



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 04/17/18
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MYOELECTRIC PROSTHETIC AND ORTHOTIC COMPONENTS FOR THE UPPER LIMB

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 04/17/18
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MYOELECTRIC PROSTHETIC AND ORTHOTIC COMPONENTS FOR THE UPPER LIMB (cont.)

Description:

Upper limb prostheses are used for amputations at any level from the hand to the shoulder.

Myoelectric Upper Limb Prosthesis:

Myoelectric upper limb prostheses use muscle activity from the remaining limb for control of joint movement. Electromyographic (EMG) signals from the limb stump are detected by surface electrodes, amplified and then processed by a controller to drive battery-powered motors that move the limb. Myoelectric control of movement may be limited to one joint at a time. Myoelectric upper limb devices include the Otto Bock myoelectric prosthesis, the LTI Boston Digital Arm™ System from Liberating Technologies, and the Utah Arm Systems from Motion Control.

Sensor and Myoelectric Controlled Upper-Limb Prosthetic Components:

The LUKE™ Arm, previously known as the DEKA Arm System, is the first commercially available myoelectric upper-limb that can perform complex tasks with multiple simultaneous powered movements. It contains a combination of mechanisms, including switches, movement sensors and force sensors. The primary control resides with inertial measurement sensors on top of the feet. Study of the current generation of the sensor and myoelectric controlled prosthesis is needed to determine whether newer models of this advanced prosthesis lead to consistent improvements in function and quality of life.

Myoelectric Hand Prosthesis:

Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis but are battery-powered. Myoelectric hand prosthesis include Bebionic from Steeper, ProDigits™ and i-limb™ from Touch Bionics, SensorHand™ Speed and the Michelangelo® Hand from Otto Bock.

Myoelectric Orthosis:

The MyoPro from Myomo is a myoelectric powered upper-extremity orthotic. This orthotic device weighs about 4 lbs, has manual wrist articulation, and myoelectric initiated bi-directional elbow movement. It detects weak muscle activity from the affected muscle groups. A therapist or prosthetist/orthoptist can adjust the gain (amount of assistance), signal boost, thresholds, and range of motion. Potential users include individuals with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, and multiple sclerosis. Use of robotic devices for therapy has been reported. The MyoPro is the first myoelectric orthotic available for home use.

Hybrid System:

A hybrid system, a combination of body-powered and myoelectric components, may be used for high-level amputations (at or above the elbow). Hybrid systems allow control of two joints at once (i.e., one body-powered and one myoelectric) and are generally lighter and less expensive than a prosthesis composed entirely of myoelectric components.



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 04/17/18
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MYOELECTRIC PROSTHETIC AND ORTHOTIC COMPONENTS FOR THE UPPER LIMB (cont.)

Criteria:

COVERAGE FOR BIOMECHANICAL DEVICES OR MYOELECTRIC LIMBS IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

All requests for myoelectric upper limb prosthesis and orthoses will be reviewed by the medical director(s) and/or clinical advisor(s).

- Myoelectric upper limb prosthetic components are considered **medically necessary** with documentation of **ALL** of the following:
 1. Individual has an amputation or missing limb at the wrist or above
 2. Standard body-powered prosthetic device cannot be used or is insufficient to meet the functional needs of the individual in performing activities of daily living (ADLs)
 3. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device
 4. Adequate physiological, neurological and cognitive ability to master use and care requirements
 5. Individual is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.)
 6. Myoelectric prosthesis meets the functional needs of the individual in performing the ADLs
 7. Evaluation by an independent, qualified professional has determined the most appropriate prosthetic components and control mechanism
- Myoelectric upper limb prosthetic components for all other indications not previously listed or if above criteria not met are considered **not medically necessary**.
- Upper-limb prosthetic components with both sensor and myoelectric controlled are considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 04/17/18
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MYOELECTRIC PROSTHETIC AND ORTHOTIC COMPONENTS FOR THE UPPER LIMB (cont.)

Criteria: (cont.)

- Myoelectric hand prosthesis with individually powered digits, including but not limited to, a partial hand prosthesis is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

- Myoelectric controlled upper-limb orthoses are considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 04/17/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.04.04 BCBS Association Medical Policy Reference Manual. Myoelectric Prosthetic and Orthotic Components for the Upper Limb. Re-issue date 03/08/2018, issue date 12/11/2008.
2. Otr OV, Reinders-Messelink HA, Bongers RM, Bouwsema H, Van Der Sluis CK. The i-LIMB hand and the DMC plus hand compared: a case report. *Prosthet Orthot Int.* 2010 Jun 2010;34(2):216-220.
3. Touch Bionics. The I-Limb Hand. 2007.



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 04/17/18
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MYOELECTRIC PROSTHETIC AND ORTHOTIC COMPONENTS FOR THE UPPER LIMB (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ 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: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's 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, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíłkígo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíłkígo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ílinígóó. Ata' halne'ígíí kojí' bich'í' hodíłnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 04/17/18
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MYOELECTRIC PROSTHETIC AND ORTHOTIC COMPONENTS FOR THE UPPER LIMB (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi: اگر شما، یا کسی که شما به او کمک میکنید، سوال در مورد Blue Cross Blue Shield of Arizona، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید.]

Assyrian: Blue Cross Blue Shield of Arizona ... 877-475-4799

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคน หรือคนทศณกลางช่วยเหลอมคาถามเกยวกับ Blue Cross Blue Shield of Arizona คนสมทททจะไดรบความช่วยเหลอมและขอมลในภาษา ของคนไดโดยไมมคาใจจ่าย พดคยกมลาม โทร 877-475-4799