Leadless Cardiac Pacemakers

Policy # 00688
Original Effective Date: 01/01/2020
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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 Are 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.*

Based on review of available data, the Company may consider the Micra™‡ VR or Aveir™‡ single-chamber transcatheter pacing system in individuals to be **eligible for coverage**** when both conditions below are met:

1. The individual has high-grade atrioventricular (AV) block (see Policy Guidelines) in the presence of atrial fibrillation or has significant bradycardia and:
    - Normal sinus rhythm with rare episodes of 2° or 3° AV block or sinus arrest (see Policy Guidelines); OR
    - Chronic atrial fibrillation; OR
    - Severe physical disability (see Policy Guidelines).
2. The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:
    - History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection (see Policy Guidelines); or
    - Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis; or
    - Presence of a bioprosthetic tricuspid valve.

Based on review of available data, the Company may consider The Micra™‡ AV single-chamber transcatheter pacing system in individuals to be **eligible for coverage**** when both conditions below are met:

1. The individual has high-grade AV block (see Policy Guidelines) in the presence of atrial fibrillation or has significant bradycardia and:
    - Normal sinus rhythm with rare episodes of (2° or 3°) AV block or sinus arrest (see Policy Guidelines); OR
    - Chronic atrial fibrillation; OR
    - Severe physical disability (see Policy Guidelines); OR
    - There is an indication for VDD pacing and the individual may benefit from maintenance of AV synchronous ventricular pacing (see Policy Guidelines).
2. The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:
    - History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection (see Policy Guidelines); or
    - Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis; or
    - Presence of a bioprosthetic tricuspid valve.

When Services Are Considered Investigational

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

Based on review of available data, the Company considers The Micra™‡ and Aveir™‡ single-chamber transcatheter pacing systems in all other situations in which the above criteria are not met.to be **investigational.***

Based on review of available data, the Company considers the Aveir™‡ DR dual-chamber pacing system to be **investigational.***

Policy Guidelines

Policy criteria are informed by U.S. Food and Drug Administration (FDA) labeled indications for use and clinical input.

Physical Disability and Infection Risk
Clinical input suggests that severe physical disability encompasses a variety of comorbidities where conventional pacemaker placement would confer undue short- or long-term risk or further compromise a limited ability to meet activities of daily living, including compliance with postoperative care instructions. Examples include individuals with short expected lifespan, individuals with end-stage heart, lung, neurologic, or skeletal conditions, and individuals with mental health or developmental challenges.

The 2019 European Heart Rhythm Association (EHRA) international consensus paper on the prevention, diagnosis, and treatment of cardiac implantable electronic device (CIED) infections has been endorsed by the Heart Rhythm Society (HRS) and lists the following non-modifiable patient-related risk factors for CIED infections:

- End-stage renal disease;
- Corticosteroid use;
- Renal failure;
- History of device infection;
- Chronic obstructive pulmonary disease;
- Heart failure (New York Heart Association [NYHA] Class ≥II);
- Malignancy;
- Diabetes mellitus.

Device Contraindications
As per the FDA label, the Aveir Leadless Pacemaker Models LSP112V, LSP201A, and LSP202V are contraindicated in the following situations:

- Use of any pacemaker is contraindicated in individuals with a co-implanted implantable cardioverter-defibrillator because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.
- Single-chamber ventricular demand pacing is relatively contraindicated in individuals who have demonstrated pacemaker syndrome, have retrograde ventriculoatrial conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.
- Programming of rate-responsive pacing is contraindicated in individuals with intolerance of high sensor-driven rates.

- Use is contraindicated in individuals with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.
- Individuals with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use, the recipient should be counseled on the materials contained in the device and a thorough history of allergies must be discussed.

The Aveir Leadless Pacemaker is conditionally safe for use in the magnetic resonance imaging (MRI) environment when used according to the instructions in the MRI-Ready Leadless System Manual (which includes equipment settings, scanning procedures, and a listing of conditionally approved components). Scanning under different conditions may result in severe patient injury, death, or device malfunction.

As per the FDA label, the Micra Model MC1VR01 (Micra VR) and Model MC1AVR1 (Micra AV) pacemakers are contraindicated for individuals who have the following types of devices implanted:

- An implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician
- An implanted inferior vena cava filter
- A mechanical tricuspid valve
- An implanted cardiac device providing active cardiac therapy which may interfere with the sensing performance of the Micra device

As per the FDA label, the Micra Model MC1VR01 and Model MC1AVR1 pacemakers are also contraindicated for individuals who have the following conditions:

- Femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity)
- Morbid obesity that prevents the implanted device to obtain telemetry communication within <12.5 cm (4.9 in)
- Known intolerance to titanium, titanium nitride, parylene C, primer for parylene C, polyether ether ketone, siloxane, nitinol, platinum, iridium, liquid silicone rubber, silicone medical adhesive, and heparin or sensitivity to contrast medical which cannot be adequately premedicated.

As per the FDA label, Micra pacemakers should not be used in individuals for whom a single dose of 1.0 mg dexamethasone acetate cannot be tolerated because the device contains a molded and cured mixture of dexamethasone acetate with the target dosage of 272 μg dexamethasone acetate. It is intended to deliver the steroid to reduce inflammation and fibrosis.

For the MRI contraindications for individuals with a Micra MRI device, refer to the Medtronic MRI Technical Manual.

As per the FDA label, some individuals will not benefit from the AV synchronous (VDD) mode supported by the Micra Model MC1AVR1 pacemaker. Individuals with the following conditions should instead be considered for a dual-chamber transvenous pacing system:

- Sinus node dysfunction;
- High sinus rates requiring atrial tracking;
- Weak atrial contraction;
- Symptoms during loss of atrioventricular (AV) synchrony;
- Frequent premature atrial or ventricular contractions.

High-Grade Atrioventricular Block

Atrioventricular block occurs when there is interference of the electrical signals from the atrium to the ventricle and is categorized based on severity. First degree AV block occurs when signals are transferred more slowly than normal. Second-degree AV block is divided into Type I and Type II. Type I is also called Mobitz Type I or Wenckebach's AV block. There is gradually slower activity which may produce skipped heartbeats. Second-degree Type II is also called Mobitz Type II where more signals fail to reach the ventricles, resulting in a slower and more abnormal heart rhythm. Second-degree AV block can be paroxysmal (not persistent) or permanent. Additionally, high-degree AV block is a form of second-degree AV block in which the conduction ratio is high representing multiple atrial contractions that are not conducting to the ventricle; however, there is still some AV conduction and as such is not a third-degree AV block. Third-degree AV block is a complete block of the electrical signals; while the ventricles contract on their own, the consequences are reduced and irregular heart rate and reduced cardiac output.

Individuals with rare episodes of AV block or sinus arrest generally do not require pacing intervention, although symptomatic individuals might have significant need for pacing. The Micra VR and Aveir devices are indicated when there is infrequent AV block. The Micra AV device is

indicated with infrequent or chronic AV block. These definitions come from the intended use definitions of the devices and clinical input. Note that there is no strict definition of the frequency of episodes or the degree of symptoms.

VDD Pacing
VDD pacing is a pacing mode used in pacemakers whereby sensing occurs in both the atrium and ventricle, with pacing only occurring in the ventricle. The first letter (V) indicates that the Ventricle is the pacing chamber, the second letter (D) indicates that both the atrium and ventricle are the sensing chambers, and the third letter (D) indicates that the mode of operation is dual (inhibited and triggered). Uses of VDD pacing include pacemaker syndrome where there is reduced coordination between the atrial and ventricular contractions resulting in lower cardiac output, and when individuals with an implant have complete AV block with preserved sinus functioning. VDD is used in dual chamber transvenous pacemakers and in single-chamber ventricular pacemakers with leads that float in the atrium for sensing. The Micra AV leadless pacemaker supports VDD pacing.

Atrioventricular Synchrony
Devices that support maintenance of AV synchrony can sense atrial electrical activity and pace the ventricular chamber accordingly. Pacemakers maintaining AV synchrony may lead to less morbidity and mortality than ventricular stimulation alone and reduce the risk of pacemaker syndrome. The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system. The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in individual recipients and may not be predictable prior to implant. The manufacturer cautions that loss of AV synchrony can be caused by the interference of mechanical vibrations stemming from various activities and environments.

Pacemaker Syndrome
In pacemaker syndrome there is reduced coordination between atrial contraction and ventricular contraction, resulting in reduced cardiac output. The syndrome is most commonly seen in the setting of a single-chamber ventricular pacemaker with ventricular sensing and pacing, as with no atrial sensing the ventricles contract at the programmed rate independently from atrial contraction.

Device Retrieval and Replacement
Leadless pacemakers have a limited lifespan. Removal of devices can be complicated by encapsulation due to fibrosis. Devices can instead be deactivated and remain in place, with another

device implanted. Use of deactivated and activated devices might result in electromagnetic interference. Based on bench testing, the current recommendation for device end of service care includes adding a replacement device with or without explantation of the deactivated implant. Explantation of the deactivated implant should be performed by a clinician with expertise in the removal of implanted leads. Use of co-implanted deactivated and activated devices has not been clinically tested, and as such Plans will need to consider the medical necessity of repeat implantation. The Aveir device features helix-based active fixation designed to facilitate device removal with a dedicated retrieval catheter; however, limited data are available on retrieval success rates.

Mechanical Interference
For axillary transvenous pacemakers, there is a concern that leads or the generator could be impacted by the recoil of using a firearm (e.g., rifles or shotguns). Thus leadless cardiac pacemakers can provide an alternative for individuals who suffer lead fracture or malfunction from mechanical stress and may be considered when axillary venous access is present only on a side of the body that would not allow use of equipment producing such mechanical stress (e.g., a firearm).

Background/Overview

Conventional Pacemakers
Pacemakers are intended to be used as a substitute for the heart's intrinsic pacing system to correct cardiac rhythm disorders. By providing an appropriate heart rate and heart rate response, cardiac pacemakers can reestablish effective circulation and more normal hemodynamics that are compromised by a slow heart rate. Pacemakers vary in system complexity and can have multiple functions as a result of the ability to sense and/or stimulate both the atria and the ventricles.

Transvenous pacemakers or pacemakers with leads (hereinafter referred to as conventional pacemakers) consist of 2 components: a pulse generator (ie, battery component) and electrodes (ie, leads). The pulse generator consists of a power supply and electronics that can provide periodic electrical pulses to stimulate the heart. The generator is commonly implanted in the infraclavicular region of the anterior chest wall and placed in a pre-pectoral position; in some cases, a subpectoral position is advantageous. The unit generates an electrical impulse, which is transmitted to the myocardium via the electrodes affixed to the myocardium to sense and pace the heart as needed.

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Conventional pacemakers are also referred to as single-chamber or dual-chamber systems. In single-chamber systems, only 1 lead is placed, typically in the right ventricle. In dual-chamber pacemakers, 2 leads are placed - 1 in the right atrium and the other in the right ventricle. Single-chamber ventricular pacemakers are more common.

Annually, approximately 200,000 pacemakers are implanted in the U.S. and 1 million worldwide. Implantable pacemakers are considered life-sustaining, life-supporting class III devices for patients with a variety of bradyarrhythmias. Pacemaker systems have matured over the years with well-established, acceptable performance standards. As per the U.S. Food and Drug Administration (FDA), the early performance of conventional pacemaker systems from implantation through 60 to 90 days have usually demonstrated acceptable pacing capture thresholds and sensing. Intermediate performance (90 days through more than 5 years) has usually demonstrated the reliability of the pulse generator and lead technology. Chronic performance (5 to 10 years) includes a predictable decline in battery life and mechanical reliability, but a vast majority of patients receive excellent pacing and sensing free of operative or mechanical reliability failures.

Even though the safety profile of conventional pacemakers is excellent, they are associated with complications particularly related to leads. Most safety data on the use of conventional pacemakers come from registries from Europe, particularly from Denmark where all pacemaker implants are recorded in a national registry. It is important to recognize that valid comparison of complication rates is limited by differences in definitions of complications, which results in a wide variance of outcomes, as well as by the large variance in follow-up times, use of single-chamber or dual-chamber systems, and data reported over more than 2 decades. As such, the following data are contemporary and limited to single-chamber systems when reported separately.

In many cases when a conventional pectoral approach is not possible, alternative approaches such as epicardial pacemaker implantation and trans-iliac approaches have been used. Cohen et al (2001) reported outcomes from a retrospective analysis of 123 patients who underwent 207 epicardial lead implantations. Congenital heart disease was present in 103 (84%) of the patients. Epicardial leads were followed for 29 months (range, 1 to 207 months). Lead failure was defined as the need for replacement or abandonment due to pacing or sensing problems, lead fracture, or phrenic/muscle stimulation. The 1-, 2-, and 5-year lead survival was 96%, 90%, and 74%, respectively. Epicardial lead survival in those placed by a subxiphoid approach was 100% at 1 year and at 10 years, by the

sternotomy approach (93.9% at 1 year and 75.9% at 10 years) and lateral thoracotomy approach (94.1% at 1 year and 62.4% at 10 years).

Doll et al (2008) reported results of a randomized controlled trial comparing epicardial implantation versus conventional pacemaker implantation in 80 patients with indications for cardiac resynchronization therapy. The authors reported that the conventional pacemaker group had a significantly shorter intensive care unit stay, less blood loss, and shorter ventilation times while the epicardial group had less exposure to radiation and less use of contrast medium. The left ventricular pacing threshold was similar in the 2 groups at discharge but longer in the epicardial group during follow-up. Adverse events were also similar in the 2 groups. The following events were experienced by 1 (3%) patient each in the epicardial group: pleural puncture, pneumothorax, wound infection, acute respiratory distress syndrome, and hospital mortality.

As a less invasive alternative to the epicardial approach, the trans-iliac approach has also been utilized. Data using trans-iliac approach is limited. Multiple other studies with smaller sample size report a wide range of lead longevity.

Harake et al (2018) reported a retrospective analysis of 5 patients who underwent a transvenous iliac approach (median age, 26.9 years). Pacing indications included AV block in 3 patients and sinus node dysfunction in 2 patients. After a median follow-up of 4.1 years (range, 1.0 to 16.7 years), outcomes were reported for 4 patients. One patient underwent device revision for lead position-related groin discomfort; a second patient developed atrial lead failure following a Maze operation and underwent lead replacement by the iliac approach. One patient underwent heart transplantation 6 months after implant with only partial resolution of pacing-induced cardiomyopathy. Tsutsumi et al (2010) reported a case series of 4 patients from Japan in whom conventional pectoral approach was precluded due to recurrent lead infections (n=1), superior vena cava obstruction following cardiac surgery (n=2) and a postoperative dermal scar (n=1). The mean follow-up was 24 months and the authors concluded the iliac vein approach was satisfactory and less invasive alternative to epicardial lead implantation. However, the authors reported that the incidence of atrial lead dislodgement using this approach in the literature ranged from 7% to 21%. Experts who provided clinical input reported that trans-iliac or surgical epicardial approach requires special expertise and long-term performance is suboptimal.

Table 1. Reported Complication Rates with Conventional Pacemakers

Complications	Rates, %[8,9,10,a]
Traumatic complications	
RV perforation	0.2 to 0.8
RV perforation with tamponade	0.07 to 0.4
Pneumo(hemo)thorax	0.7 to 2.2
Pocket complications	
Including all hematomas, difficult to control bleeding, infection, discomfort, skin erosion	4.75
Including only those requiring invasive correction or reoperation	0.66 to 1.0
Lead-related complications	
Including lead fracture, dislodgement, insulation problem, infection, stimulation threshold problem, diaphragm or pocket stimulation, other	1.6 to 3.8
All system-related infections requiring reoperation or extraction	0.5 to 0.7

Adapted from U.S. Food and Drug Administration executive summary memorandum (2016).
[a] Rates are for new implants only and ventricular single-chamber devices when data were available. Some rates listed in this column are for single- and dual-chamber devices when data were not separated in the publication. Note that Micra transcatheter pacing system is a single-chamber device.
RV: right ventricle.

Potential Advantages of Leadless Cardiac Pacemakers Over Conventional Pacemakers

The potential advantages of leadless pacemakers fall into 3 categories: avoidance of risks associated with intravascular leads in conventional pacemakers, avoidance of risks associated with pocket creation for placement of conventional pacemakers, and an additional option for patients who require a single-chamber pacer.

Lead complications include lead failure, lead fracture, insulation defect, pneumothorax, infections requiring lead extractions and replacements that can result in a torn subclavian vein or the tricuspid valve. In addition, there are risks of venous thrombosis and occlusion of the subclavian system from the leads. Use of a leadless system eliminates such risks with the added advantage that a patient has vascular access preserved for other medical conditions (eg, dialysis, chemotherapy).

Pocket complications include infections, erosions, and pain that can be eliminated with leadless pacemakers. Further, a leadless cardiac pacemaker may be more comfortable and appealing because unlike conventional pacemakers, patients are unable to see or feel the device or have an implant scar on the chest wall.

Leadless pacemakers may also be a better option than surgical endocardial pacemakers for patients with no vascular access due to renal failure or congenital heart disease.

Atrioventricular Synchrony
The Micra AV device supports maintenance of atrioventricular (AV) synchrony by sensing atrial mechanical contraction (A4 signal). Several small-cohort studies have investigated the relationship between parameters (eg, clinical and echocardiographic) and A4 signal amplitude. Briongos-Figuero et al (2023) investigated clinical and echocardiographic predictors of optimal AV synchrony, defined as ≥85% of total cardiac cycles being synchronous, in individuals with successful Micra AV implant (N=43). The authors performed univariate analyses followed by multivariate analysis. They found diabetes and chronic obstructive pulmonary disease to be associated with A4 signal amplitude, however no echocardiographic parameters were associated with A4 signal amplitude. Troisi et al (2024) studied the relationship between echocardiographic parameters and A4 signal amplitude in individuals implanted with Micra AV (N=21). The authors concluded echocardiographic parameters, particularly related to left atrial function, may be related to successful AV synchrony. Kawatani et al (2024) et al studied predictors of AV synchrony in individuals with Micra AV implants (N=50). Participants were stratified into 2 groups, high and low A4 amplitude. In a multivariate analysis, maximum deflection index was the only parameter associated with low A4 amplitude. These studies were exploratory and results among the studies were inclusive. More research is in larger cohort studies is needed to produce more conclusive evidence on parameters that are predictive of AV synchrony.

Battery Life and Device Retrieval
Currently, real-world evidence of long-term battery life for leadless pacemakers is limited. Breeman et al (2023) studied the battery life of the Micra VR after implantation (N=153). The manufacturer's predicted battery life for the Micra VR is 12 years. Using mixed models to assess changes in electrical parameters over time, the authors concluded that for a majority of individuals the expected batter longevity is >8 years. Due to the limited lifespan of leadless pacemakers, they are designed to be retrievable (eg, the helix fixation design of the Aveir devices). However, evidence on the safety and success of device retrieval is limited to case reports.

Anatomical Placement
Li et al (2023) studied different anatomical placements in the ventricular septum of the Micra VR (N=15) and found no impact on safety or electrical characteristics of the device. In a large cohort study in individuals with Micra AV or Micra VR implants (N=358) by Shantha et al (2023), the authors found apical septum placement was associated with a higher risk of pacing-induced cardiomyopathy compared to mid/high septum placement. Larger randomized studies are needed to confirm how anatomical placement of the device impacts safety and effectiveness.

Leadless Cardiac Pacemakers in Clinical Development
Leadless pacemakers are self-contained in a hermetically sealed capsule. The capsule houses a battery and electronics to operate the system. Similar to most pacing leads, the tip of the capsule includes a fixation mechanism and a monolithic controlled-release device. The controlled-release device elutes a glucocorticosteroid to reduce acute inflammation at the implantation site. Leadless pacemakers have rate-responsive functionality, and current device longevity estimates are based on bench data. Estimates have suggested that these devices may last over 10 years, depending on the programmed parameters.

Four systems are currently being evaluated in clinical trials: (1) the Micra Transcatheter Pacing System (Medtronic), (2) the Aveir VR Leadless Pacemaker (Abbott; formerly Nanostim, St. Jude Medical); (3) the Aveir DR Dual Chamber Leadless Pacemaker System (Abbott); and (4) the WiCS Wireless Cardiac Stimulation System (EBR Systems). The first 3 devices are free-standing capsule-sized devices that are delivered via femoral venous access using a steerable delivery sheath. However, the fixing mechanism differs between the Micra and Aveir devices. In the Micra Transcatheter Pacing System, the fixation system consists of 4 self-expanding nitinol tines, which anchor into the myocardium; for the Aveir devices, there is a screw-in helix that penetrates into the

myocardium. In the Micra and Aveir devices, the cathode is steroid eluting and delivers pacing current; the anode is located in a titanium case. The fourth device, WiCS system differs from the other devices; this system requires implanting a pulse generator subcutaneously near the heart, which then wirelessly transmits ultrasound energy to a receiver electrode implanted in the left ventricle. The receiver electrode converts the ultrasound energy and delivers electrical stimulation to the heart sufficient to pace the left ventricle synchronously with the right.

Of these 4, only the Micra and Aveir single-chamber transcatheter pacing systems and the Aveir dual-chamber transcatheter pacing system are approved by the FDA and commercially available in the U.S. Multiple clinical studies of the Aveir predecessor device, Nanostim, have been published but trials have been halted due to the migration of the docking button in the device and premature battery depletion. These issues have since been addressed with the Aveir device.

The Micra is about 25.9 mm in length and introduced using a 23 French catheter via the femoral vein to the right ventricle. It weighs about 1.75 grams and has an accelerometer-based rate response.

The Aveir VR is about 42 mm in length and introduced using an 25 French catheter to the right ventricle. It also weighs about 3 grams and uses a temperature-based rate response sensor.

The atrial Aveir DR is about 32.3 mm in length and weighs about 2.1 grams. The ventricular Aveir DR is about 38.0 mm in length and weighs about 2.4 grams. Both are introduced using a 25 French catheter. The system uses a temperature-based rate response.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In April 2016, the Micra transcatheter pacing system (Medtronic) was approved by the FDA through the premarket approval (PMA) process (PMA number: P150033) for use in patients who have experienced 1 or more of the following conditions:

- symptomatic paroxysmal or permanent high-grade arteriovenous block in the presence of atrial fibrillation
- paroxysmal or permanent high-grade arteriovenous block in the absence of atrial fibrillation, as an alternative to dual-chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy

- symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual-chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.

In January 2020, the Micra AV Transcatheter Pacing System Model MC1AVR1 and Application Software Model SW044 were approved as a PMA supplement (S061) to the Micra system described above. The Micra AV includes an enhanced algorithm to provide AV synchronous pacing.

In November 2021, the FDA issued a letter to health care providers regarding the risk of major complications related to cardiac perforation during implantation of leadless pacing systems. Specifically, the FDA states that "real-world use suggests that cardiac perforations associated with Micra leadless pacemakers are more likely to be associated with serious complications, such as cardiac tamponade or death, than with traditional pacemakers." This letter has been removed from the FDA website as of April 2024.

In March 2022, the Aveir VR Leadless Pacemaker was approved by the FDA through the premarket approval process (PMA number: P150035) for use in individuals with bradycardia and:

- normal sinus rhythm with only rare episodes of atrioventricular block or sinus arrest;
- chronic atrial fibrillation;
- severe physical disability.

Rate-Modulated Pacing is indicated for individuals with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

In June 2023, a premarket approval application supplement with expanded indications to include dual-chamber pacing with the Aveir DR Leadless System was approved by the FDA (PMA number: P150035) for use in individuals with 1 or more of the following permanent conditions:

- Snycope;
- Pre-syncope;
- Fatigue;
- Disorientation.

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Rate-Modulated Pacing is indicated for individuals with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.
Dual-Chamber Pacing is indicated for individuals exhibiting:

- Sick sinus syndrome;
- Chronic, symptomatic second- and third-degree atrioventricular block;
- Recurrent Adams-Stokes syndrome;
- Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Pacemakers are intended to be used as a substitute for the heart's intrinsic pacing system to correct cardiac rhythm disorders. Conventional pacemakers consist of 2 components: a pulse generator and electrodes (or leads). Pacemakers are considered life-sustaining, life-supporting class III devices for individuals with a variety of bradyarrhythmias. Even though the efficacy and safety profile of conventional pacemakers are excellent, in a small proportion of individuals, they may result in lead complications and the requirement for a surgical pocket. Further, some individuals are medically ineligible for conventional pacemakers due to lack of venous access and recurrent infection. Leadless pacemakers are single-unit devices that are implanted in the heart via femoral access, thereby eliminating the potential for complications as a result of leads and surgical pocket. The Micra and Aveir single-chamber transcatheter pacing systems and the Aveir dual-chamber pacing system are the only commercially available leadless pacemakers in the U.S. approved by the U.S. Food and Drug Administration.

Summary of Evidence

For individuals with a guidelines-based indication for a ventricular pacing system who are medically eligible for a conventional pacing system who receive a single-chamber transcatheter pacing system, the evidence includes a systematic review, pivotal prospective cohort studies, a post approval

prospective cohort study, a Medicare registry, and a retrospective US Food and Drug Administration (FDA) database analysis. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Results at 6 months and 1 year for the Micra pivotal study reported high procedural success (>99%) and device effectiveness (pacing capture threshold met in 98% of patients). Most of the system- or procedure-related complications occurred within 30 days. At 1 year, the incidence of major complications did not increase substantially from 6 months (3.5% at 6 months vs. 4% at 1 year). Results of the Micra post approval study were consistent with the pivotal study and showed a lower incidence of major complications up to 30 days post implantation as well as 1 year (1.5% and 2.7%, respectively). In both studies, the point estimates of major complications were lower than the pooled estimates from 6 studies of conventional pacemakers used as a historical comparator. While Micra device eliminates lead- and surgical pocket-related complications, its use can result in potentially more serious complications related to implantation and release of the device (traumatic cardiac injury) and less serious complications related to the femoral access site (groin hematomas, access site bleeding). Initial data from a Medicare registry found a significantly higher rate of pericardial effusion and/or perforation within 30 days in patients with the leadless Micra pacemaker compared to patients who received a transvenous device; however, overall 6-month complication rates were significantly lower in the Micra group in the adjusted analysis (p=.02). In a real-world study of Medicare patients, the Micra device was associated with a 41% lower rate of reinterventions and a 32% lower rate of chronic complications compared with transvenous pacing, with no significant difference in adjusted all-cause mortality at 3 years despite the higher comorbidity index for patients implanted with a Micra device. However, patients receiving the Micra device experienced significantly more other complications, driven by higher rates of pericarditis. No significant differences were noted in the composite endpoint of time to heart failure hospitalization or death for the full cohort (p=.28) or the subgroup without a history of heart failure (p=.98). It is also unclear whether all patients were considered medically eligible for a conventional pacing system. A single-arm study of the Micra AV device reported that 85.2% of individuals with complete atrioventricular (AV) block and normal sinus rhythm successfully achieved a >70% resting AV synchrony (AVS) rate at 1 month postimplant and that AVS rates could be further enhanced with additional device programming. However, clinically meaningful rates of AVS are unknown. Longer-term device characterization is planned in the Micra AV Post-Approval Registry through 3 years. The Aveir pivotal prospective cohort study primary safety and efficacy outcomes at 6 weeks exceeded performance goals for complication-free rate and composite success rate (96.0% and 95.9%, respectively). Results at 6 months were similar and at 1 year were 93.2% and 91.5%, respectively. Incidence of major complications at 1 year was 6.7% compared to 4.0% in

the Micra pivotal trial. The 2-year survival estimate of 85.3% is based on Phase 1 performance with the predecessor Nanostim device. Considerable uncertainties and unknowns remain in terms of the durability of the devices and device end-of-life issues. Early and limited experience with the Micra device has suggested that retrieval of these devices is unlikely because in due course, the device will be encapsulated. There are limited data on device-device interactions (both electrical and mechanical), which may occur when there is a deactivated Micra device alongside another leadless pacemaker or when a leadless pacemaker and transvenous device are both present. Although the Aveir device is specifically designed to be retrieved when therapy needs evolve or the device needs to be replaced, limited data are available on retrieval outcomes. While the current evidence is encouraging, overall benefit with the broad use of FDA-approved single-chamber transcatheter pacing systems compared with conventional pacemakers has not been shown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a single-chamber transcatheter pacing system, the evidence includes subgroup analysis of a pivotal prospective cohort study and a post approval prospective cohort study for the Micra device. It is unclear whether the Aveir pivotal study enrolled patients medically ineligible for a conventional pacing system. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Information on the outcomes in the subgroup of patients from the post approval study showed that the Micra device was successfully implanted in 98% to 99% of cases, and safety outcomes were similar to the original cohort. Even though the evidence is limited and long-term effectiveness and safety are unknown, the short-term benefits may outweigh the risks because the complex trade-off of adverse events for these devices needs to be assessed in the context of the life-saving potential of pacing systems for patients ineligible for conventional pacing systems. There are little data available regarding outcomes associated with other alternatives to conventional pacemaker systems such as epicardial leads or transiliac placement. Epicardial leads are most relevant for the patient who is already going to have a thoracotomy for treatment of their underlying condition (e.g., congenital heart disease). Epicardial leads are associated with a longer intensive care unit stay, more blood loss, and longer ventilation times compared to conventional pacemaker systems. The evidence for transiliac placement is limited to small case series and the incidence of atrial lead dislodgement using this approach in the literature ranged from 7% to 21%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Leadless Cardiac Pacemakers

Policy # 00688
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For individuals with a guidelines-based indication for a dual-chamber pacing system who are medically eligible for a conventional pacing system who receive a dual-chamber leadless pacing system, the evidence includes a pivotal prospective single cohort study. Relevant outcomes are freedom from complications and adequate atrial capture threshold and sensing amplitude. Results from 3 months and 6 months or the pivotal study reported freedom from complications in 90.3% and 89.1% of individuals, respectively, and adequate atrial capture threshold and sensing amplitude in 90.2% and 90.8% of individuals, respectively. Acute and long-term events will be captured in a post approval study through 9 years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a guidelines-based indication for a dual-chamber pacing system who are medically ineligible for a conventional pacing system who receive a dual-chamber leadless pacing system, no evidence was identified that exclusively enrolled individuals who were medically ineligible for a conventional pacing system. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
2023 Input
Clinical input was sought to help determine whether the use of an Aveir or Micra AV transcatheter pacing system for an individual with a guidelines-based indication for a ventricular pacing system would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice depending on individual medical eligibility for a conventional pacing system. In response to requests, clinical input was received from 2 respondents, including 1 specialty society-level response including physicians with academic medical center affiliation and 1 physician-level response with academic affiliation identified through a specialty society.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a Micra AV or Aveir transcatheter pacing system, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected individuals when both conditions below are met:

- The individual has significant bradycardia and:

  - Normal sinus rhythm with rare episodes of 2° or 3° atrioventricular (AV) block or sinus arrest and severe physical disability or short expected lifespan; OR
  - Chronic atrial fibrillation.
- The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:
  - History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection;
  - Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins, or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis;
  - Presence of a bioprosthetic tricuspid valve.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically eligible for a conventional pacing system who receive a Micra AV or Aveir transcatheter pacing system, clinical input indicates this use is consistent with generally accepted medical practice but reports mixed support that this use provides a clinically meaningful improvement in net health outcomes.

2019 Input
Clinical input was sought to help determine whether the use of leadless cardiac pacemakers for individuals with a guidelines-based indication for a ventricular pacing system would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 1 specialty society-level response and 1 physician-level response identified through specialty societies including physicians with academic medical center affiliations.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a Micra transcatheter pacing system, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected individuals when both conditions below are met:

- The individual has symptomatic paroxysmal or permanent high-grade arteriovenous block or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses).

- The individual has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:
    - History of an endovascular or CIED infection or who are very high-risk for infection
    - Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis
    - Presence of a bioprosthetic tricuspid valve

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.

2023 Input

Clinical input was sought to help determine whether the use of an Aveir or Micra AV transcatheter pacing system for an individual with a guidelines-based indication for a ventricular pacing system would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice depending on individual medical eligibility for a conventional pacing system. In response to requests, clinical input was received from 2 respondents, including 1 specialty society-level response including physicians with academic medical center affiliation and 1 physician-level response with academic affiliation identified through a specialty society.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a Micra AV or Aveir transcatheter pacing system, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients when both conditions below are met:

- The patient has significant bradycardia and:

  - Normal sinus rhythm with rare episodes of 2° or 3° atrioventricular (AV) block or sinus arrest and severe physical disability or short expected lifespan; OR
  - Chronic atrial fibrillation.
- The patient has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:
  - History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection;
  - Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins, or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis;
  - Presence of a bioprosthetic tricuspid valve.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically eligible for a conventional pacing system who receive a Micra AV or Aveir transcatheter pacing system, clinical input indicates this use is consistent with generally accepted medical practice but reports mixed support that this use provides a clinically meaningful improvement in net health outcomes.

2019 Input
Clinical input was sought to help determine whether the use of leadless cardiac pacemakers for individuals with a guidelines-based indication for a ventricular pacing system would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 1 specialty society-level response and 1 physician-level response identified through specialty societies including physicians with academic medical center affiliations.

For individuals with a guidelines-based indication for a ventricular pacing system who are medically ineligible for a conventional pacing system who receive a Micra transcatheter pacing system, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients when both conditions below are met:

- The patient has symptomatic paroxysmal or permanent high-grade arteriovenous block or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses).

- The patient has a significant contraindication precluding placement of conventional single-chamber ventricular pacemaker leads such as any of the following:
    - History of an endovascular or CIED infection or who are very high-risk for infection
    - Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an arteriovenous fistula for hemodialysis
    - Presence of a bioprosthetic tricuspid valve

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology Foundation et al
In 2012, The American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and the Heart Rhythm Society (HRS) issued a focused update of the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities. These guidelines included recommendations regarding permanent pacemaker implantation in individuals with class I or II indications.

Heart Rhythm Society
In 2020, HRS, along with the International Society for Cardiovascular Infectious Diseases (ISCVID) and several other Asian, European and Latin American societies, endorsed the European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections. The consensus states that for patients at high risk of device-related infections, avoiding a transvenous system and implanting an epicardial system may be preferential. It makes the following statements regarding leadless pacemakers:

- 'There is hope that 'leadless' pacemakers will be less prone to infection and can be used in a similar manner [as epicardial systems] in high-risk patients.'

- 'In selected high-risk patients, the risk of infection with leadless pacemakers appears low. The device also seems safe and feasible in patients with pre-existing [cardiovascular implantable electronic device] infection and after extraction of infected leads.'

National Institute for Health and Care Excellence
In 2018, the NICE issued evidence-based recommendations on leadless cardiac pacemaker implantation for adults with bradyarrhythmias. The guidance states that the evidence "on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well-recognised complications. The evidence on efficacy is inadequate in quantity and quality:

- For people who can have conventional cardiac pacemaker implantation, leadless pacemakers should only be used in the context of research;
- For people in whom a conventional cardiac pacemaker implantation is contraindicated following a careful risk assessment by a multidisciplinary team, leadless cardiac pacemakers should only be used with special arrangements for clinical governance, consent and audit or research."

The guidance is awaiting development as of April 2023 with expected publication in June 2024.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The Centers for Medicare & Medicaid (CMS) cover leadless pacemakers under coverage with evidence development criteria when procedures are performed in prospective longitudinal studies approved by the U.S. Food and Drug Administration (FDA) using "leadless pacemakers...in accordance with the FDA approved label for devices that have either:

- An associated ongoing FDA approved post-approval study; or
- Completed an FDA post-approval study.

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address the following research questions:

- What are the peri-procedural and post-procedural complications of leadless pacemakers?
- What are the long term outcomes of leadless pacemakers?

- What are the effects of patient characteristics (age, gender, comorbidities) on the use and health effects of leadless pacemakers?"

The following 6 studies are currently approved by CMS:

1. Aveir AR Coverage With Evidence Development (CED) Study (ARRIVE) (NCT06100770); CMS approval date: 01/18/24;
2. Aveir DR CED Study (NCT05932602); CMS approval date: 10/31/23;
3. Aveir VR Coverage With Evidence Development Post-Approval Study (NCT05336877); CMS approval date: 06/21/22;
4. Effectiveness of the EMPOWER™‡ Modular Pacing System and EMBLEM™‡ Subcutaneous ICD to Communicate Antitachycardia Pacing (NCT04798768); CMS approval date: 01/20/22;
5. The LEADLESS II IDE Study (Phase II): A Safety and Effectiveness Trial for a Leadless Pacemaker System (NCT04559945); CMS approval date: 03/16/21;
6. Longitudinal Coverage with Evidence Development Study on Micra AV Leadless Pacemakers (Micra AV CED) (NCT04235491); CMS approval date: 02/05/20;
7. The Micra CED Study (NCT03039712); CMS approval date: 03/09/17; and
8. Micra Transcatheter Pacing System Post-Approval Registry (NCT02536118); CMS approval date: 02/09/17.

See Table 1 for additional details.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06100770[a,b]	Aveir AR Coverage With Evidence Development (CED) Study	586	Jan 2031 (ongoing)

NCT05932602[a,b]	The AVEIR DR Coverage With Evidence Development (DRIVE) Study	2812	Oct 2025 (ongoing)
NCT05935007[a]	Aveir Dual-Chamber Leadless Pacemaker Real-World Evidence Post-Approval Study	1805	Jan 2030 (ongoing)
NCT05856799	Danish Randomized Trial on VDD Leadless Atrial Tracking With Micra™‡ AV Transcatheter Pacing System vs Transvenous DDD Pacing in Elderly Patients With AV-block	80	Aug 2025 (ongoing)
NCT05817695	Effect of Different Pacing Sites on Cardiac Synchronization and Tricuspid Regurgitation After Leadless Pacemaker Implantation	40	May 2023 (ongoing)
NCT04559945[a,b]	The LEADLESS II IDE Study (Phase II): A Safety and Effectiveness Trial for a Leadless Pacemaker System	326	Aug 2023 (ongoing)
NCT05528029	International Leadless Pacemaker Registry (i-LEAPER)	2000	Dec 2024 (recruiting)
NCT04253184[a]	Micra AV Transcatheter Pacing System Post-Approval Registry (Micra AV PAS)	802	Apr 2025 (ongoing)
NCT05498376	The Leadless AV Versus DDD Pacing Study: A Randomized Controlled Single-center Trial on Leadless Versus Conventional Cardiac Dual-chamber Pacing (LEAVE DDD)	100	Feb 2026 (recruiting)
NCT04235491[a,b]	Longitudinal Coverage With Evidence Development Study on Micra AV Leadless Pacemakers (Micra AV CED)	37000	Jun 2027 (ongoing)
NCT04051814	A Retrospective Trial to Evaluate the Micra Pacemaker	500	May 2025 (recruiting)

NCT03039712[a,b]	Longitudinal Coverage With Evidence Development Study on Micra Leadless Pacemakers (Micra CED)	37000	Jun 2027 (ongoing)
NCT04926792	Taiwan Registry for Leadless Pacemaker	300	Jun 2025 (not yet recruiting)
NCT05252702[a]	Aveir Dual-Chamber Leadless i2i IDE Study	550	Nov 2025 (recruiting)
NCT02536118[a,b]	Micra Transcatheter Pacing System Post-Approval Registry	3100	Aug 2026 (ongoing)
NCT05336877[a,b]	Aveir Single-Chamber Leadless Pacemaker Coverage With Evidence Development (ACED) Post-Approval Study	8744	Jan 2028 (recruiting)
NCT04798768[a,b]	Effectiveness of the EMPOWER™‡ Modular Pacing System and EMBLEM™‡ Subcutaneous ICD to Communicate Antitachycardia Pacing (MODULAR ATP)	300	Dec 2030 (recruiting)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.
[b] Denotes CMS-approved study.

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Leadless Cardiac Pacemakers

Policy # 00688
Original Effective Date: 01/01/2020
Current Effective Date: 08/12/2024

Policy History

Original Effective Date: 01/01/2020
Current Effective Date: 08/12/2024

10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. New policy.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. No change to coverage.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. No change to coverage.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. No change to coverage.
06/06/2023	Coding update
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible for coverage for the Micra VR single-chamber transcatheter pacing system and The Micra AV single-chamber transcatheter pacing system with criteria. Added investigational statement for the Aveir single-chamber transcatheter pacing system.
12/13/2023	Coding update
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Investigational policy statement added to new indications for Aveir DR dual chamber leadless pacemaker.Added coverage for single chamber Aveir.

Next Scheduled Review Date: 07/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T 0804T 33274, 33275 Add codes effective 01/01/2024: 0823T, 0824T, 0825T, 0826T Delete codes effective 08/01/2024: 0823T, 0824T, 0825T, 0826T
HCPCS	Add code effective 07/01/2024: C1605
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company

recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.