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Laboratory Tests for Heart Transplant Rejection

EFFECTIVE DATE	08/18/2009	LAST UPDATED	09/21/2010

Description:

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 6 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 on a weekly basis for the first month, and once or twice monthly for the following 6 months. Surveillance biopsies may also be performed on a yearly basis following stabilization.

While endomyocardial biopsy is the gold standard for assessing heart transplant rejection, biopsy may be limited by a high degree of interobserver variability in grading of results and the significant morbidity and even mortality 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 non-invasive 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.) is a noninvasive test that measures breath markers of oxidative stress that has been developed to assist in the detection of heart transplant rejection. In heart transplant recipients, oxidative stress appears to accompany allograft rejection that degrades membrane polyunsaturated fatty acids and evolving alkanes and methylalkanes that are in turn excreted as volatile organic compounds in breath. The Heartsbreath test analyzes the breath methylated alkane contour (BMAC), which is derived from the abundance of C4-C20 alkanes and monomethylalkanes and has been identified as a marker to detect grade 3 (significant) heart transplant rejection.

The Heartsbreath test is indicated for use as an aid in the diagnosis of grade 3 heart transplant rejection in patients who have received heart transplants within the preceding year. The device is intended to be used as an adjunct to, and not as a substitute for, endomyocardial biopsy, and is also limited to patients who have had endomyocardial biopsy within the previous month.

AlloMap™ is a commercially available molecular expression test that has been developed to detect acute heart transplant rejection or the development of graft dysfunction. The test involves PCR expression measurement of a panel of genes derived from peripheral blood cells, and applies an algorithm to the results. The algorithm produces a single score that considers the contribution of each gene in the panel.

Evidence to date is insufficient to permit conclusions concerning the effect of the technology on health outcomes. Additional clinical experience is needed to confirm and extend the current results. Furthermore, the impact of this type of testing on management decisions and health outcomes is unknown.

In 2008 the Centers for Medicare and Medicaid Services (CMS) issued a non-coverage decision for the Heartsbreath Test. (12) CMS has determined that the evidence does not adequately define the technical characteristics of the test nor demonstrate that Heartsbreath testing to predict heart transplant rejection improves health outcomes in Medicare beneficiaries.

Medical Criteria:

Not applicable.

Policy:

All uses of AlloMap and Heartsbreath tests are considered not medically necessary due to lack of peer-reviewed medical literature which supports the efficacy of the tests.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, Benefit Booklet, or RIte Care Contract for the applicable not medically necessary services.

Coding:

0085T

There is no specific CPT code for the AlloMap test.

Also Known As:

Not applicable

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