Subject: Cholecystectomy

Background: Cholecystectomy is the surgical removal of the gallbladder, generally in response to gallstones causing pain or infection. It can be performed laparoscopically or as an open procedure.

Some indications for laparoscopic and open cholecystectomy include gallbladder polyps, symptomatic and acalculous cholelithiasis, porcelain gallbladder, and asymptomatic cholelithiasis in patients who are at increased risk for gallbladder carcinoma or gallstone complications.

Authorization: Prior authorization is required for all cholecystectomy procedures provided to members enrolled in Harvard Pilgrim Health Care (HPHC) Commercial HMO, POS, or PPO, and Marketplace/Exchange HMO and PPO products.

Urgent/emergent cholecystectomy procedures (i.e., services provided immediately following an ER visit) may be reviewed retrospectively to evaluate medical necessity and clinical appropriateness of the urgent/emergent procedure.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers laparoscopic and/or open cholecystectomy procedures as medically necessary for members when medical record documentation confirms ANY of the following conditions:

1. Acute Acalculous Cholecystitis when medical record documentation confirms ALL the following:
   a. Temperature >100.4 F (38.0 C);
   b. Elevated white blood cell (WBC) count (above normal range);
   c. Absence of gallstones or sludge on ultrasound;
   d. Documented consideration given to percutaneous cholecystostomy tube insertion;
   e. EITHER of the following:
      i. Gallbladder wall thickening and pericholecystic fluid on ultrasound OR
      ii. Nonvisualization of gallbladder on HIDA scan; and
   f. ANY of the following:
      i. Biliary colic,
      ii. Pain in upper abdomen or back,
      iii. Intolerance of feeding,
      iv. Nausea or vomiting,

2. Acute Cholecystitis when medical record documentation confirms ALL the following:
   a. Temperature >100.4 F (38.0 C),
   b. Elevated WBC (above normal),
   c. Biliary colic, or pain in upper abdomen or back,
   d. Nausea or vomiting,
   e. Right upper quadrant (RUQ) tenderness to manual or sonographic probe palpation (positive sonographic Murphy’s sign), and

HPHC Medical Policy
Cholecystectomy

HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members’ unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.
f. EITHER of the following:
   i. Gallstones with gallbladder wall thickening or pericholecystic fluid on ultrasound OR
   ii. Nonvisualization of gallbladder on HIDA scan
3. Acute Biliary Colic when medical record documentation confirms ALL of the following:
   a. Emergency Room visit for acute abdominal pain refractory to IV Toradol and/or narcotics
   b. Ultrasound documenting presence of gallstones, and
   c. Right upper quadrant (RUQ) tenderness to manual or sonographic probe palpation (positive sonographic Murphy’s sign),
4. Biliary Colic when medical record documentation confirms BOTH the following:
   a. Recurrent pain in upper abdomen or back and
   b. Gallstones or sludge on imaging
5. Biliary Dyskinesia/Suspected Chronic Acalculous Cholecystitis or Biliary Hyperkinesia when medical record documentation confirms ALL the following:
   a. Recurrent postprandial pain in upper abdomen or back,
   b. Absence of gallstones or sludge (by ultrasound), and
   c. Either
      i. Gallbladder ejection fraction <35% (by CCK-HIDA or CCK-ultrasound study) or <50% with reproduction of pain by CCK injection or
      ii. Gallbladder ejection fraction >70% (by CCK-HIDA or CCK-ultrasound study)
6. Gallbladder polyp when medical record documentation confirms that polyp is not non-calcified gallstone and ANY the following:
   a. Polyp size >10 mm,
   b. Growth in polyp size on serial imaging,
   c. Sessile polyp (i.e., attached by a broad base, as opposed to being pedunculated or stalked),
7. Gallbladder Wall Abnormality when medical record documentation confirms the presence of ANY of the following:
   a. Calcified gallbladder wall without metastases (on imaging)
   b. Gallbladder mucosal wall thickening (on ultrasound) without metastases (on imaging)
   c. Suspected cancer of gallbladder
8. Pancreatitis when documentation confirms ANY the following:
   a. Common Bile Duct stones or sludge on imaging (Ultrasound, MRCP, or CT)
   b. Presence of stones or sludge in the gallbladder with documented pancreatitis.
   c. Recurrent, idiopathic pancreatitis
9. History of gallstone ileus when confirmed by computed tomography (CT), plain film or ultrasound, or
10. Suspected Chronic Cholecystitis when medical record documentation confirms BOTH the following:
    a. Recurrent pain in upper abdomen or back
    b. Gallstones or sludge on imaging

NOTE: Minilaparoscopic cholecystectomy (MLC) is an approach of laparoscopic cholecystectomy rather than a procedure in and of itself, and is therefore neither coded nor reimbursed separately. Harvard Pilgrim Healthcare (HPHC) considers single incision, natural orifice, robotic-assisted, and other forms of “improved” laparoscopic cholecystectomy besides MLC experimental/investigational and therefore not covered.

Exclusions:
Harvard Pilgrim Health Care (HPHC) does not cover laparoscopic or open cholecystectomy when the criteria above are not met. Harvard Pilgrim Healthcare (HPHC) considers single incision, natural orifice, robotic-assisted,
and other forms of "improved" laparoscopic cholecystectomy besides MLC experimental/investigational and therefore not covered.

Supporting Information:
Gallstones, crystallized deposits of cholesterol and/or bilirubin formed in the gallbladder, is one of the most common conditions in the United States. Laparoscopic cholecystectomy is the standard treatment for symptomatic and complicated cases of gallstones and gallstone-related disease. Polypoid lesions of the gallbladder, while usually benign or small, non-calcified gallstones that have been misdiagnosed due to a similar appearance in imaging, can be an early sign of gallbladder cancer, with size being the most trusted indicator of malignancy. While the traditional standard has been 10mm, recent research has indicated that polyps up to 13mm tend to be benign in patients younger than 46 years old and can be safely monitored for progression. A sessile (mound like, rather than the more typical stalk-like) shape and rapid growth are also reliable indicators of malignancy.
Cholecystectomy is the standard treatment for biliary colic, with some evidence suggesting that delaying treatment is more likely to lead to complications and morbidity than immediate cholecystectomy. Similar evidence exists for mild acute biliary or idiopathic pancreatitis.
In recent years, several less invasive forms of laparoscopic cholecystectomy, including single-incision laparoscopic cholecystectomy (SILC), minilaparoscopic cholecystectomy (MLC), natural orifice transluminal endoscopic surgery (NOTES), and robotic cholecystectomy, have been developed. As complication rates for laparoscopic cholecystectomy are already low, these procedures are largely hoped to improve recovery, patient experience, and cosmetic impact. While the advantages of MLC are marginal at best, MLC has a morbidity rate that appears to be similar if not slightly better than conventional laparoscopic cholecystectomy, uses reusable equipment common to offices that carry out laparoscopies, and uses similar technique to the more established procedure, so it can be considered and treated as a particular approach to laparoscopic cholecystectomy. While NOTES appear promising, it has yet to be subject to high-powered studies in humans and has not been extant for a sufficient period to study long term effects. SILC and robotic cholecystectomy have struggled to demonstrate non-inferiority.

Coding:
Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>47562</td>
<td>Laparoscopy, surgical; cholecystectomy</td>
</tr>
<tr>
<td>47563</td>
<td>Laparoscopic cholecystectomy with cholangiography</td>
</tr>
<tr>
<td>47564</td>
<td>Laparoscopy, surgical; cholecystectomy with exploration of common duct</td>
</tr>
<tr>
<td>47579</td>
<td>Unlisted laparoscopy procedure, biliary tract</td>
</tr>
<tr>
<td>47600</td>
<td>Cholecystectomy</td>
</tr>
<tr>
<td>47605</td>
<td>Cholecystectomy; with cholangiography</td>
</tr>
<tr>
<td>47610</td>
<td>Cholecystectomy with exploration of common duct</td>
</tr>
</tbody>
</table>

Billing Guidelines:
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.
References:

Summary of Changes

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>4/19</td>
<td>Annual review; no changes</td>
</tr>
<tr>
<td>7/18</td>
<td>Annual review, Minor language and formatting changes. Addition of Biliary Hyperkinesia.</td>
</tr>
<tr>
<td>7/17</td>
<td>Added supporting information, updated gallbladder polyp criteria, adjusted format</td>
</tr>
<tr>
<td>2/16</td>
<td>Simplify Policy statement, clarify description of Murphy’s sign, update Gallstone Pancreatitis criteria (list of planned procedures).</td>
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</table>

Approved by Medical Policy Committee: 4/9/19
Approved by Clinical Policy Operational Committee: 1/15, 2/16, 7/17, 7/18, 4/19
Policy Effective Date: 4/19
Initiated: 7/1/15