Molina Clinical Policy
Transarterial Chemoembolization (TACE) and Transarterial Embolization (TAE) for Liver Tumors: Policy No. 120

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OVERVIEW

Transarterial chemoembolization (TACE) and transarterial embolization (TAE) are catheter-based embolization procedures used to treat primary hepatocellular carcinoma and certain hepatic metastases, or as a bridge to liver transplantation. TAE works by blocking blood flow to the tumor, leading to ischemia and necrosis, while TACE enhances this effect by delivering a concentrated dose of chemotherapy directly to the tumor before embolization. This approach prolongs chemotherapy exposure to cancer cells while minimizing systemic toxicity. A variation, drug-eluting bead TACE (DEB-TACE), uses chemotherapy-loaded beads that slowly release the drug while causing embolization, further reducing systemic exposure. TACE and TAE may be used alone or alongside surgery, ablation, chemotherapy, or radiation therapy. The most common chemotherapy agent used in TACE is doxorubicin, followed by cisplatin, epirubicin, mitoxantrone, and mitomycin C. Multiple sessions may be needed to treat all lesions and recurrences; however, if significant tumor necrosis is not achieved after two TACE sessions, or if previously responsive areas fail to respond again, further treatment is not recommended (Dynamed 2025; Song & Kim 2017).

TACE and TAE both typically require hospitalization for one to two days. When treating tumors in both liver lobes, procedures are spaced about four weeks apart. Post-procedure care includes hydration, antiemetics, analgesics, and monitoring of electrolytes and liver function. The most common side effect is post-embolization syndrome, characterized by fever, right upper quadrant pain, nausea, ileus, fatigue, and temporary liver enzyme elevations, usually resolving within a week. Other complications include non-target embolization, liver failure, hepatic necrosis, and liver abscess, particularly in patients with biliary obstruction or bilirubin levels above 3 mg/dL. Less common risks include cholecystitis and, rarely, pancreatitis. TACE-specific complications include acute portal vein thrombosis, bone marrow suppression, and increased plasma levels of VEGFR and IGFR-2, which have been linked to tumor progression and metastasis. Despite these risks, TACE and TAE remain valuable treatment options for liver malignancies, helping control tumor growth and improve patient outcomes when appropriately used (Curley et al. 2025; Dynamed 2025).

Hepatocellular carcinoma (HCC) is the most common primary malignant liver tumor, typically developing in patients with chronic liver disease, particularly in those with cirrhosis or chronic hepatitis B infection. It is an aggressive cancer, with approximately 75% of primary liver tumors being HCC. While surgical resection offers the best long-term survival, most patients are not candidates due to the tumor extent or liver dysfunction. TACE is an appropriate treatment for patients with large, multifocal, or unresectable HCC who are not candidates for local ablation and do not have main or lobar branch portal vein thrombus. TACE is also commonly used as a bridging therapy for patients awaiting liver transplantation. However, preoperative TACE is generally not recommended for patients who are candidates for resection (Curley et al. 2025).

Neuroendocrine tumors (NETs) are a heterogeneous group of neoplasms believed to arise from neuroendocrine cells and their precursors, which are scatter 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 those with hepatic-predominant metastatic NETs who are not candidates for surgical resection, transarterial chemoembolization (TACE) is often applied as a palliative technique to control tumor growth and alleviate symptoms (Chan et al. 2025).

Intrahepatic cholangiocarcinoma (ICC) is a rare but aggressive malignancy that originates from the epithelial cells of the intrahepatic bile ducts. Accounting for approximately 5 to 10 percent of all cholangiocarcinomas, ICC can arise from either small intrahepatic ductules or larger intrahepatic ducts proximal to the bifurcation of the right and left hepatic ducts. ICC is likely to manifest with nonspecific symptoms such as right upper quadrant pain, weight loss, and abnormal liver function tests. Diagnosis is typically incidental or occurs during imaging for liver abnormalities. Given its advanced stage at presentation and limited treatment options, ICC is associated with a poor prognosis, making early detection and intervention critical (Lowe et al. 2023).

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. Uveal melanoma is known for its potential to metastasize, most commonly to the liver, with metastases typically appearing within 3 to 7 years of treatment for the primary tumor. While the majority of patients are asymptomatic at the time of diagnosis, 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. In cases where metastasis occurs, transarterial chemoembolization (TACE) targeted at liver metastases has been associated with clinical responses that may offer some benefit for patients not suitable for surgical resection (Carvajal & Harbour 2024).

Colorectal cancer (CRC) resection is the gold standard for managing colon cancer metastatic to the liver, particularly for patients with isolated liver metastases, where surgical resection offers the potential for cure. However, many patients with liver-limited disease are not surgical candidates due to factors such as tumor location, multifocality, or inadequate hepatic reserve. Selective therapies like TACE have been shown to benefit patients with chemorefractory CRC liver metastases. These liver-directed treatments aim to control disease progression in patients with liver-predominant or isolated CRC metastases who are not candidates for surgery, improving quality of life and potentially extending survival (Venook & Fidelman 2025).

COVERAGE POLICY

Transarterial chemoembolization

Transarterial chemoembolization (TACE) or Transarterial embolization (TAE) 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-Turcote-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-Turcote-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 a 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

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 associated with TACE 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)** Clinical Practice Guidelines recommend TACE as the standard treatment for patients with unresectable primary HCC. TACE is most effective for patients with unifocal or multifocal HCC without vascular invasion or metastases, who are asymptomatic and have a Child-Pugh score ≤ B7. It is also recommended for individuals who may become eligible for liver transplantation, serving as a bridge to transplantation. TACE is contraindicated in patients with impaired portal vein blood flow, microvascular invasion of the main portal vein, or severe liver dysfunction (e.g., bilirubin >2 mg/dL). Additionally, it should not be used for patients with a tumor burden greater than 50% of total liver volume due to increased risk of hepatic decompensation. TACE is also used in select cases of liver metastasis, including for symptomatic patients with metastatic neuroendocrine tumors whose symptoms persist despite systemic treatment and who are not candidates for surgical resection, as well as for those with liver-dominant metastatic uveal melanoma or select patients with colorectal cancer whose symptoms persist despite systemic treatment and who are not eligible for surgical resection (EASL 2019).

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 (V1.2025):
  - 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 (V5.2024):
  - Recommends hepatic regional therapies, including arterial embolization, chemoembolization (TACE), or radioembolization for the management of unresectable liver metastases (pg. 114).
- Colon Cancer (V1.2025):
  - 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 (V1.2025):
  - Recognizes arterially directed therapies, such as TACE, as potential treatment options for patients with unresectable or metastatic intrahepatic cholangiocarcinoma (pg. 22).
- Uveal Melanoma (V1.2025):
  - Recommends considering regional liver-directed therapies, including chemoembolization (TACE), radioembolization, or immunoembolization, for patients whose disease is confined to the liver (pg.53).

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

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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