

Subject:	<u>Ablative Techniques as a Treatment for Barrett’s Esophagus</u>	Publish Date:	<u>09/04/2019</u>
Guideline #:	<u>CG-SURG-101</u>	Last Review Date:	<u>06/06/2019</u>
Status:	<u>New</u>		

Description

This document addresses the use of the following ablative techniques for treating Barrett’s esophagus: radiofrequency ablation, cryoablation, laser ablation, argon plasma coagulation, and electrocoagulation.

Note: Please see the following related documents for additional information:

- **CG-MED-59 Upper Gastrointestinal Endoscopy in Adults**

Clinical Indications

Medically Necessary:

Radiofrequency ablation or cryoablation treatment of Barrett’s esophagus with high-grade dysplasia (HGD) or intramucosal cancer (IMC) is considered medically necessary as an alternative to esophagectomy in the absence of comorbid conditions that indicate less than one year life expectancy.

Radiofrequency ablation or cryoablation treatment of Barrett’s esophagus with low-grade dysplasia (LGD) is considered medically necessary in the absence of comorbid conditions that indicate less than one year life expectancy with confirmation of the biopsy finding of LGD by two independent physicians.**

Radiofrequency ablation, as an alternative to esophagectomy, is considered medically necessary in individuals with:

- **Barrett’s esophagus with high-grade dysplasia, as confirmed by endoscopy, and**

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue’s standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue’s Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member’s card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

- ~~Life expectancy of one year or greater.~~

~~Radiofrequency ablation is considered medically necessary in individuals with Barrett's esophagus with low-grade dysplasia (LGD) on biopsy with confirmation of the biopsy finding of LGD by two independent physicians.**~~

****Note: The American Gastroenterological Association recommends that LGD should be confirmed by two pathologists since published studies have reported higher rates of progression of LGD when initial readings have been confirmed by expert pathologists, thereby eliminating or minimizing the rate of false positive diagnoses of LGD.**

~~Investigational and~~ Not Medically Necessary:

Radiofrequency ablation as a treatment for Barrett's esophagus is considered ~~investigational and not~~ medically necessary for all other indications.

Cryoablation as a treatment for Barrett's esophagus is considered ~~investigational and not~~ medically necessary for all other indications.

Laser ablation as a treatment for Barrett's esophagus is considered ~~investigational and not~~ medically necessary.

Argon plasma coagulation as a treatment for Barrett's esophagus is considered ~~investigational and not~~ medically necessary.

Electrocoagulation as a treatment for Barrett's esophagus is considered ~~investigational and not~~ medically necessary.

Coding

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett’s Esophagus

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

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) [when specified as radiofrequency ablation or cryoablation]

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) [when specified as radiofrequency ablation or cryoablation]

Note: the above procedure codes are considered not medically necessary for Barrett’s esophagus when specified as ablation other than radiofrequency ablation or cryoablation

ICD-10 Procedure

0D514ZZ

For the following codes when specified as radiofrequency ablation or cryoablation:

Destruction of upper esophagus, percutaneous endoscopic approach

0D518ZZ

Destruction of upper esophagus, via natural or artificial opening endoscopic

0D524ZZ

Destruction of middle esophagus, percutaneous endoscopic approach

0D528ZZ

Destruction of middle esophagus, via natural or artificial opening endoscopic

0D534ZZ

Destruction of lower esophagus, percutaneous endoscopic approach

0D538ZZ

Destruction of lower esophagus, via natural or artificial opening endoscopic

0D544ZZ

Destruction of esophagogastric junction, percutaneous endoscopic approach

0D548ZZ

Destruction of esophagogastric junction, via natural or artificial opening endoscopic

0D554ZZ

Destruction of esophagus, percutaneous endoscopic approach

0D558ZZ

Destruction of esophagus, via natural or artificial opening endoscopic

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue’s standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue’s Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

Note: the above procedure codes are considered not medically necessary for Barrett's esophagus when specified as ablation other than radiofrequency ablation or cryoablation

ICD-10 Diagnosis

C15.5

Malignant neoplasm of lower third of esophagus

C15.8

Malignant neoplasm of overlapping sites of esophagus

C15.9

Malignant neoplasm of esophagus, unspecified

K22.710-K22.719

Barrett's esophagus with dysplasia

Note: Radiofrequency ablation or cryoablation is considered not medically necessary for the following diagnosis:

K22.70

Barrett's esophagus without dysplasia

When services are Investigational and Not Medically Necessary:

For the procedure and diagnosis codes listed above when criteria are not met, for the following diagnosis code, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary:

Discussion/General Information

Barrett's esophagus is a precancerous condition in which a thin layer of tissue lining the lower esophagus is damaged due to chronic acid reflux. The presence of Barrett's esophagus is associated with an increased risk of developing cancer of the esophagus. Surgical treatment options for Barrett's esophagus include but are not necessarily limited to esophagectomy and endoscopic mucosal resection.

Barrett's esophagus occurs as a result of chronic gastroesophageal acid reflux (GERD), a condition that affects approximately 20% of the adult population in the United States. Esophageal cancer frequently arises from untreated Barrett's esophagus. Generally, once precancerous changes are discovered, the lower esophagus is either surgically removed or the lining of the esophagus must be destroyed using endoscopic ablative techniques. Ablative techniques have been developed in an attempt to reverse Barrett's esophagus.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

Ablative techniques can be categorized as heat or cold injury such as electrocoagulation, argon plasma coagulation, radiofrequency ablation, cryoablation and laser ablation (neodymium-yttrium aluminum garnet [Nd:YAG] and potassium titanium phosphate [KTP]) and photochemical injury such as photodynamic therapy.

Radiofrequency Ablation

Radiofrequency ablation is a procedure that uses radio waves and heat to destroy abnormal cells. A balloon catheter containing many small electrodes is placed into the esophagus during endoscopy. After the balloon is inflated, radiofrequency energy is delivered, purportedly removing the diseased tissue lining the esophagus.

Shaheen and colleagues (2009) conducted a multicenter, sham-controlled trial, in which 127 individuals with dysplastic Barrett's esophagus were randomly assigned in a 2:1 ratio to receive either radiofrequency ablation or a sham procedure (control group). Participants were randomized according to the length of Barrett's esophagus and the grade of dysplasia. In the intention-to-treat analyses, among individuals with HGD, complete eradication occurred in 81.0% of those in the ablation group, compared to 19.0% of those in the control group (p<0.001). Among participants with LGD, complete eradication of dysplasia occurred in 90.5% of those in the ablation group, compared to 22.7% of those in the control group (p<0.001). Participants in the ablation group experienced complete eradication of intestinal metaplasia at a rate of 77.4% versus 2.3% of those in the control group (p<0.001). Participants in the ablation group had a lesser amount of disease progression (3.6% vs. 16.3%, p=0.03) and a smaller incidence of cancers (1.2% vs. 9.3%, p=0.045). Chest pain was reported more frequently after the ablation procedure than after the sham procedure. In the ablation group, 5 subjects (6.0%) had esophageal stricture and there was 1 incident of upper gastrointestinal hemorrhage. The authors concluded that in individuals with dysplastic Barrett's esophagus, radiofrequency ablation was associated with a reduced risk of disease progression and a high rate of complete eradication of both dysplasia and intestinal metaplasia. The authors concluded that while the risks and benefits of radiofrequency ablation in participants with Barrett's esophagus and HGD may suggest benefit in terms of both reducing need for esophagectomy and progression to cancer, the evidence at this time seems less compelling in participants with LGD, who are 10 times less likely to progress to cancer, and for whom frequent endoscopic surveillance remains standard treatment practice.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

A multicenter randomized trial by Phoa and colleagues (2014) looked at 136 participants with confirmed diagnosis of Barrett's esophagus with LGD. The participants were randomized to radiofrequency ablation (n=68) or endoscopic surveillance (n=68) (control group). Using a 3-year follow-up period, the participants were followed to determine whether there was neoplastic progression to HGD or adenocarcinoma. Of the participants in the ablation group, complete eradication of dysplasia occurred in 92.6% and 27.9% in the control group.

Haidry and colleagues (2015) looked at 508 individuals with Barrett's esophagus who received radiofrequency ablation with or without endoscopic mucosal resection. Outcomes included the clearance of dysplasia as evidenced by a lack of biopsy-proven residual dysplasia and/or intestinal metaplasia at the end of treatment. The participants were assessed over two time periods (2008-2010 and 2011-2013). A total of 266 participants were assessed at the end of the first time period and 77% of participants achieved clearance of dysplasia while 57% of participants achieved reversal of intestinal metaplasia. By the 12-month follow-up period, 9 participants progressed to invasive cancer and 18 more participants developed invasive cancer by the median follow-up period of 31 months. For the second time period, 242 participants were treated. At the 12-month follow-up, 92% of participants achieved complete reversal of dysplasia and 83% of participants achieved complete reversal of intestinal metaplasia and 2.1% of participants progressed to invasive cancer. While surgical resection is an option, this study supports the use of radiofrequency ablation as an alternative to more invasive surgery with improvements in outcome over time due to improved imaging and skill levels.

Cotton and colleagues (2017) reported the results from a 5-year follow-up analysis that aimed to evaluate the recurrence of Barrett's esophagus in prospectively followed subjects who achieved complete eradication of intestinal metaplasia (CEIM) after radiofrequency ablation as part of a randomized sham-controlled trial. Of 119 subjects, 110 subjects (92%) achieved CEIM. Recurrence of Barrett's esophagus or dysplasia after CEIM occurred in 35 of 110 subjects (32%) and of the 35 occurrences, 24 (75%) occurred in the first year. While there was greater probability of recurrence in the first year, neither Barrett's esophagus or dysplasia recurred at a constant rate. The authors concluded that subjects who remained free of Barrett's esophagus or dysplasia in the first year after radiofrequency ablation had a low risk of recurrence.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

Two retrospective cohort studies were released in 2017 that assessed the recurrence of Barrett's esophagus, metaplasia, and dysplasia after radiofrequency ablation. Guthikonda and colleagues reported that of 306 subjects, 218 (71%) achieved CEIM. Of the 218 subjects, 52 (24%) had recurrence of Barrett's esophagus or metaplasia over 540.6 person-years. Second CEIM was achieved in 30 of the 52 subjects (58%) and 4 subjects (1.8% of total, 7.7% of recurrences) progressed to invasive adenocarcinoma. The authors concluded that in subjects with recurrent Barrett's esophagus, radiofrequency ablation helps most subjects achieve second CEIM. Kahn and colleagues divided 173 subjects into one group of 79 subjects (45.7%) who received radiofrequency ablation and another group of 94 subjects (54.3%) who underwent surveillance. After radiofrequency ablation, 7 subjects (8.9%) progressed to HGD or adenocarcinoma compared to 14 subjects (14.9%) undergoing surveillance (p=0.44). The authors concluded that radiofrequency ablation of Barrett's esophagus with LGD does not significantly reduce HGD or adenocarcinoma when compared to surveillance.

In 2018, Pandey and colleagues published a systematic review and meta-analysis that evaluated the efficacy of radiofrequency ablation in individuals with LGD. The literature search yielded two randomized controlled trials and six observational cohort studies. The studies included a total of 619 individuals with LGD (radiofrequency ablation=404, surveillance=215). Primary outcome measures included the rates of eradication of CEIM and dysplasia. Secondary outcome measures included the recurrence of dysplasia, the rates of progression to HGD or cancer, and adverse events. Follow-up for the eight studies ranged from 12 to 44 months with a median of 26 months. The data showed the overall pooled rates of CEIM and dysplasia after radiofrequency ablation were 88.17% (95% confidence interval [CI], 88.13%-88.20%; p<0.001) and 96.69% (95% CI, 96.67%-96.71%; p<0.001), respectively. Radiofrequency ablation had significantly lower rates of progression to HGD or cancer when compared with surveillance (odds ratio [OR] 0.07, 95% CI, 0.02-0.22). The pooled recurrence rates of intestinal metaplasia and dysplasia were 5.6% (95% CI, 5.57-5.63; p<0.001) and 9.66% (95% CI, 9.61-9.71; p<0.001), respectively. While this study shows positive short-term safety and efficacy outcomes in the use of radiofrequency ablation in individuals with LGD, there are several limitations including retrospective design of some included studies, potential of selection bias in the included retrospective studies, and short-term evaluation in all included studies. Long-term randomized controlled trials are needed to evaluate long-term safety and efficacy of radiofrequency ablation in individuals with LGD.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

In 2011, the American Gastroenterological Association (AGA) released its medical position statement on the management of Barrett's esophagus. They note the difficulty in distinguishing an accurate degree of dysplasia (low-grade, high-grade, or nondysplastic Barrett's esophagus) due to the architecture and aberrancies of the esophagus and that there are no well-defined cut-off points that separate LGD from HGD. The risk of progression from LGD to HGD or adenocarcinoma is not well-known and varies greatly. Rates of progression have been reported as low as 0.22% per year (Bhat, 2011) to 13.4% (AGA, 2011). Despite some variations in determining the risk of progression from LGD to HGD, the AGA report concludes that radiofrequency ablation should be a therapeutic option for those with confirmed LGD in Barrett's esophagus. Radiofrequency ablative therapy for those individuals with Barrett's esophagus with LGD leads to reversion to normal-appearing squamous epithelium in greater than 90% of cases and the reversion can persist for up to 5 years.

In 2016, the American College of Gastroenterology (Shaheen, 2016) recommended endoscopic ablative therapy for individuals with Barrett's esophagus and LGD.

Cryoablation

Cryoablation is another treatment for Barrett's esophagus. This involves the use of low-pressure liquid nitrogen spray being administered through a standard endoscopy to the diseased tissue.

Johnston (2005) reported on a pilot study for a new modality using low-pressure spray cryoablation with endoscopy for individuals with Barrett's esophagus. Eleven participants with Barrett's esophagus were treated with cryoablation. Nine out of the 11 participants completed the protocol and reversal of Barrett's esophagus was achieved in all 9 individuals with cryoablation and high-dose proton pump inhibitor. During the 6-month follow-up surveillance endoscopy, 2 of the 9 participants developed intestinal metaplasia. Eradication of the Barrett's esophagus was achieved in 7 of the 9 participants (78%) who completed the protocol. With intention-to-treat analysis, eradication of Barrett's esophagus was achieved in 64% of participants. It must be noted that the primary author of this study is the inventor of the described device.

In 2009, Dumot and colleagues published the results of an open-label prospective study of cryoablation for Barrett's esophagus. The purpose of the study was to 1) determine whether cryoablation is safe for the

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

treatment of Barrett's esophagus with dysplasia and neoplasia and 2) determine whether efficacy is sufficient enough to warrant evaluation in larger studies. Thirty participants received cryoablation for treatment of high-grade dysplasia Barrett's esophagus or intramucosal carcinoma. Responses were achieved in 27 of the 30 participants (90%). With a median follow-up of 12 months, 68% of participants with HGD and 80% of participants with intramural carcinoma had persistent responses to treatment. The authors concluded that "further study with long-term follow-up is necessary and is currently under way to determine the role of cryoablation in the endoscopists' armamentarium."

In a prospective study, Greenwald (2010) reported on the safety, tolerability and efficacy of cryoablation. A total of 77 individuals were enrolled and received cryoablation for diagnoses of metaplasia, LGD, HGD, intramucosal carcinoma, invasive carcinoma, and severe squamous dysplasia. Of the 17 individuals with HGD who had completed therapy, 94% had complete eradication. Overall the cryoablation was well tolerated. The most common complaint was mild chest pain or discomfort (reported in 13.9% of the procedures). Other complaints included severe chest pain (3.7%), dysphagia (13.3%), odynophagia (12.1%) and sore throat (9.6%).

Shaheen (2010) reported on a retrospective analysis of 98 subjects who underwent cryoablation for Barrett's esophagus and HGD. Of the 98 subjects enrolled in the study, 60 completed all planned cryoablation treatments. Fifty-eight participants (97%) had complete eradication of HGD. No serious adverse events were reported. The study is limited by short follow-up of 10.5 months, no randomization, and retrospective nature without a control group.

In 2017, Künzli and colleagues published a prospective trial to study the efficacy and performance of cryoablation in subjects with flat dysplastic Barrett's esophagus. Out of 30 subjects enrolled in the trial, 29 subjects completed the trial with a total of 42 of the 44 identified Barrett's esophagus areas (95%) being fully eradicated of intestinal metaplasia and dysplasia through ablation. Some limitations include inclusion of subjects with previous treatment with radiofrequency ablation, a small sample size, the lack of randomization, and a lack of controls. The authors note that the extent of the Barrett's esophagus areas treated were limited and further research is needed in cryoablation and subjects with more extensive Barrett's esophagus segments.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

In 2018, Visrodia and colleagues reported on a systematic review and meta-analysis that evaluated the efficacy of second-line cryoablation in individuals with Barrett's esophagus who have persistent dysplasia or intestinal metaplasia after radiofrequency ablation. The literature search yielded 11 studies with a total of 148 participants. Of the 11 studies, 7 were retrospective, 3 were prospective, and 1 did not report the study design. The number of individuals enrolled in each study ranged from 5 individuals to 47 individuals. Two of the studies were multicenter, and 9 of the studies were conducted at single centers. The authors found "the pooled proportion of CE-D was 76.0% (95% CI, 57.7-88.0), with substantial heterogeneity ($I^2 = 62\%$). The pooled proportion of CE-IM was 45.9% (95% CI, 32.0-60.5) with moderate heterogeneity ($I^2 = 57\%$). Multiple preplanned subgroup analyses did not sufficiently explain the heterogeneity" (Visrodia, 2018). These results suggest cryoablation as a viable second-line option in individuals with Barrett's esophagus who have persistent dysplasia or intestinal metaplasia after radiofrequency ablation.

Another systematic review and meta-analysis on cryoablation was published in 2019 by Mohan and colleagues. The authors aimed to assess the overall efficacy and safety of cryoablation using liquid nitrogen as a treatment option for Barrett's esophagus. A total of 9 studies with 386 participants were included in the final meta-analysis. There were 6 retrospective studies and 3 prospective studies with number of participants ranging from 16 to 81 participants. Four studies were conducted at a single center and five studies were multicenter. The authors found that "the pooled rate of CE-IM was 56.5% (95% CI 48.5–64.2, $I^2 = 47$), pooled rate of CE-D was 83.5% (95% CI 78.3–87.7, $I^2 = 22.8$), and pooled rate of CE-HGD was 86.5% (95% CI 64.4–95.8, $I^2 = 88.1$). Rate of adverse events was 4.7%, and the risk of Barrett's esophagus recurrence was 12.7%" (Mohan, 2019). The findings of this meta-analysis show that cryoablation using liquid nitrogen as a treatment option for Barrett's esophagus has positive results with a low risk of adverse events.

Laser Ablation

Laser ablation involves the use of high-intensity light to treat cancer. For the esophagus, Nd:YAG lasers are applied through an endoscope, the light is precisely aimed at the diseased tissue, which is destroyed.

Weston and colleagues (2002) reported on the safety and efficacy of laser ablation of Barrett's esophagus and HGD. Seventeen participants received laser ablation therapy for high-grade dysplasia. Three participants

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

exited the study. Of the 14 participants who remained in the study, all had successful eradication of their HGD and/or cancer. Eleven participants achieved histologic and endoscopic ablation of all Barrett's esophageal tissue. Seven of the 11 participants with complete ablation had subsequent follow-up ranging from 2-36 months. Four of the 7 participants demonstrated regrowth, 2 were successfully treated with an electro-surgical generator and 2 were successfully treated with laser ablation. While treatment appears promising, the authors conclude "there is a need for additional controlled trials with a larger number of patients and longer follow-up, as well as for consideration of a head-to-head trial with Photofrin PDT."

In 2004, Norberto and colleagues reported on 15 individuals with Barrett's esophagus who underwent laser ablation treatment. The individuals received laser therapy sessions for the first 3 months then every 3 months during the first year of treatment. Therapy continued until the Barrett's esophagus was completely eradicated. Follow-up ranged from 7-61 months. Complete regression was achieved in 6 of the 15 individuals (40%).

Argon Plasma Coagulation

Argon plasma coagulation is a non-contact thermal method of delivering an electrical current by way of argon gas to the targeted tissue. The argon gas flows through a catheter that is passed through an endoscope. When the argon gas flows over the electrode it becomes ionized. A spark ionizes the argon gas as it is sprayed from the tip of the catheter in the direction of the targeted tissue and produces tissue coagulation. Argon plasma coagulation allows for treatment of a large surface area.

In 2007, Mork and colleagues reported on 25 individuals who received argon plasma coagulation and a proton-pump inhibitor prior to and following the ablation procedure. The individuals received endoscopic surveillance every 3 months during the first year following complete eradication of the glandular epithelium and continuing for 51 months. Recurrence of Barrett's esophagus was detected in 14 of the 25 individuals. Four individuals were lost during the study: 1 was excluded for compliance issues, 1 refused further argon plasma coagulation sessions and 2 others had only incomplete squamous restoration after 3 and 4 treatment sessions. One individual had relapse of Barrett's esophagus 3 times and was retreated 11 times, eventually having a fundoplication. Seven individuals had no recurrence during the follow-up period. Seven individuals had the first recurrence of Barrett's esophagus detectable by microscope. Seven individuals had relapse

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

detectable endoscopically and histologically during the same endoscopy. This study demonstrated a relapse rate of approximately two-thirds after argon plasma eradication of Barrett's esophagus. Success rates may be dependent on the thermic energy applied and the proton pump inhibitor schedule. Higher energy may carry more risks, but no standards have been established for this procedure yet.

Formentini (2007) reported on a retrospective analysis of the efficacy of ablation of Barrett's esophagus using argon plasma coagulation followed by fundoplication. Twenty-one individuals met study criteria. All individuals received argon plasma coagulation treatments approximately every 4-6 weeks until the metaplastic epithelium was ablated. Then all individuals underwent Nissen fundoplication. Response to treatment was measured every 6-12 months. Recurrence of Barrett's esophagus was observed in 6 of the 17 participants. Five of the 6 participants had ablation by argon plasma coagulation (1 participant refused) and were disease-free at the time of publication. The authors acknowledge that "further studies are required to clarify the role of ablation's procedure in the treatment of BE."

Bright (2009) reported on a randomized controlled trial which compared 57 participants with Barrett's esophagus to undergo argon plasma coagulation to annual endoscopic surveillance. Another endoscopy with biopsy was scheduled at 12 months for both groups of participants. The biopsies were examined by a pathologist who was unaware of the previous treatment (argon plasma coagulation or surveillance). At 12 months, 14 out of 23 participants who had received argon plasma coagulation showed at least 95% ablation of the metaplastic mucosa and 9 participants had complete regression of Barrett's esophagus. None of the individuals who had surveillance endoscopy had more than 95% regression. While these results look promising, ablation with argon plasma coagulation is more time-consuming than routine surveillance endoscopy, participants who have had argon plasma coagulation still need endoscopic surveillance and in this particular study, at least some of the metaplastic columnar mucosa recurred during the first 12 months. It is not possible to predict which individuals will have recurrence and the outcomes at 12 months were not as good as immediately following the treatment. The authors have concluded that argon plasma coagulation "should probably remain within clinical trials."

Manner and colleagues (2014) reported on 63 participants who had been curatively resected of Barrett's neoplasia by endoscopy and were randomized to receive either argon plasma coagulation (n=33) or

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

surveillance only (n=30). The primary outcome was recurrence-free survival. During the follow-up period of 2 years, in the ablation group 1 secondary lesion was found and 11 secondary lesions were found in the surveillance group. While the results showed fewer secondary lesions following argon plasma coagulation, this study was limited by its small group size and according to the authors a "limited follow-up of 2 years."

Electrocoagulation

Electrocoagulation uses a fine wire probe to deliver radio waves to tissues near the probe. The radio waves cause the tissue to vibrate which increases temperature causing coagulation and leading to destruction of the tissue. Electrocoagulation can be either monopolar or bipolar. For individuals with an implantable device such as a pacemaker or automatic defibrillator, bipolar is the preferred method because the electrical current does not travel beyond the depth of thermal injury and disrupt the programming of these devices.

In 1999, Sharma and colleagues reported on 6 individuals with Barrett's esophagus who received laser treatment and electrocoagulation. The number of electrocoagulation sessions ranged from 1-5. Follow-up ranged from 9-86 months. Complete ablation was achieved. The authors concluded that "Despite the success achieved in this group of patients, the use of such therapy as an alternative to surgery in all patients with early Barrett's cancer is not currently recommended."

At this time, the gastroenterological societies (American College of Gastroenterology, AGA and American Society of Gastrointestinal Endoscopy) do not have guidelines or position statements endorsing laser ablation, argon plasma ablation or electrocoagulation as a treatment for Barrett's esophagus. Current literature consists primarily of uncontrolled, small studies, with only a limited number of randomized controlled trials comparing treatments for Barrett's esophagus. While these endoscopic techniques are promising in terms of treating Barrett's esophagus, few long-term results are available (Li, 2008). The authors of a Cochrane review in 2010 concluded that ablative therapies have a role in the management of Barrett's esophagus, however; "more clinical trial data and in particular randomized controlled trials are required to assess whether or not the cancer risk is reduced in routine clinical practice."

Other Considerations

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

The American Society for Gastrointestinal Endoscopy (ASGE) (Wani, 2018) published guidelines on endoscopic eradication therapy (EET) for individuals with Barrett's esophagus-associated dysplasia and IMC. The following is a summary of the ASGE recommendations:

- **In Barrett's esophagus patients with LGD and HGD being considered for EET, we suggest confirmation of diagnosis by at least 1 expert GI pathologist or panel of pathologists compared with review by a single pathologist (Strength of recommendation: Conditional; Quality of evidence: Low).**
- **In Barrett's esophagus patients with LGD, we suggest EET compared with surveillance; however, patients who place a high value on avoiding adverse events related to EET may choose surveillance as the preferred option (Strength of recommendation: Conditional; Quality of evidence: Moderate).**
- **In Barrett's esophagus patients with confirmed HGD, we recommend EET compared with surveillance (Strength of recommendation: Strong; Quality of evidence: Moderate).**
- **In Barrett's esophagus patients with HGD/IMC, we recommend against surgery compared with EET (Strength of recommendation: Strong; Quality of evidence: Very low quality evidence).**
- **In Barrett's esophagus patients referred for EET, we recommend endoscopic resection of all visible lesions compared with no endoscopic resection of visible lesions (Strength of recommendation: Strong; Quality of evidence: Moderate).**
- **In Barrett's esophagus patients with visible lesions who undergo endoscopic resection, we suggest ablation of the remaining Barrett's segment compared with no ablation (Strength of recommendation: Conditional; Quality of evidence: Low).**
- **In Barrett's esophagus patients with dysplasia and IMC referred for EET, we recommend against routine complete endoscopic resection of entire Barrett's segment compared with endoscopic resection of visible lesion followed by ablation of remaining Barrett's segment (Strength of recommendation: Strong; Quality of evidence: Very low).**

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

- **In Barrett's esophagus patients with dysplasia and IMC who have achieved CEIM after EET, we suggest surveillance endoscopy versus no surveillance (Strength of recommendation: Conditional; Quality of evidence: Very low).**

The ASGE states EET "entails endoscopic mucosal resection (EMR) of visible lesions within the Barrett's segment and ablative techniques that include radiofrequency ablation (RFA) and cryotherapy" (Wani, 2018). In addition to combining several treatments as one management approach to Barrett's esophagus, the guideline is mostly based on moderate and low quality evidence.

Definitions

Argon plasma coagulation: A non-contact thermal technique which uses ionized argon gas to deliver a high-frequency current which coagulates tissue.

Barrett's esophagus: A complication due to chronic severe gastroesophageal reflux disease (GERD), in which the cells that line the esophagus near the stomach become pre-cancerous; resulting in an increased risk of cancer of the esophagus (adenocarcinoma).

Cryoablation: A technique which removes cancerous tissue by killing it with extreme cold.

Electrocoagulation: The use of thermal energy to destroy abnormal tissue.

Endoscopic mucosal resection (EMR): A surgical technique in which fluid is injected into the submucosa, (the layer of the gastrointestinal tract immediately below the mucosa), to elevate the mucosa and allow it to be grabbed with a snare.

Esophagectomy: The surgical removal of a portion of the esophagus; the remaining esophagus is reattached to the stomach so the individual can still swallow.

Laser ablation: The use of high intensity light to treat cancer and other illnesses.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

References**Peer Reviewed Publications:**

1. **Beaumont H, Gondrie JJ, McMahon BP, et al. Stepwise radiofrequency ablation of Barrett's esophagus preserves esophageal inner diameter, compliance, and motility. Endoscopy. 2009; 41(1):2-8.**
2. **Bhat S, Coleman HG, Yousef F, et al. Risk of malignant progression in Barrett's esophagus patients: results from a large population-based study. J Natl Cancer Inst. 2011; 103(13):1049-1057.**
3. **Birkmyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. N Engl J Med. 2002; 346(15):1128-1137.**
4. **Bright T, Watson DI, Tam W, et al. Prospective randomized trial of argon plasma coagulation ablation versus endoscopic surveillance of Barrett's esophagus in patients treated with antisecretory medication. Dig Dis Sci. 2009; 54(12):2606-2611.**
5. **Cotton CC, Wolf WA, Overholt BF, et al. Late recurrence of Barrett's esophagus after complete eradication of intestinal metaplasia is rare: final report from ablation in intestinal metaplasia containing dysplasia trial. Gastroenterology. 2017; 153(3):681-688.e2.**
6. **Dumot JA, Greenwald BD. Argon plasma coagulation, bipolar cautery, and cryotherapy: ABC's of ablative techniques. Endoscopy. 2008; 40(12):1026-1032.**
7. **Dumot JA, Vargo JJ 2nd, Falk GW, et al. An open-label, prospective trial of cryospray ablation for Barrett's esophagus high-grade dysplasia and early esophageal cancer in high-risk patients. Gastrointest Endosc. 2009; 70(4):635-644.**
8. **Eldaif SM, Lin E, Singh KA, et al. Radiofrequency ablation of Barrett's esophagus: short-term results. Ann Thorac Surg. 2009; 87(2):405-410.**
9. **Fleischer DE, Overholt BF, Sharma VK, et al. Endoscopic ablation of Barrett's esophagus: a multicenter study with 2.5-year follow-up. Gastrointest Endosc. 2008; 68(5):867-876.**
10. **Formentini A, Schwarz A, Straeter J, et al. Treatment of Barrett's esophagus with argon plasma coagulation and antireflux surgery. A retrospective analysis. Hepatogastroenterology. 2007; 54(79):1991-1996.**
11. **Greenwald BD, Dumot JA, Horwhat JD, et al. Safety, tolerability, and efficacy of endoscopic low-pressure liquid nitrogen spray cryotherapy in the esophagus. Dis Esophagus. 2010; 23(1):13-19.**

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

12. Guthikonda A, Cotton CC, Madanick RD, et al. Clinical outcomes following recurrence of intestinal metaplasia after successful treatment of Barrett's esophagus with radiofrequency ablation. Am J Gastroenterol. 2017; 112(1):87-94.
13. Haidry RJ, Butt MA, Dunn JM, et al. Improvement over time in outcomes for patients undergoing endoscopic therapy for Barrett's oesophagus-related neoplasia: 6-year experience from the first 500 patients treated in the UK patient registry. Gut. 2015; (8):1192-1199.
14. Hubbard N, Velanovich V. Endoscopic endoluminal radiofrequency ablation of Barrett's esophagus in patients with funduplications. Surg Endosc. 2007; 21(4):625-628.
15. Johnston MH, Eastone JA, Horwhat JD, et al. Cryoablation of Barrett's esophagus: a pilot study. Gastrointest Endosc. 2005; 62(6):842-848.
16. Kahn A, Al-Qaisi M, Kommineni VT, et al. Longitudinal outcomes of radiofrequency ablation versus surveillance endoscopy for Barrett's esophagus with low-grade dysplasia. Dis Esophagus. 2017; [Epub ahead of print].
17. Künzli HT, Schölvinck DW, Meijer SL, et al. Efficacy of the cryoballoon focal ablation system for the eradication of dysplastic Barrett's esophagus islands. Endoscopy. 2017; 49(2):169-175.
18. Li YM, Li L, Yu CH, et al. A systematic review and meta-analysis of the treatment for Barrett's esophagus. Dig Dis Sci. 2008; 53(11):2837-2846.
19. Manner H, Rabenstein T, Pech O, et al. Ablation of residual Barrett's epithelium after endoscopic resection: a randomized long-term follow-up study of argon plasma coagulation vs. surveillance (APE study). Endoscopy. 2014; 46(1):6-12.
20. Mohan BP, Krishnamoorthi R, Ponnada S, et al. Liquid nitrogen spray cryotherapy in treatment of Barrett's esophagus, where do we stand? A systematic review and meta-analysis. Dis Esophagus. 2019 Jan 31; [Epub ahead of print]. Available at: <https://academic.oup.com/dote/advance-article-abstract/doi/10.1093/dote/doy130/5304729?redirectedFrom=fulltext>. Accessed on May 7, 2019.
21. Mörk H, Al-Taie O, Berlin F, et al. High recurrence rate of Barrett's epithelium during long-term follow-up after argon plasma coagulation. Scand J Gastroenterol. 2007; 42(1):23-27.
22. Norberto L, Polese L, Angriman I, et al. High-energy laser therapy of Barrett's esophagus: preliminary results. World J Surg. 2004; 28(4):350-354.
23. Orman ES, Li N, Shaheen NJ. Efficacy and durability of radiofrequency ablation for Barrett's Esophagus: systematic review and meta-analysis. Clin Gastroenterol Hepatol. 2013; (10):1245-1255.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett's Esophagus

24. Pandey G, Mulla M, Lewis WG, et al. Systematic review and meta-analysis of the effectiveness of radiofrequency ablation in low grade dysplastic Barrett's esophagus. *Endoscopy*. 2018; 50(10):953-960.
25. Phoa KN, van Vilsteren FG, Weusten BL, et al. Radiofrequency ablation vs endoscopic surveillance for patients with Barrett esophagus and low-grade dysplasia: a randomized clinical trial. *JAMA*. 2014; 311(12):1209-1217.
26. Pouw RE, Gondrie JJ, Sondermeijer CM, et al. Eradication of Barrett esophagus with early neoplasia by radiofrequency ablation, with or without endoscopic resection. *J Gastrointest Surg*. 2008; 12(10):1627-1636.
27. Roorda AK, Marcus SN, Triadafilopoulos G. Early experience with radiofrequency energy ablation therapy for Barrett's esophagus with and without dysplasia. *Dis Esophagus*. 2007; 20(6):516-522.
28. Shaheen NJ, Greenwald BD, Peery AF, et al. Safety and efficacy of endoscopic spray cryotherapy for Barrett's esophagus with high-grade dysplasia. *Gastrointest Endosc*. 2010; 71(4):680-685.
29. Shaheen NJ, Sharma P, Overholt BF, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. *N Engl J Med*. 2009; 360(22):2277-2288.
30. Sharma P, Jaffe PE, Bhattacharyya A, Sampliner RE. Laser and multipolar electrocoagulation ablation of early Barrett's adenocarcinoma: long-term follow-up. *Gastrointest Endosc*. 1999; 49(4 Pt 1):442-446.
31. Sharma P, Wani S, Weston AP, et al. A randomised controlled trial of ablation of Barrett's oesophagus with multipolar electrocoagulation versus argon plasma coagulation in combination with acid suppression: long term results. *Gut*. 2006; 55(9):1233-1239.
32. Visrodia K, Zakko L, Singh S, et al. Cryotherapy for persistent Barrett's esophagus after radiofrequency ablation: a systematic review and meta-analysis. *Gastrointest Endosc*. 2018; 87(6):1396-1404.
33. Weston AP, Sharma P. Neodymium:yttrium-aluminum garnet contact laser ablation of Barrett's high grade dysplasia and early adenocarcinoma. *Am J Gastroenterol*. 2002; 97(12):2998-3006.
34. Wolfsen HC. Endoprevention of esophageal cancer: endoscopic ablation of Barrett's metaplasia and dysplasia. *Expert Rev Med Devices*. 2005; 2(6):713-723.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Gastroenterological Association, Spechler SJ, Sharma P, et al. American Gastroenterological Association medical position statement on the management of Barrett's esophagus. *Gastroenterology*. 2011; 140(3):1084-1091.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Ablative Techniques as a Treatment for Barrett’s Esophagus

2. American Society for Gastrointestinal Endoscopy Technology Committee. Mucosal ablation devices. *Gastrointest Endosc.* 2008; 68(6):1031-1042.
3. Blue Cross Blue Shield Association. Radiofrequency ablation of nondysplastic and low-grade dysplastic Barrett’s esophagus. *TEC Assessment*, 2010; 27(3).
4. Rees JRE, Lao-Sirieix P, Wong A, Fitzgerald RC. Treatment for Barrett's oesophagus. *Cochrane Database Syst Rev.* 2013;(6):CD004060.
5. Shaheen NJ, Falk GW, Iyer PG, et al. ACG clinical guideline: diagnosis and management of Barrett’s esophagus. *Am J Gastroenterol.* 2016; 111(1):30-50.
6. Wani S, Qumseya B, Sultan S, et al. Endoscopic eradication therapy for patients with Barrett's esophagus-associated dysplasia and intramucosal cancer: American Society for Gastrointestinal Endoscopy, Standards of Practice Committee. *Gastrointest Endosc.* 2018; 87(4):907-931.

Index

- Argon plasma coagulation
- Barrett’s esophagus
- Cryoablation
- Electrocoagulation
- Laser ablation
- Radiofrequency ablation

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

<u>Status</u>	<u>Date</u>	<u>Action</u>
<u>New</u>	<u>06/06/2019</u>	<u>Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of SURG.00106 Ablative Techniques as a Treatment for Barrett’s Esophagus to new clinical</u>

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue’s standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue’s Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member’s card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

utilization management guideline document with the same title. Revised Medically Necessary indications to include IMC and updated Coding to include ICD-10-CM codes C15.5, C15.8-C15.9. Added added cryoablation to Medically Necessary criteria. Updated Coding section to include ICD-10-CM codes C15.5, C15.8-C15.9.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.