

MEDICAL POLICY – 7.01.132

Transcatheter Aortic Valve Implantation for Aortic Stenosis

BCBSA Ref. Policy: 7.01.132

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RELATED MEDICAL POLICIES:

7.01.131 Transcatheter Pulmonary Valve Implantation

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Introduction

The aortic valve is a valve that separates the main pumping chamber of the heart (the left ventricle) from the large artery that takes oxygen rich blood away from the heart and out to the body (the aorta). If the valve doesn't completely open, it is called aortic stenosis. Aortic stenosis decreases the amount of oxygenated blood getting out to the body. Open surgery is one method of replacing a damaged aortic valve. A newer procedure — known as transcatheter aortic valve replacement or transcatheter aortic valve implantation — has been developed. It allows a replacement valve to be threaded through an artery and into the heart without open heart surgery. A catheter (a long thin, tube) is threaded through an artery, either in the leg or in the chest, and into the heart. The replacement valve is then lodged into the defective aortic valve. The new valve is then expanded, pushing aside parts of the old valve. This policy describes when transcatheter aortic valve replacement 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.

| Procedure | Medical Necessity |
|--|--|
| <p>Transcatheter aortic valve replacement</p> | <p>Transcatheter aortic valve replacement with a U.S. Food and Drug Administration (FDA)–approved transcatheter heart valve system, when performed via an approach consistent with the device’s FDA-approved labeling, may be considered medically necessary as a treatment for native valve aortic stenosis when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • Severe aortic stenosis (see the Definition of Terms section) with a calcified aortic annulus is present <p>AND</p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) heart failure class II, III or IV symptoms <p>AND</p> <ul style="list-style-type: none"> • Left ventricular ejection fraction greater than 20% <p>AND</p> <ul style="list-style-type: none"> • Patient is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high or intermediate risk for open surgery (see the Definition of Terms section) <p>Transcatheter aortic valve replacement with an FDA approved transcatheter heart valve system for repair of a degenerated bioprosthetic valve may be considered medically necessary when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve <p>AND</p> <ul style="list-style-type: none"> • NYHA heart failure class II, III or IV symptoms <p>AND</p> <ul style="list-style-type: none"> • Left ventricular ejection fraction greater than 20% <p>AND</p> <ul style="list-style-type: none"> • Patient is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery (see the Definition of |



| Procedure | Medical Necessity |
|-----------|--|
| | <p>Terms section)</p> <p>Transcatheter aortic valve replacement is considered investigational for all other indications and when criteria are not met.</p> |

| Documentation Requirements |
|--|
| <p>The patient's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:</p> <ul style="list-style-type: none"> • Diagnosis/condition • History and physical examination documenting the severity of the condition • NYHA heart failure class symptoms • Left ventricular ejection fraction • Patient is at high risk for open surgery or is not an operable candidate for open surgery (see definition of terms in medical policy) • Whether transcatheter heart valve system is FDA approved and will be used in a manner consistent with FDA labeling |

Coding

| Code | Description |
|------------|--|
| CPT | |
| 33361 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach |
| 33362 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach |
| 33363 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach |
| 33364 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach |
| 33365 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy) |
| 33366 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical |



| Code | Description |
|-------|--|
| | exposure (eg, left thoracotomy) |
| 33367 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure) |
| 33368 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure) |
| 33369 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure) |

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

Extreme risk or inoperable for open heart surgery: FDA definition of extreme risk or inoperable for open surgery:

- Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery

High Risk for open heart surgery: FDA definition of high risk for open surgery:

- Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
- Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery

Intermediate risk: FDA definition of intermediate risk is:

- Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.



Severe aortic stenosis: For the use of the Sapien or CoreValve devices, severe aortic stenosis is defined by the presence of one or more of the following criteria:

- An aortic valve area of less than or equal to 1 cm^2
- An aortic valve area index of less than or equal to $0.6 \text{ cm}^2/\text{m}^2$
- A mean aortic valve gradient greater than or equal to 40 mm Hg
- A peak aortic-jet velocity greater than or equal to 4.0 m/s

Evidence Review

Description

Transcatheter aortic valve implantation (TAVI; also known as transcatheter aortic valve replacement) is a potential treatment for patients with severe aortic stenosis. Many patients with aortic stenosis are elderly and/or have multiple medical comorbidities, thus indicating a high, often prohibitive, risk for surgery. This procedure is being evaluated as an alternative to open surgery, or surgical aortic valve replacement (SAVR), for high-risk patients with aortic stenosis and as an alternative to nonsurgical therapy for patients with a prohibitive risk for surgery.

Background

Aortic Stenosis

Aortic stenosis is defined as narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Progressive calcification of the aortic valve is the most common etiology in North America and Europe, while rheumatic fever is the most common etiology in developing countries.¹ Congenital abnormalities of the aortic valve, most commonly a bicuspid valve, increase the risk for aortic stenosis, but aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension, and hyperlipidemia.¹ Thus, the pathogenesis of calcific aortic stenosis is thought to be similar to that of atherosclerosis, ie, deposition of atherogenic lipids and infiltration of inflammatory cells, followed by progressive calcification.



The natural history of aortic stenosis involves a long asymptomatic period, with slowly progressive narrowing of the valve until the stenosis reaches the severe stage. At this time, symptoms of dyspnea, chest pain, and/or dizziness and syncope often occur and the disorder progresses rapidly. Treatment of aortic stenosis is primarily surgical, involving replacement of the diseased valve with a bio-prosthetic or mechanical valve by open heart surgery.

Disease Burden

Aortic stenosis is a relatively common disorder in elderly patients and is the most common acquired valve disorder in the United States. Approximately 2% to 4% of people older than 65 years of age have evidence of significant aortic stenosis,¹ increasing up to 8% of people by age 85 years.² In the Helsinki Aging Study (1993), a population-based study of 501 patients ages 75 to 86 years, the prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%.³ In the United States, more than 50,000 aortic valve replacements are performed annually due to severe aortic stenosis.

Aortic stenosis does not cause substantial morbidity or mortality when the disease is mild or moderate in severity. By the time it becomes severe, there is an untreated mortality rate of approximately 50% within 2 years.⁴ Open surgical repair is an effective treatment for reversing aortic stenosis, and artificial valves have demonstrated good durability for periods of up to 20 years.⁴ However, these benefits are accompanied by a perioperative mortality of approximately 3% to 4% and substantial morbidity,⁴ both of which increase with advancing age.

Unmet Needs

Many patients with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of patients presenting with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities.⁵ For patients who are not surgical candidates, medical therapy can partially alleviate the symptoms of aortic stenosis but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes.⁶ Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction (MI), and aortic regurgitation. Also, restenosis can occur rapidly, and there is no improvement in mortality. As a result, there is a large unmet need for less invasive treatments for aortic stenosis in patients who are at increased risk for open surgery.



Treatment

Transcatheter aortic valve implantation (TAVI) has been developed in response to this unmet need and was originally intended as an alternative for patients for whom surgery was not an option due to prohibitive surgical risk or for patients at high risk for open surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without the need for cardiopulmonary bypass.

Summary of Evidence

For individuals who have severe symptomatic aortic stenosis who are at prohibitive risk for open surgery who receive transcatheter aortic valve implantation (TAVI), the evidence includes a randomized controlled trial (RCT) comparing TAVI with medical management in individuals at prohibitive risk of surgery, a single-arm prospective trial, multiple case series, and multiple systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are not surgical candidates due to excessive surgical risk, the PARTNER B trial reported on results for patients treated with TAVI by the transfemoral approach compared with continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI patients at 1 year compared with medical care. This trial also reported improvements in other relevant clinical outcomes for the TAVI group. There was an increased risk of stroke and vascular complications in the TAVI group. Despite these concerns, the overall balance of benefits and risks from this trial indicate that health outcomes are improved. For patients who are not surgical candidates, no randomized trials have compared the self-expandable valve with best medical therapy. However, results from the single-arm CoreValve Extreme Risk Pivotal Trial met trialists' pre-specified objective performance goal. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at high risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals at high risk for surgery, multiple nonrandomized comparative studies, and systematic



reviews of these studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are high risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at 1 year for the balloon-expandable valve compared with open surgery. In this trial, TAVI patients also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk patients have reported no major differences in rates of mortality or stroke between the 2 procedures. Since publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at 1 year and 2 years for the self-expanding prosthesis. This trial reported no significant differences in stroke rates between groups. In an RCT directly comparing the self-expandable with the balloon-expandable valve among surgically high-risk patients, the devices had similar 30-day mortality outcomes, although the self-expandable valve was associated with higher rates of residual aortic regurgitation and requirement for a new permanent pacemaker. Evidence from RCT and nonrandomized studies has suggested that TAVI with a self-expanding device is associated with higher rates for permanent pacemakers postprocedure. However, survival rates appear to be similar between device types, and the evidence does not clearly support the superiority of one device over another in all patients. Two sex-specific studies were also identified in a literature search with the objective of observing mortality rates in women undergoing TAVI or SAVR. Results were varied, and further study is needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at intermediate risk for open surgery who receive TAVI, the evidence includes 3 RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, 2 RCTs only in patients with intermediate risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in patients with intermediate risk for open surgery. Three of them, which included over 4000 patients combined, reported noninferiority of TAVI vs SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of patients (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at 2 years for TAVI vs SAVR. The final study (N=70) had an unclear hypothesis and reported 30-day mortality rates favoring SAVR (15% vs 2%, p=0.07) but used a transthoracic approach. The rates of adverse events differed between groups, with bleeding, cardiogenic shock, and acute kidney injury higher in patients randomized to open surgery and permanent pacemaker requirement higher in patients randomized to TAVI. Subgroup analyses of meta-analyses and the transthoracic arm of the Leon et al RCT has suggested that the benefit of TAVI may be limited to patients who are candidates for transfemoral access. Although several RCTs have 2 years of follow-up postprocedure, it is uncertain how many individuals require



reoperation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at low risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including patients at low surgical risk, systematic reviews, and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Limited data are available comparing SAVR with TAVI in patients who had severe aortic stenosis with low risk for open surgery. A systematic review including the low surgical risk patients of these 2 RCTs, and 4 observational studies, with propensity score matching, reported that the 30-day and in-hospital mortality rates were similar for TAVI (2.2%) and SAVR (2.6%). However, TAVI was associated with increased risk of mortality with longer follow-up (median, 2 years; 17.2% vs 12.7%). TAVI was associated with reduced risk for bleeding, renal failure and, an increase in vascular complications and pacemaker implantation compared with SAVR. The evidence is insufficient to determine the effects of the technology on health outcomes. For individuals who have valve dysfunction and aortic stenosis or regurgitation after aortic valve repair who receive transcatheter aortic “valve-in-valve” implantation, the evidence includes case series (largest included 459 patients) and systematic reviews of case series. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. These case series have reported high rates of technical success of valve implantation and improvement in heart-failure symptoms for most patients. However, they have also reported high rates of short-term complications and high rates of mortality at 1 year postprocedure. There is a lack of evidence comparing valve-in-valve replacement with alternative treatment approaches. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently 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 | | | |
| NCT01586910^a | Surgical Replacement and Transcatheter Aortic Valve | 2500 | Oct 2017 |



| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|--------------------------------|--|--------------------|-----------------------|
| | Implantation (SURTA VI) | | (ongoing) |
| NCT02956915 | Evaluation of Length of Stay and Predisposing Factors of Late Discharge After Transfemoral Transcatheter Aortic Valve Implantation Using the SAPIEN-3 Prosthesis: A French Multicenter Prospective Observational Trial | 300 | Dec 2017 (ongoing) |
| NCT01057173 | Transcatheter Versus Surgical Aortic Valve Implantation in Patients With Severe Aortic Valve Stenosis (NOTION) | 280 | Apr 2018 |
| NCT01645202 | A Randomized Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve Versus Edwards SAPIEN XT (The CHOICE Trial) | 240 | Dec 2018 |
| NCT01240902^a | Medtronic CoreValve® U.S. Pivotal Trial | 1650 | Aug 2019 |
| NCT02661451^a | Transcatheter Aortic Valve Replacement to UNload the Left Ventricle in Patients With ADvanced Heart Failure: A Randomized Trial (TAVR UNLOAD) | 600 | May 2020 |
| NCT02436655 | Aortic Valve Replacement Versus Conservative Treatment in Asymptomatic Severe Aortic Stenosis: (AVATAR Trial): A Multicentre Randomized Controlled Trial | 312 | Jun 2020 |
| NCT01314313^a | The PARTNER II Trial "Placement of AoRTic TraNscathetER Valves Trial" (US) [Edwards Study 2010-12] | 6650 | Sep 2020 |
| NCT02163850^a | SALUS Trial: TranScatheter Aortic Valve RepLacement System Pivotal Trial The Safety and Effectiveness of the Direct Flow Medical Transcatheter Aortic Valve System | 878 | Dec 2021 |
| NCT01737528 | Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry) | 16,000 | Jun 2022 |
| NCT02249000 | Safety and Clinical Performance of the Self-expanding Transcatheter BIOVALVE Prosthesis in Subjects With Severe Symptomatic Aortic Stenosis Suitable for Transfemoral Transcatheter Aortic Valve Implantation | 86 | Dec 2022 |
| NCT03361046 | Evaluation of Clinical Outcomes of Transcatheter Aortic Valve-in-Valve Implantation in Polish Population – Observational Multicenter Registry | 150 | May 2024 |

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.

2016 Input

In response to requests, clinical input was received from 2 specialty societies (1 of which provided 2 responses) and 2 academic medical centers (one of which provided 3 responses) while this policy was under review in 2016. Although there was no support for the use of valve-in-valve TAVI to replace a failed bioprosthetic valve in general use, there was general support for the use of valve-in-valve TAVI for patients at high and prohibitive risk for surgery.

2014 Input

In response to requests, clinical input was received from 2 specialty societies (1 of which provided 2 responses) and 6 academic medical centers while this policy was under review in 2014. All reviewers who provided a response considered TAVI medically necessary for patients with severe aortic stenosis with a calcified aortic annulus and New York Heart Association functional class II, III, or IV symptoms, and who are not candidates for open surgery or who are operable candidates but are at high risk for open surgery. Most reviewers would require a patient to have a left ventricular ejection fraction greater than 20% for the procedure to be medically necessary. All reviewers indicated support for limiting the use of TAVI to patients who are not candidates for open surgery or who are operable candidates but are at high risk for open surgery, and most supported using the Food and Drug Administration's (FDA) definition of high risk and extreme risk for surgery. Most reviewers noted that self-expanding valves have been associated with higher rates of postprocedural pacemaker requirements but that neither type of valve was clearly superior to the other.



2011 Input

In response to requests, clinical input was received from 1 specialty society and 6 academic medical centers while this policy was under review in 2011. At the time of vetting, FDA approval had not yet been granted for any TAVI device. Reviewers were mixed in support for a medically necessary indication for patients who are not surgical candidates. However, all reviewers indicated that they would consider this procedure medically necessary if FDA granted approval. No reviewer expressed support for medical necessity in other patient populations, including patients who were at high risk for surgery, but were surgical candidates. Concerning patient selection criteria, most reviewers referred to the study selection criteria in the PARTNER trial and did not offer further options for objective patient selection.

Practice Guidelines and Position Statements

American College of Cardiology and the American Heart Association

The American College of Cardiology and the American Heart Association (2014) published joint guidelines on the management of valvular heart disease.⁸¹ Both groups issued a joint focused update in 2017.⁸² These guidelines make the following recommendations regarding the choice of surgical or transcatheter intervention for treatment of aortic stenosis (see [Table 2](#)).

Table 2. Recommendations on Surgical or Transcatheter Intervention for Aortic Stenosis

| Recommendation | COR | LOE |
|---|------------|------------|
| "Surgical AVR is recommended in patients who meet an indication for AVR with low or intermediate surgical risk." | I | A |
| "For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care" | I | C |
| "TAVR is recommended for symptomatic patients with severe AS and high risk for SAVR, depending on patient-specific procedural risks, values and preferences." | I | A |
| "TAVR is recommended for symptomatic patients with severe AS, prohibitive risk for SAVR and a predicted post-TAVR survival >12 mo." | I | A |
| "TAVR is a reasonable alternative to SAVR for symptomatic patients with severe AS and intermediate surgical risk, depending on patient-specific procedural risks, values and preferences" | IIa | B |



| Recommendation | COR | LOE |
|---|-----|-----|
| "For severely symptomatic patients with bioprosthetic stenosis or regurgitation at high or prohibitive risk for reoperation, and in whom improvement in hemodynamics is anticipated, valve-in-valve TAVR is reasonable" | IIa | B |
| "Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS." | IIb | C |
| "TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS." | III | B |

AS: aortic stenosis; AVR: aortic valve replacement; COR: class of recommendation; LOE: level of evidence; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement.

European Society for Cardiology and the European Association for Cardio-Thoracic Surgery

The European Society for Cardiology and the European Association for Cardio-Thoracic Surgery (2017) published joint guidelines on the management of valvular heart disease.⁸³ These guidelines made the following recommendations on the use of TAVI (see [Table 3](#)).

Table 3. Recommendations on Surgical or Transcatheter Intervention for Aortic Stenosis

| Recommendation | COR | LOE |
|--|-----|-----|
| "TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team." | I | B |
| In patients who are at increased surgical risk (STS or EuroSCORE II $\geq 4\%$ or logistic EuroSCORE I $\geq 10\%$ or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics, with TAVI being favoured in elderly patients suitable for transfemoral access." | I | B |

COR: class of recommendation; LOE: level of evidence; SAVR: surgical aortic valve replacement; STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation.

U.S. Preventive Services Task Force Recommendations

Transcatheter aortic valve implantation is not a preventive service.



Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS) published a decision memo on the use of transcatheter aortic valve replacement (TAVR) in 2012.⁸⁴ This memo indicated that CMS covers TAVI when used according to FDA indications when the following conditions are met:

- Device has FDA approval
- Two cardiac surgeons agree with indications for the procedure
- The patient is “under the care of a heart team”, and the hospital meets qualifications for performing TAVR.

The memo also stated that TAVR could be covered for non-FDA-approved indications under the Coverage with Evidence Development program. The following is a summary of the main conditions required for Coverage with Evidence Development:

- TAVI is performed within a clinical study that has the following characteristics:
 - “The clinical study must adhere to the... standards of scientific integrity and relevance to the Medicare population.”
 - The study must address quality of life and adverse events at follow-up periods of 1 year or longer.

Regulatory Status

Two manufacturers have transcatheter aortic valve devices with Food and Drug Administration (FDA) approval. Regulatory status data for these devices are listed in [Table 4](#).

Table 4. FDA-Approved Transcatheter Aortic Valve Device Systems

| Device and Indication | Manufacturer | Date Cleared | PMA |
|--|----------------------|--------------|---------|
| Edwards SAPIEN Transcatheter Heart Valve System™ <ul style="list-style-type: none">• Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach) | Edwards Lifesciences | 11/11 | P100041 |



| Device and Indication | Manufacturer | Date Cleared | PMA |
|---|---------------------|--------------|--------------|
| <ul style="list-style-type: none"> Expanded to include high-risk aortic stenosis (transapical approach) | | 10/12 | |
| <ul style="list-style-type: none"> Expanded to include replacement of bioprosthetic valve in high risk for death or severe complications of repeat surgery | | 06/17 | |
| <ul style="list-style-type: none"> Expanded to include severe aortic stenosis with intermediate surgical risk | | 08/16 | |
| Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories <ul style="list-style-type: none"> Severe native aortic valve stenosis at high or greater risk for open surgical therapy | | 07/14 | P130009 |
| <ul style="list-style-type: none"> Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy | | 10/15 | P130009/S034 |
| <ul style="list-style-type: none"> Expanded to include severe aortic stenosis with intermediate surgical risk | | 08/16 | |
| Medtronic CoreValve System™ <ul style="list-style-type: none"> Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy | Medtronic CoreValve | 01/14 | P130021 |
| <ul style="list-style-type: none"> Expanded to include high risk for open surgical therapy | | 06/16 | P130021/S002 |
| <ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy | | 07/17 | P130021/S033 |
| Medtronic CoreValve Evolut R System™ <ul style="list-style-type: none"> Design iteration for valve and accessories | | 06/15 | P130021/S014 |
| <ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy | | 07/17 | P130021/S033 |
| Medtronic CoreValve Evolut PRO System™ <ul style="list-style-type: none"> Design iteration for valve and accessories | | 03/17 | P130021/S029 |
| <ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy | | 07/17 | P130021/S033 |

FDA: Food and Drug Administration; PMA: postmarket approval.

Other transcatheter aortic valve systems are under development. The following repositionable valves are under investigation:



- Lotus™ Aortic Valve Replacement System (Boston Scientific)⁷
- Portico™ Transcatheter Aortic Valve (St. Jude Medical)
- JenaValve™ (JenaValve Technology); designed for transapical placement

Several embolic protection devices, which are designed to collect embolic debris distal to the transcatheter aortic valve implantation apparatus and to prevent ischemic stroke, are under investigation. No devices have FDA approval for use in the United States. Examples include the TriGuard (Keystone Heart) and the Sentinel Cerebral Protection System (Claret Medical).

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History

| Date | Comments |
|----------|--|
| 02/27/12 | New Policy – Add to Surgery section. Policy created with literature search through October 2011; considered medically necessary for patients who are not surgical candidates; investigational for all other indications. |
| 09/27/12 | Update Coding Section – ICD-10 codes are now effective 10/01/2014. |
| 02/11/13 | Replace policy. Policy updated with literature review, references 7, 15, 16, 18, 20, 23-28, 30 added. Medically necessary indications added for patients who are at high risk for open surgery using the transfemoral approach, and patients who are at high risk for open surgery using the transapical approach. Investigational statement added for treatment of degenerated bio-prosthetic valve or failed TAVI (Valve-in-Valve approach), and for vascular approaches other than transfemoral or transapical. Codes updated. |
| 12/23/13 | Coding Update. Add new CPT 33366, effective 01/01/14; 0318T discontinued effective 12/31/13; deleted codes 0256T – 0259T removed. |
| 02/10/14 | Replace policy. Policy updated with literature review through November 15, 2013. References 8, 18, 19, 22, 23, 27 added. Policy statement revised to include medically necessary indication for TAVI by the transapical approach for patients who are not suitable candidates for open surgery. ICD-10 Procedure codes 35.05 and 35.22 removed from the policy; they were provided for informational purposes only. |
| 12/17/14 | Annual Review. Policy statement revised to remove statement that “procedures performed via the transaxillary, transiliac, transaortic, or other approaches” are investigational, to reflect the approval of the CoreValve device that is labeled for use via transaxillary, transfemoral, and transaortic approaches. Policy statement added stating that devices should be used according to their FDA approved indication. Clinical input supported proposed policy statements. Policy updated with literature review through September 1, 2014, and the results of clinical input. References 9-10, 15-17, 23, 28-34, 36, 41-43, 45, 47, 49-52, 57-59 added; others renumbered/removed. Policy statements changed as noted. ICD-9 and ICD-10 diagnosis and procedure codes removed; these do not relate to policy adjudication. |
| 12/08/15 | Annual Review. Policy reviewed. No new references added. Policy statements unchanged. |
| 02/01/16 | Coding update. Added 93799. |
| 11/01/16 | Annual Review, changes approved October 11, 2016. Medically necessary policy statement added for valve-in-valve implantation in patients at high or prohibitive risk for open surgery. Policy updated with literature review through December 9, 2015, references added. Policy statement added as noted. Coding update, removed unlisted CPT code 93799. |



| Date | Comments |
|----------|---|
| 05/01/17 | Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 22, 2016; references 20, 31-34, 45, 48-55, and 85 added. Policy statements unchanged. |
| 10/24/17 | Policy moved to new format; no change to policy statements. |
| 07/01/18 | Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 19, 26, 37, 42-50, 58-60, 68, and 82-83 added. Policy statements changed to add patients at intermediate surgical risk to first medically necessary statement. |
| 04/01/19 | Minor update, added Documentation Requirements section. |

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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 ለማመጣት በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰብሰብ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار 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. Beeksisni 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 hnuv 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 nyoog 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 wenno 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 wenno 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 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):

ແຈງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងរបស់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក 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):

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