

## PHARMACY POLICY – 5.01.527

## Ampyra® (Dalfampridine)

Effective Date: Aug. 1, 2020

Last Revised: July 23, 2020

Replaces: N/A


RELATED MEDICAL POLICIES:

5.01.565 Pharmacotherapy of Multiple Sclerosis

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## Introduction

Myelin is a fatty substance that covers and protects nerves. It helps send signals between nerves, and it's the nerves that relay movement instructions to the muscles. Multiple sclerosis damages myelin. This damage interferes with the nerve signals to muscles, including the muscles that are used in walking. Dalfampridine is used to improve the walking ability. It's a potassium channel blocker. That is, it obstructs pores on nerve fibers. This blocking action is thought to improve how electrical signals move along nerves where the signal is weakened because of myelin damage. This drug won't stop the symptoms of multiple sclerosis from getting worse; rather, studies have shown that it increases walking speed. However, it won't work the same for everyone. In some people it won't work at all. This policy describes when dalfampridine or Ampyra® 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.

Drug	Medical Necessity
<b>Dalfampridine (generic)</b>	<p><b>Dalfampridine may be considered medically necessary for adult patients when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Patient has a diagnosis of Multiple Sclerosis</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Initial prescription is prescribed by a neurologist</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient does not have a history of seizures</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has Creatinine Clearance (CrCl) greater than 50mL/min</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has completed a baseline timed 25-foot Walk (T25FW)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The dose is limited to 20 mg per day (taken as 10 mg twice daily)</li> </ul>
<b>Ampyra® (dalfampridine)</b>	<p><b>Ampyra® (dalfampridine) may be considered medically necessary for adult patients when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Patient has a diagnosis of Multiple Sclerosis</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Initial prescription is prescribed by a neurologist</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient does not have a history of seizures</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has Creatinine Clearance (CrCl) greater than 50mL/min</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has completed a baseline timed 25-foot Walk (T25FW)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The dose is limited to 20 mg per day (taken as 10 mg twice daily)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has tried generic dalfampridine first and had an inadequate response or intolerance to generic dalfampridine (documentation required)</li> </ul>



Approval	Criteria
<b>Initial authorization</b>	Dalfampridine and Ampyra® (dalfampridine) may be approved up to 6 months.
<b>Re-authorization criteria</b>	Future re-authorization of dalfampridine and Ampyra® (dalfampridine) may be approved up to 1 year in duration when clinical benefit/response at the time of re-authorization show: <ul style="list-style-type: none"> <li>• Chart notes documenting improvement in the timed 25-foot Walk (T25FW) from baseline</li> </ul> <b>AND</b> <ul style="list-style-type: none"> <li>• Chart notes documenting recent kidney function with Creatinine Clearance greater than 50 mL/min</li> </ul>

## Coding

N/A

## Related Information

### Benefit Application

Dalfampridine and Ampyra® (dalfampridine) are specialty pharmacy drugs managed under the pharmacy benefit.

## Evidence Review

### Description

It is currently thought that multiple sclerosis (MS) is the result of a combination of factors including immune response, genetics, infection, and environmental issues. MS is characterized by the destruction of the myelin sheath that surrounds axons of the central nervous system (CNS) and eventual axonal damage. This is believed to be an autoimmune attack against myelin



and the myelin-producing oligodendrocytes. There is an associated inflammatory response involving B-cells, T-cells, macrophages, antibodies, and complement. The myelin sheath is replaced by sclerotic plaques. The damage to the myelin sheath can delay or halt nerve impulses. Axonal damage leads to loss of nerve impulses.

An estimated 250,000 to 400,000 cases exist in the United States. In 2000, the estimated prevalence was 191/100,000 Caucasians in the United States, with an incidence rate of 7.3/100,000 person-years at risk. Diagnosis usually occurs when patients are between 20 and 50 years of age. The disease is more prevalent: 1) further away from the equator; 2) in Caucasians; and 3) in women. Other risk factors include Epstein-Barr virus exposure, vitamin D deficiency, and smoking.

MS usually follows one of the following four disease courses, but individual presentation can vary quite widely.

1. Relapsing-remitting MS (RRMS): clearly defined acute attacks followed by periods of partial or full recovery. This is the most common course of the disease describing approximately 85% of MS patients.
2. Primary-progressive MS (PPMS): the disease steadily progresses although there may be occasional plateaus or remissions. The patient does not experience acute attacks. Approximately 10% of MS patients have PPMS.
3. Secondary-progressive MS (SPMS): often follows RRMS. Patient experiences acute attacks similar to RRMS, but with progressively less recovery after acute attacks and progressively worsening function between attacks. As with PPMS, there may be occasional plateaus or remissions.
4. Progressive-relapsing MS (PRMS): initially presents as PPMS with steady disease progression, but later experiences acute attacks with followed by partial recovery. This is only seen in approximately 5% of MS patients.

## Rationale

Ampyra® (dalfampridine) was approved by the U.S. Food and Drug Administration (FDA) in January 2010 for the indication of improvement in walking of patients with Multiple Sclerosis (MS) as demonstrated by an increase in walking speed. This approval was based on results from two phase III trials, MS-F203 and MS-F204. The primary endpoint in each of these studies was response to treatment defined as a faster walking time in the timed 25-foot walking test



(T25FW) in a majority of on-treatment visits. Using this novel endpoint, 35% of the treatment group in MS-F203 and 42.9% of the treatment group in MS-F204 responded compared to only 8% of the placebo group in MS-F203 and 9.3% of the placebo group in MS-F204 ( $p < 0.0001$  in each study). However, additional analysis by the FDA showed that the difference in the time needed to complete the timed 25-foot walk between the dalfampridine treatment group and the placebo group was less than one second in each trial.

- MS-F203 was a randomized, multi-center, double-blind, controlled phase III trial in 301 patients with multiple sclerosis of any type. Patients were 18-70 years old and able to complete the timed 25-foot walking test with an average time over two trials of 8-45 seconds. Patients with MS exacerbations within 60 days, history of seizure, evidence of epileptiform activity on ECG, or restricted changes in concomitant medications were excluded from the study. 301 patients were randomized to receive dalfampridine 10 mg or placebo twice daily for 14 weeks. The proportion of responders, defined as those whose T25FW time was faster in three of four treatment visits than in any off-treatment visit, was 35% in the treatment group compared to 8% in the placebo group ( $p < 0.0001$ ). The 12-item multiple sclerosis walking scale (MSWS-12) was used to validate the clinical significance of response, and responders irrespective of treatment group showed significant score improvement (-6.84 in treatment group versus 0.05 in placebo group,  $p = 0.0002$ ). However, additional analysis by the FDA comparing the treatment group to the placebo group showed that although the change in walking speed was statistically significantly higher in those receiving dalfampridine, the clinical significance was questionable as it translated to a 0.88 second difference in the T25FW.
- MS-F204 was another phase III, randomized, double-blind, placebo-controlled trial, the results of which have not yet been published. This trial was similar in design to MS-F203 with the same inclusion and exclusion criteria. The primary difference was a shorter nine week treatment period. The proportion of responders using the same definition as MS-F203 was 42.9% in the treatment group and 9.3% in the placebo group ( $p < 0.0001$ ). Additional FDA analysis showed that the difference in 25-foot walk time between the treatment group and the placebo group was only 0.5 seconds.
- Open-label extension studies of both MS-F203 and MS-F204 are currently underway. Two years' data is available for each extension study, but neither has been published. These studies indicate that response to dalfampridine continues in many initial responders. 41.4% of responders in MS-F203 and 71.4% of responders from MS-F204 are extension responders meaning their walking speed during a majority of open-label treatment visits is faster than any off-treatment visit.



The primary outcome responder definition from MS-F203 and MS-F204 is based on post-hoc analysis from MS-F202. MS-F202 was a multi-center, randomized, double-blind, placebo-controlled, dose-ranging study. Patients were 18-70 years of age and able to complete the timed 25-foot walking test with an average time over two trials of 8-60 seconds. Patients with recent MS relapses or recent medication changes were excluded. Patients were randomized to receive dalfampridine 10 mg, 15 mg, 20 mg, or placebo twice daily. No difference in change in walking speed was demonstrated between any treatment group and placebo. Post-hoc analysis using responder status as defined in MS-F203 showed responder rates of 35.3%-38.6% in the treatment groups compared to 8.5% in the placebo group. The MSWS-12 scores showed greater improvement in responders irrespective of treatment.

There is also an open-label extension of this trial underway. Twenty-five and two-tenths percent of those who were responders in MS-F202 are extension responders under a definition similar to that used in MS-F203 and MS-F204 extension trials.

The primary safety concern with dalfampridine is increased risk of seizure, especially at higher doses and plasma concentrations. This led to the development of the sustained-release formulation. Evidence from these trials suggests that there is no difference in seizure risk between dalfampridine 10 mg and placebo. One seizure was observed in a patient receiving dalfampridine 10 mg twice daily in the MS-F203 study, and one seizure was observed in a patient receiving placebo in MS-F204. However, seizure was observed in two patients receiving dalfampridine 20mg twice daily, just twice the approved dose, in MS-F202. For this reason, dalfampridine is contraindicated in patients with a history of seizures or moderate or severe renal impairment (CrCl < 50mL/min).

The dossier provided by Acorda reports the most common adverse events (incidence  $\geq 2\%$  and greater than the placebo rate) as urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, MS relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain. There have been no drug interactions reported.

In three placebo-controlled trials (MS-F202, MS-F203, MS-F204), treatment emergent adverse events leading to discontinuation in at least two patients and leading to discontinuation in patients treated with D-SR more frequently than with placebo were headache (D-SR 0.5%, placebo 0%), balance disorder (D-SR 0.5%, placebo 0%), dizziness (D-SR 0.5%, placebo 0%), and confusional state (D-SR 0.3%, placebo 0%).

Urinary tract infections were reported more frequently in controlled studies in patients receiving D-SR than in patients receiving placebo (12% versus 8%).



## **2011 Update**

Policy updated to include prior authorization criteria for fingolimod.

## **2012 Update**

Recent data do not indicate a need for change to the above medical necessity criteria. Detailed review of new agents for the treatment of MS approved in 2012 will be conducted in early 2013. Meanwhile, these new agents will be covered without requirement for medical necessity review.

## **2013 Update**

Policy update included prior authorization criteria for dimethyl fumarate.

## **2016 Update**

Recent data do not indicate a need for change to the above medical necessity criteria.

## **2017 Update**

Recent data do not indicate a need for change to the above medical necessity criteria.

## **2018 Update**

Re-authorization criteria updated to include reassessment of kidney function at time of request.

## **2019 Update**

Reviewed dalfampridine prescribing information and conducted a primary literature search from 1/1/18 to 3/29/19. No references were found that would impact this policy.



## 2020 Update

Reviewed dalfampridine prescribing information and no additional FDA-approved indications were identified that would impact this policy.

## References

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## History

Date	Comments
11/09/10	Add to Prescription Drug Section - New Policy. Reviewed and recommended by P&T on September 26, 2010.
11/10/11	Replace Policy – Policy updated with an additional policy statement: fingolimod (Gilenva) considered medically necessary for treatment of relapsing-remitting MS when criteria are met. Rational updated; references 13-17 added. Reviewed by P&T September 2011.
11/13/12	Replace policy. Policy updated with literature review. Detailed review of new agents for the treatment of MS approved in 2012 will be conducted in early 2013; meanwhile they will be covered without review for medical necessity.
07/08/13	Minor Update – Clarification was added to the policy that it is managed through the member’s pharmacy benefit; this is now listed in the header and within the coding section.
08/12/13	Replace policy. <i>Dimethyl fumarate (Tecfidera™)</i> added to the medically necessary policy statement in the treatment of relapsing-remitting multiple sclerosis when criteria are met. Rationale updated; references 19-23 added.
03/10/14	Replace policy. Dimethyl fumarate and fingolimod moved to new policy 5.01.550. Policy title changed from “Oral Agents for the Treatment of Multiple Sclerosis” to “Dalfampridine (Ampyra™)”.
04/08/14	Update Related Policies. Add new policy 5.01.550.
08/11/15	Annual Review. A literature search was conducted from 3/1/14-6/30/15. No new studies were found that would require changes to this policy.
01/01/17	Annual Review, approved December 13, 2016. A literature search was conducted from 5/1/15 to 12/5/16. No new studies were found that would require changes to this policy.
09/01/17	Annual Review, approved August 22, 2017. A literature search was conducted from 12/6/16 to 8/14/17. No new studies were found that would require changes to this policy. Title changed from Dalfampridine (Ampyra™) to Ampyra™ (Dalfampridine).
04/01/18	Annual Review, approved March 20, 2018. A literature search was conducted from 8/15/17 to 3/5/2018. No new studies were found that would require changes to this policy. Re-authorization criteria updated and removed table outlining Pharmacologic Treatment Strategies for MS as this policy pertains to Ampyra.
02/01/19	Interim Review, approved January 4, 2019. Added generic dalfampridine and the requirement to use generic dalfampridine prior to brand Ampyra™ (dalfampridine).
05/01/19	Annual Review, approved April 18, 2019. No changes to policy statements.



Date	Comments
08/01/20	Annual Review, approved July 23, 2020. No changes to policy statements.

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**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 hns 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 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 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 (کلیربران 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 una 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).