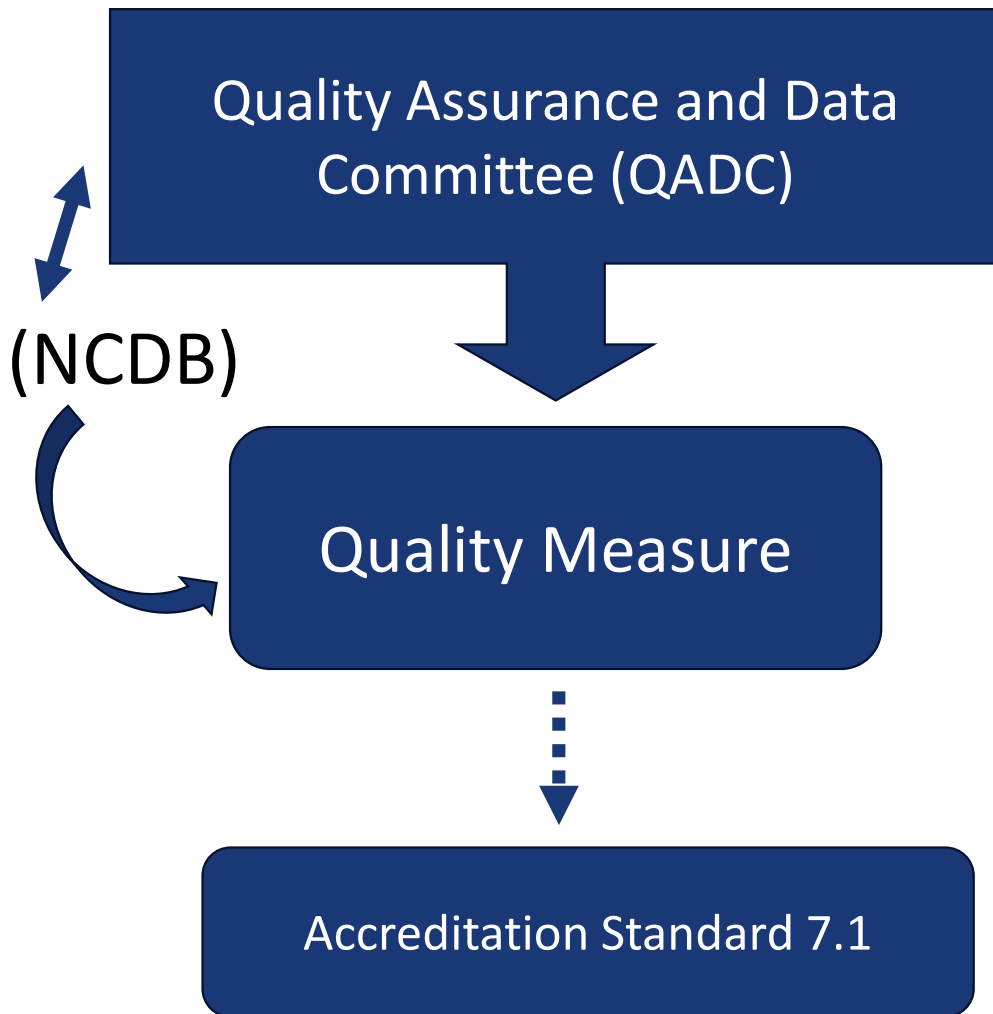


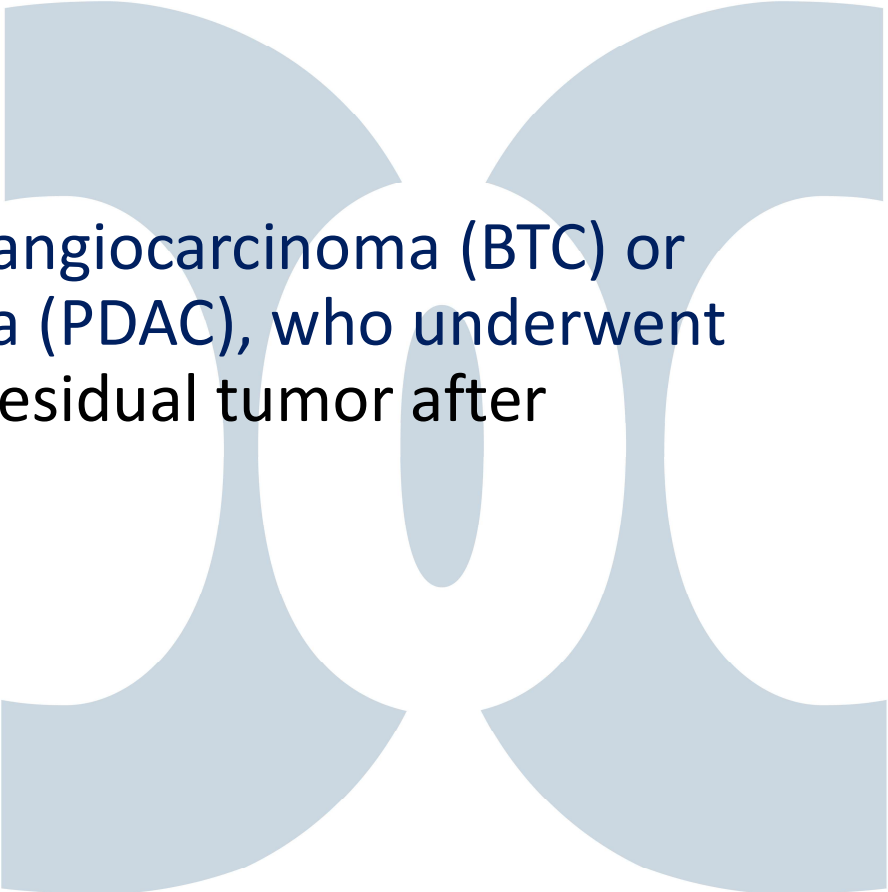
HPB quality measures

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- Does not represent views of NIH.
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 - NIH NCI K08 CA263488
 - Alliance Foundation (NIH UG1 CA189823)



For patients with stage I or II **cholangiocarcinoma (BTC)** or **pancreatic ductal adenocarcinoma (PDAC)**, who underwent **curative surgery**, should have no residual tumor after resection of the primary.

A large, light blue, stylized watermark of the ACS logo is positioned on the right side of the slide, behind the text.

ESPAC 4: Gem/Cape vs Gemcitabine



Comparison of adjuvant gemcitabine and capecitabine with gemcitabine monotherapy in patients with resected pancreatic cancer (ESPAC-4): a multicentre, open-label, randomised, phase 3 trial

ESPAC Trials: 5 Year Overall Survival

Trial	Treatment	No. of pts (N=2092)	5-Year OS (95% CI)	Stratified Log-Rank χ^2	p-value
ESPAC-1	5FU/FA	149	21 (14.6 – 28.5) %	7.03	0.030*
	No chemotherapy	143	8.0 (3.8 – 14.1) %		
	Chemoradiotherapy (5FU/Rad)	145	10.8 (6.1 – 17.0) %		
ESPAC-3	GEM	539	17.5 (14.0 – 21.2) %	0.74	0.390*
	5FU/FA	551	15.9 (12.7 – 19.4) %		
ESPAC-4	GEM	366	16.3 (10.2 – 23.7) %	4.61	0.032†
	GEMCAP	364	28.8 (22.9 – 35.2) %		

*Stratification factor: resection margin status; †stratification factors: resection margin status and country

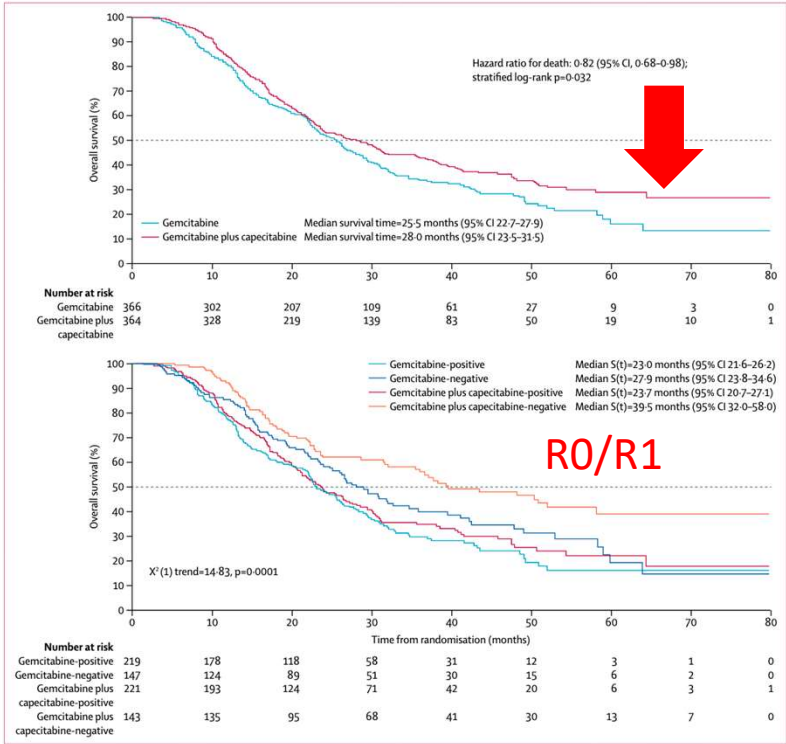
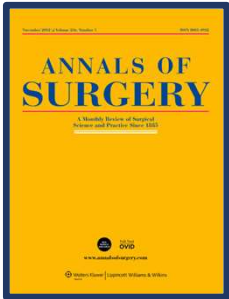


Figure 2: Kaplan Meier plots for overall survival (A) and for overall survival by resection margin status and treatment group (B)

New AJCC STAGING – 8TH EDITION



Multi-Institutional validation study of the American Joint Commission on Cancer (8th edition) changes for T and N staging in patients with pancreatic adenocarcinoma

Peter J. Allen, MD¹, Deborah Kuk, ScM², Carlos Fernandez-del Castillo, MD³, Olca Basturk, MD⁴, Christopher L. Wolfgang, MD, PhD⁵, John L. Cameron, MD⁵, Keith D. Lillemoe, MD³, Cristina R. Ferrone, MD³, Vicente Morales-Oyarvide, MD, MPH³, Jin He, MD, PhD⁵, Matthew J. Weiss, MD⁵, Ralph H. Hruban, MD⁶, Mithat Gönen, PhD², David S. Klimstra, MD⁴, and Mari Mino-Kenudson, MD⁷

<1mm = R1

Primary Tumor (T)		Regional Lymph Nodes (N)		Distant Metastases (M)	
T1	Maximum tumor diameter ≤2 cm	N0	No regional lymph node metastasis	M0	No distant metastases
T2	Maximum tumor diameter >2 ≤4 cm	N1	1–3 positive regional lymph node metastasis	M1	Distant metastases
T3	Maximum tumor diameter >4 cm	N2	≥4 regional lymph node metastases		
T4	Tumor involves the celiac axis or the superior mesenteric artery (unresectable primary tumor)				
					STAGE

- Primary sites (histology code): C22.1 (8160), C24.0 (8160), C25.0 - C25.3 (8500), C25.7 - C25.9 (8500)
- Stage: I-II
- Surgical procedure: 30 - 80
- Surgical Margins of the Primary Site: code 0
- Pancreatic ductal adenocarcinoma or cholangiocarcinoma (BTC)
- Exclude Palliative care

Diagnosis Year	2021	2022
Performance Rate	84.23%	82.58%
Measure Eligible Cases	1,294	1,194
Measure Compliant Cases	1,090	986
Measure Eligible Hospitals	376	348
Measure Compliant Hospitals	353	317

For patients with stage I or II **cholangiocarcinoma** (BTC) or **pancreatic ductal adenocarcinoma** (PDAC), who had upfront curative surgery, adjuvant chemotherapy is initiated within 180 days, or recommended.

Supporting Evidence

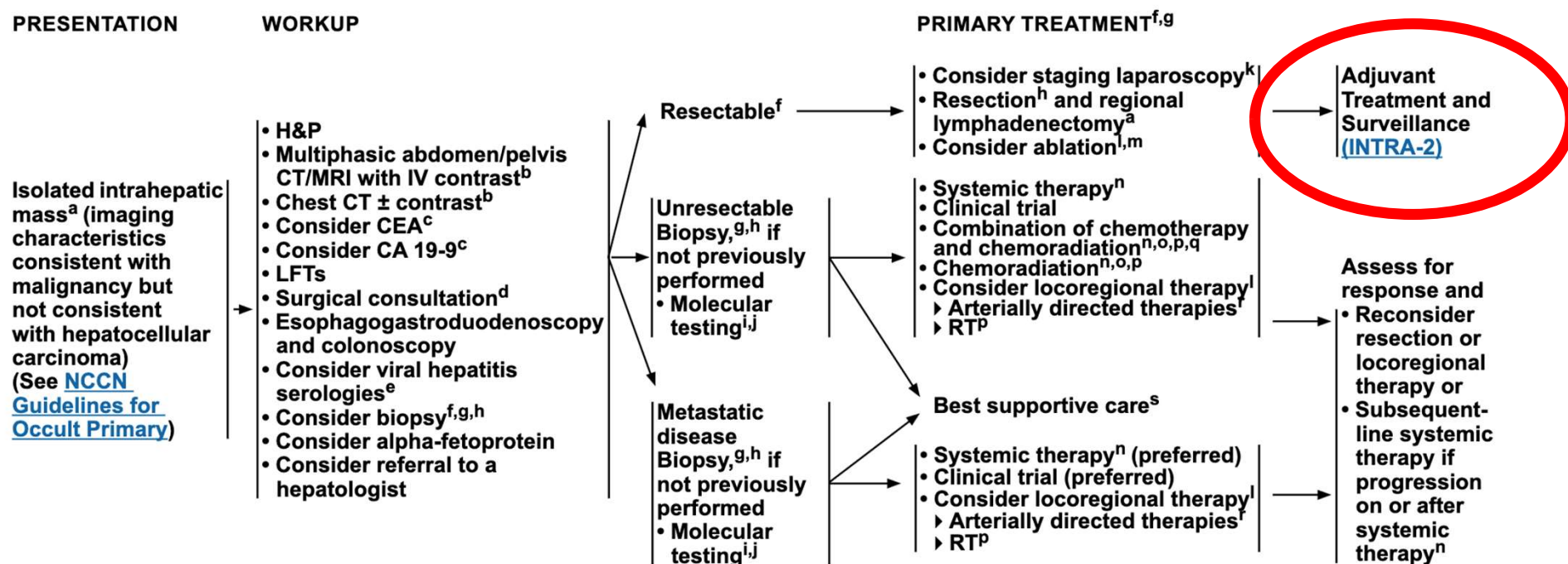
Biliary (Cholangiocarcinoma)

- BILCAP Phase III study (Capecitabine compared with observation in resected biliary tract cancer)
- ABC-02 study: Cisplatin plus Gemcitabine vs Gemcitabine for biliary tract cancer
- ACTICCA-1 study: Adjuvant chemotherapy with gemcitabine and cisplatin compared to standard of care after curative intent resection of biliary tract cancer

Pancreatic ductal carcinoma

- GI-PRODIGE group: FOLFIRINOX or gemcitabine as adjuvant therapy for pancreatic cancer (NEJM)
- CONKO-001 study: Adjuvant chemotherapy with gemcitabine and long-term outcomes among patients with resected pancreatic cancer
- ESPAC-3: Optimal duration and timing of adjuvant chemotherapy after definitive surgery for ductal adenocarcinoma of the pancreas

NCCN Recommends Adjuvant for Bile Duct



Adjuvant Therapy^{c,1}

Preferred Regimens

- Capecitabine (category 1)^{d,2}

Other Recommended Regimens

- Gemcitabine + capecitabine³
- Gemcitabine + cisplatin
- Single agents:
 - 5-fluorouracil
 - Gemcitabine

Useful in Certain Circumstances

- None

NCCN Recommends Adjuvant for Pancreas

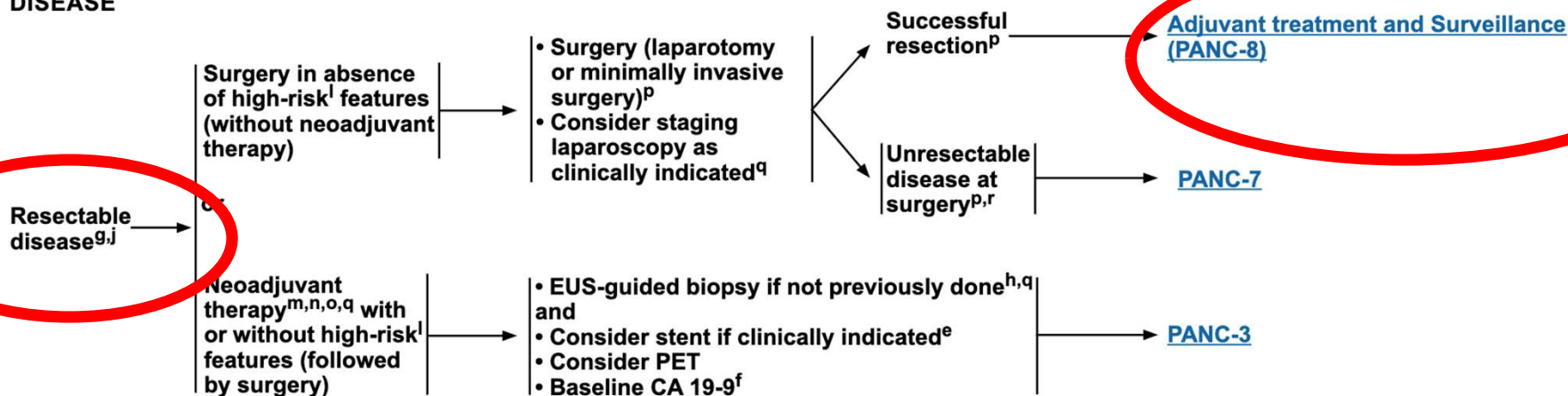


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NCCN Guidelines Version 3.2024 Pancreatic Adenocarcinoma

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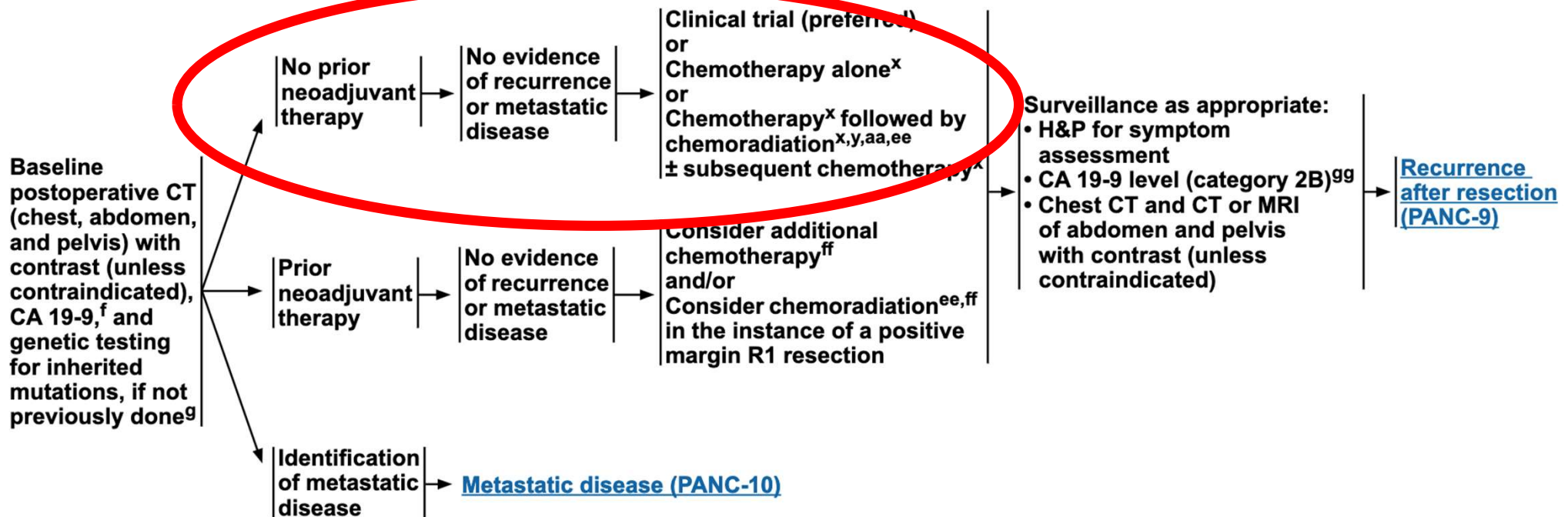
RESECTABLE DISEASE TREATMENT



NCCN Recommends Adjuvant for Pancreas

POSTOPERATIVE ADJUVANT TREATMENT^{dd}

SURVEILLANCE



- Primary sites: C22.1, C24.0, C25.0 - C25.3, C25.7 - C25.9
- Histology codes: 8160 or 8500
- Stage: I-IIIB
- Time to treatment: Date of Chemotherapy – Date of Most definitive Surgical Procedure (0-180); Chemotherapy 85-88
- Exclude: histology codes 9050-9055, 9140, 9590-9992
- Exclude neoadjuvant therapy
- Exclude if chemo not recommended, contraindicated due to patient risk:
Chemotherapy code 82

Diagnosis Year	2021	2022
Performance Rate	77.79%	75.43%
Measure Eligible Cases	1,382	1,278
Measure Compliant Cases	1,075	964
Measure Eligible Hospitals	473	431
Measure Compliant Hospitals	429	379

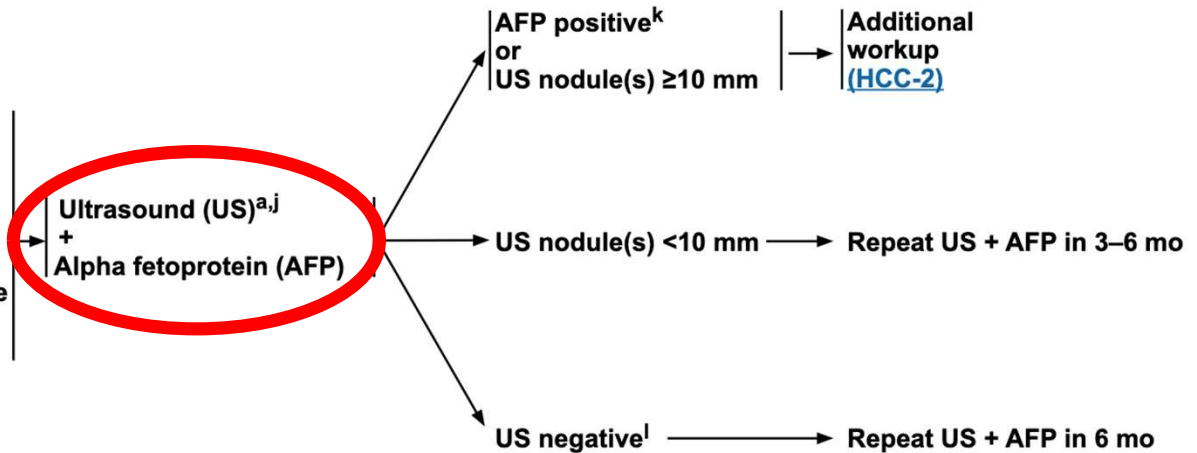
For **hepatocellular carcinoma** of any stage, AFP (alpha fetoprotein) is obtained at diagnosis.

75 - 90 % HCC has Cirrhosis

HEPATOCELLULAR CARCINOMA (HCC) SCREENING^a

Patients at risk for HCC^b:

- Child-Pugh A or B cirrhosis, any etiology
 - Hepatitis B or C^d
 - Alcohol-associated cirrhosis^e
 - Nonalcoholic steatohepatitis
 - Other etiologies^{d,f,g,h}
- Child-Pugh C cirrhosis,^c transplant candidate
- Without cirrhosis
 - Hepatitis B^{c,i}



AFP is important both for screening and workup of HCC

- Primary liver site: C22.0
- AFP obtained: 0-2, 7
- Exclude histology codes 9050-9055, 9140, 9590-9992

Diagnosis Year	2021	2022
Performance Rate	83.52%	84.93%
Measure Eligible Cases	19,929	17,158
Measure Compliant Cases	16,645	14,572
Measure Eligible Hospitals	1,278	1,247
Measure Compliant Hospitals	1,241	1,212

Questions?

2025 New Quality Measures

- For patients age ≥ 70 , grade 1 -2, hormone receptor positive and HER2 negative **invasive breast carcinoma** with tumor size ≤ 2 cm and AJCC clinical N0, who underwent breast conserving surgery, a sentinel lymph node biopsy or axillary lymph node dissection was not performed.
- For patients with newly diagnosed **oropharyngeal squamous cell carcinoma**, p16 status by immunohistochemistry (IHC) is documented.
- For patients with stage I or II **cholangiocarcinoma (BTC)** or **pancreatic ductal adenocarcinoma (PDAC)**, who underwent curative surgery, should have no residual tumor after resection of the primary.
- For patients with stage I or II **cholangiocarcinoma (BTC)** or **pancreatic ductal adenocarcinoma (PDAC)**, who had upfront curative surgery, adjuvant chemotherapy is initiated within 180 days, or recommended.
- For **hepatocellular carcinoma** of any stage, AFP (alpha fetoprotein) is obtained at diagnosis.

Starting with CoC Site Visits in 2026, Standard 7.1: Quality Measures will be reinstated as an accreditation requirement.

