



BILLING AND CODING GUIDE

Please see additional [Important Safety Information](#) throughout and accompanying full [Prescribing Information](#).

PRODUCT
INFORMATION

CODING AT
A GLANCE

CLINIC
SETTING

OUTPATIENT
DEPT SETTING

HOME INFUSION
SETTING

NTAP

Introduction and disclaimer

The use of this guide is strictly for informational purposes. The information in this document is not intended to provide clinical practice guidelines for the use of *REZZAYO*[®]. Please see accompanying full Prescribing Information for more information.

Melinta Therapeutics, LLC specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on the information in this sample form. Melinta Therapeutics cannot guarantee, nor is it responsible for, the payment of any claim. The coding, coverage, and cost for *REZZAYO*[®] may vary by payer, plan, patient, and setting of care. For more information, healthcare professionals should check with individual payers for specific coding, coverage, and payment requirements in the use of *REZZAYO*[®]. It is the sole responsibility of the healthcare professional to properly code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient's medical records.

Coding determinations and analyses should always be independently researched and assessed. Providers are responsible for selecting the most appropriate diagnosis code for each patient. Providers should contact a patient's health plan, as health plans may have specific code requirements for *REZZAYO*[®] administration.

Product information

Drug Name:	<i>REZZAYO</i> [®] (rezafungin for injection) for intravenous use
FDA Approval Date:	March 22, 2023
Link to Prescribing Information:	https://rezzayo.com/
Indication:	<i>REZZAYO</i> [®] is an echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data.
Dosage Forms and Strength:	For injection: 200 mg as a lyophilized powder in a single-dose vial for reconstitution.
Dosage and Route of Administration:	The recommended dose of <i>REZZAYO</i> [®] is to be administered once weekly by intravenous (IV) infusion, with an initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter.
Storage:	<i>REZZAYO</i> [®] infusion solution can be stored at 5°C to 25°C (41°F to 77°F). Stability of the reconstituted solution has been demonstrated for 48 hours when stored at 5°C to 25°C (41°F to 77°F).

INDICATIONS AND USAGE

REZZAYO[®] is an echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data.

Limitations of Use

REZZAYO[®] has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to *Candida*.

IMPORTANT SAFETY INFORMATION

Contraindications

REZZAYO[®] is contraindicated in patients with known hypersensitivity to rezafungin or other echinocandins.

Please see additional **Important Safety Information** throughout and accompanying full **Prescribing Information**.

Product information (cont.)

Clinical Trials:	<p>The safety and efficacy of REZZAYO® in the treatment of patients with candidemia and/or invasive candidiasis (IC) were evaluated in a multicenter, randomized, double-blind study (ReSTORE; Trial 1: NCT03667690). ReSTORE compared the efficacy and safety of intravenous rezafungin versus intravenous caspofungin in patients with candidemia and invasive candidiasis. The primary endpoints were global cure at day 14 and 30-day all-cause mortality, both with a target noninferiority margin of 20%.</p> <p>A multicenter, randomized, dose-finding, exploratory, double-blind study was conducted in subjects with candidemia and/or invasive candidiasis (STRIVE; Trial 2: NCT02734862). The primary objectives of this study were to evaluate safety and tolerability of rezafungin and overall success (mycological eradication and resolution of systemic signs attributable to candidemia and/or IC) at day 14. The study provides safety and supportive efficacy data.</p>
Efficacy:	<p>Familiar echinocandin mechanism of action with a long half-life that allows for once-weekly dosing.</p> <p>Efficacy demonstrated in the phase 3 ReSTORE clinical trial:</p> <ul style="list-style-type: none"> Once-weekly IV infusions of REZZAYO® were noninferior to daily IV infusions of caspofungin for the primary endpoint of all-cause mortality at day 30 Comparable rates of global cure (mycological eradication/presumed eradication, clinical cure, and radiological cure [for patients with documented IC by radiologic or other imaging findings at baseline]) with 2 once-weekly doses of REZZAYO® vs 14 daily doses of caspofungin
Additional Findings:	<ul style="list-style-type: none"> In a prespecified exploratory analysis of the phase 3 ReSTORE trial, length of stay with REZZAYO® was 21 days vs 24 days with caspofungin Evidence of the efficacy of REZZAYO® in the phase 3 trial is supported by the phase 2 randomized trial findings Fungicidal activity against 95% of the most common and emerging <i>Candida</i> species
Safety:	<ul style="list-style-type: none"> Documented echinocandin safety profile similar to caspofungin No clinically relevant drug-drug interactions <p>IMPORTANT SAFETY INFORMATION</p> <p>Contraindications</p> <p>REZZAYO® is contraindicated in patients with known hypersensitivity to rezafungin or other echinocandins.</p> <p>Warnings and Precautions</p> <ul style="list-style-type: none"> Hypersensitivity Reactions, including Anaphylaxis: Cases of serious hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving REZZAYO®. If these reactions occur, discontinue REZZAYO® and administer appropriate treatment. Infusion-related Reactions: REZZAYO® may cause infusion-related reactions, including flushing, sensation of warmth, urticaria, nausea, or chest tightness. If these reactions occur, slow or pause the infusion. Photosensitivity: REZZAYO® may cause photosensitivity. Advise patients to use protection from sun exposure and other sources of UV radiation. Hepatic Adverse Reactions: Abnormalities in liver tests have been seen in clinical trial patients treated with REZZAYO®. Monitor patients who develop abnormal liver tests and evaluate patients for their risk/benefit of continuing REZZAYO® therapy. <p>Adverse Reactions</p> <p>Most common adverse reactions (incidence \geq 5%) are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.</p>

Please see additional **Important Safety Information** throughout and accompanying full Prescribing Information.

National Drug Code (NDC)

Trade Name	Package Strength	10-Digit NDC	11-Digit NDC*
REZZAYO®	200-mg vial	70842-240-01	70842-0240-01

*Note that NDCs are displayed in a 10-digit format on the FDA-approved product labeling. Proper billing for most payers or electronic data interchange systems requires that the NDC be submitted in the 11-digit numeric format.

Authorized Distributors

Practice type	Distributor	Phone	Web
Hospitals	Cardinal Specialty Pharmaceutical Distribution (CAH SPD)	855-855-0708	pdlogin.cardinalhealth.com
	ASD Healthcare (ABSG)	800-746-6273	asdhealthcare.com
Clinics, infusion centers, physician offices, or home infusions	Metro Medical (Cardinal Health)	800-768-2002	metromedicalorder.com
	Besse Medical	800-543-2111	besse.com
Oncology practices	Cardinal SPD	877-453-3972	pdlogin.cardinalhealth.com
	Oncology Supply	800-633-7555	oncologysupply.com

Coding at a glance

Below is a summary of relevant coding for REZZAYO® and its administration across various settings. Additional coding information is available on pages 5-11 of this guide. Providers are responsible for choosing and reporting appropriate codes.

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

HCPCS	Description	Billing Unit
J0349	Injection, rezafungin, 1 mg	200 units (200 mg = 200 billing units)
C9399	Unclassified drugs or biologicals	1 unit

Potential Current Procedural Terminology (CPT®*) Codes

CPT	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
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)
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)

*Current Procedural Terminology (CPT®) © 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

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Coding at a glance (cont.)

International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)

Many ICD-10-PCS codes may apply. Hospitals should report the appropriate ICD-10-PCS code(s) to report the procedures performed.

Potential Revenue Codes

Revenue Code	Description
025X	Pharmacy
026X	Intravenous (IV) therapy
027X	Medical/surgical supplies and devices
0636	Drugs requiring detailed coding
076X	Treatment/observation room

Potential Diagnosis Coding for All Settings of Administration

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

ICD-10-CM is an international standard for describing medical conditions. In general, ICD-10-CM codes are reported to describe the patient's condition (or diagnosis), which will help support the medical necessity for the patient encounter. The following ICD-10-CM diagnosis codes are examples of codes that may be appropriate to describe why treatment with REZZAYO® was necessary.

ICD-10-CM	Description
B37.1	Pulmonary candidiasis
B37.49	Other urogenital candidiasis
B37.7	Candidal sepsis
B37.8	Candidiasis of other sites
B37.81	Candidal esophagitis
B37.82	Candidal enteritis
B37.89	Other sites of candidiasis

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- Hypersensitivity Reactions, including Anaphylaxis:** Cases of serious hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving REZZAYO®. If these reactions occur, discontinue REZZAYO® and administer appropriate treatment.
- Infusion-related Reactions:** REZZAYO® may cause infusion-related reactions, including flushing, sensation of warmth, urticaria, nausea, or chest tightness. If these reactions occur, slow or pause the infusion.

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Physician office/infusion clinic setting

Physician offices and infusion clinics report ICD-10-CM codes, Healthcare Common Procedure Coding System (HCPCS) codes, and Current Procedural Terminology (CPT) codes when seeking payment for drugs and administration services provided during the patient encounter. Most payers may also require inclusion of the National Drug Code (NDC) on the claim. Physicians and infusion clinics are responsible for selecting and reporting appropriate codes for the items and services they furnish.

Coding for **REZZAYO®**

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

HCPCS Level II national codes are used to identify and report drugs on claims. Level II national codes are used to identify and report drugs on claims. **REZZAYO®** has been assigned a unique HCPCS. Physician offices and non-hospital-based infusion clinics should report HCPCS code J0349. When reporting J0349, it is important to also include the NDC, drug strength, and dose administered to the patient. Note that NDCs are displayed in a 10-digit format on the FDA-approved product labeling. Proper billing for most payers or electronic data interchange systems requires that the NDC be submitted in the 11-digit numeric format. Do not use hyphens when entering the actual data on your claim. The NDC for **REZZAYO®** is available on page 4 of this guide.

HCPCS	Description	Billing Unit
J0349	Injection, rezafungin, 1 mg	200 units (200 mg = 200 billing units)

Billing Drug Wastage

For more information about billing wastage and proper use of the JW modifier, please refer to the Medicare Claims Processing Manual, Chapter 17, Drugs and Biologicals; Section 40, Discarded Drugs and Biologicals.

Potential Coding for **REZZAYO®** Administration Services

Current Procedural Terminology (CPT®*) Codes

CPT codes are used to describe procedures (ie, drug administration) performed in physician offices and infusion clinics. Drug administration CPT codes vary depending on the route of administration (eg, injection, intravenous push, etc), as well as whether concurrent or sequential drugs are administered, if applicable. Below are suggested CPT codes for reporting the administration of **REZZAYO®**. Physician offices and infusion clinics should also report any additional CPT codes that identify additional procedures performed during the patient encounter.

CPT	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
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)
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)

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Sample CMS 1500

Once-weekly
REZZAYO™ 
(rezafungin for injection)

1. MEDICARE <input type="checkbox"/> (Medicare#)	MEDICAID <input type="checkbox"/> (Medicaid#)	TRICARE <input type="checkbox"/> (ID#/DoD#)	CHAMPVA <input type="checkbox"/> (Member ID#)	GROUP HEALTH PLAN <input type="checkbox"/> (ID#)	FECA BLK LUNG <input type="checkbox"/> (ID#)	OTHER <input type="checkbox"/> (ID#)	1a. INSURED'S I.D. NUMBER (For Program in Item 1)			
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)			3. PATIENT'S BIRTH DATE MM <input type="checkbox"/> DD <input type="checkbox"/> YY		SEX M <input type="checkbox"/> F <input type="checkbox"/>	4. INSURED'S NAME (Last Name, First Name, Middle Initial)				
5. PATIENT'S ADDRESS (No., Street)			6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street)					
CITY		STATE	8. RESERVED FOR NUCC USE		CITY		STATE			
ZIP CODE	TELEPHONE (Include Area Code) ()				ZIP CODE	TELEPHONE (Include Area Code) ()				
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					
a. OTHER INSURED'S POLICY OR GROUP NUMBER			a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO		a. INSURED'S DATE OF BIRTH MM <input type="checkbox"/> DD <input type="checkbox"/> YY SEX M <input type="checkbox"/> F <input type="checkbox"/>					
b. RESERVED FOR NUCC USE			b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO PLACE (State)		b. OTHER CLAIM ID (Designated by NUCC)					
c. RESERVED FOR NUCC USE			c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		c. INSURANCE PLAN NAME OR PROGRAM NAME					
d. INSURANCE PLAN NAME OR PROGRAM NAME			10d. CLAIM CODES (Designated by NUCC)		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>					
12. RELEASE OF INFORMATION I hereby release and assign to my physician or supplier the right to release any information necessary to my care either to myself or to the party who accepts assignment			LETING & SIGNING THIS FORM. I hereby release and assign to my physician or supplier the right to release any information necessary to my care either to myself or to the party who accepts assignment		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 SERVICE MM DD YY QUAL.			15. OTHER DATE QUAL. 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. <input type="checkbox"/> 17b. NPI			17a. <input type="checkbox"/> 17b. NPI		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY LAB? \$ CHARGES S <input type="checkbox"/> NO MISSION ORIGINAL REF. NO.					
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) REZZAYO, XX mg			19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) REZZAYO, XX mg		19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) REZZAYO, XX mg					
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line			21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line		21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line					
A. <input type="checkbox"/> XX XX XX	B. <input type="checkbox"/> XX XX XX	C. <input type="checkbox"/>	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	E. MODIFIER	F. DIAGNOSIS POINTER	G. \$ CHARGES	H. EPSC Family Plan			
I. <input type="checkbox"/>	J. <input type="checkbox"/>	K. <input type="checkbox"/>					I. ID. QUAL.			
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY			C. PLACE OF SERVICE EMG		E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSC Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
XX XX XX XX XX XX 11	<input type="checkbox"/> 96365				A	XXXX.XX	1		NPI	
XX XX XX XX XX XX 11	<input type="checkbox"/> J0349				A	XXXX.XX	200		NPI	
25. FEDERAL TAX I.D. NUMBER			SSN EIN <input type="checkbox"/> <input type="checkbox"/>							
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.)			a. <input type="checkbox"/> NPI		b. <input type="checkbox"/>		a. <input type="checkbox"/> NPI		b. <input type="checkbox"/>	
SIGNED		DATE								

Please see additional **Important Safety Information** throughout and accompanying full Prescribing Information.

Hospital outpatient department setting

Hospital outpatient departments (HOPDs) report ICD-10-CM codes, HCPCS codes, CPT codes, and revenue codes when seeking payment for drugs and administration services provided during the patient encounter. Most payers may also require inclusion of the National Drug Code (NDC) on the claim. Hospitals are responsible for selecting and reporting appropriate codes for the items and services they furnish.

Coding for **REZZAYO**®

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

HCPCS Level II national codes are used to identify and report drugs on claims. *REZZAYO*® has been assigned a unique HCPCS; therefore, providers should report HCPCS codes J0349 or C9399. When reporting J0349 or C9399, it is important to also include the NDC, drug strength, and dose administered to the patient. Note that NDCs are displayed in a 10-digit format on the FDA-approved product labeling. Proper billing for most payers or electronic data interchange systems requires that the NDC be submitted in the 11-digit numeric format. Do not use hyphens when entering the actual data on your claim. The NDC for *REZZAYO*® is available on page 4 of this guide.

HCPCS	Description	Billing Unit
J0349	Injection, rezafungin, 1 mg	200 units (200 mg = 200 billing units)
C9399	Unclassified drugs or biologicals	1 unit

Medicare requires use of C9399 in the hospital outpatient setting.

Billing Drug Wastage

For more information about billing wastage and proper use of the JW modifier, please refer to the Medicare Claims Processing Manual, Chapter 17, Drugs and Biologicals; Section 40, Discarded Drugs and Biologicals.

Potential Coding for **REZZAYO**® Administration Services

Potential Current Procedural Terminology (CPT®*) Codes

CPT codes are used to describe procedures (ie, drug administration) performed in the HOPD. Drug administration CPT codes vary depending on the route of administration (eg, injection, intravenous push, etc), as well as whether concurrent or sequential drugs are administered, if applicable. Below are suggested CPT codes for reporting the administration of *REZZAYO*®. HOPDs should also report any additional CPT codes that identify additional procedures performed during the patient encounter.

CPT	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
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)
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)

*Current Procedural Terminology (CPT®) © 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

Reporting physician services when performed in the HOPD setting

Per CPT guidelines, the CPT codes for drug administration services are not intended to be reported by the physician when services are provided in the facility setting. The physician will bill the appropriate E/M service(s). As reimbursement policies vary by payer, it is important to check with the payer to understand specific guidelines for billing physician infusion services.

Potential Revenue Codes

Revenue codes are used by hospitals to indicate the department (or revenue center) to which a procedure, service, drug, or supply is assigned. Below are some of the potential revenue coding options. Some payers may have varying revenue code reporting requirements.

Revenue Code	Description
025X	Pharmacy
026X	Intravenous (IV) therapy
027X	Medical/surgical supplies and devices
0636	Drugs requiring detailed coding
076X	Treatment/observation room

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **Photosensitivity:** REZZAYO® may cause photosensitivity. Advise patients to use protection from sun exposure and other sources of UV radiation.
- **Hepatic Adverse Reactions:** Abnormalities in liver tests have been seen in clinical trial patients treated with REZZAYO®. Monitor patients who develop abnormal liver tests and evaluate patients for their risk/benefit of continuing REZZAYO® therapy.

Please see additional **Important Safety Information** throughout and accompanying full **Prescribing Information**.

Sample UB-04 (CMS 1450)

1		2		3a PAT CNTL #		4 TYPE OF BILL								
				b. MED REC #										
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH 7								
8 PATIENT NAME a.		9 PATIENT ADDRESS a.												
b.		b.												
10 BIRTHDATE		11 SEX 12 DATE ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR 17 STAT		18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28 29 ACDT STATE 30		c. d. e.								
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE DATE		37 OCCURRENCE DATE		
a.		b.		c.		d.		e.		f.		g.		
38								39 CODE VALUE CODES AMOUNT		40 CODE VALUE CODES AMOUNT		41 CODE VALUE CODES AMOUNT		
a.		b.		c.		d.								
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE		46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49
1	XXXX	N482378010101MLXX		J0349		MM/DD/YY		200						1
2														2
3	XXXX	IV Therapy - General		96365		MM/DD/YY		1						3
4														4
5														5
CREATION DATE TOTALS														23
51 HEALTH PLAN ID		52 REL INFO		53 AGS BEN		54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER		24
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Home infusion setting



Home infusion providers report ICD-10-CM codes, Healthcare Common Procedure Coding System (HCPCS) codes, and Current Procedural Terminology (CPT®) codes when seeking payment for drugs and administration services provided during the patient encounter. Providers should also report equipment and supplies. Most payers may also require inclusion of the National Drug Code (NDC) on the claim. Home infusion providers are responsible for selecting and reporting appropriate codes for the items and services they furnish.

Coding for REZZAYO®

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

HCPCS Level II national codes are used to identify and report drugs on claims. HCPCS Level II national codes are used to identify and report drugs on claims. REZZAYO® has been assigned a unique HCPCS; therefore, providers should report HCPCS codes J0349 or C9399. When reporting J0349 or C9399, it is important to also include the NDC, drug strength, and dose administered to the patient. When reporting J0349, it is important to also include the NDC, drug strength, and dose administered to the patient. Note that NDCs are displayed in a 10-digit format on the FDA-approved product labeling. Proper billing for most payers or electronic data interchange systems requires that the NDC be submitted in the 11-digit numeric format. Do not use hyphens when entering the actual data on your claim. The NDC for REZZAYO® is available on page 4 of this guide.

HCPCS	Description	Billing Unit
J0349	Injection, rezafungin, 1 mg	200 units (200 mg = 200 billing units)

Billing Drug Wastage

For more information about billing wastage and proper use of the JW modifier, please refer to the Medicare Claims Processing Manual, Chapter 17, Drugs and Biologicals; Section 40, Discarded Drugs and Biologicals.

Potential Coding for REZZAYO® Administration Services

Current Procedural Terminology (CPT®*) Codes and Healthcare Common Procedure Coding System (HCPCS) Level II Codes

CPT codes and HCPCS codes are used to describe procedures (ie, drug administration) performed in the home. Providers should select the name of the procedure or service that accurately identifies the service performed. Below are suggested CPT/HCPCS codes for reporting the administration of REZZAYO® in the home. Home health providers should also report equipment and supplies required to administer the service.

CPT	Description
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (list separately in addition to code for primary procedure)
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

*Current Procedural Terminology (CPT®) © 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

Most common adverse reactions (incidence $\geq 5\%$) are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.

Please see additional [Important Safety Information](#) throughout and accompanying full Prescribing Information.

New Technology Add-On Payment (NTAP) Approved for *REZZAYO*[®] by CMS*

Effective October 1, 2023, for Fiscal Year (FY) 2024

Beginning October 1, 2023, for FY 2024, eligible participating hospitals may receive additional payment for *REZZAYO*[®] cases when Medicare patients are treated in the inpatient setting. CMS granted approval of NTAP for *REZZAYO*[®], allowing an additional payment of up to \$4,387.50 per qualifying case. This add-on payment will be incremental to the MS-DRG reimbursement for qualifying Medicare inpatient cases.⁷

About NTAP⁸

- Helps ensure adequate payment for new medical services and technologies used to treat Medicare beneficiaries in the inpatient hospital setting
- Provides an incremental reimbursement amount for the approved service or technology, in addition to the applicable MS-DRG-based payment to eligible hospitals for inpatient Medicare cases paid under the IPPS
- Offers a temporary stop-gap measure until MS-DRG can be recalibrated

The NTAP is based on CMS determining if the medical service or technology meets the following 3 criteria through its Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices and Certain Antimicrobial Products:

1

Meets standards
for newness[†]

2

Demonstrates substantial
clinical improvement[†]

3

Is inadequately paid under
the MS-DRG system[‡]

The CMS Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices and Certain Antimicrobial Products represents the agency's commitment to addressing issues related to antimicrobial resistance and efforts to help secure access to antibiotics and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible.⁸

*Centers for Medicare & Medicaid Services.

[†]New to the market and not substantially similar to previously available technologies as determined by CMS. Products designated by the FDA as a QIDP, and received FDA marketing authorization, are considered new and not substantially similar to existing technology for purposes of the new technology add-on payment and do not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.²

[‡]Under the NTAP cost calculation established by CMS.

IPPS, inpatient prospective payment system; MS-DRG, Medicare severity diagnosis-related group; QIDP, qualified infectious disease product.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

NTAP details for REZZAYO®

Once-weekly
REZZAYO™ 
(rezafungin for injection)

Eligible facilities	Acute care hospitals that are reimbursed under the IPPS
Setting of care	Acute care hospital inpatient setting
Amount of additional payment	<p>The lesser of:</p> <ol style="list-style-type: none"> 1) 75% of the costs of the new medical service or technology or 2) 75% of the amount by which the costs of the case exceed the standard MS-DRG payment (compared to 65% for non-QIDP designated products) <p>The maximum additional payment for FY 2024 is \$4,387.50 per admission. If the total covered costs of the case do not exceed the MS-DRG payment, then no additional payment is made for the admission.</p>
Effective date	October 1, 2023; NTAP is a minimum of 2 years, no more than 3 years

ICD-10-PCS procedure codes for REZZAYO® administration

The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) procedure codes are used by hospitals to report procedures performed in the hospital inpatient setting only. In order to facilitate NTAP to hospitals, CMS established a new ICD-10-PCS procedure code to identify REZZAYO® administration during inpatient hospital stays. Hospitals must bill the following ICD-10-PCS codes to identify REZZAYO® on claims to ensure eligibility for NTAP⁷:

ICD-10-PCS	Description
XW033R9	Introduction of rezafungin into peripheral vein, percutaneous approach, new technology group 9
XW043R9	Introduction of rezafungin into central vein, percutaneous approach, new technology group 9

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

REZZAYO® is contraindicated in patients with known hypersensitivity to rezafungin or other echinocandins.

Please see additional [Important Safety Information](#) throughout and accompanying full [Prescribing Information](#).

DISCLAIMER

The content of this guide is general in nature, strictly for informational purposes only, and does not cover all situations or all payers' policies and guidance. The information in this guide was obtained from third-party sources and is subject to change without notice as a result of changes in reimbursement laws, regulations, rules, policies, and payment amounts. This guide is not intended to provide clinical practice guidelines. Melinta Therapeutics (Melinta) cannot guarantee, and is not responsible for, the payment of any claim. The coding, coverage, and payment of *REZZAYO*[®] may vary by payer, plan, patient, and setting of care. Coding determinations and analysis should always be independently researched and assessed. For more information, please check with individual payers for specific coding, coverage, and payment requirements. It is the sole responsibility of the healthcare provider to code properly and to ensure the accuracy of all claims submitted for reimbursement. Additionally, as a prerequisite for submitting a claim, the provider is responsible for ensuring that all services are medically necessary and properly supported in the patient's medical records. Melinta specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on the information in this guide.

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Indication and Important Safety Information

INDICATIONS AND USAGE

REZZAYO® is an echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data.

Limitations of Use

REZZAYO® has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to *Candida*.



IMPORTANT SAFETY INFORMATION

Contraindications

REZZAYO® is contraindicated in patients with known hypersensitivity to rezafungin or other echinocandins.

Warnings and Precautions

- Hypersensitivity Reactions, including Anaphylaxis:** Cases of serious hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving REZZAYO®. If these reactions occur, discontinue REZZAYO® and administer appropriate treatment.
- Infusion-related Reactions:** REZZAYO® may cause infusion-related reactions, including flushing, sensation of warmth, urticaria, nausea, or chest tightness. If these reactions occur, slow or pause the infusion.
- Photosensitivity:** REZZAYO® may cause photosensitivity. Advise patients to use protection from sun exposure and other sources of UV radiation.
- Hepatic Adverse Reactions:** Abnormalities in liver tests have been seen in clinical trial patients treated with REZZAYO®. Monitor patients who develop abnormal liver tests and evaluate patients for their risk/benefit of continuing REZZAYO® therapy.

Adverse Reactions

Most common adverse reactions (incidence $\geq 5\%$) are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.

Please see full [Prescribing Information](#).

Once-weekly

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(rezafungin for injection)

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