



Louisiana

Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

Policy # 00016

Original Effective Date: 06/05/2002

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Atrial Septal Defect

Based on review of available data, the Company may consider transcatheter closure of secundum atrial septal defects (ASDs) when using a device that has been approved by the U.S. Food and Drug Administration (FDA) for that purpose and used according to the labeled indications to be **eligible for coverage**** when patient selection criteria are met.

Patient Selection Criteria

Three devices have been approved by the U.S. FDA for atrial septal defect closure: the AmplatzerTM Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder.

The labeled indications for these devices are similar and include:

- Patients with echocardiographic evidence of ostium secundum atrial septal defect and either of the following:
 - Clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left to right shunt or right ventricular enlargement); or
 - Clinical evidence of paradoxical embolism

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Patent Foramen Ovale

Based on review of available data, the Company may consider the percutaneous transcatheter closure of a patent foramen ovale (PFO) using AMPLATZER PFO Occluder or the Gore Cardioform Septal Occluder to be **eligible for coverage**** to reduce the risk of recurrent ischemic stroke if patient meets all of the following criteria:

- Between 18 and 60 years of age
- Diagnosed with PFO with a right-to-left interatrial shunt confirmed by echocardiography with at least one of the following characteristics:
 - PFO with large shunt, defined as >30 microbubbles in the left atrium within 3 cardiac cycles, after opacification of the right atrium.
 - PFO associated with atrial septal aneurysm on transesophageal examination: septum primum excursion >10 mm
- Documented history of cryptogenic ischemic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude any other identifiable cause of stroke, including large vessel atherosclerotic disease and small vessel occlusive disease

AND none of the following are present:

- Uncontrolled vascular risk factors, including uncontrolled diabetes or uncontrolled hypertension
- Other sources of right-to-left shunts, including an atrial septal defect and/or fenestrated septum.
- Active endocarditis or other untreated infections
- Inferior vena cava filter.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Atrial Septal Defects

Based on review of the available data, the company considers the use of transcatheter closure of secundum ASDs when patient selection criteria are not met to be **investigational.***

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Patent Foramen Ovale

Based on review of the available data, the company considers closure of PFO when patient selection criteria are not met to be **investigational**.*

Policy Guidelines

Two devices approved by the U.S. Food and Drug Administration for patent foramen ovale closure and atrial septal defect closure are currently marketed: the Amplatzer Septal Occluder and the GORE CARDIOFORM Septal Occluder. The GORE HELEX Septal Occluder has been discontinued.

Background/Overview

Patent Foramen Ovale

The foramen ovale, a component of fetal cardiovascular circulation, consists of a communication between the right and left atrium that functions as a vascular bypass of the uninflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation, consisting of a connection between the pulmonary artery and the distal aorta. Before birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over the course of months after birth, an increase in left atrial pressure and a decrease in right atrial pressure result in permanent closure of the foramen ovale in most individuals. However, a PFO is a common finding in 25% of asymptomatic adults. In some epidemiologic studies, PFO has been associated with cryptogenic stroke, defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurologic sources. Studies have also shown an association between PFO and migraine headache.

Atrial Septal Defects

Unlike PFO, which represents the postnatal persistence of normal fetal cardiovascular physiology, ASDs represent an abnormality in the development of the heart that results in free communication between the atria. ASDs are categorized by their anatomy. Ostium secundum describes defects located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and are within the spectrum of atrioventricular septal defects. Primum defects occur commonly in patients with Down syndrome. Sinus venous defects occur high in the atrial septum and are frequently associated with anomalies of the pulmonary veins.

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Ostium secundum ASDs are the third most common form of congenital heart disorder and among the most common congenital cardiac malformations in adults, accounting for 30% to 40% of these patients older than age 40 years. The ASD often goes unnoticed for decades because the physical signs are subtle and the clinical sequelae are mild. However, virtually all patients who survive into their sixth decade are symptomatic; fewer than 50% of patients survive beyond age 40 to 50 years due to heart failure or pulmonary hypertension related to the left-to-right shunt. Symptoms related to ASD depend on the size of the defect and the relative diastolic filling properties of the left and right ventricles. Reduced left ventricular compliance, and mitral stenosis will increase left-to-right shunting across the defect. Conditions that reduce right ventricular compliance and tricuspid stenosis will reduce left-to-right shunting or cause a right-to-left shunt. Symptoms of an ASD include exercise intolerance and dyspnea, atrial fibrillation, and less commonly, signs of right heart failure. Patients with ASDs are also at risk for paradoxical emboli.

Treatment

Repair of ASDs is recommended for those with a pulmonary-to-systemic flow ratio ($Q_p: Q_s$) exceeding 1.5:1.0. Despite the success of surgical repair, there has been interest in developing a transcatheter-based approach to ASD repair to avoid the risks and morbidity of open heart surgery. A variety of devices have been researched. Technical challenges include minimizing the size of the device so that smaller catheters can be used, developing techniques to center the device properly across the ASD, and ensuring that the device can be easily retrieved or repositioned, if necessary. Individuals with ASDs and a history of cryptogenic stroke are typically treated with antiplatelet agents, given an absence of evidence that systemic anticoagulation is associated with outcome improvements.

Transcatheter Closure Devices

Transcatheter PFO and ASD occluders consist of a single or paired wire mesh discs covered or filled with polyester or polymer fabric that are placed over the septal defect. Over time, the occlusion system is epithelialized. ASD occluder devices consist of flexible mesh discs delivered via catheter to cover the ASD.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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Louisiana

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PFO Closure Devices

The U.S. Food and Drug Administration (FDA) has approved three devices for ASD closure through the premarket approval process or a premarket approval supplement: the Amplatzer Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder (see Table 1) (FDA product code: MLV).

In 2002, 2 transcatheter devices were cleared for marketing by the FDA through a humanitarian device exemption as treatment for patients with cryptogenic stroke and PFO: the CardioSEAL^{®‡} Septal Occlusion System (NMT Medical; device no longer commercially available) and the Amplatzer PFO Occluder (Amplatzer, now St. Jude Medical). Following the limited FDA approval, use of PFO closure devices increased by more than 50-fold, well in excess of the 4000 per year threshold intended under the humanitarian device exemption, prompting the FDA to withdraw the humanitarian device exemption approval for these devices in 2007.

In March 2018, the FDA granted an expanded indication to the Gore Cardioform Septal Occluder to include closure of PFO to reduce the risk of recurrent stroke (see Table 1). The new indication was based on results of the REDUCE pivotal clinical trial.

Table 1. PFO Closure Devices Approved by the Food and Drug Administration

Device	Manufacturer	PMA Approval Date	Indications
Amplatzer PFO Occluder	St. Jude Medical	Nov 2016	For percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to

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Louisiana

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			exclude known causes of ischemic stroke.
GORE HELEX Septal Occluder	W.L. Gore & Associates	Aug 2006 (discontinued)	Percutaneous, transcatheter closure of ostium secundum ASDs
GORE CARDIOFORM Septal Occluder	W.L. Gore & Associates	Mar 2018 (supplement)	PFO closure to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke

PFO: patent foramen ovale; PMA: premarket approval. FDA product code: MLV.

ASD Closure Devices

The FDA has approved three devices for ASD closure through the premarket approval process or a premarket approval supplement: the Amplatzer Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder (see Table 2) (FDA product code: MLV).

Table 2. ASD Closure Devices Approved by the Food and Drug Administration

Device	Manufacturer	PMA Approval Date	Indications
Amplatzer Septal Occluder	St. Jude Medical	Dec 2001	<ul style="list-style-type: none"> Occlusion of ASDs in the secundum position Use in patients who have had a fenestrated Fontan procedure

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Louisiana

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			<p>who require closure of the fenestration</p> <ul style="list-style-type: none"> Patients indicated for ASD closure have echocardiographic evidence of ostium secundum ASD and clinical evidence of right ventricular volume overload.
GORE HELEX Septal Occluder	W.L. Gore & Associates	Aug 2006(discontinued)	<ul style="list-style-type: none"> Percutaneous, transcatheter closure of ostium secundum ASDs
GORE CARDIOFORM Septal Occluder	W.L. Gore & Associates	Oct 2016 (supplement)	<ul style="list-style-type: none"> Percutaneous, transcatheter closure of ostium secundum ASDs

ASD: atrial septal defect; PMA: premarket approval.

Rationale/Source

Patent foramen ovale (PFO) and atrial septal defects (ASDs) are relatively common congenital heart defects that can be associated with a range of symptoms. PFOs may be asymptomatic but have been associated with higher rates of cryptogenic stroke. PFOs have also been investigated for a variety of other conditions, such as a migraine. Depending on their size, ASDs may lead to left-to-right shunting and signs and symptoms of pulmonary overload. Repair of ASDs is indicated for patients with a significant degree of left-to-right shunting. Transcatheter closure devices have been developed to repair PFO and ASDs. These devices are alternatives to open surgical repair for ASDs or treatment with antiplatelet and/or anticoagulant medications in patients with cryptogenic stroke and PFO.

For individuals who have PFO and cryptogenic stroke who receive PFO closure with a transcatheter device, the evidence includes multiple, randomized controlled trials (RCTs) comparing device-based PFO closure with medical therapy, systematic reviews, and meta-analyses of these studies. The relevant outcomes are overall survival, morbid events, and treatment-related morbidity

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and mortality. The RCTs comparing PFO closure with medical management have suggested that PFO closure is more effective than medical therapy in reducing event rates. While these results were not statistically significant by intention-to-treat analyses in the first three trials (ie, CLOSURE I, PC, and RESPECT [initial study]), they were statistically significant in later trials (ie, RESPECT [extended follow-up], REDUCE, and CLOSE). Use of appropriate patient selection criteria to eliminate other causes of cryptogenic stroke in RESPECT, REDUCE, and CLOSE trials contributed to findings of the superiority of PFO closure compared with medical management. Of note, higher rates of atrial fibrillation were reported in a few of the individual trials and in the meta-analysis that incorporated evidence from RESPECT, REDUCE, and CLOSE trials. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have PFO and migraines who receive PFO closure with a transcatheter device, the evidence includes two RCTs of PFO closure and multiple observational studies reporting on the association between PFO and migraine. The relevant outcomes are symptoms, quality of life, medication use, and treatment-related morbidity and mortality. The available sham-controlled randomized trial did not demonstrate significant improvements in migraine symptoms after PFO closure. A second RCT with blinded endpoint evaluation did not demonstrate reductions in migraine days after PFO closure but likely was underpowered. Nonrandomized studies have shown highly variable rates of migraine reduction after PFO closure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have PFO and conditions associated with PFO other than cryptogenic stroke or migraine (eg, platypnea-orthodeoxia syndrome, myocardial infarction with normal coronary arteries, decompression illness, high-altitude pulmonary edema, obstructive sleep apnea) who receive PFO closure with a transcatheter device, the evidence includes small case series and case reports. The relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity and mortality. The body of evidence only consists of small case series and case reports. Comparative studies are needed to evaluate outcomes in similar patient groups treated with and without PFO closure. The evidence is insufficient to determine the effects of the technology on health outcomes.

Given the conflicting findings from multiple systematic reviews on the use of PFO closure devices for stroke prevention, clinical input was obtained in 2016 to address device use. Clinical input did

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Louisiana

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not consistently support the use of PFO closure devices in patients with cryptogenic stroke or those with other indications.

For individuals who have ASD and evidence of left-to-right shunt or right ventricular overload who receive ASD closure with a transcatheter device, the evidence includes nonrandomized comparative studies and single-arm studies. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity and mortality. The available nonrandomized comparative studies and single-arm case series have shown rates of closure using transcatheter-based devices approaching the high success rates of surgery, which are supported by meta-analyses of these studies. The percutaneous approach has a low complication rate and avoids the morbidity and complications of open surgery. If the percutaneous approach is unsuccessful, ASD closure can be achieved using surgery. Because of the benefits of percutaneous closure over open surgery, it can be determined that transcatheter ASD closure improves outcomes in patients with an indication for ASD closure. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 academic medical centers (1 of which provided 2 responses) while this policy was under review in 2016. Input was mixed about the medical necessity of closure devices for patent foramen ovale (PFO) in patients with cryptogenic stroke or transient ischemic attack due to presumed paradoxical embolism through the PFO. There was a consensus that use of closure devices for PFO in patients with other conditions (eg, migraine, platypnea-orthodeoxia syndrome) is not medically necessary.

Practice Guidelines and Position Statements

American College of Chest Physicians

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The American College of Chest Physicians (2012) updated its guidelines on antithrombotic therapy and the prevention of thrombosis, which made the following recommendations related to PFO and cryptogenic stroke:

"We suggest that patients with stroke and PFO are treated with antiplatelet therapy following the recommendations for patients with noncardioembolic stroke.... In patients with a history of noncardioembolic ischemic stroke or TIA, we recommend long-term treatment with aspirin (75-100 mg once daily), clopidogrel (75 mg once daily), aspirin/extended release dipyridamole (25 mg/200 mg bid), or cilostazol (100 mg bid) over no antiplatelet therapy(Grade 1A),oral anticoagulants (Grade 1B),the combination of clopidogrel plus aspirin(Grade 1B),or triflusal(Grade 2B)."

American Academy of Neurology

The American Academy of Neurology (2016) updated its evidence-based guidelines on the management of patients with stroke and PFO to address whether percutaneous closure of PFO is superior to medical therapy alone. Following a systematic review of the literature and structured formulation of recommendations, the Academy developed conclusions for the Amplatzer PFO Occluder devices. For patients with cryptogenic stroke and PFO, percutaneous PFO closure with the Amplatzer PFO Occluder:

- "Possibly decreases the risk of recurrent stroke-RD [risk difference] -1.68%, 95% CI [confidence interval] -3.18% to -0.19%;"
- "Possibly increases the risk of new-onset AF [atrial fibrillation]-RD 1.64%, 95% CI 0.07%-3.2% (2 Class I studies; confidence downgraded to low for risk of bias relative to magnitude of effect and imprecision);"
- "Is highly likely to be associated with a procedural complication risk of 3.4%, 95% CI 2.3%-5% (2 Class I studies)."

The guidelines concluded:

"Clinicians should not routinely offer percutaneous PFO closure to patients with cryptogenic ischemic stroke outside of a research setting (Level R). In rare circumstances, such as recurrent strokes despite adequate medical therapy with no other mechanism identified, clinicians may offer the AMPLATZER PFO Occluder if it is available (Level C)."

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Policy # 00016

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American Heart Association and American Stroke Association

The American Heart Association and American Stroke Association (2014) updated its guidelines on the prevention of stroke in patients with ischemic stroke or transient ischemic attack. The guidelines made the following recommendations for device-based closure for PFO:

- "For patients with a cryptogenic ischemic stroke or TIA [transient ischemic attack] and a PFO without evidence for DVT [deep vein thrombosis], available data do not support a benefit for PFO closure (Class III; Level of Evidence A)."
- "In the setting of PFO and DVT, PFO closure by a transcatheter device might be considered, depending on the risk of recurrent DVT (Class IIb; Level of Evidence C)."

American College of Cardiology and American Heart Association

Guidelines issued by the American College of Cardiology and American Heart Association (2008) on the management of congenital heart disease recommended closure of an atrial septal defect by percutaneous or surgical methods for several indications. For sinus venosus, coronary sinus, or primum atrial septal defect, however, surgery rather than percutaneous closure was recommended.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT00738894 ^a	GORE [®] HELEX [®] Septal Occluder / GORE [®] Septal Occluder and Antiplatelet Medical Management for Reduction of Recurrent Stroke or Imaging-	664	Feb 2020

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	Confirmed TIA in Patients With Patent Foramen Ovale (PFO)		
NCT01960491	Prospective Single Center Pilot Clinical Study to Evaluate the Safety and Effectiveness of an Intracardiac Septal Closure Device With Biodegradable Framework in Patients With Clinically Significant Atrial Septum Defect (ASD) or Patent Foramen Ovale (PFO)	15	Jun 2018 (no results posted)
NCT01550588	Device Closure Versus Medical Therapy for Secondary Prevention in Cryptogenic Stroke Patients With High-Risk Patent Foramen Ovale: DEFENSE-PFO	210	Feb 2020
NCT03309332	AMPLATZER PFO Occluder Post Approval Study (PFO PAS)	1214	Dec 2025

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Louisiana

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Louisiana

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04/18/2002 Medical Policy Committee review

06/05/2002 Managed Care Advisory Council approval

06/24/2002 Format revision

03/31/2004 Medical Director review

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Louisiana

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04/20/2004 Medical Policy Committee review. Format revision. Coverage eligibility unchanged.

04/26/2004 Managed Care Advisory Council approval

04/05/2005 Medical Director review

04/19/2005 Medical Policy Committee review. Coverage eligibility unchanged. Investigational statement added to policy to address the use of transcatheter closure devices in situations where patient selection criteria are not met.

05/23/2005 Managed Care Advisory Council approval

04/05/2006 Medical Director review

04/19/2006 Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.

07/07/2006 Format revised. Investigational statements added to clarify coverage eligibility. Coverage eligibility unchanged.

04/04/2007 Medical Director review

04/18/2007 Medical Policy Committee approval. Coverage eligibility unchanged.

04/02/2008 Medical Director review

04/16/2008 Medical Policy Committee approval. No change to coverage eligibility.

04/02/2009 Medical Director review

04/15/2009 Medical Policy Committee approval. Closure of patent foramen ovale using a transcatheter approach is now considered to be investigational.

04/08/2010 Medical Policy Committee approval.

04/21/2010 Medical Policy Implementation Committee approval. No change to coverage.

04/07/2011 Medical Policy Committee approval.

04/13/2011 Medical Policy Implementation Committee approval. No change to coverage.

04/12/2012 Medical Policy Committee review

04/25/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

04/04/2013 Medical Policy Committee review

04/24/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/06/2014 Medical Policy Committee review

03/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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Louisiana

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05/07/2015 Medical Policy Committee review
05/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2016 Medical Policy Committee review
05/18/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017 Medical Policy Committee review
07/19/2017 Medical Policy Implementation Committee approval. Statement, “There are currently no transcatheter devices with the U.S. Food and Drug Administration [FDA] approval or clearance for this indication,” removed from investigational statement for PFO closure devices; policy statements otherwise unchanged.
08/09/2018 Medical Policy Committee review
08/15/2018 Medical Policy Implementation Committee approval. Criteria for PFO revised to track BCBSA.
04/04/2019 Medical Policy Committee review
04/24/2019 Medical Policy Implementation Committee approval. Added the GORE CARDIOFORM Septal Occluder as FDA approved for PFO.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 04/2021

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Louisiana

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Code Type	Code
CPT	93580
HCPCS	C1817
ICD-10 Diagnosis	Q21.1, Q21.2

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
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