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MEDICAL POLICY – 6.01.38

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

BCBSA Ref. Policy:	6.01.38	
Effective Date:	Aug. 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	July 24, 2023	6.01.25 Percutaneous Vertebroplasty and Sacroplasty
Replaces:	6.01.520	

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Introduction

Kyphoplasty is a type of surgery that stabilizes a vertebra (a bone of the spine) after a compression fracture. A compression fracture usually happens at the front side of the vertebra. The front collapses, leaving a vertebra that looks a bit like a wedge. The goal of kyphoplasty is to reduce pain and return the vertebra to its normal height. A hollow needle or similar instrument is inserted through the skin and into the damaged area of the bone. Either a balloon is inflated or a device is uncoiled to create a hollow space at the front of the bone, bringing it back to its normal height. If a balloon is used, it's then removed. If a coil device is used, it remains. A type of bone cement is then injected into the hollow space. The cement hardens after a few minutes. This policy describes when this procedure may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Percutaneous balloon kyphoplasty or mechanical vertebral augmentation	**Percutaneous balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device* may be considered medically necessary for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to at least 6 weeks of conservative treatment (e.g., analgesics, physical therapy, rest).** **Percutaneous balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device* may be considered medically necessary for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.** **Note:** *See Table 2 for list of FDA-cleared devices

Service	Investigational
Percutaneous balloon kyphoplasty or mechanical vertebral augmentation	**Percutaneous balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device* are considered investigational for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.** **Percutaneous radiofrequency kyphoplasty or percutaneous mechanical vertebral augmentation using any other device is considered investigational.** **Note:** *See Table 2 for list of FDA-cleared devices

Note: Based on currently available evidence, health outcomes for kyphoplasty, vertebral augmentation, and vertebroplasty appear to be equivalent, therefore, the "least costly alternative" provision of the medically necessary definition may apply.

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Relevant history and physical supporting painful osteoporotic vertebral compression fractures that have failed to respond to at least 6 weeks of conservative treatment (e.g., analgesics, physical therapy, rest)

OR

- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies

AND

- FDA-cleared device

Coding

Code	Description
CPT	
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body
HCPCS	
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)
C7507	Percutaneous vertebral augmentations, first thoracic and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance (new code effective 1/1/2023)
C7508	Percutaneous vertebral augmentations, first lumbar and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone

Code	Description
	biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance (new code effective 1/1/2023)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Percutaneous kyphoplasty may be performed by interventional radiologists or orthopedic surgeons. Percutaneous kyphoplasty is a specialized procedure, and thus some individuals may seek an out-of-network referral.

Evidence Review

Description

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty (RFK), and mechanical vertebral augmentation are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as options to provide mechanical support and symptomatic relief in individuals with osteoporotic vertebral compression fracture or those with osteolytic lesions of the spine (i.e., multiple myeloma or metastatic malignancies).

Background

Osteoporotic Vertebral Compression Fracture

Vertebral compression fractures are the most common complication of osteoporosis, with 700,000 cases reported every year in the United States.[1] The condition is more frequently seen in women than men, with an annual incidence of 10.7 per 1000 women and 5.7 per 1000 men. Furthermore, the prevalence of these fractures increases with age and has been estimated to

affect approximately 25% of postmenopausal women and 40% of women ≥80 years of age. Symptoms of vertebral compression fracture are non-specific, and more than two-thirds of fractures are detected incidentally when individuals undergo imaging for other reasons. Most symptomatic fractures will heal within 6 to 8 weeks, but a minority of individuals will exhibit chronic pain following an osteoporotic compression fracture that presents challenges for medical management.

Treatment

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently is not improved with analgesics and may be better addressed through exercise. Conventional vertebroplasty surgical intervention may be required in severe cases not responsive to conservative measures.

Osteolytic Vertebral Body Fractures

Vertebral body fractures can also be pathologic, due to osteolytic lesions, most commonly from metastatic tumors. Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint.

Treatment

While radiotherapy and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed for days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

Summary of Evidence

For individuals with osteoporotic vertebral compression fractures (OVCF) who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review, randomized controlled trials (RCTs), and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The AHRQ review concluded that vertebroplasty was probably more effective at reducing pain and improving function in individuals >65 years of age, but benefits were small. Kyphopasty was found to be probably more effective than usual care for pain and function in older individuals with vertebral compression fracture at up to one month and may be more effective at >1 month to ≥1 year but has not been compared against sham therapy. A meta-analysis and moderately sized unblinded RCT have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. One systematic review of RCTs found no significant difference in subsequent fracture between vertebroplasty and conservative treatment, and another systematic review of prospective and retrospective studies reported improved mortality with either vertebroplasty or balloon kyphoplasty compared with conservative treatment. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. Three randomized trials that compared mechanical vertebral augmentation (Kiva or SpineJack) with kyphoplasty have reported similar outcomes for both procedures. A major limitation of all these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of the results from non-sham-controlled trials is unclear. Therefore, whether these improvements represent a true treatment effect is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with osteolytic VCF who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes RCTs, case series, and a systematic review of these studies. The relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two RCTs compared balloon kyphoplasty with conservative management and another compared Kiva with balloon kyphoplasty. Results of these trials, along with case series, would suggest a reduction in pain, disability, and analgesic use in individuals with cancer-related compression fractures. However, because the results of the comparative studies of vertebroplasty have suggested possible placebo or natural history effects, the evidence these studies provide is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with osteoporotic or osteolytic VCF who receive radiofrequency kyphoplasty, the evidence includes a systematic review and an RCT. The relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The only RCT (n=80) identified showed similar results between radiofrequency kyphoplasty and balloon kyphoplasty. The systematic review suggested that radiofrequency kyphoplasty is superior to balloon kyphoplasty in pain relief, but the review itself was limited by the inclusion of a small number of studies as well as possible bias. Corroboration of these results in a larger number of individuals would be needed to determine with greater certainty whether radiofrequency kyphoplasty provides outcomes similar to balloon kyphoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished clinical trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT02700308	A Randomized, Multicenter, Open-label, Bayesian-based Phase II Study of the Feasibility of Kyphoplasty in the Local Treatment of Spine Metastases From Solid Tumors	60	Sep 2022
NCT04581707	Evaluation of Surgical Therapy of Vertebral Compression Fractures With the Kyphoplasty Single Balloon Catheter Allevo (Joline®) and the Quattroplasty Double Balloon Catheter Stop'n GO (Joline®) With BonOs® Inject Bone Cement	80	Oct 2021

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from two physician specialty societies and three academic medical centers while this policy was under review in 2014. Input was sought on the treatment of acute vertebral fractures when severe pain has led to hospitalization or persists at a level that prevents ambulation, and on the treatment of traumatic fractures that have remained symptomatic after six weeks of conservative treatment. Clinical input on these issues was mixed.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology et al

The American College of Radiology (2014) and seven other surgical and radiological specialty associations published a joint position statement on percutaneous vertebral augmentation.[28] This document stated that percutaneous vertebral augmentation, using vertebroplasty or kyphoplasty and performed in a manner consistent with public standards, is a safe, efficacious, and durable procedure in appropriate individuals with symptomatic osteoporotic and neoplastic fractures. The statement also indicated that these procedures be offered only when

nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering the individual's quality of life.

A joint practice parameter for the performance of vertebral augmentation was updated in 2017.[29]

Society of Interventional Radiology

In a quality improvement guideline on percutaneous vertebroplasty from the Society of Interventional Radiology (2014), vertebral augmentation was recommended for compression fractures refractory to medical therapy.[28] Failure of medical therapy includes the following situations:

1. Patients who are "rendered nonambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation, despite 24 hours of analgesic therapy";
2. Patients with "sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy"; or
3. Patients with "a weakened or fractured vertebral body, and unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level."

National Institute for Health and Care Excellence

The NICE (2013) issued a guidance that recommended percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatment options for treating osteoporotic vertebral compression fractures in persons having severe, ongoing pain after a recent unhealed vertebral fracture, despite optimal pain management, and whose pain has been confirmed through physical exam and imaging at the level of the fracture.[30] This guidance did not address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) stated there is limited evidence for vertebral body stenting given that the system had only recently become available.

The NICE (2008) issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. It was last reviewed in 2019, and a decision was made that the guideline required updating as "since its publication, there have been advances in the diagnosis

and management of metastatic spinal cord compression.".[31] The guidance currently still states that vertebroplasty or kyphoplasty should be considered for individuals who have vertebral metastases, and no evidence of spinal cord compression or spinal instability if they have mechanical pain resistant to conventional pain management and vertebral body collapse. Surgery should only be performed when all appropriate specialists agree. Despite a relatively small sample base, the Institute concluded the evidence suggests, in a select subset of individuals, that early surgery may be more effective at maintaining mobility than radiotherapy.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). PMMA bone cement was available as a drug product before enactment of the FDA's device regulation and was at first considered what the FDA termed a "transitional device." It was transitioned to a class III device and then to a class II device, which required future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. In July 2004, KyphX HV-RTM bone cement was cleared for marketing by the FDA through the 510(k) process for the treatment of pathologic fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix Biomimetic Bone Cement, KYPHON HV-R Bone Cement, KYPHONTM VuETM Bone Cement, and Osteopal V (Heraeus) have received 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX inflatable bone tamp (Medtronic), was cleared for marketing by the FDA through the 510(k) process. Additional devices for balloon kyphoplasty are listed in **Table 2**.

There are several mechanical vertebral augmentation devices that have received marketing clearance by the FDA through the 510(k) process; these are listed in **Table 2**.

StabiliT Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009.

FDA product code NDN.

Table 2. Kyphoplasty and Mechanical Vertebral Augmentation Devices Cleared by the U.S. Food and Drug Administration

(Note: This list is not all inclusive)

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Balloon Kyphoplasty				
TRACKER Plus Kyphoplasty System	GS Medical Co., Ltd	10/28/2021	K211797	Reduction of fractures and/or creation of a void
Joline Kyphoplasty System Allevo	Joline GmbH & Co.	5/27/2020	K192449	To repair vertebral compression fractures
TRACKER Kyphoplasty System	GS Medical Co., Ltd	12/4/2019	K192335	Reduction of fractures or creation of a void
Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)	Stryker Corporation	12/21/2018	K181752	To repair vertebral compression fractures
SpineKure Kyphoplasty System	Hanchang Co. Ltd.	5/29/2018	K172871	To repair vertebral compression fractures
Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters	G-21 s.r.l.	8/23/2017	K172214	To repair vertebral compression fractures
13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)	Pan Medical Ltd.	11/1/2016	K162453	To repair vertebral compression fractures
MEDINAUT Kyphoplasty System	Imedicom Co. Ltd.	7/29/2016	K153296	To repair vertebral compression fractures
AVAflex Vertebral Balloon System	Carefusion	11/24/2015	K151125	To repair vertebral compression fractures
Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml	Osseon LLC	4/9/2015	K150607	To repair vertebral compression fractures
InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (Balloon Length: 10 15 and 20mm)	Pan Medical Ltd	3/6/2015	K150322	To repair vertebral compression fractures

Device	Manufacturer	Date Cleared	510(k) No.	Indication
GUARDIAN-SG Inflatable Bone Expander System	BM Korea Co. Ltd.	1/16/2015	K143006	To repair vertebral compression fractures
ZVPLASTY	Zavation LLC	9/12/2014	K141419	To repair vertebral compression fractures
Kyphon Express II Inflatable Bone Tamps	Medtronic	12/21/2012	K123771	To repair vertebral compression fractures
Kyphon Xpander II Inflatable Bone Tamp	Medtronic	10/14/2010	K101864	To repair vertebral compression fractures
Mechanical Vertebral Augmentation				
Kiva VCF treatment system	Benvenue Medical Inc.	8/14/2014	K141141	To repair vertebral compression fractures
SpineJack Expansion Kit	Vexim SA	8/30/2018	K181262	To repair vertebral compression fractures
V-Strut Vertebral Implant	Hyprevention SAS	3/5/2020	K191709	Treatment of vertebral fractures in the thoracic and lumbar spine

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History

Date	Comments
06/12/12	New policy, add to Radiology section. Policy replaces 6.01.520 in conjunction with 6.01.25.
09/25/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
06/10/13	Replace policy. Policy updated with literature review through March 5, 2013; references 17, 30, 31 added and references reordered; statement added that all other percutaneous mechanical vertebral augmentation devices, including but not limited to Kiva, are considered investigational. CPT codes 22520 – 22522 added to policy.
08/12/13	Clarification. Policy statement clarified by adding "less than 6 weeks old". Percutaneous balloon kyphoplasty is considered investigational for all other indications, including use in acute (less than 6 weeks old) vertebral fractures due to osteoporosis or trauma.
06/09/14	Annual Review. Policy updated with literature review through March 27, 2014, references 31-32, 34-35, 37-39, and 41-42 added; and references reordered. Vertebral body stenting added to investigational statement. Coding update: ICD-9 and ICD-10 procedure and diagnosis codes removed – these are not utilized in adjudication of the policy.
06/09/15	Coding update. ICD-9 procedure code 81.66 and corresponding ICD-10-PCS codes added per remediation efforts.

Date	Comments
08/11/15	Annual Review. Kiva mechanical vertebral augmentation added as Medically Necessary (previously considered investigational) when criteria are met and Investigational for all other indications. Rationale added for vertebral augmentation with the Kiva VCF System compared with balloon kyphoplasty. Policy updated with literature review through March 3, 2015. References 32-34 added; others renumbered/removed. New CPT codes 22513-22515 effective 01/01/15 added to Coding table. Policy statements changed as noted.
01/08/16	Minor update. CPT codes deleted effective 12/31/15 removed from policy: 22520-22525, 72291-72292. No other changes.
08/01/16	Annual Review, approved July 12, 2016. Policy guidelines updated to remove the following statement: "Based on currently available evidence, health outcomes for kyphoplasty, Kiva and vertebroplasty appear to be equivalent, therefore the "least costly alternative" provision of the medically necessary definition may apply" as it duplicates information in the Benefit Application section. Policy reviewed with literature search through June 2016. Policy statements unchanged.
01/01/17	Interim review, approved December 13, 2016. Policy statement revised for clarity to state "…medically necessary for symptomatic vertebral fractures due to osteoporosis or trauma that have failed to respond to 6 weeks of conservative treatment." The last investigational policy statement was revised to delete the wording, "including but not limited to vertebral body stenting." Removed information about vertebral hemangiomas. Table of ACR recommendations for compression fracture treatment added to Policy Guidelines. Policy updated with literature review through October 2016; some references deleted.
10/01/17	Annual Review, approved September 21, 2017. Policy updated with literature review through June 22, 2017; references 20 and 22 added. Radiofrequency kyphoplasty added to title and investigational statement.
07/01/18	Annual Review, approved June 5, 2018. Policy updated with literature review through February 2018; references 19 and 25 added. Policy statements unchanged.
07/01/19	Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references 32-33 added. Policy statements unchanged.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through February 2020; references added. Policy statements clarified that the medically necessary statements on compression fractures apply to the thoracolumbar spine. The tradename "Kiva" was removed from policy statements and replaced with "FDA cleared device".
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 18, 2021; references added. Policy statements unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through February 16, 2022; references added. Policy statements unchanged.

Date	Comments
10/01/22	Interim Review, approved September 26, 2022. FDA cleared device added to Documentation Requirements. Added HCPCS code C1062. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/23	Coding update. Added new HCPC codes C7507 and C7508.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through February 17, 2023; reference added. Policy statements unchanged.
08/01/23	Interim Review, approved July 24, 2023. Added note that list of devices cleared by FDA is not all inclusive.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2023 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera 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, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator ─ Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the 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 Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-722-1471 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.