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Clinical Appropriateness Guidelines

Surgical

Appropriate Use Criteria: Upper Gastrointestinal Endoscopy (Esophagogastroduodenoscopy)

Table of Contents

Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Relevant citations are included in the References section attached to each Guideline. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study

- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

Upper Gastrointestinal Endoscopy (Esophagogastroduodenoscopy)

Description and Scope

This guideline addresses the appropriate use of upper gastrointestinal endoscopy (esophagogastroduodenoscopy or EGD) in the evaluation and management of adult outpatients. It does not address the use of upper endoscopy in emergency departments, inpatient settings, or in pediatric patients aged 17 years or younger.

Currently published guidelines on endoscopy quality indicators note that upper endoscopy should be performed when the information gained or intervention performed will improve patient outcomes and is not indicated when associated risks outweigh any potential patient benefit.

General Recommendations

Proton pump inhibitors (PPI) have become a standard treatment modality by both primary care providers and gastroenterologists over the past 30 years. Many publications and societal guidelines have addressed the safety, efficacy and limitations of this class of medications which are now available without a prescription. Recent reviews of PPI utilization have demonstrated superior efficacy over Histamine-2-receptor-antagonists (H2RA) and/or placebo in the treatment of peptic ulcer disease, peptic ulcer related bleeding, *Helicobacter pylori* eradication, erosive esophagitis, non-erosive esophagitis, and functional dyspepsia. The American College of Gastroenterology (ACG) has addressed the potential risks of PPI use in their 2013 guideline on gastroesophageal reflux disease which appear minimal in the literature. The ACG recommends continued use of PPIs in osteoporotic patients unless there are additional risks for hip fracture, continued use in patients being treated with Clopidogrel as there does not appear to be a risk for adverse cardiovascular events, cautious use of PPIs in patients at risk for *Clostridium difficile* (*C. diff*) infection, and an acknowledgement of potential risk of community-acquired pneumonia during short-term use. **Given their favorable safety profile, widespread availability, and literature-noted superior efficacy to alternative regimens, PPIs are considered first-line treatment when noted in this guideline but may be substituted by alternative anti-secretory agents when documented allergy or intolerance is noted.**

Helicobacter pylori (*H. pylori*) is a widespread bacterial pathogen with markedly variable prevalence across geographic regions and cohorts. The 2017 ACG guidelines on the treatment of *H. pylori* note an association between infection rates and socioeconomic status as well as a higher North American prevalence among African Americans, Hispanic Americans, Native Americans, Alaska natives, those living close to the U.S./Mexico border, and among immigrants from East Asia. Given the causal linkage between *H. pylori* and peptic ulcer disease as well as its classification by the World Health Organization as a carcinogen, the ACG recommends *H. pylori* testing in patients with peptic ulcer disease, mucosa-associated lymphoid tissue (MALT) lymphoma, early gastric cancer and dyspepsia. The ACG similarly makes a strong recommendation to treat all patients who test positive for *H. pylori*, regardless of the initial indication for testing. Several treatment regimens exist and are typically comprised of 2 to 3 antibiotics along with a PPI for a duration of 3 to 14 days. When testing to confirm eradication, the ACG recommends non-invasive testing at least 4 weeks after therapy completion. **Given the known risks of untreated *H. pylori* infection and strong literature base to support eradication, it is assumed that *H. pylori* testing and treatment for positive results (referred to as "*H. pylori* testing/treatment") will be performed when appropriate, even if not specifically included in the guideline below. Given the widespread availability of non-invasive testing such as the urea-breath test and stool antigens, confirmation of *H. pylori* eradication is not considered an independent indication for upper endoscopy.**

Screening and surveillance indications are included in several of the conditions listed in the current guideline. As the American Society for Gastrointestinal Endoscopy (ASGE) notes in their 2019 guideline on Barrett's esophagus, an appropriate screening/surveillance strategy should be able to identify individuals who have, "a disease or preclinical condition that predisposes to a disease…[who] are periodically assessed or examined to identify disease at a stage amenable to cure." The ACG similarly recommends that patients receive adequate

counseling regarding the risks and benefits of surveillance prior to surveillance of Barrett's esophagus which should include consideration of age, life expectancy, and ability to tolerate interventions. **All patients undergoing endoscopy for the indications listed below should participate in a thorough process of informed consent regarding risks and benefits, and ordering providers should pursue endoscopy only when results are expected to direct patient-centered management decisions.**

Race, ethnicity, heritage, and socioeconomic status are frequently described as risk factors for various gastrointestinal conditions. These relationships are often multifactorial and typically reflect epidemiologic data that has identified varying prevalence of *H. pylori* infection and upper GI cancers across different populations. The ASGE released a 2015 guideline on Race and Ethnicity Considerations in GI Endoscopy which emphasized the highly diverse, and often multiracial, population of the U.S. The inclusion of risk factors in this guideline that are based on race, ethnicity, heritage, and socioeconomic status are based on currently available literature and may not always be specifically defined. **It is important to acknowledge that both implicit and explicit bias may impact currently available evidence, and clinicians should assess and document any social determinants of health which may impact an individual's personal risk for disease when considering endoscopic evaluation.**

Definitions

Esophagogastroduodenoscopy (EGD): Procedure that requires the use of a flexible endoscope to examine the esophagus, stomach, and proximal small bowel (duodenum).

Upper GI signs/symptoms: Patient-reported sensations or observable findings that suggest dysfunction of the esophagus, stomach, or proximal small bowel.

Barrett's esophagus (BE): Extension of salmon-colored mucosa into the tubular esophagus extending ≥1cm proximal to the gastroesophageal junction with biopsy confirmation of intestinal metaplasia.

Intestinal metaplasia of the esophagus: Intestinal-type columnar epithelium containing goblet cells that replaces the normal stratified squamous epithelium of the distal esophagus and is diagnostic for Barrett's esophagus.

Gastric intestinal metaplasia (GIM): Abnormal tissue in the stomach believed to be a precancerous lesion; GIM may be found in multiple regions of the stomach (extensive GIM) or a single region (limited GIM) and may be characterized as complete (histology resembles small intestinal cells) or incomplete (histology resembles colonic cells).

Mapping biopsies: Strategy for collecting tissue when assessing the extent of gastric intestinal metaplasia that involves sampling from multiple regions of the stomach, notably from the gastric body (corpus), antrum, and incisura.

Celiac serologic testing: Serum testing for autoantibodies directed against gluten proteins; IgA antibodies against tissue transglutaminase (TG2) are the most sensitive for detecting celiac disease, though other IgA antibodies such as those targeting endomysium (EMA) and gliadin are also commonly used. Patients with celiac disease may also have underlying IgA deficiencies, in which case testing for IgG antibodies against TG2, EMA and gliadin is common.

Complete eradication of intestinal metaplasia (CEIM): The goal endpoint after endoscopic eradication therapy for Barrett's Esophagus with or without dysplasia. CEIM is established when endoscopy is negative for visible Barrett's Esophagus and biopsy specimens are negative for intestinal metaplasia.

Low-grade dysplasia: Cells with normal to mild distortion but still fairly uniform (minimal pleomorphism).

High-grade dysplasia/carcinoma in situ: Cells with mild to marked distortion, highly atypical and varied cell appearance (prominent pleomorphism) but remain within the epithelium and do not invade into the lamina propria.

Clinical Indications

General Indications for Upper Endoscopy

Alarm Features: New or not previously evaluated by upper endoscopy

Upper endoscopy is considered medically necessary in **ANY** of the following scenarios:

- Dysphagia or Odynophagia
- Nausea or vomiting ≥ 7 days
- Unexplained weight loss ≥ 5% of usual weight within the past 12 months
- Anorexia or early satiety
- Upper GI symptoms in patients who have a first-degree relative with upper GI malignancy
- Hematemesis, coffee-ground emesis, or melena

Discussion: Alarm Features

A joint publication on EGD quality indicators by the ACG and ASGE recommends early endoscopy in the presence of alarm features. Although these features are noted to have a low predictive value for upper GI malignancy, they represent common presentations of treatable non-malignant conditions such as malabsorption, structural disease, inflammatory disease, and motility disorders. This indication is intended to address new or persistent symptoms that are otherwise unexplained by clinical evaluation where upper endoscopy is required to determine the presence of suspected upper GI pathology.

Therapeutic Upper Endoscopy

Upper endoscopy is considered medically necessary for the management of **ANY** of the following scenarios:

- Treatment of **bleeding lesions** such as ulcers, tumors, or vascular abnormalities
- **Planned dilation** of a known stenotic lesion of the esophagus, stomach, or duodenum (for eosinophilic esophagitis, please see condition-specific indications)
- **Planned resection** of a known lesion (for routine surveillance, please see condition-specific indications)
- Endoscopic placement of **feeding or drainage tubes**
- Management of upper GI tract **foreign bodies or food impaction**
- **Palliative treatment** for stenosing neoplasms such as ablation or placement of self-expanding metal stents

Discussion: General Therapeutic Indications

The 2015 joint publication on quality indicators for EGD by the ACG and the ASGE notes several broad indications for therapeutic upper endoscopy. These indications may be considered appropriate for the management of various underlying conditions and should be used when non-endoscopic treatment is inadequate. Certain therapeutic interventions have not been included within these general therapeutic indications, including the use of botulinum toxin injections for gastroparesis. The 2011 ASGE guideline on the role of endoscopy in gastroduodenal obstruction and gastroparesis notes insufficient data to make a recommendation regarding the role of botulinum toxin in the treatment of gastroparesis. Similarly, the 2013 ACG Clinical Guideline on the management of gastroparesis makes a strong recommendation based on high-level evidence against intrapyloric injection of botulinum toxin for patients with gastroparesis based on results from randomized controlled trials. Most recently, the 2020 European Society of Gastrointestinal Endoscopy (ESGE) guideline on the endoscopic management of gastrointestinal motility disorders recommends against the use of botulinum toxin injection in the treatment of unselected patients with gastroparesis.

Endoscopic Evaluation and Management of Upper Gastrointestinal Signs, Symptoms and Conditions

Achalasia

In patients with an established diagnosis of achalasia, upper endoscopy is considered medically necessary in **ANY** of the following scenarios:

- Evaluation of **alarm features**
- For endoscopic **dilation**
- For endoscopic injection of **botulinum toxin when patient is unable to undergo dilation or surgical intervention**

Discussion: Achalasia

Achalasia is an esophageal motility disorder that results in loss of coordinated peristalsis and decreased relaxation of the lower esophageal sphincter (LES). The ACG notes that achalasia is a chronic, incurable condition for which all treatments are palliative and aimed at reducing symptoms.

The current ACG, ASGE, and ESGE guidelines on achalasia report high rates of success with pneumatic dilation of the lower esophageal sphincter and emphasize that any patient undergoing pneumatic dilation must be a surgical candidate for repair of possible esophageal perforation which occurs in approximately 2% of cases.

The ACG and ASGE guidelines note high rates of symptom control shortly after Botulinum toxin (Botox) injection into the LES. These effects are short-lived, and a cited meta-analysis reported rates of symptom control at 12 months as 73.3% for dilation and 37.5% for Botox. The ESGE recommends that Botox be considered for short-term symptom relief, while the ACG and ASGE both recommend Botox only for patients who are not candidates for dilation or surgical definitive therapy. The ACG and ESGE also recommend against the use of esophageal stents for the treatment of achalasia.

Achalasia has been associated with an increased risk for squamous cell cancer. However, the ASGE notes that surveillance strategies have not shown improved survival, and the ACG, ASGE, and ESGE all recommend against endoscopic surveillance for esophageal cancer in patients with achalasia.[94, 128, 136]

Barrett's Esophagus

Screening Endoscopy

One-time screening endoscopy is considered medically necessary in patients **without life-limiting comorbidities who are willing and able to undergo surveillance and eradication treatment** in the following scenario:

- **Men** with chronic (symptoms persisting more than 5 years) and/or frequent (at least weekly) GERD **AND at least TWO** of the following risk factors:
    - Age 50 years or older
    - Caucasian race
    - Central obesity
    - Current or past history of smoking
    - First-degree relative with history of Barrett's esophagus or esophageal adenocarcinoma

Surveillance Endoscopy for Untreated Barrett's Esophagus

Upper endoscopy is considered medically necessary for patients **without life-limiting comorbidities who are willing and able** to undergo eradication treatment in **ANY** the following scenarios:

- Barrett's esophagus **without dysplasia**: Repeat endoscopy every 3 years

- Barrett's esophagus reported as "**indefinite for dysplasia**":
    - Repeat endoscopy after 3 months of PPI
    - If repeat endoscopy reported as "indefinite for dysplasia," further surveillance annually until definitive result
- Barrett's esophagus with **low-grade dysplasia**:
    - Repeat endoscopy at 6 months, then annually
    - Once two sequential endoscopies are negative for dysplasia, follow-up every 3 years as Barrett's esophagus without dysplasia
- Barrett's esophagus with **high-grade dysplasia**:
    - Repeat endoscopy at 3-month intervals **only for patients unable to undergo immediate eradication** therapy

Treatment for Established Barrett's Esophagus

Upper endoscopy is considered medically necessary for endoscopic treatment in **ANY** the following scenarios:

- Endoscopic **resection** of Barrett's esophagus with or without dysplasia
- Endoscopic ablative treatment using radiofrequency ablation or cryoablation may be **performed and repeated until the patient achieves complete eradication of intestinal metaplasia** (CEIM) in **EITHER** of the following scenarios:
    - Low-grade dysplasia
    - High-grade dysplasia

Surveillance Endoscopy after Treatment for Barrett's Esophagus

Upper endoscopy is considered medically necessary in **ANY** the following scenarios:

- To confirm eradication of intestinal metaplasia
- Following confirmed eradication of **low-grade dysplasia**:
    - Repeat endoscopy at 6, 12, and 24 months, and then every 3 years.
- Following confirmed eradication of **high-grade dysplasia**:
    - Repeat endoscopy every 3 months for the first year, every 6 months for the second year, and then annually

Discussion: Barrett's Esophagus (BE)

The ACG lists known risk factors for BE as chronic GERD symptoms, first-degree family history of BE or esophageal adenocarcinoma (EAC), age over 50, male sex, smoking history, central obesity, and Caucasian race. A recent meta-analysis further noted a linear increase in BE risk with each additional risk factor, which further supports the ACG's recommendation for screening men with chronic or frequent GERD symptoms who have two or more risk factors for BE and EAC. Caucasian race is included as a risk factor in BE guidelines from the ACG, AGA, and ESGE. The 2015 ASGE Guideline on Race and Ethnicity Considerations in GI Endoscopy also includes Caucasian race as a BE risk factor and cites data from a Kaiser study showing annual BE incidence rates in non-Hispanic Caucasians (39/100k), Hispanics (22/100k), Asians (16/100k), and African Americans (6/100k). As the ACG 2015 guideline notes, the Hispanic population is highly heterogeneous with some studies showing equivalent rates of BE compared to non-Hispanic Caucasians and should be taken into consideration when assessing overall risk for BE.[106, 110, 117, 134, 143] Repeated screening after an initial negative screening exam, as well as the routine screening of women and the general population, are not recommended by the ACG.

Major GI societies recommend BE surveillance programs based on the increasing risk of progression to esophageal adenocarcinoma as dysplasia develops and the potential to reduce EAC mortality through the

identification and eradication of precursor lesions. Estimated annual risks of progression are noted as follows: 0.2%-0.5% for non-dysplastic BE; 0.7% for low-grade dysplasia; 7% for high-grade dysplasia.

The ACG, ASGE, and AGA all note significant interobserver variability among pathologists when making a determination of “indefinite for dysplasia” or “low-grade dysplasia,” with studies showing up to 85% of low-grade dysplasia diagnoses being downgraded to after review by at least two GI pathologists. Each of these societies recommend confirmation of low-grade dysplasia by an expert or second pathologist or subsequent endoscopic biopsy under optimal acid suppression. While confirmatory pathology evaluation is considered the standard, the realities of clinical practice may limit the availability of this approach and it is expected that clinicians acting on a report of “indefinite for dysplasia” or “low-grade dysplasia” will have high confidence in the accuracy of these diagnoses when considering the risks and benefits of further intervention.

The ACG and ESGE currently recommend against routine ablative therapy for non-dysplastic BE due to the low risk of progression to EAC, and ASGE guidelines on endoscopic eradication therapy do not include indications for ablative eradication of non-dysplastic BE. The ACG and AGA recommend radiofrequency ablation as the preferred endoscopic ablative therapy for dysplastic BE, while the ASGE considers both radiofrequency and cryoablation as appropriate endoscopic eradication therapy for BE-related neoplasia. The AGA notes a lack of literature comparing alternative modalities such as photo-dynamic therapy and argon plasma coagulation head-to-head against radiofrequency ablation and the role of these treatments has yet to be determined.

Bleeding and Anemia

New or Recurrent Upper GI Bleeding

Upper endoscopy is considered medically necessary in **ANY** of the following scenarios:

- Hematemesis or “coffee-ground” emesis
- Melena
- Unexplained **rectal bleeding or positive fecal occult blood testing** when **EITHER** of the following are present:
    - Known risk factors for upper GI bleeding
    - After non-diagnostic colonoscopy

Treatment of Bleeding Lesions

Upper endoscopy is considered medically necessary for the **treatment of bleeding lesions** such as ulcers, tumors, or vascular abnormalities.

Discussion: Bleeding

Overt upper GI bleeding may present as a medical emergency and is often managed in an inpatient setting, which is outside the scope of this guideline. Signs of upper GI bleeding include hematemesis as well as blood products that have been exposed to various levels of digestion, such as “coffee ground” emesis or dark, tarry appearing melena. Conversely, lower GI sources of bleeding such as diverticulosis, angioectasia, colitis, and hemorrhoids often present as bright red blood per rectum or bloody/maroon-colored stools known as hematochezia. Brisk upper GI bleeding may present with hematochezia though additional symptoms of significant blood loss would be expected. Risk factors for upper GI sources of bleeding include prior upper GI bleeding, hemodynamic changes, peptic ulcer disease, coagulopathy, liver disease, and medications such as NSAIDs, anticoagulants, and anti-platelet agents. Guidelines from the ACG and ASGE recommend the use of endoscopic therapies such as hemostatic clips, cauterization, and injection of vasoconstrictors or sclerosing agents for the treatment of bleeding lesions and have been shown to reduce the risks of further bleeding and need for surgical intervention.

Unexplained Iron Deficiency Anemia

Upper endoscopy is considered medically necessary when **BOTH** of the following are met:

- Hemoglobin **< 13 g/dL in men** or **< 12 g/dL in women**
- Serum **ferritin < 45 ng/mL**

- In patients with known chronic inflammatory conditions, alternate measures of low iron stores may be used in place of serum ferritin, such as increased total iron-binding capacity, low serum iron level, or low transferrin saturation

Discussion: Iron Deficiency Anemia

Iron deficiency anemia can result from various GI causes such as malignancy, occult bleeding, inflammatory disease, and malabsorption. In the 2020 AGA clinical practice guidelines evaluating iron deficiency anemia, anemia is defined as a hemoglobin < 13 g/dL in men and < 12 g/dL in nonpregnant women and recommends a ferritin cutoff of 45 ng/mL for the diagnosis of iron deficiency anemia. Ferritin may be falsely elevated in patients with underlying inflammatory conditions. In these scenarios, alternative tests that measure serum iron stores may be used to diagnosis iron deficiency anemia.

Pernicious Anemia

Upper endoscopy is considered medically necessary in patients with **established pernicious anemia** in **EITHER** of the following scenarios:

- At the time of initial diagnosis
- For new upper GI signs/symptoms

Discussion: Pernicious Anemia

Pernicious anemia results from autoantibodies that target gastric parietal cells and intrinsic factor, resulting in vitamin B12 malabsorption and deficiency. The 2015 ASGE guideline on premalignant and malignant conditions of the stomach notes a variable risk for gastric cancer and recommends endoscopic assessment at the time of diagnosis and again for the development of any new upper GI symptoms. This is similar to 2019 recommendations from the ESGE and 2018 recommendations from the British Society of Gastroenterology.

Caustic Ingestion

Upper endoscopy is considered medically necessary for patients **following caustic ingestion** in **EITHER** of the following scenarios:

- Evaluation of acute injury
- Surveillance for esophageal cancer beginning 10 years after ingestion and every 2 years thereafter

Discussion: Caustic Ingestion

Historically, ingestion of lye-based agents has been associated with an increased risk of esophageal cancer, though the ASGE notes risk following acidic exposures as well and recommends screening 10 to 20 years after injury with follow-up in 2- to 3-year intervals.

Celiac Disease

Diagnosis

Upper endoscopy is considered medically necessary in **EITHER** the following scenarios:

- Suspected celiac disease in patients with **positive IgA or IgG serologic testing**
- Suspected celiac disease in symptomatic patients, regardless of serologic testing, with **ANY** of the following risk factors:
  - Type 1 diabetes
  - First-degree relative with confirmed celiac disease
  - Documented autoimmune disorder
  - Diarrhea with clinical findings of malabsorption such as unexplained nutritional deficiencies or loss of 5% or more of usual weight

Management

Upper endoscopy is considered medically necessary for the management of established celiac disease in **EITHER** the following scenarios:

- **Persistent or recurrent signs/symptoms** when **BOTH** of the following are met:
    - At least 1 year of documented compliance with gluten-free diet
    - Non-diagnostic serologic testing
- **Asymptomatic patients to assess healing** when **BOTH** of the following are met:
    - At least 2 years of documented gluten-free diet
    - Non-diagnostic serologic testing

Discussion: Celiac Disease

Celiac disease commonly leads to malabsorption through the destruction of small intestinal villi which can be confirmed with biopsy sampling during upper endoscopy. The ACG defines celiac disease as “an immune-based reaction to dietary gluten (storage protein for wheat, barley and rye) that primarily affects the small intestine in those with a genetic predisposition and resolves with exclusion of gluten from the diet.” The ACG also acknowledges that symptoms may vary from the typical diarrhea, weight loss, bloating, flatulence, and abdominal pain to the less common findings of unexplained liver function test abnormalities, iron deficiency anemia and skin disorders.

The ACG and ESGE recommend serologic testing for suspected celiac disease and note that current assays for IgA antibodies targeting tissue transglutaminase (TG2) have a sensitivity and specificity near 95%; however, IgA deficiency is more common in this population and may require the use of IgG-based serologies.

The ACG and ESGE make strong recommendations for close monitoring by a dietitian and strict, life-long adherence to a gluten-free diet (GFD) as most persistent/recurrent symptoms can be attributed to intentional or unintentional gluten consumption. The ESGE notes villous atrophy is still present in up to 40% of patients even after one year of GFD compliance making repeat biopsy within a year unlikely to alter management. Persistent symptoms beyond this time frame with negative or low levels of celiac antibodies may warrant repeat biopsy when alternate diagnoses (such as lymphoma) or immunosuppressant treatment is being considered. The ACG notes median time to achieve mucosal healing of 3 years and suggests follow-up at least 2 years after starting GFD when assessing asymptomatic, seronegative patients for healing.

Crohn’s Disease

Upper endoscopy is considered medically necessary for the **diagnosis and management of Crohn’s disease** in **EITHER** of the following scenarios:

- **Suspected** Crohn’s disease
    - When signs/symptoms of upper GI involvement are present
    - After nondiagnostic colonoscopy
- **Established** Crohn’s disease
    - Any new or persistent signs/symptoms of upper GI involvement

Discussion: Crohn’s Disease

The ACG guidelines on the diagnosis and management of Crohn’s disease and ulcerative colitis note that ileocolonoscopy with biopsy is the initial test of choice for diagnosis, and that upper endoscopy should only be performed to evaluate Crohn’s disease when upper GI signs or symptoms are present or when colonoscopy is non-diagnostic. The 2015 ASGE guidelines similarly recommend against routine EGD in adult patients suspected of having Crohn’s disease unless colonoscopy is non-diagnostic.

Duodenal Masses

Duodenal Carcinoma

Upper endoscopy is considered medically necessary for the **management of established duodenal carcinoma**.

Ampullary and Non-ampullary Adenomas (not associated with familial polyposis syndromes)

Upper endoscopy is considered medically necessary for the **management of established ampullary and non-ampullary duodenal adenomas**.

Discussion: Duodenal Masses

The major duodenal papilla (also known as the ampulla of Vater) is located in the second portion of the duodenum where the pancreatic and common bile duct converge and empty into the small intestine. Ampullary and non-ampullary adenomas may not be distinguishable from malignancy and the ASGE and NCCN recommend surveillance of both resected and non-resected adenomas, though optimal intervals have not been established.

Dyspepsia

Upper endoscopy is considered medically necessary for patients with **predominant epigastric discomfort for 4 weeks or greater** in **ANY** of the following scenarios:

- Initial evaluation of dyspepsia in the **presence of alarm features**
- Initial evaluation of patients **aged 55 years or older**
- For patients aged 54 years or younger, when dyspepsia persists after **BOTH** of the following are met:
    - *H. pylori* testing/treatment
    - 4 weeks of treatment with PPI

Discussion: Dyspepsia

The 2017 ACG guideline on The Management of Dyspepsia considers a clinically relevant definition of dyspepsia to be “predominant epigastric pain lasting at least 1 month.” The risk of upper GI malignancy is predominantly related to age and is a common concern in patients presenting with undifferentiated dyspepsia. Age cutoffs between 50 and 60 for early endoscopy have been recommended by the ACG, the ASGE, and the American Gastroenterological Association (AGA).

In the absence of an indication for early endoscopy, the ACG, AGA and ASGE all recommend a strategy of non-invasive *H. pylori* testing/treatment as well as an empiric trial of acid suppression in this population.[52, 72, 132] The ACG’s 2017 guideline makes a strong recommendation for both a testing/treatment *H. pylori* strategy as well as empiric PPI trial for dyspeptic patients under 60, noting that given equal costs of currently available H2RA and PPI, PPI should be favored given multiple trials that showed a significant effect in favor of PPI use. The ASGE and AGA similarly recommend a PPI course of at least 4 weeks over alternate acid suppressing regimens. PPI treatment should be withheld for 1 to 2 weeks prior to either invasive or non-invasive *H. pylori* testing to maximize test sensitivity.

Eosinophilic Esophagitis

Upper endoscopy is considered medically necessary for the **management of established eosinophilic esophagitis** in **ANY** the following scenarios:

- Evaluation of alarm features
- Reassessment when required **to direct a change in therapy or perform dilation after 8-week course** of **ANY** of the following:
    - PPI
    - Topical or systemic corticosteroids
    - Elimination diet

- Following initial dilation, repeat dilation may be performed until adequate resolution of stricture

Discussion: Eosinophilic Esophagitis

Eosinophilic esophagitis (EoE) is a clinicopathologic disorder characterized by symptoms of esophageal dysfunction and eosinophil-predominant inflammation confirmed on biopsy that is typically performed during the evaluation of GERD or dysphagia. Following diagnosis, the AGA and a 2018 international consortium recommend that PPIs, swallowed steroids and dietary elimination all be considered as initial treatments, typically in 6-to-12-week regimens. Esophageal inflammation and fibrosis can lead to strictures and a “narrow-caliber esophagus,” however in the absence of a critical stricture or food impaction, the ACG recommends dilation only after a failed response to medical or dietary therapy which is also supported by recent AGA guidelines. A 2016 randomized controlled trial by Kavitt, et al. showed equivalent improvements in dysphagia scores for patients with biopsy-confirmed EoE following treatment with either dilation or dual medical therapy of swallowed steroids plus PPI at 30 and 60 days. The ACG emphasizes the chronic nature of EoE and likelihood of symptoms to recur after treatment is stopped, therefore repeat endoscopic evaluation should be limited to the development of new alarm features or when required to direct a change in therapy.

Esophageal Malignancies

Upper endoscopy is considered medically necessary for the **management of biopsy-confirmed esophageal cancer** in **ANY** the following scenarios:

- Endoscopic lesion **resection**
- Signs or symptoms of **recurrent or progressive disease**
- Following resection without esophagectomy of **squamous cell cancer**
- Management of **T1a Esophageal Adenocarcinoma** (EAC) in **EITHER** of the following:
    - **Endoscopic ablative treatment with radiofrequency ablation or cryoablation** may be performed and repeated until the patient achieves complete eradication of intestinal metaplasia (CEIM)
    - **Surveillance** endoscopy following confirmed eradication, every 3 months for the first year, every 6 months for the second year, and then annually

Discussion: Esophageal Malignancies

For patients with early EAC, the potential for curative endoscopic treatment depends on depth of invasion. Currently, the ACG strongly recommends ablative therapy for T1a EAC, also known as intramucosal cancer (IMC). The ASGE similarly recommends ablative therapy over surveillance or esophagectomy for IMC. Stage T1b EAC has a much higher risk of lymph node progression than T1a and the ACG recommends multidisciplinary surgical oncology evaluation of any patient with stage T1b EAC being considered for endoscopic therapy to assess surgical candidacy and histopathology characteristics. The ACG and NCCN note limited invasion into the sm1 region of the submucosa, well-differentiated tumors and lack of lymphovascular invasion as factors that may increase curative success of endoscopic therapy. When considering palliative therapies for non-curative obstructing lesions, the ASGE and NCCN recommend tumor ablation or debulking, self-expandable metal stents and dilation therapies.

The ACG and AGA recommend radiofrequency ablation as the preferred endoscopic ablative therapy for dysplastic BE, while the ASGE considers both radiofrequency and cryoablation as appropriate endoscopic eradication therapy for BE-related neoplasia. The AGA notes a lack of literature comparing alternative modalities such as photo-dynamic therapy and argon plasma coagulation head-to-head against radiofrequency ablation and the role of these treatments has yet to be determined.

While noting an association between upper airway squamous cell cancer and esophageal malignancies, the ASGE recommends against routine endoscopic screening due to lack of evidence of improved outcomes.

Esophageal Varices

Upper endoscopy is considered medically necessary for **patients with cirrhosis or portal hypertension** in **ANY** of the following scenarios:

- **Initial screening** for esophageal varices after diagnosis of cirrhosis or portal hypertension
- Surveillance of non-bleeding varices in patients **not treated with prophylactic beta-blockers** in the following intervals:
    - **No varices**: Every 2 years
    - **Small varices** (< 5 mm): Annually
    - Any **varices with high-risk stigmata** (such as red wale markings): Annually
    - **Decompensated cirrhosis or continued alcohol use**: Annually
- **Treatment** of bleeding or non-bleeding esophageal varices with **EITHER** of the following:
    - Endoscopic ligation, **repeated until eradication**
    - **Sclerotherapy if ligation not technically feasible**, repeated until eradication
- **Following eradication** with ligation or sclerotherapy:
    - Initial endoscopy after 3 months
    - Continued surveillance every 6 months

Discussion: Esophageal Varices

The fibrotic and vascular changes that occur during progressive liver injury increase the resistance to blood flow and lead to elevated blood pressure throughout the portal system known as portal hypertension. Clinical signs of portal hypertension include ascites, spider nevi, visible collateral vessels such as caput medusae, thrombocytopenia, or visible collateral vessels on imaging studies. Portal hypertension promotes the development of collateral veins and specifically esophageal varices (EV). The ACG notes varices are present in approximately 50% of patients with cirrhosis and develop at a rate of 8% per year. Variceal size is the main predictor of hemorrhage and used to determine treatment options for the primary prevention of bleeding.

The ACG, ASGE and American Association for the Study of Liver Disease (AASLD) recommend screening for EV at the time cirrhosis or portal hypertension is diagnosed. Two methods of primary prophylaxis against variceal bleeding are recommended by the ACG, ASGE and AASLD: EGD surveillance with the intent of ligating high-risk varices and treatment with non-selective beta-blockers (such as Propranolol or Nadolol) or Carvedilol. The ACG, ASGE and AASLD do not recommend combined treatment with beta-blockers plus EGD surveillance for the management of varices that have not bled.[33, 34, 127] However, beta-blocker intolerance is common and may result in switching to an EGD-based strategy. Following ligation or sclerotherapy for bleeding varices, the ASGE and AASLD recommend surveillance every 3 to 6 months. Signs of decompensated liver disease include hepatic encephalopathy, ascites and variceal hemorrhage which is often life threatening and may require resuscitative measures.

Gastric Intestinal Metaplasia (GIM)

GIM without Dysplasia

Upper endoscopy is considered medically necessary **following *H. pylori* testing/treatment** in **ANY** of the following scenarios:

- Initial **follow-up at 1 year for mapping biopsies** if not performed at the time of diagnosis
- Surveillance endoscopy **every 3 years** when **ANY** of the following risk factors are present:
    - Patients of racial or ethnic groups known to be at higher risk for gastric cancer
    - First-degree relative with history of gastric cancer

- Incomplete GIM
- Extensive GIM

GIM with Low-grade Dysplasia

Upper endoscopy is considered medically necessary in **ANY** of the following scenarios:

- Endoscopic lesion resection
- Repeated endoscopy for **mapping biopsies** if not performed at the time of diagnosis
- Surveillance endoscopy **following *H. pylori* testing/treatment** at the following intervals:
  - **Annually** until negative for dysplasia and no visible lesions, **then every 3 years**

GIM with High-grade Dysplasia

Upper endoscopy is considered medically necessary in **EITHER** of the following scenarios:

- Endoscopic lesion resection
- Surveillance endoscopy **following *H. pylori* testing/treatment** at the following intervals:
  - Every 6 months, 12 months, then annually for 3 years, and then every 3 years

Discussion: Gastric Intestinal Metaplasia

Gastric intestinal metaplasia (GIM) is often found incidentally during endoscopy, has been associated with gastric cancer and is believed to be a precursor lesion prior to the development of dysplasia. The most recent AGA guidelines on GIM strongly recommend testing and eradication of *H. pylori* in all patients with GIM due to its carcinogenic effects and recommends against the routine surveillance of GIM. The AGA, ASGE, and ESGE note that surveillance may be beneficial in a subset of individuals with additional risk factors for gastric cancer, some of which can only be determined by performing “mapping” biopsies taken from various areas of the stomach including the gastric body, antrum, and incisura.[41, 94, 122] The ASGE Guideline on Race and Ethnicity Considerations for Endoscopy specifies that the incidence of gastric cancer in the U.S. is significantly higher among Asian Americans, African Americans, Hispanics and Native Americans compared to Caucasians as well as immigrants from East Asia, South America, and Russia. Optimal surveillance intervals in patients with risk factors or dysplasia have not been established; however, the AGA suggests 3- to 5-year follow-up. The NCCN recommends close follow-up of high-grade dysplasia following resection and the ASGE recommends general surveillance be discontinued after two studies have been negative for dysplasia.

Gastric Malignancies

Adenocarcinoma

Upper endoscopy is considered medically necessary for **established gastric adenocarcinoma or carcinoma in situ** in **ANY** of the following scenarios:

- For endoscopic lesion resection
- For new signs/symptoms of recurrence/progression
- For **carcinoma in situ** treated with endoscopic resection:
  - Surveillance endoscopy at 6 months, 12 months, then annually for 3 years, and then every 3 years
- For **invasive gastric adenocarcinoma** treated with endoscopic resection:
  - Surveillance endoscopy at 6 months, 12 months, then annually for 5 years, and then every 3 years

Discussion: Gastric Adenocarcinoma

Adenocarcinoma makes up 95% of gastric cancers and overall incidence rates in the U.S. are decreasing. When found in early stages, gastric cancer may be treatable with curative endoscopic resection, and follow-up surveillance is recommended by the NCCN. Gastric outlet obstruction may occur in patients with incurable disease for which the NCCN recommends the use of resection, stenting, and feeding/drainage tubes when necessary for palliation.

The joint ACG and ASGE publication on EGD quality indicators notes that endoscopic surveillance for malignancy is generally not required in patients with gastric atrophy, pernicious anemia, or prior gastric operations for benign disease.

Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma

Upper endoscopy is considered medically necessary for **established MALT** in **ANY** of the following scenarios:

- For endoscopic lesion resection
- For new signs/symptoms of recurrence/progression
- Following **treatment with chemotherapy, immunotherapy, or radiotherapy** to direct further management
- Following ***H. pylori* treatment alone** at the following intervals:
    - Surveillance endoscopy every 3 months for the first 2 years, then every 6 months until 5 years, and then annually

Discussion: MALT Lymphoma

Mucosa-Associated Lymphoid Tissue Lymphoma (MALT) is a low-grade B-cell lymphoma that occurs in the lymphoid tissue that lies within the mucosa of the stomach, lung, small bowel and other organs. *H. pylori* infection is almost always present in patients diagnosed with gastric MALT and chronic inflammatory changes are believed to play a causative role. Eradication of *H. pylori* alone will lead to clinical remission in up to 95% of patients with localized MALT lymphoma; however, continued surveillance is recommended by the NCCN with follow-up endoscopic biopsy recommended by the ASGE. Patients with advanced, disseminated disease may be treated with chemotherapy, immunotherapy and/or radiation therapy and post-treatment endoscopic evaluation is recommended by the NCCN.

Upper GI Neuroendocrine Tumors (NET)

Upper endoscopy is considered medically necessary for **established upper GI neuroendocrine tumors (NET)** in **ANY** of the following scenarios:

- For endoscopic lesion resection
- For new signs/symptoms of recurrence/progression
- For **type 1 and 2 gastric NET** at the following intervals:
    - Surveillance endoscopy annually
- For **type 3 gastric NET** after resection at the following intervals:
    - Surveillance endoscopy after 3 months, then every 12 months for a total of 10 years
- For **duodenal NET**: Follow-up endoscopy when needed to direct further management

Discussion: Upper GI Neuroendocrine Tumors

Upper GI neuroendocrine tumors (NET) may also be referred to as carcinoid tumors and are categorized into three types. Type 1 is the most common and typically has a benign clinical course. Type 2 is associated with Zollinger-Ellison and multiple endocrine neoplasia syndromes, typically occurs in the setting of a gastrinoma and has a 10%-30% rate of lymph node metastases at the time of diagnosis. Type 3 tumors occur sporadically, are typically diagnosed at advanced stages with poor prognoses and should be considered for surgical resection. ASGE guidelines suggest surveillance after resection and propose 1- to 2-year intervals while noting that optimal

surveillance frequency is unknown. NCCN recommends endoscopic follow-up every 2 to 3 years for type 1 gastric NET, and notes that follow-up endoscopy should be considered for type 2 gastric NET.

Gastrointestinal Stromal Tumors (GIST)

Upper endoscopy is considered medically necessary for **established GI stromal tumors (GIST)** in **ANY** of the following scenarios:

- For endoscopic lesion resection
- For new signs/symptoms of recurrence/progression
- Surveillance endoscopy for GIST not treated with resection **annually**

Discussion: GI Stromal Tumors

Gastrointestinal stromal tumors (GIST) are a form of soft tissue sarcoma that develop below the epithelial surface and are typically identified on imaging followed by confirmatory endoscopic ultrasound-guided tissue diagnosis. Asymptomatic gastric GIST ≤ 2 cm with low-risk features are generally considered benign and candidates for surveillance with endoscopic ultrasound, whereas symptomatic tumors or those > 2 cm are typically resected. The NCCN recommends advanced imaging modalities for continued surveillance of metastatic tumors or those treated with resection rather than endoscopic surveillance.

Gastric Polyps

Hyperplastic Polyps

Upper endoscopy is considered medically necessary for **established hyperplastic polyps following *H. pylori* testing/treatment** in the following scenario:

- Surveillance endoscopy **annually** until negative for polyp or dysplasia.

Discussion: Hyperplastic Polyps

Hyperplastic polyps may occur in the presence of *H. pylori* infection and are a form of gastric epithelial polyp often found incidentally during endoscopy. Unlike sporadic fundic gland polyps which are not associated with increased cancer risk unless part of an underlying familial polyposis syndrome, the ASGE notes that dysplasia and focal cancer have been found in 5%-19% of hyperplastic polyps, with polyps > 1 cm or pedunculated morphology at highest risk.

Adenomatous Polyps

Upper endoscopy is considered medically necessary for **established adenomatous polyps** in **ANY** of the following scenarios:

- For endoscopic lesion resection
- For polyps with **no dysplasia or low-grade dysplasia**, surveillance endoscopy at the following intervals:
    - 1 year following resection and then every 3 years
- For polyps with **high-grade dysplasia**, surveillance endoscopy at the following intervals:
    - At 6 months, 12 months, then annually for 3 years, then every 3 years

Discussion: Adenomatous Polyps

Adenomatous polyps are considered a precancerous lesion and require further surveillance following resection. The ASGE recommends follow-up at one year and continued surveillance every 3 to 5 years. Additional publications have advocated for shorter initial interval follow-up for dysplastic adenomas before continuing with surveillance every 3 to 5 years.

Gastroesophageal Reflux Disease (GERD)

Upper endoscopy is considered medically necessary in **ANY** of the following scenarios:

- GERD symptoms in the presence of **alarm features**
- Persistent GERD symptoms **following an 8-week course of PPI treatment**
- Follow-up evaluation for patients noted to have **Los Angeles class C or D erosive esophagitis** on initial endoscopy following a subsequent 8-week course of PPI treatment

Discussion: GERD

GERD is commonly described as the reflux of stomach contents into the esophagus or beyond causing symptoms of heartburn or regurgitation. The ACG, AGA, and ASGE have all endorsed empiric trials of antisecretory treatment for uncomplicated GERD symptoms, with the ACG and AGA both recommending use of PPIs over H2RAs and the ACG further specifying an 8-week duration of treatment prior to considering endoscopy.[52, 55, 129]

The presence of erosive esophagitis may prevent adequate biopsy sampling or obscure histopathologic detection of Barrett's esophagus on initial endoscopy. The Los Angeles classification system is used by the ACG, AGA, and ASGE to report esophagitis severity on a scale from A to D and the ACG and ASGE both recommend follow-up endoscopy after a minimum 8-week PPI treatment course for severe, Grade C and D erosive esophagitis.

Extra-esophageal symptoms, such as chronic cough, laryngitis, and asthma, are frequently attributed to GERD; however, the ACG, AGA, and ASGE recommend against routine EGD for evaluation of these symptoms in the absence of typical GERD symptoms, as the results are unlikely to change management and the likelihood of identifying erosive disease is low.

Genetic-Familial Conditions Associated with Upper GI Malignancies

Adenomatous Polyposis Syndromes

Upper endoscopy is considered medically necessary for **patients with confirmed adenomatous polyposis syndromes** for **ANY** of the following scenarios:

- For new upper GI signs/symptoms
- For **Familial Adenomatous Polyposis (FAP)** or **Attenuated-Familial Adenomatous Polyposis (AFAP)**, surveillance endoscopy at the following intervals:

Beginning at age 20 with subsequent surveillance per Spigelman stage (

  - Table 1) for duodenal polyps

- For **MUTYH-Associated Polyposis (MAP)**, surveillance endoscopy at the following intervals:

Beginning at age 30 with subsequent surveillance per Spigelman stage (

  - Table 1) for duodenal polyps

Table 1. Endoscopic duodenal surveillance based on modified Spigelman score and stage in FAP

	SCORE			
CRITERIA	**0 Points**	**1 Point**	**2 Points**	**3 Points**
Polyp number	0	1–4	5–20	> 20
Polyp size, mm	No polyps	1–4	5–20	> 10
Histology	No adenomas	Tubular adenomas	Tubulovillous adenoma	Villous adenoma
Dysplasia	No dysplasia	Low grade	—	High grade

SPIGELMAN SCORE	SPIGELMAN STAGE	SURVEILLANCE	
0 points	0	Repeat endoscopy	Every 3–5 years
1–4 points	I	Repeat endoscopy	Every 2–3 years
5–6 points	II	Repeat endoscopy	Every 1–2 years
7–8 points	III	Repeat endoscopy	Every 6–12 months
9–12 points	IV	Expert surveillance	Every 3–6 months

Source: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Genetic/Familial High-Risk Assessment: Colorectal. Version 1.2023 Familial Adenomatous Polyposis.

Discussion: Adenomatous Polyposis Syndromes

The ACG describes three hereditary syndromes associated with early onset colorectal and upper GI adenomas related to mutations in the *APC* tumor suppressor genes and *MUTYH* DNA repair genes: familial adenomatous polyposis (FAP), attenuated-familial adenomatous polyposis (AFAP) and *MUTYH*-associated polyposis (MAP). Screening strategies for upper GI tract malignancies include an initial endoscopy between 25 and 30 years of age for FAP/AFAP and 30 years of age for MAP with subsequent follow-up determined by the Spigelman stage that incorporates the number, size, and histopathologic features of any noted duodenal polyps. Patients with Spigelman stage IV have a 36% risk of duodenal cancer within 10 years.

Lynch Syndrome (Hereditary Non-Polyposis Colon Cancer)

Upper endoscopy is considered medically necessary for **patients with confirmed Lynch syndrome** in **ANY** of the following scenarios:

- For new upper GI signs/symptoms
- Screening endoscopy beginning at age 30 with follow-up every 3 years in patients with **ANY** of the following risk factors:
    - Patients with *MLH1*, *MSH2, PMS2* or *EPCAM* mutations
    - First-degree relative with history of upper GI cancer
    - Patients of racial or ethnic groups known to be at higher risk for gastric cancer

Discussion: Lynch Syndrome

Lynch syndrome is caused by autosomal dominant mutations in DNA mismatch repair genes (*MLH1, MSH2, MSH6 and PMS2*) or the associated *EPCAM* gene, and is the most common cause of inherited colorectal cancer. The 2014 ACG guidelines on Lynch syndrome suggest screening endoscopy for high-risk patients beginning at age 30 to 35 years. A recent prospective cohort study of over 51,000 individuals with genetic mutations for Lynch syndrome reported significant associations between patient age, first-degree relatives with gastric cancer, and mutations in *MLH1* and *MSH2* genes with the development of gastric cancer. The 2020 NCCN guidelines also suggest screening only high-risk patients such as those of Asian descent or from countries with high background incidence of gastric cancer, and those with a family history of upper GI cancer.

Peutz-Jeghers Syndrome

Upper endoscopy is considered medically necessary for **patients with confirmed Peutz-Jeghers syndrome** in **ANY** of the following scenarios:

- Initial screening endoscopy
- For new upper GI signs/symptoms
- Surveillance endoscopy every 2 years

Discussion: Peutz-Jeghers Syndrome

Peutz-Jeghers syndrome (PJS) results from an autosomal dominant mutation and causes polyps throughout the GI tract and mucocutaneous pigmentation with a high risk of GI and extraintestinal cancers.

Juvenile Polyposis Syndrome

Upper endoscopy is considered medically necessary for **patients with confirmed juvenile polyposis syndrome** in **ANY** of the following scenarios:

- Initial screening endoscopy
- For new upper GI signs/symptoms
- Surveillance endoscopy every 2 years, with 1 year follow-up of any polyp

Discussion: Juvenile Polyposis Syndrome

Juvenile polyposis syndrome (JPS) results from an autosomal dominant mutation with an average age of diagnosis of 18.5 years. JPS is characterized by the early development of polyps throughout the GI tract and an increased risk for upper and lower GI cancers.

Li-Fraumeni Syndrome

Upper endoscopy is considered medically necessary for **patients with confirmed Li-Fraumeni syndrome** in **ANY** of the following scenarios:

- Screening endoscopy at age 25 (or 5 years before first known familial colon cancer diagnosis if earlier)
- For new upper GI signs/symptoms
- Surveillance endoscopy every 2 years

Discussion: Li-Fraumeni Syndrome

Li-Fraumeni syndrome is a rare hereditary cancer syndrome related to mutations in *TP53* gene pathway with an overall lifetime risk of cancer of nearly 100%. The NCCN recommends screening/surveillance upper endoscopy and colonoscopy beginning at age 25 (or 5 years before the first known familial colon cancer diagnosis) and continued every 2 to 5 years.

Hereditary Diffuse Gastric Cancer

Upper endoscopy is considered medically necessary for patients with **confirmed genetic testing for Hereditary Diffuse Gastric Cancer** in **EITHER** of the following scenarios:

- Preoperative evaluation for prophylactic gastrectomy
- Surveillance endoscopy every 6 months for patients unable to tolerate prophylactic gastrectomy

Discussion: Hereditary Diffuse Gastric Cancer

Hereditary diffuse gastric cancer results from an autosomal dominant mutation in the *CDH1* gene with an average age of gastric cancer diagnosis at 37 years. Given the extremely high risk of gastric cancer, the standard of care is prophylactic gastrectomy at the time of diagnosis, which may require a preoperative endoscopy for surgical planning.

Tylosis

Upper endoscopy is considered medically necessary for **patients with confirmed Tylosis** in **ANY** of the following scenarios:

- Screening endoscopy at time of diagnosis
- For new upper GI signs/symptoms
- Surveillance endoscopy annually

Discussion: Tylosis

Tylosis is a very rare condition resulting from an autosomal dominant mutation in the *RHBDF2* gene which increases the risk of squamous cell esophageal cancer. The NCCN recommends routine endoscopic screening beginning after age 20, while the ASGE recommends screening at age 30 or the age of onset with follow-up in 1- to 3-year intervals.

Imaging Abnormalities

Upper endoscopy is considered medically necessary for the **diagnosis of lesions identified on other imaging that have not previously been evaluated by endoscopy** in **ANY** of the following scenarios

- Suspected neoplastic lesion
- Gastric or esophageal ulcer
- Upper tract stricture or obstruction

Discussion: Imaging Abnormalities

Imaging abnormalities are common among both symptomatic and asymptomatic patients and may be incidentally noted or found during a diagnostic workup. Endoscopic evaluation is appropriate to confirm a suspected diagnosis through direct visualization or biopsy collection when expected to further direct management decisions. Many imaging findings do not require further evaluation either due to the diagnostic certainty of the imaging itself or due to the very low risk of associated pathology. While a small portion of gastric ulcers may represent underlying malignancy, duodenal ulcers are extremely unlikely to be malignant and routine biopsy and follow-up are not recommended by the ASGE. The joint publication on EGD quality indicators by the ACG and ASGE lists the following as findings that do not warrant endoscopic evaluation:

- Asymptomatic or uncomplicated sliding hiatal hernias
- Uncomplicated duodenal ulcers that have responded to therapy
- Deformed duodenal bulbs when symptoms are absent or respond adequately to ulcer.

Peptic Ulcer Disease (PUD)

Upper endoscopy is considered medically necessary in **ANY** of the following scenarios:

- Gastric or esophageal ulcer seen on other imaging that has not previously been evaluated by endoscopy
- Evaluation of alarm features
- Follow up of known PUD after an **8-week course of PPI treatment and *H. pylori* testing/treatment** in **ANY** the following scenarios:
    - Persistent symptoms
    - Follow up of ulcers that appeared suspicious for malignancy due to **ANY** of the following:
        - Associated mass lesion
        - Elevated or irregular borders
        - Abnormal adjacent mucosal folds
        - Size: Gastric ulcers > 3 cm or duodenal ulcers > 2 cm
    - Repeat surveillance **after 8-week PPI treatment intervals** for persistent unexplained ulcers until healing documented

Discussion: Peptic Ulcer Disease

Peptic ulcers are typically diagnosed during endoscopy performed for symptoms such as dyspepsia and may be located in the gastric or duodenal walls. In the absence of alarm features, the ASGE notes that the purpose of

upper endoscopy in patients with uncomplicated peptic ulcer disease is to confirm a diagnosis and rule out malignancy. The ASGE recommends against routine evaluation or surveillance of duodenal ulcers seen on radiologic imaging or those that respond to treatment due to a very low risk of underlying malignancy. Gastric ulcers, however, should generally be biopsied to rule out underlying malignancy and may warrant follow-up for persistent symptoms or suspicious features following 8 to 12 weeks of optimal antisecretory therapy. PPI treatment has repeatedly demonstrated superior ulcer healing compared to H2RA and the ACG 2017 guidelines on *H. pylori* management make a strong recommendation for testing and treatment for all patients with active peptic ulcer disease.

Postoperative/Postprocedure Complications

Upper endoscopy is considered medically necessary for **the endoscopic diagnosis and management of post-surgical or post-procedural complications**.

Preoperative Evaluation of Asymptomatic Patients prior to Bariatric Surgery

Upper endoscopy is considered medically necessary for **ANY** of the following scenarios:

- Suspected esophagitis or Barrett's esophagus **prior to sleeve gastrectomy**
- Suspected gastric lesions **prior to Roux-en-Y gastrojejunal bypass** (RYGB) **following *H. pylori* testing/treatment** in **ANY** of the following high-risk patients:
    - Age 55 years or older
    - Positive *H. pylori* testing
    - First-degree relative with history of gastric cancer
    - Patients of racial or ethnic groups known to be at higher risk for gastric cancer

Discussion: Preoperative Endoscopy for Bariatric Surgery

The likelihood of asymptomatic screening endoscopy to alter bariatric surgery management is highly dependent on patient- and procedure-specific risk factors. Esophagitis is considered a relative contraindication for sleeve gastrectomy due to the possible risk of worsening GERD and development of Barrett's esophagus after this procedure. Conversely, Roux-en-Y gastrojejunal bypass (RYGB) surgery creates an "excluded stomach" and is typically avoided in patients with increased risk for future gastric malignancy.

The 2015 ASGE guideline on The Role of Endoscopy in the Bariatric Surgery Patient suggests that preoperative endoscopy be considered on an individual basis based on the type of bariatric procedure being performed and notes that an esophagram may be a useful alternative. A 2019 multispecialty clinical practice guideline for the perioperative support of patients undergoing bariatric procedures, which included the American Society for Metabolic and Bariatric Surgery, includes a Grade D (primarily based on expert opinion) statement that "the use of preoperative endoscopy may be considered in all patients being evaluated for sleeve gastrectomy."

Exclusions

Indications and procedures other than those addressed in this guideline are considered **not medically necessary** including, but not limited to, the following:

- Endoscopic ultrasound
- Placement of pH probe

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Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

Medical necessity reviews are initiated by submitting the correct AMA CPT codes. The submitted codes must accurately identify the service or procedure to be performed. If no such code exists, contact the health plan directly and report the service or procedure using the appropriate unlisted procedure or Not Otherwise Classified (NOC) code (which often ends in 99). Do not submit a code that is "close to" the procedure performed in lieu of an unlisted code. Correct coding demands that the code reported is appropriate for the service provided (i.e., a code that most accurately represents the service provided), and not a code that is similar but represents another service. (*CPT® Assistant,* December 2010)

CPT/HCPCS

43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter
43243	Esophagogastroduodenoscopy, flexible, transoral; with injection sclerosis of esophageal/gastric varices
43244	Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter

Excluded: Endoscopic Ultrasound

43231	Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination
43232	Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)

43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis

Excluded: Placement of pH Probe

91034	Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation
91038	Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation; prolonged (greater than 1 hour, up to 24 hours)

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

History

Status	Review Date	Effective Date	Action
Created	Updated 07/13/2023; 08/31/2021	10/01/2024	Independent Multispecialty Physician Panel (IMPP) review. Updated references. Added codes. Original effective date.