MEDICAL POLICY No. 91617-R2

ENDOSCOPIC SUBMUCOSAL DISSECTION (ESD)

Effective Date: June 1, 2024

Review Dates: 5/16, 5/17, 5/18, 5/19, 5/20, 5/21, 5/22, 5/23, 5/24 Status: Current

Date Of Origin: May 11, 2016

Summary of Changes

- Clarification:
 - For esophagus region
 - Changed Barrett's esophagus with high grade dysplasia with a visible lesion greater than or equal to 15 mm to greater than 15 mm
 - For esophagus & gastric region
 - Changed from submucosal masses greater than or equal to 20 mm to greater than 20 mm
 - For duodenal & colorectal region
 - Changed from polyps greater than or equal to 20 mm to greater than 20 mm

I. POLICY/CRITERIA

Endoscopic submucosal dissection (ESD) for gastrointestinal lesions may be medically necessary when all of the following are met:

- 1. Lesion is deemed appropriate for ESD by one of the following:
 - a. Endoscopic ultrasound (EUS), OR
 - b. High magnification chromoendoscopy
- 2. **One** of the following clinical indications at any gastroenterological region of origin:
 - a. Esophagus Region (must meet one of the following)
 - 1. Barrett's esophagus with high grade dysplasia with a visible lesion >15 mm
 - 2. Early esophageal cancers by EUS with a negative PET scan
 - 3. Submucosal masses >20 mm
 - 4. Esophageal polyps unable to be removed by snare techniques
 - 5. Recurrent high-grade dysplasia or early cancer
 - b. Gastric Region (must meet one of the following)
 - 1. High grade dysplasia in non-pedunculated polyps $\geq 20 \text{ mm}$
 - 2. Early gastric cancer by EUS with negative PET scan
 - 3. Submucosal masses >20 mm
 - 4. Gastric polyps unable to be removed by snare techniques



- 5. Recurrent high-grade dysplasia or early cancer
- c. Duodenal Region (must meet one of the following)
 - 1. High grade dysplasia polyps >20 mm
 - 2. Early duodenal cancer by EUS and negative PET scan
 - 3. Duodenal polyps unable to remove by snare techniques
 - 4. Recurrent high-grade dysplasia or early cancer
- d. Colorectal Region (must meet one of the following)
 - 1. Flat large polyps >20 mm
 - 2. Early colon or rectal cancer by EUS or high magnification chromoendoscopy
 - 3. Submucosal masses
 - 4. Recurrent polyps >20 mm
- 3. None of the following:
 - a. Patients with involvement of the submucosa (sm2 or beyond*) as demonstrated by EUS or high magnification chromoendoscopy
 - b. Poorly differentiated cancers
 - c. Patients who are deemed to be unsuitable for sedation by anesthesia
 - d. Patients with obvious metastasis
- 4. Pre-ESD evaluation by gastrointestinal (GI) surgeon to discuss surgical options as alternative to ESD.

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

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, 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, please refer to the <u>Priority Health Provider Manual</u>.

III. APPLICATION TO PRODUCTS

Coverage is subject to 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) and/or the Evidence of Coverage (EOC); 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 located at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html</u>. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html</u>, 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.

IV. BACKGROUND

Developed in the mid-to-late 1990s, ESD is an endoscopic resection technique used to remove large and irregular tumors along the submucosal layer. ESD enables en-bloc removal of gastrointestinal lesions. The basic technique for the procedure is as follows: 1) Cautery is used to mark the perimeter of the lesion, 2) a lifting agent is injected into the submucosa around the perimeter of the lesion, 3) an electrosurgical knife is used to incise the mucosa and cut circumferentially around the lesion, 4) the submucosa beneath the lesion is injected and then the electrosurgical knife is used to dissect in a free-hand manner until the whole specimen has been completely resected, 5) a water jet and hemostatic forceps are used to wash and coagulate any bleeding that occurs during either the mucosal incision or submucosal dissection.

Although ESD was first described as a technique to treat early gastric neoplasia non-operatively, the technique and equipment have evolved over the past decades to expand indications to include locations throughout the gastrointestinal tract from the esophagus to the colon. The risk of malignant change increases with the histological grade of the dysplasia. Due to the discrepancies between Western and Japanese pathologic diagnosis of gastric lesions, several systems including the Japanese Society of Gastroenterological Society (JSGE), Padova, Vienna, and World Health Organization have been developed to standardize the classification of gastric dysplasia.

MEDICAL POLICY No. 91617-R2

In highly trained hands, ESD results in higher en-bloc curative resection rates and detailed histopathological evaluation, with lower recurrence when compared to the current conventional therapy in the United States.

According to American Society for Gastrointestinal Endoscopy (2019), ESD is a technically demanding procedure that requires substantial training to achieve competence; inadequate training compromises both patient safety and technical outcomes. ESD poses significant risk when undertaken by an operator inadequately trained in ESD.

The American Society for Gastrointestinal Endoscopy (ASGE)'s 2023 clinical practice guideline addressed the role of ESD versus EMR and/or surgery for the management of early esophageal squamous cell carcinoma (ESCC), esophageal adenocarcinoma (EAC), and gastric adenocarcinoma (GAC) and their corresponding precursor lesions. For ESCC, the ASGE suggests ESD over EMR for patients with early-stage, well-differentiated, nonulcerated cancer >15 mm, whereas in patients with similar lesions >15 mm, the ASGE suggests either ESD or EMR. ASGE suggests against surgery for such patients with ESCC, whenever possible. For EAC, the ASGE suggests ESD over EMR for patients with earlystage well-differentiated, nonulcerated cancer >20 mm, whereas in patients with similar lesions measuring ≤ 20 mm, the ASGE suggests either ESD or EMR. For GAC, the ASGE suggests ESD over EMR for patients with early-stage, well or moderately differentiated, nonulcerated intestinal type cancer measuring 20 to 30 mm, whereas for patients with similar lesions <20 mm, the ASGE suggests either ESD or EMR. The ASGE suggests against surgery for patients with such lesions measuring < 30 mm, whereas for lesions that are poorly differentiated, regardless of size; surgical evaluation is suggested over endoscopic approaches (ASGE, 2023).

V. CODING INFORMATION

ICD-10 Diagnoses that may support:

C15.3 - C1	5.9 Malignant neoplasm of esophagus
C16.0 - C1	6.9 Malignant neoplasm of stomach
C17.0	Malignant neoplasm of duodenum
C18.0 - C1	8.9 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.)

VI. REFERENCES

- ASGE standards of practice committee; Forbes N, Elhanafi SE, Al-Haddad MA, Thosani NC, et al; (ASGE Standards of Practice Committee Chair). American Society for Gastrointestinal Endoscopy guideline on endoscopic submucosal dissection for the management of early esophageal and gastric cancers: summary and recommendations. Gastrointest Endosc. 2023 Sep;98(3):271-284. doi: 10.1016/j.gie.2023.03.015. Epub 2023 Jul 25. PMID: 37498266.
- ASGE Standards of Practice Committee, Jue TL, Storm AC, Naveed M, Fishman DS, Qumseya BJ, McRee AJ, Truty MJ, Khashab MA, Agrawal D, Al-Haddad M, Amateau SK, Buxbaum JL, Calderwood AH, DeWitt J, DiMaio CJ, Fujii-Lau LL, Gurudu SR, Jamil LH, Kwon RS, Law JK, Lee JK, Pawa S, Sawhney MS, Thosani NC, Yang J, Wani SB; (ASGE Standards of Practice Committee Chair, 2017-2020). ASGE guideline on the role of endoscopy in the management of benign and malignant gastroduodenal obstruction. Gastrointest Endosc. 2021 Feb;93(2):309-322.e4. doi: 10.1016/j.gie.2020.07.063. Epub 2020 Nov 7. PMID: 33168194.
- Balmadrid, B. & Hwang, J.H. (2015) Endoscopic resection of gastric and esophageal cancer. Oxford Journals: Gastroenterology Report. Retrieved from <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4650978/</u>
- Baldaque-Silva, F., Marques, M., Andrade, A. P., Sousa, N., Lopes, J., Carneiro, F., & Macedo, G. (2019). Endoscopic submucosal dissection of gastrointestinal lesions on an outpatient basis. United European gastroenterology journal, 7(2), 326–334. https://doi.org/10.1177/2050640618823874
- Bliss, L. A., Maguire, L.H., Chau, Z., Yang, C.J., Nagle, D.A., Chan, A. T., & Tseng, J.F. (2015) Readmission after resections of the colon and rectum: predictors of a costly and common outcome. *Diseases of the Colon & Rectum*. DOI: 10.1097/DCR.00000000000433

- Coman, R. M, Gotoda, T., & Draganov, P.V. (2013) Training in endoscopic submucosal dissection. World Journal of Gastrointestinal Endoscopy. 5(8). 369-378. doi: <u>10.4253/wjge.v5.i8.369</u>
- Doty, J.R., Salazar, J.D., Forastiere, A.A., Heath, E.L., Kleinberg, L. & Heitmiller, R. F. (2002) Post-esophagectomy morbidity, mortality, and length of hospital stay after pre-operative chemoradiation therapy. Annals of Thoracic Surgery. 74 (1) 227-231
- Draganov PV, et al (2019). AGA Institute Clinical Practice Update: Endoscopic Submucosal Dissection in the United States. Clinical Gastroenterology and Hepatology;17:16.
- Feng, F., Zhiguo, L., Zhang, X., Guo, M., Xu, G., Ren, G., Hong, L., Sun, L., Tang, J. & Zhang, H. (2015) Comparison of endoscopic and open resection for small gastric gastrointestinal stromal tumor. Translational Oncology. 8(6). 504-508. Doi: doi:10.1016/j.tranon.2015.11.008
- Ferreira, J. & Akerman, P. (2015) Colorectal endoscopic submucosal dissection: past, present, and factors impacting future dissemination. Colon and Rectal Surgery. 28 (03). 146-151. DOI: 10.1055/s-0035-1555006.
- 11. Gotoda, T. Endoscopic resection of early gastric cancer. Gastric Cancer. 2007; 10: 1–11
- 12. Hayashi, Y., Shinozaki, S., Sunada, K., Sato,H., Miura, Y., Ino, Y., Horie, H., Fukushima, N., Lefor, A., & Yamamoto (2006) Efficacy and safety of endoscopic submucosal dissection for superficial colorectal tumors more than 50 mm in diameter. Clinical Gastroenterology and hepatology.
- 13. Hayes Clinical Research Response:"Endoscopic Submucosal Dissection for Colorectal Indications, Publication Date January 12, 2017.
- 14. Hsieh, C.C. & Chien, C.W. (2009) A cost and benefit study of esophagostomy for patients with esophageal cancer. Journal of Gastrointestinal Surgery. 13 (10). 1806-1812. DOI: 10.1007/s11605-009-0965-9
- 15. Isguder, A.S., Nazil, O., Tansug, T., Bozdag, A.D. & Onal, M.A. (2005) Total gastrectomy for gastric carcinoma. Hepatogastroenterology. 52(61) 302-304.
- Islam RS, Patel NC, Lam-Himlin D, Nguyen CC. Gastric polyps: a review of clinical, endoscopic, and histopathologic features and management decisions. Gastroenterol Hepatol (N Y). 2013 Oct;9(10):640-51. PMID: 24764778; PMCID: PMC3992058.
- 17. Kazuaki K, Fujimore K, Fujii T et al. (2004) Correlation between lymph node metastasis and depth of submucosal invasion in submucosal invasive colorectal carcinoma: A Japanese collaborative study J of Gastroenterology.39:534-543
- Ikehara H, Saito Y, Matsuda T, et al. Diagnosis of depth of Invasion for early colorectal cancer using Magnifying colonoscopy. (2010). Journal of Gastroenterology and Hepatology.1440-1746.
- 19. Matzuda T, Fujii T, Saito Y, et al. (2008) Efficacy of the invasive/noninvasive pattern by Magnifying chromoendoscopy to estimate the depth of invasion of the early colorectal neoplasm. Am J Gastroenterology. 11:2700-6

- Park CH, Yang DH, Kim JW, et al. Clinical Practice Guideline for Endoscopic Resection of Early Gastrointestinal Cancer. Clin Endosc. 2020 Mar;53(2):142-166. Pimentel-Nunes P, Pioche M, Albéniz E, et al. Curriculum for endoscopic submucosal dissection training in Europe: European Society of Gastrointestinal Endoscopy (ESGE) position statement. Endoscopy. 2019;51(10):980–992.
- Pimentel-Nunes P, Libânio D, Bastiaansen BAJ, Bhandari P, Bisschops R, Bourke MJ, Esposito G, Lemmers A, Maselli R, Messmann H, Pech O, Pioche M, Vieth M, Weusten BLAM, van Hooft JE, Deprez PH, Dinis-Ribeiro M. Endoscopic submucosal dissection for superficial gastrointestinal lesions: European Society of Gastrointestinal Endoscopy (ESGE) Guideline - Update 2022. Endoscopy. 2022 Jun;54(6):591-622. doi: 10.1055/a-1811-7025. Epub 2022 May 6. PMID: 35523224
- 22. Sung JK. Diagnosis and management of gastric dysplasia.(2016). Korean J Intern Med. 31(2): 201-209.
- 23. UpToDate: Overview of endoscopic resection of gastrointestinal tumors. Last updated February 11, 2019. Accessed March 12, 2019, March 24, 2020.
- 24. Tanaka S, Kashida H, Saito Y, et al. JGES guidelines for colorectal endoscopic submucosal dissection/endoscopic mucosal resection. *Dig Endosc*. 2015;27(4):417–434.
- 25. Tate DJ, Klein A, Sidhu M, Desomer L, Awadie H, Lee EYT, Mahajan H, McLeod D, Bourke MJ. Endoscopic submucosal dissection for suspected early gastric cancer: absolute versus expanded criteria in a large Western cohort (with video). Gastrointest Endosc. 2019 Sep;90(3):467-479.e4. doi: 10.1016/j.gie.2019.04.242. Epub 2019 May 8. PMID: 31077699.

AMA CPT Copyright Statement:

All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.