Abbott

2019 ABBOTT CODING AND REIMBURSEMENT GUIDE

Amplatzer Piccolo™ Occluder

The following codes describe the implantation of the Amplatzer Piccolo™ Occluder for Patent Ductus Arteriosus (PDA) closure. For questions regarding billing and reimbursement of the Amplatzer Piccolo™ Occluder, please contact the Abbott reimbursement team on the reimbursement hotline at (855) 569-6430 or hce@abbott.com.

COVERAGE CONSIDERATIONS FOR DEVICES INTENDED FOR PREMATURE INFANTS

The Amplatzer Piccolo™ Occluder PDA closure device is intended for very small infants; as a result, it is likely that pediatric patients will have private payer coverage or Medicaid. In some cases, these patients may have no insurance coverage. While it is not likely that these patients will be Medicare beneficiaries, we refer to Medicare payment rates in this guide as baseline or payment references for providers.

PRIVATE PAYER COVERAGE

Most private payers currently cover percutaneous PDA closure with the Amplatzer Duct Occluder II. Check with your private payers for specific coverage policies regarding the Amplatzer Piccolo™ Occluder. Prior authorization is recommended if possible.

MEDICAID COVERAGE

Babies who are born premature often may qualify for Supplemental Security Income (SSI) and Medicaid. Qualification for SSI is based on the child's birth weight and/or gestational age as well as family income and assets. (Weight requirements: a child who weighs less than 2 pounds 10 ounces, at birth or no more than 4 pounds, 6 ounces, at birth but is considered small for his or her gestational age).

In many states, a baby who receives SSI benefits maybe automatically eligible for Medicaid to help pay for health care costs. Parents may be able to apply for SSI benefits for their child at a local Social Security Administration office or be directed to the office where they can apply for Medicaid.[1]

INDICATION

The Amplatzer Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA). See Important Safety Information referenced within.

PHYSICIAN SERVICES[2]

CPT‡ code	Description
Implant Procedure	
93582	Percutaneous transcatheter closure of patent ductus arteriosus

Medicare national average physician payment level for CPT‡ code 93582 is $700 for Calendar Year 2019. While premature infants are rarely Medicare beneficiaries, the Medicare rate may serve as a baseline amount for physician payment. Private payer and Medicaid rates may vary substantially, from Medicare rates; however, differentials from Medicare rates are usually consistent across procedures.

HOSPITAL SERVICES[3]

ICD-10-PCS code	Description
Implant Billing Code	
02LR3DT	Occlusion of ductus arteriosus with intraluminal device, percutaneous

Patients are likely to receive the Amplatzer Piccolo™ Occluder during their initial inpatient stay after being born. Due to the high incidence of multiple comorbidities for these premature infants, the inpatient stay is likely to be lengthy with a significant portion of the stay in the neonatal intensive care unit (NICU). When the hospital is reimbursed under a prospective payment system, such as MS-DRGs or a negotiated per-diem rate, it is unlikely that the implant of the Amplatzer Piccolo™ Occluder will be reimbursed with a separate payment. The overall reimbursement for the inpatient stay is likely to include a single payment for all services delivered during the stay.

Payment for an isolated PDA closure is unlikely but might occur in some scenarios. Medicare payment for an isolated PDA closure can serve a baseline or payment reference amount. However, payment by Medicare is unlikely due to the premature infant patient population for which the Amplatzer Piccolo™ Occluder is indicated. The Medicare rate for PDA closure is determined by the MS-DRG assigned for the procedure. PDA closures are assigned MS-DRG 270, 271 or 272 (Other Major Cardiovascular Procedures w/MCC, w/CC, or w/o CC/MCC) that have respective Medicare national payment rates of $30,904, $21,331 and $15,985 [SA2] in fiscal year 2019, effective Oct 1, 2018 to Sept 30, 2019. Rates published as of January 1, 2019.

AMPLATZER PICCOLO™ OCCLUDER
IMPORTANT SAFETY INFORMATION

Rx ONLY

INDICATIONS AND USAGE
The AMPLATZER Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

CONTRAINDICATIONS
- Weight < 700 grams at time of the procedure
- Age < 3 days at time of procedure
- Coarctation of the aorta
- Left pulmonary artery stenosis
- Cardiac output that is dependent on right to left shunt through the PDA due to pulmonary hypertension
- Intracardiac thrombus that may interfere with the implant procedure
- Active infection requiring treatment at the time of implant
- Patients with a PDA length smaller than 3 mm
- Patients with a PDA diameter that is greater than 4 mm at the narrowest portion

WARNINGS
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or re-sterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use this device if the sterile package opened or damaged.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- Prepare for situations that require the removal of this device. Preparation includes access to a transcatheter snare kit and an on-site surgeon.
- Accurate measurements of the ductus are crucial for correct occluder size selection.
- Do not release the occluder from the delivery wire if either a retention disc protrudes into the pulmonary artery or aorta; or if the position of the occluder is not stable.
- Remove embolized devices. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a catheter.

PRECAUTIONS
- This device should be used only by physicians who are trained in standard transcatheter techniques. Determine which patients are candidates for procedures that use this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants and antiplatelet drugs before, during, and/or after the use of this device.
- Patients should have an activated clotting time (ACT) of greater than 200 sec prior to device placement, unless the patient has a significant risk for bleeding and is unable to be anti-coagulated.
- The device may be delivered via an anterograde (venous) or a retrograde (arterial) approach. However, in small infants (≤2 kg), the device should be delivered using the anterograde (venous) approach since small infants are at an increased risk for arterial injury.
- The AMPLATZER Piccolo™ Occluder contains nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days following implant. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should seek immediate medical attention if there is suspicion of an allergic reaction. Symptoms may Atherosclerosis or other arteriopathy of the intracranial and extracranial vessels associated with a ≥50% luminal stenosis include difficulty in breathing or swelling of the face or throat. While data are currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.
- Use in specific populations
  - Pregnancy — Minimize radiation exposure to the fetus and the mother.
  - Nursing mothers — There has been no quantitative assessment for the presence of leachables in breast milk.
- Store in a dry place.
- Do not use contrast power injection with delivery catheter.

POTENTIAL ADVERSE EVENTS
Potential adverse events that may occur during or after a procedure placing this device include, but are not limited to:
- Air embolus
- Allergic dye reaction
- Allergic drug reaction
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bacterial endocarditis
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Device embolization
- Device erosion
- Death
- Fever
- Headache/migraine
- Hemolysis
- Hematoma
- Hypertension
- Hypotension
- Infection
- Myocardial infarction
- Palpitations
- Partial obstruction of aorta
- Partial obstruction of pulmonary artery
- Pericardial effusion
- Pericarditis
- Peripheral embolism
- Pleural effusion
- Pulmonary embolism
- Re-intervention for device removal
- Respiratory distress
- Stroke
- Thrombus
- Transient ischemic attack
- Valvular regurgitation
- Vascular access site injury
- Vascular occlusion
- Vessel perforation

DISCLAIMER

This document and the information contained herein is for general information purposes only and is not intended and does not constitute legal, reimbursement, coding, business or other advice. Furthermore, it is not intended to increase or maximize payment by any payer. Nothing in this document should be construed as a guarantee by Abbott regarding levels of reimbursement, payment or charge, or that reimbursement or other payment will be received. Similarly, nothing in this document should be viewed as instructions for selecting any particular code. The ultimate responsibility for coding and obtaining payment/reimbursement remains with the customer. This includes the responsibility for accuracy and veracity of all coding and claims submitted to third-party payers. Also note that the information presented herein represents only one of many potential scenarios, based on the assumptions, variables and data presented. In addition, the customer should note that laws, regulations, coverage and coding policies are complex and updated frequently. Therefore, the customer should check with their local carriers or intermediaries often and should consult with legal counsel or a financial, coding or reimbursement specialist for any coding, reimbursement or billing questions or related issues. This information is for reference purposes only. It is not provided or authorized for marketing use.

REFERENCES

1. Social Security Administration website - https://www.ssa.gov/disability/professionals/bluebook/100.00-GrowthImpairment-Childhood.htm; Social Security Administration website - https://www.ssa.gov/ssi/text-other-ussi.htm.
2. Physician Fee Schedule Federal Regulation Notices – Final Rule with comment period and final CY2019 payment rates. CMS-1693-F: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html. CMS may make adjustments from time to time.
3. Inpatient Prospective Payment System- Final rule with comment period and final FY2019 payment rates. CMS-1694-F and CMS-1994-CN2: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page.html. Calculated using Tables 1A-1D and Table 5, and assuming that all hospitals are receiving the full 1.35% updates for successful quality reporting and EHR meaningful use. Actual payment may vary based on various hospital-specific factors not reflected. Some providers may be paid based on a methodology that differs from the standard MS-DRG calculation reflected in the amount shown (i.e., rural referral centers, hospitals in the state of Maryland). Actual payment may also vary based on adjustments that CMS may make from time to time.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Abbott

3200 Lakeside Dr., Santa Clara, CA 95054 USA Tel: 1.800.227.9902

www.cardiovascular.abbott

SJM-HER-0119-0168 | Item approved for U.S. use only

Abbott