BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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RADIOFREQUENCY ABLATION OR CRYOABLATION FOR ESOPHAGEAL DISORDERS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

Description:

Radiofrequency Ablation (RFA):
A minimally invasive procedure in which a bi-polar electrode balloon is placed in the esophagus and inflated using precisely controlled radiofrequency energy to ablate the dysplastic tissue. RFA has been investigated as a treatment for esophageal disorders.

Cryoablation:
A minimally invasive procedure that uses a low-pressure spray to apply liquid nitrogen through an upper endoscope to ablate dysplastic tissue in the esophagus. Cryoablation has been investigated as a treatment for Barrett's esophagus.

Barrett's Esophagus (BE):
A pre-malignant condition in which the esophageal lining is damaged by chronic acid reflux. The normal esophageal lining is replaced with one of a different type referred to as "Barrett's".

Esophageal Dysplasia:
Abnormal esophageal cellular changes that tend to lead to cancer.

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Criteria:

Radiofrequency Ablation (RFA):

- Radiofrequency ablation is considered ***medically necessary*** for Barrett's esophagus (BE) with documentation of **ONE** of the following:

  1. Barrett's esophagus with high-grade dysplasia
  2. Low-grade dysplasia confirmed by two pathologists prior to the RFA

Radiofrequency ablation for the following indications or if above criteria not met is considered ***experimental or investigational*** based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to:*

- Barrett's esophagus without dysplasia
- Esophageal metaplasia
- Esophageal adenocarcinoma

Cryoablation:

- Cryoablation is considered ***experimental or investigational*** for Barrett's esophagus with or without dysplasia based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

RADIOFREQUENCY ABLATION OR CRYOABLATION FOR ESOPHAGEAL DISORDERS (cont.)

Resources:

1. 2.01.80 BCBS Association Medical Policy Reference Manual. Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus. Reissue date 04/10/2014, issue date 12/11/2008.

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RADIOFREQUENCY ABLATION OR CRYOABLATION FOR ESOPHAGEAL DISORDERS (cont.)

Resources: (cont.)

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RADIOFREQUENCY ABLATION OR CRYOABLATION FOR ESOPHAGEAL DISORDERS (cont.)

Resources: (cont.)

25. Pouw RE, Wirths K, Eisendrath P, et al. Efficacy of Radiofrequency Ablation Combined With Endoscopic Resection for Barrett's Esophagus With Early Neoplasia. *Clin Gastroenterol Hepatol.* 2009 Aug 11 2009.

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27. Shaheen, N, J, et al. Quality of Life Following Radiofrequency Ablation of Dysplastic Barrett's Esophagus. *Endoscopy.* 2010;42:790-799.

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RADIOFREQUENCY ABLATION OR CRYOABLATION FOR ESOPHAGEAL DISORDERS (cont.)

Resources: (cont.)

FDA 510K Summary for Electrosurgical, Cutting & Coagulation & Accessories. Device names include, *but are not limited to*:

BARRX HALO 360 System
HALO 360 Coagulation Catheter
HALO 90 Coagulation System

- FDA-approved indication: For use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's esophagus, Dieulafoy Lesions, and Angiodysplasia.

FDA 510K Summary for CryoSpray Ablation System:

- FDA-approved indication: For use as a cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.