The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Several commercially available laboratory tests assess heart transplant rejection including the Heartsbreath™ test, which measures breath markers of oxidative stress, and the AlloMap™ test, which conducts gene expression profiling (GEP). These tests are proposed as an alternative to, or adjunct to, endomyocardial biopsy, which is invasive, and its interpretation may have high interobserver variability.

Background

The majority of cardiac transplant recipients experience at least one episode of rejection in the first year after transplantation. Acute cellular rejection is most likely to occur in the first six months, with a significant decline in the incidence of rejection after this time. Although immunosuppressants are required on a life-long basis, dosing is adjusted based on graft function and the grade of acute cellular rejection determined by histopathology.

Endomyocardial biopsies are typically taken from the right ventricle via the jugular vein periodically during the first six to 12 months post-transplant. The interval between biopsies varies among clinical centers. A typical schedule is weekly for the first month, once or twice monthly for the following six months, and several times (monthly to quarterly) between six months and one year post-transplant. Surveillance biopsies may also be performed after the first postoperative year, e.g., on a quarterly or semi-annual basis. This practice, although common, has not been demonstrated to improve transplant outcomes. Some centers no longer routinely perform endomyocardial biopsies after one year in patients who are clinically stable.

While endomyocardial biopsy is the gold standard for assessing heart transplant rejection, it is limited by a high degree of interobserver variability in grading of results and potential morbidity that can occur with the biopsy procedure. Also, the severity of rejection may not always coincide with the grading of the rejection by biopsy. Finally, biopsy cannot be used to identify patients at risk of rejection, limiting the ability to initiate therapy to interrupt the development of rejection. For these reasons, endomyocardial biopsy is considered a flawed gold standard by many. Therefore, noninvasive methods of detecting cellular rejection have been explored. It is hoped that noninvasive tests will assist in determining appropriate patient management and avoid overuse or underuse of treatment with steroids and other immunosuppressants that can occur with false-negative and false-positive biopsy reports. Two techniques have become commercially available for the detection of heart transplant rejection.

The Heartsbreath™ test (Menssana Research, Inc.), a noninvasive test that measures breath markers of oxidative stress, has been developed to assist in the detection of heart transplant rejection. In heart transplant recipients, oxidative stress appears to accompany allograft rejection, which degrades membrane polyunsaturated fatty
The measurement of volatile organic compounds with the Heartsbreath test to assist in the detection of grade three heart transplant rejection is considered investigational.

The use of peripheral blood genetic profiling tests in the management of patient’s post-heart transplantation, including but not limited to the detection of acute heart transplant rejection or heart transplant graft dysfunction, is considered investigational.
Medicare Advantage

AlloMap™ may be considered **medically necessary** for the FDA approved indication to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment.

The Heartsbreath™ test is considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. **For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.**

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


12. Noridian Healthcare Solutions, LLC, (Jurisdiction- Northern California) Local Coverage Determination (LCD): Molecular Diagnostic Tests (MDT) (L33541), Revision Effective Date for services performed on or after 11/01/2013.