

Medical Policy:

Implantable Cardioverter Defibrillators

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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Definitions

Transvenous implantable cardiac defibrillator (ICD)	Device designed to monitor heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT) and deliver electrical shock to terminate these arrhythmias in order to reduce the risk of sudden cardiac death (SCD). The reasons for device-implantation are twofold:		
(Aka thoracotomy systems)	 Primary prevention — those patients at high risk for SCD who have not experienced life-threatening VTs or VF Secondary prevention — those patients who have experienced a potentially life-threatening episode of VT (i.e., near SCD) 		
	The standard ICD involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.		
Subcutaneous implantable cardiac defibrillator (S-ICD)	A defibrillator device that is implanted is implanted under the skin on the side of the chest below the arm pit. The pulse generator is connected to the electrode which is implanted under the skin from the device pocket along the rib margin to the breastbone with the use of the insertion tool. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous		

tissue of the chest wall.
The S-ICD does not require a thoracotomy and does not employ transvenous leads. The goal of
this device is to reduce lead-related complications.

Related Medical Guidelines

Automatic External Defibrillators

Cardiac Resynchronization Therapy (Biventricular Pacing) — MCG #ACG: A-0167 (AC)

Indications for Coverage

Implantable cardiac defibrillation therapy using an FDA-approved ICD (thoracotomy system) or S-ICD (non-thoracotomy system) is considered medically necessary when the following criteria (I–III) are met:

I. Transvenous ICD — adults

Considered medically necessary when member is not a candidate for cardiac revascularization (i.e., coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) is not clinically appropriate and **one** of the following criteria (**1 or 2**) is met:

- Primary prevention high SCD risk without occurrence of a life-threatening VT or VF and ≥ 1
 (a—i):
 - a. Ischemic cardiomyopathy with NYHA functional Class I symptoms and both:
 - i. History of myocardial infarction (MI) ≥ 40 days prior to ICD treatment
 - ii. LVEF ≤ 30%
 - b. Ischemic cardiomyopathy with <u>NYHA functional Class II or Class III</u> symptoms and **both**:
 - i. History of MI ≥ 40 days prior to ICD treatment
 - ii. LVEF ≤ 35%
 - c. Nonischemic dilated cardiomyopathy and all:
 - i. LVEF ≤ 35%
 - ii. Reversible causes excluded
 - iii. Refractory to optimal medical therapy (defined as 3 months of maximally titrated doses, as tolerated, of an ACE inhibitor, beta-blocker and diuretic)
 - d. Hypertrophic cardiomyopathy (HCM) with ≥ 1 of the following major SCD risk factors:
 - i. History of premature HCM-related sudden death in ≥ 1 first degree relative at
 < 50 years of age
 - ii. LVH ≥ 30 mm
 - iii. Documented VT with heart rates ≥ 120 beats per minute on 24-hour Holter monitor
 - iv. Left ventricular wall thickness ≥ 3cm

- v. Hypotensive response to exercise treadmill testing (ETT)
- vi. Prior unexplained syncope that is inconsistent with neurocardiogenic origin
- e. Documented LMNA gene mutations (lamin A/C deficiency) with either:
 - i. Cardiomyopathy
 - ii. Symptomatic cardiac arrhythmias
- f. Long QT syndrome (LQTS) and any:
 - i. Prior cardiac arrest
 - ii. Syncope and/or VT while on beta blocker pharmacotherapy
 - iii. Asymptomatic with ≥1 of the following risk factors for SCD:
 - QTc greater than 500 msec
 - LQT2 or LQT3
 - Family history of sudden death
- g. Brugada syndrome (BrS) and ≥ 1:
 - i. Prior cardiac arrest
 - ii. Spontaneous sustained VT with/without syncope
 - iii. Spontaneous diagnostic type 1 ECG with positive history of syncope, seizure or nocturnal agonal respiration after noncardiac causes have been ruled out
 - iv. Development of VF during programmed electrical stimulation
- h. Catecholaminergic polymorphic ventricular tachycardia (CPVT) and ≥ 1 :
 - i. Prior cardiac arrest
 - ii. Recurrent syncope
 - iii. Polymorphic/bidirectional VT unresponsive to medical management or left cardiac sympathetic denervation
- i. Cardiac sarcoidosis, giant cell myocarditis or Chagas disease (regardless of LV ejection fraction)
- j. LV non-compaction cardiomyopathy with either of the following:
 - i. Positive family SCD history
 - ii. Impaired LVEF of < 50 %
- k. Arrhythmogenic right ventricular dysplasia (ARVD)
- **2. Secondary prevention** Member has experienced occurrence of life-threatening clinical event associated with ventricular arrhythmic events (e.g., sustained VT) when reversible causes (e.g., acute ischemia, drug toxicity, electrolyte abnormalities, etc.) have been excluded
- II. Transvenous ICD pediatrics

Considered medically necessary when ≥ 1 of the following criteria (1–9) are met:

- 1. Prior cardiac arrest after reversible causes excluded
- **2.** Symptomatic sustained VT in association with congenital heart disease in members who have undergone hemodynamic and electrophysiologic evaluation
- **3.** Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias
- **4.** Hypertrophic cardiomyopathy (HCM) with ≥ 1 of the following SCD risk factors:
 - a. History of premature HCM-related sudden death in ≥ 1 first-degree relative at < 50 years of age
 - b. Massive left ventricular hypertrophy
 - c. Prior unexplained syncope that is inconsistent with neurocardiogenic origin
- 5. Documented LMNA gene mutations (lamin A/C deficiency) with ≥ 1:
 - a. Cardiomyopathy
 - b. Symptomatic cardiac arrhythmias
- **6.** Long QT syndrome (LQTS) and > 1:
 - a. Prior cardiac arrest
 - b. Recurrent syncopal events while on beta blocker pharmacotherapy
- 7. Brugada syndrome (BrS) and ≥ 1:
 - a. Prior cardiac arrest
 - b. Documented spontaneous sustained ventricular tachycardia (VT) with/without syncope
 - c. Spontaneous diagnostic type 1 ECG with a history of syncope, seizure or nocturnal agonal respiration after noncardiac causes have been excluded
 - d. Development of VF during programmed electrical stimulation
- 8. Catecholaminergic polymorphic ventricular tachycardia (CPVT) and ≥ 1:
 - a. Prior cardiac arrest
 - b. Recurrent syncope
 - c. Polymorphic/bidirectional VT unresponsive to medical management or left cardiac sympathetic denervation

III. S-ICD — adults or pediatrics

Considered medically necessary for members who meet the transvenous ICD clinical criteria above and who do not have symptomatic bradycardia, incessant VT (or spontaneous frequently recurring VT) that is reliably terminated with anti-tachycardia pacing or who have previous endocarditis or infection associated with conventional ICDs.

Note: EmblemHealth considers the use of a FDA-approved implantable cardioverter defibrillator (ICD) device, combined with cardiac resynchronization therapy (i.e., CRT/ICD), to be medically when Resynchronization (Biventricular Pacing) criteria are met (MCG #ACG: A-0167 (AC).

Limitations/Exclusions

The use of either a subcutaneous or transvenous ICD is considered investigational and not medically necessary for clinical conditions other than those listed above, as well as when the specific criteria are not met.

Implantable cardioverter defibrillators with a built -in ST-segment monitoring feature (aka ICD -based ischemia monitors) are not considered medically necessary for any indication (in adults or children) due to insufficient evidence of therapeutic value.

Cardioverter-defibrillators are not considered medically necessary when other disease processes are present that clearly and severely limit estimated life expectancy to less than one 1 year.

EmblemHealth will cover surveillance of ICDs as a face-to-face or remote service to monitor behavior of the device, to investigate symptoms such as post-event shock, and syncope, ICD malfunction or device failure. Surveillance of ICDs is also indicated to program device evaluation and adjustment and for patients prior to surgery or other procedures to modify or disable the device during the procedure. Remote interrogation is a single 90-day service, while in-person interrogation can be reported for each day it is performed.

The replacement of an ICD pulse generator/leads is considered medically necessary when:

- 1. Equipment is damaged or malfunctioning
- 2. Manufacturer product labeling details medically necessary replacement scenario(s)
- 3. Change in member's medical condition

The placement of substernal electrode leads is considered investigational due to insufficient evidence of therapeutic value. (CPT: 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T and 0614T)

Procedure Codes

0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional
33202	Insertion of epicardial electrode(s); open incision (eg, thoracotomy, median sternotomy, subxiphoid approach)
33203	Insertion of epicardial electrode(s); endoscopic approach (eg, thoracoscopy, pericardioscopy)
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator
33223	Relocation of skin pocket for implantable defibrillator

33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)		
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)		
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)		
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads		
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads		
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead		
33241	Removal of implantable defibrillator pulse generator only		
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy		
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction		
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber		
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system		
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system		
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system		
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed		
33271	Insertion of subcutaneous implantable defibrillator electrode		
33272	Removal of subcutaneous implantable defibrillator electrode		
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode		
93260	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; implantable subcutaneous lead defibrillator system		
93261	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 subcutaneous lead defibrillator system		
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	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; dual lead transvenous implantable defibrillator system		
93284	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; multiple lead transvenous implantable defibrillator system
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
93289	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 transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements
93295	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
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
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

ICD-10 Diagnoses

B57.0	Acute Chagas' disease with heart involvement
B57.2	Chagas' disease (chronic) with heart involvement
D86.85	Sarcoid myocarditis
101.1	Acute rheumatic endocarditis
101.2	Acute rheumatic myocarditis
121.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
121.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
121.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
121.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
121.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
121.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
121.29	ST elevation (STEMI) myocardial infarction involving other sites
121.3	ST elevation (STEMI) myocardial infarction of unspecified site
121.4	Non-ST elevation (NSTEMI) myocardial infarction
121.9	Acute myocardial infarction
I21.A1	Myocardial infarction type 2
I21.A9	Other myocardial infarction type
122.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
122.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
122.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites

122.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site			
124.0	Acute coronary thrombosis not resulting in myocardial infarction			
124.1	Dressler's syndrome			
124.8	Other forms of acute ischemic heart disease			
124.9	Acute ischemic heart disease, unspecified			
125.10	Atherosclerotic heart disease of native coronary artery without angina pectoris			
125.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris			
125.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm			
125.112	Atherosclerotic heart disease of native coronary artery with refractory angina pectoris (eff. 10/1/2022)			
125.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris			
125.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris			
125.2	Old myocardial infarction			
125.5	Ischemic cardiomyopathy			
125.6	Silent myocardial ischemia			
125.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris			
125.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris			
125.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris			
125.82	Chronic total occlusion of coronary artery			
125.83	Coronary atherosclerosis due to lipid rich plaque			
125.84	Coronary atherosclerosis due to calcified coronary lesion			
125.89	Other forms of chronic ischemic heart disease			
125.9	Chronic ischemic heart disease, unspecified			
133.0	Acute and subacute infective endocarditis			
133.9	Acute and subacute endocarditis, unspecified			
138	Endocarditis, valve unspecified			
140.1	Isolated myocarditis			
142.0	Dilated cardiomyopathy			
142.1	Obstructive hypertrophic cardiomyopathy			
142.2	Other hypertrophic cardiomyopathy			
142.3	Endomyocardial (eosinophilic) disease			
142.4	Endocardial fibroelastosis			
142.5	Other restrictive cardiomyopathy			
142.6	Alcoholic cardiomyopathy			
142.7	Cardiomyopathy due to drug and external agent			
142.8	Other cardiomyopathies			
142.9	Cardiomyopathy, unspecified			
143	Cardiomyopathy in diseases classified elsewhere			
I45.81	Long QT syndrome			
145.89	Other specified conduction disorders			
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146.2	Cardiac arrest due to underlying cardiac condition			
146.8	Cardiac arrest due to other underlying condition			
146.9	Cardiac arrest, cause unspecified			
147.1	Supraventricular tachycardia			
147.20	Ventricular tachycardia, unspecified (eff. 10/1/2022)			
147.21	Torsades de pointes (eff. 10/1/2022)			
147.29	Other ventricular tachycardia (eff. 10/1/2022)			
147.9	Paroxysmal tachycardia, unspecified			
149.01	Ventricular fibrillation			
149.02	Junctional premature depolarization			
149.3	Ventricular premature depolarization			
149.8	Other specified cardiac arrhythmias			
149.9	Cardiac arrhythmia, unspecified			
150.21	Acute systolic (congestive) heart failure			
150.22	Chronic systolic (congestive) heart failure			
150.23	Acute on chronic systolic (congestive) heart failure			
150.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure			
150.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure			
150.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure			
150.84	End stage heart failure			
150.9	Heart failure, unspecified			
Q24.8	Other specified congenital malformations of heart			
Q24.9	Congenital malformation of heart, unspecified			
R55	Syncope and collapse			
T82.110A	Breakdown (mechanical) of cardiac electrode, initial encounter			
T82.110D	Breakdown (mechanical) of cardiac electrode, subsequent encounter			
T82.110S	Breakdown (mechanical) of cardiac electrode, sequela			
T82.111A	Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter			
T82.111D	Breakdown (mechanical) of cardiac pulse generator (battery), subsequent encounter			
T82.111S	Breakdown (mechanical) of cardiac pulse generator (battery), sequela			
T82.118A	Breakdown (mechanical) of other cardiac electronic device, initial encounter			
T82.118D	Breakdown (mechanical) of other cardiac electronic device, subsequent encounter			
T82.118S	Breakdown (mechanical) of other cardiac electronic device, sequela			
T82.119A	Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter			
T82.119D	Breakdown (mechanical) of unspecified cardiac electronic device, subsequent encounter			
T82.119S	Breakdown (mechanical) of unspecified cardiac electronic device, sequela			
T82.120A	Displacement of cardiac electrode, initial encounter			
T82.120D	Displacement of cardiac electrode, subsequent encounter			
T82.120S	Displacement of cardiac electrode, sequela			

T82.121A	Displacement of cardiac pulse generator (battery), initial encounter		
T82.121D	Displacement of cardiac pulse generator (battery), subsequent encounter		
T82.121S	Displacement of cardiac pulse generator (battery), sequela		
T82.128A	Displacement of other cardiac electronic device, initial encounter		
T82.128D	Displacement of other cardiac electronic device, subsequent encounter		
T82.128S	Displacement of other cardiac electronic device, sequela		
T82.129A	Displacement of unspecified cardiac electronic device, initial encounter		
T82.129D	Displacement of unspecified cardiac electronic device, subsequent encounter		
T82.129S	Displacement of unspecified cardiac electronic device, sequela		
T82.190A	Other mechanical complication of cardiac electrode, initial encounter		
T82.190D	Other mechanical complication of cardiac electrode, subsequent encounter		
T82.190S	Other mechanical complication of cardiac electrode, sequela		
T82.191A	Other mechanical complication of cardiac pulse generator (battery), initial encounter		
T82.191D	Other mechanical complication of cardiac pulse generator (battery), subsequent encounter		
T82.191S	Other mechanical complication of cardiac pulse generator (battery), sequela		
T82.198A	Other mechanical complication of other cardiac electronic device, initial encounter		
T82.198D	Other mechanical complication of other cardiac electronic device, subsequent encounter		
T82.198S	Other mechanical complication of other cardiac electronic device, sequela		
T82.199A	Other mechanical complication of unspecified cardiac device, initial encounter		
T82.199D	Other mechanical complication of unspecified cardiac device, subsequent encounter		
T82.199S	Other mechanical complication of unspecified cardiac device, sequela		
T82.6XXA	Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter		
T82.6XXD	Infection and inflammatory reaction due to cardiac valve prosthesis, subsequent encounter		
T82.6XXS	Infection and inflammatory reaction due to cardiac valve prosthesis, sequela		
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter		
T82.7XXD	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, subsequent encounter		
T82.7XXS	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, sequela		
Z00.6	Encounter for examination for normal comparison and control in clinical research program		
Z45.02	Encounter for adjustment and management of automatic implantable cardiac defibrillator		
Z76.82	Awaiting organ transplant status		
Z86.74	Personal history of sudden cardiac arrest		

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- 84. Specialty matched clinical peer review.

Revision History

Company(ies)	DATE	REVISION
EmblemHealth	Jul. 24, 2020	Added that substernal leads are investigational
ConnectiCare		

EmblemHealth	Jul. 8, 2020	Added arrhythmogenic right ventricular dysplasia (ARVD) to
ConnectiCare		adult transvenous ICD section