PREMERA | BLUE CROSS

MEDICAL POLICY – 1.04.05

Microprocessor-Controlled and Powered Prostheses for the Lower Limb

BCBSA Ref. Policy:	1.04.05*	
Effective Date:	Dec. 1, 2017	RELATED MEDICAL POLICIES:
Last Revised:	May 1, 2018	1.04.502 Myoelectric Prosthetic and Orthotic Components for the Upper Limb
Replaces:	1.01.25 and 1.01.513	8.03.01 Functional Neuromuscular Electrical Stimulation

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EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

After a person has had a limb amputated, an artificial limb (prosthesis) may be used. Computerized, microprocessor controlled prosthetic joints have been developed that contain sensors to automatically adjust movement of the joint. When the prosthesis involves a knee joint, a microprocessor controlled prosthetic joint is thought to help a person walk more safely and smoothly.

This policy describes when a microprocessor controlled prosthetic device may be 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

Service	Medical Necessity
Microprocessor-controlled knee	**A microprocessor-controlled knee may be considered medically necessary in amputees who meet ALL of the following requirements:** • Demonstrated need for long-distance ambulation at variable rates (use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications) **OR** demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application) **AND** • Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed **AND** • Adequate cognitive ability to master use and care requirements for the technology **A microprocessor-controlled knee is considered not medically necessary in individuals who do not meet these criteria.**

Service	Investigational
Powered knee	**A powered knee is considered investigational.**
Microprocessor-controlled or powered ankle-foot	**A microprocessor-controlled or powered ankle-foot is considered investigational.**
Additions to a conventional prosthesis: • **Orthotics** • **Prosthetics** • **Prosthetic components**	**Orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are considered investigational when used for experimental or investigational therapy or interventions.**

Service	Not Covered
Additions to a	**Orthotics, prosthetics, or prosthetic components added to a**

Service	Not Covered
conventional prosthesis: • **Orthotics** • **Prosthetics** • **Prosthetic components**	**conventional prosthesis are not covered when:** • It is used only for recreational, sports or athletic activities • It is available over-the-counter or off-the-shelf without a prescription from the treating physician or consultation with a prosthetist

Additional Guidelines

Microprocessor-controlled prosthetic knees are programmable devices equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds (see Table 1). These lower limb prosthetics will most likely include a prosthetic foot that may or may not be powered or controlled by a microprocessor.

Microprocessor-controlled prosthetic feet have sensors that control the flexion angle of the ankle. This programmable ankle/foot prosthetic is considered investigational (see Table 2). Other conventional types of prosthetic feet do not require review under this medical policy.

Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting.

Decisions about the potential benefits of microprocessor-knees involve multiple factors including activity levels and the patient's physical and cognitive ability. A patient's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (eg, gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, daily and frequent need of two or more of these activities would be needed to show benefit.

Patient Selection and Identification

For patients in whom the potential benefits of the microprocessor knees are uncertain, patients may first be fitted with a standard prosthesis to determine their level of function with the standard device.

Veterans Health Administration Prosthetic Clinical Management Program (VHA PCMP) Recommendations

Additional Guidelines

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees (Berry, 2000):

Contraindications for use of the microprocessor knee should include the following:

- Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear
- Inability to tolerate the weight of the prosthesis
- Medicare Level K 0—no ability or potential to ambulate or transfer
- Medicare Level K 1—limited ability to transfer or ambulate on level ground at fixed cadence
- Medicare Level K 2—limited community ambulator that does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device
- Inability to use swing and stance features of the knee unit
- Poor balance or ataxia that limits ambulation
- Significant hip flexion contracture (over 20 degrees)
- Significant deformity of remaining limb that would impair ability to stride
- Limited cardiovascular and/or pulmonary reserve or profound weakness
- Limited cognitive ability to understand gait sequencing or care requirements
- Long distance or competitive running
- Falls outside of recommended weight or height guidelines of manufacturer
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis
- Extremely rural conditions where maintenance ability is limited

Indications for use of the microprocessor knee should include the following:

- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence
- Adequate strength and balance in stride to activate the knee unit
- Should not exceed the weight or height restrictions of the device
- Adequate cognitive ability to master technology and gait requirements of device
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
- The patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue
- Daily activities or job tasks that do not permit full focus of concentration on knee control and stability—such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying
- Medicare Level K 2—limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive

Additional Guidelines
walking device, and patient has cardiovascular reserve, strength, and balance to use the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator • Medicare Level K 3—unlimited community ambulator • Medicare Level K 4—active adult, athlete who has the need to function as a K 3 level in daily activities • Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable • Potential to unload and decrease stress on remaining limb • Potential to return to an active lifestyle **Physical and functional fitting criteria for new amputees:** • New amputees may be considered if they meet certain criteria as outlined above • Premorbid and current functional assessment important determinant • Requires stable wound and ability to fit socket • Immediate postoperative fit is possible • Must have potential to return to an active lifestyle

Table 1. Microprocessor-Controlled Knee Prosthetics

Names of Microprocessor-Controlled Knee Prosthetics (company) include but are not limited to:
Adaptive (Endolite, Blatchford Inc. United Kingdom)
C-Leg Compact (Otto Bock Orthopedic Industry, Minneapolis, MN)
Endolite Intelligent/Smart Prosthesis (Endolite, Blatchford Inc. United Kingdom)
Genium Bionic Prosthetic system (Otto Bock Orthopedic Industry, Minneapolis, MN)
Intelligent Prosthesis (IP) (Blatchford, United Kingdom
Linx (Endolite, Blatchford Inc. United Kingdom)
Orion 2 (Endolite, Blatchford Inc. United Kingdom)
Power Knee™ (Ossur, Iceland)
RheoKnee® (Ossur, Iceland)
Seattle Power Knees (Seattle Systems) 3 models include: • 4-bar

Names of Microprocessor-Controlled Knee Prosthetics (company) include but are not limited to:
• Fusion • Single Axis
X2 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN)
X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN)

Table 2. Microprocessor-Controlled or Powered Foot Prosthetics

Names of Microprocessor-Controlled Foot Prosthetics (company) include but are not limited to:
élan Foot (Endolite)
iPED (developed by Martin Bionics LLC and licensed to College Park Industries)
Proprio Foot® (Össur, Iceland)
PowerFoot Biom® (developed at MIT and licensed to iWalk)

Coding

Code	Description
HCPCS	
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee skin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Related Information

Benefit Application

Contractual or benefit limitations on durable medical equipment or prostheses upgrades may be applicable.

New technologies that use microprocessor control are being developed. Based on currently available evidence, no microprocessor-controlled device has been shown to have better outcomes than other (eg, earlier) models. If more costly, the prosthesis would be considered not medically necessary using the Plan's definition of medical necessity. Benefit or contract language describing the "least costly alternative" may also be applicable to prostheses.

Evidence Review

Description

Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. Active joint control is intended to improve safety and function, particularly for patients who can maneuver on uneven terrain and with variable gait.

Background

Lower-Extremity Prosthetics

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will be quite different than the needs of a younger, active person. Key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees to vary their walking speed by matching the movement of the shin portion of the

prosthesis to the movement the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allow the prosthetist to set a pace that is adjusted to the individual amputee, from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are generally prescribed for athletic or fit individuals. Other design features include multiple centers of rotation, referred to as "polycentric knees." The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

Microprocessor-Controlled Prosthetic Knees

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (IP) (Blatchford, England); the Endolite Adaptive, (Basingstoke, Hampshire, UK); the Rheo Knee® (Össur, Iceland); the C-LEG®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN); and Seattle Power Knees (3 models include Single Axis, 4-bar and fusion, from Seattle Systems). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. The prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. Also, these devices (with the exception of the Intelligent Prosthesis) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.) By improving stance control, such devices may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble and will stiffen the knee, thus avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain and reduction in energy expenditure and concentration required for ambulation. In 1999, the C-Leg was cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process (K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses use additional environmental input (eg, gyroscope and accelerometer) and more sophisticated processing that are intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

Powered Knee Prostheses

The Power Knee™ (Össur, Iceland), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot to anticipate and respond with the appropriate movement required for the next step. The Power Knee is currently in the initial launch phase in the United States.

Microprocessor-Controlled Ankle-foot Prostheses

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries, Warren, MI), and the Elan Foot (Endolite). With sensors in the feet that determine the direction and speed of the foot's movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. The technology is designed to make ambulation more efficient and prevent falls in patients ranging from the young active amputee to the elderly diabetic patient. The Proprio Foot® and Elan Foot are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates use of the Proprio Foot® for low- to moderate-impact for transtibial amputees who are classified as level K3 (ie, community ambulatory, with the ability or potential for ambulation with variable cadence).

Powered Ankle-Foot Prostheses

In development are lower-limb prostheses that also replace muscle activity in order to bend and straighten the prosthetic joint. For example, the PowerFoot BiOM® (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement (see **Related Policies**). This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency, has the potential to reduce hip and back problems arising from an unnatural gait with use of a passive prosthesis. This technology is limited by the size and the weight required for a motor and batteries in the prosthesis.

Summary of Evidence

For individuals who have a transfemoral amputation who receive a prosthesis with a microprocessor-controlled knee, the evidence includes a number of small within-subject comparisons of microprocessor-controlled knees vs hydraulic knee joints. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures and a strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, an increase in stability, a decrease in falls, and a decrease in the cognitive burden associated with monitoring the prosthesis. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. Those considered most likely to benefit from these prostheses have both the potential and need for frequent ambulation at variable cadence, on uneven terrain, or on stairs. The potential to achieve a high functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to be able to use the advanced technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Note that the evidence does not permit conclusions regarding the effect of a microprocessor-controlled prosthesis on health outcomes in limited community ambulators or on the effect of a next-generation microprocessor-controlled prosthesis on health outcomes.

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes with a powered knee prostheses compared with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a microprocessor-controlled ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes with microprocessor-controlled ankle-foot prostheses compared with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a powered ankle-foot, no evidence or data is available. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some ongoing trials that might influence this policy are listed in **Table 3**.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02240186	Comparative Effectiveness Between Microprocessor Knees and Non-Microprocessor Knees	50	Oct 2017
Unpublished			
NCT02382991[a]	Randomized, Cross-over Study Comparing the Efficacy of the 3C60 Knee Against Non-microprocessor Controlled Knees on the Risk of Falling and Locomotor Skills of Moderately Active Persons With Leg Amputation Above Knee or Knee Disarticulation	35	Nov 2015 (completed)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

External clinical input was not formally solicited for this policy.

Practice Guidelines and Position Statements

The Veteran's Affairs Prosthetic and Sensory Aids Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program to coordinate the development of clinical practice recommendations for prosthetic prescriptive

practices.[13] A subgroup of the Pre-Post National Amputation Workgroup met in April 2004 to define patient selection and identification criteria for microprocessor-prosthetic knees. Their proposal was based on recommendations arising from the May 2003 Microprocessor Prosthetic Knee Forum. The resulting Department of Veteran's Affairs clinical practice recommendations for microprocessor knees are listed **above**.

Medicare National Coverage

Durable medical equipment regional carriers are responsible for creating coverage policies for Medicare regarding durable medical equipment. There is no specific coverage policy on microprocessor-controlled knee prosthesis, in part because there is no specific HCPCS code describing this prosthesis. However, the durable medical equipment regional carriers document has noted that a determination of medical necessity for certain components/additions to the prosthesis is based on the patient's potential functional abilities.[33] Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to:

- The patient's past history

AND

- The patient's current condition including the status of the residual limb and the nature of other medical problems

AND

- The patient's desire to ambulate

The document has also provided the following classification of rehabilitation potential (see **Table 4**).

Table 4. Classification of Rehabilitation Potential

Level	Rehabilitation Potential
Level 0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.
Level 1	Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulatory.

Level	Rehabilitation Potential
Level 2	Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulatory.
Level 3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demand of the child, active adult, or athlete.

Regulatory Status

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the U.S. Food and Drug Administration (FDA) and is exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of the FDA prior to marketing.

FDA product codes: ISW, KFX.

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History

Date	Comments
02/10/04	Add to Durable Medical Equipment Section - New Policy PR.1.01.113 replaces BCBSA 1.01.25 (Issue 3:2003).
09/01/04	Replace Policy - Policy renumbered from PR.1.01.113. No date changes.
02/08/05	Replace Policy - Policy reviewed with literature search through December 2004; no change to policy statement; references added.
02/14/06	Replace Policy - Policy reviewed with literature search; no change to policy statement; reference added.
02/22/06	Codes updated - No other changes, effective date unchanged.
05/26/06	Update Scope and Disclaimer - No other changes.
03/13/07	Replace Policy - Policy updated with literature review; reference added. No change in policy statement.
05/13/08	New BC Policy - Replaces PR.1.01.513, status changed from PR to BC. A microprocessor-controlled knee may be considered medically necessary in amputees who meet the criteria listed. When criteria are not met, it is considered not medically necessary.
05/12/09	Replace Policy - Policy updated with literature search. Policy statements added regarding ankle-foot and powered knee prostheses as investigational. References added.
02/09/10	Code Update - New 2010 codes added.
04/13/10	Replace Policy - Policy updated with literature search; no change to the policy statement. References added.

Date	Comments
06/13/11	Replace Policy - Policy updated with literature review through January 2011; reference 21 added; policy number changed from 1.01.25 to 1.04.05 (prosthetics); policy statements unchanged. ICD-10 codes added to policy.
01/27/12	HCPCS code L5312 added.
05/22/12	Replace policy. Policy updated with literature review through December 2011; Rationale revised; references 3, 16, 17, 22 added; some references removed. Policy statements unchanged.
08/24/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
05/28/13	Replace policy. Policy updated with literature review through February 1, 2013; Rationale revised; references 12, 15, 17, 23, 26-27 added and references reordered; policy statements unchanged.
08/14/13	Update Related Policies. Change title to policy 1.04.04.
03/21/14	Update Related Policies. 1.04.04 was deleted and replaced with 1.04.502.
06/13/14	Annual Review. Policy updated with literature review through February 24, 2014. References 17, 25, 27 added; others renumbered/removed. Policy statements unchanged.
08/11/14	Interim Update. Policy Guidelines added with details about when orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are not covered. No new references added. Policy statements unchanged. HCPCS codes L5845 removed from policy; this is not reviewed.
06/17/15	Annual Review. Two tables added to the Policy Guidelines section that list examples of microprocessor-controlled prosthetic knees and feet for the lower limb. Policy Guideline statement added that conventional prosthetic foot is not subject to review under this medical policy. Policy updated with literature review through January 29, 2015. Reference 19 added; others renumbered. Policy statements unchanged. ICD-9 diagnosis codes removed; no utilized in adjudication. HCPCS codes L5312 and L5856 removed; these are not reviewed.
06/01/16	Annual Review, approved May 10, 2016. Policy reviewed with literature search; policy statement unchanged.
09/22/17	Policy moved to new format. No changes to policy statements.
12/01/17	Annual Review, approved November 21, 2017. Policy updated with literature review through August 2017; no references added. Policy title changed to "Microprocessor-Controlled and Powered Prostheses for the Lower Limb". Policy statements unchanged.
05/01/18	Minor update, updated the title of Related Policy 1.04.502.

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).

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.

PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

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).

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

العربية (Arabic):
يحوي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تريد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تواريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ800-722-1471 (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 devrez 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 resevwa 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 ntsiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam los ntawm Premera Blue Cross. Tej zaum muaj cov hnub 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 apliksayonyo 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-atyo 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. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 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 ຄວາມຄຸ້ມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີສຳຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດຳເນີນການຕາມກຳນົດເວລາສະເພາະເພື່ອຮັກສາຄວາມຄຸ້ມຄອງປະກັນສຸຂະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເລື່ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄວ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໂທຫາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):
សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរ៉ាប់រងរបស់អ្នកតាមរយៈ Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ចេញសមត្ថភាព ដល់កំណត់ថ្ងៃជាក់ច្បាស់នានា ដើម្បីនឹងរក្សាទុកការជានាវ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ជំនួយចេញផ្លែ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ 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 ਨੋਜਿਸ ਜਵਚ ਖਾਸ ਤਾਰੀਖਾ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀ ਜਸਹਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ਼ ਤੋਂ ਪਹਿਲਾਂ ਕੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫ਼ਤ ਵਿੱਚ ਤੇ ਆਪਣੀ 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 (کاربران 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 zwrócic 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 dumneavoastre 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 privitoare 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'amatalaga 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. Ang paunawa na ito ay maaaring 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 ganitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน 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 страхувального 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).