TUMOR ANTIGEN BY IMMUNOASSAY: CA 19-9

Policy Number: CMP - 019
Effective Date: January 1, 2018

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BACKGROUND

Many tumor-associated antigens have been studied in connection with pancreatic adenocarcinoma, including carcinoembryonic antigen (CEA), pancreatic anti-oncofetal antigen, tissue polypeptide antigen, cancer antigen 125, and carbohydrate antigen (CA) 19-9. A sialyated Lewis a blood group antigen, CA 19-9, is commonly expressed and shed in pancreatic and hepatobiliary disease, as well as in many malignancies; thus, it is not tumor specific. However, the degree of increase in CA 19-9 levels may be useful in differentiating pancreatic adenocarcinoma from inflammatory conditions of the pancreas.
CA 19-9 is considered a standard tumor marker for pancreatic cancer. This marker can be used to monitor patients for clinical response to therapy or to detect recurrent pancreatic and biliary ductal carcinoma following surgery and/or chemotherapy. Although, CA 19-9 is not specific for gallbladder cancer/cholangiocarcinoma, it is still considered to have clinical utility for this disease.

Normal blood levels of CA 19-9 are below 37 U/mL. In those who have pancreatic cancer, higher levels of CA 19-9 tend to be associated with more advanced disease. Preoperative serum CA 19-9 levels >100 U/mL have been associated with a greater likelihood of advanced disease and an increased probability of a positive finding on staging laparoscopy.

Data are conflicting regarding the predictive significance of CA 19-9 response following chemotherapy in patients with advanced disease, however, CA 19-9 seems to have value as a prognostic marker. Low postoperative serum CA 19-9 levels and a decrease in serial CA 19-9 levels following surgery have been found to correlate with survival for patients undergoing resection for pancreatic cancer.

Although the sensitivity of the CA 19-9 level in patients with pancreatic cancer is relatively high, the specificity is lowered by elevations that occur in patients with benign pancreatic or liver disease. Non-cancerous conditions, including gallstones, pancreatitis, cirrhosis of the liver, and cholecystitis may also elevate CA 19-9 levels. CA 19-9 can also be elevated in other forms of cancer, including colorectal, gastric, hepatocellular, and lung cancer, and in some non-cancerous conditions such as thyroid disease, inflammatory bowel disease, and pancreatitis (inflammation of the pancreas).

The American Society of Clinical Oncology (ASCO) update of Recommendations for the use of Tumor Markers in Gastrointestinal Cancer stated that for pancreatic cancer, CA 19-9 can be measured every 1 to 3 months for patients with locally advanced or metastatic disease receiving active therapy. Elevating levels of CA 19-9 postoperatively may predict asymptomatic recurrent disease, which may be helpful in the management of patients following attempted definitive surgery in patients who are receiving adjuvant therapy with either or both chemotherapy and radiation therapy, or who are being observed after surgery without adjuvant therapy. Additionally, data are insufficient to recommend CA 19-9 for screening, diagnosis, staging, surveillance, or monitoring treatment of patients with colorectal cancer; or for screening for pancreatic cancer.

Similarly, guidelines on pancreatic adenocarcinoma from the National Comprehensive Cancer Network recommends measurement of serum CA 19-9 level prior to surgery (if bilirubin levels are normal), following surgery prior to administration of adjuvant therapy, and for surveillance. In addition, measurement of CA 19-9 should be considered in evaluating patients with intrahepatic or extrahepatic cholangiocarcinoma and gallbladder cancer.

**POLICY**

For the following CPT code(s) in Table 1, the patient should have a diagnosis (ICD-10-CM) code(s) listed in the attached files below.

**Table 1. HCPCS Codes (Alphanumeric, CPT® AMA)**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>86301</td>
<td>Immunoassay for tumor antigen, quantitative; CA 19-9</td>
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ICD-10 Diagnosis Codes (Proven)

CMP-019 CA19_9
ICD10_v1.1
REFERENCES


### POLICY HISTORY/REVISION HISTORY

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<tr>
<td>01/21/2017</td>
<td>Updated ICD10 codes as per CMS recommendations. Removed ICD9 code file.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>Removed ICD9 table. Embedded ICD9/ICD10 PDF files.</td>
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