# Medical Coverage Policy

**Effective Date.....10/15/2025**
**Next Review Date.....10/15/2026**
**Coverage Policy Number..... 0577**

# Mucosal Integrity Testing

## Table of Contents



## Related Coverage Resources

Esophagogastroduodenoscopy (EGD)

***INSTRUCTIONS FOR USE***

*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy*

*will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## Overview

This Coverage Policy addresses esophageal mucosal integrity testing via transoral electrical impedance which includes esophagoscopy or esophagogastroduodenoscopy (HCPCS code C9777) (MiVu™ Mucosal Integrity Testing System).

## Coverage Policy

**Esophageal mucosal integrity testing by electrical impedance is considered experimental, investigational, or unproven.**

## Coding Information

**Notes:**

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Experimental/Investigational/Unproven:**

| HCPCS Codes | Description |
|---|---|
| C9777 | Esophageal mucosal integrity testing by electrical impedance, transoral includes esophagoscopy or esophagogastroduodenoscopy |

## General Background

Gastroesophageal reflux disease (GERD) is a chronic medical condition caused by the backward flow of acidic stomach contents into the esophagus. The symptoms of GERD include heartburn and regurgitation. Complications from GERD include severe chest pain that can mimic a heart attack, esophageal stricture, gastrointestinal bleeding, and pre-cancerous changes in the lining of the esophagus (Barrett's esophagus). Tests for GERD include an upper gastrointestinal series (x-rays), upper endoscopy, and pH (acid) testing (American College of Gastroenterology, n.d.).

Eosinophilic esophagitis (EoE) is a chronic, allergic condition that causes inflammation in the esophagus. The symptoms of EoE vary by age and may include difficulty feeding, poor growth, and weight gain for infants and toddlers; abdominal pain, difficulty swallowing, and poor appetite in children; and difficulty swallowing, food getting stuck in the esophagus, heartburn, and upper abdominal and chest pain in adults. Complications from EoE include esophageal strictures, food impaction, and damage to the esophagus. Tests for EoE include upper endoscopy and an esophageal biopsy (American College of Gastroenterology, 2021).

Esophageal mucosal integrity testing by electrical impedance has been proposed as a diagnostic screening tool to help detect GERD, Non-GERD, and EoE during upper endoscopy; and to monitor treatment response for GERD and EoE. Higher electrical impedance may be indicative of a healthy and protective mucosal barrier. Lower electrical impedance may be indicative of a compromised mucosal barrier. The MiVu™ Mucosal Integrity Testing System is intended to measure and analyze the electrical impedance of esophageal tissue. During the procedure, the MiVu Endo Cap is attached to the distal end of an endoscope and contact is made with the esophageal epithelium. Real-time electrical impedance, mucosal integrity contour pattern, and a probability of GERD, non-GERD, and EoE are then displayed on a computer monitor (Diversatek, Inc., 2025).

**U.S. Food and Drug Administration (FDA)**

On December 23, 2019, the Mucosal Integrity Conductivity (MI) Test System (Diversatek Healthcare Inc.) was granted FDA De Novo authorization (DEN180067). This device is classified as esophageal tissue characterization system (FDA Product Code: QIS), and intended for obtaining measurements of electrical properties within esophageal tissue. The FDA Indications for Use states, "The MI Conductivity Test System is indicated for use by gastroenterologists, surgeons, and medically trained personnel during an endoscopy to obtain a real time measurement of esophageal epithelial impedance. The device is not for use as a sole diagnostic screening tool."

On April 25, 2023, the MiVu™ Esophageal Endo Cap (Diversatek Healthcare) received FDA 510(k) clearance (K230056). This device is classified as an esophageal tissue characterization system (FDA Product Code: QIS). The MiVu Esophageal Endo Cap is an accessory device for use with the approved predicate, ~~Diversatek Healthcare's~~ the MiVu Mucosal Integrity Testing system (MiVu System) (DEN180067). The MiVu Esophageal Endo Cap is a patient-contacting accessory used in place of the MiVu Balloon Probe previously approved as part of the MiVu System. The FDA Indications for Use states, "The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medical personnel trained in endoscopic procedures during an endoscopy to obtain real-time measurement of esophageal epithelial integrity as an adjunct for the evaluation of esophageal disorders. The device is not for use as a sole diagnostic screening tool."

**Literature Review**

Patel et al. (2019) reported on a prospective study to evaluate the ability of a balloon-incorporated mucosal impedance catheter to detect and evaluate esophageal disorders, including GERD and EoE. The study included 69 patients undergoing esophagogastroduodenoscopy (EGD) with or without wireless pH monitoring. Patients were classified as having GERD (erosive esophagitis or abnormal pH; n=24), EoE (confirmed with pathology analysis of tissues from both distal and proximal esophagus; n=21), or non-GERD (normal results from EGD and pH tests; n=24). Receiver operating characteristic curves (ROC) and area under the ROC curve (AUC) were used to compare the accuracy of balloon mucosal impedance in diagnosis. Probabilities of assignment to each group (GERD, non-GERD, or EoE) were estimated using multinomial logistic regression. Association between mucosal impedance patterns and diagnoses were validated using data from patients seen at three separate institutions. The mucosal impedance pattern along the esophageal axis differed significantly ($p<0.01$) among patients with GERD, EoE and non-GERD. Patients with non-GERD had higher mucosal impedance values along all measured segments. The mucosal impedance pattern for GERD was easily distinguished from that of EoE. In patients with GERD, mucosal impedance values were low in the distal esophagus and normalized along the proximal esophagus, whereas in patients with EoE, measurements were low in all segments of the esophagus. Intercept and rate of rise of mucosal impedance value (slope) as distance increased from the squamocolumnar junction identified patients with GERD with an AUC = 0.69, patients with EoE with an AUC = 0.89, and patients with non-GERD with an AUC = 0.84 in the

development cohort. One patient had an adverse event of mild chest pain after the procedure and was discharged from the hospital without further events. The authors concluded that the balloon mucosal impedance catheter system instantly and safely detected changes in esophageal mucosal integrity and was able to identify patients with GERD, EoE, or non-GERD. Findings were validated in a separate cohort for patients. Limitations of the study include a prediction model that assumed patients must belong to one of the three diagnosis groups, and used an equal baseline prevalence of GERD, non-GERD, and EoE (35%, 35%, and 30%, respectively) to estimate conditional (post-test) probability of the disease given mucosal impedance intercept and slope.

Choksi et al. (2018) reported on a retrospective analysis of 91 patients to quantify mucosal impedance along the esophagus and identify patterns that differentiated patients with and without GERD from those with EoE. The authors also sought to determine whether mucosal impedance values and patterns were sufficient to identify patients with EoE using histologic findings as a reference. During the first endoscopy, mucosal impedance measurements were obtained at 2, 5, and 10 cm from the squamocolumnar junction. GERD was confirmed by ambulatory pH tests. Histologic analyses of biopsies were used to confirm EoE. Statistical modeling was used to identify mucosal impedance patterns along the esophagus that associated with GERD versus EoE. Findings were validated in a prospective cohort of 49 patients undergoing elective upper endoscopy for dysphagia. The study results revealed that patients with EoE had a unique mucosal impedance pattern, with low values along the esophageal axis. Mucosal impedance measurements at 5 cm could discern patients with normal versus abnormal mucosa with 83% sensitivity and 79% specificity, and patients with EoE versus GERD with 84% sensitivity and 70% specificity. The measurements differentiated the patient populations with the highest level of accuracy of any of the six measurements tested. In the validation study, a rater using the esophageal mucosal impedance pattern identified patients with EoE with 100% sensitivity and 96% specificity. The authors concluded that a pattern of mucosal impedance along the esophagus was identified and validated that can different patients with EoE versus normal mucosa or GERD with high levels of sensitivity. Limitations of the study include the retrospective observational design.

Lowry et al. (2018) conducted a prospective study to investigate whether mucosal impedance measurements can be used to monitor disease activity in 173 pediatric patients with EoE. Mucosal impedance was measured at three locations in the esophagus in pediatric patients (1-18 years old), 32 with active EoE, 10 with inactive EoE, 32 with nonerosive reflux disease (NERD) and 53 children with symptoms but normal findings from histologic analyses (controls) undergoing routine EGD. Pathologists reviewed biopsies per routine protocol, determined eosinophilic density, and graded spongiosis on an ordinal visual scale. Mucosal impedance measurements were compared within patient groups. The primary outcome was correlation of mucosal impedance measurements with disease activity, based on severity of spongiosis and eosinophil counts. The study results revealed that mucosal impedance measurements were significantly lower in patients with active EoE at 2, 5, and 10 cm above the squamocolumnar junction (median values of 1069, 1368, and 1707, respectively) compared to patients with inactive EoE (median values of 3663, 3657, and 4494, respectively), NERD (median values of 2754, 3243, and 4387), and controls (median values of 3091, 3760, and 4509) ($p<0.001$ for all comparisons to patients with active EoE). Inverse correlations were found between mucosal impedance measurements and eosinophil count ($p<0.001$), and spongiosis severity ($p<0.001$). The authors concluded that mucosal impedance measurements may provide immediate information about mucosal inflammation in children. However, this needs to be confirmed by further, prospective studies. Limitations of the study include the cross-sectional study design, which does not allow for conclusions about causality.

**Professional Societies/Organizations**

**American College of Gastroenterology (ACG):** ACG Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease state, "We expect that new diagnostic tools and

treatments will be developed and those that we have will be further refined. Mucosal integrity testing, for example, is available commercially but is not developed sufficiently to warrant discussion in this guideline" (Katz, et al., 2022).

## Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

## Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|---|---|---|---|
| NCD | National | No determination found. | |
| LCD | | No determination found. | |

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

## References


1. American College of Gastroenterology. Acid Reflux/GERD. Gastrointestinal (GI) Health and Disease. (n.d.). Accessed July 2025. Available at URL address: https://gi.org/topics/acid-reflux/

2. American College of Gastroenterology. Eosinophilic Esophagitis. Gastrointestinal (GI) Health and Disease. (Updated March 2021). Accessed July 2025. Available at URL address: https://gi.org/topics/eosinophilic-esophagitis/

3. Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database. Accessed July 2025. Available at URL address: https://www.cms.gov/medicare-coverage-database/search.aspx

4. Choksi Y, Lal P, Slaughter JC, Sharda R, Parnell J, Higginbotham T, Vaezi MF. Esophageal Mucosal Impedance Patterns Discriminate Patients With Eosinophilic Esophagitis From Patients With GERD. Clin Gastroenterol Hepatol. 2018 May;16(5):664-671.e1.

5. Diversatek Healthcare. MiVu™ Mucosal Integrity Testing System. Accessed July 2025. Available at URL address: https://diversatekhealthcare.com/mucosal-integrity-mivu-3/

6. Katz PO, Dunbar KB, Schnoll-Sussman FH, Greer KB, Yadlapati R, Spechler SJ. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. 2022 Jan 1;117(1):27-56.

7. Lowry MA, Vaezi MF, Correa H, Higginbotham T, Slaughter JC, Acra S. Mucosal Impedance Measurements Differentiate Pediatric Patients With Active Versus Inactive Eosinophilic Esophagitis. J Pediatr Gastroenterol Nutr. 2018 Aug;67(2):198-203.

8. Patel DA, Higginbotham T, Slaughter JC, Aslam M, Yuksel E, Katzka D. Development and Validation of a Mucosal Impedance Contour Analysis System to Distinguish Esophageal Disorders. Gastroenterology. 2019 May;156(6):1617-1626.e1.

9. U.S. Food and Drug Administration (FDA). Mucosal Integrity Conductivity (MI) Test System. De Novo Classification Request. DEN180067. December 23, 2019. Accessed July 2025. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180067.pdf

10. U.S. Food and Drug Administration (FDA). MiVu™ Esophageal Endo Cap. 510(k) Premarket Notification. April 25, 2023 (K230056). Accessed July 2025. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230056.pdf

## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Annual review | • No clinical policy statement changes. | 10/15/2025 |
| Annual review | • No clinical policy statement changes. | 10/15/2024 |

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