MEDICAL POLICY

POLICY TITLE	UPPER LIMB PROSTHESES
POLICY NUMBER	MP-6.052

Effective Date:	9/1/2023

I. POLICY

Preparatory Prosthesis

A preparatory prosthesis may be considered **medically necessary** after surgery to prevent edema of the residual limb. Additions are not medically necessary for preparatory prosthesis since these have all initial components.

All other uses of preparatory prosthesis are considered **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Passive Functional

Passive functional prosthesis does not include any mechanical working parts. The passive prosthesis relies on manual repositioning, typically using the opposite arm, and cannot restore function. A passive functional prosthesis may be considered **medically necessary** only when there is clear documentation that the requested prosthesis is required to perform activities of daily living (ADL's).

All other uses of passive functional prosthesis are considered **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Body-Powered Prostheses

A body-powered prostheses will consist of a socket or interface, suspension system, harness, wrist unit, terminal device (such as a hook or hand), and possibly a triceps cuff (below elbow), hinges (below elbow), elbow (above elbow) and a shoulder (if a shoulder disarticulation or higher).

Body-powered upper extremity prostheses may be considered **medically necessary** when ALL the following are met:

- The member has history of upper limb amputation or absence of upper limb(s);
- A certified prosthetist determines a body-powered upper extremity prostheses is appropriate to meet the member's functional needs.

Sockets and Suspension Systems:

No more than two test (diagnostic) sockets may be considered **medically necessary** for an individual prosthesis without additional documentation of medical necessity. No more than two of the same socket inserts are allowed at the same time. Socket and socket insert replacements may be considered **medically necessary** if there is documentation of functional and/or physiological need. Explanation to include but is not limited to:

- Changes in residual limb
- Functional need changes
- Irreparable damage due to wear and tear
- Wear and tear due to excessive weight
- Prosthetic demands of a very active amputee

Terminal Devices (Above and Below Elbow, Shoulder, Hand)

Terminal devices may be considered **medically necessary** for work and when essential to ADLs. Terminal devices are considered **not medically necessary** when used solely for activities related to sports or recreation.

All other uses of body-powered prostheses are considered **not medically necessary** as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Electric/ Myoelectric Prostheses

Electric and Myoelectric upper limb prosthetic components may be considered **medically necessary** when the following conditions are met:

- The patient has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); and
- Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing ADLs; and
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device; and
- The patient has demonstrated neurological and cognitive function to operate the prosthesis effectively; and
- The patient is free of co-morbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); and
- Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., gripping, releasing, holding, and coordinating movement of the prosthesis) when performing ADLs. This evaluation

should consider the patient's needs for control, durability (maintenance), function (speed, work capability), and usability.

A prosthesis with individually powered digits, including but not limited to, a partial hand prosthesis, is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these item(s).

Myoelectric upper limb prosthetic components are considered **not medically necessary** under all other conditions, as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this item.

Additions and Accessories

Accessories such as sheaths, socks, hinges, switches, extensions, adaptors, cables for residual limbs, etc. may be considered **medically necessary** when these appliances aid in or are essential to the effective use of the prosthetic limb. Additions should be billed on the same claim as the base procedure when supplied at the same time as the base procedure.

Adjustments

Adjustments and/or modifications to the prosthesis required by wear and tear or due to a change in individual's condition (such as growth in a child) or to improve the function may be considered **medically necessary**.

Repairs

Repairs necessary to make the prosthetic functional may be considered **medically necessary**. The expense for repairs may not exceed the estimated expense of purchasing another prosthesis.

Replacement

The life of a prosthesis is approximately 5-years. A replacement prosthesis may be considered **medically necessary** only if the previous prosthesis is no longer functional. Requests for upgrades/newer technology will be reviewed for medical necessity.

Cross-references:

MP-6.018 Prosthetics and Accessories
MP-6.042 Lower Limb Prostheses

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

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FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Upper-Limb Amputation

The need for a prosthesis can occur for a number of reasons, including trauma, surgery, or congenital anomalies.

Treatment

The primary goals of the upper-limb prostheses are to restore function and natural appearance. Achieving these goals also requires sufficient comfort and ease of use for continued acceptance by the wearer. The difficulty of achieving these diverse goals with an upper-limb prosthesis increases with the level of amputation (digits, hand, wrist, elbow, shoulder), and thus the complexity of joint movement increases.

Upper-limb prostheses are classified into 3 categories depending on the means of generating movement at the joints: passive, body-powered, and electrically powered movement. All 3 types of prostheses have been in use for more than 30 years; each possesses unique advantages and disadvantages.

Passive Prostheses

The passive prostheses rely on manual repositioning, typically using the opposite arm, and cannot restore function. This unit is the lightest of the 3 prosthetic types and is thus generally the most comfortable.

Body-Powered Prostheses

The body-powered prostheses use a body harness and cable system to provide functional manipulation of the elbow and hand. Voluntary movement of the shoulder and/or limb stump extends the cable and transmits the force to the terminal device. Prosthetic hand attachments, which may be claw-like devices that allow good grip strength and visual control of objects, or latex-gloved devices that provide a more natural appearance at the expense of control, can be opened and closed by the cable system. Patient complaints with body-powered prostheses include harness discomfort, particularly the wear temperature, wire failure, and the unattractive appearance.

Myoelectric Prostheses

Myoelectric prostheses are powered by electric motors with an external power source. The joint movement of an upper limb prosthesis (e.g., hand, wrist, and/or elbow) is driven by microchip-processed electrical activity in the muscles of the remaining limb stump.

- Myoelectric prostheses use muscle activity from the remaining limb for the 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 hand, wrist, or elbow. Although upper arm movement may be slow and limited to 1 joint at a time, myoelectric control of movement may be considered the most physiologically natural. Patient dissatisfaction with myoelectric prostheses includes the increased cost, maintenance (particularly for the glove), and weight.

- Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis but are battery-powered. Commercially available examples are listed in the Regulatory Status section.
- 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.

Technology in this area is rapidly changing, driven by advances in biomedical engineering and by the U.S. Department of Defense Advanced Research Projects Agency (DARPA), which is funding a public and private collaborative effort on prosthetic research and development. Areas of development include the use of skin-like silicone elastomer gloves, “artificial muscles,” and sensory feedback. Smaller motors, microcontrollers, implantable myoelectric sensors, and re-innervation of remaining muscle fibers are being developed to allow fine movement control. Lighter batteries and newer materials are being incorporated into myoelectric prostheses to improve comfort.

The LUKE Arm (previously known as the DEKA Arm System) was developed in a joint effort between DEKA Research and Development and U.S. DARPA, which is funding a public and private collaborative effort on prosthetic research and development. It is the first commercially available myoelectric upper-limb that can perform complex tasks with multiple simultaneous powered movements (eg, movement of the elbow, wrist, and hand at the same time). In addition to the electromyographic electrodes, the LUKE Arm 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. The prosthesis includes vibration pressure and grip sensors.

Regulatory Status

Manufacturers must register prostheses with the Restorative and Repair Devices Branch of the U.S. Food and Drug Administration (FDA) and keep a record of any complaints, but do not have to undergo a full FDA review.

Available myoelectric devices include ProDigits™ and i-limb™ (Touch Bionics), the SensorHand™ Speed and Michelangelo® Hand (Otto Bock), the LTI Boston Digital Arm™ System (Liberating Technologies), the Utah Arm Systems (Motion Control), and bebionic (steeper).

In 2014, the DEKA Arm System (DEKA Integrated Solutions, now DEKA Research & Development) now called LUKE™ Arm (Mobius Bionics), was cleared for marketing by FDA

through the de novo 513(f)(2) classification process for novel low- to moderate-risk medical devices that are first-of-a-kind.

FDA product codes: GXY, IQZ.

The MyoPro® (Myomo) is registered with the FDA as a class 1 limb orthosis.

IV. RATIONALE

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Summary of Evidence

For individuals who have a missing limb at the wrist or above who receive myoelectric upper limb prosthesis components at the wrist or proximal to the wrist, the evidence includes a systematic review and comparative studies. Relevant outcomes are functional outcomes and quality of life. The goals of upper-limb prostheses relate to restoration of both appearance and function while maintaining sufficient comfort for continued use. The identified literature focuses primarily on patient acceptance and rejection; data are limited or lacking in the areas of function and functional status. The limited evidence suggests that, compared with body-powered prostheses, myoelectric possess the similar capability to perform light work; however, myoelectric components could also suffer a reduction in performance when operating under heavy working conditions. The literature also indicates that the percentage of amputees who accept use of a myoelectric prosthesis is approximately the same as those who prefer to use a body-powered prosthesis, and that self-selected use depends at least in part on the individual's activities of daily living. Appearance is most frequently cited as an advantage of myoelectric prostheses, and for patients who desire a restorative appearance, the myoelectric prosthesis can provide greater function than a passive prosthesis, with equivalent function to a body-powered prosthesis for light work. Because of the differing advantages and disadvantages of currently available prostheses, myoelectric components for persons with an amputation at the wrist or above may be considered when passive or body-powered prostheses cannot be used or are insufficient to meet the functional needs of the patient in activities of daily living. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a missing limb at the wrist or higher who receive sensor and myoelectric controlled upper-limb prosthetic components, the evidence includes a series of publications from a 12-week home study. Relevant outcomes are functional outcomes and quality of life. The prototypes for the advanced prosthesis were evaluated by the U.S. military and Veterans Administration. Demonstration of improvement in function has been mixed. After several months of home use, activity speed was shown to be similar to the conventional prosthesis, and there were improvements in the performance of some activities, but not all. There were no differences between the prototype and the participants' prostheses for outcomes of dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a missing limb distal to the wrist who receive a myoelectric prosthesis with individually powered digits, no peer-reviewed publications evaluating functional outcomes in amputees were identified. Relevant outcomes are functional outcomes and quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
L6000	L6010	L6020	L6050	L6055	L6100	L6110	L6120
L6130	L6200	L6205	L6250	L6300	L6310	L6320	L6350

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Procedure Codes							
L6360	L6370	L6400	L6450	L6500	L6550	L6570	L6580
L6582	L6584	L6586	L6588	L6590	L6600	L6605	L6610
L6611	L6615	L6616	L6620	L6621	L6623	L6624	L6625
L6628	L6629	L6630	L6632	L6635	L6637	L6638	L6640
L6641	L6642	L6645	L6646	L6647	L6648	L6650	L6655
L6660	L6665	L6670	L6672	L6675	L6676	L6677	L6680
L6682	L6684	L6686	L6687	L6688	L6689	L6690	L6691
L6692	L6693	L6694	L6695	L6696	L6697	L6698	L6703
L6704	L6706	L6707	L6708	L6709	L6711	L6712	L6713
L6714	L6721	L6722	L6805	L6810	L6881	L6882	L6883
L6884	L6885	L6890	L6895	L6900	L6905	L6910	L6915
L6920	L6925	L6930	L6935	L6940	L6945	L6950	L6955
L6960	L6965	L6970	L6975	L7007	L7008	L7009	L7040
L7045	L7170	L7180	L7181	L7185	L7186	L7190	L7191
L7259	L7360	L7362	L7364	L7366	L7400	L7401	L7402
L7403	L7404	L7405	L7499	L8415	L8435	L8465	L8485

Investigational; **there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these item(s).**

Procedure Codes							
L6026	L6715	L6880					

IX. REFERENCES

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X. POLICY HISTORY

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MP 6.052	**CAC 08/28/2012 – New policy**. Adopt BCBSA. Policy criteria were previously in MP- 6.042 Upper and Lower Limb Prosthetics. A statement was added that a prosthesis with individually powered digits, including but not limited to a partial hand prosthesis, is considered investigational. Policy coded.
	CAC 07/30/2013 Consensus. No change to policy statements. References updated. No coding changes
	CAC 03/25/2014 Consensus. Added statement **"**Myoelectric upper limb prosthetic components are considered not medically necessary under all other conditions." Changed title to Myoelectric Prosthetic Components for the Upper Limb. Formerly Myoelectric Prosthesis for the Upper Limb. Added rationale section. No coding changes
	01/2015-New 2015 codes added to policy.
	CAC 07/21/2015 Consensus review. No changes to the policy statements. Background, reference, and rationale update**.**
	CAC 07/26/2016 Consensus review. No changes to policy statements. Rational and references reviewed. Coding reviewed. ICD 9 codes removed
	Admin Update 11/09/2016 Variation reformatting.
	CAC 07/25/2017 Consensus review. No changes to the policy statements. Rationale updated. Coding reviewed.
	05/02/2018 Minor review. Updated policy to include direction for all upper extremity prosthetics with coding in policy statements. Title changed. References added and updated.
	03/22/2019 Consensus review. Policy statement unchanged. References updated.
	03/18/2020 Consensus Review. Policy statement unchanged. References updated. HCPC coding tables inserted.
	06/10/2021 Consensus Review. Policy statement unchanged. Description/background, regulatory status, and references updated.
	06/01/2022 Consensus review. No change to policy statement. Coding table format updated. References reviewed. FEP language updated. Procedure code L7499 added to policy.
	6/13/2023 Consensus Review. No change to policy statement. Updated background and rationale. No coding changes.

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