

Once-weekly

REZZAYO™ 

(rezafungin for injection)

BILLING AND CODING GUIDE

REZZAYO™
(rezafungin for injection)
for intravenous use

PRODUCT
INFORMATION

CODING AT
A GLANCE

CLINIC SETTING

OUTPATIENT
DEPT SETTING

HOME INFUSION
SETTING

INDICATION AND USAGE

REZZAYO™ (rezafungin for injection) 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*.

Please see [Important Safety Information](#) for **REZZAYO™ (rezafungin for injection)** on [page 12](#) and [full Prescribing Information](#).

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:	REZZAYO™ (rezafungin for injection) for intravenous use
FDA Approval Date:	March 22, 2023
Link to Prescribing Information:	https://rezzayo.com/
Indication:	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.
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 REZZAYO™ 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:	REZZAYO™ 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).

INDICATION AND USAGE

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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 [Important Safety Information](#) for **REZZAYO™** (rezafungin for injection) on [page 12](#) and full [Prescribing Information](#).

Product information (cont.)

<p>Clinical Trials:</p>	<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>
<p>Efficacy:</p>	<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
<p>Additional Findings:</p>	<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
<p>Safety:</p>	<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 REZZAYO™ is contraindicated in patients with known hypersensitivity to rezafungin or other echinocandins.</p> <p>Warnings and Precautions</p> <p>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.</p> <p>Photosensitivity: REZZAYO™ may cause photosensitivity. Advise patients to use protection from sun exposure and other sources of UV radiation.</p> <p>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> <p>Adverse Reactions Most common adverse reactions (incidence ≥ 5%) are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.</p>

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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	https://pdlogin.cardinalhealth.com/
	ASD Healthcare (ABSG)	800-746-6273	www.asdhealthcare.com
Clinics, infusion centers, Physician offices, home infusion	Metro Medical (Cardinal Health)	800-768-2002	www.metromedicalorder.com
	Besse Medical	800-543-2111	www.besse.com
Oncology practices	Cardinal SPD	877-453-3972	https://pdlogin.cardinalhealth.com/
	Oncology Supply	800-633-7555	www.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
J3490	Unclassified drugs
C9399	Unclassified drugs or biologicals

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)

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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

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. **REZZAYO™** has not yet been assigned a unique HCPCS; therefore, physician offices and non-hospital-based infusion clinics should report HCPCS code J3490. When reporting J3490, 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
J3490	Unclassified drugs

Billing Drug Wastage

Medicare requires the use of the JW modifier when billing for drugs with J3490. 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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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 not yet been assigned a unique HCPCS; therefore, providers should report HCPCS codes J3490 or C9399. When reporting J3490 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
J3490	Unclassified drugs
C9399	Unclassified drugs or biologicals

Medicare requires use of C9399 in the hospital outpatient setting.

Billing Drug Wastage

Medicare requires the use of the JW modifier when billing for drugs with J3490. 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)

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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

Sample UB-04 (CMS 1450)

1		2		3a PAT. CNTL. #		4 TYPE OF BILL	
				b. MED. REG. #			
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH	
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18		19		20		21	
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26		27		28		29 ACCT STATE	
30		31 OCCURRENCE DATE		32 CODE		33 OCCURRENCE DATE	
34		35 CODE		36 OCCURRENCE DATE		37	
38		39 VALUE CODES AMOUNT		40 CODE		41 VALUE CODES AMOUNT	
42		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
46		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
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73		74 PRINCIPAL PROCEDURE DATE		75 OTHER PROCEDURE DATE		76 ATTENDING NP1	
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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. **REZZAYO™** has not yet been assigned a unique HCPCS; therefore, providers should report HCPCS code J3490. When reporting J3490, 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
J3490	Unclassified drugs

Billing Drug Wastage

Medicare requires the use of the JW modifier when billing for drugs with J3490. 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 (i.e. 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

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Indication and Important Safety Information

INDICATION AND USAGE

REZZAYO™ (rezafungin for injection) 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

- **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 accompanying full Prescribing Information for REZZAYO™ (rezafungin for injection).

References: **1.** REZZAYO™. Prescribing information. Melinta Therapeutics, LLC; 2023. **2.** American Medical Association. CPT Professional 2023. ed. American Medical Association; 2022. **3.** American Medical Association. ICD-10-CM: The Complete Official Codebook. 2023. American Medical Association; 2022. **4.** AAPC. HCPCS Level II Expert. 2023 ed. AAPC; 2022. **5.** Thompson GR 3rd, Soriano A, Cornely OA, et al. Rezafungin versus caspofungin for treatment of candidaemia and invasive candidiasis (ReSTORE): a multicentre, double-blind, double-dummy, randomised phase 3 trial. *Lancet*. 2023;401(10370):49-59. doi:10.1016/S0140-6736(22)02324-8 **6.** Medicare Program: Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Centers for Medicare & Medicaid Services. Published January 1, 2017. Accessed May 23, 2023. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospital-outpatientpps/downloads/jw-modifier-faqs.pdf>



Once-weekly
REZZAYO™ 
(rezafungin for injection)

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