Oscar Clinical Guideline: Rezzayo (rezafungin) (PG145, Ver. 4)

Rezzayo (rezafungin)

Summary

Candidemia and invasive candidiasis (IC) are serious infections caused by the invasion of Candida species into the bloodstream and deep tissues. These infections predominantly affect immunocompromised individuals and those with significant comorbidities. Candidemia is associated with high morbidity and mortality rates, with a conservative estimate of approximately 70% all-cause mortality in those receiving no or inadequate treatment.

The current standard of care for candidemia/IC involves the use of systemic antifungal therapy in combination with control of the infection source, whenever possible. Echinocandins, including caspofungin, micafungin, and anidulafungin, are considered the first-line initial therapy for these infections, except for certain cases involving the central nervous system, urinary tract, or eyes. All of the echinocandins are structurally similar, and all have reliable activity against Candida spp., including fluconazole-resistant *Candida glabrata* and *Candida krusei*. They are also the drugs of choice for *Candida auris*.These echinocandins are administered intravenously on a daily basis. Alternative treatment options include azole drugs (e.g., fluconazole) and amphotericin B. Typically, individuals receive intravenous antifungal therapy initially for 3 to 7 days, followed by a switch to an oral formulation upon clinical improvement. The total duration of treatment usually extends for at least 2 weeks after the clearance of Candida species from the blood in the case of candidemia, or after achieving adequate source control and clinical response in the case of invasive candidiasis. However, most patients are transitioned to oral azole therapy once they become clinically stable. It is important to note that the only available oral stepdown therapies belong to the azole class of antifungals. Therefore, those who are intolerant to azoles, have concomitant medications with significant drug-drug interactions, or are infected with azole-resistant Candida species must continue receiving daily intravenous antifungal therapy for the entire duration of treatment.

In the context of treating candidemia and invasive candidiasis, Rezzayo (rezafungin for injection) has emerged as a potential treatment option. It is an echinocandin antifungal indicated for those 18 years of age or older who have limited or no alternative options for these infections. Rezafungin is a next-generation echinocandin with enhanced pharmacokinetic properties that allow for once-weekly dosing. In the U.S. it is approved for the treatment of candidemia and IC in adults who have limited or no alternative options.

- The approval of this indication is based on limited clinical safety and efficacy data specific to Rezzayo (rezafungin). Approval of Rezzayo was based on the phase 3 ReSTORE trial which showed Rezzayo (rezafungin) to be non-inferior to caspofungin (a first line echinocandin) based on global cure rates at day 14 and all-cause mortality at day 30, in adults with candidemia or IC. Rezafungin was also generally well tolerated and has a safety and tolerability profile consistent with the other echinocandins
- It is important to note that Rezzayo (rezafungin) has not been studied in those with endocarditis, osteomyelitis, and meningitis caused by Candida. While there are case reports of this drug being used in such settings, this is considered off-label use.
- Prior to initiating antifungal therapy, it is recommended to obtain specimens for culture and other laboratory data, including histopathology and non-culture diagnostics. While therapy can be initiated before the test results are known, it is essential to adjust the antifungal treatment based on the results once they become available.

Definitions

"Candidemia" refers to the presence of Candida species, specifically yeast, in the bloodstream. It is a bloodstream infection caused by the invasion of Candida fungi.

"Chorioretinitis" is an inflammation of the choroid and retina, the tissues at the back of the eye. It can be caused by various factors, including infections such as Candida, leading to potential vision loss if left untreated.

"Endocarditis" is an inflammation of the inner lining of the heart chambers and heart valves, known as the endocardium. It is typically caused by a bacterial or fungal infection, including Candida, that affects the heart.

"Endophthalmitis" is a severe inflammation of the intraocular tissues, specifically the vitreous and aqueous humor of the eye. It can occur as a result of an infection, including fungal infections like Candida, and can lead to significant visual impairment or loss.

"Invasive candidiasis" refers to the invasion of Candida fungi into deep tissues and organs, beyond the bloodstream. It typically occurs in individuals with compromised immune systems and can affect various organs, leading to serious complications.

"Meningitis" is an inflammation of the protective membranes covering the brain and spinal cord, known as the meninges. It can be caused by different pathogens, including Candida, and is characterized by symptoms such as fever, headache, neck stiffness, and altered mental status.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the applicant does not qualify.

"Osteomyelitis" is an infection of the bone and bone marrow, usually caused by bacteria but can also be caused by fungi like Candida. It results in inflammation, pain, and can lead to bone destruction if not treated promptly.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Invasive Candidiasis and Candidemia

The Plan considers Rezzayo (rezafungin) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an infectious disease specialist; *AND*

2. The member is 18 years of age or older; *AND*
3. Rezzayo (rezafungin) is being requested for ONE (1) of the following:
    a. Empiric antifungal therapy of suspected invasive candidiasis for a critically ill non-neutropenic member with fever and no other known cause; *or*
    b. Treatment of candidemia (non-neutropenic or neutropenic); *or*
    c. The treating provider has indicated that Rezzayo (rezafungin) is the treatment of choice based the clinical status of member, knowledge of species or antifungal susceptibility, relative drug toxicity, presence of organ dysfunction, available knowledge of the use of the drug in a given patient population and member prior exposure to antifungal agents; *AND*
4. The member is unable to use, or has tried and failed ONE (1) of the following (as diagnostically appropriate, see Appendix A):
    a. Other IV echinocandin (anidulafungin, caspofungin, micafungin); *or*
    b. IV amphotericin B (or its derivatives); *or*
    c. Fluconazole (IV or oral); *or*
    d. Voriconazole (IV or oral); *or*
    e. The member has no alternative options for the treatment of the infection*; AND*
5. No evidence that the member has a known hypersensitivity to any echinocandin (i.e., rezafungin, caspofungin, micafungin, and anidulafungin); *AND*
6. Rezzayo (rezafungin) is being prescribed at a dose and frequency that is within FDA approved labeling (i.e., initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter) OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria is met, the requested medication will be approved for up to 4 weekly doses.

Experimental or Investigational / Not Medically Necessary

Rezzayo (rezafungin) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

Applicable Billing Codes

Table 1	
CPT/HCPCS Codes for Invasive Candidiasis and Candidemia considered medically necessary if criteria are met:	
Code	*Description*

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
J0349	Injection, rezafungin, 1 mg

Table 2	
ICD-10 diagnosis codes considered medically necessary for Invasive candidiasis and candidemia with Table 1 if criteria are met:	
Code	*Description*
B37.0	Candidal stomatitis
B37.1	Pulmonary candidiasis
B37.2	Candidiasis of skin and nail
B37.31	Acute Candidiasis Of Vulva And Vagina
B37.32	Chronic Candidiasis Of Vulva And Vagina
B37.41	Candidal cystitis and urethritis
B37.49	Other urogenital candidiasis
B37.6	Candidal endocarditis
B37.7	Candidal sepsis
B37.81	Candidal esophagitis
B37.82	Candidal enteritis
B37.83	Candidal cheilitis
B37.84	Candidal otitis externa
B37.89	Other sites of candidiasis
B37.9	Candidiasis, unspecified
B44.0	Invasive pulmonary aspergillosis
B44.1	Other pulmonary aspergillosis

B44.2	Tonsillar aspergillosis
B44.7	Disseminated aspergillosis
B44.89	Other forms of aspergillosis
B44.9	Aspergillosis, unspecified
D70.3	Neutropenia due to infection
D70.8	Other neutropenia
Z48.290	Encounter for aftercare following bone marrow transplant
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status

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Appendix A

Table 1: Guideline Recommended Use of Antifungal Therapies for Candidemia, Candidiasis and Related Indications

Drug Class or Drug Name		Therapeutic Use(s)
Intravenous Echinocandins	Anidulafungin (Eraxis)	• Aspiergillosis, invasive (off-label) • Candida Endocarditis (high dose) • Candida Osteomyelitis • Candida Septic Arthritis • Candida Suppurative Thrombophlebitis • Candidiasis, invasive • Candidiasis, prophylaxis (in high-risk patients in adult ICUs with a high rate (>5%) of invasive candidiasis) • Candidemia, intra-abdominal, peritoneal candidiasis, hepatosplenic • Candidemia (nonneutropenic patients) • Candidemia - neutropenic • Esophageal Candidiasis • Neonatal candidiasis, including central nervous systemic infections (salvage therapy) • Neutropenic fever, empiric antifungal therapy (off-label) • Oropharyngeal Candidiasis • Prophylaxis against invasive fungal infections (off-label)
	Caspofungin (Cancidas)	• Aspiergillosis, invasive • Candida Endocarditis (high dose) • Candida Osteomyelitis • Candida Septic Arthritis • Candida Suppurative Thrombophlebitis • Candidiasis, invasive, hepatosplenic • Candidiasis, prophylaxis (in high-risk patients in adult ICUs with a high rate (>5%) of invasive candidiasis) • Candida infection, treatment, independent of HIV status • Candidemia - nonneutropenic patients • Candidemia - neutropenic • Fungal infection, empiric therapy in neutropenic patients • Fungal infection, prophylaxis in patients with acute myeloid leukemia

		• Fungal infection, prophylaxis in allogeneic hematopoietic stem cell transplantation recipients • Esophageal Candidiasis • Neonatal candidiasis, including central nervous systemic infections (salvage therapy) • Neutropenic fever, empiric antifungal therapy • Oropharyngeal Candidiasis • Prophylaxis against invasive fungal infections (off-label)
	Micafungin (Mycamine)	• Aspiergillosis, invasive (off-label) • Candida Endocarditis (high dose) • Candida Osteomyelitis • Candida Septic Arthritis • Candida Suppurative Thrombophlebitis • Candidiasis (esophageal, invasive, systemic, hepatosplenic) • Candidiasis, prophylaxis (in high-risk patients in adult ICUs with a high rate (>5%) of invasive candidiasis) • Candidemia - nonneutropenic patients • Candidemia - neutropenic • Esophageal Candidiasis • Fungal infection, prophylaxis in hematopoietic stem cell transplantation recipients • Neonatal candidiasis, including central nervous systemic infections (salvage therapy) • Neutropenic fever, empiric antifungal therapy (off-label) • Oropharyngeal Candidiasis • Prophylaxis against invasive fungal infections
	Rezafungin (Rezzayo)	• Candida Endocarditis (high dose) • Candida Osteomyelitis • Candida Septic Arthritis • Candida Suppurative Thrombophlebitis • Candidemia and invasive candidiasis (nonneutropenic patients) • Candidemia - neutropenic • Candidiasis, hepatosplenic • Candidiasis, prophylaxis (in high-risk patients in adult ICUs with a high rate (>5%) of invasive candidiasis) • Esophageal Candidiasis • Neonatal candidiasis, including central nervous systemic infections (salvage therapy)

		• Oropharyngeal Candidiasis
Fluconazole (Intravenous or oral)		• Blastomycosis (off-label) • Candida Chorioretinitis Without Vitritis • Candida Endocarditis (step-dose therapy; in patients who have susceptible Candida isolates, have demonstrated clinical stability, and have cleared Candida from the bloodstream) • Candida Osteomyelitis • Candida Septic Arthritis • Candida Suppurative Thrombophlebitis (including step-down therapy) • Candidemia - nonneutropenic (non-critically ill, considered unlikely to have a fluconazole-resistant Candida species; step down in those clinically stable, have isolates that are susceptible to fluconazole (eg, C. albicans), and have negative repeat blood cultures following initiation of antifungal therapy) • Candidemia - neutropenic (patients who are not critically ill and have had no prior azole exposure; step-down therapy during persistent neutropenia in clinically stable patients who have susceptible isolates and documented bloodstream clearance) • Candidiasis, treatment (invasive, those with no recent azole exposure and are not colonized with azole-resistant Candida species); central nervous system (for step-down therapy) • Candidiasis, prophylaxis (in high-risk patients in adult ICUs with a high rate (>5%) of invasive candidiasis • Coccidioidomycosis, treatment (off-label) • Coccidioidomycosis, prophylaxis (off-label) • Cryptococcosis, isolated asymptomatic antigenemia in patients with HIV (off-label) • Cryptococcal meningitis • Cryptococcosis, pulmonary infection (off-label) • Esophageal Candidiasis • Neonatal candidiasis, including central nervous systemic infections (in patients who have not been on fluconazole prophylaxis) • Onychomycosis (off-label) • Oropharyngeal Candidiasis (moderate to severe)

	• Symptomatic Ascending Candida Pyelonephritis • Symptomatic Candida Cystitis • Tinea infection (off-label) • Vulvovaginal Candidiasis (severe)
Intravenous Amphotericin B or its derivatives (e.g., Amphotericin B lipid complex [ABLC, Abelcet], conventional [deoxycholate], Liposomal [AmBisome])	• Aspergillosis, endophthalmitis • Aspergillosis, invasive • Blastomycosis, moderately severe to severe, non-CNS disease • Candida Chorioretinitis Without Vitritis (for fluconazole-/voriconazole-resistant isolates) • Candida Chorioretinitis With Vitritis • Candida Endocarditis • Candida Osteomyelitis • Candida Septic Arthritis • Candida Suppurative Thrombophlebitis • Candidiasis, hepatosplenic, invasive, central nervous system (alternative if there is intolerance to other antifungal agents) • Candidemia - nonneutropenic (if there is intolerance, limited availability, or resistance to other antifungal agents or suspected azole- and echinocandin-resistant Candida infections) • Candidemia - neutropenic • Coccidioidomycosis, severe, nonmeningeal infection • Cryptococcal meningoencephalitis, disseminated disease, or severe pulmonary infection • Cryptococcosis • Endophthalmitis, fungal • Esophageal Candidiasis • Febrile neutropenia, empiric therapy • Fungal infection, pulmonary, prophylaxis in lung transplant recipients (off-label) • Fungal sinusitis • Fusariosis, invasive • Histoplasmosis • Leishmaniasis • Mucormycosis, invasive • Neonatal candidiasis, including central nervous systemic infections (disseminate candidiasis) • Neutropenic fever, empiric antifungal therapy (off-label) • Oropharyngeal Candidiasis • Peritonitis • Sporotrichosis, pulmonary, meningeal,

	osteoarticular, or disseminated ● Symptomatic Ascending Candida Pyelonephritis (fluconazole resistant) ● Symptomatic Candida Cystitis ● Talaromycosis (off-label)
Voriconazole (Intravenous and oral)	● Aspergillosis ● Blastomycosis (off-label) ● Candida Chorioretinitis Without Vitritis ● Candida Endocarditis (step-dose therapy; for isolates that are susceptible to voriconazole but not susceptible to fluconazole) ● Candidiasis, treatment ● Candidemia (nonneutropenic as step-down oral therapy for selected cases of candidemia due to C. krusei) ● Candidemia - neutropenic (where additional mold coverage is desired; as step-down therapy during neutropenia in clinically stable patients who have had documented bloodstream clearance and isolates that are susceptible to voriconazole) ● Coccidioidomycosis, refractory to conventional therapy (off-label) ● Cryptococcal meningitis (off-label) ● Esophageal Candidiasis ● Fusariosis ● Histoplasmosis (off-label) ● Neutropenic fever (off-label) ● Oropharyngeal Candidiasis ● Prophylaxis against invasive fungal infections (off-label) ● Scedosporiosis ● Talaromycosis (off-label)
Please see the most up-to-date guidelines from the Infectious Diseases Society of America (IDSA) at https://www.idsociety.org/ *Note: The 2016 IDSA Clinical Practice Guideline for the Management of Candidiasis did not yet include Rezzayo (Rezafungin), which was approved in 2023. The above indications for Rezzayo (Rezafungin) are based on the FDA-approved package insert and the 2016 IDSA guideline wherever the echinocandin class was noted.*	

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