

**THIRD QUARTER 2017 CODING AND BILLING
REFERENCE SHEET (07/01/2017 - 09/30/2017)**



Appropriate and accurate coding is important for healthcare providers to receive reimbursement for drug therapies like AmBisome. Coding should reflect services provided to the patient as documented in the patient's medical record. Medicare uses the Medicare Physician Fee Schedule (MPFS) to pay physicians for services provided to patients. Medicare adjusts the payments based on the geographic location of the physician. For specific payment levels in your area, visit www.cms.gov/PFSlookup.

Medicare bases payment for hospital outpatient facilities on Ambulatory Payment Classifications (APCs). Procedures that share similar clinical characteristics and are similar in terms of cost requirements are grouped together into an APC. Medicare assigns each APC group a payment amount that is made to the hospital.

Effect of Sequestration: For the items and services shown here, the Medicare program pays 80% of the payment amount and the beneficiary is responsible for the remaining 20%. Effective April 1, 2013, the Medicare program payment was reduced by 2% because of the sequester required by the Budget Control Act of 2011. The beneficiary portion of the payment was not affected by the sequester. As a result of the sequester, the total payment to the physician or hospital is reduced 1.6%. For example, without the sequester, the payment for 96365 would be \$69.98, of which the program would pay \$55.98 and the beneficiary would pay \$14.00. With the sequester, the program pays \$54.86, the beneficiary still pays \$14.00, and the total payment to the physician is \$68.86. The sequester affects all fee-for-service program payments, including those for physician services, hospital outpatient department services, drugs, and dispensing and supplying fees.¹

CPT Codes ^a	Description	3Q 2017 Medicare Payment				Home Health DME Infusion Limit
		Physician Office	Hospital Outpatient		Unadjusted Payment Amount ^c	
		MPFS ^b (Unadjusted Payment Amount)	APC	Description		
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	\$69.98	5693	Level 3 Drug Administration	\$179.77	—
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	\$19.02	5691	Level 1 Drug Administration	\$34.78	—

Medicare pays for many outpatient drugs like AmBisome using Average Sales Price (ASP). Medicare updates ASP quarterly. Including the effect of sequestration, the total payment to physicians is ASP + **4.3%** and to hospital outpatient facilities is ASP + **4.3%** for separately covered outpatient drugs. Section 5004 of 21st Century Cures Act changes how Medicare pays for drugs furnished in the patient's home through covered durable medical equipment (DME). Beginning January 1, 2017, drugs supplied through covered DME are paid ASP + 6% (before sequestration).²

HCPCS Codes	Description	Physician Office	Hospital Outpatient		Home Health DME Infusion Limit ³	
		ASP Payment Rate ³	APC	Description		ASP Payment Rate ^c
J0289	Injection, amphotericin B liposome, 10 mg	\$20.750	0736	Amphotericin B liposome injection	\$20.75	\$20.750

^a CPT copyright 2016 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

^b Calculated based on relative value units (RVUs) from the Physician Fee Schedule Relative Value File and 2017 conversion factor using the following formula: Work RVU + Non-Facility PE RVU + MP RVU x 2017 Conversion Factor of \$35.8887.^{4,5}

^c Medicare Program: Hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; organ procurement organization reporting and communication; transplant outcome measures and documentation requirements; electronic health record (EHR) incentive programs; payment to nonexcepted off-campus provider-based department of a hospital; hospital value-based purchasing (VBP) program; establishment of payment rates under the Medicare physician fee schedule for nonexcepted items and services furnished by an off-campus provider-based department of a hospital. 81 Fed. Reg. 79562. 2017 unadjusted hospital outpatient amounts obtained from CMS Addendum B file.⁶

PLEASE SEE IMPORTANT SAFETY INFORMATION.

PLEASE SEE FULL PRESCRIBING INFORMATION HERE OR PROVIDED BY YOUR ASTELLAS REPRESENTATIVE.

INDICATIONS AND USAGE

AmBisome[®] is indicated for the following:

- Empirical therapy for presumed fungal infection in febrile, neutropenic patients
- Treatment of Cryptococcal Meningitis in HIV-infected patients
- Treatment of patients with *Aspergillus* species, *Candida* species, and/or *Cryptococcus* species infections refractory to amphotericin B deoxycholate, or in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate
- Treatment of visceral leishmaniasis. In immunocompromised patients with visceral leishmaniasis treated with AmBisome, relapse rates were high following initial clearance of parasites

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

AmBisome is contraindicated in those patients who have demonstrated or have a known hypersensitivity to amphotericin B deoxycholate or any other constituents of the product, unless benefit of therapy outweighs the risk.

WARNINGS AND PRECAUTIONS

Anaphylaxis has been reported with amphotericin B-containing drugs, including AmBisome. If a severe reaction occurs, the AmBisome infusion should be immediately discontinued and the patient should not receive further infusions of AmBisome.

General: During the initial dosing period, patients should be under close observation. AmBisome has been shown to be significantly less toxic than amphotericin B deoxycholate; however, adverse events may still occur.

Laboratory Tests: Patient management should include laboratory evaluation of renal, hepatic, and hematopoietic function, and serum electrolytes (magnesium and potassium).

Drug-Laboratory Interactions: Serum Phosphate false elevation. False elevations of serum phosphate may occur when samples from patients receiving AmBisome are analyzed using the PHOSm assay.

Drug Interactions: No formal drug-interaction studies have been conducted with AmBisome. However, the following drugs are known to interact with amphotericin B and may interact with AmBisome: antineoplastic agents, corticosteroids and corticotropin (ACTH), digitalis glycosides, flucytosine, azoles (e.g. ketoconazole, miconazole, clotrimazole, fluconazole), leukocyte transfusions, other nephrotoxic medications, and skeletal muscle relaxants. (Please see Package Insert, Drug Interactions)

ADVERSE REACTIONS

The commonly reported adverse reactions across all studies with an incidence of >20% with AmBisome include: rash, hyperglycemia, hypokalemia, hypomagnesemia, diarrhea, nausea, vomiting, anemia, increased alkaline phosphatase, increased blood urea nitrogen, chills, insomnia, increased creatinine, and dyspnea.

Infusion related reactions include chills/rigors, fever, nausea, vomiting, hypertension, tachycardia, dyspnea, and hypoxia. There were a few reports of flushing, back pain with or without chest tightness, and chest pain associated with AmBisome administration; on occasion this has been severe. Where these symptoms were noted, reaction developed within a few minutes after the start of infusion and disappeared rapidly when the infusion was stopped. These symptoms do not occur with every dose and usually do not recur on subsequent administrations when the infusion rate is slowed.

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IMPORTANT INFORMATION: *The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials provided by Astellas Pharma Support SolutionsSM are to assist healthcare providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider. Information provided should in no way be considered a guarantee of coverage, rate, or reimbursement for any product or service.*

1. Centers for Medicare & Medicaid Services. Mandatory payment reduction in the Medicare Fee-for-Service (FFS) Program – “Sequestration.” Washington, DC: CMS Medicare FFS Provider e-News; March 8, 2013. www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf. Accessed 01-04-2017.
2. The 21st Century Cures Act, Pub. L. No. 114-255, § 5004 (2016) amending 42 U.S.C. § 1395u. <http://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf>. Accessed 04-05-2017.
3. Centers for Medicare & Medicaid Services. 2017 ASP Drug Pricing Files. ASP Drug Pricing Files July 2017 Update. www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2017ASPFiles.html. Accessed 06-08-2017.
4. Centers for Medicare & Medicaid Services. CY 2017 revisions to payment policies under the physician fee schedule and other revisions to Part B. www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1654-F.html. Accessed 01-04-2017.
5. Centers for Medicare & Medicaid Services. Final policy, payment, and quality provisions in the Medicare physician fee schedule for calendar year (CY) 2017. www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-02.html. Accessed 01-04-2017.
6. Centers for Medicare & Medicaid Services. Hospital outpatient prospective payment - addendum A and addendum B updates. www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates-Items/2017-July-Addendum-B.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending. Accessed 06-22-2017.

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