

# US Decisions Inc.

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## NOTICE OF INDEPENDENT REVIEW DECISION

DATE NOTICE SENT TO ALL PARTIES: Feb/28/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Abraxane 11/07/2011 and 11/14/2011

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: M.D. Board Certified Internal Medicine

REVIEW OUTCOME:

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

**Provide a description of the review outcome that clearly states whether medical necessity exists for each health care service in dispute.** It is the opinion of the reviewer that the request for Abraxane on 11/07/11 and 11/14/11 is not recommended as medically necessary

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

CT scan abdomen and pelvis 11/11/10  
Clinical notes 01/19/11-01/04/13  
EGD reports 04/21/11-06/02/11  
Procedure notes 06/24/11  
CT scan 08/08/11-12/07/12  
Previous utilization review 09/11/12  
Healthcare services plan and policy language  
Lab studies 02/28/11-12/07/12

**PATIENT CLINICAL HISTORY [SUMMARY]:** The patient is a male who reported an injury to his abdomen/pelvis. CT scan of the abdomen and pelvis dated 11/11/10 revealed a stable appearance of a sigmoid colon and mild pericolonic fat straining a chronic inflammation. Diverticulitis was also noted and clinical note dated 01/19/11 detailed the patient presenting with chest and epigastric pain rated as 5/10. The patient noted an increase in pain during meals and bedtime. The patient stated that he was having feelings of being bloated. The patient also noted difficulty swallowing solids. Clinical note dated 01/24/11 revealed the patient having adenocarcinoma with signet ring cell. Soft tissue density was noted on CT scan of the same date in the retroperitoneum at the inferior medial aspect of the left anterior pararenal space. Clinical oncology note dated 02/11/11 detailed the patient undergoing an orchiectomy and four courses of BEP chemotherapy. The patient was in complete remission at that time. Procedure note dated 02/14/11 detailed the patient undergoing CT scan which revealed a focal intense FDG accumulation at the gastroesophageal junction compatible with the tumor. The area measured approximately 4x2.2cm. EGD report dated 03/31/11 revealed

a mass in the cardia and distal esophagus. Clinical note and oncology note dated 04/06/11 detailed the patient utilizing carboplatin as part of a pharmacological intervention involving chemotherapy. EGD report dated 04/21/11 revealed a nodule at the distal esophagus. EGD report dated 05/12/11 revealed or confirmed that esophageal nodule. It also noted an infiltrative mass found at the GE junction measuring 38cm at the proximal end and 40cm at the distal end. Oncology note dated 05/23/11 detailed the patient undergoing a third course of carboplatin started on 04/11/11. EGD report dated 06/02/11 detailed the patient continuing with a nodule at the distal esophagus. No significant changes were noted with the ulcerated mass. Procedure note dated 06/24/11 detailed the patient undergoing upper endoscopy and endoscopic ultrasound evaluation.

Two small perigastric lymph nodes were noted. CT scan dated 08/08/11 revealed a low density lesion measuring 1.1x1.3cm. This was possibly an abscess as opposed to a metastatic disease. An additional low density lesion was noted on the left lobe of the liver measuring 1.1x1.6cm. Oncology note dated 08/08/11 detailed the patient showing positive changes regarding the previous treatments. The note specifically stated that the patient had recovered but was continuing with antibiotic therapy. Clinical note dated 08/17/11 detailed the patient continuing with a course of carboplatin that started on 06/13/11. Lab studies revealed white blood cell count down to 10.2 from 18.1. The patient had bilateral plural effusion in an abscess at the anterior portion of the abdomen. IV antibiotics consisting of Rocephin and Cubicin were noted. CT scan dated 08/22/11 revealed post-surgical changes at the abdomen. Small fluid collection was noted superior to the pancreas without previously noted air pockets. Clinical note dated 08/29/11 detailed lab studies revealing white blood cell count of 4.47. Oncology note dated 09/29/11 detailed the patient restarting course of carboplatin. However, the patient noted severe stomach cramps with the use of this medication. Clinical note dated 10/03/11 detailed the patient presenting for follow up. The patient was on a 14 day course of CPT-11 including carboplatin. The patient noted an increase of pain in the stomach. The patient had complaints of severe abdominal cramps. The patient stated that the carboplatin was creating no difficulty; however, the administration of the CPT-11 caused abdominal cramping. Clinical note dated 10/17/11 detailed the patient doing well. The patient had no specific complaints of nausea, vomiting, diarrhea, or constipation. No abdominal pain was noted. Clinical note and CT scan dated 10/21/11 revealed a development of right upper lobe reticulonodular infiltrates which was likely infectious in etiology. No evidence of metastatic disease was noted. Oncology note dated 10/31/11 detailed the patient utilizing Abraxane 75mg on alternating days. Clinical notes dated 11/07/11 and 11/14/11 detailed the patient continuing with the use of Abraxane. There were not really asking for anything in the future after 11/14/11 so I will not address it.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:** Clinical documentation provided for review notes the patient initially presenting with complaints of abdominal pain. The patient was subsequently diagnosed with metastatic disease. Following a course of chemotherapy, the patient was in complete remission. However, CT scan subsequently indicated bilateral plural effusion without evidence of metastatic disease. Clinical notes dated 11/07/11 and 11/14/11 detailed the patient utilizing Abraxane in conjunction with carboplatin. Abraxane is indicated as a cancer medication interfering with the growth and spread of cancer cells in the body. However, it is noted that Abraxane is primarily used in the treatment of breast cancer or other cancer medicines after having a lack of success with other medications. Generally, Abraxane is used in combination with carboplatin to treat advanced non-small cell lung cancer. There is a lack of clinical information regarding the specific findings indicating breast cancer, or non-small cell lung cancer. Given the lack of findings that would support the use of Abraxane on 11/07/11 and 11/14/11, this request is not indicated as medically necessary. As such, it is the opinion of the reviewer that the request for Abraxane on 11/07/11 and 11/14/11 is not recommended as medically necessary.

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

ACOEM-AMERICA COLLEGE OF OCCUPATIONAL & 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 & PRACTICE PARAMETERS

TEXAS TACADA GUIDELINES

TMF SCREENING CRITERIA MANUAL

PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

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

- 1.) Miele E, Spinelli GP, Miele E, Tomao F, Tomao S (2009). "Albumin-bound formulation of paclitaxel (Abraxane ABI-007) in the treatment of breast cancer". International Journal of Nanomedicine 4: 99–105. PMC 2720743. PMID 19516888. Retrieved 2012-08-27.
- 2.) Abraxane Medication Insert.