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PLANS IN SCOPE

Aspirus Health Plan

BACKGROUND & PURPOSE:

Implantable surgical mesh is a medical device used to reinforce weakened or damaged tissue. Leadless cardiac pacemakers are intracardiac devices used to treat symptomatic bradyarrhythmias. These systems eliminate the need for transvenous leads and subcutaneous generator pockets.

Conventional transvenous pacemakers remain the standard of care due to established safety, effectiveness, and long-term durability. Leadless pacemakers are considered an alternative option for select patients when transvenous systems are not appropriate or pose increased risk.

The purpose of this policy is to:

- Define when leadless pacemakers are medically necessary
- Distinguish appropriate use from experimental or non-covered scenarios
- Ensure consistent, evidence-aligned utilization
- Clarify that coding does not determine coverage

This policy does not endorse specific devices or manufacturers and defers clinical decision-making to provider judgment and specialty guidelines.

COVERAGE INDICATIONS:

Medically Necessary Use

Leadless pacemakers may be considered medically necessary when ALL of the following criteria are met:

1. Documented Clinical Indication
 - Symptomatic bradyarrhythmia, including:
 - Sinus node dysfunction
 - High-grade atrioventricular (AV) block
 - Symptomatic bradycardia requiring pacing
2. Device Appropriateness
 - Clinical condition aligns with device capabilities
 - Atrial pacing is not required unless clearly justified
3. Contraindication or Elevated Risk for Transvenous Pacemaker
EITHER:
 - A. One Major Contraindication
 - Prior cardiac implantable electronic device (CIED) infection requiring extraction
 - Active infection or high infection risk
 - Central venous occlusion or lack of venous access
 - Prosthetic or mechanical tricuspid valve
 - Anatomical limitation preventing safe lead placement
 - Active venous thrombosis affecting device delivery
 - OR
 - B. Two Moderate Risk Factors
 - Venous stenosis or compromised access
 - Recurrent venous thromboembolism or hypercoagulable state
 - Need to preserve venous access (e.g., dialysis planning)
 - Prior lead complications or high lead burden
 - Increased infection risk
 - Immunocompromised state
 - History of multiple prior device procedures

Device Specific Use

Single-Chamber Systems

- Covered when base criteria are met
- No requirement for atrial pacing unless justified

AV-Synchronous Systems

- Covered when:
 - Base criteria are met
 - Sinus rhythm is present

- Clinical need for AV synchrony is documented

Dual-Chamber Systems (Restricted)

- Covered only when:
 - Base criteria are met (preferably with a major contraindication)
 - Clear indication for dual-chamber pacing exists
 - Transvenous system is not clinically appropriate
- Not medically necessary when transvenous pacing remains appropriate

Experimental/ Investigational Use

- Leadless pacemakers are considered experimental or investigational when:
 - Used without a valid pacing indication
 - Used as first-line therapy in standard-risk patients
 - Used for convenience or preference
 - Used in non–FDA-approved indications
- Used in clinical scenarios requiring:
 - Cardiac resynchronization therapy (CRT)
 - Implantable cardioverter-defibrillator (ICD) functionality
 - Multi-lead pacing beyond device capability

Services determined to be experimental or investigational are not covered.

Exclusions

The following are not covered:

- Absence of a documented pacing indication
- Lack of contraindication or elevated risk
- Use in conditions requiring CRT, ICD, or multi-lead pacing
- Combination use with other implantable cardiac systems
- Atrial-only leadless pacing
- Use outside FDA-approved indications

LIMITATIONS

Coverage is subject to the following:

- No demonstrated mortality benefit compared to transvenous systems
- Limited long-term data for newer technologies (e.g., dual-chamber systems)
- Uncertainty regarding:
 - Device longevity
 - Retrieval and replacement
- Femoral access requirements may limit use (e.g., inferior vena cava filter)

Selection of device type and approach is delegated to the treating provider and should consider:

- Evidence maturity
- Patient-specific clinical factors
- Professional judgment

MEDICAL RECORDS DOCUMENTATION

Benefit coverage is determined based on member-specific plan information and applicable laws. Documentation must support all coverage criteria and may include:

- Symptomatic clinical indication
- Device type and clinical rationale
- Contraindication(s) or risk factors
- Evidence that transvenous pacing is not appropriate or higher risk
- Device-specific justification (if applicable)

Submission of records does not guarantee coverage.

DEFINITIONS

Leadless Pacemaker: Intracardiac pacing device without transvenous leads

Transvenous Pacemaker: Traditional lead-based pacing system

CIED: Cardiac implantable electronic device

AV Synchrony: Coordinated atrial and ventricular contraction

Contraindication: Clinical factor limiting safe use of standard therapy

APPLICABLE CODES

Note: Codes are provided for reference only. Coverage is determined by clinical criteria above.

CPT Codes

- 33274 – Leadless pacemaker implantation
- 33275 – Leadless pacemaker removal

Category III Codes

- 0795T–0804T (dual chamber)
- 0823T–0826T (atrial systems)

HCPCS Codes

- C1605- Leadless pacemaker (dual chamber)
- C1740- Leadless pacemaker (left ventricle)

POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
09/09/26	Initial Policy Development	Optum Medical and Pharmacy Subcommittee

REFERENCES:

Guidelines & Consensus Statements

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Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).