

# **INDEPENDENT REVIEWERS OF TEXAS, INC.**

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## Notice of Independent Review Decision

**DATE OF REVIEW:** 06/21/11

**IRO CASE NO.:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Item in dispute: Proton Beam Therapy CPT codes 77523 77525 x28 services fractions

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

Texas Board Certified General Surgeon

Texas Board Certified Colon & Rectal Surgeon

**REVIEW OUTCOME**

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

Denial Upheld

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

1. Article – Proton Beam Therapy
2. Article – Proton Therapy: New Data to Consider
3. Article – Future of Proton Beam Therapy
4. Comparative Summary Distribution Plans: Proton Dose vs IMRT Dose
5. 02/12/10 – Letter – M.D.
6. 04/20/11 – Surgical Pathology Report
7. 05/05/11 – Laboratory Report
8. 05/05/11 – Radiographs Chest
9. 05/05/11 – CT Abdomen/Pelvis
10. 05/06/11 – CT Chest
11. 05/06/11 – PET Scan
12. 05/09/11 – Surgical Pathology Report
13. 05/11/11 – Consultation – M.D.
14. 05/17/11 – Pulmonary Function Report
15. 05/19/11 – Radiology Oncology Stimulation Note
16. 06/03/11 – Expedited Appeal Letter –M.D.
17. 06/06/11-06/08/11 – Fax Cover Sheets
18. 06/07/11 – Request for External Review
19. 06/07/11 – Peer Reviewer Final Report
20. 06/08/11 – Notice of Final Internal Adverse Benefit Determination
21. 06/08/11 – Request for Review by an Independent Review Organization
22. 06/14/11 – Request for External Review

**PATIENT CLINICAL HISTORY (SUMMARY):**

The patient is a XX-year-old male with a diagnosis of stage T3N1 poorly differentiated adenocarcinoma of the distal esophagus and gastroesophageal junction. A pathology report dated 04/20/11 demonstrated invasive mucinous adenocarcinoma.

Radiographs of the chest performed 05/05/11 demonstrated no evidence of acute cardiopulmonary process or pulmonary nodule.

A CT of the chest performed 05/05/11 demonstrated thickening of the distal esophagus at the level of the gastroesophageal junction extending into the cardia of the stomach. There was no evidence of esophageal obstruction. There were no enlarged lymph nodes, but there are several small lymph nodes in the lower paraesophageal and left gastric region.

A CT of the abdomen and pelvis performed 05/05/11 demonstrated distal esophageal/gastroesophageal junction thickening, compatible with the patient's history of esophageal cancer. There were small paraesophageal and left gastric lymph nodes. There was no paraceliac adenopathy.

A PET scan performed 05/06/11 demonstrated the primary tumor was located in the distal esophagus with extension to the proximal stomach with SUV of 6.1. There was no evidence of metastatic disease.

Surgical pathology report of the esophagus tumor dated 05/09/11 demonstrated invasive, poorly differentiated adenocarcinoma with mucinous features and ulceration. Pathology of the left gastric lymph node demonstrated metastatic adenocarcinoma.

The patient saw Dr. on 05/11/11. Physical examination revealed palpable lymphadenopathy at bilateral cervical, supraclavicular, or infraclavicular area. The lungs were clear to auscultation bilaterally without crackles, rales, or wheezing. The heart was in regular rate and rhythm without murmur. The patient was assessed with stage T3 N1 poorly differentiated adenocarcinoma of the gastroesophageal junction. The patient was recommended for concurrent chemoradiation therapy followed by surgical resection.

An appeal letter dated 06/03/11 stated the patient underwent repeat EGD and biopsy on 05/09/11 with findings indicating a friable and ulcerated esophageal mass and blood in contact, which occupied 50% to 74% of the circumference of the esophagus with the distal end 41 cm from the incisors and proximal end 37 cm from the incisors. Ultrasound examination showed a hypoechoic esophageal mass. The outer margin of the mass is irregular, consistent with a T3 tumor. There were 2 peri-tumoral nodes and also a left gastric node. A pathological report from the nodal biopsy at the left gastric station was consistent with metastatic adenocarcinoma. Biopsy from the primary lesion showed invasive poorly differentiated adenocarcinoma with mucinous feature and ulceration. The patient was recommended for a total dose of 50.4 CGE proton beam radiation therapy with concurrent chemotherapy to the target.

The request for proton beam therapy was denied by utilization review on 06/07/11 due to insufficient data to suggest an improvement in overall clinical outcome with the use of proton beam therapy over IMRT.

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

The requested proton beam therapy is not recommended as medically necessary. There is limited and insufficient clinical evidence to establish that proton beam therapy is as beneficial in regards to long-term clinical outcome as standard radiotherapy. There is no indication from the clinical notes provided that the patient had no significant improvements with standard radiotherapy that would warrant the use of proton beam therapy given the limited amount of evidence to support the procedure in clinical literature. Without additional evidence based clinical literature to support the requested procedure over standard radiotherapy, medical necessity is not established at this time.

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

1. Proton Therapy in Clinical Practice: Current Clinical Evidence. *Journal of Clinical Oncology*, Vol 25, No 8 (March 10), 2007: pp. 965-970.