APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

The GORE® CARDIOFORM ASD Occluder Clinical Study will evaluate safety and efficacy in the treatment of transcatheter closure of ostium secundum atrial septal defects (ASDs). The study will take place at Children’s Hospital of Atlanta. ¹ The new investigational device exemption (IDE) trial is researching the new GORE® CARDIOFORM ASD Occluder for the interventional closure of ASDs, sized 8 to 35 mm. The device is designed with an anatomically adaptable waist to accommodate the natural anatomy of the heart and reduce the risk for cardiac injury.²

The study will include 125 patients over a 3 year period. Patients will be assessed for technical, safety, and closure success at 6 months. Results are expected in mid-2018, which will allow Gore to submit to the U.S. Food and Drug Administration (FDA) for device approval.²

The trial is for patients of any age who have been diagnosed with ostium secundum atrial septal defect measuring 8 to 35 mm by stop-flow balloon sizing. The patient must have inter-atrial shunting with evidence of right heart volume overload to demonstrate the need for septal defect closure. The patient also must not have any concurrent cardiac conditions that could elevate the morbidity or mortality risk beyond what is common for atrial septal defect.¹

All participants must have a physical exam, electrocardiogram and echocardiogram within 6 months of the procedure. Within 90 days of the procedure each participant is required to have another echocardiogram and physical exam as well as a stop-flow balloon sizing of the defect and fluoroscopy. Once the procedure has been completed the participant will need a follow up assessment at 30 days and 6 months. The follow assessment up will include a physical exam, electrocardiogram, echocardiogram and fluoroscopy. After the initial assessments the participant will need to follow up annually at 1, 2 and 3 years. The annual appointments for years 1 and 3 will include a physical exam, echocardiogram and electrocardiogram. The 2 year follow up will be a questionnaire completed telephonically.¹
An atrial septal defect is the most common congenital cardiac anomaly present at birth and occurs in 0.1% of all live births. The defect is a hole in the heart’s septum that allows blood flow between the right and left upper chambers of the heart, most commonly, causing a left to right shunt. Approximately 75% of all cases are secundum defects, which occur in the fossa ovalis with the remainder occurring in other parts of the atrial septum. Defects may be single or multiple and can range in size from several millimeters up to 3 centimeters in diameter. These variations can result in differing degrees of impact on the patient.2,3

Although a family history of congenital heart disease can increase risk for an ASD, most cases have no known cause. Drinking alcohol, smoking and taking certain antidepressants during pregnancy can increase the risk for a baby to be born with an ASD. Diabetes during pregnancy or a high dietary glycemic index in the absence of diabetes and advanced maternal age can also increase risk. Certain genetic syndromes such as Down, Holt-Oram, Budd-Chiari, Ellis van Crevel, and Jarcho-Levin have been associated with ASDs.3

A small septal defect with a small amount of shunting may cause little to no right heart enlargement and some smaller defects may close on their own in childhood. Large defects, however, can affect the heart muscles and vasculature and lead to enlargement of the heart, decreased filling of the left diastolic ventricle, increased pulmonary blood flow and reduced systemic output. Larger defects grow over time and can lead to more severe problems such as right sided heart failure, arrhythmia or atrial fibrillation and even pulmonary hypertension or stroke if untreated.2,3

The most common symptoms associated with ASD are fatigue, palpitations, syncope, activity intolerance and shortness of breath. Some patients experience cyanosis, peripheral edema and even thromboembolisms. Children with ASDs commonly present with recurrent respiratory infections. Some patients are asymptomatic and an ASD may go undetected or be discovered incidentally by echocardiogram or chest x-ray.3

ASDs can be diagnosed by physical examination, electrocardiography, chest radiography, and echocardiography. Magnetic resonance imaging (MRI) or computed tomography (CT) scans may be conducted in cases where standard diagnostics are inconclusive.3

Patients with small ASD who are asymptomatic and without overload can typically be monitored. Patients with arrhythmia or significant volume overload may require drug therapy. Standard treatment for an ASD that has caused enlargement of the heart is closure of the defect either by open heart surgery or catheter placement of a special closure device. There are two FDA approved devices to close the defect including the Gore® Septal Occluder, which can close a hole up to 17 mm in diameter, and the Amplatzer Septal Occluder, which can close larger defects, but has rarely been associated with complications. The newest device, the Gore® Cardioform ASD Occluder has been designed to close defects that are 8 to 35 mm and is currently part of a new investigational device exemption (IDE) trial.1,2,3

POSITION STATEMENT

Applicable To:
☑ Medicaid – Georgia

Exclusions4

The Gore® Cardioform ASD Occluder Clinical Study is not considered medically necessary and not a covered benefit when any of the below apply:

1. Member is unable to take anti-platelet or anticoagulant medications such as aspirin heparin, or warfarin.
2. Member’s anatomy is such that the ASD occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins.
3. Members with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement.
4. Members with known intracardiac thrombi.
Coverage

The Gore® Cardioform ASD Occluder Clinical Study is considered medically necessary and a covered benefit when all of the below criteria apply:

1. There are no age limitations; AND,
2. Member has an ostium secundum atrial septal defect measuring 8-35 mm by stop-flow balloon sizing; AND,
3. Member has inter-atrial shunting with evidence of right heart volume overload, demonstrating the need for septal defect closure; AND,
4. Member has an absence of concurrent cardiac conditions that could elevate morbidity/mortality beyond what is common for atrial septal defect.

Coding

Covered CPT® Codes

93580  Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant
93303  Transthoracic echocardiography for congenital cardiac anomalies; complete
93304  Transthoracic echocardiography for congenital cardiac anomalies; follow-up or limited study
93315  Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
93316  Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only
93317  Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only
+93662  Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)

Covered HCPCS Code

C2638  Brachytherapy source, stranded, iodine-125, per source
C2639  Brachytherapy source, nonstranded, iodine-125, per source

Covered ICD-10 CM Codes

Q21.1  Atrial septal defect
123.1  Atrial septal defect as current complication following acute myocardial infarction

Coding information is provided for informational purposes only. The inclusion or omission of a CPT®, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/ state laws.
REFERENCES

1. Gore ASureD Trial – Executive Summary
4. MD151455 GORE® CARDIOFORM ASD Occluder Investigator’s Brochure Revision #1. W. L. Gore & Associates

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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Original Effective Date: 1/11/2018 - Revised: 2/7/2019, 3/10/2020
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