New Century Health

Cardio Policy:

Wireless Pulmonary Artery Pressure Device Placement and Monitoring

POLICY NUMBER UM CARDIO_1402	**SUBJECT** Wireless Pulmonary Artery Pressure Device Placement and Monitoring		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 06/10/20, 06/14/21, 11/09/21, 08/10/22, 02/01/23	**APPROVAL DATE** February 1, 2023	**EFFECTIVE DATE** February 1, 2023	**COMMITTEE APPROVAL DATES** 06/10/20, 06/14/21, 11/09/21, 08/10/22, 02/01/23	
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 the implantation of a Wireless Invasive Pulmonary Artery Pressure Monitoring device and ongoing data collection.

II. DEFINITIONS

Patients with chronic congestive heart failure (CHF), who have been hospitalized for this diagnosis are at an increased risk of rehospitalization, regardless of their left ventricular ejection fraction (LVEF). Since 2011, several studies have demonstrated a reduction in CHF hospitalizations through the method of following patient's pulmonary artery pressure (PAP) as a predictor of an impending CHF exacerbation and subsequent hospitalization.

This is an implantable PAP monitoring device that allows a direct monitoring of the PAP via a sensor implanted in the PA. The sensor monitors changes in the PAPs and communicates via wireless to an external analyzer. This information is then uploaded to a web-based interface from which healthcare providers can track the results and manage patients.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. 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 the 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. [5]

III. POLICY

Indications for approving a request for medical necessity are:

A. Patients with CHF of any LVEF type who have been hospitalized at least once over the prior year and still have Class III symptoms, and have been re-hospitalized with decreasing time intervals over the prior year, and have demonstrated chronically elevated mean PAP (greater than 30 mmHg) and PCWP greater than or equal to 20 mmHg by invasive means, or a PAS pressure greater than 40 mmHg by echocardiography measured in between acute exacerbations and within 30 days of the intended Wireless Pulmonary Artery Pressure device implant, despite documented compliance with maximally tolerated GDMT in conjunction with non-pharmacological adjuvant treatments (e.g. daily weights, dietary restrictions, VNS home visits) to prevent hospitalization for CHF. **(AUC Score 4)**[1,2,3,4]

B. Remote monitoring of the data is billable once per 30 days and must include at least once weekly downloads of pulmonary artery pressure recordings, interpretations(s), trend analysis, and report(s) by a physician or other qualified health care professional. **(AUC Score 4)**[1,2,3,4]

Limitations

A. The Wireless Pulmonary Artery Pressure Device System is contraindicated for patients with:
   1. an inability to take dual antiplatelet or anticoagulants for one-month post implant
   2. Have a GFR less than 25 cc/min or who are non-responsive to diuretic therapy or are on chronic renal replacement therapy
   3. Have a history of recurrent PE or DVT
   4. Have congenital heart disease
   5. Are likely to undergo heart transplantation or VAD placement within the next 6 months

B. The patient must be followed by a heart failure team within the health care facility.

C. Before a wireless pulmonary artery pressure device system can be implanted in a patient with heart failure the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[2,3,4,5]

D. 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.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request from Interventional Cardiologist/ Heart Failure
   2. Echocardiogram and right heart catheterization reports

B. Primary codes appropriate for this service: Implantation of wireless PAP sensor monitor: 33289. For remote monitoring of an implantable wireless pulmonary artery pressure sensor monitor, use 93264
   1. Codes 93451 and 93568 are not to be used with 33289
   2. If 93264 is being billed, then physiologic monitoring codes i.e. 93297 can no longer be used

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. CardioMEMS HF System Post Approval Study; ClinicalTrials.gov Identifier: NCT02279888; Study Completion Date: February 3, 2020; https://clinicaltrials.gov/ct2/show/study/NCT02279888
2. Piotr Ponikowski, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC); Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. European Heart Journal, Volume 37, Issue 27, 14 July 2016, Pages 2129–2200, https://doi.org/10.1093/eurheartj/ehw128
3. Abraham WT, Stevenson LW, Bourge RC, Lindenfeld JA, Bauman JG, Adamson PB. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomized trial. Lancet 2016; 387:453–461.
4. Abraham, WT, Adamson, PB, Bourge, RC. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. Lancet 2011; 377: 658–666.
5. Maddox TM, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2021 Feb 16;77(6):772-810.
6. NCQA UM 2022 Standards and Elements