

## MEDICAL POLICY – 7.01.131

## Transcatheter Pulmonary Valve Implantation

BCBSA Ref. Policy: 7.01.131

Effective Date: Dec. 1, 2017

Last Revised: Nov. 14, 2017

Replaces: N/A

## RELATED MEDICAL POLICIES:


2.02.30 Transcatheter Mitral Valve Repair

7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

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[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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## Introduction

Congenital heart disease is a term that means a person was born with heart problems. These difficulties affect the heart's function and structure. Congenital heart disease can range from mild, which may not need treatment, to severe, which often does. One congenital heart defect is known as right ventricular outflow tract (RVOT) dysfunction. Essentially, it's a problem with how the blood flows as it leaves the heart and goes to the lungs. Repairing it requires reconstructing certain areas of the heart and placing a tube (conduit) to allow the blood to flow correctly. Over a long period of time the conduit can become narrowed or a specific valve can become leaky. A second valve replacement surgery may be needed in this situation. This second surgery is usually done as an open surgery. However, surgery using a long, thin tube (a heart catheter) instead of open heart surgery can be done in certain situations. This policy describes when an additional RVOT surgery using a catheter 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.

Service	Medical Necessity
<b>Transcatheter pulmonary valve implantation (TPVI)</b>	<p><b>Transcatheter pulmonary valve implantation (TPVI), when performed according to FDA-approved indications, is considered medically necessary for patients with prior repair of congenital heart disease and right ventricular outflow tract (RVOT) dysfunction, who are not good candidates for open repair due to one or more of the following conditions:</b></p> <ul style="list-style-type: none"> <li>• High-risk for surgery due to concomitant medical comorbidities</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Poor surgical candidate due to multiple prior thoracotomies for open heart surgery</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Moderate to severe pulmonary valve regurgitation</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Pulmonary valve stenosis, with mean (RVOT) gradient <math>\geq</math> 35 mm Hg</li> </ul> <p><b>Transcatheter pulmonary valve implantation is considered investigational for all other indications.</b></p>

## Coding

Code	Description
<b>CPT</b>	
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

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## Related Information



N/A

## Evidence Review

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### Description

Transcatheter pulmonary valve implantation (TPVI) received approval from the U.S. Food and Drug Administration under a humanitarian device exception in January 2010 for patients with previous repair of congenital heart disease (CHD) and right ventricular outflow tract (RVOT) obstruction. Patients with prior CHD repair are at risk of needing repeated reconstruction procedures. TPVI has been proposed as a less invasive alternative to open surgical pulmonary valve replacement or reconstruction for RVOT obstruction.

### Background

#### *Description of Disease*

Congenital heart disease, including tetralogy of Fallot, pulmonary atresia, and transposition of the great arteries, is generally treated by surgical repair at an early age. This involves reconstruction of the right ventricular outflow tract (RVOT) and pulmonary valve by means of a surgical homograft or a bovine-derived valved conduit. These repairs are prone to development of pulmonary stenosis or regurgitation over long periods of follow-up.

Because individuals who have had surgically corrected congenital heart disease are living longer into adulthood, RVOT dysfunction following initial repair has become more common. Calcification of the RVOT conduit can lead to pulmonary stenosis, while aneurysmal dilatation can result in pulmonary regurgitation. RVOT dysfunction can lead to decreased exercise tolerance, potentially fatal arrhythmias, and/or irreversible right ventricular dysfunction.<sup>1</sup>

Interventions for RVOT dysfunction often require repeat open heart surgery, resulting in numerous open heart procedures for patients who live into adulthood. Treatment options for pulmonary stenosis are open surgery with valve replacement, balloon dilatation, or percutaneous stenting.<sup>1</sup> Interventions for pulmonary regurgitation are primarily surgical, either reconstruction of the RVOT conduit or replacement of the pulmonary valve through open surgery. The optimal timing of these interventions is not well understood.<sup>2</sup>



Transcatheter pulmonary valve replacement offers a potentially less invasive treatment option for patients with prior surgery for congenital heart disease and RVOT dysfunction. It is possible that the use of less invasive valve replacement techniques can spare patients from multiple repeat open heart procedures over long periods of follow-up.

### ***Description of Technology***

The Melody Transcatheter Pulmonary Valve (TPV) and the Ensemble Transcatheter Valve Delivery System are used together for percutaneous replacement of a dysfunctional pulmonary valve. The Melody valve consists of a section of bovine jugular vein with an intact native venous valve. The valve and surrounding tissue is sutured within a platinum-iridium stent scaffolding. The transcatheter delivery system consists of a balloon-in-balloon catheter with a retractable sheath and distal cup into which the valve is placed. The procedure is performed on the beating heart without use of cardiopulmonary bypass.

The Melody valve is first crimped to fit into the delivery system. It is introduced through the femoral vein and advanced into the right side of the heart and put into place at the site of the pulmonary valve. The inner balloon is inflated to open the artificial valve, and then the outer balloon is inflated to position the valve into place.

The Edwards Sapien XT Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) and the NovaFlex + delivery system, composed of a stainless steel frame with bovine pericardial tissue leaflets and available in 23-mm, 26-mm, and 29 mm sizes and accessories, gained Food and Drug Administration approval under Investigational Device Exemption (IDE) for use in the United States in February of 2016.

### **Summary of Evidence**

#### ***FDA-Approved Device and Indication***

For individuals who have a history of congenital heart disease (CHD) and current right ventricular outflow tract (RVOT) obstruction who receive transcatheter pulmonary valve implantation (TPVI) with a Food and Drug Administration (FDA)-approved device and indication, the evidence includes 1 prospective, interventional, noncomparative study and multiple prospective and retrospective case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity and mortality. Results of the case series indicate that there is a high rate of procedural success and



low procedural mortality, although the rates of serious procedural adverse events reported ranges from 3.0% to 7.4%. Most valves demonstrate competent functioning by Doppler echocardiography at 6- to 12-month follow-up, but complications (eg, stent fractures, need for re-interventions) were reported in an FDA analysis to occur at rates of 18% and 7%, respectively. Other publications with longer follow-up have reported stent fractures in up to 26% of patients; however, most stent fractures have not required reintervention. Studies with follow-up extending to a maximum of 7 years postprocedure have suggested that the functional and hemodynamic improvements are durable, but a relatively high proportion of patients (20%-30%) require reintervention on the pulmonary valve. No comparative studies were identified, and there is no direct evidence that TPVI leads to a reduction in future open heart procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

According to Hayes, the available observational studies found generally consistent short-term benefits of TPVI for RVOT, with some results dependent on etiology and pathology of the pulmonary valve defect, operator experience, and procedure protocol. Most of the hemodynamic measures improved consistently across 22 observational studies. Only 6 observational studies evaluated pulmonary regurgitation, but they reported significant improvement from baseline; however, long-term pulmonary regurgitation severity remains unknown. Results from 11 observational studies were less consistent, with some showing significant improvements from baseline and others showing small improvements only. The TPVI procedure itself was technically successful in most cases, but reintervention was required in approximately 25% to 33% of patients at 5-year follow-up. Overall, TPVI was relatively safe, compared with open chest surgery; however, it has caused severe, potentially life-threatening complications. (Hayes, January 2017)

### ***Non-FDA-Approved Device or Indication***

For individuals who have a history of CHD and current RVOT obstruction who receive TPVI with a non-FDA-approved device or indication, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity and mortality. There is currently limited published evidence on the off-label use of TPVI, including implantation of a non-FDA-approved valve, or use of an approved valve for a non-FDA-approved indication. The published relatively small case series are heterogeneous in terms of the device used and the indications for TPVI. 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 review are listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT00676689</a> <sup>a</sup>	Implantation of the SAPIEN Transcatheter Heart Valve (THV) in the Pulmonic Position	81	Nov 2019 ongoing but not recruiting
<a href="#">NCT00740870</a> <sup>a</sup>	Implantation of the Medtronic Melody Transcatheter Pulmonary Valve in Patients With Dysfunctional RVOT Conduits: A Feasibility Study	171	July 2020 ongoing but not recruiting
<a href="#">NCT02987387</a>	Post-approval Study of the SAPIEN XT THV in Patients with Pulmonary Valve Dysfunction	191	Jan 2024

NCT: national clinical trial

<sup>a</sup> 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 provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 6 academic medical centers while this policy was under review in 2011. Overall response to whether TPVI was investigational was mixed, with 2 of 5 reviewers indicating they agree with the investigational status, and 3 reviewers who indicated partial support. Most reviewers (4/5) indicated that there is a subpopulation of patients who are at high risk for surgery or who are not candidates for surgery, and for whom there are no other available options. These reviewers felt TPVI was a viable alternative that offered potential benefit for these patients.



## Practice Guidelines and Position Statements

### *Society for Cardiovascular Angiography and Interventions et al*

In 2015, the Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American College of Cardiology (ACC) and the Society of Thoracic Surgeons published a consensus-based report on operator and institutional requirements for TPVI.<sup>39</sup> Recommendations to qualify for a TPVI program included 150 catheterizations/year, association with a surgical program, submission of all cases to a national registry, and, for patients, 80% freedom from re-intervention at 1 year.

### *American Heart Association and American College of Cardiology*

In 2014, the American Heart Association (AHA) and the ACC issued guidelines for the management of patients with valvular disease.<sup>40</sup> These guidelines do not make specific recommendations on the treatment of primary pulmonary valve disease (stenosis or regurgitation), but instead refer to the 2008 guidelines for the management of adults with congenital heart disease.

In 2008, the AHA and ACC (in collaboration with other medical societies) issued guidelines for the management of adults with congenital heart disease.<sup>41</sup> For patients with isolated valvular pulmonary stenosis, the guidelines make recommendations on balloon valvulotomy or surgical intervention; however, TPVI is not addressed.

## Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

## Regulatory Status

On January 25, 2010, the Melody® Transcatheter Pulmonary Valve (TPV) and the Ensemble® Transcatheter Valve Delivery System (Medtronic, Minneapolis, MN) were approved by the U.S. Food and Drug Administration (FDA) under the humanitarian device exemption program for use



as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) right ventricular outflow tract (RVOT) conduit that is 16 mm or greater in diameter when originally implanted, and
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
  - Regurgitation: moderate-to-severe regurgitation, or
  - Stenosis: mean RVOT gradient  $\geq 35$  mm Hg

In 2015, approval of the Melody® device was amended to a premarket approval (PMA) because the FDA determined that the device represented a breakthrough technology.<sup>3</sup> The PMA was based, in part, on 2 prospective clinical studies, the Melody® TPV Long-term Follow-up Post Approval Study (PAS) and the Melody TPV New Enrollment PAS.

FDA product code: NPV.

On February 29, 2016 the Food and Drug Administration (FDA) granted expanded approval of the Sapien XT™ transcatheter heart valve (Edwards Lifesciences Corporation) and the NovaFlex + delivery system to include use in percutaneous pulmonary valve implantation (PPVI) procedures.

The Sapien XT was first approved in 2014 for aortic valve implantation in patients with severe aortic stenosis in whom open surgery would be risky. The expanded approval allows for use of the Sapien XT to replace pulmonary valves in adult and pediatric patients who suffer from either a narrowed pulmonary valve or moderate or greater pulmonary regurgitation caused by congenital heart disease. The current supplement was submitted to expand the indication for the Edwards SAPIEN XT Transcatheter Heart Valve to include pulmonic implantation

The SAPIEN XT Transcatheter Heart Valve and Accessories received FDA approval through the PMA process on February 29, 2016. According to the PMA approval order, this device is indicated for use in pediatric and adult patients with a dysfunctional, non-compliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and pulmonary regurgitation  $\geq$  moderate and/or mean RVOT gradient  $\geq 35$  mmHg.

The FDA SSED states that Edwards Lifesciences performed a clinical study to establish a reasonable assurance of safety and effectiveness of pulmonic implantation with the Edwards SAPIEN THV in patients with dysfunctional RVOT conduits in the United States under Investigational Device Exemption (IDE) (entitled the Congenital Multicenter trial of Pulmonic Valve regurgitation Studying the SAPIEN Interventional THV, "COMPASSION" trial). Data from this clinical study were the basis for the PMA approval decision





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## History

Date	Comments
01/10/12	New Policy – Policy created with literature search through June 15, 2011; considered medically necessary for patients who are high risk for open surgery and are poor surgical candidates due to multiple prior thoracotomies for open heart surgery. Considered investigational for all other indications. Clinical vetting information added.
09/27/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
01/29/13	Replace policy. Policy updated with literature review, references 4, 5, 13-15, 17 added. Medically necessary statement amended to include “when performed according to FDA-approved indications”.
01/21/14	Replace policy. Policy updated with literature review, references 4, 5, 13-15, 17 added. Medically necessary statement amended to include “when performed according to



Date	Comments
	FDA-approved indications". Policy updated with literature review through September 30, 2013. References 13, 14, 16, 18, 21 added. No change to policy statement. Remove ICD-9 procedure and diagnosis codes; remove all ICD-10 codes except 02RH4JZ (which specifically applies) – these will not be used for adjudication.
09/23/14	Update Related Policies. Add 2.02.30.
01/28/15	Annual Review. Policy updated with literature review through September 23, 2014. References 13, 16-19, and 26-31 added; others renumbered. Policy statement unchanged.
01/19/16	Coding update. New CPT code 33477, effective 1/1/16, added to policy.
02/01/16	Coding update. Added 93799.
09/01/16	Annual Review, approved August 9, 2016. Policy updated with literature review through April 28, 2016; references 3, 5, 7-8, 16, 19, and 36-37 added. Policy statement unchanged. CPT coding updated.
12/01/17	Annual Review, approved November 14, 2017. Policy updated with literature review through October 2017. References 42-44 added. Policy statement changed to include specific FDA approved device indications for pulmonary valve regurgitation and stenosis. Removed CPT codes 0262T and 93799.

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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 ቀዳሾች ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፋፈል እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታ 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 التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينه للحفاظ على تغطيتك الصحية أو المساعدة 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):**

**Tsawb ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb.** Tej zaum tsawb 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 pab 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 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-ato 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. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ 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 ដល់កិច្ចការផ្ទៃក្នុងដូចជា ឆ្លើយតបនូវសំណួរ ឬប្រាកដន្នយល់ចេញផ្លូវ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដំណោះស្រាយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ 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 ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ 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 (کلیران 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. Această notificare poate 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 คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย 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).