



# Louisiana

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

**Policy #** 00227

**Original Effective Date:** 03/19/2008

**Current Effective Date:** 06/12/2023

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Radioembolization for Primary and Metastatic Tumors of the Liver is addressed separately in medical policy 00110.*

*Note: Radiofrequency Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00182.*

*Note: Cryosurgical Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00220.*

### **When Services Are Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transcatheter arterial chemoembolization (TACE) of the liver to treat individuals with the following conditions to be **eligible for coverage:\*\***

- Liver metastasis in symptomatic individuals with metastatic neuroendocrine tumor whose symptoms persist despite systemic therapy and who are not candidates for surgical resection; or
- Liver-dominant metastatic uveal melanoma.

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## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transcatheter arterial chemoembolization (TACE) of the liver to treat hepatocellular cancer (HCC) to be **eligible for coverage.\*\***

### Patient Selection Criteria

Coverage eligibility for TACE of the liver to treat HCC will be considered when **ALL** of the following criteria are met:

- Tumor is unresectable; **AND**
- Confined to the liver; **AND**
- Not associated with portal vein thrombosis; **AND**
- Child-Pugh class is either A or B.

Based on review of available data, the Company may consider the use of transcatheter arterial chemoembolization (TACE) of the liver as a bridge to transplant in individuals with hepatocellular cancer (HCC) where the intent is to prevent further tumor growth and to maintain an individual's candidacy for liver transplant to be **eligible for coverage.\*\***

### Patient Selection Criteria

Coverage eligibility when using TACE of the liver as a bridge to transplantation to prevent further tumor growth and to maintain an individual's candidacy for liver transplant will be considered when **ALL** of the following criteria are met:

- A single tumor less than 5cm or no more than 3 tumors each less than 3cm in size; **AND**
- Absence of extrahepatic disease or vascular invasion; **AND**
- Child-Pugh class of either A or B.

Child-Pugh Score Calculator:

<https://www.mdcalc.com/child-pugh-score-cirrhosis-mortality>

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## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of transcatheter arterial chemoembolization (TACE) of the liver as neoadjuvant or adjuvant therapy in hepatocellular cancer (HCC) that is considered resectable to be **investigational**.\*

Based on review of available data, the Company considers the use of transcatheter arterial chemoembolization (TACE) of the liver as part of combination therapy (with radiofrequency ablation) for resectable or unresectable hepatocellular carcinoma to be **investigational**.\*

Based on review of available data, the Company considers the use of transcatheter arterial chemoembolization (TACE) of the liver to treat hepatocellular tumors prior to liver transplantation, except as noted above, to be **investigational**.\*

Based on review of available data, the Company considers the use of transcatheter arterial chemoembolization (TACE) of the liver to treat liver metastases from any other tumors or to treat hepatocellular cancer (HCC) for those conditions not listed as eligible for coverage, including recurrent HCC, to be **investigational**.\*

Based on review of available data, the Company considers the use of transcatheter arterial chemoembolization (TACE) of the liver to treat unresectable cholangiocarcinoma to be **investigational**.\*

The use of transcatheter arterial chemoembolization (TACE) of the liver when the patient selection criteria are not met is considered to be **investigational**.\*

## Policy Guidelines

When using transcatheter arterial chemoembolization of the liver as a bridge to transplantation to prevent further tumor growth, the candidate should have the following characteristics: a single tumor

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less than 5 cm or no more than 3 tumors each less than 3 cm in size, absence of extrahepatic disease or vascular invasion, and Child-Pugh class A or B.

### **Background/Overview**

#### **Transcatheter Arterial Chemoembolization**

Transcatheter arterial chemoembolization (TACE) is a minimally invasive procedure performed by interventional radiologists who inject highly concentrated doses of chemotherapeutic agents into the tumor tissues and embolic agent(s) to restrict tumor blood supply. The embolic agent(s) causes ischemia and necrosis of the tumor and slows anticancer drug washout. The most common anticancer drugs used in published TACE studies for hepatocellular carcinoma include doxorubicin (36%), followed by cisplatin (31%), epirubicin (12%), mitoxantrone (8%), and mitomycin C (8%).

The TACE procedure requires hospitalization for placement of a hepatic artery catheter and workup to establish eligibility for chemoembolization. Before 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 1 lobe of the liver is treated during a single session, with subsequent embolization procedures scheduled 5 days to 6 weeks later. In addition, because the embolized vessel recanalizes, chemoembolization can be repeated as many times as necessary.

#### **Adverse Events**

Transcatheter arterial chemoembolization of the liver has been associated with potentially life-threatening toxicities and complications, including severe postembolization syndrome, hepatic insufficiency, abscess, or infarction. Transcatheter arterial chemoembolization 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, other locally ablative techniques (eg, radiofrequency ablation, cryoablation), and chemotherapy administered systemically or by hepatic artery infusion. Hepatic artery infusion

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involves the continuous infusion of chemotherapy with an implanted pump, while TACE is administered episodically. Hepatic artery infusion does not involve the use of embolic material.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Chemoembolization for hepatic tumors is a medical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration. However, the embolizing agents and drugs are subject to U.S. Food and Drug Administration approval.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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. Transcatheter arterial chemoembolization combines the infusion of chemotherapeutic drugs with particle embolization. Tumor ischemia secondary to the embolization raises the drug concentration compared with 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 2 independent blood supplies, and the ability of healthy hepatic tissue to grow and thus compensate for tissue mass lost during chemoembolization.

## **Summary of Evidence**

### **Unresectable and Resectable Hepatocellular Carcinoma**

For individuals who have unresectable hepatocellular carcinoma (HCC) confined to the liver and not associated with portal vein thrombosis who receive TACE, the evidence includes several randomized controlled trials (RCTs), large observational studies, and systematic reviews. Relevant

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outcomes are overall survival (OS), disease-specific survival, quality of life, and treatment-related mortality and morbidity. Evidence from 1 RCT has suggested that survival with TACE is at least as good as with systemic chemotherapy. One systematic review has highlighted possible biases associated with RCTs that compared TACE with no therapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have resectable HCC who receive neoadjuvant or adjuvant TACE, the evidence includes several RCTs and systematic reviews. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related mortality and morbidity. Studies have shown little to no difference in OS rates with neoadjuvant TACE compared with surgery alone. A meta-analysis found no significant improvements in survival or recurrence with preoperative TACE for resectable HCC. While both RCTs and the meta-analyses that evaluated TACE as adjuvant therapy to hepatic resection in HCC reported positive results, the quality of individual studies and the methodologic issues related to the meta-analyses preclude certainty when interpreting the results. Well-conducted multicentric trials from the U.S. or Europe representing relevant populations with adequate randomization procedures, blinded assessments, centralized oversight, and publication in peer-reviewed journals are required. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have resectable HCC who receive TACE plus radiofrequency ablation (RFA), the evidence includes a single RCT and a systematic review. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related mortality and morbidity. The RCT failed to show the superiority in survival benefit with combination TACE plus RFA treatment compared with surgery for HCC lesions 3 cm or smaller. Further, an ad hoc subgroup analysis showed a significant benefit for surgery in recurrence and OS in patients with lesions larger than 3 cm. It cannot be determined from this trial whether TACE plus RFA is as effective as a surgical resection for these small tumors. The systematic review, which included mostly retrospective observational studies, did not find a survival benefit with TACE plus RFA over surgery alone. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unresectable HCC who receive TACE plus RFA, the evidence includes multiple systematic reviews and RCTs. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related mortality and morbidity. Multiple meta-analyses and RCTs have shown

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a consistent benefit in survival and recurrence-free survival favoring combination TACE plus RFA over RFA alone. However, results of these meta-analyses are difficult to interpret because the pooled data included heterogeneous patient populations and, in a few cases, data from a study retracted due to questions about data veracity. A larger well-conducted RCT has reported a relative reduction in the hazard of death by 44% and a 14% difference in 4-year survival favoring combination therapy. The major limitations of this trial were its lack of a TACE-alone arm and the generalizability of its findings to patient populations that have unmet needs such as those with multiple lesions larger than 3 cm and Child-Pugh class B or C. Further, this single-center trial was conducted in China, and until these results have been reproduced in patient populations representative of pathophysiology and clinical stage more commonly found in the U.S. or Europe, the results may not be generalizable. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Bridge to Liver Transplant**

For individuals who have a single hepatocellular tumor less than 5 cm or no more than 3 tumors each less than 3 cm in size, absence of extrahepatic disease or vascular invasion, and Child-Pugh class A or B seeking to prevent further tumor growth and to maintain candidacy for liver transplant who receive pretransplant TACE, the evidence includes multiple small prospective studies. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related mortality and morbidity. There is a lack of comparative trials on various locoregional treatments as a bridge therapy for liver transplantation. Multiple small prospective studies have demonstrated that TACE can prevent dropouts from the transplant list. Transcatheter arterial chemoembolization has become an accepted method to prevent tumor growth and progression while patients are on the liver transplant waiting list. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

### **Unresectable Cholangiocarcinoma**

For individuals who have unresectable cholangiocarcinoma who receive TACE, the evidence includes several retrospective observational studies and systematic reviews. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related mortality and morbidity. Randomized controlled trials evaluating the benefit of adding TACE to the standard of care for patients with unresectable cholangiocarcinoma are lacking. Results of retrospective studies have shown a survival benefit with TACE over the standard of care. These studies lacked matched patient

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controls. Although the observational data are consistent, the lack of randomization limits definitive conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Transcatheter Arterial Chemoembolization for Symptomatic Unresectable Neuroendocrine Tumors**

For individuals who have symptomatic metastatic neuroendocrine tumors despite systemic therapy and are not candidates for surgical resection who receive TACE, the evidence includes retrospective single-cohort studies. Relevant outcomes are OS, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence from RCTs supporting the use of TACE. Uncontrolled trials have suggested that TACE reduces symptoms and tumor burden and improves hormone profiles. Generally, the response rates are over 50% and include patients with massive hepatic tumor burden. While many studies have demonstrated symptom control, survival benefits are less clear. Despite the uncertain benefit on survival, the use of TACE to palliate the symptoms associated with hepatic neuroendocrine metastases can provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

### **Liver-Dominant Metastatic Uveal Melanoma**

For individuals who have liver-dominant metastatic uveal melanoma who receive TACE, the evidence includes observational studies and reviews. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence from RCTs assessing the use of TACE. Noncomparative prospective and retrospective studies have reported improvements in tumor response and survival compared with historical controls. Given the very limited treatment response from systemic therapy and the rarity of this condition, the existing evidence may support conclusions that TACE meaningfully improves outcomes for patients with hepatic metastases from uveal melanoma. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

### **Other Unresectable Hepatic Metastases**

For individuals who have unresectable hepatic metastases from any other types of primary tumors (eg, colorectal or breast cancer) who receive TACE, the evidence includes multiple RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, disease-specific survival,

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quality of life, and treatment-related mortality and morbidity. Multiple RCTs and numerous nonrandomized studies have compared TACE with alternatives in patients who have colorectal cancer and metastases to the liver. Nonrandomized studies have reported that TACE can stabilize disease in 40% to 60% of treated patients but whether this translates into a prolonged survival benefit relative to systemic chemotherapy alone is uncertain. Two small RCTs have reported that TACE with drug-eluting beads has resulted in statistically significant improvements in response rate and progression-free survival. Whether this translates into a prolonged survival benefit relative to systemic chemotherapy alone is uncertain. For cancers other than colorectal, the evidence is extremely limited and no conclusions can be made. Studies have assessed small numbers of patients and the results have varied due to differences in patient selection criteria and treatment regimens used. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

#### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

#### **2012 Input**

In response to requests, input was received from 1 specialty medical society (2 reviewers) and 3 academic medical centers while this policy was under review in 2012. There was general agreement that the use of transcatheter arterial chemoembolization (TACE) was medically necessary for indications in the policy; however, reviewers were split for its use as a bridge to transplant. There was general support for the investigational policy statement for the use of TACE as neoadjuvant or adjuvant therapy in resectable hepatocellular carcinoma. Reviewers were split over the investigational policy statement to treat other liver metastases or for recurrent hepatocellular carcinoma. Four reviewers provided input on the use of TACE in unresectable cholangiocarcinoma; 2 reviewers considered it investigational and 2 others considered it investigational but also medically necessary, the latter citing data showing a survival benefit of TACE compared with supportive therapy.

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### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### Hepatocellular Carcinoma

The National Comprehensive Cancer Network (NCCN) (v.1.2022) guidelines on hepatocellular carcinoma list TACE as an option for patients who are not candidates for surgically curative treatments or as a part of a strategy to bridge patients for other curative therapies. Arterially directed therapies, including TACE, are appropriate for patients with unresectable or inoperable tumors that are not amenable to ablation therapy. Additionally, TACE in highly selected patients has been shown to be safe in the presence of limited tumor invasion of the portal vein. The American Association for the Study of Liver Diseases 2018 guidelines on hepatocellular carcinoma suggest using liver-directed therapies (which may include TACE) for bridging to liver transplant in patients with T2 lesions, in order to prevent disease progression and prevent dropouts from the waiting list. The guidelines recommend the use of locoregional therapies, including TACE, in patients with cirrhosis and T2 or T3 disease that is not amenable to resection or transplantation.

### Intrahepatic Cholangiocarcinoma

The NCCN (v.1.2022) guidelines on intrahepatic cholangiocarcinoma consider arterially directed therapies, including TACE, to be treatment options for unresectable and metastatic intrahepatic cholangiocarcinoma.

### Neuroendocrine and Adrenal Tumors

The NCCN (v.4.2021) guidelines on neuroendocrine and adrenal tumors recommend hepatic regional therapy, including arterial embolization, chemoembolization, or radioembolization, for unresectable liver metastases (category 2B).

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### **Uveal Cancer**

The NCCN (v.2.2022) guidelines on uveal melanoma state that in patients with disease that is confined to the liver, regional liver-directed therapies such as chemoembolization, radioembolization, or immunoembolization should be considered.

### **Colon Cancer**

The NCCN (v.1.2022) guidelines on colon cancer recommend TACE only for clinical trials. The American Society of Clinical Oncology (2020) resource-stratified guidelines on late-stage colorectal cancer state that patients with unresectable liver metastases may receive TACE (weak recommendation). However, this recommendation should only be implemented in centers with expertise in the technique, after multidisciplinary review, or in the context of a clinical trial.

### **Breast Cancer**

The NCCN (v.3.2022) guidelines on breast cancer do not address TACE as a treatment option for breast cancer metastatic to the liver.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### **Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.



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**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03960008 <sup>a</sup>	A Randomized Multi-Center Phase III Study of Individualized Stereotactic Body Radiation Therapy (SBRT) Versus Trans-Arterial Chemoembolization (TACE) as a Bridge to Transplant in Hepatocellular Carcinoma	196	Dec 2024
NCT04143191	Sorafenib Plus Transarterial Chemoembolization Versus Sorafenib Alone as Postoperative Adjuvant Treatment for Resectable Primary Advanced Hepatocellular Carcinoma: A Phase 3, Multicenter, Randomized Controlled Trial	158	Sep 2023
NCT02936388	A Randomized Phase II Trial of Transarterial Radioembolisation With Yttrium-90 (SIRT) in Comparison to Transarterial Chemoembolisation With Cisplatin (TACE) in Patients With Liver Metastases From Uveal Melanoma	108	Dec 2022
NCT01906216	Sorafenib With or Without Transarterial Chemoembolization (TACE) in Advanced Hepatocellular Carcinoma: A Multicenter, Randomized, Controlled Trial	246	Dec 2020
NCT04912258	Trans-arterial Chemoembolization With Irinotecan Drug-eluting Beads Before Liver Surgery for Patients With Primary Unresectable Colorectal Liver Metastasis: A Randomized Control Trial	80	Jun 2023
NCT02724540 <sup>a</sup>	Randomized Embolization Trial for NeuroEndocrine Tumor Metastases To The Liver	162	Mar 2024

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NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT01512407	Randomised Controlled Trial on Adjuvant Transarterial Chemoembolisation After Curative Hepatectomy for Hepatocellular Carcinoma	58 (actual enrollment)	Dec 2019

NCT: national clinical trial.

<sup>a</sup>Denotes an industry sponsored or cosponsored clinical trial

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

Policy # 00227

Original Effective Date: 03/19/2008

Current Effective Date: 06/12/2023

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### **Policy History**

Original Effective Date: 03/19/2008

Current Effective Date: 06/12/2023

- |            |   |
|------------|---|
| 03/12/2008 | Medical Director review   |
| 03/19/2008 | Medical Policy Committee approval.  |
| 03/04/2009 | Medical Director review   |
| 03/18/2009 | Medical Policy Committee approval. No change to coverage.   |
| 06/03/2010 | Medical Policy Committee approval   |
| 06/16/2010 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 05/05/2011 | Medical Policy Committee review   |
| 05/18/2011 | Medical Policy Implementation Committee approval. Added that the use of transcatheter hepatic arterial chemoembolization as neoadjuvant or adjuvant therapy in hepatocellular cancer that is considered resectable is considered to be investigational. |
| 05/03/2012 | Medical Policy Committee review   |
| 05/16/2012 | Medical Policy Implementation Committee approval. Added that TACE for unresectable cholangio-carcinoma is considered investigational. Revised the format of the remaining investigational statements while preserving their intent.                     |

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05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. Format Coverage eligibility unchanged.
05/01/2014	Medical Policy Committee review
05/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2015	Medical Policy Committee review
05/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
05/05/2016	Medical Policy Committee review
05/18/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. Changed formatting from one statement to bulleted conditions in the “When Services Are Eligible for Coverage” section. Changed formatting by grouping individual coverage statements into 2 separate coverage statements for TACE with criteria by adding a “When Services May Be Eligible for Coverage” section. Added “Child-Pugh class is either A or B” as criteria for TACE to treat HCC. Replaced “hepatic” with “of the liver” in all statements in the coverage section. Added a link for the Child-Pugh Score calculator in the coverage section.
05/02/2019	Medical Policy Committee review
05/15/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/21/2019	Minor revision for clarity changing “and” to “or” to separate bulleted conditions that are eligible for coverage for transcatheter arterial chemoembolization (TACE) of the liver to treat patients.

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12/10/2019	Coding update
05/07/2020	Medical Policy Committee review
05/13/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Added an investigational statement for transcatheter arterial chemoembolization (TACE) of the liver as part of combination therapy (with radiofrequency ablation) for resectable or unresectable hepatocellular carcinoma.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/04/2023	Medical Policy Committee review
05/10/2023	Medical Policy Implementation Committee approval. Replaced “patients” with “individuals” in the coverage section. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2024

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	37243, 75894
HCPCS	C1982, Q0083
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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