

Melinta Therapeutics Announces Expanded Reimbursement and Access for REZZAYO™ (rezafungin for injection)

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REZZAYO receives product-specific J-Code and is granted NTAP

PARSIPPANY, N.J.--(BUSINESS WIRE)-- Melinta Therapeutics (Melinta), a commercial-stage company providing innovative therapies for acute and life-threatening illnesses, today announced expanded reimbursement and access for REZZAYO™ (rezafungin for injection). REZZAYO, the first new treatment option approved for adult patients with candidemia and invasive candidiasis in over a decade, has been commercially available in the U.S. since July.

The Centers for Medicare & Medicaid Services (CMS) issued a permanent product-specific J-Code (J0349, Injection, rezafungin, 1 mg) for REZZAYO injection effective October 1, 2023. CMS also granted a new technology add-on payment (NTAP) for REZZAYO for eligible participating hospitals when Medicare patients are treated in the inpatient acute care hospital setting.

“We are very excited to share the news of the issuance of the J-Code and the NTAP for REZZAYO,” said Christine Ann Miller, Melinta President and CEO. “These two important milestones will help facilitate access to this innovative treatment option in both inpatient and outpatient settings. For Melinta, this is a significant step toward realizing our vision that all patients who need our therapies will receive them.”

A permanent J-Code plays a pivotal role in establishing reimbursement for medical products and services, offering a standardized way to identify the drug across various payers. The unique J-Code can be used for REZZAYO in all outpatient treatment settings. The NTAP, in turn, will provide eligible, participating hospitals with an incremental

payment for REZZAYO in addition to the standard Medicare Severity Diagnostic Related Group (MS-DRG) reimbursement for inpatient Medicare cases beginning October 1, 2023. Under NTAP, this additional payment is the lesser of 75% of the costs of REZZAYO, or 75% of the amount by which the costs of the qualifying case exceed the MS-DRG payment, up to a maximum payment of \$4,387.50 for a patient treated with REZZAYO per qualifying case.

REZZAYO was granted Qualified Infectious Disease Product (QIDP) designation and was approved by the U.S. Food and Drug Administration under Priority Review on March 22, 2023. Last year, Melinta acquired the exclusive rights to commercialize REZZAYO in the U.S. from Cidara Therapeutics. Once-weekly REZZAYO has been available by prescription since July 31, 2023.

While echinocandins have been available since the early 2000's, their use has been primarily limited to the hospital inpatient setting due to their requirement of daily IV infusions. In contrast, REZZAYO is administered as a once-weekly infusion, which may allow appropriate patients to leave the hospital sooner to continue their treatment at home, potentially reducing the burden on patients and the healthcare system.

“REZZAYO offers a needed option for physicians, and those patients who may be able to transition out of the hospital sooner. The J-Code and NTAP will support broader access to this innovative treatment for patients suffering from invasive Candida infections,” said John Harlow, Melinta’s Chief Commercial Officer. “This is another opportunity for Melinta to deliver on our mission to provide innovative therapies to people impacted by acute and life-threatening illnesses.”

About REZZAYO™ (rezafungin for injection)

INDICATIONS AND USE

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.

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 full Prescribing Information for REZZAYO™ (rezafungin for injection), available at www.rezzayo.com.

About Melinta Therapeutics

Melinta Therapeutics is a biopharmaceutical company dedicated to providing innovative therapies to people impacted by acute and life-threatening illnesses. We focus our expanding portfolio on serving patients with an unmet need because that's how we make the most meaningful impact. At Melinta, we're visionaries dedicated to innovation while staying grounded in what matters most: patients. Our portfolio currently includes seven commercial-stage products: BAXDELA® (delafloxacin), KIMYRSA® (oritavancin), MINOCIN® (minocycline) for Injection, ORBACTIV® (oritavancin), REZZAYO™ (rezafungin for injection), TOPROL-XL® (metoprolol succinate) and VABOMERE® (meropenem and vaborbactam). For more information about Melinta Therapeutics, our commitment to patients, and to learn about our portfolio of therapies, visit Melinta.com.

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