

**POSFREA™**  
(palonosetron) Injection

# BILLING AND CODING GUIDE

If you have additional billing and coding questions, please call your Field Reimbursement Manager or AVYXASSIST™ at 866-939-8927. Our Patient Access Specialists are available to assist Monday through Friday, 8 AM to 8 PM ET.

Please see Important Safety Information on pages 3 and 13-16 and full [Prescribing Information](#) for POSFREA.™



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The contents herein provide general coverage, coding, and payment information about POSFREA.™ The information within this guide was obtained from third-party sources and is made available for reference only. It is not exhaustive, is subject to change, and does not constitute billing, coding, or legal advice. Healthcare professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA™ does not guarantee coverage or payment. 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.

CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; NDC: National Drug Code

**Please see Important Safety Information on pages 3 and 13-16 and full [Prescribing Information](#) for POSFREA.™**

# INDICATIONS AND IMPORTANT SAFETY INFORMATION

## INDICATIONS

### Chemotherapy-Induced Nausea and Vomiting in Adults

POSFREA™ is indicated for:

- Moderately emetogenic cancer chemotherapy -- prevention of acute and delayed nausea and vomiting associated with initial and repeat courses
- Highly emetogenic cancer chemotherapy -- prevention of acute nausea and vomiting associated with initial and repeat courses

### Postoperative Nausea and Vomiting in Adults

POSFREA™ is indicated for prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and vomiting must be avoided during the postoperative period, POSFREA™ is recommended even where the incidence of postoperative nausea and/or vomiting is low.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATION

POSFREA™ is contraindicated in patients known to have hypersensitivity to the drug or any of its components

## WARNINGS AND PRECAUTIONS

### Hypersensitivity

Hypersensitivity reactions, including anaphylaxis, have been reported with or without known hypersensitivity to other 5-HT<sub>3</sub> receptor antagonists.

### Serotonin Syndrome

The development of serotonin syndrome has been reported with 5-HT<sub>3</sub> receptor antagonists. Most reports have been associated with concomitant use of serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors, mirtazapine, fentanyl, lithium, tramadol, and intravenous methylene blue). Some of the reported cases were fatal. Serotonin syndrome occurring with overdose of another 5-HT<sub>3</sub> receptor antagonist alone has also been reported. The majority of reports of serotonin syndrome related to 5-HT<sub>3</sub> receptor antagonist use occurred in a post-anesthesia care unit or an infusion center.

Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes (e.g. agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, with or without gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Patients should be monitored for the emergence of serotonin syndrome, especially with concomitant use of POSFREA™ and other serotonergic drugs. If symptoms of serotonin syndrome occur, discontinue POSFREA™ and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if POSFREA™ is used concomitantly with other serotonergic drugs

Please see Important Safety Information on pages 3 and 13-16 and full [Prescribing Information](#) for POSFREA.™

# POSFREA™

## (palonosetron) Injection

### Ordering Information

To order POSFREA™ (palonosetron) Injection, please contact one of these authorized specialty distributors and use the appropriate order #:



0.25 mg/5 mL (0.05 mg/mL)  
NDC: 83831-0105-01

Institutions/Hospitals	0.25 mg/5 mL (0.05 mg/mL)
Cardinal Health Specialty	5945779
CENCORA - ASD Healthcare	10292116
Physician Offices	0.25 mg/5 mL (0.05 mg/mL)
Cardinal Health Specialty	5945779
Oncology Supply	10292154
McKesson Specialty Health	5018368

UNIQUE  
J-CODE

**J2468**

### Highlights<sup>1</sup>

- Free from disodium edetate (EDTA)
- Free from sodium citrate
- Not made with natural rubber
- Unique J-Code: J2468

Please see Important Safety Information on pages 3 and 13-16 and full [Prescribing Information](#) for POSFREA.™



## Simplifying Patient Access, Providing Comprehensive Support.

AVYXASSIST™ can offer support to qualifying patients in need. The program provides the following services\*

- ✓ Benefit verification
- ✓ Prior authorization requirements
- ✓ Appeals process information
- ✓ Referrals to 501(c)(3) foundations when applicable
- ✓ Free product assistance (uninsured or underinsured), bridge supply (coverage delays)
- ✓ Product replacement
- ✓ Copay assistance

### COPAY ASSISTANCE PROGRAM

Eligible patients may pay as little as **\$0** per dose\*

TO ENROLL, PLEASE CHOOSE ONE OF THE FOLLOWING OPTIONS



#### Phone

866-939-8927  
Monday through Friday  
8 AM to 8 PM ET

CALL NOW

OR



#### Online

Click on the link below  
to begin your online  
enrollment

ENROLL NOW

OR



#### Fax

Download, print and fax  
the completed enrollment  
form to 833-852-3420

DOWNLOAD NOW

\*For Eligibility Requirements Please Contact A Patient Access Specialist. Terms And Conditions Apply.

Please see Important Safety Information on pages 3 and 13-16  
and full [Prescribing Information](#) for POSFREA.™

## Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA™ concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. AVYXA™ does not recommend the use of any particular diagnosis code in any billing situation for POSFREA™ (palonosetron) Injection. The below codes are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

### NDCs for POSFREA™ INJECTION<sup>1</sup>

NDC	Strength	Vial Size
83831-0105-01	0.25 mg/5 mL (0.05 mg/mL)	Single-dose vial, carton of 1

### HCPCS Code<sup>2</sup>

HCPCS Level II codes are used to identify most drugs and biologics that are given in the office.

POSFREA™ Unique J-Code	Description
<b>J2468</b>	Injection, palonosetron hydrochloride (AVYXA™), not therapeutically equivalent to J2469, 25 micrograms

### POSFREA™ J-Code Billing Unit Conversion<sup>3</sup>

25 micrograms of POSFREA™ equals one (1) billing unit. When billing for quantities greater than 25 micrograms, indicate the total amount used as a multiple of billing units on the claim form. Examples:

Vial Strength	Billing Units
One (1) Vial (5 mL) or 0.25 mg	10 billing units

**NOTE:** There are a few HCPCS codes for palonosetron but there is only one HCPCS code for POSFREA™ (J2468), so please make sure the HCPCS code matches the product purchased and administered.

## CPT Drug Administration Codes<sup>3,4</sup>

CPT codes are used to bill drug administration services provided in the physician's office and other outpatient settings.

CPT Code	Description
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)

CPT codes, descriptions, and other data only are copyright 2022 American Medical Association. All Rights Reserved. Applicable FARS/ HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

POSFREA™ is packaged as a single-dose vial<sup>1</sup>. Medicare will pay for drug waste on single-use items that are medically necessary and appropriately documented in the patient's medical record. Medicare requires discarded drugs to be reported with the JW modifier on a separate line; if there is no waste, POSFREA™ must be billed on one line with modifier -JZ. Medicare requires this; please ascertain if other payers require JZ and JW modifiers.<sup>5</sup>

\*The recommended dosage of POSFREA™ for chemotherapy-induced nausea and vomiting is a 0.25 mg dose over 30 seconds, starting the dosing approximately 30 minutes before the start of chemotherapy.<sup>1</sup> If administered 30 minutes before chemotherapy, providers may bill CPT Code 96375, indicating POSFREA™ as an additional, sequential push of a new substance or drug.

## ICD Diagnosis Codes<sup>6,7</sup>

For Drugs with multiple indications, it is best practice to code the most specific ICD-10-CM Code within the indication to justify medical necessity.

International Classification of Disease, 10th Edition, Clinical Modification Codes for POSFREA™	
Indication	ICD-10-CM Codes
Adverse Effect – Anesthetics	T41.0X5A, T41.1X5A, T41.205A, T41.295A, T41.45XA, T88.59XA
Adverse Effect – Antineoplastic and Immunosuppressive Drugs	T41.1X5A, T41.1X5D, T41.1X5S
Encounter for Antineoplastic Chemotherapy	Z51.11
Encounter for Antineoplastic Immunotherapy	Z51.12
Vomiting and Nausea	R11.0, R11.10, R11.11, R11.12, R11.2



## POSFREA™ Billing and Coding Information: ICD Diagnosis Codes by Indication

ICD-10-CM coding for POSFREA™ varies greatly by payer. Please check with each payer to ascertain the best coding for POSFREA™ according to their policy.

Adverse Effect – Anesthetics: ICD-10-CM Diagnosis Coding	
ICD-10 Code	Descriptor
T41.0X5A	Adverse effect of inhaled anesthetics, initial encounter
T41.1X5A	Adverse effect of intravenous anesthetics, initial encounter
T41.205A	Adverse effect of unspecified general anesthetics, initial encounter
T41.295A	Adverse effect of other general anesthetics, initial encounter
T41.45XA	Adverse effect of unspecified general anesthetics, initial encounter
T88.59XA	Adverse effect of other general anesthetics, initial encounter

Adverse Effect – Antineoplastic and Immunosuppressive Drugs: ICD-10-CM Diagnosis Coding	
ICD-10 Code	Descriptor
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela

Encounter for Chemotherapy: ICD-10-CM Diagnosis Coding	
ICD-10 Code	Descriptor
Z51.11	Encounter for antineoplastic chemotherapy

Encounter for Immunotherapy: ICD-10-CM Diagnosis Coding	
ICD-10 Code	Descriptor
Z51.12	Encounter for antineoplastic immunotherapy

Vomiting and Nausea: ICD-10-CM Diagnosis Coding	
ICD-10 Code	Descriptor
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified

Please see Important Safety Information on pages 3 and 13-16  
and full [Prescribing Information](#) for POSFREA.™



# SAMPLE UB-04 / CMS 1450 Claim Form

## Form Locator (FL) 42

### (Electronic Claim Form = Loop 2400, Segment Type SV201):

List the appropriate revenue code for the drug. Match the descriptor for POSFREA™ Injection to your revenue code, 0260.

Additionally, enter an appropriate revenue code for the administration service, 0335 for chemotherapy, or others based on the cost center in which the service was performed.

## FL 43

### (NOT REQUIRED BY MEDICARE):

Enter the description of the procedure for the Revenue Code billed. If required, the N4 indicator first, then the 11-digit NDC code. In the third place, list the unit measurement code and the quantity. Check with other payers for their requirements.

## FL 44

### (Electronic Claim Form = Loop 2400, SV202-1=HC/HP):

Enter the appropriate HCPCS code - J2468: Injection, palonosetron hydrochloride (AVYXA™), not therapeutically equivalent to J2469, 25 micrograms

POSFREA™ Injection is packaged as a single-dose vial. Medicare requires drug waste be reported with the -JW modifier on a separate line. If there is no waste, POSFREA™ Injection must be billed on one line with modifier -JZ. Medicare requires this; please ascertain if other payers require JZ and JW modifiers.

For administration, enter the appropriate code or codes for the infusion duration. As an example, a 30 second infusion of POSFREA™ Injection requires code CPT Code 96374.

FL 42

FL 44

1. PATIENT NAME		2. PATIENT ADDRESS		3a. PAY CNTL #		4. TOP OF BILL	
5. MED REC #		6. STATEMENT COVERS PERIOD FROM		7. THROUGH			
8. PATIENT NAME		9. PATIENT ADDRESS		10. BIRTHDATE		11. SEX	
12. DATE		13. ADMISSION		14. TYPE		15. SRC	
16. DHR		17. STAT		18. 19		20. 21	
22. 23		24. 25		26. 27		28. 29	
30. 31		32. 33		34. 35		36. 37	
38. 39		40. 41		42. 43		44. 45	
46. 47		48. 49		50. 51		52. 53	
54. 55		56. 57		58. 59		60. 61	
62. 63		64. 65		66. 67		68. 69	
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118. 119		120. 121		122. 123		124. 125	
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134. 135		136. 137		138. 139		140. 141	
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558. 559		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	
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934. 935		936. 937		938. 939		940. 941	
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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. 1			

### FL 45

#### (Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service

### FL 46

#### FL 46 (Electronic Claim Form Loop 2400, SV205):

Enter the units for the HCPCS code billed. Enter the number of service units for each item. For example, 10 units if using one .25mg/5ml single-dose vial of POSFREA™ Injection

### FL 63

#### (Electronic Claim Form= Loop 2300, REF/G1/02):

Enter treatment authorization code.

### FL 67A-Q

#### FL 67A-Q (Electronic Claim Form = Loop 2300, HI01-2 (HI01-1+BK):

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible. The code listed here is an example for POSFREA™ Injection: Z51.11, Encounter for antineoplastic chemotherapy

### FL 63

### FL 67A-Q

Form 100-0101 (Rev. 10/2019) - Electronic Claim Form (Loop 2400, Segment DTP/472/03)

1. PATIENT NAME, 2. PATIENT ADDRESS, 3. PATIENT PHONE, 4. PATIENT FAX, 5. MED. REC. #, 6. STATEMENT COVERS PERIOD, 7. FROM, 8. THROUGH, 9. STATE, 10. DATE OF BILL

11. BIRTHDATE, 12. SEX, 13. ADMISSION, 14. TYPE, 15. SRC, 16. DHR, 17. STAT, 18. CONDITION CODES, 19. FROM, 20. THROUGH, 21. FROM, 22. THROUGH, 23. FROM, 24. THROUGH, 25. FROM, 26. THROUGH, 27. FROM, 28. THROUGH, 29. FROM, 30. THROUGH, 31. FROM, 32. THROUGH, 33. FROM, 34. THROUGH, 35. FROM, 36. THROUGH, 37. FROM, 38. THROUGH, 39. FROM, 40. THROUGH, 41. FROM, 42. THROUGH, 43. FROM, 44. THROUGH, 45. FROM, 46. THROUGH, 47. FROM, 48. THROUGH, 49. FROM, 50. THROUGH, 51. FROM, 52. THROUGH, 53. FROM, 54. THROUGH, 55. FROM, 56. THROUGH, 57. FROM, 58. THROUGH, 59. FROM, 60. THROUGH, 61. FROM, 62. THROUGH, 63. FROM, 64. THROUGH, 65. FROM, 66. THROUGH, 67. FROM, 68. THROUGH, 69. FROM, 70. THROUGH, 71. FROM, 72. THROUGH, 73. FROM, 74. THROUGH, 75. FROM, 76. THROUGH, 77. FROM, 78. THROUGH, 79. FROM, 80. THROUGH, 81. FROM, 82. THROUGH, 83. FROM, 84. THROUGH, 85. FROM, 86. THROUGH, 87. FROM, 88. THROUGH, 89. FROM, 90. THROUGH, 91. FROM, 92. THROUGH, 93. FROM, 94. THROUGH, 95. FROM, 96. THROUGH, 97. FROM, 98. THROUGH, 99. FROM, 100. THROUGH

42. REV. CD, 43. DESCRIPTION, 44. HCPCS / RATE / UNIT, 45. SERV. DATE, 46. SERV. UNITS, 47. TOTAL CHARGES, 48. NON COVERED CHARGES, 49. TOTAL CHARGES

PAGE OF, CREATION DATE, TOTALS

50. PRIOR NAME, 51. HEALTH PLAN ID, 52. REL. RPD, 53. REL. BEN, 54. PRIOR PAYMENTS, 55. EST. AMOUNT DUE, 56. NPI, 57. OTHER PRIV. ID

58. INSURED'S NAME, 59. PREL, 60. INSURED'S UNIQUE ID, 61. GROUP NAME, 62. INSURANCE GROUP NO.

63. TREATMENT AUTHORIZATION CODES, 64. DOCUMENT CONTROL NUMBER, 65. EMPLOYER NAME

66. C50.111, 67. A, 68. B, 69. C, 70. D, 71. E, 72. F, 73. G, 74. H, 75. I, 76. J, 77. K, 78. L, 79. M, 80. N, 81. O, 82. P, 83. Q, 84. R, 85. S, 86. T, 87. U, 88. V, 89. W, 90. X, 91. Y, 92. Z, 93. AA, 94. AB, 95. AC, 96. AD, 97. AE, 98. AF, 99. AG, 100. AH

74. PRINCIPAL PROCEDURE CODE, 75. OTHER PROCEDURE CODE, 76. ATTENDING, 77. OPERATING, 78. OTHER, 79. OTHER, 80. REMARKS, 81. CC, 82. A, 83. B, 84. C, 85. D

UB-04 CMS-1450, APPROVED CMS NO. 0858-0987, NUBC, THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

[1] CPT Code 96374: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug. Initial infusion times may vary. **Electronic Claims Reference:** ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk." Palmettogba.Com. Palmetto GBA, Accessed April 3, 2023. [https://www.palmettogba.com/palmetto/providers.nsf/files/EDI\\_837I\\_v5010A2\\_crosswalk.pdf/\\$FILE/EDI\\_837I\\_v5010A2\\_crosswalk.pdf](https://www.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$FILE/EDI_837I_v5010A2_crosswalk.pdf).

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# SAMPLE CMS 1500 Claim Form

## Box 21

(Electronic Claim Form = Loop 2300, Segment H101-2 through H112=2):

Enter the patient's diagnosis from the patient's medical record. An example code for POSFREA™ injection is **Z51.11 - Encounter for Antineoplastic Chemotherapy**

Use Box 21 B-L fields for secondary diagnoses.

## Box 23

(Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.

## Box 24D

(Electronic Claim Form = Loop 2400, Segment SV101):

Enter the appropriate HCPCS code - **J2468: Injection, palonosetron hydrochloride (AVYXA™), not therapeutically equivalent to J2469, 25 micrograms**

POSFREA™ Injection is packaged as a single-dose vial. Medicare requires drug waste be reported with the -JW modifier on a separate line. If there is no waste, POSFREA™ Injection must be billed on one line with modifier -JZ. Medicare requires this; please ascertain if other payers require JZ and JW modifiers.

For administration, enter the appropriate code or codes for the infusion duration. As an example, CPT code 96375 indicates a therapeutic, prophylactic, or diagnostic injection. List this code separately to primary procedure, 96413, chemotherapy administration.

## Box 24E

(Electronic Claim Form = Loop 2400, Segment SV107):

Specify the diagnosis letter that corresponds with the drug and drug administration code(s) in Box 21.

**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 08/01/05

**BOX 21** (Patient's Diagnosis): Z51.11 - Encounter for Antineoplastic Chemotherapy

**BOX 23** (Prior Authorization Number): [Blank]

**BOX 24D** (HCPCS Code): J2468

**BOX 24E** (Diagnosis Letter): JZ

### Box 24G

(Electronic Claim Form = Loop 2400, SV104):

Enter the number of service units for each item.

### Box 24A-B

(Electronic Claim Form: Box 24A (Electronic Claims = Loop 2400, DTP02 Box 24 B (Loop 2300/2400, Segment CLM05-1/ SV105)

In the non-shaded area, enter the appropriate date of service and place of service code. Example: Office = 11

In the shaded area, enter the N4 indicator first, then the 11-digit NDC code. In the third space, list the quantity and, last, the unit measurement code.

An example for this drug is  
N4838310105015ML

Box 24A-B

Box 24G

[1] CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug/initial infusion times may vary. **Electronic Claim Reference:** Noridian Healthcare (n.d.). CMS-1500 Claim Form Crosswalk to EMC Loops and Segments. Noridian Healthcare Solutions. Retrieved April 5, 2023, from <https://med.noridianmedicare.com/web/jeb/topics/claim-submission/cms-1500-crosswalk-emc-loops-segments>

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# IMPORTANT SAFETY INFORMATION (CONTINUED)

## ADVERSE REACTIONS

### Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of POSFREA™ has been established from adequate and well-controlled studies of another intravenous formulation of palonosetron HCl. Below is a display of the adverse reactions of palonosetron HCl in these adequate and well-controlled studies.

#### Chemotherapy-Induced Nausea and Vomiting:

In clinical trials for the prevention of nausea and vomiting induced by moderately or highly emetogenic chemotherapy, 633 adult patients received a single 0.25 mg dose of palonosetron HCl, 410 patients received a single 32 mg dose of ondansetron and 194 patients received a single 100 mg dose of dolasetron. Adverse reactions were similar in frequency and severity with intravenous palonosetron HCl, ondansetron or dolasetron. The following adverse reactions were reported by ≥ 2% of patients in these trials who received palonosetron HCL 0.25 mg intravenously, ondansetron 32 mg intravenously, or dolasetron 100 mg intravenously, respectively: headache (9%, 8%, 16%, respectively), constipation (5%, 2%, 6%, respectively), diarrhea (1%, 2%, 2%, respectively), dizziness (1%, 2%, 2%, respectively), fatigue (<1%, 1%, 2%, respectively), abdominal pain (<1%, <1%, 2%, respectively), insomnia (<1%, 1%, 2%, respectively).

In other studies, 2 subjects experienced severe constipation following a single palonosetron HCl dose of approximately 0.75 mg, three times the recommended dose.

In clinical trials, the following infrequently reported adverse reactions, assessed by investigators as treatment-related or causality unknown, occurred following administration of palonosetron HCl to adult patients receiving concomitant cancer chemotherapy:

*Cardiovascular:* 1%: non-sustained tachycardia, bradycardia, hypotension, < 1%: hypertension, myocardial ischemia, extrasystoles, sinus tachycardia, sinus arrhythmia, supraventricular extrasystoles and QT prolongation. In many cases, the relationship to palonosetron was unclear.

*Dermatological:* < 1%: allergic dermatitis, rash.

*Hearing and Vision:* < 1%: motion sickness, tinnitus, eye irritation and amblyopia.

*Gastrointestinal System:* 1%: diarrhea, < 1%: dyspepsia, abdominal pain, dry mouth, hiccups and flatulence.

*General:* 1%: weakness, < 1%: fatigue, fever, hot flash, flu-like syndrome.

*Liver:* < 1%: transient, asymptomatic increases in AST and/or ALT and bilirubin. These changes occurred predominantly in patients receiving highly emetogenic chemotherapy.

*Metabolic:* 1%: hyperkalemia, < 1%: electrolyte fluctuations, hyperglycemia, metabolic acidosis, glycosuria, appetite decrease, anorexia.

Please see Important Safety Information on pages 3 and 13-16 and full [Prescribing Information](#) for POSFREA.™

## IMPORTANT SAFETY INFORMATION (CONTINUED)

*Musculoskeletal:* < 1%: arthralgia.

*Nervous System:* 1%: dizziness, < 1%: somnolence, insomnia, hypersomnia, paresthesia.

*Psychiatric:* 1%: anxiety, < 1%: euphoric mood.

*Urinary System:* < 1%: urinary retention.

*Vascular:* < 1%: vein discoloration, vein distention.

### Postoperative Nausea and Vomiting:

Adverse reactions occurred in adults receiving intravenous palonosetron HCl 0.075 mg immediately before induction of anesthesia in three randomized placebo-controlled trials. Rates of adverse reactions between palonosetron HCl and placebo groups were similar. Some events are known to be associated with, or may be exacerbated by concomitant perioperative and intraoperative medications administered in this surgical population. The following adverse reactions were reported by  $\geq 2\%$  of patients in these trials who received palonosetron HCl 0.075 mg intravenously (N=336) compared to placebo (N=369): electrocardiogram QT prolongation (5% vs. 3%), bradycardia (4% vs. 4%), headache (3% vs 4%), and constipation (2% vs 3%).

In these clinical trials, the following infrequently reported adverse reactions, assessed by investigators as treatment-related or causality unknown, occurred following administration of palonosetron HCl to adult patients receiving concomitant perioperative and intraoperative medications including those associated with anesthesia:

*Cardiovascular:* 1% electrocardiogram QTc prolongation, sinus bradycardia, tachycardia; <1%: blood pressure decreased, hypotension, hypertension, arrhythmia, ventricular extrasystoles, generalized edema; ECG T wave amplitude decreased, platelet count decreased. The frequency of these adverse effects did not appear to be different from placebo.

*Dermatological:* 1%: pruritus.

*Gastrointestinal System:* 1%: flatulence, < 1%: dry mouth, upper abdominal pain, salivary hypersecretion, dyspepsia, diarrhea, intestinal hypomotility, anorexia.

*General:* < 1%: chills.

*Liver:* 1%: increases in AST and/or ALT < 1%: hepatic enzyme increased.

*Metabolic:* < 1%: hypokalemia, anorexia.

*Nervous System:* : < 1%: dizziness.

*Respiratory:* < 1%: hypoventilation, laryngospasm.

*Urinary System:* 1%: urinary retention.

### **Postmarketing Experience**

The following adverse reactions have been identified during post approval use of another intravenous formulation of palonosetron HCl. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

## IMPORTANT SAFETY INFORMATION (CONTINUED)

Very rare cases (<1/10,000) of hypersensitivity reactions including anaphylaxis and anaphylactic shock and injection site reactions (burning, induration, discomfort and pain) were reported from postmarketing experience of palonosetron HCl 0.25 mg in the prevention of chemotherapy- induced nausea and vomiting.

## DRUG INTERACTIONS

### Serotonergic Drugs

Serotonin syndrome (including altered mental status, autonomic instability, and neuromuscular symptoms) has been described following the concomitant use of 5-HT<sub>3</sub> receptor antagonists and other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs). Monitor for the emergence of serotonin syndrome. If symptoms occur, discontinue POSFREA™ and initiate supportive treatment.

## USE IN SPECIFIC POPULATIONS

### Pregnancy

#### Risk Summary:

There are no available data on palonosetron HCl use in pregnant women to inform a drug- associated risk. In animal reproduction studies, no effects on embryo-fetal development were observed with the administration of oral palonosetron HCl to rats and rabbits during organogenesis at doses up to 1894 and 3789 times the recommended human intravenous dose, respectively [see Data below].

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

#### Data:

##### *Animal Data*

In animal reproduction studies, no effects on embryo-fetal development were observed in pregnant rats given oral palonosetron HCl at doses up to 60 mg/kg/day (1894 times the recommended human intravenous dose based on body surface area) or pregnant rabbits given oral doses up to 60 mg/kg/day (3789 times the recommended human intravenous dose based on body surface area) during the period of organogenesis.

### Lactation

#### Risk Summary:

There are no data on the presence of palonosetron in human milk, the effects of palonosetron on the breastfed infant, or the effects of palonosetron on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for POSFREA™ and any potential adverse effects on the breastfed infant from palonosetron or from the underlying maternal condition.

**Please see Important Safety Information on pages 3 and 13-16 and full [Prescribing Information](#) for POSFREA.™**



## IMPORTANT SAFETY INFORMATION (CONTINUED)

### Pediatric Use

This product has not been approved for use in pediatric patients for prevention of chemotherapy- induced nausea and vomiting.

The safety and effectiveness of POSFREA™ for prevention of postoperative nausea and vomiting have not been established in pediatric patients.

### Geriatric Use

Of the 1374 adult cancer patients in clinical studies of intravenously administered palonosetron HCl for CINV, 316 (23%) were aged 65 years and over, while 71 (5%) were aged 75 years and over. Of the 1520 adult patients in clinical studies of intravenously administered palonosetron HCl for PONV, 73 (5%) were age 65 years older. No overall differences in safety or effectiveness were observed between these subjects and the younger subjects, but greater sensitivity in some older individuals cannot be ruled out. Population pharmacokinetics analysis did not reveal any differences in palonosetron pharmacokinetics between cancer patients  $\geq 65$  years of age and younger patients. No dose adjustment or special monitoring are required for geriatric patients.

No overall differences in safety were observed between older and younger subjects in these studies, though the possibility of heightened sensitivity in some older individuals cannot be excluded. No differences in efficacy were observed in geriatric patients for the CINV indication and none are expected for geriatric PONV patients. However, palonosetron HCl efficacy in geriatric patients has not been adequately evaluated.

## OVERDOSAGE

There is no known antidote to palonosetron HCl. Overdose should be managed with supportive care.

Dialysis studies have not been performed, however, due to the large volume of distribution, dialysis is unlikely to be an effective treatment for palonosetron HCl overdose. A single intravenous dose of palonosetron HCl at 30 mg/kg (947 and 474 times the human dose for rats and mice, respectively, based on body surface area) was lethal to rats and mice. The major signs of toxicity were convulsions, gasping, pallor, cyanosis and collapse.

Please see the full [Prescribing Information](#) for safety information, and dosing guidelines.

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There is no text or other markings on the paper.

## References:

1. POSFREA™ Full Prescribing Information. Parsippany, NJ. AVYXA™ Pharma. Revised July 2024.
2. CMS. Healthcare Common Procedure Coding System Level II Coding Procedures 2023. Accessed August 19, 2024. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system>
3. CMS. Billing and Coding: Approved Drugs and Pharmaceuticals; Includes Cancer Chemotherapeutic Agents. Revised November 2, 2023. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53049&ver=98>
4. Current Procedural Terminology. 2024 ® American Medical Association
5. CMS. Billing and Coding: JW and JZ Modifier Billing Guidelines. Article ID A55932. Revised March 21, 2024. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55932>.
6. CDC. Classification of Diseases, Functioning, and Disability. Revised June 7, 2024 <https://www.cdc.gov/nchs/icd/>
7. CDC. National Center for Health Statistics. ICD-10-CM Fiscal Year Releases. Revised April 1, 2024. <https://www.cdc.gov/nchs/icd/icd-10-cm/files.html>

