Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Gene expression profiling (e.g., AlloMap) for the detection of heart transplantation rejection is COVERED for monitoring rejection in heart transplant recipients more than six months post-heart transplant.

Gene expression profiling for detection of heart transplantation for all other indication is investigative and therefore NOT COVERED.

Description
Heart transplantation is common therapy for the treatment of end-stage heart failure. Since the first heart transplant procedure performed in 1967, overall survival rates have increased dramatically, and current estimated survival rates are approximately 90% at one year, 70% at five years, and 50% at 10 years. However, life-threatening complications may occur with heart transplantation, including infection, allograft rejection, and allograft vascular disease. Immunosuppressive drugs are provided to patients following heart transplantation. Graft rejection is most frequent within the first month following transplantation, and patient survival is dependent on accurate monitoring for allograft rejection and dysfunction.

Endomyocardial biopsy is the current standard for detecting allograft rejection after transplantation, occurring on a regular basis. As endomyocardial biopsy is invasive and have several limitations, alternative noninvasive techniques to detect rejection have been investigated. The AlloMap (CareDx, Brisbane, CA) test is intended for patients a low probability of moderate to severe acute cellular rejection (ACR) at the time of testing. It incorporates gene expression profiles of 11 informative genes and 9 control genes using a laboratory-generated algorithm to determine an AlloMap score to determine rejection risk in heart transplant patients 55 days or more post-transplant.

FDA Approval
In 2008 the FDA granted 510(k) Class II approval for AlloMap to “aid in the identification of heart transplant recipients with stable allograft function who have low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment.”
Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
81595 - cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score

Original Effective Date: 5/1/2017

Re-Review Date(s):