Cardio Policy:

Cardiac Resynchronization Therapy Implantation

POLICY NUMBER UM CARDIO_1149	**SUBJECT** Cardiac Resynchronization Therapy Implantation		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 02/13/19, 03/08/19, 07/30/19, 12/11/19, 08/12/20, 10/14/20, 07/14/21, 08/11/21, 07/13/22, 02/01/23, 03/16/23, 12/20/23	**APPROVAL DATE** December 20, 2023	**EFFECTIVE DATE** December 22, 2023	**COMMITTEE APPROVAL DATES** 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 02/13/19, 03/08/19, 07/30/19, 12/11/19, 08/12/20, 10/14/20, 07/14/21, 08/11/21, 07/13/22, 02/01/23, 03/16/23, 12/20/2023	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Cardiac Resynchronization Therapy Implantation.

II. DEFINITIONS

Cardiac pacing modalities that utilize BiV (Biventricular) or LV (Left Ventricular) stimulation to optimize cardiac pump function through synchronization of ventricular contraction is referred to as cardiac resynchronization therapies (CRT). The rationale for resynchronization is based on the clinical observation that CHF patients with intraventricular conduction defects (IVCD) have mechanical dyssynchronization between the left ventricle (LV) and the right ventricle (RV) throughout the cardiac cycle which adversely affects LV performance.

BiV pacing simultaneously activates the right and left ventricles using a combination of conventional dual chambers pacing of the right atrium and the right ventricle and specialized pacing of the left ventricle through leads positioned via the coronary sinus.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC

is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[2,3,4,5]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity for CRT-D implantation include:

A. Ischemic Cardiomyopathy with prior MI greater than 40 days, LVEF less than or equal to 35%, QRS120-149ms, LBBB, Sinus rhythm with NYHA Class II, despite being on optimal guideline directed medical therapy for at least 3 months. **(AUC Score 7)**[1,2,3]

B. Ischemic Cardiomyopathy with prior MI greater than 40 days, LVEF less than or equal to 35%, QRS120-149ms, LBBB, Sinus rhythm with NYHA Class III, ambulatory Class IV, despite being on optimal guideline directed medical therapy for at least 3 months. **(AUC Score 8)**[1,2,3]

C. Ischemic Cardiomyopathy with prior MI greater than 40 days, LVEF less than or equal to 35%, QRS greater than or equal to 150ms, LBBB, Sinus rhythm with NYHA Class II despite being on optimal guideline directed medical therapy for at least 3 months. **(AUC Score 8)**[1,2,3]

D. Ischemic Cardiomyopathy with prior MI greater than 40 days, LVEF less than or equal to 35%, QRS greater than or equal to 150ms, LBBB, Sinus rhythm with NYHA Class III, ambulatory Class IV, despite being on optimal guideline directed medical therapy for at least 3 months. **(AUC Score 9)**[1,2,3]

E. Non-Ischemic Cardiomyopathy LVEF less than or equal to 35%, QRS120-149ms, LBBB, Sinus rhythm with NYHA Class II, despite being on optimal guideline directed medical therapy stable for at least 3 months. **(AUC Score 7)**[1,2,3]

F. Non-Ischemic Cardiomyopathy LVEF less than or equal to 35%, QRS120-149ms, LBBB, Sinus rhythm with NYHA Class III, ambulatory IV despite being on optimal guideline directed medical therapy stable for at least 3 months. **(AUC Score 8)**[1,2,3]

G. Non-Ischemic Cardiomyopathy LVEF less than or equal to 35%, QRS greater than or equal to 150ms, LBBB, Sinus rhythm with NYHA Class II, III, ambulatory IV despite being on optimal guideline directed medical therapy stable for at least 3 months. **(AUC Score 9)**[1,2,3]

H. Patients with symptomatic permanent AFib, NYHA Class III-IV, LVEF less than or equal to 35%, QRS greater than or equal to 130ms may benefit with CRT-D implantation when done along with AV Nodal Ablation. **(AUC Score 5)**[1,2,3]

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I. Patients with symptomatic permanent AFib with slow ventricular response or have pacemaker dependency, NYHA Class III-IV, LVEF less than or equal to 35%, QRS greater than or equal to 130ms may benefit with CRT-D implantation. **(AUC Score 5)**[1,2,3]

J. Repositioning or revision of previously implanted cardiac venous system (LV) lead is reasonable when there is documentation of LV lead malfunction on a recent device interrogation. **(AUC Score 7)**[1,2,3]

K. Limitations- Patients with ischemic cardiomyopathy should have a measured LVEF less than or equal to 35%. Patients must NOT have any of the following:

1. Cardiogenic shock or symptomatic hypotension while in stable baseline rhythm
2. Had a coronary artery bypass graft (CABG) or percutaneous trans luminal coronary angioplasty (PTCA) within past 3 months
3. Had an enzyme-positive MI within past 40 days
4. Clinical symptoms or findings that would make them a candidate for coronary revascularization
5. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure) associated with a likelihood of survival less than 1 year.

Indications for approving a request for medical necessity for CRT-P implantation include:

A. CRT-P implantation is indicated in patients with need for frequent RV pacing greater than 40% of time, regardless of NYHA class, in the setting of LVEF less than or equal to 50% with narrow QRS. **(AUC Score 7)**[1,2,3]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

B. Before implantation of CRT-D/CRT-P for heart failure the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT [2,3,4,5]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review

1. Progress note that prompted request
2. Recent EKG (within 10 days) if not documented in notes
3. Most recent Echocardiogram/Nuclear Stress Test/MUGA/Cardiac Cath Report, if not documented in notes

B. Primary codes appropriate for this service: 33249+33225 - CRT-D Implant, 33208+33225 - CRT-P, 33225+33228 or 33229 - Conversion of existing pacemaker system to biventricular system. 33225+33263 or 33264 - Conversion of existing IDC system to biventricular system. 33226 - Repositioning or revision of LV lead. 33215 - Repositioning of PM or ICD lead, 33216 - Insertion of single lead, 33217 - Insertion of 2 leads PM or ICD, 33218 - Repair single lead PM or ICD, 33220 - Repair 2 leads for PM or ICD.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

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B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. National Coverage Determination - NCD - Biventricular Pacing/ Cardiac Resynchronization Therapy NCD 20.4. [Accessed December 19, 2023].
2. Andrea M. Russo, MD, FACC, FHRS, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy. March 2013, Volume 61, Number 12, Pages 1318-1368.
3. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
4. Ann B. Curtis, et al. Biventricular Pacing for Atrioventricular Block and Systolic Dysfunction. N Engl J Med 2013; 368:1585-1593 DOI: 10.1056/NEJMoa1210356.
5. Al-Khatib SM, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2018 Oct 2;72(14):e91-e220.
6. NCQA UM 2023 Standards and Elements.

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