Abbott

Cardiac Rhythm Management

AVEIR™ LEADLESS PACEMAKERS (LP) COVERAGE WITH DEVELOPEMENT FAQ's

Effective Dates

Inpatient Rates	Oct 1, 2023 - Sept 30, 2024
Outpatient & Physician Rates	Jan 1, 2024 - Dec 31, 2024

TERMS AND CONDITIONS

All content herein may be based upon several sources, included but not limited to primary sources, scientific literature, commercially available data sets, customer supplied information, and external sources.
Estimates shown are for illustrative purposes only. This content is not intended for any other purpose.

It should be noted that there are usually differences between economic modelling actual results. Abbott does not take responsibility for any such discrepancies. There is no guarantee of any potential economic outcome, including payment, cost savings, or procedure volume. Economic outcomes are dependent on many factors and will vary.

Certain Maryland hospitals paid under Maryland Waiver provisions using All Patient Refined Diagnosis Related Group (APR-DRG) are excluded from payment under the Medicare Inpatient Prospective Payment System (IPPS).

Reimbursement Calculators should not be provided at no charge to actively licensed Healthcare Professionals (HCPs) who regularly practice in Vermont.

This information is not to be distributed to third parties.

COVERAGE WITH EVIDENCE DEVELOPMENT FREQUENTLY ASKED QUESTIONS (FAQs)

These FAQs are intended for general informational purposes only to help provide information that may assist in understanding of Medicare's Coverage with Evidence Development (CED) Study policy relating to the AVEIR™ AR Right Atrial Leadless Pacemaker System when used in accordance with its FDA approved labeling. Physician is responsible for determining whether the procedure meets the criteria for coverage and confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete and supported by documentation in the patient's medical record.

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Is AVEIR™AR Right Atrial LP covered by CMS? The Centers for Medicare and Medicaid has a National Coverage Determination for leadless pacemakers, Policy 20.8.4. This is a CED policy that is applicable to all leadless pacemaker procedures for all Medicare beneficiaries, including Medicare fee-for-service and Medicare Advantage. As part of the coverage criteria, CMS requires all patients to be included in a CMS approved study. Abbott has a real-world study for AVEIR™ AR Right Atrial LP, AVEIR™ AR Right Atrial LP CED study to meet these coverage requirements and has obtained approval. The AVEIR™ AR Right Atrial LP CED study has a clinical trial number to be utilized only for patients indicated for AVEIR™ AR Right Atrial LP.	Medicare coverage is now available for AVEIR™ AR Leadless Pacemaker implant procedures for any Medicare beneficiaries indicated for a leadless pacemaker and included in the AVEIR™ AR Right Atrial LP CED study.
How do I report that the AVEIR™ AR Right Atrial LP patient is part of a CMS approved study? Under the CMS CED policy, CMS requires that you report a National Clinical Trial number on the applicable claim. The NCT number for the AVEIR™ AR Right Atrial LP CED study is NCT06100770.	The inclusion of the AVEIR™ AR Right Atrial LP CED study NCT number (NCT 06100770) is required for CMS coverage purposes.
Is the AVEIR™ AR Right Atrial LP CED study the same as AVEIR™ AR's Leadless Pacemaker FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The AVEIR™ AR Right Atrial LP CED study study is a CMS approved CED Study that is required for CMS coverage. The PAS is a predetermined group of sites participating in a registry that was established to meet post approval FDA requirements, independent from the CED study.	The NCT number (NCT 06100770) assigned to the AVEIR™ AR Right Atrial LP CED study is unique to the AVEIR™ AR Leadless Pacemaker. The inclusion of the unique AVEIR™ AR Right Atrial LP CED study NCT number (NCT 006100770) is a requirement for CMS coverage for AVEIR™ AR LP procedures.

COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Does my hospital's Institutional Review Board (IRB) need to approve the AVEIR™ AR Right Atrial LP CED study? The AVEIR™ AR Right Atrial LP CED study involves CMS claims or clinical data that are collected in the context of healthcare delivery, and the data collection involves no direct patient contact and will not influence the care a patient receives during routine interactions with the healthcare system. Therefore, IRB approvals are unlikely to be required by the hospital. Abbott, being the main entity in the AVEIR™ AR Right Atrial LP CED study study, has requested and been granted a waiver of informed consent and a HIPAA waiver from Western IRB. The Council for International Organizations of Medical Sciences (CIOMS), in a publication issued jointly with the World Health Organization (WHO), has stated that a waiver of the informed consent requirement may be granted by an IRB, "when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records)". (Data on file at Abbott)	It is unlikely an IRB approval would be required by the hospital. We recommend that you review the hospital's policies and procedures along with this information.
Is the AVEIR™ AR Right Atrial LP CED study NCT number (NCT 06100770) required to be reported on private payer or Medicaid patient claims for coverage? The NCT number (NCT 06100770) does not apply to private payers or Medicaid. The AVEIR™ AR Right Atrial LP CED study NCT number (NCT 06100770) is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.	AVEIR™ AR Right Atrial LP CED study NCT number (NCT 06100770) is only required in connection with claims for coverage for Medicare beneficiaries.
Who can I contact if I have more questions? Contact the Health Economics team at Abbott: LeadlessReimbursement@abbott.com or you can contact the reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430	Please contact the Abbott team using these channels when needed.

COVERAGE WITH EVIDENCE DEVELOPMENT FREQUENTLY ASKED QUESTIONS (FAQs)

These FAQs are intended for general informational purposes only to help provide information that may assist in understanding of Medicare's Coverage with Evidence Development (CED) Study policy relating to the AVEIR™ VR Ventricular Leadless Pacemaker System when used in accordance with its FDA approved labeling. Physician is responsible for determining whether the procedure meets the criteria for coverage and confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete and supported by documentation in the patient's medical record.

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Is AVEIR™ VR Ventricular LP covered by CMS? The Centers for Medicare and Medicaid has a National Coverage Determination for leadless pacemakers, Policy 20.8.4. This is a CED policy that is applicable to all leadless pacemaker procedures for all Medicare beneficiaries, including Medicare fee-for-service and Medicare Advantage. As part of the coverage criteria, CMS requires all patients to be included in a CMS approved study. Abbott has a real-world study for AVEIR™ VR Ventricular LP, AVEIR™ VR Ventricular LP CED study to meet these coverage requirements and has obtained approval. The AVEIR™ VR Ventricular LP CED study has a clinical trial number to be utilized only for patients indicated for AVEIR™ VR Ventricular LP.	Medicare coverage is now available for AVEIR™ VR Leadless Pacemaker implant procedures for any Medicare beneficiaries indicated for a leadless pacemaker and included in the AVEIR™ VR Ventricular LP CED study.
How do I report that the AVEIR™ VR Ventricular LP patient is part of a CMS approved study? Under the CMS CED policy, CMS requires that you report a National Clinical Trial number on the applicable claim. The NCT number for the AVEIR™ VR Ventricular LP CED study is NCT05336877.	The inclusion of the AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is required for CMS coverage purposes.
Is the AVEIR™ VR Ventricular LP CED study study the same as AVEIR™ VR's Leadless Pacemaker FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The AVEIR™ VR Ventricular LP CED study study is a CMS approved CED Study that is required for CMS coverage. The PAS is a predetermined group of sites participating in a registry that was established to meet post approval FDA requirements, independent from the CED study.	The NCT number (NCT 05336877) assigned to the AVEIR™ VR Ventricular LP CED study is unique to the AVEIR™ VR Leadless Pacemaker. The inclusion of the unique AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is a requirement for CMS coverage for AVEIR™ VR LP procedures.

COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Does my hospital's Institutional Review Board (IRB) need to approve the AVEIR™ VR Ventricular LP CED study? The AVEIR™ VR Ventricular LP CED study involves CMS claims or clinical data that are collected in the context of healthcare delivery, and the data collection involves no direct patient contact and will not influence the care a patient receives during routine interactions with the healthcare system. Therefore, IRB approvals are unlikely to be required by the hospital. Abbott, being the main entity in the AVEIR™ VR Ventricular LP CED study study, has requested and been granted a waiver of informed consent and a HIPAA waiver from Western IRB. The Council for International Organizations of Medical Sciences (CIOMS), in a publication issued jointly with the World Health Organization (WHO), has stated that a waiver of the informed consent requirement may be granted by an IRB, "when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records)". (Data on file at Abbott)	It is unlikely an IRB approval would be required by the hospital. We recommend that you review the hospital's policies and procedures along with this information.
Is the AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) required to be reported on private payer or Medicaid patient claims for coverage? The NCT number (NCT 05336877) does not apply to private payers or Medicaid. The AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.	AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is only required in connection with claims for coverage for Medicare beneficiaries.
Who can I contact if I have more questions? Contact the Health Economics team at Abbott: LeadlessReimbursement@abbott.com or you can contact the reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430	AVEIR™ VR Ventricular LP CED study NCT number (NCT 05336877) is only required in connection with claims for coverage for Medicare beneficiaries.

COVERAGE WITH EVIDENCE DEVELOPMENT FREQUENTLY ASKED QUESTIONS (FAQs)

These FAQs are intended for general informational purposes only to help provide information that may assist in understanding of Medicare's Coverage with Evidence Development (CED) Study policy relating to the AVEIR™ DR Dual Chamber LP when used in accordance with its FDA approved labeling. Physician is responsible for determining whether the procedure meets the criteria for coverage and confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete and supported by documentation in the patient's medical record.

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Is AVEIR™ DR Dual Chamber LP covered by CMS? The Centers for Medicare and Medicaid has a National Coverage Determination for leadless pacemakers, Policy 20.8.4. This is a CED policy that is applicable to all leadless pacemaker procedures for all Medicare beneficiaries, including Medicare fee-for-service and Medicare Advantage. As part of the coverage criteria, CMS requires all patients to be included in a CMS approved study. Abbott has a real-world study for AVEIR™ DR Dual Chamber LP, AVEIR™ DR Dual Chamber LP CED study to meet these coverage requirements and has obtained approval. The AVEIR™ DR Dual Chamber LP CED study study has a clinical trial number to be utilized only for patients indicated for AVEIR™ DR Dual Chamber LP.	Medicare coverage is now available for AVEIR™ DR Dual Chamber Leadless Pacemaker Leadless Pacemaker implant procedures for any Medicare beneficiaries indicated for a leadless pacemaker and included in the AVEIR™ DR Dual Chamber LP CED study.
How do I report that the AVEIR™ DR Dual Chamber LP patient is part of a CMS approved study? Under the CMS CED policy, CMS requires that you report a National Clinical Trial number on the applicable claim. The NCT number for the AVEIR™ DR Dual Chamber LP CED study is NCT05932602.	The inclusion of the AVEIR™ DR Dual Chamber LP CED study NCT number (NCT 05932602) is required for CMS coverage purposes.
Is the AVEIR™ DR Dual Chamber LP CED study the same as AVEIR™ DR Dual Chamber Leadless Pacemaker's FDA post-approval study (PAS)? No. They are two separate studies with two different NCT numbers. The AVEIR™ DR Dual Chamber LP CED study is a CMS approved CED Study that is required for CMS coverage. The PAS is a predetermined group of sites participating in a registry that was established to meet post approval FDA requirements, independent from the CED study.	The NCT number (NCT 05932602) assigned to the AVEIR™ DR Dual Chamber LP CED study is unique to the AVEIR™ DR Dual Chamber LP. The inclusion of the unique ACED study NCT number (NCT 05932602) is a requirement for CMS coverage for AVEIR™ DR Dual Chamber LP procedures.

COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
Does my hospital's Institutional Review Board (IRB) need to approve the AVEIR™ DR Dual Chamber LP CED study? The AVEIR™ DR Dual Chamber LP CED study involves CMS claims or clinical data that are collected in the context of healthcare delivery, and the data collection involves no direct patient contact and will not influence the care a patient receives during routine interactions with the healthcare system. Therefore, IRB approvals are unlikely to be required by the hospital. Abbott, being the main entity in the AVEIR™ DR Dual Chamber LP CED study, has requested and been granted a waiver of informed consent and a HIPAA waiver from Western IRB. The Council for International Organizations of Medical Sciences (CIOMS), in a publication issued jointly with the World Health Organization (WHO), has stated that a waiver of the informed consent requirement may be granted by an IRB, "when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records)". (Data on file at Abbott)	It is unlikely an IRB approval would be required by the hospital. We recommend that you review the hospital's policies and procedures along with this information.
Is the AVEIR™ DR Dual Chamber LP CED NCT number (NCT 05932602) required to be reported on private payer or Medicaid patient claims for coverage? The NCT number (NCT 05932602) does not apply to private payers or Medicaid. The AVEIR™ DR Dual Chamber LP CED NCT number (NCT 05932602) is required for Medicare beneficiaries' coverage only, including Fee-For-Service and Medicare Advantage.	AVEIR™ DR Dual Chamber LP CED study NCT number (NCT 05932602) is only required in connection with claims for coverage for Medicare beneficiaries.
Who can I contact if I have more questions? Contact the Health Economics team at Abbott: LeadlessReimbursement@abbott.com or you can contact the reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430	Please contact the Abbott team using these channels when needed.

COVERAGE WITH EVIDENCE DEVELOPMENT FAQs (continued)

FAQ	WHAT DOES THIS MEAN FOR MY HOSPITAL?
If a patient with an existing AVEIR™ VR ventricular leadless pacemaker is being upgraded to a dual chamber leadless pacemaker with an AVEIR™ AR atrial component, what NCT number would apply? NCT 05932602 for the AVEIR™ DR Dual Chamber LP CED Study, as these patients are now receiving dual chamber leadless pacing therapy post procedure.	
If a patient with an existing AVEIR™ AR atrial leadless pacemaker is being upgraded to a dual chamber leadless pacemaker with an AVEIR™ VR ventricular component, what NCT number would apply? NCT 05932602 for the AVEIR™ DR Dual Chamber LP CED Study, as these patients are now receiving dual chamber leadless pacing therapy post procedure.	

REFERENCES

1. Leadless Pacemakers [cited: June 2022].
   https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Leadless-Pacemakers

2. Claim Submission [cited: June 2022].
   https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00232303

3. National Coverage Determination Leadless Pacemakers 20.8.4 [cited: January 2024]
   https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370

4. Medicare Claims Processing Manual, Chapter 32, Section 380 - Leadless Pacemakers [cited: January 2024]
   https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c32.pdf

5. Aveir AR Coverage With Evidence Development Post-Approval Study (CED) [cited: April 2024]
   https://clinicaltrials.gov/study/NCT06100770?lead=Abbott%20Medical%20Devices&rank=5

6. Aveir DR Coverage With Evidence Development Post-Approval Study (CED) [cited: November 2023]
   https://clinicaltrials.gov/study/NCT05932602

7. Aveir VR Coverage With Evidence Development Post-Approval Study (CED) [cited: June 2022]
   https://clinicaltrials.gov/ct2/show/NCT05336877?term=NCT05336877&draw=2&rank=1

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