

General Surgery

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Appendectomy, without Abscess or Peritonitis (MCG ORG: S-170 ISC, 30th Edition)
- Cholecystectomy by Laparoscopy (MCG ORG: S-365 ISC, 30th Edition)
- Breast Biopsy, Percutaneous: Needle Core or Fine Needle Aspiration (MCG ORG: A-0444 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
44950	Appendectomy (open)
0DTJ0ZZ	Resection of appendix, open approach (ICD-10-PCS procedure)
47562, 47563	Laparoscopic cholecystectomy; cholecystectomy by laparoscopy with cholangiography
0FT44ZZ, 0FT44ZG	Resection of gallbladder, percutaneous endoscopic approach (ICD-10-PCS procedure)
10004-10012, 10021	Fine needle aspiration biopsy, with or without imaging guidance
19081-19085	Percutaneous breast biopsy with imaging guidance (stereotactic, ultrasound, magnetic resonance), including placement of localization device
C7501, C7502	Hospital outpatient breast biopsy and related percutaneous procedure services (HCPCS)

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding general surgery services, including appendectomy for suspected acute appendicitis, laparoscopic cholecystectomy for symptomatic and high-risk gallbladder disease, and percutaneous breast biopsy for evaluation of abnormal breast findings, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of general surgery services and to determine when such services are medically necessary.

These procedures span the acute surgical and ambulatory diagnostic spectrum and carry distinct clinical stakes in the Medicare Advantage population, which features higher comorbidity burden and reduced physiologic reserve. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary surgical and diagnostic services and inappropriate approval of procedures that are not indicated or could be safely managed by an alternative approach.

Potential Clinical Harms:

Appendectomy: Inappropriate denial of appendectomy for suspected acute appendicitis could result in progression to perforation, abscess, generalized peritonitis, and sepsis. In an older

population, delayed source control for appendicitis carries elevated morbidity and mortality and may convert a routine ambulatory procedure into a complicated emergency requiring prolonged inpatient and intensive care.

Cholecystectomy: Inappropriate denial of laparoscopic cholecystectomy for symptomatic gallstone disease, acute cholecystitis, or biliary complications could result in recurrent biliary colic, ascending cholangitis, gallstone pancreatitis, gallbladder perforation, or progression of an unrecognized gallbladder malignancy in high-risk patients (e.g., calcified gallbladder wall, polyp greater than 1 cm). Delay exposes patients to repeated acute presentations and conversion to higher-risk open or emergent surgery.

Percutaneous breast biopsy: Inappropriate denial of percutaneous breast biopsy for an abnormal imaging finding or inconclusive prior sampling could delay the histologic diagnosis of breast cancer, allowing tumor progression, nodal involvement, and a worse stage at definitive treatment. Forcing reliance on less definitive evaluation risks both missed malignancy and unnecessary open surgical biopsy with its greater morbidity.

Clinical Benefits:

Appendectomy: MCG criteria provide validated clinical indications drawn from surgical specialty society guidance and a surgical textbook, reserving appendectomy for suspected acute appendicitis, defined-criteria interval appendectomy, and selected appendiceal tumors, while recognizing nonoperative management as an evidence-based alternative for uncomplicated cases. A meta-analysis of 8 studies (3,528 patients) found no significant difference in treatment success between appendectomy and nonoperative management for uncomplicated appendicitis, which allows appropriate matching of operative intervention to the patients most likely to benefit. By ensuring appropriate use of appendectomy using MCG criteria, the risk of perforation, peritonitis, and sepsis from undertreated appendicitis identified above is materially reduced while avoiding nonindicated surgery.

Cholecystectomy: MCG criteria specify the symptomatic and high-risk indications for cholecystectomy, including symptomatic gallstone disease, acute cholecystitis, biliary complications, and asymptomatic disease in patients at elevated cancer or complication risk, citing surgical textbooks, specialty society guidelines, and review articles. This directly counters the harms of recurrent biliary events, cholangitis, pancreatitis, and missed gallbladder cancer identified above, while the criteria support same-day or next-day discharge: a national database review of 10,646 elective and 2,744 urgent laparoscopic cholecystectomy patients found 75% discharged the day of surgery and by postoperative day 1 respectively, supporting appropriate ambulatory-level care.

Percutaneous breast biopsy: MCG criteria apply diagnostic accuracy evidence to reserve percutaneous biopsy for abnormal imaging findings and inconclusive prior sampling, where it provides at least moderate net benefit. A meta-analysis of 26 studies (33,055 fine needle aspiration biopsies) demonstrated sensitivity of 96.3% and specificity of 98.8%, and a technology assessment of 160 studies found core needle biopsy sensitivity exceeding 97%, establishing percutaneous biopsy as the accurate, less invasive alternative to open surgical biopsy. Appropriate use of these criteria directly mitigates both the harm of delayed cancer diagnosis and the harm of unnecessary surgical biopsy identified above.

Reduction of unwarranted variation and overutilization: MCG criteria also identify circumstances where a less invasive alternative is appropriate (e.g., nonoperative management of uncomplicated appendicitis, follow-up imaging for a simple breast cyst, observation of asymptomatic low-risk gallstones), reducing unnecessary operative exposure in this elderly population. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current surgical specialty society guidelines and high-quality diagnostic evidence. Use of these criteria ensures patients receive the most clinically appropriate level of care, and decreases inappropriate denials

by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use:

Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for specific general surgery services, including appendectomy, laparoscopic cholecystectomy, and percutaneous breast biopsy. While Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical indications and thresholds (e.g., criteria for suspected appendicitis versus nonoperative management, symptomatic versus high-risk asymptomatic gallstone disease, imaging findings warranting tissue diagnosis) required to distinguish indicated from nonindicated procedures and inpatient-appropriate from ambulatory-appropriate care.

Applicable Medicare References:

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard
- Medicare Benefit Policy Manual, Chapter 1: Inpatient Hospital Services Covered Under Part A (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 14: Medical Devices (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (CMS IOM Publication 100-02)
- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: For appendectomy, laparoscopic cholecystectomy, and percutaneous breast biopsy, no specific NCD or LCD fully establishes clinical procedural thresholds; Original Medicare criteria are not fully established for these services, requiring supplementation.
- Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

Within the above statutes and regulations, coverage criteria for these specific general surgery and diagnostic services are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of appendectomy for suspected acute appendicitis, interval appendectomy, and selected appendiceal tumors, versus nonoperative management;
- Medical necessity and appropriateness of laparoscopic cholecystectomy for symptomatic gallstone disease, biliary complications, and high-risk asymptomatic disease;
- Medical necessity and appropriateness of percutaneous breast biopsy for abnormal imaging findings and inconclusive prior sampling, versus follow-up imaging or surgical biopsy;

- Appropriate level of care (ambulatory versus inpatient), expected clinical course, and identification of complications that warrant inpatient admission or stay extension.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of general surgery services. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure surgical and diagnostic services are not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Background

Appendectomy, without Abscess or Peritonitis (MCG ORG: S-170 ISC)

Appendectomy is performed for suspected acute appendicitis and is among the most common urgent general surgical procedures. This guideline addresses appendectomy in the absence of abscess or peritonitis and may be performed by an open or laparoscopic approach. Selected appendiceal tumors and interval appendectomy following nonoperative management in adults 40 years or older are additional indications. The procedure is treated as ambulatory, recognizing that an ambulatory procedure may include one postoperative overnight stay depending on payer and regulatory definitions, including the CMS Two-Midnight Rule.

Cholecystectomy by Laparoscopy (MCG ORG: S-365 ISC)

Laparoscopic cholecystectomy is the standard surgical treatment for symptomatic gallstone disease and acute cholecystitis, and is indicated for other symptomatic biliary disease, prophylaxis after stone clearance, gallbladder trauma, and asymptomatic disease in patients at high risk for gallbladder cancer or biliary complications. The procedure is treated as ambulatory, with most patients discharged the day of or the day after surgery.

Breast Biopsy, Percutaneous: Needle Core or Fine Needle Aspiration (MCG ORG: A-0444 AC)

Percutaneous breast biopsy by needle core or fine needle aspiration is an ambulatory diagnostic procedure indicated for abnormal findings on breast imaging, inconclusive prior sampling, the need to determine invasiveness of a carcinoma, and aspiration of palpable lesions lacking simple-cyst characteristics. It provides tissue or cytologic material for diagnosis as a less invasive alternative to open surgical biopsy. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

Evidence Summary

Appendectomy, without Abscess or Peritonitis (MCG ORG: S-170 ISC)

The evidence for the clinical indications in this guideline includes 10 published peer-reviewed articles, 1 specialty society or other evidence-based guideline, and 1 book section. Key evidence includes:

- A surgical textbook recommends either open or laparoscopic appendectomy for acute appendicitis.
- For some low-grade appendiceal mucinous neoplasms or small (less than 2 cm) low-grade appendiceal neuroendocrine tumors, a specialty society guideline and a review article

recommend simple appendectomy for definitive management. A specialty society guideline recommends appendectomy over nonoperative management for acute appendicitis during pregnancy.

- A meta-analysis of 8 studies encompassing 3,528 patients with acute uncomplicated appendicitis (no appendicolith, perforation, abscess, or suspicion of tumor) randomized to nonoperative management or appendectomy found no differences in treatment success (risk ratio 0.85, 95% confidence interval 0.66 to 1.11) and no difference in absence of 1-year recurrence or major complications, supporting nonoperative management as an evidence-based alternative for appropriately selected patients.

Cholecystectomy by Laparoscopy (MCG ORG: S-365 ISC)

The evidence for the clinical indications in this guideline includes 9 published peer-reviewed articles and 4 book sections. Key evidence includes:

- For symptomatic gallstone or biliary disease with biliary colic or acute cholecystitis, a general surgery textbook, a specialty society guideline, and a narrative review state that laparoscopic or open cholecystectomy should be performed, with the route depending on surgeon experience, patient anatomy, and suspicion for concomitant malignancy.
- For patients at high risk for gallbladder carcinoma (e.g., calcified gallbladder wall, gallbladder polyp greater than 1 cm, choledochal cyst, anomalous pancreaticobiliary junction), a review article and a specialty society guideline advise cholecystectomy to reduce cancer-related morbidity and mortality.
- For asymptomatic gallstone disease in patients at high risk for biliary tract complications (e.g., pretransplant, history of common bile duct stones), review articles recommend consideration of prophylactic cholecystectomy.
- A retrospective national database review found that, of 10,646 adult patients undergoing elective laparoscopic cholecystectomy, 75% were discharged the day of surgery, and of 2,744 patients undergoing urgent laparoscopic cholecystectomy, 75% were discharged by postoperative day 1, supporting ambulatory-level care.

Breast Biopsy, Percutaneous: Needle Core or Fine Needle Aspiration (MCG ORG: A-0444 AC)

The evidence for the clinical indications in this guideline includes 17 published peer-reviewed articles and 2 book sections. Key evidence includes:

- For abnormal findings on a breast imaging study, evidence demonstrates at least moderate certainty of at least moderate net benefit. Core needle biopsy provides tissue for histologic confirmation of invasive disease and assessment of hormone and HER2 status and is the preferred technique.
- A meta-analysis of 26 studies including 33,055 breast fine needle aspiration biopsies found a sensitivity of 96.3% and specificity of 98.8%, with a positive predictive value of 98.7% and negative predictive value of 95%.
- A technology assessment based on a systematic review of 160 studies reported that both ultrasound-guided and stereotactically guided core needle biopsies had average sensitivity exceeding 97% and average specificity ranging from 92% to 99%.
- For inconclusive prior fine needle aspiration, a systematic review and meta-analysis of 46 studies (16,642 patients) reported a pooled sensitivity of 93% and specificity of 95%, supporting core needle biopsy to improve diagnostic certainty when initial sampling is inadequate or inconclusive.

Rationale (from MCG)

Use of these MCG care guidelines helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate setting for general surgical and diagnostic procedures. For the surgical guidelines, the evidence-based clinical criteria assist the

clinician in the decision to appropriately perform a procedure and to determine the appropriate level of care, including identification of complex factors that make it reasonable to expect a necessity for hospital care across 2 or more midnights and CMS Two-Midnight Rule exceptions for Medicare enrollees. For the breast biopsy guideline, the criteria help the clinician decide when percutaneous tissue diagnosis is appropriate as a less invasive alternative to surgical biopsy. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition):

- Code of Federal Regulations (CFR): 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101 (appendectomy and cholecystectomy); 42 CFR 419.22; 42 CFR 422.101 (percutaneous breast biopsy)
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 1 (Inpatient Hospital Services); Chapter 6 (Hospital Services Under Part B); Chapter 14 (Medical Devices); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5
- Medicare Coverage Determinations: Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx>

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