



Louisiana

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

Policy # 00227

Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

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.

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. 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

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randomized controlled trials (RCTs), large observational studies, and systematic reviews. Relevant 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

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of life, and treatment-related mortality and morbidity. Multiple meta-analyses and RCTs have shown 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

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shown a survival benefit with TACE over the standard of care. These studies lacked matched patient 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,

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observational studies, and systematic reviews. Relevant outcomes are OS, disease-specific survival, 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

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necessary, the latter citing data showing a survival benefit of TACE compared with supportive therapy.

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.1.2024) 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.1.2024) 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.1.2023) 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.1.2024) 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.2.2024) 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 ^a	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 ^a	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.

^aDenotes an industry sponsored or cosponsored clinical trial

References

1. Marelli L, Stigliano R, Triantos C, et al. Transarterial therapy for hepatocellular carcinoma: which technique is more effective? A systematic review of cohort and randomized studies. *Cardiovasc Intervent Radiol.* Jan-Feb 2007; 30(1): 6-25. PMID 17103105
2. National Cancer Institute, Surveillance Epidemiology and End Results Program. *Cancer Stat Facts: Liver and Intrahepatic Bile Duct Cancer.* 2022; <https://seer.cancer.gov/statfacts/html/livibd.html>.
3. Qi X, Wang D, Su C, et al. Hepatic resection versus transarterial chemoembolization for the initial treatment of hepatocellular carcinoma: A systematic review and meta-analysis. *Oncotarget.* Jul 30 2015; 6(21): 18715-33. PMID 26243835
4. Tian X, Dai Y, Wang DQ, et al. Transarterial chemoembolization versus hepatic resection in hepatocellular carcinoma treatment: a meta-analysis. *Drug Des Devel Ther.* 2015; 9: 4431-40. PMID 26309396
5. Oliveri RS, Wetterslev J, Gluud C. Transarterial (chemo)embolisation for unresectable hepatocellular carcinoma. *Cochrane Database Syst Rev.* Mar 16 2011; (3): CD004787. PMID 21412886
6. Xie F, Zang J, Guo X, et al. Comparison of transcatheter arterial chemoembolization and microsphere embolization for treatment of unresectable hepatocellular carcinoma: a meta-analysis. *J Cancer Res Clin Oncol.* Mar 2012; 138(3): 455-62. PMID 22179199
7. Ahmad J, Rhee J, Carr BI. The effects of hepatic artery chemotherapy on viral hepatitis in patients with hepatocellular carcinoma. *Dig Dis Sci.* Feb 2005; 50(2): 331-5. PMID 15745096

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8. Akamatsu M, Yoshida H, Obi S, et al. Evaluation of transcatheter arterial embolization prior to percutaneous tumor ablation in patients with hepatocellular carcinoma: a randomized controlled trial. *Liver Int.* Dec 2004; 24(6): 625-9. PMID 15566514
9. Bruix J, Llovet JM, Castells A, et al. Transarterial embolization versus symptomatic treatment in patients with advanced hepatocellular carcinoma: results of a randomized, controlled trial in a single institution. *Hepatology.* Jun 1998; 27(6): 1578-83. PMID 9620330
10. Cao GW, Hu S, Li G, et al. The clinical and experimental research of transhepatic arterial injection of 32P-glass microsphere therapy for hepatic carcinoma. *J Med Imaging.* 2005;15(8):678681.
11. Cao XC, Wang X, Tan J, et al. Clinical research of intra-arterial radioembolization with 32P-glass microspheres combined with chemoembolization for treatment of liver cancer. *Chin J Radiol.* 2005;39(10):10681072.
12. Carr BI, Kondragunta V, Buch SC, et al. Therapeutic equivalence in survival for hepatic arterial chemoembolization and yttrium 90 microsphere treatments in unresectable hepatocellular carcinoma: a two-cohort study. *Cancer.* Mar 01 2010; 116(5): 1305-14. PMID 20066715
13. Cheng SQ, Wu MC, Chen H, et al. [Transcatheter hepatic arterial chemoembolization and thymosin alpha1 in postoperative treatment of hepatocellular carcinoma]. *Zhonghua Zhong Liu Za Zhi.* May 2004; 26(5): 305-7. PMID 15312371
14. Doffoel M, Bonnetain F, Bouche O, et al. Multicentre randomised phase III trial comparing Tamoxifen alone or with Transarterial Lipiodol Chemoembolisation for unresectable hepatocellular carcinoma in cirrhotic patients (Federation Francophone de Cancerologie Digestive 9402). *Eur J Cancer.* Mar 2008; 44(4): 528-38. PMID 18242076
15. Du W, Lin S, Luo K, et al. Clinical analysis of TACE plus 32P-GMS in advanced hepatic carcinoma. *J Hepatobilia Surg.* 2002;10(5):351352.
16. Groupe d'Etude et de Traitement du Carcinome Hepatocellulaire. A comparison of lipiodol chemoembolization and conservative treatment for unresectable hepatocellular carcinoma. *N Engl J Med.* May 11 1995; 332(19): 1256-61. PMID 7708069
17. Hao N, Xiao X, Han X, et al. Efficacy of intra-arterial chemoembolization using drug microspheres in compare with chemoembolization in the treatment of primary hepatic carcinoma. *Tumor (Shanghai).* 2000;20(5):375378.
18. Hou P, Guan G, Zhang X, Lu H, Wang S. Effects of intra-advanced 32P glass microspheres for advanced hepatic carcinoma. *Academic Journal of Fujian Medical University.* 2006;40(1):4850.

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19. Kirchoff TD, Rudolph KL, Layer G, et al. Chemoocclusion vs chemoperfusion for treatment of advanced hepatocellular carcinoma: a randomised trial. *Eur J Surg Oncol*. Mar 2006; 32(2): 201-7. PMID 16373084
20. Kooby DA, Egnatashvili V, Srinivasan S, et al. Comparison of yttrium-90 radioembolization and transcatheter arterial chemoembolization for the treatment of unresectable hepatocellular carcinoma. *J Vasc Interv Radiol*. Feb 2010; 21(2): 224-30. PMID 20022765
21. Lee W, Luo J, Yan Z, et al. Hepatic radioembolization with epirubicin mixed microsphere for the treatment of hepatocellular carcinoma. *J Nantong Univ (Medical Sciences)*. 2008;28(4):268270.
22. Lewandowski RJ, Kulik LM, Riaz A, et al. A comparative analysis of transarterial downstaging for hepatocellular carcinoma: chemoembolization versus radioembolization. *Am J Transplant*. Aug 2009; 9(8): 1920-8. PMID 19552767
23. Li JQ, Zhang YQ, Zhang WZ, et al. Randomized study of chemoembolization as an adjuvant therapy for primary liver carcinoma after hepatectomy. *J Cancer Res Clin Oncol*. 1995; 121(6): 364-6. PMID 7541051
24. Li Q, Wang J, Sun Y, et al. Postoperative transhepatic arterial chemoembolization and portal vein chemotherapy for patients with hepatocellular carcinoma: a randomized study with 131 cases. *Dig Surg*. 2006; 23(4): 235-40. PMID 16943671
25. Liu T, Zu M. Treatment of primary hepatic carcinoma by hepatic arterial chemoembolization with KMG microspheres and chemotherapeutic agents. *Acad Med Xuzhou*. 2005;25(2):126129.
26. Llovet JM, Real MI, Montana X, et al. Arterial embolisation or chemoembolisation versus symptomatic treatment in patients with unresectable hepatocellular carcinoma: a randomised controlled trial. *Lancet*. May 18 2002; 359(9319): 1734-9. PMID 12049862
27. Lo CM, Ngan H, Tso WK, et al. Randomized controlled trial of transarterial lipiodol chemoembolization for unresectable hepatocellular carcinoma. *Hepatology*. May 2002; 35(5): 1164-71. PMID 11981766
28. Pelletier G, Roche A, Ink O, et al. A randomized trial of hepatic arterial chemoembolization in patients with unresectable hepatocellular carcinoma. *J Hepatol*. Sep 1990; 11(2): 181-4. PMID 2174933
29. Pelletier G, Ducreux M, Gay F, et al. Treatment of unresectable hepatocellular carcinoma with lipiodol chemoembolization: a multicenter randomized trial. *Groupe CHC. J Hepatol*. Jul 1998; 29(1): 129-34. PMID 9696501

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Policy # 00227

Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

30. Salem R, Lewandowski RJ, Kulik L, et al. Radioembolization results in longer time-to-progression and reduced toxicity compared with chemoembolization in patients with hepatocellular carcinoma. *Gastroenterology*. Feb 2011; 140(2): 497-507.e2. PMID 21044630
31. Xiao E, Li D, Shen S, et al. Effect of preoperative transcatheter arterial chemoembolization on apoptosis of hepatocellular carcinoma cells. *Chin Med J (Engl)*. Feb 2003; 116(2): 203-7. PMID 12775230
32. Bush DA, Smith JC, Slater JD, et al. Randomized Clinical Trial Comparing Proton Beam Radiation Therapy with Transarterial Chemoembolization for Hepatocellular Carcinoma: Results of an Interim Analysis. *Int J Radiat Oncol Biol Phys*. May 01 2016; 95(1): 477-482. PMID 27084661
33. Mabed M, Esmael M, El-Khodary T, et al. A randomized controlled trial of transcatheter arterial chemoembolization with lipiodol, doxorubicin and cisplatin versus intravenous doxorubicin for patients with unresectable hepatocellular carcinoma. *Eur J Cancer Care (Engl)*. Sep 2009; 18(5): 492-9. PMID 19453695
34. Shen PC, Chang WC, Lo CH, et al. Comparison of Stereotactic Body Radiation Therapy and Transarterial Chemoembolization for Unresectable Medium-Sized Hepatocellular Carcinoma. *Int J Radiat Oncol Biol Phys*. Oct 01 2019; 105(2): 307-318. PMID 31175903
35. Biederman DM, Titano JJ, Korff RA, et al. Radiation Segmentectomy versus Selective Chemoembolization in the Treatment of Early-Stage Hepatocellular Carcinoma. *J Vasc Interv Radiol*. Jan 2018; 29(1): 30-37.e2. PMID 29169782
36. Molinari M, Kachura JR, Dixon E, et al. Transarterial chemoembolisation for advanced hepatocellular carcinoma: results from a North American cancer centre. *Clin Oncol (R Coll Radiol)*. Nov 2006; 18(9): 684-92. PMID 17100154
37. Takayasu K, Arii S, Ikai I, et al. Prospective cohort study of transarterial chemoembolization for unresectable hepatocellular carcinoma in 8510 patients. *Gastroenterology*. Aug 2006; 131(2): 461-9. PMID 16890600
38. Biselli M, Andreone P, Gramenzi A, et al. Transcatheter arterial chemoembolization therapy for patients with hepatocellular carcinoma: a case-controlled study. *Clin Gastroenterol Hepatol*. Sep 2005; 3(9): 918-25. PMID 16234031
39. Si T, Chen Y, Ma D, et al. Preoperative transarterial chemoembolization for resectable hepatocellular carcinoma in Asia area: a meta-analysis of random controlled trials. *Scand J Gastroenterol*. Dec 2016; 51(12): 1512-1519. PMID 27598831

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Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

40. Zhou Y, Zhang X, Wu L, et al. Meta-analysis: preoperative transcatheter arterial chemoembolization does not improve prognosis of patients with resectable hepatocellular carcinoma. *BMC Gastroenterol.* Mar 19 2013; 13: 51. PMID 23509884
41. Chua TC, Liauw W, Saxena A, et al. Systematic review of neoadjuvant transarterial chemoembolization for resectable hepatocellular carcinoma. *Liver Int.* Feb 2010; 30(2): 166-74. PMID 19912531
42. Kaibori M, Tanigawa N, Kariya S, et al. A prospective randomized controlled trial of preoperative whole-liver chemolipiodolization for hepatocellular carcinoma. *Dig Dis Sci.* May 2012; 57(5): 1404-12. PMID 22271410
43. Zhou WP, Lai EC, Li AJ, et al. A prospective, randomized, controlled trial of preoperative transarterial chemoembolization for resectable large hepatocellular carcinoma. *Ann Surg.* Feb 2009; 249(2): 195-202. PMID 19212170
44. Cui H, Gao QQ, Li YY, et al. Influence of preventive effects of transcatheter arterial chemoembolization on primary hepatocellular carcinoma. *J Med Forum.* 2003;24:13.
45. Yamasaki S, Hasegawa H, Kinoshita H, et al. A prospective randomized trial of the preventive effect of pre-operative transcatheter arterial embolization against recurrence of hepatocellular carcinoma. *Jpn J Cancer Res.* Feb 1996; 87(2): 206-11. PMID 8609071
46. Wu CC, Ho YZ, Ho WL, et al. Preoperative transcatheter arterial chemoembolization for resectable large hepatocellular carcinoma: a reappraisal. *Br J Surg.* Jan 1995; 82(1): 122-6. PMID 7881929
47. Yeh ML, Huang CI, Huang CF, et al. Neoadjuvant transcatheter arterial chemoembolization does not provide survival benefit compared to curative therapy alone in single hepatocellular carcinoma. *Kaohsiung J Med Sci.* Feb 2015; 31(2): 77-82. PMID 25645985
48. Choi GH, Kim DH, Kang CM, et al. Is preoperative transarterial chemoembolization needed for a resectable hepatocellular carcinoma?. *World J Surg.* Dec 2007; 31(12): 2370-7. PMID 17912587
49. Liang L, Li C, Diao YK, et al. Survival benefits from adjuvant transcatheter arterial chemoembolization in patients undergoing liver resection for hepatocellular carcinoma: a systematic review and meta-analysis. *Therap Adv Gastroenterol.* 2020; 13: 1756284820977693. PMID 33329759
50. Liao M, Zhu Z, Wang H, et al. Adjuvant transarterial chemoembolization for patients after curative resection of hepatocellular carcinoma: a meta-analysis. *Scand J Gastroenterol.* Jun 2017; 52(6-7): 624-634. PMID 28276833

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

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Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

51. Li Q, Wang J, Sun Y, et al. Efficacy of postoperative transarterial chemoembolization and portal vein chemotherapy for patients with hepatocellular carcinoma complicated by portal vein tumor thrombosis--a randomized study. *World J Surg*. Nov 2006; 30(11): 2004-11; discussion 2012-3. PMID 17058027
52. Zhong C, Guo RP, Li JQ, et al. A randomized controlled trial of hepatectomy with adjuvant transcatheter arterial chemoembolization versus hepatectomy alone for Stage III A hepatocellular carcinoma. *J Cancer Res Clin Oncol*. Oct 2009; 135(10): 1437-45. PMID 19408012
53. Peng BG, He Q, Li JP, et al. Adjuvant transcatheter arterial chemoembolization improves efficacy of hepatectomy for patients with hepatocellular carcinoma and portal vein tumor thrombus. *Am J Surg*. Sep 2009; 198(3): 313-8. PMID 19285298
54. Gui CH, Baey S, D'cruz RT, et al. Trans-arterial chemoembolization + radiofrequency ablation versus surgical resection in hepatocellular carcinoma - A meta-analysis. *Eur J Surg Oncol*. May 2020; 46(5): 763-771. PMID 31937433
55. Liu H, Wang ZG, Fu SY, et al. Randomized clinical trial of chemoembolization plus radiofrequency ablation versus partial hepatectomy for hepatocellular carcinoma within the Milan criteria. *Br J Surg*. Mar 2016; 103(4): 348-56. PMID 26780107
56. Ako S, Nakamura S, Nouse K, et al. Transcatheter Arterial Chemoembolization to Reduce Size of Hepatocellular Carcinoma before Radiofrequency Ablation. *Acta Med Okayama*. Feb 2018; 72(1): 47-52. PMID 29463938
57. Haochen W, Jian W, Li S, et al. Transarterial chemoembolization plus multi-imaging-guided radiofrequency ablation for elimination of hepatocellular carcinoma nodules measuring 3.1 to 5.0 cm: a single-center study. *J Int Med Res*. Jul 2018; 46(7): 2650-2657. PMID 29683022
58. Bholee AK, Peng K, Zhou Z, et al. Radiofrequency ablation combined with transarterial chemoembolization versus hepatectomy for patients with hepatocellular carcinoma within Milan criteria: a retrospective case-control study. *Clin Transl Oncol*. Jul 2017; 19(7): 844-852. PMID 28070766
59. Lan T, Chang L, Mn R, et al. Comparative Efficacy of Interventional Therapies for Early-stage Hepatocellular Carcinoma: A PRISMA-compliant Systematic Review and Network Meta-analysis. *Medicine (Baltimore)*. Apr 2016; 95(15): e3185. PMID 27082558
60. Li L, Tian J, Liu P, et al. Transarterial chemoembolization combination therapy vs monotherapy in unresectable hepatocellular carcinoma: a meta-analysis. *Tumori*. Jun 02 2016; 2016(3): 301-10. PMID 27002950

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Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

61. Lu Z, Wen F, Guo Q, et al. Radiofrequency ablation plus chemoembolization versus radiofrequency ablation alone for hepatocellular carcinoma: a meta-analysis of randomized-controlled trials. *Eur J Gastroenterol Hepatol*. Feb 2013; 25(2): 187-94. PMID 23134976
62. Wang X, Hu Y, Ren M, et al. Efficacy and Safety of Radiofrequency Ablation Combined with Transcatheter Arterial Chemoembolization for Hepatocellular Carcinomas Compared with Radiofrequency Ablation Alone: A Time-to-Event Meta-Analysis. *Korean J Radiol*. Jan-Feb 2016; 17(1): 93-102. PMID 26798221
63. Peng ZW, Zhang YJ, Liang HH, et al. Recurrent hepatocellular carcinoma treated with sequential transcatheter arterial chemoembolization and RF ablation versus RF ablation alone: a prospective randomized trial. *Radiology*. Feb 2012; 262(2): 689-700. PMID 22157201
64. Morimoto M, Numata K, Kondou M, et al. Midterm outcomes in patients with intermediate-sized hepatocellular carcinoma: a randomized controlled trial for determining the efficacy of radiofrequency ablation combined with transcatheter arterial chemoembolization. *Cancer*. Dec 01 2010; 116(23): 5452-60. PMID 20672352
65. Shibata T, Isoda H, Hirokawa Y, et al. Small hepatocellular carcinoma: is radiofrequency ablation combined with transcatheter arterial chemoembolization more effective than radiofrequency ablation alone for treatment?. *Radiology*. Sep 2009; 252(3): 905-13. PMID 19567647
66. Cheng BQ, Jia CQ, Liu CT, et al. Chemoembolization combined with radiofrequency ablation for patients with hepatocellular carcinoma larger than 3 cm: a randomized controlled trial. *JAMA*. Apr 09 2008; 299(14): 1669-77. PMID 18398079
67. DeAngelis CD, Fontanarosa PB. Retraction: Cheng B-Q, et al. Chemoembolization combined with radiofrequency ablation for patients with hepatocellular carcinoma larger than 3 cm: a randomized controlled trial. *JAMA*. 2008;299(14):1669-1677. *JAMA*. May 13 2009; 301(18): 1931. PMID 19380477
68. Yi Y, Zhang Y, Wei Q, et al. Radiofrequency ablation or microwave ablation combined with transcatheter arterial chemoembolization in treatment of hepatocellular carcinoma by comparing with radiofrequency ablation alone. *Chin J Cancer Res*. Feb 2014; 26(1): 112-8. PMID 24653633
69. Peng ZW, Zhang YJ, Chen MS, et al. Radiofrequency ablation with or without transcatheter arterial chemoembolization in the treatment of hepatocellular carcinoma: a prospective randomized trial. *J Clin Oncol*. Feb 01 2013; 31(4): 426-32. PMID 23269991
70. Martin AP, Bartels M, Hauss J, et al. Overview of the MELD score and the UNOS adult liver allocation system. *Transplant Proc*. Dec 2007; 39(10): 3169-74. PMID 18089345

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Policy # 00227

Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

71. Organ Procurement and Transplantation Network (OPTN). OPTN Policies. Updated April 28, 2022; https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.
72. Mazzaferro V, Regalia E, Doci R, et al. Liver transplantation for the treatment of small hepatocellular carcinomas in patients with cirrhosis. *N Engl J Med*. Mar 14 1996; 334(11): 693-9. PMID 8594428
73. Pomfret EA, Washburn K, Wald C, et al. Report of a national conference on liver allocation in patients with hepatocellular carcinoma in the United States. *Liver Transpl*. Mar 2010; 16(3): 262-78. PMID 20209641
74. Butcher DA, Brandis KJ, Wang H, et al. Long-term survival and postoperative complications of pre-liver transplantation transarterial chemoembolisation in hepatocellular carcinoma: A systematic review and meta-analysis. *Eur J Surg Oncol*. Mar 2022; 48(3): 621-631. PMID 34774394
75. Si T, Chen Y, Ma D, et al. Transarterial chemoembolization prior to liver transplantation for patients with hepatocellular carcinoma: A meta-analysis. *J Gastroenterol Hepatol*. Jul 2017; 32(7): 1286-1294. PMID 28085213
76. Graziadei IW, Sandmueller H, Waldenberger P, et al. Chemoembolization followed by liver transplantation for hepatocellular carcinoma impedes tumor progression while on the waiting list and leads to excellent outcome. *Liver Transpl*. Jun 2003; 9(6): 557-63. PMID 12783395
77. Maddala YK, Stadheim L, Andrews JC, et al. Drop-out rates of patients with hepatocellular cancer listed for liver transplantation: outcome with chemoembolization. *Liver Transpl*. Mar 2004; 10(3): 449-55. PMID 15004776
78. Obed A, Beham A, Pullmann K, et al. Patients without hepatocellular carcinoma progression after transarterial chemoembolization benefit from liver transplantation. *World J Gastroenterol*. Feb 07 2007; 13(5): 761-7. PMID 17278200
79. Yao FY. Liver transplantation for hepatocellular carcinoma: beyond the Milan criteria. *Am J Transplant*. Oct 2008; 8(10): 1982-9. PMID 18727702
80. Gabr A, Abouchaleh N, Ali R, et al. Comparative study of post-transplant outcomes in hepatocellular carcinoma patients treated with chemoembolization or radioembolization. *Eur J Radiol*. Aug 2017; 93: 100-106. PMID 28668402
81. Park SY, Kim JH, Yoon HJ, et al. Transarterial chemoembolization versus supportive therapy in the palliative treatment of unresectable intrahepatic cholangiocarcinoma. *Clin Radiol*. Apr 2011; 66(4): 322-8. PMID 21356394

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Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

82. Seidensticker R, Seidensticker M, Doegen K, et al. Extensive Use of Interventional Therapies Improves Survival in Unresectable or Recurrent Intrahepatic Cholangiocarcinoma. *Gastroenterol Res Pract.* 2016; 2016: 8732521. PMID 26966431
83. Boehm LM, Jayakrishnan TT, Miura JT, et al. Comparative effectiveness of hepatic artery based therapies for unresectable intrahepatic cholangiocarcinoma. *J Surg Oncol.* Feb 2015; 111(2): 213-20. PMID 25176325
84. Knuppel M, Kubicka S, Vogel A, et al. Combination of conservative and interventional therapy strategies for intra- and extrahepatic cholangiocellular carcinoma: a retrospective survival analysis. *Gastroenterol Res Pract.* 2012; 2012: 190708. PMID 21776251
85. Tai E, Kennedy S, Farrell A, et al. Comparison of transarterial bland and chemoembolization for neuroendocrine tumours: a systematic review and meta-analysis. *Curr Oncol.* Dec 2020; 27(6): e537-e546. PMID 33380868
86. Nazario J, Gupta S. Transarterial liver-directed therapies of neuroendocrine hepatic metastases. *Semin Oncol.* Apr 2010; 37(2): 118-26. PMID 20494704
87. Ruutiainen AT, Soulen MC, Tuite CM, et al. Chemoembolization and bland embolization of neuroendocrine tumor metastases to the liver. *J Vasc Interv Radiol.* Jul 2007; 18(7): 847-55. PMID 17609443
88. Gupta S, Yao JC, Ahrar K, et al. Hepatic artery embolization and chemoembolization for treatment of patients with metastatic carcinoid tumors: the M.D. Anderson experience. *Cancer J.* Jul-Aug 2003; 9(4): 261-7. PMID 12967136
89. Osborne DA, Zervos EE, Strosberg J, et al. Improved outcome with cytoreduction versus embolization for symptomatic hepatic metastases of carcinoid and neuroendocrine tumors. *Ann Surg Oncol.* Apr 2006; 13(4): 572-81. PMID 16511671
90. Rowcroft A, Loveday BPT, Thomson BNJ, et al. Systematic review of liver directed therapy for uveal melanoma hepatic metastases. *HPB (Oxford).* Apr 2020; 22(4): 497-505. PMID 31791894
91. Huppert PE, Fierlbeck G, Pereira P, et al. Transarterial chemoembolization of liver metastases in patients with uveal melanoma. *Eur J Radiol.* Jun 2010; 74(3): e38-44. PMID 19467811
92. Sharma KV, Gould JE, Harbour JW, et al. Hepatic arterial chemoembolization for management of metastatic melanoma. *AJR Am J Roentgenol.* Jan 2008; 190(1): 99-104. PMID 18094299
93. Bedikian AY, Legha SS, Mavligit G, et al. Treatment of uveal melanoma metastatic to the liver: a review of the M. D. Anderson Cancer Center experience and prognostic factors. *Cancer.* Nov 01 1995; 76(9): 1665-70. PMID 8635073

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

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Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

94. Patel K, Sullivan K, Berd D, et al. Chemoembolization of the hepatic artery with BCNU for metastatic uveal melanoma: results of a phase II study. *Melanoma Res.* Aug 2005; 15(4): 297-304. PMID 16034309
95. Zacharias AJ, Jayakrishnan TT, Rajeev R, et al. Comparative Effectiveness of Hepatic Artery Based Therapies for Unresectable Colorectal Liver Metastases: A Meta-Analysis. *PLoS One.* 2015; 10(10): e0139940. PMID 26448327
96. Richardson AJ, Laurence JM, Lam VW. Transarterial chemoembolization with irinotecan beads in the treatment of colorectal liver metastases: systematic review. *J Vasc Interv Radiol.* Aug 2013; 24(8): 1209-17. PMID 23885916
97. Swierz MJ, Storman D, Riemsma RP, et al. Transarterial (chemo)embolisation versus no intervention or placebo for liver metastases. *Cochrane Database Syst Rev.* Mar 12 2020; 3: CD009498. PMID 32163181
98. Hunt TM, Flowerdew AD, Birch SJ, et al. Prospective randomized controlled trial of hepatic arterial embolization or infusion chemotherapy with 5-fluorouracil and degradable starch microspheres for colorectal liver metastases. *Br J Surg.* Jul 1990; 77(7): 779-82. PMID 2200559
99. Eichler K, Zangos S, Mack MG, et al. First human study in treatment of unresectable liver metastases from colorectal cancer with irinotecan-loaded beads (DEBIRI). *Int J Oncol.* Oct 2012; 41(4): 1213-20. PMID 22842404
100. Martin RC, Scoggins CR, Tomalty D, et al. Irinotecan drug-eluting beads in the treatment of chemo-naive unresectable colorectal liver metastasis with concomitant systemic fluorouracil and oxaliplatin: results of pharmacokinetics and phase I trial. *J Gastrointest Surg.* Aug 2012; 16(8): 1531-8. PMID 22528576
101. Vogl TJ, Jost A, Nour-Eldin NA, et al. Repeated transarterial chemoembolisation using different chemotherapeutic drug combinations followed by MR-guided laser-induced thermotherapy in patients with liver metastases of colorectal carcinoma. *Br J Cancer.* Mar 27 2012; 106(7): 1274-9. PMID 22382689
102. Martin RC, Joshi J, Robbins K, et al. Hepatic intra-arterial injection of drug-eluting bead, irinotecan (DEBIRI) in unresectable colorectal liver metastases refractory to systemic chemotherapy: results of multi-institutional study. *Ann Surg Oncol.* Jan 2011; 18(1): 192-8. PMID 20740319
103. Aliberti C, Fiorentini G, Muzzio PC, et al. Trans-arterial chemoembolization of metastatic colorectal carcinoma to the liver adopting DC Bead(R), drug-eluting bead loaded with

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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: 06/10/2024

- irinotecan: results of a phase II clinical study. *Anticancer Res.* Dec 2011; 31(12): 4581-7. PMID 22199334
104. Fiorentini G, Aliberti C, Tilli M, et al. Intra-arterial infusion of irinotecan-loaded drug-eluting beads (DEBIRI) versus intravenous therapy (FOLFIRI) for hepatic metastases from colorectal cancer: final results of a phase III study. *Anticancer Res.* Apr 2012; 32(4): 1387-95. PMID 22493375
105. Martin RC, Scoggins CR, Schreeder M, et al. Randomized controlled trial of irinotecan drug-eluting beads with simultaneous FOLFOX and bevacizumab for patients with unresectable colorectal liver-limited metastasis. *Cancer.* Oct 15 2015; 121(20): 3649-58. PMID 26149602
106. Vogl TJ, Gruber T, Balzer JO, et al. Repeated transarterial chemoembolization in the treatment of liver metastases of colorectal cancer: prospective study. *Radiology.* Jan 2009; 250(1): 281-9. PMID 19092099
107. Vogl TJ, Mack MG, Balzer JO, et al. Liver metastases: neoadjuvant downsizing with transarterial chemoembolization before laser-induced thermotherapy. *Radiology.* Nov 2003; 229(2): 457-64. PMID 14500854
108. Hong K, McBride JD, Georgiades CS, et al. Salvage therapy for liver-dominant colorectal metastatic adenocarcinoma: comparison between transcatheter arterial chemoembolization versus yttrium-90 radioembolization. *J Vasc Interv Radiol.* Mar 2009; 20(3): 360-7. PMID 19167245
109. Rivera K, Jeyarajah DR, Washington K. Hepatectomy, RFA, and Other Liver Directed Therapies for Treatment of Breast Cancer Liver Metastasis: A Systematic Review. *Front Oncol.* 2021; 11: 643383. PMID 33842354
110. Vogl TJ, Naguib NN, Nour-Eldin NE, et al. Transarterial chemoembolization (TACE) with mitomycin C and gemcitabine for liver metastases in breast cancer. *Eur Radiol.* Jan 2010; 20(1): 173-80. PMID 19657653
111. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Hepatobiliary Cancers, Version 2.2024. Updated April 19, 2024. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf.
112. Heimbach JK, Kulik LM, Finn RS, et al. AASLD guidelines for the treatment of hepatocellular carcinoma. *Hepatology.* Jan 2018; 67(1): 358-380. PMID 28130846
113. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Neuroendocrine and Adrenal Tumors, Version 1.2023. Updated August 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf.

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Policy # 00227

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- 114. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Melanoma: Uveal, Version 2.2022. Updated April 5, 2022. https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf.
- 115. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer, Version 1.2024. Updated January 29, 2024. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf.
- 116. Chiorean EG, Nandakumar G, Fadelu T, et al. Treatment of Patients With Late-Stage Colorectal Cancer: ASCO Resource-Stratified Guideline. JCO Glob Oncol. Mar 2020; 6: 414-438. PMID 32150483
- 117. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Breast Cancer, Version 2.2024. Updated March 11, 2024. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

Policy History

Original Effective Date: 03/19/2008

Current Effective Date: 06/10/2024

- 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.
- 03/28/2024 Coding update
- 05/02/2024 Medical Policy Committee review
- 05/08/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2025

Coding

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CPT is a registered trademark of the American Medical Association.

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 Add code effective 04/01/2024: C9797
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:

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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.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- 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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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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