

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. Unresectable intrahepatic cholangiocarcinoma
 d. 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*	
Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	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
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

* As published in Am. J. Clin. Oncol.:

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.

Eastern Cooperative Oncology Group, Robert Comis M.D., Group Chair.

For Medicaid Lines of Business:

Selective Internal Radiation Therapy is not on the MA fee schedule and is therefore not covered for Medicaid except through a Program Exception.

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.**

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

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
- 77778 Interstitial radiation source application; complex
- 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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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 supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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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); 7/22 (add Unresectable intrahepatic cholangiocarcinoma indication)

Reviewed: 6/12, 8/13, 8/14; 8/15; 7/16, 7/17, 6/18, 7/19, 7/20, 7/21

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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