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Coding and Billing Guide for FOCINVEZ™ (fosaprepitant injection) for intravenous use



Overview and Disclaimer

Amneal developed this guide to support healthcare providers (HCPs) treating patients with FOCINVEZ 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 the services rendered and documented in the patient's medical record. The information here is current as of June 2024.

Indications¹

FOCINVEZ is a substance P/neurokinin-1 (NK₁) receptor antagonist, indicated in adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy (HEC) including high-dose cisplatin.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC).

Limitations of Use:

- FOCINVEZ has not been studied for the treatment of established nausea and vomiting.

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 may apply.

ICD-10-CM Code ²	Description	Appropriate Use
R11.0	Nausea	
R11.10	Vomiting, unspecified	
R11.11	Vomiting without nausea	Report the appropriate ICD-10-CM diagnosis code based on HCP medical record documentation
R11.2	Nausea with vomiting, unspecified	
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	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 cancer diagnosis as secondary ³
Z51.11	Encounter for antineoplastic chemotherapy	

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

Reporting Use of FOCINVEZ and Its Administration

Product-Specific Billing Code

FOCINVEZ 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
J1434	Injection, fosaprepitant (focinvez), 1 mg	Physician office, HOPD	For dates of service on and after April 1, 2024

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



When billing FOCINVEZ using J1434, 1 billing unit is equal to 1 milligram

HCPCS Modifiers

Payers may require one or more HCPCS modifiers to be reported along with J1434 on outpatient claims to provide additional information about the services provided.

Modifier ⁴	Description	Site(s) of Care	Appropriate Use
JZ⁵	Zero drug amount discarded/not administered to any patient		Attach modifier “-JZ” to J1434 when all of the drug in a single-use vial (150 mg) is administered to a patient and none is discarded
JW⁵	Drug amount discarded/not administered to any patient	Physician office, HOPD	Attach modifier “-JW” to J1434 when some of the drug in a single-use vial (150 mg) is discarded. This requires 2 claim lines: <ul style="list-style-type: none"> • <u>Claim line 1</u>: Report the amount of drug administered with the appropriate number of billing units for the HCPCS code and no modifier • <u>Claim line 2</u>: Report modifier “-JW” with the HCPCS code and the appropriate number of billing units for any amount of discarded drug
JG⁶	Drug or biological acquired with a 340B Drug Pricing Program discount, reported for informational purposes	340B-covered entities	340B-covered entities may append to J1434 either modifier “-JG” or “-TB,” as appropriate, on claims with dates of service through December 31, 2024
TB⁶	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 FOCINVEZ.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 The leading 0 in the 11-digit FOCINVEZ NDC is underlined below.

11-Digit NDC ¹	NDC Descriptor ¹	Site(s) of Care	Appropriate Use
70121-2631-<u>01</u>	150 mg/50 mL (3 mg/mL) 1 SDV in a carton	Physician office, HOPD	The NDC is typically preceded with NDC qualifier “N4”: eg, N470121263101. Report without dashes or other punctuation When required by payers, report “ML” as the unit of measure with the appropriate NDC quantity

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

Current Procedural Terminology (CPT®) Codes⁹

The following code may be used to report the intravenous (IV) administration of FOCINVEZ:

CPT Code	Description	Site(s) of Care	Appropriate Use
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/ substance, up to 1 hour (list separately in addition to code for primary procedure)	Physician office, HOPD	Drug administration codes depend on other therapies administered on the same day as FOCINVEZ Check payer policy and medical record documentation

Key: CPT – Current Procedural Terminology; HOPD – hospital outpatient department.

^a CPT © 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

Revenue Codes¹⁰

The following revenue codes may be appropriate to report the use of FOCINVEZ and its administration in the HOPD setting to some payers:

Used For	Revenue Code	Description	Site(s) of Care
FOCINVEZ	0636	Drugs requiring detailed coding	
Drug administration procedure	0260 ^a	IV therapy – general	HOPD
	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:

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(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, FOCINVEZ was administered to a 5-year-old patient weighing 20 kg. An 80 mg FOCINVEZ (4 mg/kg) single-dose regimen for the prevention of nausea and vomiting was administered as an IV infusion over 60 minutes.

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

- ICD-10-CM: Z51.11 Encounter for antineoplastic chemotherapy

Payers may require the underlying cancer diagnosis code to be reported on claims. Final code depends on medical record documentation and payer guidelines.

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; eg:

- For J1434, 1 billing unit is equal to 1 mg of FOCINVEZ. Use separate lines on the claim for amount administered and amount discarded
- For 96367, 1 unit represents up to a 90-minute IV infusion

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: Relate A-L to service line below (24E)										ICD Ind.		22. RESUBMISSION CODE		23. REFERENCE AUTHORIZATION NUMBER				
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q		
Z51.11																		
24. A. DATE(S) OF SERVICE										B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)			E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. NPI
From	To	MM	DD	YY	MM	DD	YY	11				CPT/HCPCS	MODIFIER					
N470121263101	ML26.667											J1434			A		80	
N470121263101	ML23.333											J1434	JW		A		70	
												96367			A		1	

Item Number 24A, Date(s) of Service: Enter the NDC in the shaded area above the month, day, and year. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the 2-character unit of measure qualifier and quantity.

Check payer requirements and format for reporting NDCs.

Item Number 24D, Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg:

- Drug: J1434 for FOCINVEZ
- Modifier: -JW to show that some product was discarded
- Administration: 96367 for IV infusion

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, 150 mg of FOCINVEZ was administered to an adult patient for the prevention of nausea and vomiting associated with highly emetogenic chemotherapy.

FL 42, Revenue Code: Enter the appropriate revenue code; eg:

- 0636 for FOCINVEZ
- 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; eg:

- For J1434, 1 billing unit is equal to 1 mg of FOCINVEZ
- For 96367, 1 unit represents up to a 90-minute IV infusion

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	N470121263101 ML50 FOCINVEZ	J1434 JZ	MMDDYY	150	XXX XX		
0260	IV infusion	96367	MMDDYY	1	XXX XXX		

FL 43, Revenue Description: Enter the NDC. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the 2-character unit of measure qualifier and quantity.

Check payer requirements and format for reporting NDCs.

FL 44, HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers; eg:

- Drug: J1434 for FOCINVEZ
- Modifier: -JZ to show that no amount of drug was discarded
- Administration: 96367 for IV infusion

66 DX Z51.11

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

- ICD-10-CM: Z51.11 Encounter for antineoplastic chemotherapy

Payers may require the underlying cancer diagnosis code to be reported on claims. Final code depends on medical record documentation and payer guidelines.

Key: CPT – Current Procedural Terminology; FL – Form Locator; HCP – healthcare provider; HCPCS – Healthcare Common Procedure Coding System; ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification; IV – intravenous; NDC – National Drug Code.

Please see [Full Prescribing Information](#), including Important Safety Information on page 6, for FOCINVEZ.

Important Safety Information

Contraindications

- FOCINVEZ™ is contraindicated in patients who are hypersensitive to any component of the product.
- Concurrent use of FOCINVEZ™ with pimozone is contraindicated.

Warnings and Precautions

- **Clinically Significant CYP3A4 Interactions:** Fosaprepitant, a prodrug of aprepitant, is a weak inhibitor of CYP3A4, and aprepitant is a substrate, inhibitor, and inducer of CYP3A4. See full Prescribing Information for recommendations regarding contraindications, risk of adverse reactions, and dosage adjustment of FOCINVEZ™ and concomitant drugs.
- **Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylaxis and anaphylactic shock, during or soon after infusion of fosaprepitant have occurred. Monitor patients during and after infusion. If hypersensitivity reactions occur, discontinue the infusion and administer appropriate medical therapy. Do not reinitiate FOCINVEZ™ in patients who experienced these symptoms with previous use.
- **Infusion Site Reactions:** Infusion site reactions (ISRs), including thrombophlebitis and vasculitis, have been reported with the use of intravenous fosaprepitant. The majority of severe ISRs were reported with concomitant vesicant (anthracycline-based) chemotherapy administration. Avoid infusion into small veins. Discontinue infusion and administer treatment if a severe reaction develops.
- **Warfarin:** Coadministration of fosaprepitant with warfarin, a CYP2C9 substrate, may result in a clinically significant decrease in the international normalized ratio (INR) of prothrombin time. Monitor the INR in patients on chronic warfarin therapy in the 2-week period, particularly at 7 to 10 days, following initiation of FOCINVEZ™ with each chemotherapy cycle.
- **Hormonal Contraceptives:** The efficacy of hormonal contraceptives may be reduced during treatment with FOCINVEZ™ and for 1 month following administration of the last dose of either fosaprepitant or oral aprepitant. Advise patients to use effective alternative or back-up methods of contraception.

Adverse Drug Reactions

- The most common adverse drug reactions in adults (≥2%) treated with FOCINVEZ™ are neutropenia, leukopenia, peripheral neuropathy, anemia, fatigue, diarrhea, asthenia, dyspepsia, urinary tract infection, pain in extremity.
- Adverse reactions in pediatric patients treated with FOCINVEZ™ are similar to adults.

Drug Interactions

- Co-administration of FOCINVEZ™ with drugs that are inhibitors or inducers of CYP3A4 may result in increased or decreased plasma concentrations of aprepitant.
- See full Prescribing Information for a list of clinically significant drug interactions.

Use in Specific Populations

- **Pregnancy:** There are insufficient data on the use of fosaprepitant in pregnant women to identify a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.
- **Lactation:** There are no data on the presence of aprepitant in human milk.

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

References

1. FOCINVEZ prescribing information. Amneal Pharmaceuticals LLC; 2023. 2. CMS. International Classification of Diseases, 10th Revision, Clinical Modification ICD-10-CM 2024 code descriptions in tabular order. Updated February 1, 2024. Accessed June 13, 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 FY 2024 – Updated April 1, 2024 (April 1, 2024 – September 30, 2024). Accessed June 13, 2024. <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 June 13, 2024. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> 5. CMS. Discarded drugs and biologicals – JW modifier and JZ modifier policy frequently asked questions. Updated December 4, 2023. Accessed June 13, 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 June 13, 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 June 13, 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 June 13, 2024. <https://www.fda.gov/media/173715/download> 9. Current Procedural Terminology (CPT®) 2024. American Medical Association. 10. Noridian Healthcare Solutions. Revenue codes. Accessed June 13, 2024. <https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes>

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Please see [Full Prescribing Information](#), including Important Safety Information on page 6, for FOCINVEZ.