

EVIDENCE-BASED CRITERIA SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 01/02/24
CURRENT EFFECTIVE DATE: 01/02/24
LAST CRITERIA REVISION DATE: 01/03/23
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**NEXT ANNUAL REVIEW DATE: 1ST QTR 2025** 

### TRANSANAL ENDOSCOPIC MICROSURGERY

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 quidelines.

The section identified as "<u>Description</u>" 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 "<u>Criteria</u>" 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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O543.16.docx Page 1 of 9



EVIDENCE-BASED CRITERIA SECTION: SURGERY

ORIGINAL EFFECTIVE DATE:
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01/02/24 01/02/24 01/03/23

09/19/22

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# TRANSANAL ENDOSCOPIC MICROSURGERY

## **Description:**

Transanal endoscopic microsurgery (TEM) is a minimally invasive approach for local excision of rectal lesions that cannot be directly visualized. It is an alternative to open or laparoscopic excision and has been studied in the treatment of both benign and malignant conditions of the rectum.

# Transanal Endoscopic Microsurgery

Transanal endoscopic microsurgery (TEM) is a minimally invasive approach to local excision of rectal lesions. It has been used in benign conditions such as large rectal polyps (that cannot be removed through a colonoscope), retrorectal masses, rectal strictures, rectal fistulae, pelvic abscesses, and in malignant conditions (e.g., malignant polyps). Use of TEM for resection of rectal cancers is more controversial. TEM can avoid the morbidity and mortality associated with major rectal surgery, including the fecal incontinence related to stretching of the anal sphincter, and can be performed under general or regional anesthesia.

The TEM system has a specialized magnifying rectoscope with ports for insufflation, instrumentation, and irrigation. This procedure has been available in Europe but has not been widely used in the U.S. Two reasons for this slow adoption are the steep learning curve for the procedure and the limited indications. For example, most rectal polyps can be removed endoscopically, and many rectal cancers need a wide excision and are thus not amenable to local resection.

U.S. Food and Drug Administration (FDA) approved devices for use in transanal endoscopic microsurgery include, *but are not limited to*:

- AP50/30 Insufflator with Insuflow Port Lexion Medical LLC
- AirSeal ConMed Corporation
- GRI-Alleset Veress Needle GRI Medical and Electronic Technology Co. Ltd.
- SurgiQuest AIRSEAL iFS System ConMed Corporation
- TEMED Gas Diffuser TEMED
- AP 50/30 Insufflator with Insuflow Port LEXION Medical LLC
- Veress Needle WickiMed (Huizhou) Medical Equipment Manufacturing Co.Ltd.
- GelPOINT Path Transanal Access Platform Applied Medical Resources Corp.
- HumiGard Surgical Humidification System HumiGard Humidified Insufflation Kit FISHER & PAYKEL HEALTHCARE
- LaparoLight Veress Needle Buffalo Filter LLC
- PNEUMOCLEAR W.O.M World Of Medicine GmbH
- ENDOFLATOR 40/ ENDOFLATOR 50 KARL STORZ ENDOSCOPY-AMERICA INC.
- U-Blade Veress Needle TIANJIN UWELL MEDICAL DEVICE MANUFACTURING CO.LTD.
- S698 Symbioz flow SOPRO ACTEON GROUP
- Insufflator 50L FM134 W.O.M WORLD OF MEDICINE GMBH
- Unimicro Veress Needle Unimicro Medical Systems (ShenZhen) Co.Ltd.
- SurgiQuest AirSeal iFS System SURGIQUEST INC.
- GELPOINT PATH TRANSANAL ACCESS PLATFORM APPLIED MEDICAL RESOURCES CORP

O543.16.docx Page 2 of 9



EVIDENCE-BASED CRITERIA SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: LAST REVIEW DATE: CURRENT EFFECTIVE DATE: LAST CRITERIA REVISION DATE:

ARCHIVE DATE:

09/19/22

01/02/24

01/02/24

01/03/23

**NEXT ANNUAL REVIEW DATE: 1ST QTR 2025** 

# TRANSANAL ENDOSCOPIC MICROSURGERY

## Criteria:

- Transanal endoscopic microsurgery for treatment of rectal adenomas, including recurrent adenomas that cannot be removed using other means of local excision is considered *medically necessary*.
- Transanal endoscopic microsurgery for treatment of clinical stage T1 rectal adenocarcinomas that cannot be removed using other means of local excision is considered *medically necessary* with documentation of **ALL** of the following:
  - 1. Located in the middle or upper part of the rectum
  - 2. Well- or moderately differentiated (G1 or G2) by biopsy
  - 3. Without lymphadenopathy
  - 4. Less than one-third the circumference of the rectum.
- Transanal endoscopic microsurgery for all other indications not previously listed or if above criteria not met 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.

### **Resources:**

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

Resources prior to 01/02/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

 Al-Najami I, Rancinger CP, Larsen MK, Thomassen N, Buch N, Baatrup G. Transanal endoscopic microsurgery for advanced polyps and early cancers in the rectum-Long-term outcome: A STROBE compliant observational study. *Medicine (Baltimore)*. Sep 2016;95(36):e4732. doi:10.1097/MD.0000000000004732

O543.16.docx Page 3 of 9



EVIDENCE-BASED CRITERIA SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/19/22
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# TRANSANAL ENDOSCOPIC MICROSURGERY

- 2. Bach SP, Gilbert A, Brock K, et al. Radical surgery versus organ preservation via short-course radiotherapy followed by transanal endoscopic microsurgery for early-stage rectal cancer (TREC): a randomised, open-label feasibility study. *Lancet Gastroenterol Hepatol*. Feb 2021;6(2):92-105. doi:10.1016/S2468-1253(20)30333-2
- 3. Barendse RM, van den Broek FJ, Dekker E, et al. Systematic review of endoscopic mucosal resection versus transanal endoscopic microsurgery for large rectal adenomas. *Endoscopy*. Nov 2011;43(11):941-9. doi:10.1055/s-0030-1256765
- 4. Blackstock W, Russo SM, Suh WW, et al. ACR Appropriateness Criteria: local excision in early-stage rectal cancer. *Curr Probl Cancer*. May-Jun 2010;34(3):193-200. doi:10.1016/j.currproblcancer.2010.04.005
- 5. Cataldo PA. Transanal endoscopic microsurgery. *Surg Clin North Am*. Aug 2006;86(4):915-25. doi:10.1016/j.suc.2006.06.004
- 6. Chan T, Karimuddin AA, Raval MJ, Phang PT, Tang V, Brown CJ. Predictors of rectal adenoma recurrence following transanal endoscopic surgery: a retrospective cohort study. *Surg Endosc*. Aug 2020;34(8):3398-3407. doi:10.1007/s00464-019-07114-0
- 7. D'Ambrosio G, Paganini AM, Balla A, et al. Quality of life in non-early rectal cancer treated by neoadjuvant radio-chemotherapy and endoluminal loco-regional resection (ELRR) by transanal endoscopic microsurgery (TEM) versus laparoscopic total mesorectal excision. *Surg Endosc.* Feb 2016;30(2):504-511. doi:10.1007/s00464-015-4232-8
- 8. Hompes R, Ashraf SQ, Gosselink MP, et al. Evaluation of quality of life and function at 1 year after transanal endoscopic microsurgery. *Colorectal Dis*. Feb 2015;17(2):O54-61. doi:10.1111/codi.12858
- Issa N, Murninkas A, Schmilovitz-Weiss H, Agbarya A, Powsner E. Transanal Endoscopic Microsurgery After Neoadjuvant Chemoradiotherapy for Rectal Cancer. J Laparoendosc Adv Surg Tech A. Aug 2015;25(8):617-24. doi:10.1089/lap.2014.0647
- Laliberte AS, Lebrun A, Drolet S, Bouchard P, Bouchard A. Transanal endoscopic microsurgery as an outpatient procedure is feasible and safe. Surg Endosc. Dec 2015;29(12):3454-9. doi:10.1007/s00464-015-4158-1
- 11. Lezoche E, Baldarelli M, Lezoche G, Paganini AM, Gesuita R, Guerrieri M. Randomized clinical trial of endoluminal locoregional resection versus laparoscopic total mesorectal excision for T2 rectal cancer after neoadjuvant therapy. *Br J Surg*. Sep 2012;99(9):1211-8. doi:10.1002/bjs.8821
- 12. Lezoche G, Baldarelli M, Guerrieri M, et al. A prospective randomized study with a 5-year minimum follow-up evaluation of transanal endoscopic microsurgery versus laparoscopic total mesorectal excision after neoadjuvant therapy. *Surg Endosc*. Feb 2008;22(2):352-8. doi:10.1007/s00464-007-9596-y

O543.16.docx Page 4 of 9



EVIDENCE-BASED CRITERIA SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/19/22
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ARCHIVE DATE:

**NEXT ANNUAL REVIEW DATE: 1ST QTR 2025** 

### TRANSANAL ENDOSCOPIC MICROSURGERY

- 13. Li W, Xiang XX, Da Wang H, Cai CJ, Cao YH, Liu T. Transanal endoscopic microsurgery versus radical resection for early-stage rectal cancer: a systematic review and meta- analysis. *Int J Colorectal Dis.* Feb 17 2023;38(1):49. doi:10.1007/s00384-023-04341-9
- 14. Middleton PF, Sutherland LM, Maddern GJ. Transanal endoscopic microsurgery: a systematic review. *Dis Colon Rectum*. Feb 2005;48(2):270-84. doi:10.1007/s10350-004-0804-8
- 15. Mora Lopez L, Serra Aracil X, Hermoso Bosch J, Rebasa P, Navarro Soto S. Study of anorectal function after transanal endoscopic surgery. *Int J Surg*. Jan 2015;13:142-147. doi:10.1016/j.ijsu.2014.11.021
- 16. Motamedi MAK, Mak NT, Brown CJ, et al. Local versus radical surgery for early rectal cancer with or without neoadjuvant or adjuvant therapy. *Cochrane Database Syst Rev.* Jun 13 2023;6(6):CD002198. doi:10.1002/14651858.CD002198.pub3
- 17. National Cancer Institute (NCI). Rectal Cancer Treatment (PDQ). Healthcare Provider Version. Updated June 30, 2023. Accessed September 13, 2023. https://www.cancer.gov/types/colorectal/hp/rectal-treatment-pdq#\_43
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer. Version 4.2023. Accessed September 13, 2023. https://www.nccn.org/login?ReturnURL=https://www.nccn.org/professionals/physician\_gls/pdf/rectal.pdf
- 19. Restivo A, Zorcolo L, D'Alia G, et al. Risk of complications and long-term functional alterations after local excision of rectal tumors with transanal endoscopic microsurgery (TEM). *Int J Colorectal Dis.* Feb 2016;31(2):257-66. doi:10.1007/s00384-015-2371-y
- 20. Russo S, Blackstock AW, Herman JM, et al. ACR Appropriateness Criteria(R) Local Excision in Early Stage Rectal Cancer. *Am J Clin Oncol*. Oct 2015;38(5):520-5. doi:10.1097/COC.000000000000197
- 21. Samalavicius N, Ambrazevicius M, Kilius A, Petrulis K. Transanal endoscopic microsurgery for early rectal cancer: single center experience. *Wideochir Inne Tech Maloinwazyjne*. Dec 2014;9(4):603-7. doi:10.5114/wiitm.2014.44138
- 22. Sgourakis G, Lanitis S, Gockel I, et al. Transanal endoscopic microsurgery for T1 and T2 rectal cancers: a meta-analysis and meta-regression analysis of outcomes. *Am Surg.* Jun 2011;77(6):761-72.
- 23. Stipa F, Picchio M, Burza A, Soricelli E, Vitelli CE. Long-term outcome of local excision after preoperative chemoradiation for ypT0 rectal cancer. *Dis Colon Rectum*. Nov 2014;57(11):1245-52. doi:10.1097/DCR.0000000000000221

O543.16.docx Page 5 of 9

EVIDENCE-BASED CRITERIA SECTION: SURGERY

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### TRANSANAL ENDOSCOPIC MICROSURGERY

- van Heinsbergen M, Leijtens JW, Slooter GD, Janssen-Heijnen ML, Konsten JL. Quality of Life and Bowel Dysfunction after Transanal Endoscopic Microsurgery for Rectal Cancer: One Third of Patients Experience Major Low Anterior Resection Syndrome. *Dig Surg.* 2020;37(1):39-46. doi:10.1159/000496434
- 25. Verseveld M, Barendse RM, Dawson I, Vos EL, de Graaf EJ, Doornebosch PG. Intramucosal carcinoma of the rectum can be safely treated with transanal endoscopic microsurgery; clinical support of the revised Vienna classification. *Surg Endosc.* Nov 2014;28(11):3210-5. doi:10.1007/s00464-014-3593-8
- 26. Verseveld M, Barendse RM, Gosselink MP, Verhoef C, de Graaf EJ, Doornebosch PG. Transanal minimally invasive surgery: impact on quality of life and functional outcome. *Surg Endosc.* Mar 2016;30(3):1184-7. doi:10.1007/s00464-015-4326-3
- 27. Verseveld M, de Graaf EJ, Verhoef C, et al. Chemoradiation therapy for rectal cancer in the distal rectum followed by organ-sparing transanal endoscopic microsurgery (CARTS study). *Br J Surg.* Jun 2015;102(7):853-60. doi:10.1002/bjs.9809
- 28. Xiong X, Wang C, Wang B, et al. Can transanal endoscopic microsurgery effectively treat T1 or T2 rectal cancer? A systematic review and meta-analysis. *Surg Oncol.* Jun 2021;37:101561. doi:10.1016/j.suronc.2021.101561
- 29. You YN, Hardiman KM, Bafford A, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Rectal Cancer. *Dis Colon Rectum*. Sep 2020;63(9):1191-1222. doi:10.1097/DCR.00000000001762
- 30. Zacharakis E, Freilich S, Rekhraj S, et al. Transanal endoscopic microsurgery for rectal tumors: the St. Mary's experience. *Am J Surg*. Nov 2007;194(5):694-8. doi:10.1016/j.amjsurg.2007.03.005
- 31. Zhang Y, Yu P, Wang P, et al. Analysis of the therapeutic effect of transanal endoscopic microsurgery on large rectal adenoma. *J Minim Access Surg*. Oct-Dec 2022;18(4):571-577. doi:10.4103/jmas.jmas\_273\_21

# Coding:

CPT: 0184T, 45123, 45171, 45172

History:	Date:	Activity:
Medical Policy Panel	01/02/24	Review with revisions
Medical Policy Panel	01/03/23	Review with revisions
Medical Policy Panel	08/16/22	Approve guideline

O543.16.docx Page 6 of 9



EVIDENCE-BASED CRITERIA SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 01/02/24
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LAST CRITERIA REVISION DATE: 01/03/23
ARCHIVE DATE:

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## TRANSANAL ENDOSCOPIC MICROSURGERY

# **Policy Revisions:**

01/03/23 Added: "Insufficient evidence to support improvement of the net health outcome;

or", and "Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or" to

experimental or investigational criteria bullets

01/03/23 Revised: "Insufficient evidence to support improvement outside the investigational

setting" from #3 to #5 in experimental or investigational criteria bullets

01/03/23 Updated: Description section; Resources section

O543.16.docx Page 7 of 9



EVIDENCE-BASED CRITERIA SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/19/22
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# TRANSANAL ENDOSCOPIC MICROSURGERY

## **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, <a href="mailto:cro@azblue.com">cro@azblue.com</a>. 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 <a href="https://ocrportal.hhs.gov/ocr/portal/lobby.jsf">https://ocrportal.hhs.gov/ocr/portal/lobby.jsf</a>, 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 <a href="http://www.hhs.gov/ocr/office/file/index.html">http://www.hhs.gov/ocr/office/file/index.html</a>

### 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 hólo díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojj' bich'j' 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 المتحدث مع مترجم اتصل ب. 877-475-4798

O543.16.docx Page 8 of 9



EVIDENCE-BASED CRITERIA SECTION: SURGERY

LAST REVIEW DATE:
CURRENT EFFECTIVE DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

09/19/22

01/02/24

01/02/24

01/03/23

ORIGINAL EFFECTIVE DATE:

NEXT ANNUAL REVIEW DATE: 1ST QTR 2025

### TRANSANAL ENDOSCOPIC MICROSURGERY

## **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 حتی این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 479-475-877 اتوان حاصل نماید

#### Assyrian:

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 หรอคนทคณกาลงช่วยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะใดรบความช่วยเหลอและขอมลในภาษา ของคณไดโดยไม่มคาใช้จาย พดคยกบลาม โทร 877-475-4799

O543.16.docx Page 9 of 9