Molina Clinical Policy
Arterially Directed Embolic Therapy for Liver Tumors (e.g., TACE, TAE, DEB-TACE)
Policy No. 120

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DISCLAIMER

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OVERVIEW

Transarterial chemoembolization (TACE) and transarterial embolization (TAE) are established local regional therapies for patients with unresectable liver tumors, particularly hepatocellular carcinoma HCC. TAE involves selective catheter-based delivery of embolic material into the hepatic artery branches supplying the tumor, producing ischemia and tumor necrosis. TACE adds intra-arterial chemotherapy to the embolization process. Post embolization syndrome is common, while serious complications such as liver failure, abscess, or non-target embolization occur less frequently. TACE and TAE both typically require hospitalization for one to two days. Post-procedure care includes hydration, antiemetics, analgesics, and monitoring of electrolytes and liver function. (Curley 2026). These techniques are used as part of multimodal management strategies for liver dominant malignancies when curative options are not feasible.

Drug-eluting bead transarterial chemoembolization (DEB-TACE) is a form of TACE in which chemotherapy is pre-loaded into tiny embolic beads that are delivered directly into the hepatic artery supplying the tumor. These beads simultaneously occlude the tumor's arterial blood flow and provide sustained, localized release of chemotherapy, allowing high intratumoral drug concentrations with reduced systemic exposure (Curley 2026).

Hepatocellular carcinoma (HCC) is an aggressive primary liver tumor that most often develops in the setting of cirrhosis. Prognosis and treatment options are determined primarily by tumor burden and the patient's hepatic reserve. Potentially curative options include surgical resection and liver transplantation, but many patients are not candidates due to underlying liver dysfunction or the extent of the disease. For patients with liver-limited HCC who are not eligible for resection, transplantation, or local thermal ablation, locoregional liver-directed therapies such as TAE and TACE are options. TACE is recommended for patient with unresectable or multifocal HCC who have preserved liver function and no main or lobar branch portal vein tumor thrombosis. TACE is also commonly used as a bridging therapy for patients awaiting liver transplantation (Curley et al. 2026).

Neuroendocrine tumors (NETs) are a heterogeneous group of neoplasms believed to arise from neuroendocrine cells and their precursors, which are scattered throughout the body. These tumors often display indolent biological behavior and are characterized by their ability to secrete peptides, leading to distinct hormonal syndromes. NETs can arise in various sites, with gastroenteropancreatic NETs being among the most common. These tumors are typically classified into well-differentiated, indolent NETs and poorly differentiated, aggressive neuroendocrine carcinomas, which resemble small cell carcinoma. Well-differentiated NETs, which include previously recognized carcinoid and pancreatic islet cell tumors, tend to have a more indolent course, while poorly differentiated neuroendocrine carcinomas are far more aggressive. For patients with hepatic-predominant metastatic NETs who are not candidates for surgical resection, liver-directed transarterial therapies including hepatic arterial embolization, transarterial chemoembolization (TACE), and radioembolization are reasonable palliative options to control tumor growth and alleviate symptoms (Chan et al. 2026).

Intrahepatic cholangiocarcinoma (ICC) is a rare but aggressive malignancy that originates from the epithelial cells of the intrahepatic bile ducts. Approximately 5 to 10 percent of cholangiocarcinomas are intrahepatic , and these tumors may originate from either small intrahepatic ductules or larger intrahepatic ducts proximal to the bifurcation of the right

and left hepatic ducts. Patients often present with nonspecific symptoms, including right upper quadrant pain, weight loss, and abnormal liver function tests. Diagnosis is typically incidental or occurs during imaging for liver abnormalities. Because many cases present at an advance stage, ICC is associated with a poor overall prognosis (Lowe et al. 2025). For patients with locally advanced, unresectable ICC, locoregional liver-directed therapies such as TAE or TACE may be considered in appropriate candidates. These approaches can provide local palliation and disease control (Anderson 2026).

Uveal melanoma is a rare malignancy that arises from melanocytes within the uveal tract of the eye, which includes the iris, ciliary body, and choroid. It accounts for about 85% of all ocular melanomas, with the remainder arising from the conjunctive or other sites. The liver is the most common site of metastasis, and metastatic disease typically develops within five to seven years after treatment of the primary tumor, with a median time of three years, although metastasis may also appear a decade or more after initial therapy. Many patients are asymptomatic at the time metastatic disease is detected, while those with significant disease burden may present with symptoms such as fatigue, weight loss, abdominal pain, or chest pain depending on the site of metastasis. For patients with hepatic dominant uveal melanoma who are not candidates for surgical resection, liver -directed therapies including hepatic arterial embolization, TACE, and radioembolization may provide tumor control and symptom relief. (Carvajal & Harbour 2024).

Colorectal cancer (CRC) surgical resection is the treatment of choice for patients with CRC that has metastasized to the liver, and many individuals with liver-isolated metastases can achieve long-term survival or potential cure when resection is feasible. However, even among patients with liver-limited disease, a substantial portion are not surgical candidates because of factors such as tumor location, multifocality, or inadequate hepatic reserve. For patients with unresectable, liver-dominant or liver-isolated CRC metastases, nonsurgical liver-directed therapies, including TACE may be considered in selected, often chemo refractory cases. These approaches are primarily used with the goal of controlling intrahepatic disease and providing palliation (Venook & Fidelman 2025).

COVERAGE POLICY

Transarterial Embolization (TAE) and Chemoembolization (TACE)

Transarterial embolization (TAE) or Transarterial chemoembolization (TACE) may be **considered medically necessary** for ANY of the following conditions:

1. Treatment of unresectable primary hepatocellular liver carcinoma (HCC) when ALL the following criteria are met:
   a. Preserved liver function defined as Childs-Turcotte-Pugh Class A or B
   b. No evidence of extra-hepatic metastases
   c. No evidence of severe renal function impairment
   d. No evidence of portal vein occlusion

2. Treatment of unresectable primary HCC as a bridge therapy in individuals who may become eligible for liver transplantation when any ONE of the following criteria are met:
   a. One lesion greater than 5 cm and less than or equal to 8 cm
   b. Two or three lesions each greater than 3 cm and less than or equal to 5 cm and total diameter of all lesions less than or equal to 8 cm
   c. Four to five lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm

3. Treatment of unresectable primary intrahepatic cholangiocarcinoma

4. Treatment of liver metastasis in symptomatic patients with metastatic neuroendocrine tumors whose symptoms persist despite systemic treatment, and who are not candidates for surgical resection

5. Treatment of liver metastasis in patients with liver-dominant metastatic uveal melanoma

6. Treatment of liver metastasis in select patients with colorectal cancer whose symptoms persist despite systemic treatment and who are not candidates for surgical resection

* The Child-Turcotte-Pugh score determines short-term prognosis among groups of patients awaiting liver transplantation and has been widely adopted for risk-stratifying patients before transplantation. **Child-Turcotte-Pugh Score of Severity of Liver Disease**			
Points	**1**	**2**	**3**
Encephalopathy	None	Grade 1 – 2	Grade 3 – 4
Ascites	Absent	Slight	Moderate
Bilirubin (mg/dL)	< 2	2 – 3	> 3
Albumin (g/dL)	> 3.5	2.8 – 3.5	< 2.8
INR*	< 1.7	1.7 – 2.3	> 2.3
PT* (seconds prolonged)	< 4	4 - 6	> 6

The individual scores are summed and then grouped as a classification: < 7 = A, 7-9 = B, > 9 = C (forecasts a survival of less than 12 months). *INR = International Normalized Ratio; PT = prothrombin time.

Drug Eluting Bead Transarterial Chemoembolization

Drug Eluting Bead Transarterial chemoembolization (DEB-TACE) may be **considered medically necessary** when ANY of the following criteria are met:

1. Treatment of unresectable primary hepatocellular liver carcinoma (HCC) when ALL the following criteria are met:
   a. Preserved liver function defined as Childs-Turcotte-Pugh Class A or B
   b. No evidence of extra-hepatic metastases
   c. No evidence of severe renal function impairment
   d. No evidence of portal vein occlusion

2. Treatment of unresectable primary HCC as a bridge therapy in individuals who may become eligible for liver transplantation when any ONE of the following criteria are met:
   a. One lesion greater than 5 cm and less than or equal to 8 cm
   b. Two or three lesions each greater than 3 cm and less than or equal to 5 cm and total diameter of all lesions less than or equal to 8 cm
   c. Four to five lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm

Continuation of Therapy

1. TACE may be repeated after the first two sessions if there is a partial but incomplete response

2. Multiple courses of TACE, especially if spaced too closely together, can increase deaths from liver failure despite successful tumor shrinkage, and these excess deaths from deterioration of liver function may outweigh any prolongation of survival that results from improved tumor control

3. TACE may cause hepatic artery damage, the likelihood of which is higher in patients with impaired liver function

4. Hepatic artery interruption by repeated TACE or arterial dissection also leads to the development of extrahepatic collateralization, which may create an alternative blood supply to the tumor and contribute to treatment failure

Limitations and Exclusions

1. Absence of ALL the following absolute contraindications must be confirmed prior to TACE:
   a. Absent or severely reduced portal vein flow (e.g., tumoral or nontumoral portal vein occlusion, or hepatofugal blood flow)
   b. Decompensated cirrhosis (Child-Turcotte-Pugh C, or Child-Turcotte-Pugh B score >8 including jaundice, clinical hepatic encephalopathy, refractory ascites, and/or hepatorenal syndrome)

2. Member must be evaluated and cleared for ANY of the following relative contraindications:
   a. Serum bilirubin > 3 mg/dL
   b. Lactate dehydrogenase >425 units/L
   c. Aspartate aminotransferase >100 units/L
   d. Tumor burden involving >50 percent of the liver

e. Severe comorbidities
f. Untreated esophageal varices at high risk of bleeding
g. Prior transjugular intrahepatic portosystemic shunting (TIPS)

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Hepatocellular Carcinoma

Randomized Controlled Trials

Ikeda et al. (2022) conducted a randomized controlled trial (RCT) to compare the efficacy of selective transarterial chemoembolization (TACE) with drug-eluting bead transarterial chemoembolization (DEB-TACE) loaded with epirubicin versus conventional TACE (cTACE) using epirubicin-ethiodized oil in patients with unresectable hepatocellular carcinoma (HCC). The study enrolled 200 patients (99 in the DEB-TACE arm and 101 in the cTACE arm) who met specific eligibility criteria, including histologically or clinically diagnosed HCC, ineligibility for curative treatment, and hypervascular tumors measurable by imaging. The primary endpoint was the complete response (CR) rate at three months with secondary endpoints including the CR rate at one month and AE incidence. Results demonstrated that cTACE had significantly higher CR rates at both one month (84.2% vs. 35.7%) and three months (75.2% vs. 27.6%) compared to DEB-TACE ($p < 0.0001$). However, the frequency of AEs, including pyrexia, fatigue, abdominal pain, increased liver enzymes, and hypoalbuminemia, was significantly higher in the cTACE group, indicating a higher risk of postembolization syndrome. However, the frequency of AEs, including pyrexia ($p = 0.0001$), fatigue ($p = 0.0194$), abdominal pain ($p = 0.0423$), hypoalbuminemia ($p = 0.0154$), and increased liver enzymes ($p < 0.0001$), was significantly higher in the cTACE group, indicating a higher risk of postembolization syndrome. Three serious AEs were reported: biloma and biliary tract infection (both in the DEB-TACE arm) and a liver abscess (cTACE arm), though no treatment-related deaths occurred. The study had limitations, including its unblinded design, potential overestimation of response in the cTACE arm due to ethiodized oil accumulation, and the inability to compare OS due to treatment crossover and subsequent systemic therapy. Despite these limitations, the findings suggest that cTACE is more effective in achieving local tumor control than DEB-TACE, but its increased toxicity should be considered when selecting treatment, particularly in patients with lower tolerance for postembolization syndrome.

Golfieri et al. (2014) conducted an RCT comparing DEB-TACE vs TACE for HCC. One hundred and seventy-seven patients were enrolled in the study and randomized 1:1 into either conventional TACE (n=88) or DEB-TACE (n=89). The primary outcome of the study was to compare the 2-year-survival rate between the two arms, in addition to tracking adverse events and serious adverse events. The patients included were 18 years or older with HCC unsuitable for curative treatment or had a failed resection/ablation. Patients in the cTACE arm received 47.2±14.6 mg of epirubicin and 10.3±3.8 ml of Lipiodol, and patients in the DEB-TACE arm received 57.8±24.1 mg of doxorubicin. Two-thirds of the patients in each arm underwent segmental TACE treatment with a median number of treatments being 2 in both treatment arms. At the two year follow up a total of 73 (41.2%) patients died [1 (1.4%) due to sepsis, 49 (67.1%) due to tumor progression, 17 (23.3%) due to liver failure, and 6 (8.2%) due to other causes], 36 (40.9%) in the cTACE arm, and 37 (41.6%) in the DEB-TACE arm demonstrating no different between two year death rates between the treatment arms. There was no significant difference in adverse events between the two arms, and serious adverse events were rare (< 7%) in both arms, as well. The 1- and 2-year survival rates were 83.5% and 55.4% in the cTACE arm, and 86.2% and 56.8% in the DEB-TACE (P=0.949) arm. After analyzing the data, the authors concluded that the type of TACE did not affect patient survival at the univariate regression analysis whereas ECOG-1, low serum albumin, and multiple tumors independently and adversely conditioned survival. The authors did note that DEB-TACE is more costly than cTACE, making it hard to justify its systemic use when it does not increase positive clinical outcomes.

Llovet et al. (2002) published a RCT to evaluate the survival benefits of repeated arterial embolization (gelatin sponge) or chemoembolization (gelatin sponge plus doxorubicin) versus conservative treatment in patients with unresectable HCC who were ineligible for curative therapy. The trial included 112 patients with Child-Pugh class A or B and Okuda

stage I or II disease. The primary endpoint was survival. The study terminated after the ninth sequential analysis, which revealed that chemoembolization significantly improved survival compared to conservative treatment, with a hazard ratio of death of 0.47 (p=0.025). One-year and two-year survival rates were 82% and 63% for chemoembolization, compared to 75% and 50% for embolization, and 63% and 27% for the control group (p=0.009). Chemoembolization also achieved objective responses lasting at least 6 months in 35% of cases and resulted in a lower rate of portal vein invasion than conservative treatment. Treatment allocation was the only independent factor associated with survival (p=0.02). In conclusion, chemoembolization significantly improved survival in carefully selected patients with unresectable HCC.

Systematic Reviews and Meta-Analyses

Chernyshenko et al. (2025) conducted a systematic review and meta-analysis to compare the efficacy and safety of two approaches for treating HCC in adult patients: DEB-TACE and cTACE. The analysis included 32 studies, assessing tumor response using mRECIST criteria, including CR, Partial Response (PR), Stable Disease (SD), and Progressive Disease (PD), with 455 DEB-TACE patients and 502 cTACE patients. Results showed that DEB-TACE led to significantly higher rates of CR (p=0.0001) and PR (p<0.00001) compared to cTACE. Disease progression was lower in the DEB-TACE group (15.3%) versus cTACE (22.7%) (p<0.00001). Furthermore, DEB-TACE patients had better OS (p<0.00001) and progression-free survival (PFS) (p<0.0001). Both groups had similar complication rates. The study also highlighted that DEB-TACE may improve patient outcomes in terms of radiological response and survival, potentially influencing decisions about surgery, chemotherapy, and liver transplantation. However, the findings are limited by the retrospective nature of the studies, lack of randomization, and heterogeneity in the embolic agents and chemotherapy drugs used. Despite these limitations, the results suggest that DEB-TACE may offer clinical benefits over cTACE, though further prospective randomized studies are needed to confirm these findings and assess the procedures' safety and efficacy in a larger cohort.

Usman et al. (2025) performed a systematic review and meta-analysis of 28 studies involving 3,740 patients to evaluate the efficacy and safety of TACE in treating HCC patients with vascular invasion or extrahepatic metastasis. The review included randomized controlled trials and observational studies, focusing on overall survival (OS), mean survival, PFS, and adverse outcomes. Of the included studies, 9 reported OS, with the highest survival rate recorded at 12.3 months for stage 1 tumors with Child-Pugh A or B classifications. In contrast, survival for patients with advanced stages (T3, CPS B) was much shorter, with an average of 5 months. Studies also reported a 1-month mortality rate, with the highest reported at 18 deaths in a month. Common side effects included fever, pain, vomiting, and gastrointestinal dysfunction. Of the 19 studies reporting safety, 4 reported fever, 3 reported pain, and 3 reported vomiting and gastrointestinal dysfunction. Chemotherapeutic agents like doxorubicin, cisplatin, and mitomycin were commonly used in TACE, with variability in treatment approaches across studies. The study also highlighted survival rates for PFS, with a study reporting PFS of 1.5 months for TACE compared to 9.6 months for other treatments. Survival rates at 3, 6, 12, 18, and 24 months were also evaluated, with the highest 3-month survival reported at 93.4%. At 6 months, survival was 86.7%, with a 12-month survival rate of 77.6%. Despite promising outcomes in certain patient groups, the review highlighted several limitations, including inconsistencies in study designs, lack of uniform data for meta-analysis, and insufficient patient demographic details, which may influence the generalizability of findings. Additionally, the review noted the pivotal role of tumor extent and Child-Pugh classification in determining survival outcomes, with limited parenchymal tumors and Child-Pugh A classification correlating with better survival outcomes. In conclusion, TACE appears to be a safe and potentially effective treatment for advanced HCC, particularly in patients with vascular invasion or extrahepatic metastasis, though further research is needed to confirm its benefits and optimize treatment protocols.

Wang et al. (2020) published a systematic review and meta-analysis to evaluate the efficacy and safety of cTACE versus DEB-TACE for HCC. The analysis included six RCTs with patients diagnosed with inoperable HCC, assessing key outcomes such as OS, objective response rate (ORR), disease control rate (DCR), and AEs. The pooled analysis found no significant differences between cTACE and DEB-TACE in complete response (p = 0.170), PR (p = 0.609), DCR (p = 0.113), or SD (p = 0.251) at six months. Similarly, no significant differences were observed in OR at 3 months (p = 0.491), 6 months (p = 0.093), 9 months (p = 0.105), or 12 months (p = 0.707). Additionally, no significant differences were noted in OS (p = 0.715) or major complications (p = 0.255). Limitations of the analysis included a small sample size, potential selection bias, variability in TACE procedures across institutions, and a lack of subgroup analyses. Despite these limitations, the findings suggest that DEB-TACE and cTACE provide comparable therapeutic effects and safety profiles.

Hepatic Metastases

Systematic Reviews and Meta-Analyses

Tai et al. (2020) published a systematic review and meta-analysis comparing TACE and transarterial embolization (TAE) for treating hepatic metastases. The analysis included eight studies with a total of 504 patients. Outcomes of interest were OS, PFS, radiographic response, complications, and symptom control, with hazard ratios (HRs) and odds ratios (ORs) estimated and pooled. Results showed no statistically significant differences between TACE and TAE for OS and PFS at 1, 2, and 5 years. The pooled analysis found a trend favoring TAE in 2-year OS, but the difference was not statistically significant. Both techniques demonstrated safety and effectiveness for symptom control. Complication rates were similar, with post-embolization syndrome being the most common AEs. While radiologic response varied depending on the criteria used (RECIST, WHO), no significant differences between TACE and TAE were observed. Symptom control was reported in four studies, with no statistically significant differences between groups. While some studies suggested a greater symptomatic response with TAE, results were heterogeneous. The study was limited by the rarity of neuroendocrine tumors (NETs) and the predominance of retrospective data. Despite these limitations, findings indicate that both TACE and TAE are viable treatment options for hepatic metastases from NETs, with no clear superiority of one over the other.

Rowcroft et al. (2019) published a systematic review analyzing evidence from 55 studies involving 2,446 patients to assess treatment options for liver metastases from uveal melanoma (UM). Various therapeutic approaches were evaluated, including surgery, isolated hepatic perfusion (IHP), percutaneous hepatic perfusion (PHP), hepatic artery infusion (HAI), TACE, selective internal radiotherapy (SIRT), and immunoembolization (IE). OS was the primary outcome, with disease-free survival as a secondary measure. Surgical resection demonstrated improved OS compared to systemic chemotherapy or supportive care, with median survival ranging from 10 to 35 months. IHP and PHP, particularly with melphalan-based regimens, yielded OS between 9 and 25 months, though IHP was associated with significant morbidity. HAI demonstrated mixed results, with one randomized trial showing no OS difference between intra-arterial and intravenous Fotemustine, despite longer PFS with HAI ($p = 0.002$). TACE studies reported OS between 5 and 29 months, with survival linked to treatment response. SIRT, evaluated in six retrospective studies, yielded OS ranging from 9 to 24 months. IE with granulocyte-macrophage colony-stimulating factor was associated with a median OS of 21 months, showing a significant survival benefit in patients with extensive liver involvement ($p = 0.047$). While retrospective findings suggest that surgery and locoregional therapies may improve survival, the lack of high-quality evidence underscores the need for standardized study designs and prospective trials to better define optimal management strategies.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

DePietro et al. (2024) completed a narrative review evaluating the use of TACE for hepatic metastasis from colorectal cancer (CRC), NETs, and uveal melanoma. The authors report that TACE has been studied across these tumor types primarily in retrospective studies, phase II trials, and institutional experiences, with evidence demonstrating feasibility and hepatic disease control in appropriately selected patients. For CRC metastasis, the review notes that TACE, particularly irinotecan- loaded DEB-TACE has shown consistent hepatic responses in unresectable, liver dominant disease, most often after prior systematic therapy. In NETs liver metastasis, TACE is described as an established liver-directed modality associated with high rates of symptomatic improvement, biochemical response, and durable disease stabilization. For uveal melanoma, the review summarizes small, non-randomized studies demonstrating radiologic responses and palliative benefit with TACE, including approaches used specifically for uveal melanoma, in a population with limited systematic treatment options. Overall, the review supports TACE as a therapeutic consideration for liver-dominant metastatic disease across these tumor types, while noting the evidence remains heterogeneous and largely non comparative.

Shibayama et al. (2017) published a retrospective review evaluating the effectiveness and safety of TACE in treating liver metastases from uveal melanoma in an Asian patient population. Clinical records from 29 patients treated between 1997 and 2008 with cisplatin (70 mg/m²) and gelatin sponge were analyzed. The study reported an ORR of 21%, with a median survival of 23 months and 1-, 2-, and 5-year survival rates of 72.4%, 39.4%, and 0%, respectively. Adverse effects were common, with all patients experiencing elevated liver enzymes, while nausea (72.4%), abdominal pain (65.5%), vomiting (55.2%), post-embolization syndrome (34.5% of patients, 9.6% of procedures), and fever (24.1%) were also frequently reported. Severe (Grade ≥3) toxicities included increased aspartate aminotransferase (34.5%), alanine aminotransferase (51.7%), and serum creatinine (3.4%). Despite its moderate clinical benefit and tolerable side effects, the limited long-term survival underscores the necessity for improved therapeutic approaches.

Intrahepatic Cholangiocarcinoma

Systematic Reviews and Meta-Analyses

Pan et al. (2024) conducted a meta-analysis to compare the safety and efficacy of DEB-TACE and cTACE in treating intrahepatic cholangiocarcinoma (ICC). The analysis included six studies involving 283 patients treated with cTACE and 178 with DEB-TACE. The primary outcome of interest was OS, while secondary outcomes included PFS, DCR, ORR, and AE. The results showed that DEB-TACE was superior to cTACE in DCR ($P = 0.004$), PFS ($P < 0.001$), and OS ($P = 0.004$), although both treatments had similar AE rates. DEB-TACE demonstrated a higher DCR ($P = 0.004$) and a longer PFS ($P < 0.001$), though no significant difference in ORR was observed ($P = 0.05$). The analysis highlighted significant heterogeneity in the data, particularly for OS. AEs such as elevated liver enzymes and bilirubin levels were similar between the two treatments. The study's limitations include the retrospective design of most included studies, potential selection bias, and differences in treatment assessment time points. In conclusion, DEB-TACE showed greater therapeutic efficacy than cTACE while maintaining similar safety profiles, suggesting it may be a more effective option for managing inoperable ICC.

Liver Transplantation Bridge Therapy

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Jotz et al. (2023) conducted a retrospective cohort study to evaluate the impact of TACE as a bridging therapy for liver transplantation, focusing on tumor necrosis and survival outcomes. Among 118 patients, total necrosis was observed in 64.4%, with 77.8% showing a complete response on imaging. While DEB-TACE resulted in fewer complications than conventional TACE, it was associated with a lower degree of total necrosis, though the difference was not statistically significant. Survival analysis indicated that patients with total necrosis had better outcomes, with a trend toward lower mortality ($p = 0.078$), although statistical significance was not reached. The OS rate was 87.3% at one year, 82.1% at two years, and 77.5% at five years. Complications related to TACE were observed in 11.76% of patients, with abdominal pain being the most common. The primary causes of death were postoperative complications (46.2%), non-tumor-related infections (38.5%), and progressive neoplastic disease (15.4%). The study's limitations include its retrospective design, small sample size, and lack of tumor recurrence analysis. Larger prospective studies are needed to confirm the association between total tumor necrosis and improved survival.

Sneiders et al. (2021) conducted a multicenter observational cohort and propensity score-matched analysis to evaluate the impact of TACE before liver transplantation in HCC patients. The study included adult liver transplant recipients from 2007 to 2018, excluding those with incidental HCC, living donor transplants, or retransplants. Patients receiving TACE were compared to a control group, which included those undergoing other locoregional therapies such as radiofrequency ablation. The primary outcome was intraoperative hepatic artery complications requiring technical adaptations, while secondary outcomes included postoperative complications such as thrombosis, stenosis, and aneurysm formation. Among 825 recipients, 8.4% required intraoperative hepatic artery interventions. In the propensity score-matched analysis (253 TACE vs. 253 control patients), TACE was not significantly associated with an increased risk of intraoperative hepatic artery interventions ($p = 0.870$) or overall postoperative complications ($p = 0.149$). However, hepatic artery thrombosis was more frequent in the TACE group ($p = 0.046$). Despite these findings, arterialization time and overall hepatic artery complication rates were comparable between groups. The study's limitations include its retrospective design, variability in institutional protocols, and a relatively low event rate, potentially underestimating risks. While previous studies suggested an increased risk of hepatic artery complications following TACE, advancements in interventional techniques may have mitigated this effect. Overall, TACE did not significantly increase intraoperative vascular challenges or post-transplant hepatic artery complications, although a potential association with hepatic artery thrombosis warrants further investigation.

National/Specialty Organizations

The **European Association for the Study of the Liver (EASL)** published the *EASL Clinical Practice Guidelines on the management of hepatocellular carcinoma* (2025) that identify TACE as the standard treatment for patients with intermediate-stage HCC. In the locoregional therapy section, EASL notes that TACE is appropriate for patients with multifocal disease confined to the liver, preserved liver function, and no vascular invasion or extrahepatic spread. The guideline emphasizes the importance of careful patient selection and multidisciplinary evaluation when considering TACE. EASL notes that embolic techniques include bland transarterial embolization (TAE), conventional TACE (cTACE), and drug-eluting bead TACE (DEB-TACE). EASL also describes circumstances in which TACE is not appropriate, including cases with main portal vein invasion, poor liver function, or extensive tumor burden where the

risk of hepatic decompensation outweighs potential benefit. EASL identifies TACE as an accepted option for bridging or downstaging therapy in transplant candidates.

The **International Society of Multidisciplinary Interventional Oncology (ISMIO)** published a consensus statement on the clinical practice of TACE for HCC. The expert panel recommends TACE for patients with Child-Pugh A and B for unresectable primary HCC, including those awaiting liver transplantation or downstaging to meet transplant criteria. TACE is also indicated for liver metastasis in patients with neuroendocrine tumors, liver-dominant uveal melanoma, and select colorectal cancer cases, especially when symptoms persist despite systemic treatment. TACE should be performed on demand and can be combined with therapies like ablation, radiotherapy, or systemic treatment for better outcomes. Doxorubicin is the main chemotherapeutic agent, and while DEB-TACE has less toxicity, there is no clear advantage over cTACE. Emerging combinations of TACE with immunotherapies show promise, particularly for patients at high risk of recurrence or TACE failure (Lu et al. 2021).

The **American Association for the Study of Liver Disease (AASLD)** published the 2023 *Practice Guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma,* recommending liver-directed therapy (LRT) as a bridge to transplantation for patients within OPTN T2 (Milan) criteria to reduce disease progression and subsequent dropout off the waiting list. The AASLD does not recommend one form of LRT over another for the purposes of bridging to liver transplantation for patients within OPTN T2 (Milan) criteria. The guidelines also suggest that patients beyond the Milan criteria (T3) may be treated with LRT to downstage into the Milan criteria and become eligible for transplant (Singal et al. 2023).

The **National Comprehensive Cancer Network (NCCN)** published the following *Clinical Practice Guidelines in Oncology*:

- Hepatocellular Carcinoma (v1.2026):
  - Recommends TACE for patients not eligible for curative surgical treatments or as a bridging therapy to other curative interventions.
  - Arterially directed therapies, including TACE, DEB-TACE, TAE, and Y-90 radioembolization, are considered appropriate for patients with unresectable or inoperable tumors unsuitable for ablation.
  - TACE has been deemed safe in carefully selected cases with limited tumor invasion of the portal vein (pg. 23).
- Neuroendocrine and Adrenal Tumors (v3.2025):
  - Recommends hepatic regional therapies, including arterial embolization (TAE), chemoembolization (TACE), or radioembolization for the management of unresectable liver metastases (pg. 104).
- Colon Cancer (v1.2026):
  - States that arterially directed treatment is an option for highly selected patients with chemotherapy-resistant, refractory disease with predominant hepatic metastases (pg. 37).
- Biliary Tract Cancers (v1.2026):
  - Recognizes arterially directed therapies, such as TAE, TACE, (DEB-TACE) and yttrium-90 (Y-90) as potential treatment options for patients with unresectable or metastatic intrahepatic cholangiocarcinoma (pg. 22).
- Uveal Melanoma (v2.2026):
  - Recommends considering regional liver-directed therapies, including chemoembolization (TACE), radioembolization, or immunoembolization, for patients whose disease is confined to the liver (pg. 52).

SUPPLEMENTAL INFORMATION

Table of Terminology

Term	Definition
AEs	Adverse events
CR	Complete response
CRC	Colorectal cancer
cTACE	Conventional transarterial chemoembolization
DCR	Disease control rate
DEB-TACE	Drug-Eluting Bead Transarterial chemoembolization

HCC	Hepatocellular carcinoma
ICC	Intrahepatic cholangiocarcinoma
NET	Neuroendocrine tumor
ORR	Objective response rate
OS	Overall survival
PD	Progressive disease
PFS	Progression-free survival
PR	Partial response
SD	Stable disease
TACE	Transarterial chemoembolization
TAE	Transarterial embolization

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C9797	Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction

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APPROVAL HISTORY

04/08/2026	Policy reviewed. No changes to coverage criteria. Updated Overview, Summary of Medical Evidence and References.
04/09/2025	Policy reviewed. Updated coverage criteria to include intrahepatic cholangiocarcinoma as indication for TACE treatment, and DEB TACE as a covered procedure with its own criteria. Updated bilirubin concentration to >3 mg/dL under relative contraindications. Updated Summary of Medical Evidence and References. IRO Peer Review on April 1, 2025, by a practicing physician board-certified in Medical Oncology.
04/10/2024	Policy reviewed. No changes in coverage criteria. Updated references.
04/13/2023	Policy reviewed. No changes in coverage criteria. Updated references.
04/13/2022	Policy reviewed, updated references and Summary of Evidence. Criteria updated to remove limit of 5 cm tumor size from the indications of TACE for HCC as well as the coverage of continued TACE for tumors showing partial but incomplete response. IRO Peer Review. Policy reviewed on March 24, 2022, by a practicing, board-certified physician in Gastroenterology.
04/05/2021	Policy reviewed. No changes. Updated references.
04/23/2020	Policy reviewed. No changes. Updated references.
09/18/2019	Policy reviewed. No changes. Updated references.
07/10/2018	Policy reviewed and updated with revisions to criteria. For TACE and the addition of TAE for conditions including metastatic colorectal cancer, neuroendocrine tumors, uveal melanoma, as a bridge to liver transplant and in individuals who may become eligible for liver transplantation. Updated contraindications to TACE with additional recommendations. Updated sections for General Information, Summary of Medical Evidence, Coding and References.
06/22/2017	Policy reviewed, no changes.

12/14/2016	Policy reviewed, no changes.
07/16/2015	Policy reviewed and updated with revisions to criteria (TACE utilizing chemotherapy-loaded microspheres [e.g., drug-loaded microspheres, drug-eluting beads, and doxorubicin drug-eluting bead transarterial chemoembolization (DEB-TACE)]; added Embozene Microspheres are considered experimental, investigational, and unproven for all liver-related conditions.
10/31/2012	New policy.

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