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## 1.0 Description of the Procedure, Product, or Service

Hepatic tumors can arise either as primary liver cancer or by metastasis to the liver from other tissues or organs. Local therapy for hepatic metastasis is indicated only when there is no extrahepatic disease, which rarely occurs for recipients with primary cancers other than colorectal carcinoma (CRC) or certain neuroendocrine malignancies. At present, surgical resection with tumor-free margins and liver transplantation are the only potentially curative treatments. For liver metastases from CRC, randomized trials have reported that postsurgical adjuvant chemotherapy (administered systemically or via the hepatic artery) decreases recurrence rates and increases time to recurrence. Important prognostic factors for survival include site and extent of primary tumor, hepatic tumor burden, and performance status.

Unfortunately, most hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, number of lesions, concurrent nonmalignant liver disease, or insufficient hepatic reserve. Palliative chemotherapy by combined systemic and hepatic artery infusion (HAI) may increase disease-free intervals for recipients with unresectable hepatic metastases from CRC. However, durable responses to chemotherapy are less likely for recipients with unresectable primary hepatocellular cancer (HCC).

Various nonsurgical ablative techniques have been investigated that seek to cure or palliate unresectable hepatic tumors by improving locoregional control. These techniques rely on extreme temperature changes, particle and wave physics (microwave or laser ablation), or pharmacologic/biochemical interventions. Another of these, selective internal radiation therapy (SIRT), relies on targeted delivery of small beads (microspheres) impregnated with yttrium-90 (90Y). The rationale for SIRT is based on the following: the liver parenchyma is sensitive to radiation; the hepatic circulation is uniquely organized, whereby tumors greater than 0.5 cm rely on the hepatic artery for blood supply while normal liver is primarily perfused via the portal vein; and 90Y is a pure beta-emitter with a relatively limited effective range and short half-life that helps focus the radiation and minimize its spread. Candidates for SIRT are initially examined by liver angiography and technetium (99mTc) lung scan to rule out aberrant hepatic vasculature or significant lung shunting that would permit diffusion of injected microspheres. Currently two commercial forms of 90Y microspheres are available: TheraSphere® (Theragenics; Atlanta, GA) and SIR-Spheres® (Sirtex Medical Limited; Lake Forest, IL).

Non-commercial forms are used mostly outside the United States. While the commercial products use the same radioisotope (90Y) and have the same target dose (100 Gy), they differ in microsphere size profile, base material (i.e., resin vs. glass), and size of commercially available doses. These physical characteristics of the active and inactive ingredients affect the flow of microspheres during injection, their retention at the tumor site, spread outside the therapeutic target region, and dosimetry calculations. The FDA granted premarket approval of SIR-Spheres® for use in combination with 5-fluorouridine (5-FU) chemotherapy by HAI to treat unresectable hepatic metastases from colorectal cancer. In contrast, TheraSphere® was approved by humanitarian device exemption (HDE) for use as monotherapy to treat unresectable HCC. In January 2007, this HDE was expanded to include recipients with hepatocellular carcinoma who have partial or branch portal vein thrombosis. For these reasons, results obtained with one product do not necessarily apply to other commercial (or non-commercial) products.

## 1.1 Medical Term Definitions

- a. Anatomic: pertaining to anatomy or the structure of an organism.
- b. Angiography: a radiographic technique where a radio-opaque contrast material is injected into a blood vessel for the purpose of identifying its anatomy on x-ray.
- c. Curative: treatment designed to overcome a disease and promote recovery.
- d. Extrahepatic: situation or occurring outside the liver.
- e. Half-life: the time required for half the amount of a substance (as a drug or radioactive tracer) in or introduced to the body to be eliminated by natural processes.
- f. Hepatic: liver cells.
- g. Hepatocellular: pertaining to or affecting liver cells.
- h. Metastasis: spread of a disease, generally cancer, from the original site to another organ or body part.
- i. Neuroendocrine: pertains to the interaction between the nervous and the endocrine system.
- j. Palliative: affording relief, but not cure.
- k. Radioisotope: a radioactive element
- l. Systemic: affects the entire body; as a whole.
- m. Unresectable: cannot be removed by surgery.

## 2.0 Eligible Recipients

### 2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

## 3.0 When the Procedure, Product, or Service Is Covered

### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### 3.2 Specific Criteria

Selective internal radiation therapy using intra-arterial injection of radiolabeled microspheres to treat primary or metastatic liver tumors is not covered under the NC Health Choice Program because it is considered investigational. The Program does not cover investigational services.

## 4.0 When the Procedure, Product, or Service Is Not Covered

### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

### 4.2 Specific Criteria

The NC Health Choice Program does not provide coverage for selective internal radiation therapy using intra-arterial injection of radiolabeled microspheres to treat primary or metastatic tumors of the liver because it is considered investigational.

### 4.3 Policy Guidelines

Selective Internal Radiation Therapy (SIRT) is considered investigational for the treatment of primary and metastatic tumors of the liver due to a lack of sufficient randomized clinical trials demonstrating the safety and efficacy of the use of yttrium-90 microspheres. Some outcomes indicate that SIRT is effective in producing anti-tumor activity but it is unclear what affects this has on quality of life and safety. There continues to be questions regarding dosages, recipient selection criteria, and outcomes as stand alone or in combination with other conventional treatment. Larger controlled randomized clinical trials are needed to determine health outcomes and survival rates.

The 2009 National Comprehensive Cancer Network (NCCN) guidelines remain unchanged from previous versions, and state that randomized, controlled studies on the use of radioembolization therapy in the treatment of recipients with HCC are needed. SIRT treatment of inoperable metastases is not mentioned in the current NCCN guidelines for either colon or breast cancers.

## 5.0 Requirements for and Limitations on Coverage

### 5.1 Prior Approval

Prior approval does not apply to SIRT for Tumors of the Liver as it is not covered and considered investigational. Refer to **Subsection 4.2**.

## 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## 7.0 Additional Requirements

### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

| Date               | Section Revised | Change   |
|--------------------|-----------------|--|
| July 1, 2010       |                 | Policy Conversion: Implementation of Session Law 2009-451, <b>Section 10.32</b><br><b>“NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”</b> |
| September 30, 2011 | Throughout      | Policy Date of Termination   |

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines. As selective internal radiation therapy using intra-arterial injection of radiolabeled microspheres to treat primary or metastatic liver tumors is non-covered, claims-related information is not applicable.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

| CPT Codes |
|-----------|
| 37204     |
| 75894     |
| 77778     |
| 79445     |

  

| HCPCS Codes |
|-------------|
| S2095       |

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Inpatient Hospital and Outpatient Hospital

### G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services

### H. Reimbursement

Providers must bill their usual and customary charges.