New Century Health

# Cardio Policy:

# Endomyocardial Biopsy

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| **POLICY NUMBER**<br>UM CARDIO_1388 | **SUBJECT**<br>Endomyocardial Biopsy | | **DEPT/PROGRAM**<br>UM Dept | **PAGE 1 of 3** |
| **DATES COMMITTEE REVIEWED**<br>02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23 | **APPROVAL DATE**<br>January 11, 2023 | **EFFECTIVE DATE**<br>January 27, 2022 | **COMMITTEE APPROVAL DATES**<br>02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23 | |
| **PRIMARY BUSINESS OWNER:** UM | | **COMMITTEE/BOARD APPROVAL**<br>Utilization Management Committee | | |
| **URAC STANDARDS**<br>HUM v8: UM 1-2; UM 2-1 | **NCQA STANDARDS**<br>UM 2 | | **ADDITIONAL AREAS OF IMPACT** | |
| **CMS REQUIREMENTS** | **STATE/FEDERAL REQUIREMENTS** | | **APPLICABLE LINES OF BUSINESS**<br>Commercial, Exchange, Medicaid | |

## I. PURPOSE

Indications for determining medical necessity for Endomyocardial Biopsy.

## II. DEFINITIONS

Endomyocardial biopsy (EMB) is an invasive procedure used routinely to obtain small samples of heart muscle, primarily for detecting rejection of a donor heart following heart transplantation. It is also used as a diagnostic tool in some heart diseases. A bioptome which is a small pincer/grasper cutting instrument is used to gain access to the heart via a sheath inserted into the right internal jugular or less commonly the femoral vein. Guidance and confirmation of correct positioning of the bioptome is made by echocardiography or fluoroscopy before the biopsy specimen is taken and in the case of transplants, usually three or four or more samples are taken.

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

## III. POLICY

### Indications for approving a request for medical necessity are:

A. It is reasonable to perform EMB in a Heart Transplant candidate suspected of having an infiltrative cardiomyopathy or an inflammatory process, such as giant cell myocarditis, amyloidosis, or sarcoidosis. **(AUC Score 6)**[1,3,4,6]

B. The standard of care for adult Heart Transplant recipients is to perform periodic EMB, every week for the first 4 weeks post heart transplant followed by every 3 months during the first 6 to 12 post-operative months for surveillance of HT rejection. **(AUC Score 8)**[1,3,4,6]

C. After the first post-operative year, EMB surveillance for an extended period (e.g., every 4–6 months) is recommended in Heart Transplant recipients who are at higher risk for late acute rejection. **(AUC Score 7)**[1,3,4,6]

D. The use of routine EMB later than 5 years after HT is optional in adults and is dependent on clinical judgment and the risk for late allograft rejection. **(AUC Score 5)**[1,3,4,6]

E. EMB can be performed in the setting of unexplained, new-onset heart failure of less than 2 weeks' duration associated with a normal-sized or dilated left ventricle in addition to hemodynamic compromise i.e. cardiogenic shock or require inotropic agents or mechanical assistance for circulatory support. Example: Giant Cell myocarditis, Necrotizing Eosinophilic Myocarditis. **(AUC Score 8)**[1,2,4,5,6]

F. EMB is reasonable in the clinical setting of unexplained heart failure of greater than 3 months' duration associated with a dilated left ventricle and new ventricular arrhythmias, Mobitz type II second- or third-degree AV heart block, or failure to respond to usual care within 1 to 2 weeks. Example: suspected Cardiac Sarcoidosis or Idiopathic Granulomatous Myocarditis. **(AUC Score 6)**[1,2,4,5,6]

G. EMB is reasonable to perform in heart failure patients with suspected cardiomyopathy related to cardiotoxic drugs like anthracycline or suspected restrictive cardiomyopathy. **(AUC Score 5)**[1,2,4,5,6]

### Limitations

A. The accuracy of diagnosis by EMB depends on whether the correct site is biopsied. There is a risk that a diagnosis can be missed if the biopsy misses the diseased part of heart muscle, particularly with myocardial inflammation or fibrosis.

B. 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
2. Echo / MUGA / Cardiac Cath report
3. Any previous Endomyocardial biopsy report

B. Primary codes appropriate for this service: 93505; Endomyocardial biopsy

## V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

## VI. ATTACHMENTS

A. None

## VII. REFERENCES


1. Current Status of Endomyocardial Biopsy. Mayo Clin Proc. 2011;86(11):1095-1102
2. Cooper LT Jr. Role of left ventricular biopsy in the management of heart disease. Circulation 2013; 128:1492.
3. Costanzo et al. Guidelines for Heart Transplant Care. The Journal of Heart and Lung Transplantation, Vol 29, No 8, August 2010.
4. The role of endomyocardial biopsy in the management of cardiovascular disease: AHA/ACCF/ESC scientific statement. European Heart Journal (2007) 28, 3076–3093.
5. Cooper LT, Baughman KL, Feldman AM, et al. The role of endomyocardial biopsy in the management of cardiovascular disease: a scientific statement from the American Heart Association, the American College of Cardiology, and the European Society of Cardiology. Circulation 2007; 116:2216.
6. 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.
7. NCQA UM 2022 Standards and Elements.






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