RESPONDER-HF Clinical Trial

US Reimbursement Guide 2025

IDE# G150210
NCT05425459

DISCLAIMER
Reimbursement information provided in this guide is gathered from third-party sources and is presented for informational purposes only. Corvia Medical, Inc. (Corvia) makes no representation, warranty or guarantee as to the timeliness, accuracy or completeness of the information, and the information is not, and should not be construed as reimbursement, coding or legal advice. Any and all references to reimbursement codes are provided as examples only and are not intended to be a recommendation or advice as to the appropriate code for a particular patient, diagnosis, product, or procedure or a guarantee or promise of coverage or payment, nor does Corvia warrant that the codes listed are appropriate in all related clinical scenarios. It is the responsibility of the provider to determine if coverage exists and what requirements are necessary for submitting a proper claim for reimbursement to a health plan or payer, including the appropriate code(s) for products provided or services rendered. Laws, regulations, and payer policies concerning reimbursement are complex and change frequently; service providers are responsible for all decisions relating to coding and reimbursement submissions. Medicare's Correct Coding Initiative and commercial payer policies are reviewed and updated several times each year. Accordingly, Corvia strongly recommends consultation with payers, reimbursement specialists and/or legal counsel regarding appropriate product or procedure codes, coverage, and reimbursement matters.

Clinical sites may consult the Approved IDE Studies site (https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDEStudies.html) to confirm that a study has been approved for coverage prior to submitting IDE-related claims.

CONFIDENTIALITY: This document contains confidential information for use only by personnel participating in the Corvia Medical, Inc. RESPONDER-HF Clinical Trial. This document should be maintained in a secure location and should not be made available for review by any unauthorized person or entity.

FOR INVESTIGATIONAL USE ONLY
This document should only be used for the RESPONDER-HF Clinical Trial.

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QUICK REFERENCE – HOSPITAL OUTPATIENT CODING

The Corvia® Atrial Shunt is a Category B IDE device	
IDE Number G150210	NCT Number NCT05425459

ICD-10-CM Diagnosis Code	Code Description
I50.1 – I50.9	Heart Failure
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Mandatory Reporting of NCT Number		
CMS directs providers to report the 8-digit NCT number (05425459) on the following claims locators: • 837 professional claim format (do not use "CT" on the electronic claim), or • CMS-1500 paper form – place in Field 19 (preceded by "CT")		
HCPCS Coding (Hospital)	**APC**	**APC Description**
C9758-FD Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, transesophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	1590	New Technology – Level 39 ($15,001-$20,000)
C1889* Implantable/insertable device, not otherwise classified	–	–
APC 1590 - Patient Coinsurance applies	–	–
FD – indicates item provided Without Cost to Provider, required to be appended to the procedure code that reports the services to furnish the device. CMS instructs that hospitals report condition code 53 - Initial placement of a medical device provided as part of a clinical trial or free sample.		

Condition Code (Medicare hospital use)	
30	Non-research services provided to patients enrolled in a qualified clinical trial, including managed care enrollees
ICD-10-CM diagnosis code Z00.6 must be reported in either the primary or secondary position on a condition code 30 regardless of whether all services are related to the clinical trial or not	

Hospital Revenue Code	
0624	FDA investigational device
CMS instructs providers billing for routine care items and services of clinical trials involving a Category B IDE to bill the following on a 0624 revenue code line: Category B IDE device HCPCS code (if applicable), appropriate HCPCS modifier (Q0 or Q1), Category B IDE number (G150210/S033), and charges for the device billed as covered charges. Hospitals paid under Outpatient Prospective Payment System (OPPS) that implant a device furnished at no cost to the hospital shall report a charge of zero for device, or, if hospital's billing system requires that a charge be entered, hospital shall submit a token charge (e.g. $1.00) on the line with the device code.	

CPT Procedural Coding (for Physician Use) Transcatheter Interatrial Shunt Procedure	
0613T	*Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed
*Use of a Category III CPT® code requires special documentation, detailing the procedure.	

Modifiers (for Physician Use Only)	
-Q0	Investigational clinical service provided in a clinical research study that is an approved clinical research study
-Q1	Routine clinical services provided in a clinical research study that is an approved clinical research study
Note: The Q1 modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare-covered clinical trial.	
Patient Coinsurance applies	

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf

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ICD-10-PCS Coding	**MS-DRG**	**MS-DRG Description**
02173J6 Bypass Left Atrium to Right Atrium with Synthetic Substitute, Percutaneous Approach	270	Other Major Cardiovascular Procedures with MCC
	271	Other Major Cardiovascular Procedures with CC
	272	Other Major Cardiovascular Procedures without CC/MCC

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Hospital Revenue Code	
0624	FDA investigational device
CMS instructs providers billing for routine care items and services of clinical trials involving a Category B IDE to bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospitals paid under Medicare Inpatient Prospective Payment System (IPPS) that implant a device furnished at no cost to the hospital shall report a charge of zero for device, or, if hospital's billing system requires that a charge be entered, hospital shall submit a token charge (e.g. $1.00) on the line with the device code.	

CPT Procedural Coding (for Physician Use) Transcatheter Atrial Shunt Procedure	
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PRIVATE INSURED PATIENTS WRITTEN PRIOR-AUTHORIZATION, PEER-TO-PEER REVIEWS AND APPEALS

It is strongly recommended that a written prior authorization for your commercial patients is obtained **prior** to scheduling the hemodynamic evaluation/potential randomization as coverage will vary from one insurer to another.

The mere presence of codes does not automatically result in coverage.

In addition to the operative notes, a well written clinically documented overview of the medical necessity for the procedure is the cornerstone to successfully and consistently obtain private insurers written prior authorizations.

The most effective way to obtain written prior authorization (or to appeal a claim) is to provide the insurer with a couple of paragraphs that provide a clear clinical justification for the procedure based on the individual patient's medical need and necessity. Fill-in-the-blank requests are very easy for payers to deny as they are not patient specific. Medical necessity does not have to be unique in every detail, but you should thoroughly support and document the argument for medical necessity based on each individual patient's situation. Among other things, both the written prior authorization request or appeal letters should include the following information:

- Detailed patient history with description of patient's status including diagnosis, complaints, physical examination results, all correlating diagnostic test results, other clinician's notes and level of impairment. Describe functional impairments, and how the patient's condition has impacted his/her activities of daily life, e.g., XXX, XXX, XXX, etc.,
- Severity of the signs and symptoms exhibited by the patient,
- Previous treatments and interventions – noting procedures, medications, and/or therapies attempted; include outcome of each treatment to include trauma, e.g., XXX, XXX, XXX, etc.,
- The medical necessity and rationale for the Corvia Atrial Shunt procedure; clinical specifics substantiating why this is an appropriate medical option at this point in the patient's care; note therapeutic goals and anticipated outcomes, and risk to patient if procedure is not performed,
- Medical predictability of something adverse happening to the patient should be documented, and
- Some sites have found it helpful to reference that the RESPONDER-HF Study has received CMS national IDE Category B clinical trial coverage approval.

For all RESPONDER-HF reimbursement needs, please contact

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Monday-Friday 8:00am Eastern – 5:00pm Pacific

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CAUTION: Investigational Device. Limited by United States law to investigational use.