BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 01/17/23**
SECTION: MEDICINE	**LAST REVIEW DATE: 01/02/24**
	CURRENT EFFECTIVE DATE: 01/02/24
	LAST CRITERIA REVISION DATE: 01/17/23
NEXT ANNUAL REVIEW DATE: 1ST QTR 2025	**ARCHIVE DATE:**

ENDOSCOPIC RADIOFREQUENCY ABLATION OR CRYOABLATION FOR BARRETT ESOPHAGUS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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

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

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

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

In Barrett esophagus (BE), the normal squamous epithelium is replaced by specialized columnar-type epithelium, known as intestinal metaplasia. Intestinal metaplasia is a precursor to adenocarcinoma and may be treated with mucosal ablation techniques such as radiofrequency ablation (RFA) or cryoablation.

Management of Barrett Esophagus
The management of Barrett Esophagus (BE) includes the treatment of gastroesophageal reflux disease and surveillance endoscopy to detect progression to high-grade dysplasia (HGD) or adenocarcinoma. The finding of HGD or early-stage adenocarcinoma warrants mucosal ablation or resection (either endoscopic mucosal resection [EMR] or esophagectomy).

Radiofrequency ablation for Barrett esophagus with high-grade dysplasia (HGD) may be used in combination with endoscopic mucosal resection (EMR) of nodular or visible lesions. The diagnosis of HGD should be confirmed by 2 pathologists before initiating radiofrequency ablation. The American Society for Gastrointestinal Endoscopy and the American Gastroenterological Association both recommend that a reading of HGD should be confirmed by an experienced gastrointestinal pathologist. Two cohort studies found that reevaluation of HGD after an initial evaluation resulted in 40% to 53% of individuals receiving a lower-grade evaluation on repeat endoscopy, highlighting the need for confirmation by an expert center. Additionally for HGD, it is important to rule out adenocarcinoma; referral to an expert center that can conduct high-definition white-light endoscopy and other diagnostic techniques has been found to increase the rate of adenocarcinoma detection and proper referral for EMR.

There is considerable interobserver variability in the diagnosis of low-grade dysplasia (LGD), and the potential exists for overdiagnosis of LGD by nonexpert pathologists (overdiagnosis is due primarily to the difficulty in distinguishing inflammatory changes from LGD). There is evidence in the literature that expert gastrointestinal pathologists will downgrade a substantial portion of biopsies that are initially read as LGD by nonexperts. As a result, it is ideal that 2 experts in gastrointestinal pathology agree on the diagnosis to confirm LGD; this may result in greater than 75% of initial diagnoses of LGD being downgraded to nondysplasia. A review by a single expert gastrointestinal pathologist will also result in a large number of LGD diagnoses being downgraded, although probably not as many as achieved using 2 expert pathologists.

Radiofrequency ablation (RFA):
A minimally invasive procedure in which a bi-polar electrode balloon is placed in the esophagus and inflated using precisely controlled radiofrequency energy to ablate the dysplastic tissue.

Cryoablation:
A minimally invasive procedure that uses a low-pressure spray to apply liquid nitrogen through an upper endoscope to ablate dysplastic tissue in the esophagus.

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Criteria:

- Radiofrequency ablation for the treatment of Barrett esophagus with high-grade dysplasia is considered ***medically necessary***.

- Radiofrequency ablation for the treatment of Barrett esophagus with low-grade dysplasia, when the initial diagnosis of low-grade dysplasia is confirmed by 2 pathologists is considered ***medically necessary***.

- Radiofrequency ablation for the treatment of Barrett esophagus when the above criteria are not met, including but not limited to Barrett esophagus in the absence of dysplasia is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

    1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
    2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
    3. Insufficient evidence to support improvement of the net health outcome; or
    4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
    5. Insufficient evidence to support improvement outside the investigational setting.

- Cryoablation for the treatment of Barrett esophagus, with or without dysplasia is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

    1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
    2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
    3. Insufficient evidence to support improvement of the net health outcome; or
    4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
    5. Insufficient evidence to support improvement outside the investigational setting.

ENDOSCOPIC RADIOFREQUENCY ABLATION OR CRYOABLATION FOR BARRETT ESOPHAGUS

Resources:

Literature reviewed 01/02/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 01/17/23 may be requested from the BCBSAZ Medical Policy and Technology Research Department..

1. Agarwal S, Alshelleh M, Scott J, et al. Comparative outcomes of radiofrequency ablation and cryoballoon ablation in dysplastic Barrett's esophagus: a propensity score-matched cohort study. *Gastrointest Endosc*. Mar 2022;95(3):422-431 e2. doi:10.1016/j.gie.2021.09.037

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*. Jul 6 2011;103(13):1049-57. doi:10.1093/jnci/djr203

3. Chadwick G, Groene O, Markar SR, Hoare J, Cromwell D, Hanna GB. Systematic review comparing radiofrequency ablation and complete endoscopic resection in treating dysplastic Barrett's esophagus: a critical assessment of histologic outcomes and adverse events. *Gastrointest Endosc*. May 2014;79(5):718-731.e3. doi:10.1016/j.gie.2013.11.030

4. Curvers WL, ten Kate FJ, Krishnadath KK, et al. Low-grade dysplasia in Barrett's esophagus: overdiagnosed and underestimated. *Am J Gastroenterol*. Jul 2010;105(7):1523-30. doi:10.1038/ajg.2010.171

5. Downs-Kelly E, Mendelin JE, Bennett AE, et al. Poor interobserver agreement in the distinction of high-grade dysplasia and adenocarcinoma in pretreatment Barrett's esophagus biopsies. *Am J Gastroenterol*. Sep 2008;103(9):2333-40; quiz 2341. doi:10.1111/j.1572-0241.2008.02020.x

6. Duits LC, Phoa KN, Curvers WL, et al. Barrett's oesophagus patients with low-grade dysplasia can be accurately risk-stratified after histological review by an expert pathology panel. *Gut*. May 2015;64(5):700-6. doi:10.1136/gutjnl-2014-307278

7. Dumot JA, Vargo JJ, 2nd, Falk GW, Frey L, Lopez R, Rice TW. 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*. Oct 2009;70(4):635-44. doi:10.1016/j.gie.2009.02.006

8. Ell C, May A, Pech O, et al. Curative endoscopic resection of early esophageal adenocarcinomas (Barrett's cancer). *Gastrointest Endosc*. Jan 2007;65(1):3-10. doi:10.1016/j.gie.2006.04.033

9. Eloubeidi MA, Wallace MB, Hoffman BJ, et al. Predictors of survival for esophageal cancer patients with and without celiac axis lymphadenopathy: impact of staging endosonography. *Ann Thorac Surg*. Jul 2001;72(1):212-9; discussion 219-20. doi:10.1016/s0003-4975(01)02616-9

10. Fasullo M, Shah T, Patel M, et al. Outcomes of Radiofrequency Ablation Compared to Liquid Nitrogen Spray Cryotherapy for the Eradication of Dysplasia in Barrett's Esophagus. *Dig Dis Sci*. Jun 2022;67(6):2320-2326. doi:10.1007/s10620-021-06991-7

11. 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*. Nov 2008;68(5):867-76. doi:10.1016/j.gie.2008.03.008

12. Fleischer DE, Overholt BF, Sharma VK, et al. Endoscopic radiofrequency ablation for Barrett's esophagus: 5-year outcomes from a prospective multicenter trial. *Endoscopy*. Oct 2010;42(10):781-9. doi:10.1055/s-0030-1255779

13. Ganz RA, Overholt BF, Sharma VK, et al. Circumferential ablation of Barrett's esophagus that contains high-grade dysplasia: a U.S. Multicenter Registry. *Gastrointest Endosc*. Jul 2008;68(1):35-40. doi:10.1016/j.gie.2007.12.015

14. Hamade N, Desai M, Thoguluva Chandrasekar V, et al. Efficacy of cryotherapy as first line therapy in patients with Barrett's neoplasia: a systematic review and pooled analysis. *Dis Esophagus*. Dec 30 2019;32(11)doi:10.1093/dote/doz040

15. Hvid-Jensen F, Pedersen L, Drewes AM, Sørensen HT, Funch-Jensen P. Incidence of adenocarcinoma among patients with Barrett's esophagus. *N Engl J Med*. Oct 13 2011;365(15):1375-83. doi:10.1056/NEJMoa1103042

16. Kerkhof M, van Dekken H, Steyerberg EW, et al. Grading of dysplasia in Barrett's oesophagus: substantial interobserver variation between general and gastrointestinal pathologists. *Histopathology*. Jun 2007;50(7):920-7. doi:10.1111/j.1365-2559.2007.02706.x

17. Klair JS, Zafar Y, Nagra N, et al. Outcomes of Radiofrequency Ablation versus Endoscopic Surveillance for Barrett's Esophagus with Low-Grade Dysplasia: A Systematic Review and Meta-Analysis. *Dig Dis*. 2021;39(6):561-568. doi:10.1159/000514786

18. NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers. Version 4.2022. National Comprehensive Cancer Network. Accessed September 14, 2023. https://www.nccn.org/professionals/physician_gls/PDF/esophageal.pdf

19. Overholt BF, Lightdale CJ, Wang KK, et al. Photodynamic therapy with porfimer sodium for ablation of high-grade dysplasia in Barrett's esophagus: international, partially blinded, randomized phase III trial. *Gastrointest Endosc*. Oct 2005;62(4):488-98. doi:10.1016/j.gie.2005.06.047

20. Pandey G, Mulla M, Lewis WG, Foliaki A, Chan DSY. Systematic review and meta-analysis of the effectiveness of radiofrequency ablation in low grade dysplastic Barrett's esophagus. *Endoscopy*. Oct 2018;50(10):953-960. doi:10.1055/a-0588-5151

21. Pech O, Ell C. Endoscopic therapy of Barrett's esophagus. *Curr Opin Gastroenterol*. Sep 2009;25(5):405-11. doi:10.1097/MOG.0b013e32832d9b71

22. Pentax Medical. Pentax Medical Introduces Next-Generation C2 Cryoballoon Ablation System for Treatment of Barrett's Esophagus. Accessed September 14, 2023. https://www.pentaxmedical.com/pentax/en/99/1/PENTAX-MEDICAL-INTRODUCES-NEXT-GENERATION-C2-CRYOBALLOON-ABLATION-SYSTEM-FOR-TREATMENT-OF-BARRETTS-ESOPHAGUS

23. Phoa KN, Pouw RE, Bisschops R, et al. Multimodality endoscopic eradication for neoplastic Barrett oesophagus: results of an European multicentre study (EURO-II). *Gut*. Apr 2016;65(4):555-62. doi:10.1136/gutjnl-2015-309298

24. 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*. Mar 26 2014;311(12):1209-17. doi:10.1001/jama.2014.2511

25. Radiofrequency ablation of nondysplastic or low-grade dysplastic Barretts esophagus TEC Assessments. 2010;25:Tab 5. Located at: Blue Cross Blue Shield Association Technology Evaluation Center (TEC), Chicago, USA.

26. Sengupta N, Ketwaroo GA, Bak DM, et al. Salvage cryotherapy after failed radiofrequency ablation for Barrett's esophagus-related dysplasia is safe and effective. *Gastrointest Endosc*. Sep 2015;82(3):443-8. doi:10.1016/j.gie.2015.01.033

27. Shaheen NJ, Falk GW, Iyer PG, et al. Diagnosis and Management of Barrett's Esophagus: An Updated ACG Guideline. *Am J Gastroenterol*. Apr 1 2022;117(4):559-587. doi:10.14309/ajg.0000000000001680

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*. Apr 2010;71(4):680-5. doi:10.1016/j.gie.2010.01.018

29. Shaheen NJ, Overholt BF, Sampliner RE, et al. Durability of radiofrequency ablation in Barrett's esophagus with dysplasia. *Gastroenterology*. Aug 2011;141(2):460-8. doi:10.1053/j.gastro.2011.04.061

30. Shaheen NJ, Sharma P, Overholt BF, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. *N Engl J Med*. May 28 2009;360(22):2277-88. doi:10.1056/NEJMoa0808145

31. Sharma P, Shaheen NJ, Katzka D, Bergman J. AGA Clinical Practice Update on Endoscopic Treatment of Barrett's Esophagus With Dysplasia and/or Early Cancer: Expert Review. *Gastroenterology*. Feb 2020;158(3):760-769. doi:10.1053/j.gastro.2019.09.051

32. Standards of Practice C, Wani S, Qumseya B, et al. Endoscopic eradication therapy for patients with Barrett's esophagus-associated dysplasia and intramucosal cancer. *Gastrointest Endosc*. Apr 2018;87(4):907-931 e9. doi:10.1016/j.gie.2017.10.011

33. Tariq R, Enslin S, Hayat M, Kaul V. Efficacy of Cryotherapy as a Primary Endoscopic Ablation Modality for Dysplastic Barrett's Esophagus and Early Esophageal Neoplasia: A Systematic Review and Meta-Analysis. *Cancer Control*. Jan-Dec 2020;27(1):1073274820976668. doi:10.1177/1073274820976668

34. van Vilsteren FG, Pouw RE, Seewald S, et al. Stepwise radical endoscopic resection versus radiofrequency ablation for Barrett's oesophagus with high-grade dysplasia or early cancer: a multicentre randomised trial. *Gut*. Jun 2011;60(6):765-73. doi:10.1136/gut.2010.229310

35. Wang KK, Sampliner RE. Updated guidelines 2008 for the diagnosis, surveillance and therapy of Barrett's esophagus. *Am J Gastroenterol*. Mar 2008;103(3):788-97. doi:10.1111/j.1572-0241.2008.01835.x

36. Wang Y, Ma B, Yang S, Li W, Li P. Efficacy and Safety of Radiofrequency Ablation vs. Endoscopic Surveillance for Barrett's Esophagus With Low-Grade Dysplasia: Meta-Analysis of Randomized Controlled Trials. *Front Oncol*. 2022;12:801940. doi:10.3389/fonc.2022.801940

37. Westerveld DR, Nguyen K, Banerjee D, et al. Safety and effectiveness of balloon cryoablation for treatment of Barrett's associated neoplasia: systematic review and meta-analysis. *Endosc Int Open*. Feb 2020;8(2):E172-E178. doi:10.1055/a-1067-4520

38. Yerian L. Histology of metaplasia and dysplasia in Barrett's esophagus. *Surg Oncol Clin N Am*. Jul 2009;18(3):411-22. doi:10.1016/j.soc.2009.03.011

39. 510(k) Premarket Notification to Check-Med Systems, Inc. U.S. Food and Drug Administration. 2002. Accessed September 14, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf2/k021387.pdf

40. 510(k) Safety Summary: CryoSpray Ablation System. No. K072651. U.S. Food and Drug Administration. 2007. Accessed September 14, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf7/K072651.pdf

41. 510(k) Summary: BARRX Channel RFA Endoscopic Catheter. No. K130623. U.S. Food and Drug Administration. 2013. Accessed September 13, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf13/K130623.pdf

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42. 510(k) Summary: C2 Cryoballoon Ablation System. No. K163684. U.S. Food and Drug Administration. 2018. Accessed September 14, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163684.pdf

Coding:

CPT: 43229, 43270, 43499

History:	Date:	Activity:
Medical Policy Panel	01/02/24	Review with revisions
Medical Policy Panel	01/17/23	Approved guideline

Policy Revisions:

01/02/24 Updated: Resources section

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید.

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona [illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799