

DATE

SAMPLE RADIOLOGY-ONCOLOGY-A

CONTACT

COMPANY

CITY, STATE

CLAIMANT:

EMPLOYEE:

POLICY:

Records Received:

1. COMPANY Memorandum.
2. COMPANY Medical Policy SIRT.
3. CT report of chest, abdomen and pelvis dated 4/7/XX.
4. Lab results dated 4/7/XX and 1/7/XX.
5. Letter from Clinic dated 4/8/XX.
5. Appeal letter from Dr. A dated 6/11/XX.
6. COMPANY Medical Review Sheet.
7. Abdominal MRI report dated 1/8/XX.
8. Colonoscopy report dated 1/12/XX.
9. Upper endoscopy report dated 1/12/XX.
10. Gastroenterology and Hepatology Clinic notes dated 1/5/XX and 1/7/XX.
11. Neurology consult note dated 1/8/XX.
12. Gastroenterology and Hepatology Research Consent and Enrollment note dated 1/8/XX.
13. General Surgery Consult note dated 1/8/XX.
14. Vascular Interventional Radiology clinic note dated 1/8/XX.
15. Vascular Interventional Radiology Post-Procedure note dated 1/9/XX.
16. Gastroenterology and Hepatology subsequent visit note dated 1/9/XX.
17. Gastroenterology and Hepatology Limited Exam note dated 1/12/XX.
18. Gastroenterology and Hepatology Research note dated 1/12/XX.
19. Vascular Interventional Radiology note dated 1/21/09.
20. Letters from Dr. B to XXXX, P.A. dated 2/2/XX and 4/9/XX.
21. Lab results from January and February 20XX.
22. Email from Dr. C of the FDA dated 6/9/XX.
23. Scientific literature submitted with the review.

Summary of Treatment/Case History:

This 61-year-old patient with unresectable metastatic cholangiocarcinoma underwent treatment of the liver with Sir-Sphere radioembolization.

Questions for Review:

1. Do you consider SIRT an investigational treatment for patient? Specifically, does it conform to accepted medical practice? Please refer to the Plan definition of Investigational/Experimental Service or Clinical Trial.
2. If you determine this is not investigational, does it meet the Plan language definition of Medically Necessary?
3. If you find this service is Medically Necessary, please explain the reasoning and submit any pertinent literature citations.
4. Please review the COMPANY medical policy and comment on what is generally accepted in the provider community for this service.

Explanation of Findings:

1. Do you consider SIRT an investigational treatment for patient? Specifically, does it conform to accepted medical practice? Please refer to the Plan definition of Investigational/Experimental Service or Clinical Trial.

Currently there is no uniformly accepted medical practice for the treatment of unresectable cholangiocarcinoma. Results of systemic chemotherapy in treating patients with advanced disease have been poor (1,2). There are several options for treatment of unresectable disease in order to improve patient survival. For those patients whose tumor(s) is/are small and are deemed inoperable for other reasons, local ablative techniques such as radiofrequency ablation have been used for treatment. For those patients with larger tumors, hepatic chemoembolization and selective internal radiation therapy (SIRT) have been used. All of these medically accepted treatments, including SIRT, have been studied in small case series, which have demonstrated them to be safe and therapeutic options for the treatment of this condition. However, there are no randomized controlled trials because the number of patients with this condition who are not surgical candidates and yet are still candidates for these local treatments is small. For most patients, the disease is too advanced at presentation for any of these treatments. Even for the gold standard of surgery, there are no randomized controlled trials proving its efficacy, but it has been accepted as the best option for those patients who are candidates for surgical resection.

There are several published series suggesting SIRT improves survival and quality of life

for patients with primary and metastatic disease to the liver, two of which are listed below (3). The articles covering metastatic disease also include patients with cholangiocarcinoma in their series. To date, there is one study that specifically looks at Y90 SIRT in the treatment of cholangiocarcinoma (5). In this study, which included a wide range of patients with this condition, those who had an ECOG performance status of 0 (fully functional) demonstrated a median survival of 31.8 months. Considering the typically dismal survival of inoperable patients with this condition, this preliminary data is very promising. Patient, based upon the histories submitted, has an ECOG performance status of 0, and therefore is an ideal candidate for this treatment. Her potential for survival without treatment is very poor. SIRT is therefore not considered an investigational treatment for patient.

This treatment does conform to accepted medical practice for the treatment of her condition. The product has received final market approval from the FDA for the treatment of colorectal liver metastases, but has been used extensively around the world in the treatment of metastases from other primary tumors and in the treatment of cholangiocarcinoma. Based upon the preliminary published data in the peer-reviewed medical literature, one can conclude that this treatment does improve survival (improved health outcome) in patients who are at an ECOG performance status of 0. It has been demonstrated to be at least as beneficial as established alternatives in the treatment of unresectable cholangiocarcinoma (5). The improvements claimed are obtainable outside of the investigational and experimental setting.

2. If you determine this is not investigational, does it meet the Plan language definition of Medically Necessary?

This treatment is one that a physician exercising prudent judgment would provide for a patient for the purpose of treating cholangiocarcinoma in accordance with accepted standards of medical practice. It is clinically appropriate in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness (3,5). This treatment is not provided primarily for the convenience of the patient, physician or other health care provider, nor is it more costly than any alternative service (such as chemoembolization) at least as likely to produce equivalent therapeutic results in the treatment of this condition.

3. If you find this service is Medically Necessary, please explain the reasoning and submit any pertinent literature citations.

As stated above, patient has an ECOG performance status of 0, and therefore is an ideal candidate for this treatment. Her potential for survival without treatment is very poor. This treatment is not considered investigational for her. See references below.

4. Please review the COMPANY medical policy and comment on what is generally accepted in the provider community for this service.

The treatment of primary and secondary liver tumors with SIRT has been accepted in the medical community in the treatment of patients for whom there are no other good alternative.

Conclusion/Decision to Certify:

SIRT is medically necessary for this patient and is not considered investigational.

References Used in Support of Decision:

1. Falkson G, et al: Eastern Cooperative Oncology Group experience with chemotherapy for inoperable gallbladder and bile duct cancer. *Cancer* 1984; 54: 965–969.
2. Park JS, et al: Single-agent Gemcitabine in the treatment of advanced biliary tract cancers; A phase II study *Jpmj Clin Oncol* 2005;35: 68–73.
3. Sato KT, et al: Unresectable chemorefractory liver metastases: radioembolization with 90Y microspheres—safety, efficacy, and survival. *Radiology* 2008; 247: 507–515.
4. Salem R, et al: Treatment of unresectable hepatocellular carcinoma with use of 90Y microspheres (TheraSphere): safety, tumor response, and survival. *JVasc Interv Radiol* 2005; 16: 1627–1639.
5. Ibrahim SM, et al: Treatment of unresectable cholangiocarcinoma using Yttrium-90 microspheres. Results from a pilot study. *Cancer* 2008; 113: 2119–2128.

This review is provided by a physician who is certified by the American Board of Radiology, with subspecialty in Vascular and Interventional Radiology, and has been

licensed since 1996. This reviewer is a member of the Society of Cardiovascular and Interventional Radiology, American Roentgen Ray Society, Radiological Society of North American and the American College of Radiology. This reviewer has published many articles and has been an invited presenter numerous times.