

# Protocol

## Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies

(80111)

<b>Medical Benefit</b>		<b>Effective Date:</b> 07/01/13	<b>Next Review Date:</b> 03/15
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 09/09, 09/10, 03/11, 03/12, 05/12, 03/13, 03/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### Description

Transcatheter arterial chemoembolization (TACE) of the liver is a proposed alternative to conventional systemic or intra-arterial chemotherapy, and to various nonsurgical ablative techniques, to treat resectable and nonresectable tumors. TACE combines the infusion of chemotherapeutic drugs with particle embolization. Tumor ischemia secondary to the embolization raises the drug concentration compared to infusion alone, extending the retention of the chemotherapeutic agent and decreasing systemic toxicity. The liver is especially amenable to such an approach, given its distinct lobular anatomy, the existence of two independent blood supplies, and the ability of healthy hepatic tissue to grow and thus compensate for tissue mass lost during chemoembolization.

### Background

TACE of the liver has been associated with potentially life-threatening toxicities and complications, including severe postembolization syndrome, hepatic insufficiency, abscess, or infarction. TACE has been investigated to treat resectable, unresectable, and recurrent hepatocellular carcinoma, cholangiocarcinoma, liver metastases, and in the liver transplant setting. Treatment alternatives include resection when possible, chemotherapy administered systemically or by hepatic artery infusion (HAI). HAI involves continuous infusion of chemotherapy with an implanted pump, while TACE is administered episodically. Also, HAI does not involve the use of embolic material.

The TACE procedure requires hospitalization for placement of the hepatic artery catheter and workup to establish eligibility for chemoembolization. Prior to the procedure, the patency of the portal vein must be demonstrated to ensure an adequate posttreatment hepatic blood supply. With the patient under local anesthesia and mild sedation, a superselective catheter is inserted via the femoral artery and threaded into the hepatic artery. Angiography is then performed to delineate the hepatic vasculature, followed by injection of the embolic chemotherapy mixture. Embolic material varies but may include a viscous collagen agent, polyvinyl alcohol particles, or ethiodized oil. Typically, only one lobe of the liver is treated during a single session, with subsequent embolization procedures scheduled from five days to six weeks later. In addition, since the embolized vessel recanalizes, chemoembolization can be repeated as many times as necessary.

### Related Protocols

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Radioembolization for Primary and Metastatic Tumors of the Liver

**Policy (Formerly Corporate Medical Guideline)**

Transcatheter hepatic arterial chemoembolization may be considered **medically necessary** to treat hepatocellular cancer that is unresectable but confined to the liver and not associated with portal vein thrombosis.

Transcatheter hepatic arterial chemoembolization may be considered **medically necessary** as a bridge to transplant in patients with hepatocellular cancer where the intent is to prevent further tumor growth and to maintain a patient's candidacy for liver transplant (see Policy Guidelines).

Transcatheter hepatic arterial chemoembolization may be considered **medically necessary** to treat liver metastasis in symptomatic patients with metastatic neuroendocrine tumors whose symptoms persist despite systemic therapy and who are not candidates for surgical resection.

Transcatheter hepatic arterial chemoembolization may be considered **medically necessary** to treat liver metastasis in patients with liver-dominant metastatic uveal melanoma.

Transcatheter hepatic arterial chemoembolization is considered **investigational** as neoadjuvant or adjuvant therapy in hepatocellular cancer that is considered resectable.

Transcatheter hepatic arterial chemoembolization is considered **investigational** to treat hepatocellular tumors prior to liver transplantation except as noted above.

Transcatheter hepatic arterial chemoembolization is considered **investigational** to treat liver metastases from any other tumors or to treat hepatocellular cancer that does not meet the criteria noted above, including recurrent hepatocellular carcinoma.

Transcatheter hepatic arterial chemoembolization is considered **investigational** to treat unresectable cholangiocarcinoma.

**Policy Guideline**

When using transcatheter hepatic arterial chemoembolization as a bridge to transplantation to prevent further tumor growth, the patient candidate should have the following characteristics: a single tumor less than 5 cm or no more than three tumors each less than 3 cm in size, absence of extrahepatic disease or vascular invasion, and Child-Pugh score of either A or B.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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