HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Pennsylvania
Certification(s)/Specialty: Internal Medicine

<table>
<thead>
<tr>
<th>Case Number:</th>
<th>CM15-0021258</th>
<th>Date Assigned:</th>
<th>02/10/2015</th>
<th>Date of Injury:</th>
<th>01/01/1974</th>
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<tr>
<td>Decision Date:</td>
<td>06/15/2015</td>
<td>UR Denial Date:</td>
<td>01/14/2015</td>
<td>Application Received:</td>
<td>02/03/2015</td>
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CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 64-year-old male injured worker suffered and industrial injury on 1/1/1974. The diagnoses include diabetes, heart transplant 7/28/2013, immunosuppression, prostatic hypertrophy, and hypertension. Prior treatments have included medications. Progress note of 10/1/14 notes that the last cardiac biopsy was performed in August. The injured worker complained of fatigue, soreness, not sleeping well, and urinating 3-4 times per night. Examination showed normal cardiac examination, and 1-2 plus bilateral ankle edema. The physician noted that the injured worker was stable post transplant, with plan for labs. Progress note of 11/6/14 addressed the treatment of diabetes. Examination showed normal heart rate and rhythm, normal heart sounds, normal breath sounds without rales or wheezes, and no edema. The indications and reasons for the requested testing now under Independent Medical Review was not discussed in the documentation submitted. The Utilization Review Determination on 1/14/2015 non-certified cylex study quantity 1, Flow-PRA study quantity 1, EKG quantity 1, and chest x-ray quantity 1, citing The International Society of Heart and Lung Transplantation Guidelines for The Care of Heart Transplant Recipients. J Heart Lung Transplant. 2010 Aug; 29(8):933-44.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Cylex study, quantity: 1: Upheld
Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation The International Society of Heart and Lung Transplantation Guidelines for The Care of Heart Transplant Recipients. J Heart Lung Transplant. 2010 Aug; 29(8):933-44.


Decision rationale: This injured worker is status post heart transplantation in 2013. The MTUS and ODG are silent with regards to Cylex study. The Cylex immune assay has been proposed as a means of tailoring immunosuppression after organ transplantation. There are limited data regarding its utility in cardiac transplant recipients. A retrospective review of the clinical course of adult cardiac transplant recipients who underwent a Cylex assay found that the assay had limited utility as an adjunct to routine clinical evaluation in assessing risk of infection or rejection in cardiac transplant patients. In this case, the treating physician has not provided sufficient clinical information to support the requested testing. No clear indication for the requested testing was documented. The cited reference notes that this assay has limited utility in the assessment of risk of infection or rejection in cardiac transplant patients. Due to lack of specific indication, the request for Cylex study is not medically necessary.

Flow -PRA, study, quantity: 1: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation The International Society of Heart and Lung Transplantation Guidelines for The Care of Heart Transplant Recipients. J Heart Lung Transplant. 2010 Aug; 29(8):933-44.


Decision rationale: This injured worker is status post heart transplantation in 2013. The MTUS and ODG are silent with regards to Flow-PRA study. Acute rejection is a common problem after heart transplantation, particularly early after transplantation. Most cases are due to cellular rejection. Antibody-mediated rejection is a less easily diagnosed process. Surveillance endomyocardial biopsies are performed most frequently in the first three to six months after transplantation, and are continued less frequently in subsequent years. Potential noninvasive alternatives to biopsy for detection of acute rejection have been investigated. Historically, panel reactive antibody (PRA) analysis to detect HLA antibodies has been performed using cell based complement dependent cytotoxicity techniques. A Flow cytometric procedure is an alternative approach to detect HLA antibodies. This approach may identify cardiac allograft recipients at risk for rejection. In this case the treating physician has not provided sufficient clinical information to support the requested testing. No clear indication for the requested testing was documented. The documentation indicates that the injured worker had undergone cardiac biopsy. The guidelines suggest that the use of Flow-PRA studies are considered investigational. Due to lack of specific indication, the request for Flow-PRA study is not medically necessary.
EKG (electrocardiogram), quantity:1: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation The International Society of Heart and Lung Transplantation Guidelines for The Care of Heart Transplant Recipients. J Heart Lung Transplant. 2010 Aug; 29(8):933-44.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Electrocardiogram in the diagnosis of myocardial ischemia and infarction. In UpToDate, Post TW (Ed), UpToDate, Waltham, MA 2015The International Society of Heart and Lung Transplantation Guidelines for the care of heart transplant recipients. J Heart Lung Transplant. 2010 Aug; 29(8):933-44.

Decision rationale: This injured worker is status post heart transplantation in 2013. The MTUS and ODG are silent with regards to Flow-PRA study. Acute rejection is a common problem after heart transplantation, particularly early after transplantation. Most cases are due to cellular rejection. Antibody-mediated rejection is a less easily diagnosed process. Surveillance endomyocardial biopsies are performed most frequently in the first three to six months after transplantation, and are continued less frequently in subsequent years. Potential noninvasive alternatives to biopsy for detection of acute rejection have been investigated. Historically, panel reactive antibody(PRA) analysis to detect HLA antibodies has been performed using cell based complement dependent cytotoxicity techniques. A Flow cytometric procedure is an alternative approach to detect HLA antibodies. This approach may identify cardiac allograft recipients at risk for rejection. In this case, the treating physician has not provided sufficient clinical information to support the requested testing. No clear indication for the requested testing was documented. The documentation indicates that the injured worker had undergone cardiac biopsy. The guidelines suggest that the use of Flow-PRA studies are considered investigational. Due to lack of specific indication, the request for Flow-PRA study is not medically necessary.

Chest x-ray, quantity: 1: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation The International Society of Heart and Lung Transplantation Guidelines for The Care of Heart Transplant Recipients. J Heart Lung Transplant. 2010 Aug; 29(8):933-44.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG pulmonary chapter: x-ray.

Decision rationale: The ODG recommends a chest x-ray for acute cardiopulmonary findings by history and physical, or for chronic cardiopulmonary disease in the elderly. A chest x-ray is typically the first imaging test used to help diagnose symptoms such a shortness of breath, persistent cough, chest pain or injury, and fever. In this case, the injured worker had undergone a heart transplant in 2013. The treating physician has not provided sufficient clinical information to support the requested chest x-ray. No clear indication for the chest x-ray was documented. There was no documentation of current symptoms of shortness of breath, cough, chest pain, or fever. Heart and lung examination were normal. Due to lack of presence of cardiopulmonary symptoms or findings, the request for chest x-ray is not medically necessary.