFEXY® J-Code Billing Unit Conversion
7	CPT Drug Administration Codes
7	National Drug Code for PEMFEXY®
8	Sample Claim Form CMS-1450 (UB-04)
10	Sample Claim Form CMS-1500
12	EAGLE CAN® Reimbursement Support
13	PEMFEXY® Copay Assistance Program
14	Important Safety Information, Continued

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; FDA=Food and Drug Administration; HCPCS= Healthcare Common Procedure Coding System; ICD=International Classification of Diseases; POS=Place of Service

Please see Important Safety Information on page 14, and accompanying full Prescribing Information for PEMFEXY®.

PEMFEXY®
(PEMETREXED INJECTION)

500 mg/20 mL (25 mg/mL)

INDICATION

PEMFEXY is 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.

PEMFEXY is indicated in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC).

PEMFEXY is indicated as a single agent for the maintenance treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

PEMFEXY is indicated as a single agent for the treatment of patients with recurrent, metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy.

Limitation of Use: PEMFEXY is not indicated for the treatment of patients with squamous cell non-small cell lung cancer.

PEMFEXY is indicated in combination with cisplatin for the initial treatment of patients with malignant pleural mesothelioma (MPM), whose disease is unresectable or who are otherwise not candidates for curative surgery.

IMPORTANT SAFETY INFORMATION

(Continued on Page 14)

CONTRAINDICATION

PEMFEXY is contraindicated in patients who have a history of severe hypersensitivity reaction to pemetrexed.

WARNINGS AND PRECAUTIONS

Myelosuppression and Increased Risk of Myelosuppression Without Vitamin Supplementation

PEMFEXY can cause severe myelosuppression resulting in a requirement for transfusions and which may lead to neutropenic infection. The risk of myelosuppression is increased in patients who do not receive vitamin supplementation.

7 Days prior to treatment with PEMFEXY, patients must be instructed to initiate supplementation with oral folic acid. Intramuscular injections of vitamin B₁₂ are also required 7 days prior to PEMFEXY treatment. Continue vitamin supplementation during treatment and for 21 days after the last dose of PEMFEXY to reduce the severity of treatment-related hematologic and gastrointestinal toxicities. Obtain a complete blood count at the beginning of each cycle. Do not administer PEMFEXY until the ANC is at least 1500 cells/mm³ and platelet count is at least 100,000 cells/mm³. Permanently reduce PEMFEXY in patients with an ANC of less than 500 cells/mm³ or platelet count of less than 50,000 cells/mm³ in previous cycles.

In Studies JMDB and JMCH, among patients who received vitamin supplementation, incidence of Grade 3-4 neutropenia was 15% and 23%, the incidence of Grade 3-4 anemia was 6% and 4%, and incidence of Grade 3-4 thrombocytopenia was 4% and 5%, respectively. In Study JMCH, 18% of patients in the pemetrexed arm required red blood cell transfusions compared to 7% of patients in the cisplatin arm. In Studies JMEN, PARAMOUNT, and JMEI, where all patients received vitamin supplementation, incidence of Grade 3-4 neutropenia ranged from 3% to 5%, and incidence of Grade 3-4 anemia ranged from 3% to 5%.

PEMFEXY[®]

Ordering Information

Wholesale		
Distributor	Item Number	Telephone Number
AmerisourceBergen	10265697	844.222.2273
Cardinal Health	5774443	800.926.3161
McKesson	2600252	855.625.4677
Morris & Dickson	204560	800.388.3833
Specialty		
Cardinal Health	5774443	800.926.3161
McKesson	5011811	800.482.6700
Oncology Supply	10264556	800.633.7555

PEMFEXY[®] Packaging Specifications

Specifications	
How Supplied ¹	Multi-Dose Vial, 500 mg/20 mL (25 mg/mL)
NDC ¹	42367- 0 531-33*

*FDA standard NDC has been "zero-filled" to create an 11-digit code that meets HIPAA standards. The zero-fill location is indicated in **bold**.

HIPAA= Health Insurance Portability and Accountability Act; NDC= National Drug Code

Please see Important Safety Information on page 14,
and accompanying full Prescribing Information for PEMFEXY[®].

PEMFEXY® Billing and Coding Information

ICD Diagnosis Codes²

Non-Squamous, Non-Small Cell Lung Cancer (NSCLC)	
ICD-10-CM Code	Description
Malignant neoplasm of bronchus and lung	
C34.00 C34.01 C34.02	Unspecified main bronchus Right main bronchus Left main bronchus
C34.10 C34.11 C34.12	Upper lobe, unspecified bronchus or lung Upper lobe, right bronchus or lung Upper lobe, left bronchus or lung
C34.2	Middle lobe, bronchus or lung
C34.30 C34.31 C34.32	Lower lobe, unspecified bronchus or lung Lower lobe, right bronchus or lung Lower lobe, left bronchus or lung
C34.80 C34.81 C34.82	Overlapping sites of unspecified bronchus and lung Overlapping sites of right bronchus and lung Overlapping sites of left bronchus and lung
C34.90 C34.91 C34.92	Unspecified part of unspecified bronchus and lung Unspecified part of right bronchus and lung Unspecified part of left bronchus and lung
Malignant Pleural Mesothelioma (MPM)	
ICD-10-CM Code	Description
Mesothelioma	
C38.4	Malignant neoplasm of pleura
C45.0	Mesothelioma of pleura

Please see Important Safety Information on page 14,
 and accompanying full Prescribing Information for PEMFEXY®.

PEMFEXY® Billing and Coding Information, continued

Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies.

HCPCS Code

Applicable Settings

PEMFEXY® Unique J-Code ³	Description	Place of Service (POS) Codes ⁴
J9304	Injection, pemetrexed (pemfexy), 10 mg	<ul style="list-style-type: none"> Physician Office (11) Off-Campus Outpatient Hospital (19) On-Campus Outpatient Hospital (22)

PEMFEXY® J-Code Billing Unit Conversion

J9304 Billing Unit ³	=	10 mg
One Multi-Dose Vial of PEMFEXY® (500 mg/20 mL) ¹	=	50 Units

The total number of mg administered will vary based on patient body surface area, and based on the potential need for dosage modifications.¹

Is PEMFEXY® (pemetrexed injection) a generic drug?

No. PEMFEXY® is a proprietary formulation of pemetrexed approved via the 505(b)(2) pathway, with no listed therapeutic equivalence rating in the FDA Orange Book.⁵

What's the difference between a generic drug, and a drug approved via the 505(b)(2) pathway? How are they billed differently?

Drugs submitted via a 505(b)(2) New Drug Application (NDA) specify a Listed Drug (LD), but unlike generics, which are approved via an abbreviated regulatory pathway, they are not required to be therapeutically equivalent nor pharmaceutically equivalent to a Reference Listed Drug. Most 505(b)(2) applications consist of changes to a previously approved drug product (ie, a new dosage form, new route of administration, new formulation, etc.).⁶ For example, PEMFEXY® was approved via a 505(b)(2) drug application, does not have a therapeutic equivalence rating, and must be billed using a Unique J-Code: J9304.^{3,5} Whereas, ALIMTA® and its therapeutically equivalent generic versions share the same J-Code: J9305.^{3†}

What is a Unique J-Code?

J-codes are reimbursement codes used by commercial insurance plans, Medicare, Medicare Advantage, and other government payers for physician-administered drugs like PEMFEXY® and are intended to simplify the claims submission and documentation process, facilitating access for patients.⁷

Can discarded units of PEMFEXY® be billed using the JW modifier?

No. PEMFEXY® is supplied in a multi-dose vial, therefore the JW modifier does not apply to PEMFEXY® billing. The JW modifier is only valid when used to identify wasted drugs or biologicals from a single-dose vial or package. Multi-dose vials are not subject to payment for any discarded amounts of the drug.⁸

[†]ALIMTA® is a registered trademark of Eli Lilly and Company.

Please see Important Safety Information on page 14, and accompanying full Prescribing Information for PEMFEXY®.

PEMFEXY® Billing and Coding Information, continued

CPT Drug Administration Codes⁹

Code	Description
96409	Chemotherapy, intravenous push, single or initial drug [†]
96411	Chemotherapy, intravenous push, each additional drug [†]
96413	Chemotherapy, intravenous infusion, 1 hour
96415	Chemotherapy, intravenous infusion, each additional hour
96417	Chemotherapy, intravenous infusion, each additional sequential infusion

[†]PEMFEXY® is indicated to be administered as an intravenous infusion over 10 minutes¹ by the FDA. However, this code may be appropriate for use for billing purposes only, as CMS's Billing and Coding Guidelines define an intravenous push, in part, as "an infusion of 15 minutes or less." Please see the Important Safety Information on Page 14 and accompanying full Prescribing Information for PEMFEXY®.

National Drug Code for PEMFEXY^{*1}

Vial Description	NDC
Multi-Dose Vial, 500 mg/20 mL (25 mg/mL)	42367-0531-33*

*FDA standard NDC has been "zero-filled" to create an 11-digit code that meets HIPAA standards. The zero-fill location is indicated in **bold**.

Please see Important Safety Information on page 14,
and accompanying full Prescribing Information for PEMFEXY®.

Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies.

Revenue Codes and Description

Enter revenue code and description corresponding to HCPCS or CPT codes filled in Field 44.

FIELD 44:

Product and Procedure Coding

Enter HCPCS drug code and CPT code
for the administration of PEMFEXY®.

HCPCS³:

J9304	Injection, pemetrexed (pemfexy), 10 mg
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CPT⁹:

96409	Chemotherapy, intravenous push, single or initial drug
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96411	Chemotherapy, intravenous push, each additional drug
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96413	Chemotherapy, intravenous infusion, 1 hour
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96415	Chemotherapy, intravenous infusion, each additional hour
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96417	Chemotherapy, intravenous infusion, each additional sequential infusion
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Please see additional CMS-1450
claim form information on page 9.

Please see Important Safety Information on page 14,
and accompanying full Prescribing Information for PEMFEXY®.

Sample Claim Form CMS-1450 (UB-04), continued^{10,11}

Hospital Outpatient

Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies.

FIELD 46:

Service Units

Enter the number of service units for PEMFEXY[®] HCPCS code (J9304).
Billable unit = 10 mg.
One vial = 50 units.

1		2		3a. PRE. CNTL. # b. MED. REQ. #		4. TYPE OF BILL	
5. PATIENT NAME		6. PATIENT ADDRESS		7. STATEMENT COVERS PERIOD FROM THROUGH		8. FED. TAX NO.	
9. BIRTHDATE		10. SEX		11. DATE		12. ADMISSION	
13. HR		14. TYPE		15. SRC		16. DHR	
17. STAY		18. 19		20. 21		22. 23	
24. 25		26. 27		28. 29		30. 31	
32. 33		34. 35		36. 37		38. 39	
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560. 561		562. 563		564. 565		566. 567	
568. 569		570. 571		572. 573		574. 575	
576. 577		578. 579		580. 581		582. 583	
584. 585		586. 587		588. 589		590. 591	
592. 593		594. 595		596. 597		598. 599	
600. 601		602. 603		604. 605		606. 607	
608. 609		610. 611		612. 613		614. 615	
616. 617		618. 619		620. 621		622. 623	
624. 625		626. 627		628. 629		630. 631	
632. 633		634. 635		636. 637		638. 639	
640. 641		642. 643		644. 645		646. 647	
648. 649		650. 651		652. 653		654. 655	
656. 657		658. 659		660. 661		662. 663	
664. 665		666. 667		668. 669		670. 671	
672. 673		674. 675		676. 677		678. 679	
680. 681		682. 683		684. 685		686. 687	
688. 689		690. 691		692. 693		694. 695	
696. 697		698. 699		700. 701		702. 703	
704. 705		706. 707		708. 709		710. 711	
712. 713		714. 715		716. 717		718. 719	
720. 721		722. 723		724. 725		726. 727	
728. 729		730. 731		732. 733		734. 735	
736. 737		738. 739		740. 741		742. 743	
744. 745		746. 747		748. 749		750. 751	
752. 753		754. 755		756. 757		758. 759	
760. 761		762. 763		764. 765		766. 767	
768. 769		770. 771		772. 773		774. 775	
776. 777		778. 779		780. 781		782. 783	
784. 785		786. 787		788. 789		790. 791	
792. 793		794. 795		796. 797		798. 799	
800. 801		802. 803		804. 805		806. 807	
808. 809		810. 811		812. 813		814. 815	
816. 817		818. 819		820. 821		822. 823	
824. 825		826. 827		828. 829		830. 831	
832. 833		834. 835		836. 837		838. 839	
840. 841		842. 843		844. 845		846. 847	
848. 849		850. 851		852. 853		854. 855	
856. 857		858. 859		860. 861		862. 863	
864. 865		866. 867		868. 869		870. 871	
872. 873		874. 875		876. 877		878. 879	
880. 881		882. 883		884. 885		886. 887	
888. 889		890. 891		892. 893		894. 895	
896. 897		898. 899		900. 901		902. 903	
904. 905		906. 907		908. 909		910. 911	
912. 913		914. 915		916. 917		918. 919	
920. 921		922. 923		924. 925		926. 927	
928. 929		930. 931		932. 933		934. 935	
936. 937		938. 939		940. 941		942. 943	
944. 945		946. 947		948. 949		950. 951	
952. 953		954. 955		956. 957		958. 959	
960. 961		962. 963		964. 965		966. 967	
968. 969		970. 971		972. 973		974. 975	
976. 977		978. 979		980. 981		982. 983	
984. 985		986. 987		988. 989		990. 991	
992. 993		994. 995		996. 997		998. 999	
1000. 1001		1002. 1003		1004. 1005		1006. 1007	
1008. 1009		1010. 1011		1012. 1013		1014. 1015	
1016. 1017		1018. 1019		1020. 1021		1022. 1023	
1024. 1025		1026. 1027		1028. 1029		1030. 1031	
1032. 1033		1034. 1035		1036. 1037		1038. 1039	
1040. 1041		1042. 1043		1044. 1045		1046. 1047	
1048. 1049		1050. 1051		1052. 1053		1054. 1055	
1056. 1057		1058. 1059		1060. 1061		1062. 1063	
1064. 1065		1066. 1067		1068. 1069		1070. 1071	
1072. 1073		1074. 1075		1076. 1077		1078. 1079	
1080. 1081		1082. 1083		1084. 1085		1086. 1087	
1088. 1089		1090. 1091		1092. 1093		1094. 1095	
1096. 1097		1098. 1099		1100. 1101		1102. 1103	
1104. 1105		1106. 1107		1108. 1109		1110. 1111	
1112. 1113		1114. 1115		1116. 1117		1118. 1119	
1120. 1121		1122. 1123		1124. 1125		1126. 1127	
1128. 1129		1130. 1131		1132. 1133		1134. 1135	
1136. 1137		1138. 1139		1140. 1141		1142. 1143	
1144. 1145		1146. 1147		1148. 1149		1150. 1151	
1152. 1153		1154. 1155		1156. 1157		1158. 1159	
1160. 1161		1162. 1163		1164. 1165		1166. 1167	
1168. 1169		1170. 1171		1172. 1173		1174. 1175	
1176. 1177		1178. 1179		1180. 1181		1182. 1183	
1184. 1185		1186. 1187		1188. 1189		1190. 1191	
1192. 1193		1194. 1195		1196. 1197		1198. 1199	
1200. 1201		1202. 1203		1204. 1205		1206. 1207	
1208. 1209		1210. 1211		1212. 1213		1214. 1215	
1216. 1217		1218. 1219		1220. 1221		1222. 1223	
1224. 1225		1226. 1227		1228. 1229		1230. 1231	
1232. 1233		1234. 1235		1236. 1237		1238. 1239	
1240. 1241		1242. 1243		1244. 1245		1246. 1247	

Sample Claim Form CMS-1500^{4,12}

Physician Office

Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies.

BOX 21:

Diagnosis or Nature of Illness or Injury

Lines A-L

Enter ICD diagnosis code on lines A-L, one code per line.

ICD Indicator

Enter ICD Indicator in top right corner to identify which version of ICD codes are being used, i.e. "0" for ICD-10-CM codes as shown on page 5.

See ICD-10-CM codes on page 5.

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

1. MEDICARE (Medicare) ☐ MEDICAID (Medicaid) ☐ TRICARE (TRICARE) ☐ CHAMPVA (CHAMPVA) ☐ GROUP HEALTH PLAN (Group Health Plan) ☐ 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 (1-6)

15. OTHER DATE (MM/DD/YY)

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM/TO) (MM/DD/YY)

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

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM/TO) (MM/DD/YY)

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 Ind. 0-9)

22. SUBMISSION CODE (ORIGINAL REF. NO.)

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE (FROM/TO) (MM/DD/YY) (RECORD SERVICE) (EMG) (EXPLAIN UNUSUAL CIRCUMSTANCES) (MODIFIER) (DIAGNOSIS POINTER) (F. \$ CHARGES) (G. DAYS OR UNITS) (H. FIRST/REPEAT) (I. ID. QUAL) (J. RENDERING PROVIDER ID. #)

25. FEDERAL TAX I.D. NUMBER (SSN EIN)

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (YES/NO)

28. TOTAL CHARGE (\$)

29. AMOUNT PAID (\$)

30. Read for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER (INCLUDING DEGREE 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. NPI)

33. BILLING PROVIDER INFO & PH# (a. NPI, b. NPI)

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

BOX 24A: Date(s) of Service

Enter NDC in the red shaded area.

Please see additional CMS-1500 claim form information on page 11.

Please see Important Safety Information on page 14, and accompanying full Prescribing Information for PEMFEXY®.

Sample Claim Form CMS-1500, continued^{4,12}

Physician Office

Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies.

BOX 24B:

Place of Service

Enter POS code, such as:

- Physician Office (11)
- Off-Campus Outpatient Hospital (19)
- On-Campus Outpatient Hospital (22)

BOX 24D:

Procedures, Services, or Supplies

Enter HCPCS drug code and CPT code for the administration of PEMFEXY®.

HCPCS³:

J9304 Injection, pemetrexed (pemfexy), 10 mg

CPT⁹:

96409	Chemotherapy, intravenous push, single or initial drug
96411	Chemotherapy, intravenous push, each additional drug
96413	Chemotherapy, intravenous infusion, 1 hour
96415	Chemotherapy, intravenous infusion, each additional hour
96417	Chemotherapy, intravenous infusion, each additional sequential infusion

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 (Group Health Plan) ☐ 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 (QUAL)

15. OTHER DATE (MM/DD/YY)

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM MM/DD/YY TO MM/DD/YY)

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

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM MM/DD/YY TO MM/DD/YY)

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)

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

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

25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (YES/NO) 28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Read 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# (a. NPI b.)

SIGNED DATE PLEASE PRINT OR TYPE APPROVED CMS-0938-1197 FORM 1500 (02-12)

BOX 24E: Diagnosis Pointer

Enter ICD diagnosis code reference letter from Box 21, relative to the date of service and the procedure performed.

BOX 24G: Days or Units

Enter the number of service units for PEMFEXY® HCPCS code (J9304). Billable unit = 10 mg. One vial = 50 units.

See Billing Unit Conversion on page 6.

Please see Important Safety Information on page 14, and accompanying full Prescribing Information for PEMFEXY®.

EAGLE CAN[®]

Care & Access Network

Reimbursement Support

Providing You and Your Patients Comprehensive Reimbursement and Access Solutions

EAGLE CAN[®] Program Benefits:

Benefit Verification

Access Support

- Prior authorization assistance
- Coverage counseling
- Reimbursement guidance
- Appeals investigation and counseling

Patient Assistance

- Product access through our Patient Financial Assistance Program[§]
- Product Credit Replacement Program[§]
- Referrals to 501 (c)(3) foundations when applicable

PEMFEXY[®] Copay Assistance Program

- Patients may pay as little as \$0 per dose[†]
- 12-Month rolling enrollment period[†]
- Enrollment period maximum benefit of \$25,000 per year[§]

Local, Dedicated Field Reimbursement Support

- Contact your regional Field Reimbursement Manager for assistance

**For Additional Support, or to Enroll Your Eligible Patients,
Contact an EAGLE CAN[®] Patient Access Specialist Today:**



CALL 833-324-5322

Fax: 1-833-324-5346

Monday through Friday
9:00 AM to 5:00 PM ET



**Download the EAGLE CAN[®]
Enrollment Form:**

VISIT PEMFEXY.COM

[§]For eligibility requirements please contact a program representative.

[†]Terms and conditions apply; see terms and conditions on the next page.

PEMFEXY® Copay Assistance Program

The PEMFEXY® Copay Assistance Program is for commercially insured, eligible patients whose insurance does not cover the full cost of their PEMFEXY® treatment. Learn more about eligibility requirements in the **Terms and Conditions** on this page.

Patients prescribed PEMFEXY® may pay as little as

\$0 per dose

TERMS AND CONDITIONS APPLY

- Patient out-of-pocket cost may be as little as \$0 per dose

- 12-Month rolling enrollment period

Patients and providers must renew enrollment when the active eligibility period ends. There is no limit to how many times a patient may enroll.

- Enrollment period maximum benefit of \$25,000 per year

Uninsured patients prescribed PEMFEXY® may qualify for other, separate financial assistance. Speak with an EAGLE CAN® Patient Access Specialist to learn more by calling **833-324-5322**.

Scan to download
the Enrollment Form
on PEMFEXY.COM



PEMFEXY® COPAY ASSISTANCE PROGRAM TERMS AND CONDITIONS

Patient Eligibility:

1. You must have commercial insurance that covers PEMFEXY but it does not cover the full cost and you are responsible for a portion of the cost.
2. You are not able to receive copay assistance for PEMFEXY if you participate in any state or federal healthcare program, including Medicaid, Medicare, Medigap, CHAMPUS, DoD, VA, TRICARE, or any other state patient or pharmaceutical assistance program.
3. You must immediately notify the EAGLE CAN Program if your insurance situation changes and that you may no longer be eligible to receive copay assistance for PEMFEXY if you begin to participate in one of the programs noted above.
4. You must be 18 years of age or older and receiving PEMFEXY for an FDA approved use. Please ask your doctor for information about FDA approved uses.
5. You must reside in the United States or Puerto Rico.

Program Benefits:

1. You will be eligible to receive up to \$25,000 in assistance for your documented out-of-pocket costs for PEMFEXY.
2. You will be responsible for as little as \$0 in out-of-pocket costs for each date of service submitted for copay assistance.
3. You must submit documentation of your out-of-pocket costs for PEMFEXY within 180 days of the treatment date.

4. Your healthcare provider can submit documentation for your out-of-pocket costs for PEMFEXY on your behalf.
5. For enrolled patients, the Program may provide support for claims with a date of service that falls within 120 days prior to the date the application is received by the Program.

Program Timing:

1. You will be eligible for 12 months from the approval date and will need to apply again if copay assistance continues to be needed when your eligibility ends.

Additional Terms and Conditions of Program:

1. Copay assistance will only be provided for out-of-pocket costs for PEMFEXY. Copay assistance will not be provided for your out-of-pocket costs related to the administration procedure, office visits, or other expenses.
2. You will not seek reimbursement from any third-party payers, including flexible spending accounts or healthcare savings accounts, for the value of any payment received from the EAGLE CAN Program.
3. Patients are not re-enrolled automatically prior to the end of the current eligibility period. Re-enrollment of the Program is initiated by the provider and patient.
4. This Program is not insurance.
5. Eagle Pharmaceuticals reserves the right to terminate, rescind, revoke, or amend this offer at any time without notice.

IMPORTANT SAFETY INFORMATION

(Continued)

WARNINGS AND PRECAUTIONS (Continued)

Renal Failure

Pemetrexed can cause severe, and sometimes fatal, renal toxicity. Determine creatinine clearance before each dose and periodically monitor renal function during treatment with PEMFEXY. The incidences of renal failure in clinical studies in which patients received pemetrexed with cisplatin were 2.1% in Study JMDB and 2.2% in Study JMCH. The incidence of renal failure in clinical studies in which patients received pemetrexed as a single agent ranged from 0.4% to 0.6% (Studies JMEN, PARAMOUNT, and JMEI).

Withhold PEMFEXY in patients with a creatinine clearance of less than 45 mL/min.

Bullous and Exfoliative Skin Toxicity

Serious and sometimes fatal, bullous, blistering, and exfoliative skin toxicity, including cases suggestive of Stevens-Johnson Syndrome/toxic epidermal necrolysis, can occur with pemetrexed. Permanently discontinue PEMFEXY for severe and life-threatening bullous, blistering, or exfoliating skin toxicity.

Interstitial Pneumonitis

Serious interstitial pneumonitis, including fatal cases, can occur with pemetrexed. Withhold PEMFEXY 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 PEMFEXY.

Radiation Recall

Radiation recall can occur with pemetrexed in patients who have received radiation weeks to years previously. Monitor patients for inflammation or blistering in areas of previous radiation treatment. Permanently discontinue PEMFEXY for signs of radiation recall.

Increased Risk of Toxicity with Ibuprofen in Patients with Renal Impairment

Exposure to pemetrexed is increased in patients with mild to moderate renal impairment who take concomitant ibuprofen, increasing the risks of adverse reactions of pemetrexed. In patients with creatinine clearances between 45 mL/min and 79 mL/min, avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of PEMFEXY. If concomitant ibuprofen use cannot be avoided, monitor patients more frequently for pemetrexed adverse reactions, including myelosuppression, renal, and gastrointestinal toxicity.

Embryo-Fetal Toxicity

Based on findings from animal studies and its mechanism of action, PEMFEXY can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, intravenous administration of pemetrexed to pregnant mice during the period of organogenesis was teratogenic, resulting in developmental delays and increased malformations at doses lower than the recommended human dose of 500 mg/m². Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with PEMFEXY and for 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMFEXY and for 3 months after the final dose.

DRUG INTERACTIONS

Ibuprofen increases exposure (AUC) of pemetrexed. In patients with creatinine clearance between 45 mL/min and 79 mL/min:

- Avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of PEMFEXY.
- Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity, if concomitant administration of ibuprofen cannot be avoided.

ADVERSE REACTIONS

Severe adverse reactions (Grade 3-4) occurring in $\geq 20\%$ of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed in combination with pembrolizumab and platinum chemotherapy (carboplatin or cisplatin) versus pemetrexed with platinum chemotherapy + placebo for initial treatment (KEYNOTE-189), respectively, were fatigue (12% vs 6%); diarrhea (5% vs 3%); dyspnea (3.7% vs 5%); vomiting (3.7% vs 3%); nausea (3.5% vs 3.5%); rash (2% vs 2.5%); decreased appetite (1.5% vs 0.5%); constipation (1% vs 0.5%); and pyrexia (0.2% vs 0%).

Common adverse reactions (all grades) occurring in $\geq 20\%$ of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed in combination with pembrolizumab and platinum chemotherapy (carboplatin or cisplatin) versus pemetrexed with platinum chemotherapy + placebo for initial treatment (KEYNOTE-189), respectively, were nausea (56% vs 52%); fatigue (56% vs 58%); constipation (35% vs 32%); diarrhea (31% vs 21%); decreased appetite (28% vs 30%); rash (25% vs 17%); vomiting (24% vs 23%); cough (21% vs 28%); dyspnea (21% vs 26%); and pyrexia (20% vs 15%).

Severe adverse reactions (Grade 3-4) occurring in fully vitamin supplemented patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed in combination with cisplatin versus gemcitabine in combination with cisplatin for initial treatment (JMDB), respectively, were neutropenia (15% vs 27%); fatigue (7% vs 5%); nausea (7% vs 4%); anemia (6% vs 10%); vomiting (6% vs 6%); thrombocytopenia (4% vs 13%); anorexia (2% vs 1%); diarrhea (1% vs 2%); elevated creatinine (1% vs 1%); stomatitis/pharyngitis (1% vs 0%); and constipation (1% vs 0%).

Common adverse reactions (all grades) occurring in $\geq 5\%$ fully vitamin supplemented patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed in combination with cisplatin versus gemcitabine in combination with cisplatin for initial treatment (JMDB), respectively, were nausea (56% vs 53%); fatigue (43% vs 45%); vomiting (40% vs 36%); anemia (33% vs 46%); neutropenia (29% vs 38%); anorexia (27% vs 24%); constipation (21% vs 20%); stomatitis/pharyngitis (14% vs 12%); alopecia (12% vs 21%); diarrhea (12% vs 13%); thrombocytopenia (10% vs 27%); elevated creatinine (10% vs 7%); sensory neuropathy (9% vs 12%); taste disturbance (8% vs 9%); rash/desquamation (7% vs 8%); and dyspepsia/heartburn (5% vs 6%).

Severe adverse reactions (Grade 3-4) occurring in patients with non-progressive locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed as a single agent versus placebo as maintenance treatment (JMEN), respectively, following non-pemetrexed containing, platinum-based induction therapy were fatigue (5% vs 1%); anemia (3% vs 1%); neutropenia (3% vs 0%); infection (2% vs 0%); anorexia (2% vs 0%); nausea (1% vs 1%); mucositis/stomatitis (1% vs 0%); diarrhea (1% vs 0%); and sensory neuropathy (1% vs 0%).

Common adverse reactions (all grades) occurring in $\geq 5\%$ patients with non-progressive locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed as a single agent versus placebo as maintenance treatment (JMEN), respectively, following non-pemetrexed containing, platinum-based induction therapy were fatigue (25% vs 11%); nausea (19% vs 6%); anorexia (19% vs 5%); anemia (15% vs 6%); increased ALT (10% vs 4%); rash/desquamation (10% vs 3%); sensory neuropathy (9% vs 4%); vomiting (9% vs 1%); increased AST (8% vs 4%); mucositis/stomatitis (7% vs 2%); neutropenia (6% vs 0%); diarrhea (5% vs 3%); and infection (5% vs 2%).

Severe adverse reactions (Grade 3-4) occurring in patients with non-progressive locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed as a single agent versus placebo as maintenance treatment (PARAMOUNT), respectively, following pemetrexed plus cisplatin induction therapy were anemia (4.8% vs 0.6%); fatigue (4.5% vs 0.6%); neutropenia (3.9% vs 0%); nausea (0.3% vs 0%); and mucositis/stomatitis (0.3% vs 0%).

Common adverse reactions (all grades) occurring in $\geq 5\%$ patients with non-progressive locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed as a single agent versus placebo as maintenance treatment (PARAMOUNT), respectively, following pemetrexed plus cisplatin induction therapy were fatigue (18% vs 11%); anemia (15% vs 4.8%); nausea (12% vs 2.4%); neutropenia (9% vs 0.6%); vomiting (6% vs 1.8%); edema (5% vs 3.6%); and mucositis/stomatitis (5% vs 2.4%).

Severe adverse reactions (Grade 3-4) occurring in fully supplemented patients with recurrent metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed as a single agent versus docetaxel as 2nd-line treatment after prior chemotherapy (JMEI), respectively, were neutropenia (5% vs 40%); fatigue (5% vs 5%); anemia (4% vs 4%); nausea (3% vs 2%);

anorexia (2% vs 3%); vomiting (2% vs 1%); thrombocytopenia (2% vs 0%); increased ALT (2% vs 0%); alopecia (1% vs 2%); stomatitis/pharyngitis (1% vs 1%); and increased AST (1% vs 0%).

Common adverse reactions (all grades) occurring in $\geq 5\%$ of fully supplemented patients with recurrent metastatic non-squamous non-small cell lung cancer (NSCLC) receiving pemetrexed as a single agent versus docetaxel as 2nd-line treatment after prior chemotherapy (JMEI), respectively, were fatigue (34% vs 36%); nausea (31% vs 17%); anorexia (22% vs 24%); anemia (19% vs 22%); vomiting (16% vs 12%); stomatitis/pharyngitis (15% vs 17%); rash/desquamation (14% vs 6%); diarrhea (13% vs 24%); neutropenia (11% vs 45%); fever (8% vs 8%); thrombocytopenia (8% vs 1%); increased ALT (8% vs 1%); pruritus (7% vs 2%); increased AST (7% vs 1%); alopecia (6% vs 38%); and constipation (6% vs 4%).

Severe adverse reactions (Grade 3-4) occurring in fully supplemented subgroup of patients with malignant pleural mesothelioma (MPM) receiving pemetrexed in combination with cisplatin versus cisplatin alone (JMCH), respectively, were neutropenia (23% vs 3%); nausea (12% vs 6%); vomiting (11% vs 4%); fatigue (10% vs 9%); thrombocytopenia (5% vs 0%); dehydration (4% vs 1%); anemia (4% vs 0%); diarrhea (4% vs 0%); stomatitis/pharyngitis (3% vs 0%); decreased creatinine clearance (1% vs 2%); elevated creatinine (1% vs 1%); anorexia (1% vs 1%); constipation (1% vs 1%); dyspepsia (1% vs 0%); and rash (1% vs 0%).

Common adverse reactions (all grades) occurring in $\geq 5\%$ of fully supplemented subgroup of patients with malignant pleural mesothelioma (MPM) receiving pemetrexed in combination with cisplatin versus cisplatin alone (JMCH), respectively, were nausea (82% vs 77%); vomiting (57% vs 50%); neutropenia (56% vs 13%); fatigue (48% vs 42%); anemia (26% vs 10%); thrombocytopenia (23% vs 9%); stomatitis/pharyngitis (23% vs 6%); anorexia (20% vs 14%); diarrhea (17% vs 8%); decreased creatinine clearance (16% vs 18%);

rash (16% vs 5%); constipation (12% vs 7%); elevated creatinine (11% vs 10%); alopecia (11% vs 6%); sensory neuropathy (10% vs 10%); taste disturbance (8% vs 6%); dehydration (7% vs 1%); conjunctivitis (5% vs 1%); and dyspepsia (5% vs 1%).

USE IN SPECIFIC PATIENT POPULATIONS

Pregnancy

There are no available data on pemetrexed use in pregnant women. Based on findings from animal studies and its mechanism of action, PEMFEXY can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, intravenous administration of pemetrexed to pregnant mice during the period of organogenesis was teratogenic, resulting in developmental delays and malformations at doses lower than the recommended human dose of 500 mg/m². Advise pregnant women on the potential risk to a fetus.

Lactation

There is no information regarding the presence of pemetrexed or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed infants from PEMFEXY, advise women not to breastfeed during treatment with PEMFEXY and for one week after last dose.

Females and Males of Reproductive Potential

Verify pregnancy status of females of reproductive potential prior to initiating PEMFEXY. PEMFEXY can cause fetal harm when administered to a pregnant woman. Because of the potential for genotoxicity, advise females of reproductive potential to use effective contraception during treatment with PEMFEXY and for 6 months after the final dose. Because of the potential for genotoxicity, advise males with female partners of reproductive potential to use

effective contraception during treatment with PEMFEXY and for 3 months after the final dose. PEMFEXY may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.

Pediatric Use

The safety and effectiveness of PEMFEXY in pediatric patients have not been established. Adverse reactions observed in pediatric patients studied were similar to those observed in adults.

Geriatric Use

The incidences of Grade 3-4 anemia, fatigue, thrombocytopenia, hypertension, and neutropenia were higher in patients 65 years of age and older as compared to younger patients in at least one of five randomized clinical trials.

Renal Impairment

PEMFEXY is primarily excreted by the kidneys. Decreased renal function results in reduced clearance and greater exposure (AUC) to pemetrexed compared with patients with normal renal function. No dosage is recommended for patients with creatinine clearance less than 45 mL/min.

For safety and dosing guidelines for PEMFEXY, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact Eagle Pharmaceuticals, Inc. at 1-855-318-2170 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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PEMFEXY[®]
(PEMETREXED INJECTION)

500 mg/20 mL (25 mg/mL)

EAGLE[®]
PHARMACEUTICALS

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