FEP Medical Policy Manual

FEP 1.04.04 Myoelectric Prosthetic Components for the Upper Limb

Effective Date: January 15, 2018
Related Policies:
FEP 1.04.05 Microprocessor-Controlled Prostheses for the Lower Limb
FEP 8.03.01 Functional Neuromuscular Electrical Stimulation

Myoelectric Prosthetic Components for the Upper Limb

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

FDA REGULATORY STATUS
Manufacturers must register prostheses with the restorative devices branch of 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 [Livingston, U.K.]), the SensorHand™ Speed and Michelangelo® Hand (Otto Bock [Duderstadt, Germany]), the LTI Boston Digital Arm™ System (Liberating Technologies [Holliston, MA]), the Utah Arm Systems (Motion Control [Salt Lake City, UT]), and bebionic (steeper).

In 2014, the DEKA Arm System, now called the LUKE™ arm (DEKA Integrated Solutions, now DEKA Research & Development) was cleared for marketing by FDA through the de novo 513(f)(2) classification process for some novel low- to moderate-risk medical devices that are first-of-a-kind.

FDA product codes: GXY, IQZ.

POLICY STATEMENT
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 (eg, forearm, elbow); and
- Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing activities of daily living; 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 sufficient neurologic and cognitive function to operate the prosthesis effectively; and
- The patient is free of comorbidities that could interfere with function of the prosthesis (eg, neuromuscular disease); and

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Functional evaluation indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (eg, gripping, releasing, holding, coordinating movement of the prosthesis) when performing activities of daily living. This evaluation should consider the patient’s needs for control, durability (maintenance), function (speed, work capability), and usability.

Prosthesis with individually powered digits, including but not limited to partial hand prosthesis, is considered investigational.

Myoelectric upper-limb prosthetic components are considered not medically necessary under all other conditions.

POLICY GUIDELINES

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals with a missing limb at the wrist or higher who receive myoelectric upper-limb prosthesis components at or proximal to the wrist; the evidence includes cohort studies and survey data. 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 reasons for disuse; detailed data are limited or lacking in the areas of function and functional status, as well as direct comparisons between body-powered and newer model myoelectric prostheses. The limited evidence suggests that, when compared with body-powered prostheses, myoelectric components possess similar capability to perform light work, and that myoelectric components may improve range of motion (to an extent); however, myoelectric components could also suffer a reduction in performance when operating under heavy working conditions. The literature has also indicated that the percentage of amputees who accept the 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 partly 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. Nonuse of any prosthesis is associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback. 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 when 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 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.
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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review. Reference 4 added; title changed to &quot;Myoelectric Prosthetic Components for the Upper Limb&quot;; policy statements unchanged</td>
</tr>
<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review, no references added; policy statement added on powered digits, included but not limited to a partial hand prosthesis added as not medically necessary.</td>
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<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review, no references added; policy statement unchanged.</td>
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<tr>
<td>March 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review; no references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through July 21, 2017; no references added. Policy statements unchanged except “Prosthesis with individually powered digits” was corrected from not medically necessary to investigational.</td>
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