


PHARMACY / MEDICAL POLICY – 5.01.574

Pharmacotherapy of Spinal Muscular Atrophy (SMA)

Effective Date:	Nov. 1, 2020	RELATED MEDICAL POLICIES:
Last Revised:	Oct. 13, 2020	None
Replaces:	N/A	

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Introduction

Spinal muscular atrophy (SMA) is a rare disease that leads to muscle weakness and atrophy. SMA affects the muscles of the limbs and trunk. SMA is caused by changes to the survival motor neuron 1 gene (SMN1). This gene creates a protein called the survival motor neuron (SMN) protein. Too little of the SMN protein leads to muscle weakness that gets worse over time and muscles that waste away (atrophy). There are different types of SMA. Type 1 SMA, also known as Werdnig-Hoffman disease or infantile SMA, is the most severe form. Symptoms usually start before 6 months of age. The chance of survival to one year of age is 50 percent. Less severe forms are Type 2, also known as Dubowitz disease, and Type 3, or Kugelberg-Welander disease. Evrysdi™ (risdiplam), Spinraza® (nusinersen), and Zolgensma® (onasemnogene abeparvovec-xioi) are three treatments the Food and Drug Administration has approved for SMA. This policy discusses when the use of Evrysdi™, Spinraza®, and Zolgensma® may be considered medically necessary.

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

Policy Coverage Criteria

Drug	Medical Necessity
<p>Evrysdi™ (risdiplam)</p> <p>Managed under Pharmacy benefit</p>	<p>Evrysdi™ (risdiplam) may be considered medically necessary for the treatment of spinal muscular atrophy (SMA) when:</p> <ul style="list-style-type: none"> • Patient is 2 months of age and older <p>AND</p> <ul style="list-style-type: none"> • Has a diagnosis of SMA Type 1, 2 or 3 attributed to the bi-allelic mutations of survival motor neuron 1 (SMN1) gene documented by genetic testing <p>AND</p> <ul style="list-style-type: none"> • Prescribed by a neurologist with expertise treating SMA <p>AND</p> <ul style="list-style-type: none"> • The dose is limited to the following: <ul style="list-style-type: none"> ○ 0.2 mg/kg per day; 2 months to less than 2 years of age ○ 0.25 mg/kg per day; 2 years of age and older weighing less than 20 kg ○ 5 mg per day; 2 years of age and older weighing 20 kg or more <p>Note: Although Types 2 and 3 manifest in childhood, treatment may be continued throughout the patient’s lifetime.</p>
<p>Spinraza® (nusinersen)</p> <p>Managed under Medical benefit</p>	<p>Spinraza® (nusinersen) may be considered medically necessary for the treatment of spinal muscular atrophy (SMA) when:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of SMA Type 1, 2 or 3 attributed to the bi-allelic mutations of survival motor neuron 1 (SMN1) gene documented by genetic testing <p>Note: Although Types 2 and 3 manifest in childhood, treatment may be continued throughout the patient’s lifetime.</p> <p>Note: The recommended dosage is 12 mg (5mL) per administration. Treatment with Spinraza® should be initiated with 4 loading doses. The first 3 loading doses should be administered at 14-day intervals. The 4th loading dose should be administered 30 days after the 3rd dose. The maintenance dose for Spinraza® is administered once every 4 months thereafter.</p>



Drug	Medical Necessity
<p>Zolgensma® (onasemnogene abeparvovec-xioi)</p> <p>Managed under Medical benefit</p>	<p>Zolgensma® (onasemnogene abeparvovec-xioi) may be considered medically necessary for the treatment of spinal muscular atrophy (SMA) when:</p> <ul style="list-style-type: none"> • Patient is less than 2 years of age at the time of infusion <p>AND</p> <ul style="list-style-type: none"> • Has a diagnosis of SMA attributed to the bi-allelic mutations of survival motor neuron 1 (SMN1) gene documented by genetic testing <p>AND</p> <ul style="list-style-type: none"> • Documented genetic test confirms 3 or fewer copies of the SMN2 gene <p>AND</p> <ul style="list-style-type: none"> • Patient does not have advanced SMA <p>AND</p> <ul style="list-style-type: none"> • Baseline anti-adenovirus serotype 9 (AAV9) antibody levels are $\leq 1:50$ <p>AND</p> <ul style="list-style-type: none"> • Prescribed by a neurologist with expertise treating SMA <p>AND</p> <ul style="list-style-type: none"> • Zolgensma is administered as a one-time infusion <p>Note: The recommended dosage is 1.1×10^{14} vector genomes per kg of body weight administered as an intravenous infusion over 60 minutes</p>

Drug	Investigational
<p>Evrysdi™ (risdiplam), Spinraza® (nusinersen)</p>	<p>All other uses of Evrysdi™ (risdiplam) and Spinraza® (nusinersen) for conditions not outlined in this policy are considered investigational, including but not limited to:</p> <ul style="list-style-type: none"> • SMA that is not attributed to the bi-allelic mutations of SMN1 gene • SMA type 4 (adult onset) • Evrysdi™ or Spinraza® use after Zolgensma® infusion • Evrysdi™ and Spinraza® used in combination with each other
<p>Zolgensma® (onasemnogene abeparvovec-xioi)</p>	<p>All other uses of Zolgensma® (onasemnogene abeparvovec-xioi) for conditions not outlined in this policy are considered investigational, including but not limited to:</p>



Drug	Investigational
	<ul style="list-style-type: none"> SMA that is not attributed to the bi-allelic mutations of SMN1 gene Patient's with 4 or more copies of the SMN2 gene

Length of Approval	
Approval	Criteria
Initial authorization	<p>Evrysdi™ (risdiplam) and Spinraza® (nusinersen) may be approved up to 1 year.</p> <p>Zolgensma® (onasemnogene abeparvovec-xioi) may be approved as a one-time infusion.</p>
Re-authorization criteria	<p>Future re-authorization of Evrysdi™ (risdiplam) and Spinraza® (nusinersen) may be approved up to 12 months in duration when clinical benefit/response at the time of re-authorization based on evidence show continued benefit.</p> <p>Future re-authorization of Zolgensma® (onasemnogene abeparvovec-xioi) beyond a one-time infusion is considered investigational.</p>

Documentation Requirements
<ul style="list-style-type: none"> Initial approval requires chart notes documenting the diagnosis and genetic testing documenting bi-allelic mutations of SMN1 gene and the copies of SMN2 gene Evrysdi™ (risdiplam) and Spinraza® reauthorization requires chart notes documenting progress, including functional measures appropriate to the patient's current abilities, eg, ambulation, arm strength or pulmonary function.

Coding

Code	Description
HCPCS	
J2326	Injection, nusinersen (Spinraza®), 0.1 mg



Code	Description
J3590	Unclassified biologics (use this code only to report Zolgensma®)

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

Benefit Application

Evrysdi™ (risdiplam) is managed through the pharmacy benefit and Spinraza® (nusinersen) and Zolgensma® (onasemnogene abeparvovec-xioi) are managed through the medical benefit.

Consideration of Age

Age limits specified in this policy for Evrysdi™ and Zolgensma® are determined according to the FDA-approved indication. The use of Spinraza® for SMA type 1, 2, and 3 is based on the clinical trial experience as described in the full prescribing information of the FDA label. The controlled trial was a study of infantile-onset SMA patients. The patients in these studies had or were likely to develop type 1, 2, or 3 SMA.

Availability

Zolgensma® is only available at certified treatment centers. Information on certified treatment centers is available by emailing treatments@curesma.org.

Evidence Review

Disease Background

Spinal muscular atrophy (SMA) is a rare recessive neurodegenerative disease that leads to muscle weakness and atrophy of the voluntary muscles of the limbs and trunk, due to the



progressive loss of anterior horn cells of the spinal cord and brainstem nuclei.² SMA has an incidence of about 1:10,000 live births and is the leading genetic cause of infant death. It has a carrier frequency estimated to be between 1:40 to 1:60

SMA is caused by the homozygous deletion of the survival motor neuron 1 gene (SMN1), which encode stable survival motor neuron (SMN) protein. The absence of enough SMN leads to increasing motor neuron dysfunction and progressive muscle weakness and atrophy. Cases are classified based on their severity and maximal achieved motor abilities, inversely correlating with the age of onset as well as the number of survival motor neuron 2 gene (SMN2) copies present. SMN2 encodes for SMN proteins that are less stable than those produced by SMN1 and do not have as lasting an impact on motor neuron function. SMN1 and SMN2 are nearly identical and encode the same protein. The critical sequence difference between the two genes is a single nucleotide in exon 7, which is thought to be an exon splice enhancer.

Type 1 SMA, also known as Werdnig-Hoffman disease or infantile SMA, is the most severe with symptomatic onset usually before 6 months and the probability of survival at 1 year is 50%.^{2,7} Type 2 SMA is also called intermediate SMA or Dubowitz disease while type 3 SMA is also called juvenile SMA or Kugelberg-Welander disease, and both have slightly older age of onsets and more varied disease progression. Type 4 SMA is an adult onset form of SMA that is usually not symptomatic until later in life and rarely affects life expectancy.

Table 1. Clinical Classification of SMA

SMA Type	Age of Onset	Highest Achieved Motor Function	Natural Age of Death	Typical Number of SMN2 Copies
0	Prenatal/fetal	None	< 6 months	1
I	< 6 months	Sit with support only	< 2 years	2
II	6 – 18 months	Sit independently	> 2 years	3 or 4
III	> 18 months	Walk independently	Adulthood	3 or 4
IV	Adult (20s-30s)	Walk through adulthood	Adult	4 to 8



Evrysdi™ (risdiplam)

Risdiplam is an orally administered/available, centrally and peripherally distributed, pyridazine derived, small molecule designed to modify the splicing of the survival motor neuron (SMN2) pre-mRNA and thus increase levels of functional SMN protein. The importance of adequate SMN protein levels which, are found to be depressed in SMA patients, is in the maintenance of motor neurons which control muscle movement. This increase in functional SMN protein allows SMA patients to achieve motor milestones and improve their functional abilities.

Evidence of Efficacy

Currently there are four ongoing trials investigating the safety, efficacy, and use of risdiplam in patients with SMA. As these trials are all unpublished, it should be noted that the below evaluations are based on the limited results available for three of these studies. The fourth study RAINBOWFISH does not currently have any available preliminary results.

In the SUNFISH phase II/III two-part, randomized, placebo-controlled trial of SMA Types 2/3, being the only placebo-controlled trial in progress to date, initial results showed an average increase from baseline after 12 months of treatment in MFM-32 score (an assessment of motor function) of 2.66 (± 3.70) and a ≥ 3 -point change (95% CI) for 58% (42-73%) for all patients with available data in part one of the study (N=43). The second part of the trial saw statistically significant improvements at 12 months of treatment in MFM-32 and Revised Upper Limb Module scores with risdiplam in comparison with placebo of 1.55 ($p=0.0156$; N=170) and 1.59 ($p=0.028$; N=186), respectively. Caregiver reported SMA Independence Scale changes showed statistically significant improvement at 12 months compared to placebo. However, the patient reported improvement was not statistically significant. Minimal important difference (MID) information is unavailable for the previously mentioned outcome measures. However, an MID of 3 points is proposed for MFM-32 although the research supporting this is not yet available. At 12 months the difference from placebo for Hammersmith Functional Motor Score – Expanded was not statistically significant at 0.58 ($p=0.3015$) and failed to meet the MID of 3 points.

In the FIREFISH phase II/III two-part, open-label trial of SMA Type 1, initial results of part one (N=21) showed a median increase of 16 points in all patients as well as a ≥ 4 -point increase in 93% of patients in their CHOP-INTEND score at 245 days of treatment. Clinical and statistical significance of these results are uncertain due to lack of placebo control as well as lack of MID for this outcome measure. At 245 days of treatment, a ≥ 40 -point total score was achieved in 57% of patients which is rare and considered clinically meaningful in comparison with known natural history data.



In the JEWELFISH phase II open-label trial of SMA patients previously treated with other agents targeting SMN2 splicing, initial results for 4 patients (12 months of treatment; Study enrollment N=174) shows a >2-fold increase in median SMN protein levels in the blood compared to baseline. Clinical significance of this change is uncertain at this point.

Evidence of Safety

In the natural course of SMA common areas of complications include pulmonary issues, gastrointestinal/ digestive issues, and musculoskeletal issues among others. It is important to consider these issues in the natural course of SMA as well as the poor prognosis for SMA, especially in the case of earlier onset, in the evaluation of adverse events experienced during treatment and risk/benefit analysis.

In the SUNFISH phase II/III two-part, randomized, placebo-controlled trial of SMA Types 2/3, being the only placebo-controlled trial in progress to date, initial results showed no significant difference in serious adverse events (SAE) occurrence between the risdiplam and placebo groups at 20% (24/120) and 18.3% (11/60), respectively. The most common SAEs for patients taking risdiplam were pneumonia (n=9), gastroenteritis (n=2), bacteremia (n=2), influenza (n=2), and pyrexia (n=2). This study did note a trend towards more grade 3-4 AEs in the risdiplam group compared to placebo was seen at 17.5% (21/120) and 13.3% (8/60), respectively.

In the FIREFISH phase II/III two-part, open-label trial of SMA Type 1, initial results of part one showed at least one SAE in 47.6% (10/21; most commonly pneumonia) and at least one grade 3-5 AE in 38.1% (8/21). In part one of this study 3 deaths have occurred due to respiratory complications which were considered unrelated to risdiplam use.

In the JEWELFISH phase II open-label trial of SMA patients previously treated with other agents targeting SMN2 splicing, there have been no SAEs reported in 12 patients (57-512 days of drug exposure; Study enrollment N=174) with available data.

Spinraza® (nusinersen)

Spinraza® is a SMN2 directed antisense oligonucleotide that increases the production of complete SMN protein by increasing exon 7 inclusion into SMN2 mRNA transcripts (alternative splicing). The resulting protein resembles those produced by SMN1 and is more stable than regular SMN protein produced by SMN2. SMN protein is involved in the maintenance of motor



neurons which control muscle movement. This allows SMA patients to achieve motor milestones and improve their functional abilities.

In one clinical study, Spinraza® resulted in platelet levels below the lower limit of normal in 6 of the 56 patients who had normal baseline levels; however none of these patients developed a sustained low platelet count. In two different studies, 17 out of 51 patients and 36 out of 52 patients on Spinraza® had elevated urine protein. Common adverse reactions recorded in infantile SMA patients included lower respiratory infection (43%), upper respiratory infection (39%), and constipation (30%), while common adverse reactions recorded in later onset patients include headache (50%), back pain (41%), and post-lumbar puncture syndrome (41%) and were associated with the intrathecal administration.

Evidence of Efficacy

Currently, there are ten clinical trials that evaluate the use of Spinraza® for SMA treatment, with efficacy endpoints focused on survival, growth parameters, electro-physiology, and motor function. The ENDEAR study, which provided much of the efficacy evidence, was a phase 3 sham procedure controlled study which depicted a 29% reduction in risk of death or permanent ventilation in the nusinersen group compared to the sham procedure controlled group. Mean improvements in motor milestones for the nusinersen group was observable starting at 2 months post treatment initiation with an increased difference from the sham control patients as the study went on.

In another study, the interim analysis of 13 pre-symptomatic patients SMA patients demonstrated that patients treated with nusinersen exceeded expected outcomes with improvements in various motor function and motor milestone measures. Compared to the Pediatric Neuromuscular Clinical Research natural-history studies of SMA patients that received standard of care, patients with type 1 SMA treated with nusinersen had a significant differentiation in age at death or permanent ventilation as well as increased motor function and nerve response. The CS2 and CS12 studies showed additional milestone attainment and maintenance in type 2 and 3 SMA patients who received nusinersen compared to the decline in milestone maintenance commonly seen in SMA patients, with independent walking achieved in three patients and increased mean ambulation. Nusinersen has not been studied in type 4 patients.



Evidence of Safety

In the limited studies available, Spinraza® has been shown to be generally safe, with most adverse events associated with the route of administration or the natural progression of SMA. Elevated urine protein and low platelet levels have been observed in a few studies with nusinersen; however, the coagulation abnormalities, thrombocytopenia, and renal toxicity associated with antisense oligonucleotides has not been observed with nusinersen though they are still listed as precautions. The majority of adverse events associated with nusinersen were mild to moderate in severity and mirrored events seen in the controlled historical groups, including respiratory distress, respiratory failure, pneumonia, acute respiratory failure, atelectasis, pneumonia aspiration, rhinovirus infection, and cardiorespiratory arrest.

Zolgensma® (onasemnogene abeparvovec-xioi)

Zolgensma® is a gene therapy that uses the adeno-associated virus serotype 9 vector (AAV9) to deliver a copy of the SMN gene to the nucleus of the patient's cells to replace the defective SMN1 gene without modifying the existing DNA of the patient.

Evidence of Efficacy

A Phase I, single-arm, open-label trial evaluated Zolgensma for the treatment of 15 patients with genetically confirmed diagnosis of SMA1, homozygous SMN1 exon 7 deletions, and two copies of SMN2. Subjects were excluded if they had anti-AAV9 antibody titers > 1:50. Of the 15 study patients, the three patients in cohort 1 received a low dose of adeno-associated virus serotype 9 carrying SMN (6.7×10^{13} vg per kg of body weight) and the 12 patients in cohort 2 received a high dose (2.0×10^{14} vg per kg of body weight). The mean age of patients at the time of treatment was 6.3 months (range 5.9 to 7.2) in cohort 1 and 3.4 months (range 0.9 to 7.9) in cohort 2. As a result of serum aminotransferase elevations in Patient 1 in cohort 1, which led to a protocol amendment, Patients 2 to 15 received oral prednisolone at a dose of 1 mg per kg per day for approximately 30 days, starting 24 hours before the administration of gene therapy. The gene vector was delivered in normal saline that was infused IV during a period of approximately 60 minutes.

The primary outcome was the determination of safety on the basis of any treatment-related adverse events (AEs) of grade 3 or higher. The secondary outcome was the time until death or the need for permanent ventilatory assistance. Permanent ventilatory assistance was defined as



at least 16 hours of respiratory assistance per day continuously for at least 14 days in the absence of an acute, reversible illness or a perioperative state. As of August 7, 2017, all the patients had reached an age of at least 20 months and did not require permanent mechanical ventilation; the median age at their last pulmonary assessment was 30.8 months in cohort 1 and 25.7 months in cohort 2. At 29 months of age, one patient in cohort 1 required permanent ventilation because of hypersalivation. After salivary gland ligation, the requirement for the use of noninvasive ventilation was reduced by 25% to 15 hours per day.

Exploratory outcomes included motor-milestone achievements (particularly, sitting unassisted) and The Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) scores. All the patients in cohorts 1 and 2 had increased scores from baseline on the CHOP INTEND scale and maintained these changes during the study. Patients in cohort 2 had mean increases of 9.8 points at 1 month and 15.4 points at 3 months ($P < 0.001$ for both comparisons); 11 patients attained and sustained scores of more than 40 points. No patients in cohort 1 attained any motor milestones. A total of 11 of 12 patients in cohort 2 were able to sit unassisted for at least 5 seconds, 10 for at least 10 seconds, and 9 for at least 30 seconds. A total of 11 achieved head control, 9 could roll over, and 2 were able to crawl, pull to stand, stand independently, and walk independently. Eleven patients attained the ability to speak.

Evidence of Safety

As of August 7, 2017, a total of 56 serious adverse events were observed in 13 patients in the two cohorts. Of these, 2 events were treatment-related grade 4 based on laboratory values. Patient 1 in cohort 1 had elevations in serum aminotransferase levels (31 times the ULN for ALT and 14 times the ULN for AST) without other liver-function abnormalities and without clinical manifestations. These elevations were attenuated by prednisolone treatment, which was subsequently administered in the remaining patients. One patient in cohort 2 required additional prednisolone to attenuate elevated serum ALT and AST levels. Of the 241 non-serious adverse events, 3 were deemed to be treatment-related and consisted of asymptomatic elevations in serum aminotransferase levels in 2 patients. The most common adverse events were upper respiratory tract infection (73%), vomiting (53%), constipation (53%), pyrexia (47%), nasal congestion (40%), and gastroesophageal reflux (40%).



2018 Update

A literature search from 1/1/17 to 3/30/18 did not reveal new clinical data requiring change to the above criteria. Added reauthorization period and criteria.

2019 Update

Added criteria for Zolgensma® (onasemnogene abeparvovec-xioi) which was approved by the FDA in May 2019. Reviewed prescribing information for Spinraza® (nusinersen) and no new information was identified that would change coverage criteria.

2020 Update

Reviewed prescribing information for Zolgensma® (onasemnogene abeparvovec-xioi) and Spinraza® (nusinersen) and no new information was identified that would change coverage criteria. Added criteria for Evrysdi™ (risdiplam) which is an oral medication that was approved by the FDA in August 2020 for the treatment of SMA in patients 2 months of age and older.

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History

Date	Comments
04/01/17	New policy, approved March 14, 2017. Add to Prescription Drug section. Nusinersen (Spinraza®) may be considered medically necessary to treat SMA when criteria are met; all other uses are considered investigational.
07/01/17	Coding update; added HCPCS code C9489 (new code effective 7/1/17).
11/01/17	Interim Review, approved October 10, 2017. Clarified Spinraza® (nusinersen) criteria to include Type 1, 2, and 3 information.
01/01/18	Coding update; added HCPCS code J2326 (new code effective 1/1/18).
05/01/18	Annual Review, approved April 3, 2018. Added reauthorization criteria and duration. Removed HCPCS C9489 (it was terminated 1/1/18) and J3490 from policy.
09/21/18	Minor update. Added Consideration of Age statement.
07/01/19	Annual Review, approved June 11, 2019. Added criteria for Zolgensma (onasemnogene abeparvovec-xioi). Added HCPCS code J3590.
11/01/20	Annual Review, approved October 13, 2020. Added criteria for Evrysdi (risdiplam) for the treatment of SMA Type 1, 2 or 3.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit



booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

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



Discrimination is Against the Law

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

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Getting Help in Other Languages

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

አማርኛ (Amharic):

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

العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار 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 معينة 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):

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 pab kom koj ua tsis pub dhau cov caij nyuog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):

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

Italiano (Italian):

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

日本語 (Japanese):

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

한국어 (Korean):

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 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 ដល់កំណត់ថ្លៃជាតំបន់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអន្តរជាតិរបស់អ្នក ឬប្រាក់ដុល្លារចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ 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 ਜਦ 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 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 (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. 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 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).