



Radiofrequency Ablation for Barrett's Esophagus

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Definitions

Barrett's Esophagus and Dysplasia — Barrett's esophagus (BE) is defined as a pre-malignant lesion where the normal squamous epithelium that lines the esophagus is replaced by columnar epithelium similar to that in the lining of the intestines. It is detected in the majority of patients with esophageal and gastroesophageal adenocarcinomas.

HALO Systems (BÂRRX Medical, Inc.) — FDA-approved radiofrequency ablation (RFA) treatment system that utilizes heat to destroy BE tissue lining the inside of the esophagus. RFA is an alternative to esophagectomy or endomucosal resection for high or low-grade esophageal dysplasia.

1. HALO³⁶⁰ System — the HALO³⁶⁰⁺ Ablation Catheter is used to introduce a heated balloon that provides a circumferential (360 degree 3 cm long) ablation of circumferential segments \geq 3cm long. If the heater element is not long enough to cover all of the BE tissue present, the procedure can be repeated at different sites along the esophagus.
2. HALO⁹⁰ System — introduced endoscopically, the HALO⁹⁰ Ablation Catheter is used for the primary treatment of smaller areas (e.g., islands and tongues) or as a secondary treatment after circumferential ablation or other therapeutic devices.

Patients typically undergo BÂRRX therapy as outpatients using conscious sedation. This therapy is administered by a trained gastroenterologist.

Guideline

Members are eligible for RFA coverage for BE dysplasia as follows:

1. High-grade:
 - a. Confirmed by endoscopy
 - b. Life expectancy \geq 1 year
2. Low-grade:
 - a. Confirmed by 2 pathologists

Limitations/Exclusions

1. Repeat RFA may be medically necessary for recurrent high-grade dysplasia.
2. RFA is not considered medically necessary for nondysplastic BE, as it has not been shown to improve health outcomes when coupled with endoscopic surveillance.
3. Coverage is limited to FDA-approved devices.

Applicable Procedure Codes

43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (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)

Applicable Diagnosis Codes

K22.710	Barrett's esophagus with low grade dysplasia
K22.711	Barrett's esophagus with high grade dysplasia

References

1. American Gastroenterological Association. Medical Position Statement on the Management of Barrett's Esophagus. 2011. http://www.gastro.org/practice/medical-position-statements/Barretts_MPS.pdf. Accessed May 12, 2017.
2. BARRX Medical. Healthcare Professionals Page. <http://www.barrx.com/healthcare-professionals/why-treat-barretts-esophagus.php>. Accessed May 12, 2017.
3. U.S. Food and Drug Administration 510(k) Premarket Notification Database. BARRX Medical's HALO360 and HALO360+ Coagulation Catheter. No. K062441. Rockville, MD: FDA. November 14, 2006. http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062441.pdf. Accessed May 12, 2017.
4. U.S. Food and Drug Administration 510(k) Premarket Notification Database. BARRX Medical's HALO360 Energy Generator. No. K082202. Rockville, MD: FDA. October 08, 2008. http://www.accessdata.fda.gov/cdrh_docs/pdf8/K082202.pdf. Accessed May 12, 2017.