NO. 91617

ENDOSCOPIC SUBMUCOSAL DISSECTION (ESD)

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Policy scope: This policy addresses coverage for endoscopic submucosal dissection (ESD) for select gastrointestinal lesions.

Related policies:

- Peroral Endoscopic Myotomy (POEM) No. 91616

I. MEDICAL NECESSITY CRITERIA

Inclusions:

General Requirements (applies to all sites below):

A. Conventional (non-robotic) endoscopic submucosal dissection (ESD) may be considered medically necessary when **all** of the following are met:

1. The lesion has been evaluated with high-definition white-light endoscopy with chromoendoscopy (virtual or dye-based).
2. The lesion is superficial gastrointestinal neoplasia (e.g., high-grade dysplasia or early cancer) appropriate for endoscopic resection based on site-specific criteria.

3. En bloc resection is required and cannot be reliably achieved with endoscopic mucosal resection (EMR).
4. There is no evidence of distant metastatic disease.

Site Specific Requirements:

B. Esophageal Squamous Cell Carcinoma and Esophageal Dysplasia

ESD may be considered medically necessary when **all** of the following are met:

1. The lesion:
    a. Is **>**15 mm or is smaller but not suitable for en bloc resection with EMR.
    b. Is well or moderately differentiated.
    c. Is non-ulcerated.
    d. Shows no evidence of deep submucosal invasion.

C. Early-Stage (T1) Esophageal Adenocarcinoma and Barrett's Esophagus Dysplasia

ESD may be considered medically necessary when **all** of the following are met:

1. The lesion:
    a. Is >20 mm, or ≤20 mm but not suitable to en bloc resection with EMR.
    b. Is well or moderately differentiated.
    c. Is non-ulcerated.
    d. Shows no evidence of deep submucosal invasion.

D. Stomach- Early Gastric Adenocarcinoma

ESD may be considered medically necessary when **all** of the following are met:

1. The lesion:
    a. Is ≤30 mm.
    b. Is well or moderately differentiated, intestinal- type
    c. Is non-ulcerated (or meets expanded criteria if ulcerated)
    d. Shows no evidence of deep submucosal invasion

E. Colon and Rectum - Superficial Colorectal Neoplasia

ESD may be considered medically necessary for superficial colorectal neoplasia when **all** of the following are met:

1. The lesion:
    a. Is >20 mm
    b. Requires en bloc resection that cannot be reliably achieved with EMR.
    c. Exhibits high-risk morphology risk such as:
        i. Non-granular laterally spreading tumors
        ii. Depressed morphology
        iii. Prominent nodular or bulky components
        iv. Non-lifting/ fibrosis, including prior manipulation
    d. Shows no evidence of deep submucosal invasion

F. Duodenal/Small-Bowel

ESD may be considered medically necessary for select non-ampullary duodenal or small-bowel lesions when **all** of the following are met:

1. The lesion:
    a. Is mucosa confined.
    b. Is non-invasive (e.g., adenoma; low- or high-grade dysplasia**,** Intramucosal neoplasia without lymphovascular invasion).
    c. Not amendable to complete EMR, and en bloc resection is required.
2. EMR is not appropriate or is unlikely to achieve complete resection due to factors such as non-lifting, submucosal fibrosis, recurrent or residual lesion after prior EMR, or lesion morphology where piecemeal resection would compromise pathology.

Exclusions:

Not Medically Necessary (exclusions applicable across ALL sites):

A. Conventional ESD is not medically necessary when **any** of the following apply:

1. The patient is not a candidate for procedural sedation or anesthesia.
2. The lesion is ulcerated and associated with endoscopic or histologic features indicating a high risk of lymph-node metastasis or non-curative endoscopic resection.
3. There is evidence of disease beyond accepted early-stage criteria, stage exceeding accepted early-stage criteria.

B. Post-Procedure Pathologic Findings Indicating Non-Curative ESD:

1. ESD is not considered definitive therapy and additional management (e.g., surgical or oncology evaluation) is indicated when post-procedure pathology demonstrates **any** of the following:
    a. Positive margins (non-R0 resection)
    b. Lymphovascular invasion (LVI)
    c. Submucosal invasion (≥ sm2*)
    d. Poorly differentiated cancers

*Non-pedunculated lesions with invasion of more than 1000 μm and pedunculated lesions with stalk invasion were considered as submucosal deep invasive cancer (sm2–3)

Site Specific Exclusions:

C. Gastric Cancer - Specific Exclusions:

ESD is not medically necessary for gastric lesions when **any** of the following are present

1. Poorly differentiated or undifferentiated histology.
2. Deep submucosal invasion.
3. Ulcerated lesions with features indicating increased risk of lymph-node metastasis, outside accepted curative ESD criteria.

4. Regional lymph-node or distant metastatic disease.

D. Esophageal Cancer - Specific Exclusions

ESD is not medically necessary for esophageal lesions when **any** of the following are present:

1. Poorly differentiated or undifferentiated histology.
2. Deep submucosal invasion including disease beyond superficial T1b (SM1) when SM1 criteria are not met.
3. Ulcerated lesions with features indicating increased risk of lymph-node metastasis, outside accepted curative ESD criteria.
4. Regional lymph-node or distant metastatic disease.

E. Colon and Rectum - Cancer-Specific Exclusions

ESD is not medically necessary for colorectal lesions based on size alone (e.g., ≥20 mm) without:

1. Endoscopic features suggestive of superficial submucosal invasion, or
2. Inability to reliably achieve en bloc or complete resection with snare-based EMR.

Not medically Necessary as Considered Experimental / Investigational / Unproven:

A. Robotic-assisted or computer-enhanced endoluminal systems intended to perform or assist ESD (e.g., EndoQuest Endoluminal Surgical [ELS] System) are experimental and investigational and not medically necessary.

1. These systems are under FDA Investigational Device Exemption (IDE) evaluation.
2. They do not have FDA marketing authorization for performing or assisting endoscopic submucosal dissection.

B. All other uses of endoscopic submucosal dissection (ESD) that do not meet the medical necessity criteria in this policy are experimental, investigational, and/or unproven and not medically necessary, due to insufficient high-quality clinical evidence supporting safety and effectiveness.

C. Duodenal/Small-Bowel Endoscopic Submucosal Dissection (ESD):

1. Duodenal or small-bowel ESD is experimental, investigational, and/or unproven (E/I/U) and not medically necessary when performed outside the medical necessity criteria in this policy, including when any of the following apply:
    a. Routine or widespread use for duodenal or small-bowel lesions.
    b. Suspected or confirmed deep submucosal invasion.
    c. Ampullary lesions.
    d. Lesions for which EMR is appropriate and expected to achieve complete resection.
    e. Use for training, proficiency development, or case volume building, rather than patient-specific medical necessity.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None Identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None Identified
First Coast Service Options, Inc.	None Identified
National Government Services, Inc.	None Identified
Noridian Healthcare Solutions	None Identified
Novitas Solutions, Inc.	None Identified
Palmetto GBA	None Identified
WPS Insurance Corporation	None Identified

III. BACKGROUND

Endoscopic submucosal dissection (ESD), developed in Japan in the mid-to-late 1990s, is an advanced endoscopic technique designed to achieve en-bloc resection of superficial gastrointestinal neoplasia, enabling accurate histopathologic assessment of lesion margins and depth of invasion (Pimentel-Nunes et al., 2022). The procedure involves marking the lesion perimeter, submucosal injection to achieve mucosal lifting, circumferential mucosal incision, controlled submucosal dissection using an electrosurgical knife, and endoscopic hemostasis as needed during resection (Pimentel-Nunes et al., 2022).

Initially developed for the non-operative treatment of early gastric neoplasia, ESD techniques and dedicated devices have evolved, allowing application in selected lesions of the esophagus, stomach, colon, and rectum. Compared with standard endoscopic mucosal resection (EMR), ESD permits en- bloc resection of larger or morphologically complex lesions, resulting in higher rates of R0 resection and lower local recurrence when applied to appropriately selected superficial neoplasia (Pimentel-Nunes et al., 2022). The foundational clinicopathologic criteria for endoscopic resection of early gastric cancer were initially developed in Japan and refined through long-term outcomes data, forming the basis for the absolute and expanded indications that continue to inform contemporary ESD practice worldwide (Gotoda & Ono, 2022; Japanese Gastric Cancer Association, 2026).

Appropriate lesion selection for endoscopic resection relies on standardized endoscopic classification systems that describe macroscopic morphology and help predict histology and invasion depth, thereby guiding selection of EMR, ESD, or surgery. The Paris classification provides a unified morphology framework for superficial (type 0) lesions across the esophagus, stomach, and colon (e.g., protruding 0-I, flat 0-IIa/IIb/IIc, and excavated 0-III), and morphology, particularly depressed or excavated patterns—can inform risk stratification for submucosal invasion and the need for en bloc resection (Participants in the Paris Workshop, 2003).

In the colon and rectum, laterally spreading tumors are further described by the LST classification (granular vs non-granular subtypes), which is clinically useful because certain patterns, especially non-granular and pseudo-depressed morphologies are associated with higher likelihood of submucosal invasion and therefore more often warrant en bloc resection approaches (Shigita et al., 2016).

Optical diagnosis using image-enhanced endoscopy is commonly operationalized with the NICE classification, a non-magnified NBI system that categorizes lesions by color, vessel, and surface patterns into types that broadly correlate with hyperplastic/serrated histology (type 1), adenoma/superficial neoplasia (type 2), and features concerning for deep submucosal invasive cancer (type 3) (Hewett et al., 2012). When magnification is available, the JNET classification refines invasion-risk stratification using vessel and surface patterns (types 1, 2A, 2B, 3), supporting distinction between serrated/non-neoplastic patterns, low-grade neoplasia, high-grade and/or shallow invasion risk, and deep submucosal invasive cancer, with type 2B lesions often benefiting from additional corroboration with pit pattern diagnosis (Sano et al., 2016; Kobayashi et al., 2019).

Surface crypt architecture can also be assessed using Kudo pit pattern classification (types I–V), where irregular pit patterns, particularly type V and subclassifications of type VI—support depth assessment and identification of lesions more likely to harbor deep submucosal invasion requiring surgical management (Kudo et al., 1996; Kanao et al., 2008). For esophageal neoplasia, endoscopic selection for curative endoscopic therapy is frequently aligned with standardized staging concepts such as AJCC T category distinctions (e.g., Tis/T1a mucosal disease vs T1b submucosal invasion), which help define the boundary between curative endoscopic resection and disease with higher nodal risk that may warrant surgical or oncologic evaluation (Rice et al., 2017).

Because ESD is performed with curative intent only in appropriately selected superficial neoplasia, final determination of “curative” endoscopic therapy is confirmed by the resection specimen, including achievement of R0 resection and absence of adverse histopathologic features (e.g., lymphovascular invasion, poor differentiation, or deep submucosal invasion) that are associated with higher risk of lymph node metastasis and may warrant additional management such as surgical and/or oncology evaluation (Forbes et al., 2023; Shaukat et al., 2020).

Both European and U.S. societies emphasize that ESD is technically demanding and associated with longer procedure times and a higher risk of adverse events when performed by inadequately trained operators. Outcomes are strongly influenced by operator expertise and center experience, and ESGE and ASGE recommend that ESD be performed by appropriately trained endoscopists in centers capable of managing

potential complications (Pimentel-Nunes et al., 2022; Forbes et al., 2023). In addition, the European Society of Gastrointestinal Endoscopy (ESGE) Technical Review provides detailed guidance on ESD techniques, devices, adverse-event management, and training considerations, emphasizing that procedural safety and outcomes are closely linked to operator experience and institutional expertise (Libânio et al., 2023).

The American Society for Gastrointestinal Endoscopy (ASGE) 2023 clinical practice guideline provides evidence-based recommendations for the role of ESD compared to EMR and surgery in early esophageal and gastric cancers. For esophageal squamous cell carcinoma (ESCC), ASGE suggests ESD over EMR for well-differentiated, nonulcerated lesions larger than 15 mm, while either ESD or EMR may be appropriate for lesions 15 mm or smaller. For esophageal adenocarcinoma (EAC), ESD is suggested over EMR for well-differentiated, non-ulcerated lesions larger than 20 mm, with EMR or ESD acceptable for smaller lesions. For early gastric adenocarcinoma (GAC), ASGE suggests ESD over EMR for well or moderately differentiated, non-ulcerated, intestinal-type lesions measuring 20–30 mm, while recommending surgical evaluation for poorly differentiated lesions regardless of size (Forbes et al., 2023; Al-Haddad et al., 2023).

The European Society of Gastrointestinal Endoscopy (ESGE) 2022 guideline update similarly recommends ESD as the treatment of choice for most superficial ESCC and selected early gastric cancers, selective use in Barrett's-associated neoplasia and colorectal lesions with suspected superficial submucosal invasion, and does not recommend routine ESD for duodenal or small-bowel lesions, except in highly selected cases at expert centers (Pimentel-Nunes et al., 2022). In the U.S. context, the American Gastroenterological Association (AGA) similarly supports endoscopic eradication therapy for Barrett's esophagus–associated dysplasia and early adenocarcinoma, with ESD favored over EMR for larger or more complex lesions where en-bloc resection is required for accurate histopathologic staging (Rubenstein et al., 2024).

Emerging robotic-assisted or computer-enhanced endoluminal platforms intended to perform or assist ESD are under active clinical investigation in the United States, including studies conducted under FDA Investigational Device Exemption (IDE) protocols, and are being evaluated in pivotal clinical trials in advance of planned De Novo regulatory submissions (EndoQuest Robotics, 2024; EndoQuest Robotics, 2026; CMS, 2025).

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Society for Gastrointestinal Endoscopy (ASGE)	American Society for Gastrointestinal Endoscopy guideline on endoscopic submucosal dissection for the management of early esophageal and gastric cancers: summary and recommendations (2023)
Japanese Gastric Cancer Association (JGCA)	Japanese gastric cancer treatment guidelines 2025 (7th edition)

European Society of Gastrointestinal Endoscopy (ESGE)	European Society of Gastrointestinal Endoscopy (ESGE) Guideline Endoscopic submucosal dissection for superficial gastrointestinal lesions (2022)
American Gastroenterological Association (AGA)	AGA Clinical Practice Guideline on Endoscopic Eradication Therapy of Barrett's Esophagus and Related Neoplasia - Gastroenterology (2024) AGA Institute Clinical Practice Update: Endoscopic Submucosal Dissection in the United States (2019)
NCCN	colorectal_screening.pdf (2025) esophageal.pdf (2026) gastric.pdf (2026)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
Olympus ESD Knives	K182408	05/15/2019
ERBE HybridKnife®	K083608	08/26/2009
ERBE HYBRIDkinfe Flex	K232033	11/29/2023
Multi-Functional Electrosurgical Knife (Anrei Medical)	K212999	03/21/2022
ORISE ProKnife (Boston Scientific Corporation)	K200404	12/03/2020
Creo Medical SpydrBlade™ Flex	K242774	06/06/2025

VI. CODING

ICD-10 Codes that may support medical necessity

C15.3 - C15.9	Malignant neoplasm of esophagus
C16.0 - C16.9	Malignant neoplasm of stomach
C17.0	Malignant neoplasm of duodenum
C18.0 - C18.9	Malignant neoplasm of colon
C19	Malignant neoplasm of rectosigmoid junction

C20	Malignant neoplasm of rectum
D00.1	Carcinoma in situ of esophagus
D00.2	Carcinoma in situ of stomach
D13.2	Benign neoplasm of duodenum
D48.7	Neoplasm of uncertain behavior of other specified sites
D49.0	Neoplasm of unspecified behavior of digestive system
K22.711	Barrett's esophagus with high grade dysplasia
K31.7	Polyp of stomach and duodenum
K63.5	Polyp of colon

CPT/HCPCS Codes

C9779	Endoscopic submucosal dissection (ESD), including endoscopy or colonoscopy, mucosal closure, when performed (billable by Facility only)
43499	Unlisted procedure, esophagus
43999	Unlisted procedure, stomach
44799	Unlisted procedure, small intestine
45399	Unlisted procedure, colon
45999	Unlisted procedure, rectum

(Explanatory notes must accompany claims billed with unlisted codes.)

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.

- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Professional and Society Guidelines

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SUMMARY OF CHANGES

Additions:

- Added site specific exclusions per society guidelines
- Added Robotic-assisted/computer-enhanced ESD platforms are explicitly classified as experimental/investigational

Changes:

- Updated Gastric Region indications as they were broad and aligned them with society guidelines.
- Colon/Rectum: Updated criteria from size-alone to morphology + suspected SMI.
- Duodenum/Small bowel — eliminated broad coverage and aligned medical necessity criteria with ESGE and NCCN guidelines.
- Converted to the new standardized policy template.
- Replaced broad indications with guideline-style inclusion features (size + histology + ulceration + invasion depth) for Esophagus site. Split into two distinct pathways with specific thresholds and staging language for Esophageal squamous cell carcinoma / esophageal dysplasia and Early-stage (T1) esophageal adenocarcinoma / Barrett's dysplasia

Clarifications:

- Reorganized criteria into general requirements plus detailed site-specific criteria (esophagus, stomach, colorectal, duodenal/small bowel).
- Replaced vague indications (e.g., "polyps not removable by snare," "submucosal masses," "recurrent lesions") with explicit guideline-based thresholds (size, histology, ulceration status, depth of invasion, need for en-bloc resection).

Past committee review dates: 05/2016, 05/2017, 05/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023, 05/2024, 05/2025, 05/2026

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