

MEDICAL POLICY – 7.01.108

Artificial Intervertebral Disc: Cervical Spine

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RELATED MEDICAL POLICIES:


7.01.87 Artificial Intervertebral Disc: Lumbar Spine

7.01.560 Cervical Spine Surgeries: Discectomy, Laminectomy, and Fusion in Adults

11.01.524 Site of Service: Select Surgical Procedures

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Introduction

The bones that make up the neck are called cervical vertebrae. Between each of the vertebra is a disc, which acts as a shock absorber and prevents the bones from rubbing together. As a person ages, these discs may break down and become thinner because they lose water and the gel-like substance that's inside each disc. This is known as degenerative disc disease. Studies show that most adults over the age of forty have some degenerative disc disease when x-rays are done. However, for many people no treatment is needed because the neck continues to move normally without pain. In some people who have pain and severe degenerative disc disease is present, treatment may be helpful. An artificial disc is one type of treatment. The artificial disc replaces the damaged natural disc, with the goal being to keep the normal space between the bones and preserve the motion of the neck. This treatment may be considered when there is significant pain that has not responded to other types of treatments. This policy describes when an artificial disc replacement in the neck 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

We will review for medical necessity these elective surgical procedures.

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

| Site of Service for Elective Surgical Procedures | Medical Necessity |
|---|--|
| <p>Medically necessary sites of service:</p> <ul style="list-style-type: none"> • Off campus-outpatient hospital/medical center • On campus-outpatient hospital/medical center • Ambulatory Surgical Center | <p>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.</p> |
| <p>Inpatient hospital/medical center</p> | <p>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):</p> <ul style="list-style-type: none"> • Anesthesia Risk <ul style="list-style-type: none"> ○ ASA classification III or higher (see definition) ○ Personal history of complication of anesthesia ○ Documentation of alcohol dependence or history of cocaine use ○ Prolonged surgery (>3 hours) • Cardiovascular Risk <ul style="list-style-type: none"> ○ Uncompensated chronic heart failure (NYHA class III or IV) ○ Recent history of myocardial infarction (MI) (<3 months) ○ Poorly controlled, resistant hypertension* ○ Recent history of cerebrovascular accident (< 3 months) |



| Site of Service for Elective Surgical Procedures | Medical Necessity |
|--|---|
| | <ul style="list-style-type: none"> ○ Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty <90 days) ○ Symptomatic cardiac arrhythmia despite medication ○ Significant valvular heart disease ● Liver Risk <ul style="list-style-type: none"> ○ Advance liver disease (MELD Score > 8)** ● Pulmonary Risk <ul style="list-style-type: none"> ○ Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) ○ Poorly controlled asthma (FEV1 <80% despite treatment) ○ Moderate to severe obstructive sleep apnea (OSA)*** ● Renal Risk <ul style="list-style-type: none"> ○ End stage renal disease (on dialysis) ● Other <ul style="list-style-type: none"> ○ Morbid obesity (BMI ≥ 50) ○ Pregnancy ○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion]) ○ Anticipated need for transfusion(s) <p>* 3 or more drugs to control blood pressure</p> <p>** https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease</p> <p>*** Moderate-AHI ≥15 and ≤ 30, Severe-AHI ≥30</p> <p>****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)</p> |
| Inpatient hospital/medical center | <p>This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.</p> |



| Surgery | Medical Necessity |
|--|--|
| <p>Artificial cervical intervertebral disc implantation</p> | <p>Cervical artificial intervertebral disc implantation may be considered medically necessary when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • The device is approved by Food and Drug Administration (FDA): <ul style="list-style-type: none"> ○ For <u>one level</u>: <ul style="list-style-type: none"> ▪ Bryan® Cervical Disc (Medtronic) ▪ M6-C Artificial Cervical Disc (Spinal Kinetics LLC) ▪ Mobi-C® Cervical Disc (Zimmer Biomet/LDR Medical) ▪ PCM (porous-coated motion) Cervical Disc® (NuVasive) ▪ Prestige® ST Cervical Disc System (Medtronic) ▪ ProDisc-C® Total Disc Replacement (DePuySynthes) ▪ SECURE-C® Cervical Artificial Disc (Globus Medical) ○ For <u>two contiguous levels</u>: <ul style="list-style-type: none"> ▪ Mobi-C® Cervical Disc (Zimmer Biomet/LDR Medical) ▪ Prestige LP Cervical Disc • The patient is skeletally mature • The patient has intractable cervical radicular pain or myelopathy <ol style="list-style-type: none"> a. Which has failed at least 6 weeks of conservative non-operative treatment including physical therapy and at least one of the following: <ul style="list-style-type: none"> ▪ Acupuncture ▪ Cervical collar ▪ Corticosteroids ▪ Exercise program ▪ Medical treatment with NSAIDs or other analgesics OR b. The patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment. • Degeneration is documented by imaging within the prior 12 months (magnetic resonance imaging, computed tomography or myelography) • Cervical degenerative disc disease is from C3 through C7 |



| Surgery | Medical Necessity |
|--|---|
| | <ul style="list-style-type: none"> The patient is free from contraindication to artificial cervical intervertebral disc implantation |
| Subsequent artificial cervical intervertebral disc implantation | Subsequent implantation of a second artificial cervical intervertebral disc at an adjacent level (contiguous to a previous placed artificial disc) may be considered medically necessary if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (eg, Mobi-C, Prestige LP) and the initial cervical artificial disc implantation is fully healed. |

| Surgery | Investigational |
|---|---|
| Artificial cervical intervertebral disc implantation | Cervical artificial intervertebral disc implantation is considered investigational for all other indications, including the following: <ul style="list-style-type: none"> Active infection Anatomical deformity (eg, ankylosing spondylitis) Combined use of an artificial cervical disc and fusion (hybrid surgery) Disc implantation at more than 2 levels Malignancy Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia) Presence of facet arthritis Previous fusion at another cervical level Prior surgery at the treated level Rheumatoid arthritis or other autoimmune disease Translational instability |

| Documentation Requirements |
|---|
| <p>The following information must be submitted to ensure an accurate, expeditious, and complete review for artificial intervertebral disc implantation:</p> <ul style="list-style-type: none"> Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted Clinical notes that include a current history and physical exam |



Documentation Requirements

- Detailed documentation of extent and response to non-operative conservative therapy, if applicable, including outcomes of any procedural interventions, medications used and physical therapy/physiatrist notes
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months.

Coding

| Code | Description |
|------------|--|
| CPT | |
| 0095T | Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical |
| 0098T | Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical |
| 0375T | Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels |
| 22856 | Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical |
| 22858 | Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); second level, cervical |
| 22861 | Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical |

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

Definition of Terms

American Society of Anesthesiologists (ASA) Score:



ASA 1 A normal healthy patient.

ASA 2 A patient with mild systemic disease.

ASA 3 A patient with severe systemic disease.

ASA 4 A patient with severe systemic disease that is a constant threat to life.

ASA 5 A moribund patient who is not expected to survive

Cervical myelopathy: Loss of function in the upper and lower extremities due to compression of the spinal cord within the neck.

Cervical radiculopathy: Persistent neck pain that radiates into the shoulder/arm in a dermatomal/single nerve pattern, or progressive weakness caused by irritation or injury near the root of a spinal nerve in the neck. The North American Spine Society describes the most common clinical findings as arm pain, neck pain, scapular or periscapular pain, and paresthesias, numbness and sensory changes, weakness, or abnormal deep tendon reflexes in the arm.

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.

Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.

Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Subsidence: Sinking or settling in bone, for example from a prosthetic component of an implant.

Evidence Review

Description

Several prosthetic devices are currently available for cervical disc arthroplasty. Cervical disc arthroplasty is proposed as an alternative to anterior cervical discectomy and fusion for patients with symptomatic cervical degenerative disc disease.



Background

Cervical Degenerative Disc Disease

Cervical degenerative disc disease (DDD) is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical DDD include arm pain, weakness, and paresthesias associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis, or instability that compress the spinal cord can result in myelopathy, which is manifested by subtle changes in gait or balance, and, in severe cases, leads to weakness in the arms or legs and numbness of the arms or hands. The prevalence of DDD secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical DDD. By age 65, 95% of men and 70% of women have at least one degenerative change evident at the radiographic examination. It is estimated that approximately 5 million adults in the United States are disabled to some extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Treatment

Anterior cervical discectomy and fusion (ACDF) has historically been considered the definitive surgical treatment for symptomatic DDD of the cervical spine. The goals of ACDF are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability. Resolution of pain and neurologic symptoms may be expected in 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and placement of a PEEK (polyetheretherketone) or titanium interbody cage plus autograft or allograft of bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and reduce the need for prolonged postoperative brace application that is needed following ACDF without an anterior plate. Although there may be slight differences between autograft and allograft bone sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90%-100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent-segment kinematics following fusion may lead to adjacent-level DDD and need for secondary surgery.

Cervical disc arthroplasty is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In cervical disc arthroplasty, an artificial disc device is secured in the prepared intervertebral space rather than an interbody cage and/or bone. An anterior plate is not used to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. The



cervical disc arthroplasty was designed to maintain anatomic disc space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels. The potential to reduce the risk of adjacent-level DDD above or below a fusion site has been the major reason driving device development and use. Disc arthroplasty and ACDF have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in cervical disc arthroplasty candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis or spondylolisthesis.

Summary of Evidence

For individuals who have cervical radicular pain or myelopathy who receive single-level cervical disc arthroplasty, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At two-year follow-up, trials of all artificial cervical discs met noninferiority criteria compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on five devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [porous coated motion]). At four to five years, the trial results have been consistent with the continued noninferiority of cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige and ProDisc-C pivotal trials continues to show lower secondary surgery rates, although this is not a consistent finding in other reports. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs but does not appear to lead to a decline in clinical outcomes. The evidence to date shows outcomes that are at least as good as the standard treatment of anterior cervical discectomy and fusion. There have been no safety signals with discs approved by the U.S. Food and Drug Administration (FDA) for single-level cervical disc arthroplasty. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level cervical disc arthroplasty of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. FDA approval for the Prestige LP™ was based on superiority to 2-level ACDF in overall success at two years. The increase in overall success rates at two years has been maintained for those patients who have reached the 10-year follow-up. At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to ACDF for Neck Disability Index (NDI) scores, NDI success rates, reoperation rates, and overall success composite outcome.



At five years, trial results were consistent with the continued superiority of 2-level cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Adjacent-segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared with 2-level ACDF patients. Based on this evidence, it can be concluded that 2-level cervical disc arthroplasty with either of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished 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 |
|--|---|--------------------|----------------------|
| Ongoing | | | |
| NCT02403453 ^a | RHINE™ Cervical Disc Clinical Study | 166 | Aug 2026 |
| NCT03123549 ^a | Clinical Study Protocol for the Investigation Of The Two Level Simplify® Cervical Artificial Disc | 200 | Nov 2020 |
| NCT02667067 ^a | Clinical Study Protocol for the Investigation Of The Simplify® Cervical Artificial Disc | 150 | Jan 2023 |
| Unpublished | | | |
| NCT00432159 ^a | A Multi-Center, Prospective, Randomized Controlled Trial Comparing Cervical Arthroplasty to Anterior Cervical Discectomy and Fusion for the Treatment of Cervical Degenerative Disc Disease (DISCOVER™ IDE Study) | 500 | May 2016 (completed) |
| NCT01763619 ^a | Freedom® Cervical Disc Use In The Treatment of Cervical Degenerative Disc Disease | 50 | Jul 2017 (unknown) |

NCT: national clinical trial

^a Denotes industry-sponsored or cosponsored trial



Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

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.

2015 Input

In response to requests, input was received from 3 physician specialty societies and 2 academic medical centers while this policy was under review in 2015. There was agreement that cervical disc replacement may be medically necessary under specified conditions. Likewise, there was agreement that combined use of an artificial disc and fusion over two levels was investigational. Input was mixed regarding the medical necessity of 2 level artificial intervertebral disc arthroplasty.

2009 Input

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2009. Input did not support the conclusion that artificial intervertebral disc arthroplasty is investigational.

Practice Guidelines and Position Statements

North American Spine Society

In 2015, the guidelines from the North American Spine Society indicate that⁴⁰:

“Cervical artificial disc replacement, (also known as cervical total disc replacement and cervical arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. “Radiculopathy related to nerve root compression from one or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or nonoperative management.



2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or 2-level degenerative disc disease from C3-4 to C6-7 with or without neck pain.”

National Institute for Health and Care Excellence

In 2010, the National Institute for Health and Care Excellence (NICE) issued guidance on the artificial cervical disc, concluding that⁴¹:

“Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is at least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures. ...

This procedure should only be carried out in specialist units where surgery of the cervical spine is undertaken regularly.

NICE encourages further research into prosthetic intervertebral disc replacement in the cervical spine. Research outcomes should include long-term data on preservation of mobility, occurrence of adjacent segment disease and the avoidance of revision surgery.”

Medicare National Coverage

A search of the Medicare National Database identified a national coverage determination on artificial intervertebral discs for the lumbar spine, but not for the cervical spine.⁴²

Regulatory Status

In 2007, the Prestige® ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process as a class III device. The Prestige® ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3 through C7 following single-level discectomy. The device is implanted using an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least one of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (eg, pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (eg, magnetic resonance imaging, computed tomography, x-rays): herniated disc and/or osteophyte



formation. The FDA required Medtronic (the Prestige disc manufacturer) to conduct a 7-year post approval clinical study of the safety and function of the device and a 5 year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

In 2014, the Prestige® LP artificial cervical disc (Medtronic Sofamor Danek) was approved by the FDA through the premarket approval process. The Prestige® LP differs from the original Prestige cervical disc regarding material and fixation. The LP implant is composed of a proprietary titanium-ceramic composite and has 2 rails that press-fit into holes created during the surgical procedure. In 2016, the Prestige® LP was approved by the FDA for 2 adjacent levels. A post approval study will follow the investigational device exemption patients who received the Prestige® LP at 2 contiguous levels for 10 years. Medtronic will also submit to the FDA adverse events, device failures, and complaint analysis for 10 years. This includes subsequent surgeries, heterotopic ossification, device malfunction, and other serious device-related complications.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine), was approved by the FDA through the premarket approval process in 2007. As with the Prestige® ST Cervical Disc, the FDA approval of ProDisc-C® was made conditional on 7-year follow-up of the 209 subjects included in the noninferiority trial, 7-year follow-up of 99 continued-access subjects, and a 5-year enhanced surveillance study to characterize more fully adverse events when the device is used under general conditions of use. Post approval study reports are to be delivered to the FDA annually. The ProDisc C Vivo is currently marketed by Centinal Spine.

The Bryan® Cervical Disc (Medtronic Sofamor Danek) consists of 2 titanium-alloy shells encasing a polyurethane nucleus and has been available outside of the United States since 2002. In 2009, the Bryan® Cervical Disc was approved by the FDA for treatment using an anterior approach of single-level cervical degenerative disc disease defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurologic sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography, myelography and computed tomography, and/or magnetic resonance imaging results. Patients receiving the Bryan® Cervical Disc should have failed at least six weeks of nonoperative treatment before implantation. As a condition for device approval, the FDA required Medtronic Sofamor Danek to extend its follow-up of enrolled subjects to 10 years after surgery. The study will involve the investigational and control patients from the pivotal investigational device exemption study arm, as well as the patients who received the device as part of the continued-access study arm. Also, Medtronic Sofamor Danek must perform a 5-year enhanced surveillance study of the disc to characterize more fully adverse events when the device is used in a broader patient population.



More recently, continued FDA approval requires completion of two post-approval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 years. The second study provides ten-year enhanced surveillance of adverse event data. Continued approval is contingent on submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, other serious device-related complications, and analysis of all explanted discs.

The following have also received the FDA approval:

- The PCM [porous-coated motion] Cervical Disc® (NuVasive) received the FDA approval in 2012 (P100012). The PCM® is a semi-constrained device consisting of two metal (cobalt-chromium alloy) endplates and a polyethylene insert that fits between the endplates.
- SECURE®-C (Globus Medical) was approved in 2012 (P100003). The SECURE®-C is a three-piece semi-constrained device with two metal (cobalt chromium molybdenum alloy) endplates and a polyethylene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C® is three-piece semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. The Mobi-C® is approved for 1-level (P110002) or 2-level (P110009) disc replacement.
- The M6-C Artificial Cervical Disc (Spinal Kinetics LLC) received FDA approval for single level degenerative radiculopathy in 2019 (P170036). The device is comprised of ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates. The device is secured with low profile pins.

Other devices are in FDA investigational device exemption trials in the United States (see [Table 2](#)).

Table 2. Cervical Disc Prostheses Under Investigation in the United States

| Prosthesis | Manufacturer | FDA Status |
|------------|------------------|---------------|
| Simplify | Simplify Medical | FDA IDE trial |
| Freedom® | AxioMed | FDA IDE trial |

FDA: U.S. Food and Drug Administration; IDE: investigational device exemption



Updates to the regulatory status of these devices can be viewed online using FDA product code MJO (available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. Accessed July 2020).

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. TEC Assessments. 2007;Volume 22:Tab 12.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. TEC Assessments. 2009;Volume 24:Tab 3.
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disease of the cervical spine. TEC Assessments. 2011;Volume 26:Tab 5.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. TEC Assessments. 2013;Volume 28:Tab 13.
5. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. *J Manipulative Physiol Ther.* Sep 1991;14(7):409-415. PMID 1834753
6. Hu Y, Lv G, Ren S, et al. Mid- to long-term outcomes of cervical disc arthroplasty versus anterior cervical discectomy and fusion for treatment of symptomatic cervical disc disease: a systematic review and meta-analysis of eight prospective randomized controlled trials. *PLoS One.* Feb 2016;11(2):e0149312. PMID 26872258
7. Burkus JK, Traynelis VC, Haid RW, Jr., et al. Clinical and radiographic analysis of an artificial cervical disc: 7- year follow-up from the Prestige prospective randomized controlled clinical trial: Clinical article. *J Neurosurg Spine.* Oct 2014;21(4):516-528. PMID 25036218
8. Sasso RC, Anderson PA, Riew KD, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. *J Bone Joint Surg Am.* Sep 21 2011;93(18):1684-1692. PMID 21938372
9. Phillips FM, Geisler FH, Gilder KM, et al. Long-term outcomes of the US FDA IDE prospective, randomized controlled clinical trial comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion. *Spine (Phila Pa 1976).* May 15 2015;40(10):674-683. PMID 25955086
10. Coric D, Kim PK, Clemente JD, et al. Prospective randomized study of cervical arthroplasty and anterior cervical discectomy and fusion with long-term follow-up: results in 74 patients from a single site. *J Neurosurg Spine.* Jan 2013;18(1):36-42. PMID 23140129
11. Davis RJ, Nunley PD, Kim KD, et al. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow- up results. *J Neurosurg Spine.* Jan 2015;22(1):15-25. PMID 25380538
12. Hisey MS, Bae HW, Davis RJ, et al. Prospective, randomized comparison of cervical total disk replacement versus anterior cervical fusion: results at 48 months follow-up. *J Spinal Disord Tech.* May 2015;28(4):E237-243. PMID 25310394
13. Janssen ME, Zigler JE, Spivak JM, et al. ProDisc-C Total Disc replacement versus anterior cervical discectomy and fusion for single-level symptomatic cervical disc disease: seven-year follow-up of the prospective randomized U.S. Food and Drug Administration Investigational Device Exemption Study. *J Bone Joint Surg Am.* Nov 4 2015;97(21):1738-1747. PMID 26537161



14. Zhang HX, Shao YD, Chen Y, et al. A prospective, randomised, controlled multicentre study comparing cervical disc replacement with anterior cervical decompression and fusion. *Int Orthop*. Dec 2014;38(12):2533-2541. PMID 25209344
15. Latka D, Kozłowska K, Miekisiak G et al. Safety and efficacy of cervical disc arthroplasty in preventing the adjacent segment disease: a meta-analysis of mid- to long-term outcomes in prospective, randomized, controlled multicenter studies. *Ther Clin Risk Manag*. 2019;15:531-539. PMID 30992666
16. Mummaneni PV, Burkus JK, Haid RW, et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine*. Mar 2007;6(3):198-209. PMID 17355018
17. Gornet MF, Burkus JK, Shaffrey ME, et al. Cervical disc arthroplasty with PRESTIGE LP disc versus anterior cervical discectomy and fusion: a prospective, multicenter investigational device exemption study. *J Neurosurg Spine*. Jul 31 2015:1-16. PMID 26230424
18. Murrey D, Janssen M, Delamarter R, et al. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J*. Apr 2009;9(4):275-286. PMID 18774751
19. Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. *Spine (Phila Pa 1976)*. Jan 15 2009;34(2):101-107. PMID 19112337
20. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): Mobi-C. 2013; https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002b.pdf. Accessed July, 2020.
21. Phillips FM, Lee JY, Geisler FH, et al. A prospective, randomized, controlled clinical investigation comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion: 2-year results from the US FDA IDE clinical trial. *Spine (Phila Pa 1976)*. Jul 1 2013;38(15):E907-918. PMID 23591659
22. Vaccaro A, Beutler W, Peppelman W, et al. Clinical outcomes with selectively constrained SECURE-C cervical disc arthroplasty: two-year results from a prospective, randomized, controlled, multicenter investigational device exemption study. *Spine (Phila Pa 1976)*. Dec 15 2013;38(26):2227-2239. PMID 24335629
23. U.S. Food and Drug Administration. Summary of Safety and Effectiveness: M6-C Artificial Cervical Disc. 2019. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170036>. Accessed July, 2020
24. Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial. *J Neurosurg Spine*. Sep 2010;13(3):308-318. PMID 20809722
25. Delamarter RB, Murrey D, Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients. *SAS J*. Jan 2010;4(4):122-128. PMID 25802660
26. Zigler JE, Delamarter R, Murrey D, et al. ProDisc-C and anterior cervical discectomy and fusion as surgical treatment for single-level cervical symptomatic degenerative disc disease: five-year results of a Food and Drug Administration study. *Spine (Phila Pa 1976)*. Feb 1 2013;38(3):203-209. PMID 23080427
27. Delamarter RB, Zigler J. Five-year reoperation rates, cervical total disc replacement versus fusion, results of a prospective randomized clinical trial. *Spine (Phila Pa 1976)*. Nov 2 2013;38(9):711-717. PMID 23124255
28. Lavelle WF, Riew KD, Levi AD et al. Ten-year Outcomes of Cervical Disc Replacement With the BRYAN Cervical Disc: Results From a Prospective, Randomized, Controlled Clinical Trial. *Spine*. 2019 May;44(9). PMID 30325888
29. Hisey MS, Bae HW, Davis R, et al. Multi-center, prospective, randomized, controlled investigational device exemption clinical trial comparing Mobi-C Cervical Artificial Disc to anterior discectomy and fusion in the treatment of symptomatic degenerative disc disease in the cervical spine. *Int J Spine Surg*. Feb 2014;8. PMID 25694918
30. Hisey MS, Zigler JE, Jackson R, et al. Prospective, randomized comparison of one-level Mobi-C Cervical Total Disc replacement vs. anterior cervical discectomy and fusion: results at 5-year follow-up. *Int J Spine Surg*. 2016;10:10. PMID 27162712



31. U.S. Food and Drug Administration. Summary of Safety and Effectiveness: Prestige LP Cervical Disc. PMA Number P090029/S003. 2016; https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090029s003b.pdf. Accessed July, 2020.
32. Davis RJ, Kim KD, Hisey MS, et al. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial. *J Neurosurg Spine*. Nov 2013;19(5):532-545. PMID 24010901
33. Radcliff K, Coric D, Albert T. Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. *J Neurosurg Spine*. Aug 2016;25(2):213-224. PMID 27015130
34. Bae HW, Kim KD, Nunley PD, et al. Comparison of clinical outcomes of 1- and 2-level total disc replacement: four-year results from a prospective, randomized, controlled, multicenter IDE clinical trial. *Spine (Phila Pa 1976)*. Jun 1 2015;40(11):759-766. PMID 25785955
35. Huppert J, Beaurain J, Steib JP, et al. Comparison between single- and multi-level patients: clinical and radiological outcomes 2 years after cervical disc replacement. *Eur Spine J*. Sep 2011;20(9):1417-1426. PMID 21336970
36. Staub LP, Ryser C, Roder C, et al. Total disc arthroplasty versus anterior cervical interbody fusion: use of the Spine Tango registry to supplement the evidence from randomized control trials. *Spine J*. Feb 2016;16(2):136- 145. PMID 26674445
37. MacDowall A, Skeppholm M, Lindhagen L et al. Artificial disc replacement versus fusion in patients with cervical degenerative disc disease with radiculopathy: 5-year outcomes from the National Swedish Spine Register. *J Neurosurg Spine*. 2018 Nov;30(2). PMID 30485205
38. Chen J, Wang X, Bai W, et al. Prevalence of heterotopic ossification after cervical total disc arthroplasty: a meta- analysis. *Eur Spine J*. Apr 2012;21(4):674-680. PMID 22134486
39. Nunley PD, Cavanaugh DA, Kerr EJ et al. Heterotopic Ossification After Cervical Total Disc Replacement at 7 Years-Prevalence, Progression, Clinical Implications, and Risk Factors. *Int J Spine Surg*. 2018 Jun;12(3). PMID 30276092
40. North American Spine Society. NASS coverage policy recommendations: Cervical artificial disc replacement. 2015; <https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx>. Accessed July, 2020.
41. National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the cervical spine [IPG341]. 2010; <https://www.nice.org.uk/guidance/ipg341>. Accessed July, 2020.
42. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Lumbar Artificial DISC Replacement (LADR) (150.10). 2007; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=313&ncdver=2&CoverageSelection=National&Keyword=disc&KeywordLookUp=Title&KeywordSearchType=And&from2=search.asp&bc=gAAAAA%3d%3d&>. Accessed July 2020.

History

| Date | Comments |
|----------|---|
| 08/11/15 | New Policy. Replaces policy 7.01.537. Also added definitions of cervical myelopathy and cervical radiculopathy. ICD-9 procedure code 84.61 added. |
| 01/08/16 | Minor update. CPT code 0092T, deleted 12/31/14, removed from policy. No other changes. |



| Date | Comments |
|----------|---|
| 10/01/16 | Annual Review, approved September 13, 2016. New policy statement added that 2-level cervical disc replacement may be considered medically necessary when criteria are met. Policy updated with literature review through June 2016; references added, updated and/or removed. Policy statement added as noted. |
| 07/01/17 | Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; Rationale revised, some references removed. Policy statements unchanged. |
| 03/01/18 | Interim Review, approved February 27, 2018. Note added that this policy has been revised. Added Surgery Site of Service criteria, which becomes effective June 1, 2018. |
| 06/01/18 | Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective. |
| 07/01/18 | Annual Review, approved June 12, 2018. Policy updated with literature review through February 2018; no references added. Medical necessity policy statement revised to include subsequent implantation of a second artificial cervical intervertebral disc at an adjacent level (contiguous to a previous placed artificial disc) when criteria are met. Investigational statements prior artificial disc placement and replacement at another cervical level removed. Prior artificial disc placement at another cervical level changed. |
| 02/01/19 | Minor update, updated title of related policy 7.01.560. |
| 05/01/19 | Minor update, clarified Site of Service requirements. |
| 07/01/19 | Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. M6-C Artificial Cervical Disc was added to the list of single level FDA approved devices. Otherwise, policy statements unchanged. Removed CPT code 22864. |
| 04/01/20 | Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020. |
| 06/10/20 | Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020. |
| 08/01/20 | Annual Review, approved July 23, 2020. Policy updated with literature review through March, 2020; references added. Rationale changed to tabular format. Change in terminology from 'artificial intervertebral disc arthroplasty of the cervical spine' to 'cervical disc arthroplasty'. |
| 01/01/21 | Minor correction only made to Documentation Requirement section – no other changes. |

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). ©2020 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 complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - 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, or sex, 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 800-842-5357
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 Avenue 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>.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

አማርኛ (Amharic):

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለማመጠን በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታወቅ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحتوي هذا الإشعار على معلومات مهمة بخصوص طلبك أو التخطيط التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Oromoo (Cushite):

Beeksisni kun odeeffannoo barbaachisaa qaba. Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

Français (French):

Cet avis a d'importantes informations. Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Diese Benachrichtigung enthält wichtige Informationen. Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):

Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnu ntawm Premera Blue Cross. Tej zaum muaj cov hnu tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyuog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenna coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyto wenna tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

日本語 (Japanese):

この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາອ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກໍານົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងរបស់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ដុល្លារចេញផ្លូវ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਕੱਠ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਰਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Prezenta notificare conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).