Abelecet (ampho B, lipid complex)
Policy Number: C10144-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
2/1/2017	8/1/2018	8/1/2019
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J0287	RxPA	Q3 2019

PRODUCTS AFFECTED:
Abelecet (ampho B, lipid complex)

DRUG CLASS:
Antifungals

ROUTE OF ADMINISTRATION:
Intravenous

PLACE OF SERVICE:
Buy and Bill

AVAILABLE DOSAGE FORMS:
Abelcet Vial 5MG/ML

FDA-APPROVED USES:
indicated for the treatment of invasive fungal infections in patients who are refractory to or intolerant of conventional amphotericin B therapy. This is based on open-label treatment of patients judged by their physicians to be intolerant to or failing conventional amphotericin B therapy.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: Aspergillus, invasive (salvage); Blastomycosis, moderately severe to severe, non-CNS disease; Candidemia (non-neutropenic patients); Candidemia (neutropenic patients); Candidiasis, Central nervous system (eg, meningitis); Candidiasis, Chronic disseminated (hepatosplenic); Candidiasis, Empiric therapy, suspected invasive candidiasis (non-neutropenic ICU patients); Candidiasis, Endocarditis (native or prosthetic valve) or infected implantable cardiac devices (eg, pacemaker, ICD, VAD); Candidiasis, Intra-abdominal candidiasis (alternative agent); Candidiasis, Osteomyelitis or septic arthritis due to Candida (alternative agent); Candidiasis, Suppurative thrombophlebitis; Coccidioidomycosis, progressive, disseminated (alternative agent); Coccidioidomycosis in HIV-infected patients; Cryptococcosis; Empiric antifungal therapy (neutropenic fever) (alternative agent); Histoplasmosis;Leishmaniasis in HIV patients (visceral); Sporotrichosis, meningeal, pulmonary, osteoarticular, and disseminated;

REQUIRED MEDICAL INFORMATION:
A. FUNGAL INFECTION:
1. Patient has a diagnosis of an invasive fungal infection (e.g., blastomycosis, candidiasis [cardiovascular, CNS, osteoarticular, endophthalmitis], cryptococcosis, leishmaniasis, systemic mycosis, coccidioidomycosis, histoplasmosis) with confirmation the infection is senstive to Ablecet

AND
2. Documentation of baseline labs including serum creatinine, magnesium and potassium levels
AND
3. Documentation that renal function will be monitored

DURATION OF APPROVAL:
Initial authorization: up to 12 weeks per approval, or shorter depending on the request and recommendations for the indication, Continuation of Therapy: up to 12 weeks per approval

QUANTITY:
None

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist

AGE RESTRICTIONS:
No restriction

GENDER:
Male and female

CONTINUATION OF THERAPY:

A. FUNGAL INFECTION:
1. Renal function is being monitored
AND
2. Documentation submitted to show that patient's condition has improved or stabilized, or that continued therapy is otherwise medically necessary and the benefits outweigh the risks

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
ABELCET® is contraindicated in patients who have shown hypersensitivity to amphotericin B or any other component in the formulation.
The recommended duration of treatment is complete, and clinical documentation supporting continuation has been requested, but not been received

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND: None

APPENDIX:
Labeled and recommended off-label uses and dosing (Lexicomp) –
Aspergillosis, invasive (salvage therapy): IV: 5 mg/kg/day; minimum duration of treatment is 6 to 12 weeks and depends on site of infection, extent of disease, and level/duration of immunosuppression. Note: Amphotericin B lipid complex should be reserved as salvage therapy for those intolerant of or refractory to voriconazole, isavuconazole, or liposomal amphotericin B.

Blastomycosis, moderately severe to severe, non-CNS disease (off-label dose): IV: 3 to 5 mg/kg/day for 1 to 2 weeks or until improvement, followed by oral itraconazole.

Candidiasis: IV:Candidemia (non-neutropenic patients) (alternative agent) (off-label dose): 3 to 5 mg/kg/day; may transition to fluconazole (usually after 5 to 7 days) in clinically stable patients, with fluconazole-susceptible isolates and negative repeat cultures. Total duration of antifungal therapy is at least 2 weeks after the documented clearance of Candida from the bloodstream and resolution of candidemia-associated symptoms in patients without metastatic complications.

Candidemia (neutropenic patients) (alternative agent) (off-label dose): 3 to 5 mg/kg/day; may transition to fluconazole during persistent neutropenia in clinically stable patients, with fluconazole-susceptible isolates and negative repeat cultures. Total duration of antifungal therapy is at least 2 weeks after the documented clearance of Candida from the bloodstream and resolution of neutropenia and candidemia-associated symptoms in patients without metastatic complications.

Chronic disseminated (hepatosplenic) (off-label dose): 3 to 5 mg/kg/day for several weeks; transition to oral fluconazole in clinically stable patients unlikely to have a fluconazole-resistant isolate.

Empiric therapy, suspected invasive candidiasis (non-neutropenic ICU patients) (alternative agent) (off-label use): 3 to 5 mg/kg/day; treatment should continue for 14 days in patients with clinical improvement. Consider discontinuing after 4 to 5 days in patients with no clinical response.

Endocarditis (native or prosthetic valve) or infected implantable cardiac devices (eg, pacemaker, ICD, VAD) (off-label dose): 3 to 5 mg/kg/day (with or without flucytosine); for native or prosthetic valve endocarditis, therapy should continue for at least 6 weeks after valve replacement surgery (longer durations in patients with abscesses or other complications); for patients with implantable cardiac devices, therapy should continue for 4 to 6 weeks after surgery (4 weeks for infections limited to generator pockets and at least 6 weeks for infections involving the wires). Note: May transition to fluconazole if patient clinically stable with fluconazole-susceptible isolates in whom Candida has cleared from the bloodstream.

Intra-abdominal candidiasis (alternative agent) (off-label dose): 3 to 5 mg/kg/day; duration of therapy determined by clinical response and source control.

Osteomyelitis or septic arthritis (alternative agent) (off-label dose): 3 to 5 mg/kg/day for at least 2 weeks, followed by fluconazole.

Suppurative thrombophlebitis (off-label dose): 3 to 5 mg/kg/day; continue for at least 2 weeks after candidemia has cleared; consider transition to fluconazole in clinically stable patients with a fluconazole-susceptible isolate who have responded to initial therapy.

Coccidioidomycosis, progressive, disseminated (alternative agent) (off-label dose): IV: 2 to 5 mg/kg/day
Coccidioidomycosis in HIV-infected patients with severe, nonmeningeal infection (ie, diffuse pulmonary or severely ill with extrathoracic disseminated disease) (off-label use): 3 to 5 mg/kg/day until clinical improvement, then switch to fluconazole or itraconazole.

*Cryptococcosis: IV:*Cryptococcal meningitis in HIV-infected patients (alternative agent) (off-label use): Induction therapy: 5 mg/kg/day with flucytosine for at least 2 weeks, followed by fluconazole for consolidation therapy. Note: If flucytosine is not given due to intolerance, duration of amphotericin B lipid complex therapy should be 4 to 6 weeks.

Cryptococcal meningoencephalitis in HIV-negative patients and non-transplant patients (alternative agent): Induction therapy: 5 mg/kg/day (with flucytosine) for ≥4 weeks followed by oral fluconazole. Note: If flucytosine is not given or treatment is interrupted, consider prolonging induction therapy for an additional 2 weeks.

Cryptococcal meningoencephalitis in transplant recipients: Induction therapy: 5 mg/kg/day (with flucytosine) for at least 2 weeks, followed by oral fluconazole Note: If flucytosine is not given, duration of amphotericin B lipid complex therapy should be 4 to 6 weeks.

Nonmeningeal cryptococcosis: Induction therapy: 5 mg/kg/day (with flucytosine) for ≥4 weeks may be used for severe pulmonary cryptococcosis or for cryptococcemia with evidence of high fungal burden, followed by oral fluconazole. Note: If flucytosine is not given or treatment is interrupted, consider prolonging induction therapy for an additional 2 weeks.

Empiric antifungal therapy (neutropenic fever) (alternative agent) (off-label use): IV: 5 mg/kg/day once daily. Note: Guidelines recommend amphotericin B lipid formulations be considered for invasive aspergillosis only when triazoles, specifically voriconazole, are contraindicated or not tolerated.

*Histoplasmosis: IV:*Acute pulmonary (moderately severe to severe): 5 mg/kg/day for 1 to 2 weeks, followed by oral itraconazole

Moderate to severe disseminated disease in HIV-infected patients (alternative agent) (off-label use): 3 mg/kg/day for at least 2 weeks, followed by itraconazole maintenance therapy.
Progressive disseminated, non-CNS disease (alternative agent): 5 mg/kg/day for 1 to 2 weeks, followed by oral itraconazole.

Leishmaniasis (visceral) in HIV-infected patients (off-label use): IV:Treatment (alternative agent): 2 to 4 mg/kg/dose once daily or an interrupted schedule of 4 mg/kg/dose on days 1 to 5, and on days 10, 17, 24, 31, and 38 to achieve a total dose of 20 to 60 mg/kg.

Chronic maintenance therapy (for patients with a CD4 count <200 cells/mm3): 3 mg/kg every 21 days.

Sporotrichosis (off-label dose): IV:
Meningeal: 5 mg/kg/day for 4 to 6 weeks, followed by oral itraconazole.
Pulmonary, osteoarticular, and disseminated: 3 to 5 mg/kg/day, followed by oral itraconazole after a favorable response is seen with amphotericin initial therapy.

REFERENCES:

1. Abelcet (amphotericin B lipid complex) [prescribing information]. Indianapolis, IN: Exelead, Inc; December 22, 2017.
2. Lexicomp Online, Amphotericin B lipid complex: Drug information. Hudson, Ohio: Lexi-Comp, Inc.; 2018; July 26, 2018.