



Notice of Independent Review Decision
IRO REVIEWER REPORT

DATE OF REVIEW: 7/2/10

IRO CASE #: _____ **NAME:** _____
DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Determine the appropriateness of the previously denied request for Liver transplantation.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

General surgeon with transplant experience

REVIEW OUTCOME:

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- | | |
|--|----------------------------------|
| <input type="checkbox"/> Upheld | (Agree) |
| <input checked="" type="checkbox"/> Overturned | (Disagree) |
| <input type="checkbox"/> Partially Overturned | (Agree in part/Disagree in part) |

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

The previously denied request for liver transplantation.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Confirmation of Receipt of a Request for a Review by an Independent Review Organization dated 6/24/10.
- Letter dated 6/24/10, 6/9/10
- Request Form Request for a Review by an Independent Review Organization dated 6/23/10.
- Notification Letter dated 6/22/10.
- Medical Determination Letter dated 6/9/10.
- Urgent Appeal Letter dated 6/15/10.
- Laboratory Test Results dated 6/3/10 – 2/15/10
- Liver Recipient Evaluation Form dated 6/2/10.
- Abdomen Examination Results dated 5/21/10, 4/5/10.

- Transplant Clinic Note dated 5/21/10.
- Tumor Examination Results dated 5/20/10.
- Pulmonary Function Analysis Results dated 5/19/10.
- Trans Thoracic Echo Cardiogram Results dated 5/19/10.
- Chest Examination Results dated 5/19/10, 4/2/10.
- Non-Gyn Final Report dated 4/7/10.
- Operative Report dated 3/30/10.
- Surg Path Final Report dated 3/24/10.
- Transplant Clinic Psychosocial Assessment dated 2/17/10.
- Whole Body Examination Results dated 2/17/10.
- Company Request for IRO Information (unspecified date).
- Appeal Information and Procedure (unspecified date).
- Appeal Request Form (unspecified date).
- Request for a Review by an Independent Review Organization Instructions (unspecified date).
- Health Care Service Corporation Report (unspecified date).
- Case Event Summary Report (unspecified date).
- Article Source (unspecified date).
- There were no guidelines provided by the URA for this referral.

PATIENT CLINICAL HISTORY (SUMMARY):

Age:

Gender: Male

Date of Injury: N/A

Mechanism of Injury: N/A

Diagnosis: Neuroendocrine tumor of the pancreas metastatic to the liver.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Liver transplantation is now a routine procedure for patients with end stage liver disease. The priority is based on liver function criteria such as serum bilirubin, creatinine, and prothrombin time (INR). There is a second set of criteria for liver transplant when functional failure of the liver is not the issue. Biliary atresia is one of the childhood indications in which failure of the liver is secondary to anatomical cause. Certain types of cancer are now accepted as indications for transplantation. Hepatocellular cancer is one indication, although the results are dependent on the absence of extrahepatic disease. Cholangiocarcinoma is an indication for transplantation so long as certain criteria are met. Among these is the size of the tumor. HIV-positive patients are now being accepted in some centers.

Liver transplantation for metastatic disease from extrahepatic sources has been

generally been considered unacceptable because of the development of further metastases, even in the transplanted liver. Certain very slow growing primary cancers have recently been reassessed for the possibility of transplantation when the disease is confined to the liver. An example is carcinoid, which may produce massive hepatomegaly but follow a benign course for many years. Other neuroendocrine tumors have similar behavior. The results of several small series may be compared to the results for other tumors, such as cholangiocarcinoma (CCA). The Mayo Clinic has published a series from 1993 to 2006 with a five-year survival rate of 76%. Other centers have published less encouraging results. Among the reports considered for this review, it is apparent that a steep learning curve in patient selection has occurred the past decade. In a 2000 report from Sloan Kettering Cancer Center, recommended treatment was hepatic artery embolization and hepatic resection. No attempts at cure by transplant were reported. "Patients with bilobar or more than 75% liver involvement by tumor were least likely to benefit from surgical resection. One-, 3-, and 5-year survival rates for the entire group were 83%, 61%, and 53%, respectively. The 1-, 3-, and 5-year survivals for patients treated with medical therapy, HAE, and operation were 76%, 39%, and not available; 94%, 83%, and 50%; and 94%, 83%, and 76%, respectively." The five-year survival indicates the indolent nature of these tumors. A recent study from Brussels describes more current practice. "Summary: Neuroendocrine tumor (NET) metastases represent at this moment the only accepted indication of liver transplantation (LT) for liver secondaries. Between 1984-2007, nine (1.1%) of 824 adult LTs were performed because of NET. There were five well differentiated functioning NETs (four carcinoids and one gastrinoma), three well differentiated non functioning NETs and one poorly differentiated NET. Indications for LT were an invalidating unresectable tumor (4x), and/or a diffuse tumor localization (3x) and/or a refractory hormonal syndrome (5x). Median post-LT patient survival is 60.9 months (range 4.8-119). One-, 3- and 5-year actuarial survival rates are 88%, 77%, and 33%; 1, 3, and 5 years disease free survival rates are 67%, 33%, and 11%. Due to a more rigorous selection procedure, results improved since 2000; three out of five patients are alive disease-free at 78, 84, and 96 months. Review of these series together with a review of the literature reveals that results of LT for this oncological condition can be improved using better selection criteria, adapted immunosuppression and neo- and adjuvant surgical as well as medical treatment. LT should be considered earlier in the therapeutic algorithm of selected NET patients as it is the only therapy that can offer a cure." It is the opinion of this reviewer that this young patient should be given the opportunity of LT since the requesting providers are an experienced transplant center and the results of such procedures now approximate the results of other non-optimal candidates.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

□ ACOEM – AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE.

- AHCPR – AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES.
- DWC – DIVISION OF WORKERS' COMPENSATION POLICIES OR GUIDELINES.
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN.
- INTERQUAL CRITERIA.
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS.
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES.
- MILLIMAN CARE GUIDELINES.
- ODG – OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES.
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR.
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE AND PRACTICE PARAMETERS.
- TEXAS TACADA GUIDELINES.
- TMF SCREENING CRITERIA MANUAL.

X PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION).

1. Transplant International. 2010 May 5. [Epub ahead of print] Liver transplantation and neuroendocrine tumors: lessons from a single centre experience and from the literature review.,” by Bonaccorsi-Riani E, Apestegui C, Jouret-Mourin A, Sempoux C, Goffette P, Ciccarelli O, Borbath I, Hubert C, Gigot JF, Hassoun Z, Lerut J., Starzl Unit of Abdominal Transplantation, University Hospitals St Luc, Université Catholique de Louvain (UCL), Brussels, Belgium.
2. Journal of the American College of Surgeons. 2000 Apr;190(4):432-45. Hepatic neuroendocrine metastases: does intervention alter outcomes?,” by Chamberlain RS, Canes D, Brown KT, Saltz L, Jarnagin W, Fong Y, Blumgart LH. Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY 10021, USA.
3. Surgical Oncology Clinics of North America. 2003 Jan; 12(1):231-42. “Hepatic surgery for metastases from neuroendocrine tumors.” by

□ OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION).