

Cardiac Device Monitoring Services

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Frequently Used CPT[‡] Codes

See Page 3 for CPT‡ Footnotes

Pacemaker and CRT-P

	CPT [‡] Co	de and Description
Programming ¹	93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber
Trogramming	93280	dual lead pacemaker system
	93281	multiple lead pacemaker system
In-Person Interrogation ²	93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system
Domoto	93294	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, or leadless pacemaker system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
Remote Interrogation ³	93296	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
Peri-Procedural Device Evaluation ⁴	93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system
Transtelephonic Rhythm Strip Evaluation ⁵	93293	Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and without magnet application with analysis, review and report(s) by a physician or other qualified health care professional, up to 90 days

Implantable Cardioverter Defibrillator (ICD) and CRT-D

	CPT‡ Co	de and Description									
Programming ¹	93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system									
	93283	dual lead transvenous implantable defibrillator system									
	93284	multiple lead transvenous implantable defibrillator system									
In-Person Interrogation ²	93289	dual lead transvenous implantable defibrillator system									
Remote Interrogation ³	93295										
	93296										
Peri-Procedural Device Evaluation ⁴	93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system									

Frequently Used CPT[‡] Codes

See Page 3 for CPT[‡] Footnotes

2020 Remote Interrogation Reimbursement Changes

Effective January 1, 2020, the code for the technical component of remote monitoring for Implantable Cardiovascular Physiologic Monitoring Systems, Implantable/Insertable Cardiac Monitors (ICMs) and Implantable Wireless Pulmonary Artery Sensor/Monitors, CPT[‡] Code 93299, will be deleted. The Centers for Medicare & Medicaid Services (CMS) created a new G-code, G2066, to report this service. G2066 can be reported by physicians and outpatient hospitals. G2066 will continue to be carrier-priced, as 93299 was, and the description of the code will be the same. See page 6 for more information.

Implantable Cardiovascular Physiologic Monitoring (CorVue™ Impedance Monitoring)

	CPT [‡] Co	CPT [‡] Code and Description											
In-Person Interrogation ²	93290	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors											
Remote Interrogation ³	93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional											
	G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results											

Subcutaneous Cardiac Rhythm Monitor/ Insertable Cardiac Monitor (Confirm Rx™ ICM)

	CPT [‡] Co	CPT [‡] Code and Description										
Programming ¹	93285	Programming device evaluation, (in person) with iterative adjustment of the implantable device to test function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; subcutaneous cardiac rhythm monitor system										
In-Person Interrogation ²	93291	Interrogation device evaluation, (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; including heart rhythm derived data analysis, subcutaneous cardiac rhythm monitor system, including heart rhythm derived data										
Remote Interrogation ³	93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of heart rhythm derived data, analysis review(s) and report(s) by a physician or other qualified health care professional										
	G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results										

Implantable Wireless Pulmonary Artery Sensor/Monitor (CardioMEMS™)

	CPT [‡] Coc	CPT [‡] Code and Description										
Remote	93264 [‡]	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified healthcare professional										
Monitoring ⁶	G2066*	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results										

[‡]CPT[‡] code 93264 is reported with status indicator "M" which indicates that it is not payable in the outpatient hospital prospective payment system.

^{*}Physicians should not report codes 93264 and G2066 together because 93264 includes the professional and technical components in the payment rate.

G2066 may be billable by outpatient hospitals for the technical data acquisitions of PA pressure sensor remote monitoring if the requirements of the code are met. It is important that hospitals verify reporting with their institutional coders and follow up with their payers regarding their payment coverage policies for G2066.

CPT[‡] Footnotes (Reporting Instructions)⁷

All Services	 Programming, interrogation device evaluations, and peri procedural device evaluations may not be reported in conjunction with device and/or lead insertion or revision services by the same individual ECG rhythm derived elements are distinct from physiologic data, even when the same device is capable of producing both Implantable cardiovascular physiologic monitor device services are always reported separately from implantable defibrillator services When cardiac rhythm data are derived from an implantable defibrillator or pacemaker, do not report subcutaneous cardiac rhythm monitor services with pacemaker or ICD services
1. Programming	 Reported per procedure May be reported with remote interrogation device evaluations during the remote interrogation device evaluation period May not be reported with in person interrogation device evaluations on the same date by the same individual For subcutaneous cardiac rhythm monitors, may not be reported with programming device evaluations for pacemakers and ICDs
2. In-Person Interrogation	 Reported per procedure May not be reported with programming on the same date by the same individual May not be reported with remote interrogation device evaluations on the same date by the same individual
3. Remote Interrogation	 Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy (CRT) Reported no more than once every 90 days. A period is established by the initiation of the remote monitoring or the 91st day of monitoring and extends for the subsequent 90 days for which remote monitoring is occurring Do not report if the monitoring period is less than 30 days May be reported with programming device evaluations during the remote interrogation device evaluation period May not be reported with in person interrogation device evaluations on the same date by the same individual. Report only remote services when an in person interrogation device evaluation is performed during a period of remote interrogation device evaluation. However, a service center may report the technical code for remote interrogation (93296) during a period in which a physician or other qualified health professional performs an in-person interrogation device evaluation.
	 Implantable Cardiovascular Physiologic Monitor/Subcutaneous Cardiac Rhythm Monitor Reported no more than once every 30 days. A period is established by the initiation of the remote monitoring or the 31st day of monitoring and extends for the subsequent 30 days for which remote monitoring is occurring Do not report if the monitoring period is less than 10 days May be reported with programming device evaluations during the remote interrogation device evaluation period May not be reported with in person interrogation device evaluations on the same date by the same individual. Report only remote services when an in person interrogation device evaluation is performed during a period of remote interrogation device evaluation. However, a service center may report the technical code for remote interrogation (G2066) during a period in which a physician or other qualified health professional performs an in-person interrogation device evaluation. Remote interrogation of implantable cardiovascular physiologic monitors may be reported with remote interrogation of subcutaneous cardiac rhythm monitors
4. Peri-Procedural Device Evaluation	 Reported once before and once after surgery, procedure or test, when device evaluation and programming is performed before and after surgery, procedure or test May not be reported with programming device evaluations or in-person interrogation device evaluations If one provider performs both the pre- and post- evaluation and programming service, the appropriate code (93286 for pacemakers or 93287 for implantable defibrillators) would be reported two times. If one provider performs the pre-surgical service and a <i>separate</i> provider performs the post-surgical service, each provider reports either code only one time.
5. Transtelephonic Rhythm Strip Evaluation	 Reported no more than once every 90 days Do not report if the monitoring period is less than 30 days May not be reported with the professional code for remote pacemaker interrogations (93294) For in person evaluation, see ECG codes (93040, 93041, 93042)
6. Remote Monitoring of Pulmonary Artery Pressure	 Reported no more than once every 30 days. A period is established by the initiation of the remote monitoring or the 31st day of monitoring and extends for the subsequent 30 days for which remote monitoring is occurring Do not report if the monitoring period is less than 30 days Do not report if download(s), interpretation(s), trend analysis, and report(s) do not occur at least weekly during the 30-day time period Do not report if review does not occur at least weekly during the 30-day time period

Quick Reference Guide

Summary of CPT[‡] Codes

		Pacemaker (PM)	Implantable Cardioverter Defibrillator (ICD)	Implantable Cardiovascular Physiologic Monitoring (ICPM)	Subcutaneous Cardiac Rhythm Monitor/ Insertable Cardiac Monitor (SCRM/ICM)	Implantable Pulmonar Pressure (PAP Mo	y Artery Sensor
			PHYSICIAN/ OUTI	PATIENT HOSPITAL (OPPS)	PHYSICIAN	OPPS
Programming	93279-93281	93282-93284		93285			
In-Person Interrogation		93288	93289	93290	93291		
Remote Interrogation/	Professional	93294 *90	93295 *90	93297 *30	93298 *30	*30	NA
Remote Monitoring	Technical	93296 *90	93296 *90	G2066 ^{‡30}	G2066 *30	93264	G2066 ^{‡30}
Peri-Procedural Device Ev	93286	93287					
Transtelephonic Rhythm S	93293 *90						

^{*90:} Reported no more than once every 90 days. Do not report if the monitoring period is less than 30 days.

Code Edits (X: Cannot be Reported Together by Same Individual for Same Date of Service)

		PM				ICD				ICPM			SCRM/ICM [‡]				PAP Monitor				
		93279-81	93288	93294	93296	93286	93293	93282-84	93289	93295	93296	93287	93290	93297	G2066	93285	93291	93298	G2066	93264	G2066
	93279-81		Х			Х															
	93288	Х		Х	X*	Х															
Σ	93294		Х				Х											Х			
≖	93296		X*											Х	Х			Х	Х		
	93286	х	Х																		
	93293			Х																	
	93282-84								Х			Х									
	93289							х		Х	X*	Х									
8	93295								Х					Х				Х	Х		
	93296								X*					Х	Х			Х			
	93287							Х	Х												
_	93290													Х	Х						
ICPM	93297				Х					Х	Х		х								
	G2066				Х						Х		Х								
#=	93285																Х				
Σ	93291															Х		Х	Х		
SCRM/ICM [‡]	93298			Х	Х					Х	Х						Х				
	G2066				Х						Х						Х				
itor	93264																				X**
PAP Monitor	G2066																			X**	

Note: All procedures reported should be deemed medically necessary by the physician. Programming, interrogation device evaluations, and peri procedural device evaluations may not be reported in conjunction with device and/or lead insertion or revision services

[‡]30: Reported no more than once every 30 days. Do not report if the monitoring period is less than 10 days.

^{*30:} Reported no more than once every 30 days. Do not report if the monitoring period is less than 30 days.

NA: CPT* code 93264 is reported with status indicator "M" which indicates that it is not payable in the outpatient hospital prospective payment system.

^{*}A service center may report the technical codes for remote interrogation during a period in which a physician or other qualified health professional performs an in-person interrogation.

^{*}When cardiac rhythm data are derived from an implantable defibrillator or pacemaker, do not report subcutaneous cardiac rhythm monitor services with pacemaker or ICD services.

^{**} Physicians should not report codes 93264 and G2066 together because 93264 includes the professional and technical components in the payment rate. However, G2066 may be billable by Outpatient Hospitals for the technical data acquisitions of PA pressure sensor remote monitoring if the requirements of the code are met.

Responses to Common Questions

2020 REMOTE INTERROGATION CHANGES

How are the codes for the technical portion of remote monitoring for certain systems such as Confirm RxTM Insertable Cardiac Monitors (ICM) and CorVueTM Impedance Monitoring changing in 2020?

The Medicare 2020 Physician Final Rule created a new code: G2066, effective January 1, 2020, to report the technical portion of remote monitoring services for subcutaneous cardiac rhythm monitor systems (such as Confirm RxTM) and cardiovascular physiologic monitor systems (such as CorVueTM Impedance Monitoring). Under the appropriate circumstances, this code may be used to report these services to Medicare and some commercial payers. Check with your commercial payers before reporting code G2066.

Note, the code previously used to report the technical portion of remote monitoring (CPT[‡] code 93299) applies to claims with a date of service *on* or *before* December 31, 2019. The new code (G2066) applies to claims with a date of service on or after January 1, 2020.

How is the new code (G2066) different from the old code (93299)?

The new code (G2066) is a Level II HCPCS G-code, whereas the old code (93299) was a CPT[‡] code. Level II HCPCS G-codes are temporary national codes for items and services that require uniform national coding but do not have a corresponding CPT[‡] code. ¹⁴ These codes remain active until they are converted into permanent codes or until Medicare notifies contractors to delete them. G-codes are created by Medicare for Medicare use, but they may also be used by some commercial payers.

What is the Medicare payment for code G2066?

G2066 is contractor-priced, meaning payment rates for the code are developed at the discretion of each local Medicare Administrative Contractor (MAC).¹⁴ The old code (CPT[‡] Code 93299) was also contractor-priced.

When will the contractor rates for G2066 be announced?

Medicare Administrative Contractors (MACs) typically release their contractor-priced fee schedules during the first quarter of the year. Contact your local MAC for their specific fee schedule information.

What code should be reported to commercial payers?

Some commercial payers may accept code G2066 but you should always check first with your commercial payers before reporting code G2066 to verify their coding recommendations for this service.

<u>Is the modifier -TC (technical component) required when reporting G2066?</u>

No, according to the 2020 Final Medicare Physician Rule, G2066 is a "technical component only" code. ¹⁵ This means that it is a "stand alone code that describe[s] the technical component (such as staff and equipment costs) of selected diagnostic tests" and therefore the modifiers -26 and TC cannot be used with these codes. ¹⁶

Have the codes changed for reporting the professional component of remote monitoring for subcutaneous cardiac rhythm monitor systems and cardiovascular physiologic monitor systems?

No, the professional codes for remote monitoring have not changed. Under the appropriate circumstances, CPT[‡] Code 93298 may be used to report the professional portion of remote monitoring services for subcutaneous cardiac rhythm monitor systems and CPT[‡] Code 93297 may be used to report the professional portion of remote monitoring for cardiovascular physiologic monitor systems.⁷

Which code (93299 or G2066) is applicable if the remote monitoring period spans 2019 and 2020, i.e., if the RM period occurs partly in 2019 and partly in 2020?

According to the Medicare Learning Network, for technical services, the appropriate date of service is the date the monitoring concludes. ¹⁷ Therefore, if the last day of monitoring occurs in 2020, then the date of service is in 2020, meaning the 2020 code (G2066) is applicable.

Who can I contact for more information?

Call our Reimbursement Hotline at (855) 569-6430, available 8-5pm CT, or email hce@abbott.com.

REMOTE INTERROGATION

If the health care provider downloads or reviews data multiple times during the remote interrogation period, can he/she report the applicable code(s) multiple times?

No, according to CPT[‡] guidelines, the remote interrogation codes may only be reported once per 90 days for pacemakers/ICDs/CRT and once per 30 days for Implantable Cardiovascular Physiologic Monitors, Subcutaneous Cardiac Rhythm Monitors and Implantable Wireless Pulmonary Artery Sensors.⁷ This applies to both the professional and technical remote interrogation codes.

Can the physician report both the professional and technical codes for remote interrogation if a device industry representative is involved in performing the technical service, under the physician's direction?

No. If a device industry representative is involved in performing the technical service under the physician's direction, then the physician may NOT bill for the technical service and may only bill the professional services that are actually performed by the physician, i.e., physician analysis, review(s) and report(s).

<u>Do the technical component codes require that the physician/facility own the device interrogation and programming equipment?</u>

No. There is no reference to equipment ownership as a requirement for billing the technical component codes.

Responses to Common Questions

PROGRAMMING

<u>Can the physician report programming or in-person interrogation at the time of implant?</u>

No, according to CPT[‡] guidelines, "pacemaker and implantable defibrillator interrogation device evaluations, peri procedural device evaluations and programming, and programming device evaluations may not be reported in conjunction with pacemaker or implantable defibrillator device and/or lead insertion or revision services by the same individual."⁷ According to the CMS National Correct Coding Initiative, ICM insertions should also not be reported with programming or interrogations.⁹

Are there specific frequency limitations for programming, within CPT[‡] guidelines or Medicare coverage determinations?

No. Neither CPT[‡] guidelines nor Medicare's National Coverage Determinations contain frequency limitations on the use of programming codes for pacemakers and ICDs.⁷ However, you should check with your local MAC to verify whether they have established local frequency guidelines for these codes.

As always, all code requirements must be met (as described in the code description) and the procedure must be deemed medically necessary by the physician.

If a patient being remotely monitored receives programming, can both the programming and the remote interrogation be reported?

Yes, CPT[‡] guidelines state, "programming device evaluations and remote interrogation device evaluations may both be reported during the remote interrogation device evaluation period."⁷

IN PERSON INTERROGATION

When performing programming or an in-person interrogation and a separately identifiable Evaluation and Management service during the same visit, what coding rules apply?

In general, when multiple coding options exist for a given service, coding convention mandates the use of the code with the highest level of specificity. Therefore, if a *specific* CPT code exists for a given service (as is the case with device programming and inperson interrogations), that specific code should be reported instead of a *general* E/M (Evaluation and Management) code.

However, according to CPT guidelines, "it may be necessary to indicate that on the day a procedure or service identified by a CPT code was performed, the patient's condition required a significant, separately identifiable E/M [Evaluation and Management] service above and beyond the other service provided or beyond the usual preoperative and postoperative care associated with the procedure that was performed." ¹¹ In such qualifying cases, a -25 modifier (for Significant, Separately Identifiable Evaluation and Management Service by the Same Physician or Other Qualified Health Care Professional on the Same Day of the Procedure or Other Service) is available to report the E/M service. ¹¹

IN PERSON INTERROGATION, continued

<u>Are there specific frequency limitations for in-person</u> <u>interrogation codes, within CPT[‡] guidelines or Medicare coverage determinations?</u>

For pacemakers, Medicare's National Coverage Determination (NCD) indicates that, "The decision as to how often any patient's pacemaker should be monitored is the responsibility of the patient's physician who is best able to take into account the condition and circumstances of the individual patient." ¹⁰ The NCD contains guidelines for the frequency of monitoring and recommends that MACs develop their own policies for the frequency of these services. ¹⁰ Check with your local MAC to verify their policies.

For ICDs, neither CPT[‡] guidelines nor Medicare's National Coverage Determinations contain frequency limitations on the use of in person interrogation codes.⁷ However, check with your local MAC to verify whether they have established frequency guidelines for these codes.

As always, all code requirements must be met (as described in the code description) and the procedure must be deemed medically necessary by the physician.

What happens if a patient being remotely monitored receives an in-person interrogation?

CPT[‡] guidelines state that "the same individual may not report an in-person and remote interrogation of the same device during the same period. Report only remote services when an in-person interrogation device evaluation is performed during a period of remote interrogation device evaluation."

However, the CPT[‡] codebook provides that a "service center" may report qualifying technical codes for remote interrogation "during a period in which a physician or other qualified health professional performs an in-person interrogation device evaluation."⁷

PHYSICIAN SUPERVISION

What are the physician supervision guidelines for remote interrogations?

According to the 2020 Final Medicare Physician Rule, the codes for the <u>professional</u> component of remote monitoring are "professional component only codes" and the concept of physician supervision "does not apply." This means that the physician or other qualified health care professional must *personally* perform the work.

According to the 2020 Final Medicare Physician Rule, the codes for the <u>technical</u> component of remote monitoring are "technical component only codes" that requires "general supervision." ¹⁵ According to the Medicare Benefit Policy Manual, "general supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure."⁸

Responses to Common Questions

DOCUMENTATION

Who is responsible for storing device interrogation data? Since the device interrogation data is stored digitally, does the physician practice need to also retain this information in the patient's medical records?

Although some device interrogation data may be available through digital platforms provided by device manufacturers, these are not electronic medical records. It is the physician's responsibility to maintain appropriate documentation, including all relevant device interrogation data, in the patient's medical record.

DIAGNOSES

What diagnosis codes may apply in connection with Programming, Device Elective Replacement Indication (ERI)/ End of Life (EOL) and Device Interrogations?

Diagnosis codes are used by both hospitals and physicians to document the medical necessity and clinical rationale for applicable procedures. It is incumbent upon the physician to determine the appropriate diagnosis code, given the patient's circumstances. There are many possible diagnosis code scenarios and a wide variety of possible combinations. This list is not exhaustive of all the diagnosis codes supporting device monitoring procedures; it is meant to serve as an example for your review. Nothing in this document should be viewed as instructions for selecting any particular code, and Abbott does not advocate or warrant the appropriateness of the use of any particular code. Note that laws, regulations, and coverage policies are complex and are updated frequently, and, therefore, the customer should check with its local carriers or intermediaries often and should consult with legal counsel or a financial, coding, or reimbursement specialist for any questions related to coding, billing, reimbursement or any related issues.

The following are some codes that may apply under the appropriate circumstances:

Programming or Device ERI/EOL13

- <u>Z45.01</u> Encounter for adjustment and management of cardiac pacemaker or cardiac resynchronization therapy pacemaker (CRT-P)
- <u>Z45.02</u> Encounter for adjustment and management of automatic implantable cardiac defibrillator, automatic implantable cardiac defibrillator with synchronous cardiac pacemaker or cardiac resynchronization therapy defibrillator (CRT-D)
- <u>Z45.09</u> Encounter for adjustment and management of other cardiac device [used for ICMs]

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- <u>Z95.0</u> Presence of cardiac pacemaker or cardiac resynchronization therapy (CRT-P) pacemaker
- <u>Z95.810</u> Presence of automatic (implantable) cardiac defibrillator, automatic (implantable) cardiac defibrillator with synchronous cardiac pacemaker, cardiac resynchronization therapy defibrillator (CRT-D) or cardioverter-defibrillator (ICD)
- <u>Z95.818</u> Presence of other cardiac implants and grafts [for ICMs]

GLOBAL SURGICAL PACKAGES

Do global surgical packages include/apply to programming or remote/in-person interrogations following a device implant?

No. According to the Final 2020 Medicare Physician Rule, the codes for remote and in-person interrogations are assigned a Global Surgery indicator of "XXX" meaning that the "global concept does not apply." This means that these procedures are not included in the global surgical package. 12

Important Safety Information

BRIEF SUMMARY

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Confirm Rx™ Insertable Cardiac Monitor

Model DM3500

Insertable Cardiac Monitor

Indications: The Confirm Rx[™] ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. Confirm Rx ICM Model DM3500 is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

Contraindications: There are no known contraindications for the implantation of the Confirm Rx ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation and Migration. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Limitations: Patients may use their own Apple‡ or Android‡ mobile digital device to transmit information from their Confirm Rx ICM using the myMerlin™ mobile app. To do so the device must be powered on, app must be installed, Bluetooth® wireless technology connection enabled and data coverage (cellular or WiFi‡) available. The myMerlin™ mobile app provides periodic patient monitoring based on clinician configured settings. Transmission data is resent if not sent successfully. However there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of ICM and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, ICM memory capacity, clinic environment, schedule/configuration changes or data processing.

The CardioMEMS™ HF System

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

Contraindications: The CardioMEMS™ HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death and Device embolization. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

References and Disclaimer

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REFERENCES

For references 1 through 6, see CPT[‡] Footnotes on page 3.

- ⁷ American Medical Association, CPT[‡] 2020 Professional Edition.
- ⁸ Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services. https://www.cms.gov/media/125221
- ⁹ Centers for Medicare & Medicaid Services. National Correct Coding Initiative Procedure to Procedure (PTP) Coding Edits. https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/NCCI-Coding-Edits
- ¹⁰ Centers for Medicare & Medicaid Services. Medicare National Coverage Determinations Manual. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf
- ¹¹ American Medical Association. CPT[‡] 2020 Professional Edition, Appendix A.
- ¹² Medicare Claims Processing Manual, Chapter 12: Physicians/Nonphysician Practitioners. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf
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