



BILLING AND CODING GUIDE

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

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.)

Once-weekly
REZZAYO™ >>>
(rezafungin for injection)

| | |
|----------------------|---|
| 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 <i>REZZAYO®</i> 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 Most common adverse reactions (incidence ≥ 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](#).

PRODUCT
INFORMATION

CODING AT
A GLANCE

CLINIC
SETTING

OUTPATIENT
DEPT SETTING

HOME INFUSION
SETTING

NTAP

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) |

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

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.

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

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



1. MEDICARE
☐ (Medicare#)

MEDICAID
☐ (Medicaid#)

TRICARE
☐ (ID#/DoD#)

CHAMPVA
☐ (Member ID#)

GROUP HEALTH PLAN
☐ (ID#)

FECA BLK LUNG
☐ (ID#)

OTHER
☐ (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 DD YY
SEX
M ☐ F ☐

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED
Self ☐ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)
()

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:
a. EMPLOYMENT? (Current or Previous)
☐ YES ☐ NO
b. AUTO ACCIDENT?
☐ YES ☐ NO PLACE (State) _____
c. OTHER ACCIDENT?
☐ YES ☐ NO
10d. CLAIM CODES (Designated by NUCC)

11. INSURED'S POLICY GROUP OR FECA NUMBER
a. INSURED'S DATE OF BIRTH
MM DD YY
SEX
M ☐ F ☐
b. OTHER CLAIM ID (Designated by NUCC)
c. INSURANCE PLAN NAME OR PROGRAM NAME
d. IS THERE ANOTHER HEALTH BENEFIT PLAN?
☐ YES ☐ NO If yes, complete items 9, 9a, and 9d.

12.

Box 19: When submitting a claim using J0349, enter the drug name and dosage. If required information is missing, the code will be deemed unprocessable.

12. SIGNATURE OF PHYSICIAN OR SUPPLIER
I authorize the release of any medical or other information necessary either to myself or to the party who accepts assignment
DATE
SIGNED

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
SIGNED

14. DATE
MM DD YY
QUAL.

15. OTHER DATE
MM DD YY
QUAL.

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.
17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES
FROM MM DD YY TO MM DD YY
LAB? ☐ YES ☐ NO \$ CHARGES
MISSION ORIGINAL REF. NO.
AUTHORIZATION NUMBER

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
REZZAYO, XX mg

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service I
A. XX XX XX B. XX XX XX C.
E. F. G.
I. J. K.

Box 21A: Report the primary diagnosis (ICD-10-CM).
Box 21B-L: Report any secondary diagnoses (ICD-10-CM) as applicable.

24. A. DATE(S) OF SERVICE
From MM DD YY To MM DD YY
B. PLACE OF SERVICE
C. EMG
D. PROCEDURES, SERVICES, OR SUPPLIES
(Explain Unusual Circumstances)
CPT/HCPSCS MODIFIER
E. DIAGNOSIS POINTER
F. \$ CHARGES
G. DAYS OR UNITS
H. EPST Family Plan
I. ID. QUAL.
J. RENDERING PROVIDER ID. #
XX XX XX XX XX XX 11 96365 A XXXX.XX 1 NPI
XX XX XX XX XX XX 11 J0349 A XXXX.XX 200 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN
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.)
SIGNED DATE
a. NPI b.
a. NPI b.

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) |

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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 |

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](#).

[illegible]

REVENUE CODES (Field 42):
Report the most appropriate revenue codes and descriptions of items and services for the revenue center. Revenue codes may vary by payer.

(Field 43): Enter a detailed drug description, list the N4 indicator first (which is the qualifier that indicates an NDC is being used), then the 11-digit NDC number. Third is the unit of measurement qualifier (eg, “ML” for milliliters); the unit quantity is listed at the end. Example N482378010101MLXX.

PRODUCT AND SERVICES CODES and UNITS (Field 44 and 46):
Report J0349 and 200 units.
Report C9399 and one unit.
Also include the CPT code(s) for administration. Most payers require that any periods in the code be removed.

DIAGNOSIS (Field 67 and 67A-Q): Report the appropriate diagnosis code(s). Most payers require that any periods in the code be removed.

REMARKS (Field 80): Identify the drug being administered and include the NDC number, if required by the payer.

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 |

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IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

Most common adverse reactions (incidence ≥ 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:



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
REZZAYO™
(rezafungin for injection)

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