


## BENEFIT COVERAGE GUIDELINE – 10.01.518

## Clinical Trials

Effective Date:	May 1, 2018	RELATED MEDICAL GUIDELINES/POLICIES:
Last Revised:	April 10, 2018	5.01.549 Off Label Use of Drugs and Biologic Agents
Replaces:	N/A	10.01.517 Non-covered Services and Procedures

Select a hyperlink below to be directed to that section.

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## Introduction

A clinical trial is a research study that uses human volunteers. These studies are designed to answer questions about how a treatment (drug, medical device, biologic agent, gene therapy or surgery) might work for a specific disease. Some studies also test new approaches to diagnosing, preventing or testing for diseases. Based on the specific plan you are covered under and where you live, the health plan will cover the usual medical costs when you decide to participate in certain clinical studies. The decision to participate in a clinical study is made by you and your doctor, based on your disease or condition, and what treatments are available to you. This policy provides background about different types of studies, outlines what services the plan covers when you participate in a study and includes references to laws that govern what types of studies are covered under your specific type of plan.

**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 providers about when a service may be covered.

This guideline includes requirements of the Affordable Care Act (ACA) for non-grandfathered plans and Washington and Alaska state mandates regarding clinical trial coverage. See [Mandate Information](#) for state-specific information.

Service	Coverage Criteria
<p><b>Clinical trial participation</b></p>	<p><b>Routine patient care costs that occur during participation in an approved clinical trial for qualified individuals for treatment of cancer or other life threatening disease* or condition are eligible for coverage when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual meets the eligibility requirements of the approved clinical trial according to the trial protocol</li> <li>• The individual’s participation in the approved clinical trial is appropriate for the treatment of cancer or other life threatening disease as documented by a referring health care professional <b>OR</b> by the medical and scientific information provided by the individual</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The study in which the patient requests participation is a <b>Phase I, Phase II, Phase III</b> or <b>Phase IV</b> clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and is funded or approved by one of the following:               <ul style="list-style-type: none"> <li>○ National Institutes of Health (NIH) (includes National Cancer Institute (NCI))</li> <li>○ Centers for Disease Control and Prevention (CDC)</li> <li>○ Agency for Healthcare Research and Quality (AHRQ)</li> <li>○ Centers for Medicare and Medicaid Services (CMS)</li> <li>○ A cooperative group or center of any of the entities noted above or the Department of Defense (DOD) or the Department of Veterans Affairs</li> <li>○ A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants</li> <li>○ The Department of Veterans Affairs, the Department of Defense, and the Department of Energy if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of Health and Human Services determines to be comparable to the</li> </ul> </li> </ul>



Service	Coverage Criteria
	<p>system of peer review used by the NIH, ensuring an unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review</p> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>○ The study is conducted under an investigational new drug application reviewed by the Food and Drug Administration</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>○ The study is a drug trial that is exempt from having an investigational new drug application</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>○ An <b>institutional review board (IRB)</b> of an institution in Washington state that has a multiple project assurance contract approval by the Office of Protection for the Research Risks of the NIH</li> </ul> <p><b>Clinical trial or other study participation is considered investigational if the criteria above are not met</b></p> <p><b>Note:</b> The clinical trial must have a written protocol that describes a scientifically sound study that has been approved by all relevant IRBs before participants are enrolled in the trial</p> <p><b>Note:</b> A patient registry is not considered a clinical trial</p> <p>* "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted (death need not be imminent for a disease or condition to be life-threatening)</p> <p>Search <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a> for a registry of federally and privately supported clinical trials</p>
<p><b>Routine patient costs covered during a clinical trial</b></p>	<p><b>Covered routine patient care costs for an enrolled member in an approved clinical trial at the time coverage of routine costs is requested include:</b></p> <ul style="list-style-type: none"> <li>• Items and services that are consistent with the coverage that applies to routine care for individuals not enrolled in clinical trials such as laboratory services, radiologic services, office visits, hospital services, etc.</li> </ul>



Service	Coverage Criteria
	<ul style="list-style-type: none"> <li>• Items or services that are needed for the reasonable and necessary care used to prevent, diagnose, and treat complications arising from participation in the approved clinical trial</li> </ul>
<p><b>Patient costs NOT covered during a clinical trial</b></p>	<p><b>Routine patient costs NOT eligible for coverage include:</b></p> <ul style="list-style-type: none"> <li>• The drug, item, or service being studied (unless the drug, item or service is covered outside a clinical trial for other members)</li> <li>• Items and services provided solely for data collection and analysis needs that are not used in the direct clinical management of the patient (eg, monthly CT scans for a condition where one single scan is the standard of care for the diagnosis or treatment studied)</li> <li>• Items and services provided free of charge by the research sponsors for anyone enrolled in the trial</li> <li>• A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis</li> <li>• Travel and transportation expenses (unless otherwise covered by the plan) including, but not limited to the following: <ul style="list-style-type: none"> <li>○ Fees for personal vehicle, rental car, taxi, medical van, ambulance, commercial airline, or train</li> <li>○ Mileage reimbursement for driving a personal vehicle</li> <li>○ Lodging</li> <li>○ Meals</li> </ul> </li> </ul>

State	Mandate Information
<p><b>Alaska</b> (See below for self-funded groups)</p>	<p><b>Effective September 29, 2010, Alaska has a specific state statute (Senate Bill 10) that requires health care insurers to provide insurance coverage for medical care received by a patient during certain approved clinical trials designed to test and improve prevention, diagnosis, treatment or palliation of cancer. More information regarding covered and non-covered services and other administrative criteria can be found at the following link: <a href="http://www.legis.state.ak.us/basis/get_fulltext.asp?session=26&amp;bill=SB10">http://www.legis.state.ak.us/basis/get_fulltext.asp?session=26&amp;bill=SB10</a>. Accessed April 2018.</b></p>



State	Mandate Information
	<p><b>Note:</b> This state mandate addresses clinical trials related only to cancer.</p>
<p><b>Alaska self-funded groups</b></p>	<p><b>The Alaska state mandate does not generally apply if the group is self-funded. However, some self-funded groups may elect to add state mandates or similar provisions to their contracts. If the member is in a self-funded group, please check the member contract for benefits regarding clinical trials or how the group defines experimental and investigational services. The provisions for clinical trials or definitions of what is considered experimental and investigational should be administered as outlined in the group’s health plan contract.</b></p> <p><b>Note:</b> In the absence of contract language addressing clinical trials, the criteria of this policy should be applied to members covered by self-funded group health plan contracts.</p>
<p><b>Oregon</b> (See below for Self-funded Groups)</p>	<p><b>Effective January 1, 2010, Oregon has a specific state statute (Senate Bill 316) that mandates benefit coverage for the routine costs of the care of patients enrolled in and participating in qualifying clinical trials. More information regarding covered and non-covered services and other administrative criteria can be found at the following link:</b></p> <p><a href="https://www.oregonlegislature.gov/bills_laws/ors/ors743A.html">https://www.oregonlegislature.gov/bills_laws/ors/ors743A.html</a>. (See section 743A.192 Clinical Trials). Accessed April 2018.</p> <p><b>Note:</b> This state mandate addresses clinical trials related to cancer or other life-threatening disease or condition.</p>
<p><b>Oregon Self-Funded Groups</b></p>	<p><b>The Oregon state mandate does not generally apply if the group is self-funded. However, some self-funded groups may elect to add state mandates or similar provisions to their contracts. If the member is in a self-funded group, please check the member contract for benefits regarding clinical trials or how the group defines experimental and investigational services. The provisions for clinical trials or definitions of what is considered experimental and investigational should be administered as outlined in the group’s health plan contract.</b></p> <p><b>Note:</b> In the absence of contract language addressing clinical trials, the criteria of this policy should be applied to members covered by self-funded group</p>



State	Mandate Information
	health plan contracts.
<b>Washington</b>	<p><b>Effective November 8, 2012, Washington has a specific Washington Administrative Code (WAC284-43-850 recodified as WAC284-43-5420) that mandates benefit coverage for the routine costs of patients enrolled in and participating in qualifying clinical trials for Phases I - IV. More information regarding covered and non-covered services and other administrative criteria can be found at the following link:</b></p> <p><b><a href="http://apps.leg.wa.gov/WAC/default.aspx?cite=284-43-5420">http://apps.leg.wa.gov/WAC/default.aspx?cite=284-43-5420</a>.</b></p> <p><b>Accessed April 2018.</b></p> <p><b>Note:</b> This mandate addresses clinical trials related to cancer or other life-threatening disease or condition.</p>

**Documentation Requirements**

**The patient’s medical records submitted for review for participation in an approved clinical trial for the prevention, detection or treatment of cancer or other life-threatening disease or condition should document that these requirements are met. The record should include ALL of the following:**

- History and physical supporting patient has a life-threatening condition that has a poor response with the most effective treatment currently available
- The trial is for treatment, not diagnosis or support
- Clinical trial name and the NCT number
- The trial is phase I, II, III or IV and has been approved by the National Institutes of Health (NIH) or an organization affiliated with the NIH, or institutional review boards (IRBs) or the departments of Veterans Affairs or Defense
- The patient’s medical records demonstrate the member agrees to participate in a clinical trial
- The drug or device has been approved by the Food and Drug Administration (FDA) for testing

**Coding**



Code	Description
<b>HCPCS</b>	
<b>Eligible for Coverage</b>	
S9988	Services provided as part of a Phase I clinical trial
S9990	Services provided as part of a Phase II clinical trial
S9991	Services provided as part of a Phase III clinical trial
<b>Non-covered</b>	
S9992	Transportation costs to and from trial location and local transportation costs (eg, fares for taxicab or bus) for clinical trial participant and one caregiver/companion
S9994	Lodging costs (eg, hotel charges) for clinical trial participant and one caregiver/companion
S9996	Meals for clinical trial participant and one caregiver/companion
<b>ICD-10-Diagnosis</b>	
Z00.6	Encounter for examination for normal comparison and control in clinical research program

## Related Information

### Benefit Application

Benefit determinations will be made in accordance with the following:

- All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials.
- All utilization management guidelines and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials.
- Members must meet all applicable plan requirements for preauthorization, eligibility, and referrals.



- In the event a claim contains charges related to covered clinical trial services but those charges have not been or cannot be separated from costs related to non-covered services, benefits will **not** be provided.
- Services may be approved for coverage as part of a qualifying clinical trial when they would typically be covered by the health plan for a member who is not enrolled in a clinical trial. The services will be provided under the applicable benefit category (eg, pharmacy, durable medical equipment, medical care, etc.). Services may not be covered by the plan if they are fully funded by another source and are provided as part of the clinical trial.

## Definition of Terms

**Institutional Review Board (IRB):** An IRB is a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research. IRBs approve the clinical trial protocols, which describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives and other details. IRBs make sure the study is acceptable, that participants have given consent and are fully informed of their risks, and that researchers take appropriate steps to protect patients from harm.

**Investigational New Drug (IND):** In an IND application, sponsors - companies, research institutions, and other organizations that take responsibility for marketing a drug - must show the FDA results of pre-clinical testing they've done in laboratory animals and what they propose to do for human testing. At this stage, the FDA decides whether it is reasonably safe to move forward with testing the drug on humans. Drug studies in humans can begin only after an IND is reviewed by the FDA and a local IRB. Drugs with a treatment IND may not be marketed.

**Phase of clinical trial:** The progress of a clinical trial is categorized by the "phase" category assigned. Most trials can be categorized into one of four phases. A generally accepted categorization follows. Note that the cohort size is not absolute and there are exceptions.

**Note:** In any phase of a treatment clinical trial, the FDA can impose a clinical hold if the treatment is found to be unsafe or if the protocol is clearly deficient in design in meeting its stated objectives. **Institutional Review Boards (IRBs)** also may cause a trial to be suspended if some aspect of the study is found to be unsafe.

**Phase I clinical trial:** The therapeutic intervention is tested in a small group of people (20-80) for the first time to evaluate its safety and effectiveness. Phase I studies may determine the metabolic mechanism of action of the treatment in humans. In the case of drug trials, the side effects associated with increasing doses, drug metabolism and structure-activity relationships may be examined. The primary focus is on safety.





**Phase II clinical trial:** The treatment is applied to a larger group of people (100-300) to further evaluate effectiveness and safety. In drug studies, this phase often consists of pilot studies which may be open label, single or double blind.

**Phase III clinical trial:** The treatment is applied to large groups of people (1000-3000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow safe use of the treatment.

**Phase IV clinical trial:** The treatment continues to be tested after marketing approval of the device or drug has been given by the Food and Drug Administration (FDA). This testing is performed to collect information about the effect in various populations and any side effects associated with long-term use.

**Registry:** "A registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes."<sup>3</sup>

**NIH Definition of a Clinical Trial:** A research study in which one or more human subjects are prospectively assigned\* to one or more interventions\*\* (which may include placebo or other control) to evaluate the effects of those interventions on health-related\*\*\* biomedical or behavioral outcomes.

\* "prospectively assigned" refers to a pre-defined process (eg, randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (eg, intervention, placebo, or other control) of a clinical trial.

\*\* "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (eg, surgical techniques); delivery systems (eg, telemedicine, face-to-face interviews); strategies to change health-related behavior (eg, diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

\*\*\*A "health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (eg, improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (eg, mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Source: [https://grants.nih.gov/grants/policy/faq\\_clinical\\_trial\\_definition.htm](https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm)

**U.S. Food and Drug Administration (FDA) approval:** Clinical trials may investigate drugs or devices that have received different types of FDA approval. Some approvals may allow marketing of drugs or devices; some may approve their use only in investigational settings.



### Background

The Company may be asked to cover services that are provided within the context of clinical trials. These requests often represent relatively new technology, therapies, or application of established therapies to treat new or rare diagnoses.

Clinical trials are performed to determine if new treatments and procedures, new drugs, and combinations of drugs, or new devices are clinically safe and effective and if they should be considered as standard care for patients in the future. Clinical trials help determine whether or not a new treatment works as well or better than an existing treatment. Participation in a clinical trial is often considered when standard therapies have failed. Sponsorship of clinical trials can come from federal agencies such as the National Institutes of Health, pharmaceutical and medical device companies, or individual or hospital-based researchers.

Clinical trials are designed and used to research one or more interventions for treating a disease, syndrome, or condition before they are made available to the general public. Examples of these interventions, though not all-inclusive, are new medical products, drugs, devices, radiation therapy or surgical procedures. Services, supplies and drugs that are a standard of care throughout the medical community may have a clinical trial designed to demonstrate their efficacy for a different diagnosis or when they are used in combination with other therapeutic agents. Many clinical trials are designed to study and report therapeutic effectiveness over a prolonged period of time.

Some life threatening malignant conditions are the subject of clinical trials when the currently available treatments are not known to be effective. During the consecutive phases of some clinical trials, evidence emerges which strongly suggests that the services under study may be as effective, or more effective, than conventional treatment.

In addition, there may be important quality of life considerations if preliminary data from clinical trials show medical outcomes that are at least comparable to standard treatment. These quality of life issues may include reduction of treatment side effects and simpler treatment strategies.

By providing coverage for members who chose to participate in qualifying trials, the member benefits from having access to new technology that has early evidence of efficacy, often in circumstances where no effective alternative treatments are available.



Clinical trials aid in the advancement of medicine and the improvement of patient outcomes in many areas of healthcare. Whether testing a new therapy or exploring a new way to use an existing therapy, clinical trials measure care and are responsible for breakthroughs in science, as well as key information about treatment risks to different populations.

## References

1. Patient Protection and Affordable Care Act; Section 2709. Coverage for individuals participating in approved clinical trials. 2010. <http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf>. Accessed April 2018.
2. Center for Medicare and Medicaid Services (CMS). Routine costs in clinical trials. NCD 310.1, version 2. Effective 07/09/2007. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA>. Accessed April 2018.
3. Gliklich R, Dreyer N. Registries for Evaluating Patient Outcomes: A User’s Guide. Rockville, MD: Agency for Healthcare Research and Quality; 2010. AHRQ Publication No. 10-EHC049.

## History

Date	Comments
03/18/05	Add to Administrative Section - New Policy
05/10/05	Replace Policy and move to Medicine, sub-section Oncology - Policy title and policy number changed for clarification purposes.
05/09/06	Replace Policy - Policy reviewed; no change to policy statement.
05/08/07	Replace Policy - Policy reviewed; no changed to policy statement.
01/08/08	Replace Policy - Policy updated with literature review. Policy statement clarified for ease of use, but no substantial change to criteria. Criteria for devices added. Description and Rationale revised. HCPCS codes added.
06/10/08	Cross Reference Update - No other changes.
01/13/09	Replace Policy - Policy statement and guidelines clarified to define routine costs eligible for coverage and costs not eligible for coverage. Intent of policy statement unchanged.
10/13/09	Replace Policy - Benefit Application revised to include Oregon mandate to provide coverage for all clinical trials and links to AZ and OR mandates.
01/12/10	Minor update - Note added at the top of the description section regarding Arizona



Date	Comments
	and Oregon Members to view benefit application.
08/10/10	Replace Policy - Benefit Application revised to add Alaska mandate for cancer clinical trials and delete Arizona mandate.
10/12/10	Minor update - Benefit Application clarified regarding AK and OR mandates and self-funded groups.
09/15/11	Replace Policy – Policy reviewed; no change in policy statements.
10/19/11	Related Policies updated; new title for 5.01.01.
03/23/12	Replace Policy. Policy reviewed; no change in policy statements.
11/13/12	Replace policy. Policy title changed to “Clinical Trials”. All references to “oncology” clinical trials changed to “Clinical Trials”. Policy statements revised to meet Washington state specific mandates, which require coverage of routine costs of all qualifying clinical trials phases I-IV when criteria are met. (The prior policy related only to clinical trials phase II-III). Used the PPACA definition of “life threatening condition”. Added statement about the PPACA to the benefit application section. Reference 1 added. Added code V70.7. Policy moved to the UM section of the Medical Policy classification index and renumbered; previously 2.03.503, the policy is now 11.01.503.
08/16/13	Replace policy. Policy reviewed; no change in policy statements.
11/20/13	Update Related Policies. Delete 5.01.01 and replace with 5.01.549.
06/24/14	Update Related Policies. Add 8.01.530 and 8.01.531.
09/03/14	Annual Review. Policy reviewed. Literature search through June 2014 did not prompt addition of new references. In Benefit Application section, the hyperlink to Oregon State law is revised. Policy Statement unchanged.
10/23/14	Update Related Polices. Add 10.01.517.
03/10/15	Annual Review. Search through January 2015 did not prompt addition of new references. Policy statement unchanged. Converted to Benefit Coverage Guideline, renumbered from 11.01.503 to 10.01.518.
01/12/16	Annual Review. Policy reviewed. No references added. Guidelines statements unchanged.
06/01/16	Interim Review, approved May 10, 2016. Policy updated to address coverage of complications resulting from participation in a clinical trial.
08/09/16	Policy converted to new policy format; no changes in content or coverage.
01/01/17	Annual Review Policy reviewed, reference added. Coverage statements unchanged.
06/01/17	Minor update. Reformatted Coding section for clarification.
08/01/17	Interim update, approved July 11, 2017. Policy clarification made; requirement for member consent form replaced with records demonstrating member agrees to participate in a clinical trial. No other changes.



Date	Comments
05/01/18	Annual Review, approved April 10, 2018. Updated policy with ACA requirements for clinical trials. Deleted CMS requirements and related definitions.

**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). ©2018 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.



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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

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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 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 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 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):**

**Tsawm ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb.** Tej zaum tsawm ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnuv 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 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-ato 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 ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ធានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ជំនួយចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ 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 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).