Policy: MP208  
Section: Medical Benefit Policy  
Subject: Selective Internal Radiation Therapy (aka, Intrahepatic Radioembolization)

I. Policy: Selective Internal Radiation Therapy (aka, Intrahepatic Radioembolization)

II. Purpose/Objective:
To provide a policy of coverage regarding Selective Internal Radiation Therapy (aka, Intrahepatic Radioembolization)

III. Responsibility:
A. Medical Directors  
B. Medical Management Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.  
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.  
3. Devised – the date the policy was implemented.  
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.  
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions  
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
  a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;  
  b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;  
  c. in accordance with current standards of good medical treatment practiced by the general medical community;  
  d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment  
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Selective Internal Radiation Therapy (aka, Intrahepatic Radioembolization) involves the use of Intra-hepatic microspheres which are radio-labeled particles composed of glass or resin polymers. The spheres are tagged with Y-90 and injected via the hepatic artery to target radiation directly to liver tumors. Evidence suggests that the microspheres are selectively deposited in vascular tumor tissue, which allows much higher radiation doses while sparing the injury and morbidity that accompanies external beam radiation

INDICATIONS:
Selective Internal Radiation with Y-90 microspheres may be considered medically necessary for members with the following criteria:
1. a. Unresectable primary Hepatocellular Carcinoma; or
   b. Unresectable liver tumors from primary colorectal cancer; or
   c. Treatment of unresectable liver-only or liver dominant metastases from neuroendocrine cancers when other systemic therapy has failed to control symptoms
   and
2. There is documentation of:
   a. adequate hematological and hepatic function; and
   b. Eastern Cooperative Oncology Group performance status of 0-2*

CONTRAINDICATIONS
• Disseminated extra-hepatic disease
• Abnormal vascular anatomy that would result in reflux of hepatic arterial blood to the stomach, pancreas, bowel, etc. as evidenced by angiogram
• Shunting of hepatic artery blood flow to the lungs greater than 20% evidenced by a technetium macroaggregated albumin lung perfusion scan
• Portal vein thrombosis (relative contraindication for SIR Microspheres, but not Theraspheres)

ECOG PERFORMANCE STATUS*

<table>
<thead>
<tr>
<th>Grade</th>
<th>ECOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Fully active, able to carry on all pre-disease performance without restriction</td>
</tr>
<tr>
<td>1</td>
<td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work</td>
</tr>
<tr>
<td>2</td>
<td>Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours</td>
</tr>
<tr>
<td>3</td>
<td>Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours</td>
</tr>
<tr>
<td>4</td>
<td>Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair</td>
</tr>
<tr>
<td>5</td>
<td>Dead</td>
</tr>
</tbody>
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For Medicaid Lines of Business:
Selective Internal Radiation Therapy is not on the MA fee schedule and is therefore not covered for Medicaid.

EXCLUSIONS:
The Plan considers the use of Selective Internal Radiation for the treatment of all other conditions to be experimental, investigational or unproven and NOT COVERED.
Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Selective Internal Radiation Therapy

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

S2095 Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres
C2616 Brachytherapy source, Yttrium 90, per source
37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
77263 Therapeutic radiology treatment planning; complex
77370 Special medical radiation physics consultation
77399 Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services
77790 Supervision, handling, loading of radiation source
75894 Transcatheter therapy, embolization, any method, radiological supervision and interpretation
79445 Radiopharmaceutical therapy, by intra-arterial particulate administration


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Geisinger Technology Assessment Committee Triage Group. Selective Internal Radiation Therapy, May 2011


Center for Devices and Radiologic Health. TheraSphere Yttrium-90 Glass Microspheres [package insert]. [US Food and


ECRI. Target Database (Online) Intrhepatic yttrium-90 microsphere therapy for primary liver cancer. Plymouth Meeting, PA; ECRI Institute June 2006.

ECRI. Target Database (Online) Intrhepatic yttrium-90 microsphere therapy for metastatic colorectal cancer. Plymouth Meeting, PA; ECRI Institute June 2006.


This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/07

Revised: 04/10 (ref. added), 6/11 (added indications), 8/12 (removed cirrhosis limitation), 12/14 (added contraindication)

Reviewed: 6/12, 8/13, 8/14; 8/15; 7/16, 7/17, 6/18