HEALTH ECONOMICS & REIMBURSEMENT

CODING FOR CORONARY PHYSIOLOGY WITH THE COROFLOW‡ CARDIOVASCULAR SYSTEM

Coronary Microvascular Dysfunction ICD-10 Diagnosis Codes Effective October 1, 2023.

Coronary microvascular dysfunction is now formally recognized as a diagnosis through the creation of four ICD-10-CM codes. Visit the CDC's website for a comprehensive list of ICD-10-CM codes.

ICD-10-CM Codes	Description
I20.81	Angina pectoris with coronary microvascular dysfunction
I21.B	Myocardial infarction with coronary microvascular dysfunction
I24.81	Acute coronary microvascular dysfunction
I25.85	Chronic coronary microvascular dysfunction

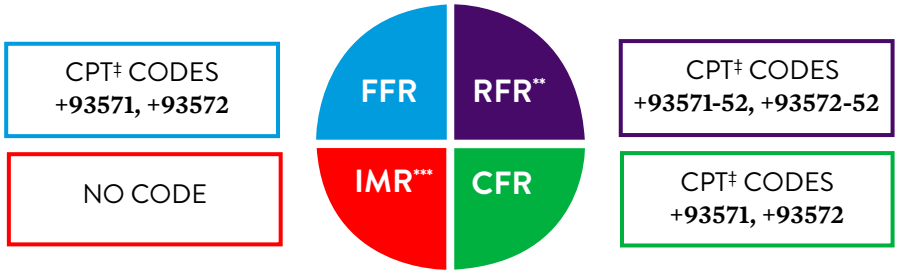
What procedure codes describe physiology assessments with the CoroFlow‡ Cardiovascular System?

There are two CPT‡ add-on codes that may be used to describe fractional flow reserve (FFR), resting full-cycle ratio (RFR), and case facility rate (CFR) assessments.

CPT‡ Code (add-on)*	Description
+93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel, list separately in addition to primary procedure
+93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel, list separately in addition to primary procedure

(+) = Indicates add-on code. List add-on code separately in addition to code for primary procedure

•Billing and Coding: Percutaneous Coronary Interventions



**Modifier -52 signifies a reduced service. For physician billing, RFR requires Modifier -52 as this is a reduced service due to the lack of pharmacologic stress agent.
***There is no designated CPT‡ code for IMR alone. However, +93571/+93572 can apply if FFR/CFR assessment is also performed during the same procedure.
NOTE: When measuring the index of microcirculatory resistance (IMR) with CoroFlow‡ Cardiovascular system, the system will always record FFR/CFR as well.[1,2]

Can the applicable CPT‡ add-on codes be applied multiple times if multiple physiology assessments are taken during one procedure?

Although CPT‡ add-on codes +93571 and +93572 apply to multiple types of physiology assessments, these codes only apply once per applicable vessel regardless of the number of physiology assessments performed in each vessel. These add-on codes must be used with primary procedure code and cannot be used independently.

Is there a billing code (HCPCS Level II) for the PressureWire™ X Guidewire?

The PressureWire™ X Guidewire can be billed on medical claims forms using HCPCS Level II Code C1769 (Guide Wire).

See Important Safety Information referenced within
Information contained herein for DISTRIBUTION in the U.S. ONLY.

Important Safety Information

Rx ONLY Coroflow‡ Cardiovascular System

INDICATIONS
CoroFlow‡ is indicated to provide hemodynamic information for use in the diagnosis of patients with cardiovascular diseases.

CoroFlow‡ is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display various physiological parameters based on the output from one or more measuring devices.

CONTRAINDICATIONS
The system has no patient alarm functions. Do not use for cardiac/vital signs monitoring.

WARNINGS
- If CoroFlow‡ is used together with 3rd party infusion catheters for assessment of Absolute Flow and Resistance, ensure that the maximum infusion rate per manufacturers instruction is not exceeded or vessel injury may occur.
- Do not use the CoroFlow‡ measurement system if there is reason to believe the system's security has been compromised or if the system was unaccounted for a period of time (i.e., misappropriated, modified or tampered with).
- Do not leave the CoroFlow‡ measurement system unattended when logged in as a PC Administrator.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), and to protect the integrity of the system itself, the system should be located in a physically secure, access-controlled environment.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), the PC on to which CoroFlow‡ is installed must be configured according to the Installation Instructions in this manual. Failure to configure the PC correctly may result in increased risk for unauthorized release of protected health information. Windows settings include:
  - Activation and configuration of restricted user Access
  - Activation of Windows Firewall and blocking of network connections
  - Activation of Windows Bitlocker drive encryption
  - Activation of Windows Secure Boot
  - Activation of Windows Anti-Virus scanning
  - Activation of Windows update
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by Coroventis‡ could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of CoroFlow‡, including cables specified by Coroventis‡. Otherwise, degradation of the performance of this equipment could result.

PRECAUTIONS
- The PC and CoroHub‡ shall not be placed within the patient environment (1.5 m from patient).
- For operation of other devices used in conjunctionwith CoroFlow‡ consult the IFU for each of these devices for details on indication, handling and safety information.
- It is recommended to ensure local routines for data backup of stored recordings. CoroFlow‡ does not create backup of stored data.
- Always check minimum performance requirement on PC to ensure compatibility with CoroFlow‡.
- It is recommended to install CoroFlow‡ on a PC with backup battery to avoid interruption in case of power failure.
- Always manually review and confirm valid cursor positions and detected heart beats.
- Ensure that Pa and Pd pressure waveforms are aligned in phase and offset after equalization, or indices can be mis-calculated.
- Confirm that the correct Wi-Box is selected by manually matching the Wi-Box ID number with the Wi-Box in the lab.
- Changing parameter settings outside of default values may affect measurement performance, only for research purposes.
- Only to be used by healthcare professionals
- Using a network location to store data may cause previously unidentified risks if the network malfunctions
- The assembly of medical electrical systems and modifications during the actual service life require evaluation to the requirements according to IEC 60601-1 standard series.
- CoroHub‡ does not have any serviceable parts and require no field maintenance. No modification or tampering with CoroHub‡ is permitted.
- CoroHub‡ shall not be immersed in liquid.
- CoroHub‡ shall not be used if it has been subject to damage.
- Direct connection to a non-secure network, like the internet, may interfere with correct operation and/or result in inappropriate access to patient information. Furthermore, it should be noted that reconfiguring a used network may lead to inability to import patient as well as export examination data, ultimately leading to a risk of loss of patient and examination data. To avoid this problem Coroventis‡ recommends verifying network settings in the system setup for each change.

Rx ONLY PressureWire™ X Guidewire

INDICATIONS
The PressureWire™ X Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels. Physiological parameters include blood pressure. The PressureWire™ X Guidewire can also measure blood temperature.

CONTRAINDICATIONS
This guidewire is contraindicated for use in the cerebral vasculature.

WARNINGS
- No modification of this device is allowed.
- The PressureWire™ X Guidewire is supplied sterile. Discard the guidewire if the pouch is opened or damaged, compromising the sterile barrier. The guidewire is designed for single use only and shall not be reused or resterilized. Adverse effects of using a non-sterile or resterilized guidewire may include, but are not limited to:
- Local and/or systemic infection
- Mechanical damage
- Inaccurate readings
- Observe all guidewire movements. Whenever the guidewire is moved or torqued, the tip movement should be examined under fluoroscopy. Never push, withdraw, or torque the guidewire if it meets resistance or without observing corresponding movement of the tip, otherwise vessel/ventricle trauma may occur.
- Torquing or excessive manipulation of the guidewire in a sharp bend, against resistance, or repeated attempts to cross a total vessel occlusion may:
- Cause dissection or perforation of blood vessels
- Cause vessel spasm
- Damage and/or fracture the guidewire
- When introducing the guidewire, flush the catheter and administer anticoagulation as for a standard catheterization procedure or clotting may occur.
- Do not use the guidewire in the ventricles if the patient has a prosthetic mechanical or biological valve. It may result in damage to both the prosthesis and the guidewire, which may cause injury or death.
- Use of the PressureWire™ X Guidewire in conjunction with interventional devices with a short rapid exchange may result in a folded or fractured guidewire.
- High frequency surgical devices must not be used on a patient at the same time as the guidewire.

PRECAUTIONS
- The PressureWire™ X Guidewire is a delicate instrument and should be handled carefully.
- Make sure that the transmitter is kept dry to ensure accurate pressure and/or temperature readings. Inaccurate readings may necessitate device replacement.
- Do not use the guidewire in conjunction with atherectomy catheters. It may damage the guidewire.
- Do not withdraw or manipulate the guidewire in a sharp-edged object. It may result in abrasion of the guidewire coating.
- Factors that may affect the accuracy of the diagnostic information include, but are not limited to:
- Improper placement of the aortic pressure sensor.
- Failure to achieve maximum coronary and myocardial hyperemia in FFR procedures
- Blood flow affected by the position of interventional devices, such as balloon catheters.
- Guidewire readings may be affected by defibrillation. Rezero the guidewire after defibrillation use.
- Do not measure pressure when the guidewire sensor element is in a sharp bend or in contact with atrial or ventricular walls. It might result in pressure artifacts.
- Do not use the PressureWire™ X Guidewire together with another guidewire, for so called jailed wire technique, due to difficulty in guidewire withdrawal and possible guidewire entrapment.
- Store at room temperature (15°c – 25°c) in a dry and dark place.

POTENTIAL ADVERSE EVENTS
Potential complications which may be encountered during all catheterization procedures include but are not limited to: vessel dissection or occlusion, perforation, embolus, spasm, local and/or systemic infection, pneumothorax, congestive heart failure, myocardial infarction, hypotension, chest pain, renal insufficiency, serious arrhythmias, or death.

In addition, this device has a coating containing Polyethylene Glycol (PEG); potential allergic reactions (anaphylaxis) may occur during the interventional procedure if the patient is allergic to PEG.

Related Material:
1. Cardiovascular System IFU. Refer to IFU for additional information.
2. PressureWire™ X Guidewire Instructions for use (IFU). Refer to IFU for additional information.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

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