Uniform Medical Plan coverage limits

Updates effective 7/1/2019

The benefit coverage limits listed below apply to these UMP plans:
Uniform Medical Plan Classic (UMP Classic)
UMP Consumer-Directed Health Plan (UMP CDHP)

- UMP Plus–Puget Sound High Value Network
- UMP Plus–UW Medicine Accountable Care Network

Some services listed under these benefits have coverage limits. These limits are either determined by a Health Technology Clinical Committee (HTCC) decision or a Regence BlueShield medical policy. **The table below does not include every limit or exclusion under this benefit. For more details, refer to your plan's Certificate of Coverage.**

Durable Medical Equipment

These services or supplies have coverage limits	The rules or policies that define the coverage limits	Limit applies to these codes (chosen by your provider to bill for services)
Bone Growth Stimulation	HTCC decision	• 20974, 20975, 20979 • E0747, E0748, E0749, E0760
Continuous Glucose Monitoring	HTCC decision	• A9277, A9278, K0554, S1030, S1031
Implantable Drug Delivery System	HTCC decision	• C1772, C1889, C1891, C2626, E0782, E0783, E0785, E0786
Microprocessor-Controlled Lower Limb Prosthetics	HTCC decision	• L5856, L5857, L5858 Use Regence Medical Policy DME81 in addition to the HTCC to review requests regarding "functional level 2" and "experienced user exceptions".
Myoelectric Prosthetic and Orthotic Components for the Upper Limb	Regence Medical Policy DME80	• L6026, L6693, L6715, L6880, L6881, L6882, L6925, L6935, L6945, L6955, L6965, L6975, L7007, L7008, L7009, L7045, L7180, L7181, L7190, L7191

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions	Regence Medical Policy DME45	• E0481, E0483
Programmable Pneumatic Compression Pumps	Regence Medical Policy DME78	• E0652
Stents, Drug Coated or Drug-Eluting (DES)	HTCC decision	Refer to Cardiac Stenting in the Surgery section.

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Medical Policy Manual Durable Medical Equipment, Policy No. 80

Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Effective: January 1, 2019

Next Review: June 2019
Last Review: December 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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

MEDICAL POLICY CRITERIA

Note: The plan provides coverage for either an upper limb prosthesis with myoelectric components if criteria are met or for a mechanical prosthesis without myoelectric function, but not for both for a single limb.

I. Myoelectric upper limb prostheses may be **medically necessary** when all of the following criteria are met (A - F):

A. The patient has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); and

B. 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;

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and

C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device, as demonstrated by functional testing using a physical or computer model prosthesis; and

D. The patient has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; and

E. The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); and

F. Functional evaluation by a qualified professional (e.g., prosthetist) indicates that with training, use of a myoelectric prosthesis and associated components is necessary to meet the functional needs of the individual (e.g., automatic grasp features, microprocessor control features, or other components to aid gripping, releasing, holding, and 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. Both of the following criteria must be met (1 and 2):

1. The device is necessary for the patient to perform instrumental activities of daily living including job functioning; and
2. The device is *not* primarily for the purpose of allowing the patient to perform leisure or recreational activities.

II. Myoelectric upper limb prosthetic components are considered **not medically necessary** under all other conditions including but not limited to replacement of an existing, functioning prostheses (e.g., as an "upgrade" for a prosthesis that still works and fits).

III. Upper-limb prosthetic components with both sensor and myoelectric control are considered **investigational**.

IV. Myoelectric controlled upper-limb orthoses are considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of amputation or missing limb at the wrist or above
- Documentation that standard body-powered devices can't be used or are not efficient including the ADLs that cannot be accomplished currently
- Documentation that the remaining musculature in the limb contains the minimum microvolt threshold to allow operation of the device including a functional test using a physical or computer model prosthesis
- Documentation the patient is cognitively and neurologically able to operate the prosthetic

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- Documentation the patient doesn't have any comorbidities that might interfere with the use of the prosthetic
- An evaluation by a qualified professional such as a prosthetist that show the patient will be able to use the prosthetic for ADLs including the patient's ability to control, maintain, function, and use the prosthetic including why it is necessary for the patient to perform ADLs or job functions and evidence it is not being requested only for leisure or recreational activities
- Documentation that the prosthetic is not being requested to replace a functioning prosthetic

CROSS REFERENCES

1. Powered Knee Prosthesis, or Powered Ankle-Foot Prosthesis, and Microprocessor-Controlled Ankle-Foot Prosthesis, DME, Policy No. 81

BACKGROUND

Upper limb prostheses are used following amputation at any level from the hand to the shoulder. The need for a prosthesis can occur for a number of reasons, including trauma, surgery, or congenital anomalies. The primary goals of the upper limb prosthesis are to restore natural appearance and function. 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 as the level of amputation (digits, hand, wrist, elbow, and shoulder), and thus the complexity of joint movement, increases.

Upper limb prostheses are classified based on the means of generating movement at the joints as follows:

PASSIVE PROSTHESIS:

- The lightest weight upper extremity prosthesis
- Patients generally describe this as the most comfortable of the three types
- Must be repositioned manually, typically by moving it with the opposite arm
- Cannot restore function.

BODY-POWERED PROSTHESIS

- Uses 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 PROSTHESIS

Uses muscle activity from the remaining limb for the control of joint movement.

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- 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.
- Implantable EMG sensors with wireless signal transmission (e.g., Implantable Myoelectric Sensors [IMES®]) are being studied as alternatives to surface electrodes to improve prosthetic hand function. These implantable sensors may eliminate the limitations inherent in surface electrodes such as issues related to poor skin contact (e.g., skin sweating) and the ability to detect signals only from superficial muscles.
- Although upper arm movement may be slow and limited to one joint at a time, myoelectric control of movement may be considered the most physiologically natural.
- Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis, but are battery powered.
- Patient dissatisfaction with myoelectric prostheses includes the increased cost, maintenance (particularly for the glove), and weight.
- Examples of available technologies:
    - The SensorHand™ by Advanced Arm Dynamics, which is described as having an AutoGrasp feature, an opening/closing speed of up to 300 mm/second, and advanced EMG signal processing.
    - The Utah Arm 3 by Motion Control has a microprocessor interface that allows individualized adjustments to achieve maximum performance.
    - The i-LIMB™ hand (Touch Bionics), sometimes referred to as the bionic hand, is the first commercially available myoelectric hand prosthesis with individually powered digits.
    - ProDigits™, also from Touch Bionics, are prosthetic digits for one or more fingers in patients with amputation at a transmetacarpal level or higher.
    - Otto Bock has a number of myoelectric hand and elbow prostheses including the AutoGrasp feature, the Michelangelo® Hand, and the Electrohand 2000 designed for children.
    - LTI Boston Digital Arm™ System by Liberating Technologies Inc. is marketed as having greater torque than any other powered prosthetic elbows
    - These devices may be covered by LIVINGSKIN™, a high-definition silicone prosthesis created to resemble a patient's natural skin.

SENSOR AND MYOELECTRIC PROSTHESIS

The LUKE Arm (previously known as the DEKA Arm System) can perform complex tasks with multiple simultaneous powered movements (e.g., movement of the elbow, wrist, and hand at the same time). In addition to the EMG electrodes, the LUKE Arm contains a combination of mechanisms including switches, movement sensors, and force sensors. The Luke Arm is the same shape and weight as an adult arm.

HYBRID SYSTEM, A COMBINATION OF BODY-POWERED AND MYOELECTRIC COMPONENTS

- May be used for high-level amputations (at or above the elbow).
- Allows control of two joints at once (i.e., one body-powered and one myoelectric)
- Generally lighter weight and less expensive than a prosthesis composed entirely of myoelectric components.

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- An example of a hybrid system is the ErgoArm by Otto Bock which has a myoelectric hand and a cable-controlled elbow joint

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.

MYOELECTRIC ORTHOSES

The MyoPro (Myomo) is a myoelectric powered upper-extremity orthotic. This orthotic device weighs about 1.8 kilograms (4 pounds), has manual wrist articulation, and myoelectric initiated bi-directional elbow movement. The MyoPro 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 patients 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.

Regulatory Status

Prostheses are class I devices that are exempt from U.S. Food and Drug Administration (FDA) marketing clearance, but manufacturers must register prostheses with the restorative devices branch of the FDA and keep a record of any complaints.

Examples of available myoelectric devices are listed above.

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

EVIDENCE SUMMARY

In evaluating the effects of the increased sophistication of myoelectric upper limb prostheses compared with body-powered prostheses, passive prostheses, or no prosthesis, the most informative data are from prospective comparative studies with objective and subjective measures that directly address function and health-related quality of life.

In light of the magnitude of functional loss in upper extremity amputation, evaluation of the evidence is based on two assumptions:

1. Use of any prosthesis confers clinical benefit, and

2. Self-selected use is an acceptable measure of the perceived benefit (combination of utility, comfort, and appearance) of a prosthesis for that individual.

It should be considered that the upper limb amputee’s needs may depend on their situation. For example, increased functional capability may be needed with heavy work or domestic duties, while a more natural appearing prosthesis with reduced functional capability may be acceptable for an office, school, or another social environment.

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MYOELECTRIC UPPER LIMB PROSTHESIS

Systematic Reviews

A 2015 systematic review (SR) by Carey evaluated differences between myoelectric and body-powered prostheses. The SR included 31 studies.[1] The evidence was conflicting for functional performance between the two prostheses. The authors concluded that there is insufficient evidence to show that one system provides a significant advantage over the other and that prosthetic selection should be based on patient preference and functional needs.

A 2007 SR by Biddis of 40 articles published over the previous 25 years assessed upper limb prosthesis acceptance and abandonment.[2] For pediatric patients the mean rejection rate was 38% for passive prostheses (one study), 45% for body-powered prostheses (three studies), and 32% for myoelectric prostheses (12 studies). For adults there was considerable variation between studies, with mean rejection rates of 39% (six studies), 26% (eight studies), and 23% (10 studies) for passive, body-powered and myoelectric prostheses, respectively. The authors found no evidence that the acceptability of passive prostheses had declined over the period from 1983 to 2004, “despite the advent of myoelectric devices with functional as well as cosmetic appeal.” Body-powered prostheses were also found to have remained a popular choice, with the type of hand-attachment being the major factor in acceptance. Body-powered hooks were considered acceptable by many users, but body-powered hands were frequently rejected (80%–87% rejection rates) due to slowness in movement, awkward use, maintenance issues, excessive weight, insufficient grip strength, and the energy needed to operate. Rejection rates of myoelectric prostheses tended to increase with longer follow-up. There was no evidence of a change in rejection rates over the 25 years of study, but the results are limited by sampling bias from isolated populations and the generally poor quality of the studies included.

Randomized Controlled Trials

In comparative studies of prostheses, subjects served as their own control. Since these studies included use by all subjects of both a myoelectric and a body-powered prosthesis, randomization was directed at the order in which each amputee used the prostheses. Two trials were found in which a total of 196 children used both a myoelectric and a body-powered hand prosthesis, in randomized order, for a period of three months each.[3,4] No clinically relevant objective or subjective difference was found between the two types of prostheses.

Nonrandomized Studies

A number of small (n<50) non-randomized case series[5-7] and online or mailed surveys[8-11] were found, but few studies directly addressed whether myoelectric prostheses improved function and health-related quality of life. Most of the studies identified described amputees’ self-selected use or rejection rates. The results were usually presented as hours worn at work or school, hours worn at home, and hours worn in social situations. Amputees’ self-reported reasons for use and abandonment were also frequently reported. The limited evidence available suggests that, in comparison with body-powered prostheses, myoelectric components may improve range of motion to some extent, have similar capability for light work, but may have reduced performance under heavy working conditions. The literature also indicated that the percentage of amputees who accepted use of a myoelectric prosthesis was about the same as those who prefer to use a body-powered prosthesis, and that self-selected use depended at least in part on the individual’s activities of daily living. Appearance was most

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frequently cited as an advantage of myoelectric prostheses. Nonuse of any prosthesis was associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback.

Section Summary: Myoelectric Upper-Limb Prosthesis

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 the percentage of amputees who accept 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. When compared with body-powered prostheses, myoelectric components possess similar capability to perform light work, and myoelectric components may improve range of motion. The literature has also indicated that 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.

SENSOR AND MYOELECTRIC UPPER LIMB COMPONENTS

Investigators from three Veterans Administration medical centers and the Center for the Intrepid at Brooke Army Medical Center published a series of reports on home use of the LUKE prototype (DEKA Gen 2 and DEKA Gen 3) in 2017 and 2018.[12-16] Participants were included in the in-laboratory training if they met criteria and had sufficient control options (e.g., myoelectric and/or active control over one or both feet) to operate the device. In-lab training included a virtual reality training component. At the completion of the in-lab training, the investigators determined, using a priori criteria, which participants were eligible to continue to the 12-week home trial. The criteria included the independent use of the prosthesis in the laboratory and community setting, fair, functional performance, and sound judgment when operating or troubleshooting minor technical issues. On ClinicalTrials.gov, the total enrollment target is listed as 100 patients with study completion by February 2018 (NCT01551420).

One of the publications (Resnick, 2017) reported on the acceptance of the LUKE prototype before and after a 12-week trial of home use.[14] Of 42 participants enrolled at the time, 32 (76%) participants completed the in-laboratory training, 22 (52%) wanted to receive a LUKE Arm and proceeded to the home trial, 18 (43%) completed the home trial, and 14 (33%) expressed a desire to receive the prototype at the end of the home trial. Over 80% of those who completed the home trial preferred the prototype arm for hand and wrist function, but as many preferred the weight and look of their own prosthesis. One-third of those who completed the home training thought that the arm was not ready for commercialization. Participants who completed the trial were more likely to be prosthesis users at study onset ($p=0.03$), and less likely to have musculoskeletal problems ($p=0.047$).[12] Reasons for attrition during the in-laboratory training were reported in a separate publication by Resnik and Klinger (2017).[15] Attrition was related to the prosthesis entirely or in part by 67% of the participants, leading to a recommendation to provide patients with an opportunity to train with the prosthesis before a final decision about the appropriateness of the device.

Functional outcomes of the Gen 2 and Gen 3 arms, as compared with participants' prostheses, were reported by Resnick et al (2018).[13] At the time of the report, 23 regular prosthesis users had completed the in-lab training, and 15 had gone on to complete the home use portion of the study. Outcomes were both performance-based and self-reported measures. At the end of the

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lab training, dexterity was similar, but performance was slower with the LUKE prototype than with their conventional prosthesis. At the end of the home study, activity speed was similar to the conventional prostheses, and one of the performance measures (Activities Measure for Upper-Limb Amputees) was improved. Participants also reported that they were able to perform more activities, had less perceived disability, and less difficulty in activities, but there were no differences between the two prostheses on many of the outcome measures including dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. Post hoc power analysis suggested that evaluation of some outcomes might not have been sufficiently powered to detect a difference.

In a separate publication, Resnick et al (2017) reported that participants continued to use their prosthesis (average, 2.7 h/d) in addition to the LUKE prototype, concluding that availability of both prostheses would have the greatest utility.[16] This conclusion is similar to those from earlier prosthesis surveys, which found that the selection of a specific prosthesis type (myoelectric, powered, or passive) could differ depending on the specific activity during the day. In the DEKA Gen 2 and Gen 3 study reported here, 29% of participants had a body-powered device, and 71% had a conventional myoelectric prosthesis.

Section Summary: Sensor and Myoelectric Upper-Limb Components

The LUKE Arm was cleared for marketing in 2014 and is now commercially available. The prototypes for the LUKE Arm, the DEKA Gen 2 and Gen 3, were evaluated by the U.S. military and Veteran's Administration in a 12-week home study, with study results reported in a series of publications. Acceptance of the advanced prosthesis in this trial was mixed, with one-third of enrolled participants desiring to receive the prototype at the end of the trial. Demonstration of improvement in function has also been mixed. After several months of home use, activity speed was shown to be similar to the conventional prosthesis. There was an improvement in the performance of some, but not all, activities. Participants continued to use their prosthesis for part of the day, and some commented that the prosthesis was not ready for commercialization. There were no differences between the LUKE Arm prototype and the participants' prostheses for many outcome measures. Study of the current generation of the LUKE Arm is needed to determine whether the newer models of this advanced prosthesis lead to consistent improvements in function and quality of life.

MYOELECTRIC ORTHOTIC

Peters (2017) evaluated the immediate effect (no training) of a myoelectric elbow-wrist-hand orthosis on paretic upper-extremity impairment.[17] Participants (n=18) were stable and moderately impaired with a single stroke 12 months or later before study enrollment. They were tested using a battery of measures without, and then with the device; the order of testing was not counterbalanced. The primary measure was the upper-extremity section of the Fugl-Meyer Assessment, a validated scale that determines active movement. Upper-extremity movement on the Fugl-Meyer Assessment was significantly improved while wearing the orthotic (a clinically significant increase of 8.71 points, $p<0.001$). The most commonly observed gains were in elbow extension, finger extension, grasping a tennis ball, and grasping a pencil. The Box and Block test (moving blocks from one side of a box to another) also improved ($p<0.001$). Clinically significant improvements were observed for raising a spoon and cup, and there were significant decreases in the time taken to grasp a cup and gross manual dexterity. Performance on these tests changed from unable to able to complete. The functional outcome measures (raising a spoon and cup, turning on a light switch, and picking up a laundry basket

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with two hands) were developed by the investigators to assess these moderately impaired participants. The authors noted that performance on these tasks was inconsistent, and proposed a future study that would include training with the myoelectric orthosis before testing.

Page (2013) compared the efficacy of a myoelectric orthosis combined with repetitive task-specific practice to repetitive task-specific practice alone in improving performance following stroke.[18] Sixteen subjects at a mean of 75 months post-stroke were divided into two groups. Both groups received therapist-supervised repetitive task-specific practice for three days a week for eight weeks. One group used the orthotic during practice. After intervention, there was no significant difference between groups in Fugl-Meyer score increases, six measures of the Stroke Impact Scale, or Canadian Occupational Performance Measure Performance. There was a significant difference in the Stroke Impact Scale Total (p=0.027).

Section Summary: Myoelectric Orthotic

The largest study identified tested participants with and without the orthosis. This study evaluated the function with and without the orthotic in stable poststroke participants who had no prior experience with the device. Outcomes were inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients.

PRACTICE GUIDELINE SUMMARY

No practice guidelines identified.

SUMMARY

There is enough research to show that myoelectric upper limb prostheses improve health outcomes for people with an amputation or missing limb at the wrist or above when the medical policy criteria are met. Therefore, myoelectric upper limb prostheses may be considered medically necessary when policy criteria are met. Myoelectric upper limb prostheses, under all other conditions including but not limited to replacement of an existing functioning prostheses are considered not medically necessary when policy criteria are not met.

There is not enough research to show that upper-limb prosthetic components with both sensor and myoelectric control improve health outcomes compared with conventional prostheses. Therefore, upper-limb prosthetic components with both sensor and myoelectric control are considered investigational.

There is not enough research to show that myoelectric controlled upper-limb orthoses improve health outcomes for people with upper limb weakness or paresis. Only two comparative studies have been published examining myoelectric orthoses. They had small sample sizes and demonstrated inconsistent performance. Therefore, myoelectric controlled upper-limb orthoses are considered investigational.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous
	L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)
	L6693	Upper extremity addition, locking elbow, forearm counterbalance
	L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement
	L6880	Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)
	L6881	Automatic grasp feature, addition to upper limb electric prosthetic terminal device
	L6882	Microprocessor control feature, addition to upper limb prosthetic terminal device
	L6925	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6935	Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6945	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6955	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6965	Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6975	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L7007	Electric hand, switch or myoelectric controlled, adult
	L7008	Electric hand, switch or myoelectric controlled, pediatric
	L7009	Electric hook, switch or myoelectric controlled, adult
	L7045	Electric hook, switch or myoelectric controlled, pediatric

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Codes	Number	Description
	L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
	L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
	L7190	Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled
	L7191	Electronic elbow, child, Variety Village or equal, myoelectronically controlled
	L7259	Electronic wrist rotator, any type
	L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
	L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

Date of Origin: *June 2010*

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Powered Knee Prosthesis, Powered Ankle-Foot Prosthesis, Microprocessor-Controlled Ankle-Foot Prosthesis, and Microprocessor-Controlled Knee Prosthesis

Effective: July 1, 2019

Next Review: September 2019
Last Review: June 2019

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

These computerized prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis.

MEDICAL POLICY CRITERIA

I. Microprocessor-controlled knee may be considered **medically necessary** in amputees when all of the following criteria are met (A – E):

A. At least one of the following criteria are met:

1. Demonstrated need for ambulation at variable rates or for long distances such that the patient would benefit from a device that may reduce energy consumption. (Use of the limb only in the home and/or for basic community ambulation does not establish medical necessity of the computerized limb over standard limb applications); or

2. Demonstrated daily activities or job tasks that do not permit full focus of concentration on knee control and stability, including but not limited to ambulation on uneven terrain, curbs, ramps, regular use on stairs or repetitive

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lifting and/or carrying. (Use of the limb for limited stair climbing in the home or employment environment does not establish medical necessity of the computerized limb over standard prosthetic application).

B. All of the following criteria must be met to demonstrate adequate physical ability:

1. Adequate cardiovascular and pulmonary reserve for ambulation at faster than normal walking speed; and
2. Adequate stride strength and balance to activate the knee unit; and
3. Classified as one of the following Medicare Functional Levels:
    a. Select Level K2—Patients capable of limited community ambulation, but only if improved stability in stance permits increased independence, decreased risk of falls, and potential to advance to a less restrictive walking device. The microprocessor is required to enable fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator; or
    b. Level K3—Patients who have 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; or
    c. Level K4—Patients who have the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

C. Adequate cognitive ability to master use and care requirements for the technology; and

D. Patients with amputation from hemi-pelvectomy through knee-disarticulation level including bilateral lower extremity; and

E. All of the following criteria must also be met:

1. Stable or absent wound; and
2. The request is for either a microprocessor-controlled knee or a non-microprocessor-controlled mechanical prosthesis but not both for a single knee; and
3. Adequate socket fitting with the potential to return to active lifestyle.

II. A microprocessor-controlled knee is considered **not medically necessary** when Criterion I. is not met or when any of the following apply:

A. Medicare Functional Levels K0, K1, and the subset of K2 patients capable of limited community ambulation who do not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, decreased risk of falls and potential to advance to a less restrictive walking device

B. When the primary benefit is to allow the patient to perform leisure or recreational activities

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C. Inability to tolerate the weight of the prosthesis

D. Significant hip flexion contracture (over 20 degrees)

E. Patient falls outside of recommended weight or height guidelines of manufacturer

III. A powered knee or ankle-foot or a microprocessor-controlled ankle-foot is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of need at variable rates or for long distance ambulation from a device that reduces energy consumption
- Documentation of specific ADLS including job tasks that call do not permit full focus of concentration on knee control and stability
- Documentation of adequate ability to ambulate faster than normal walking speed including cardiovascular/pulmonary reserve, stride length, balance, Medicare Functional Level, and cognitive ability
- Type of amputation
- Wound status if applicable

CROSS REFERENCES

1. Myoelectric Prosthetic Components for the Upper Limb, DME, Policy No. 80

BACKGROUND

MICROPROCESSOR-CONTROLLED PROSTHETIC KNEES

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (IP) (Blatchford, England), the Adaptive (Endolite, England), 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. For example, the prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. In addition, these devices (with the exception of the IP) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control). By improving stance control, they may provide increased safety, stability, and function. For example, the sensors are designed to recognize a stumble and 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.

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The C-Leg was cleared for marketing in 1999 through the 510(k) process of the U.S. Food and Drug Administration (FDA; K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses utilize additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is 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, for example, in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

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), 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 intent of the technology is 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 and 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 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence).

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

REGULATORY STATUS

Microprocessor-controlled prostheses are categorized as class I, exempt devices. 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. FDA product codes include ISW and KFX.

EVIDENCE SUMMARY

Evaluating the effects of the increased sophistication of powered knee, powered ankle-foot, and microprocessor-controlled ankle-foot prostheses requires comparison with body-powered prostheses, passive prostheses, or no prosthesis. The most informative data are prospective

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comparative studies with objective measures that directly address function, safety, and health-related quality of life.

The evidence review below does not address microprocessor-controlled knees which have been shown to improve function measures and decrease the cognitive burden associated with monitoring the prosthesis.

MICROPROCESSOR-CONTROLLED ANKLE-FOOT PROSTHESES

Systematic Reviews

A 2004 Cochrane review of ankle-foot prostheses (assessed as up-to-date through June 2006) concluded that there is insufficient evidence from high quality comparative studies to determine the overall superiority of any individual type of prosthetic ankle-foot mechanism.[1] The review included 26 cross-over studies with 3-16 participants in each study (N=245). Only one study was considered to be of high methodological quality while the remainders were considered of moderate quality. The vast majority of clinical studies on human walking have used standardized gait assessment protocols (e.g., treadmills) with limited “ecological validity”. The authors recommended that for future research, functional outcomes should be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, and changes in walking speed.

Randomized Controlled Trials

A 2012 randomized, within-subject crossover study compared self-reported and objective performance outcomes for four types of prosthetic feet, including the SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux mechanical foot, and the Proprio Foot microprocessor-controlled ankle prosthesis.[2] Ten patients with transtibial amputation were tested with their own prosthesis and then, in random order, each of the other prostheses after training and a two week acclimation period. No differences between prostheses were detected for the following measures:

- Prosthesis Evaluation Questionnaire (PEQ) (self-reported subjective rating of ease of use, social and emotional issues, and function over different surfaces)
- Locomotor Capabilities Index (self-reported subjective rating of capability to perform certain activities such as walking in various environments on various surfaces, sitting, standing, bending)
- Six-minute walk test (objective distance measurement)
- Steps per day
- Hours of daily activity

In 2014, the same investigators reported the effects of these prosthetic feet on ramp ambulation in 10 unilateral transtibial amputees.[3] Higher symmetry was reported with the Talux mechanical foot and the Proprio Foot during ramp descent, while no significant difference was found between the prostheses during ramp ascent.

Due to the limited sample sizes in these studies, conclusions cannot be reached about the comparisons between the various types of foot prostheses.

Nonrandomized Comparative Studies

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Two comparative trials of the microprocessor-controlled ankle were published since the 2004 Cochrane Review.[4,5] Both studies were from the same investigators and included the Proprio Foot in 16 transtibial amputees during stair ascent and descent[4] or while walking up and down a ramp[5]. These studies were limited to the effect of flexion angles (flexion versus neutral angle). Healthy controls were also used for comparison. The outcomes of these studies were mixed. For example, the adapted mode (ankle flexion) resulted in more normal gait analysis results during ramp ascent but not during descent; however, some patients reported feeling safer with the adaptive mode ankle than with the Proprio Foot. Other small studies have reported on ankle flexion using individuals as their own comparison group.[6] A within-subject study of six patients reported no benefit of an active Proprio Foot compared with the same prosthesis turned off with level walking or with slope ascent or descent.[7] An additional study reported a lower energy cost of floor walking with the Proprio Foot compared with a dynamic carbon fiber foot in 10 transtibial amputees.[8]

Section Summary

These studies do not permit conclusions about the clinical benefits and risks of the microprocessor-controlled foot compared with mechanical prostheses due to methodological limitations. These limitations included but were not limited to the small sample size which limits the ability to rule out chance as an explanation of the study findings.

POWERED KNEE AND/OR ANKLE-FOOT PROSTHESES

Ferris compared the BiOM powered ankle-foot prosthesis with an energy-storing and –returning (ESR) foot in 11 transtibial amputees.[9] These results were also compared with 11 matched controls with intact limbs. Compared with the ESR foot, the powered ankle-foot increased walking speed, but there were no significant differences in physical performance measure or conditions on the PEQ. Compared with the intact limb, the powered ankle-foot had increased step length and greater ankle peak power, but had reduced range of motion. There appeared to be an increase in compensatory strategies at proximal joints with the powered prosthesis; the authors noted that normalization of gait kinematics and kinetics may not be possible with a uniarticular device. Seven patients preferred the PowerFoot BiOM and 4 preferred the ESR prosthesis.

Another small study of seven amputees and seven intact controls reported gross metabolic cost and preferred walking speed to be more similar to non-amputee controls with the powered foot than with the ESR prosthesis.[10]

Mancinelli compared the PowerFoot BiOM with a passive-elastic foot in five transtibial amputees.[11] At the time of this study the powered prosthesis was a prototype and subjects' exposure to the prosthesis was limited to the laboratory. Laboratory assessment of gait biomechanics showed an average increase of 54% in the peak ankle power generation during late stance. Metabolic cost measured by oxygen consumption while walking on an indoor track was reduced by an average of 8.4% (p=0.06). This study did not report the impact of these measurements on patient function.

Section Summary

The current evidence is insufficient to permit conclusions about the benefits of powered lower extremity prostheses compared with other prostheses. These small studies mainly report on

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the feasibility of various prototypes. Larger, higher quality studies are needed to determine the impact of these devices on functional outcomes with greater certainty.

PRACTICE GUIDELINE SUMMARY

The VAs' 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.[2] The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management program:

A. Contraindications for use of the microprocessor knee should include:
- 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.

B. Indications for use of the microprocessor knee should include:
- 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
- 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.

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- 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 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.

C. 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 active lifestyle.

SUMMARY

Research for microprocessors of the knee have reported improved function for some amputees and a decrease in the cognitive burden associated with monitoring the prosthesis. Those considered most likely to benefit from these prostheses have both the potential and need for frequent movement at a variable pace, uneven ground, or on stairs. Therefore, microprocessors of the knee may be considered medically necessary when policy criteria are met.

There is not enough research to show if or how well microprocessors of the knee improve health outcomes when criteria are not met. Therefore, microprocessors of the knee are not medically necessary, when policy criteria are not met.

There is not enough research to conclude improved health outcomes for microprocessor-controlled ankle-foot prosthesis compared with conventional prostheses. Therefore, microprocessor-controlled ankle-foot prostheses are considered investigational.

There is not enough research to evaluate the health benefits and risks of powered lower limb prostheses. Therefore, powered knee and/or powered ankle-foot prostheses are considered investigational.

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12. BlueCross BlueShield Association Medical Policy Reference Manual "Microprocessor Controlled Prostheses for the Lower Limb." Policy No. 1.04.05

CODES

Codes	Number	Description
CPT	None	
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	;swing phase only, includes electronic sensor(s), any type
	L5858	;stance phase only, includes electronic sensor(s), any type
	L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered
	L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)

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L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, include power source
L5999	Lower extremity prosthesis, not otherwise specified

Date of Origin: *May 2010*

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Medical Policy Manual Durable Medical Equipment, Policy No. 45

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

Effective: May 1, 2019

Next Review: June 2019
Last Review: March 2019

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage (P/PD) method of airway clearance for patients with cystic fibrosis, diffuse bronchiectasis and other respiratory conditions (such as chronic obstructive pulmonary disease).

MEDICAL POLICY CRITERIA

Notes:

- This policy does not address oscillatory positive expiratory pressure (OPEP) devices as they are considered medically necessary. Examples are listed in the Regulatory Status section.
- This policy addresses outpatient use of oscillatory devices. Inpatient device use (e.g., in the immediate post-surgical period), is not addressed by this policy.

I. Use of high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices may be considered **medically necessary** when either of the following criteria are met:

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A. For patients with cystic fibrosis when all of following criteria (1-2) are met:

1. Demonstrated need for airway clearance, and
2. Documentation of the reason standard chest physiotherapy has failed, is not tolerated, or is unavailable or cannot be performed (e.g., caregiver inability). Failure is defined as continued frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (e.g., chest physiotherapy and, if appropriate, use of a positive expiratory pressure device).

B. For patients with chronic diffuse bronchiectasis when all of the following criteria (1-3) are met:

1. Demonstrated need for airway clearance; and
2. Documentation of the reason standard chest physiotherapy has failed, is not tolerated, or is unavailable or cannot be performed (e.g., caregiver inability). Failure is defined as continued frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (e.g., chest physiotherapy and, if appropriate, use of a positive expiratory pressure device).
3. Chronic diffuse bronchiectasis must be documented by high resolution or spiral chest computed tomography scan *and* any one or more of the following must be present:
   a. Daily productive cough for at least six continuous months; or
   b. Exacerbations requiring antibiotic therapy three or more times per year.

II. Use of high-frequency chest wall oscillation (HFCWO) devices and intrapulmonary percussive ventilation (IPV) devices is considered **not medically necessary** as an alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis in any other clinical situations.

III. Other applications of high-frequency chest wall oscillation devices and intrapulmonary percussive ventilation (IPV) devices are considered **investigational**, including but not limited to the following:

A. Use as an adjunct to chest physical therapy

B. Use in other lung diseases, such as chronic obstructive pulmonary disease or respiratory conditions associated with neuromuscular disorders

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of specific device being requested

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- Documentation of disease process including disease name (e.g. hypersecretory lung disease, cystic fibrosis, chronic diffuse bronchiectasis)
- For high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) include the following:
    - Documentation of need for airway clearance
    - Documentation of why standard chest physiotherapy has failed including reasons, if not tolerated, or is unavailable/cannot be performed including reasons.
    - If patient has chronic diffuse bronchiectasis include documentation by high resolution or spiral chest computed tomography scan along with documentation that there is a daily productive cough that has been present for six continuous months or exacerbations requiring antibiotic therapy three or more times per year.
    - Documentation if the request is going to be an adjunct to chest clinical therapy

CROSS REFERENCES

None

BACKGROUND

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some devices require active participation of patients. They include oscillating positive expiratory pressure (PEP, or OPEP) devices, such as Flutter and Acapella, in which the patient exhales multiple times through a device. The Flutter device is a small pipe-shaped, easily portable handheld device, with a mouthpiece at one end. It contains a high-density stainless steel ball that rests in a plastic circular cone. During exhalation, the steel ball moves up and down, creating oscillations in expiratory pressure and airflow. When the oscillation frequency approximates the resonance frequency of the pulmonary system, vibration of the airways occurs, resulting in loosening of mucus. The Acapella device is similar in concept but uses a counterweighted plug and magnet to create air flow oscillation.

Other airway clearance techniques also require active patient participation. For example, autogenic drainage and active cycle of breathing technique both involve a combination of breathing exercises performed by the patient. PEP therapy requires patients to exhale through a resistor to produce PEPs during a prolonged period of exhalation. It is hypothesized that the positive pressure supports the small airway such that the expiratory airflow can better mobilize secretions.

In contrast, high-frequency chest wall oscillation (HFCWO) devices (e.g., the Vest Airway Clearance System, formerly the ABI Vest, or the ThAIRapy Bronchial Drainage System) are oscillatory devices designed to provide airway clearance without the active participation of the patient. The Vest Airway Clearance System provides high-frequency chest compression using an inflatable vest and an air-pulse generator. Large-bore tubing connects the vest to the air-pulse generator. The air-pulse generator creates pressure pulses that cause the vest to inflate and deflate against the thorax, creating HFCWO and mobilization of pulmonary secretions.

The Percussionaire oscillatory device delivers intrapulmonary percussive ventilation. This device combines internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer.

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All of these techniques can be used as alternatives to daily percussion and postural drainage, also known as chest physical therapy, in patients with cystic fibrosis. Daily percussion and postural drainage need to be administered by a physical therapist or another trained adult in the home, typically a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who lead independent lifestyles. Oscillatory devices can also potentially be used by patients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and chronic obstructive pulmonary disease. In addition, they could benefit patients with neuromuscular disease who have impaired cough clearance.

REGULATORY STATUS

The following are examples of high frequency chest wall oscillation (HFCWO), and intrapulmonary percussive ventilation (IPV) devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510K approval process. FDA product codes: BYI, BYT.

Table 1. Examples of high frequency chest wall oscillation (HFCWO) and intrapulmonary percussive ventilation (IPV) devices. This list may not encompass *all* HFCWO and IPV devices.

Device	Device Type	Manufacturer	FDA number
ABI® Vest System	high frequency chest wall oscillation (HFCWO)	American Biosystems, Inc.	K993629
AffloVest	HFCWO	International Biophysics Corporation	K122480
Bird IPV®	Intrapulmonary percussive ventilation (IPV)	Percussionaire Corp.	K895485
Monarch® Airway Clearance System	HFCWO	Hill-Rom	K163378
SmartVest® SQL® System	HFCWO	Electromed, Inc.	K132794
SmartVest SV2100 System	HFCWO	Electromed, Inc.	K053248
ThAIRaphy®	HFCWO	American Biosystems, Inc.	K965192
Vest® Airway Clearance System	HFCWO	Hill-Rom	K142482, K024309

The following are examples of OPEP devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510K approval process. FDA product codes: BYI, BYT.

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Table 2. Non-exhaustive list of oscillatory positive expiratory pressure (OPEP) devices which are not reviewed by this policy.

Device	Manufacturer	FDA number
Acapella®	Smiths Medical, Inc.	K002768
Aerobika Oscillating Positive Expiratory Pressure (OPEP)	Trudell Medical	K123400
Aerobika OPEP with Manometer	Trudell Medical	K150173
Aerosure Medic	Actegy Ltd.	K140772
Flutter® Mucus Clearance Device	Axcan Scandipharm, Inc.	K946083, K940986, K972859
Lung Flute®	Medical Acoustics LLC	K091557
MetaNeb® 4 System	Hill-Rom	K151689
RC-Cornet™	PARI Respiratory Equipment	K983308
Roadrunner	DHD Healthcare	K991561
PARI PEP	PARI Respiratory Equipment, Inc.	K972042
PARI PEP S Positive Expiratory Pressure Device	PARI Respiratory Equipment, Inc.	K090829
TheraPEP®	Smiths Medical, Inc.	K944900, K962749, K983467
Vibralung Acoustical Percussor	Westmed Inc.	K133057
VibraPEP™	Curaplex	K153441

EVIDENCE SUMMARY

Evaluating the safety and effectiveness of any oscillatory device requires randomized comparisons with standard airway clearance techniques (e.g., percussion and postural drainage). These comparisons are necessary to determine whether the benefits of oscillatory devices outweigh any risks and whether they offer advantages over conventional methods with respect to increasing quality of life and decreasing long-term morbidity and mortality, or secondary outcomes such as improved mucus clearance, lung function or rate of respiratory exacerbations.

CYSTIC FIBROSIS

Systematic Review

A 2014 updated Cochrane review evaluated oscillating devices for the treatment of cystic fibrosis.[1,2] Investigators searched the literature for randomized controlled trials (RCTs) comparing oscillatory devices to another recognized airway clearance technique. A total of 35 RCTs with 1,050 patients met inclusion criteria. Fifteen studies used a parallel design and 20 were crossover studies. The majority (16 studies) were conducted in the United States. Sample sizes of individual studies ranged from 5 to 166, and half the studies included children. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and

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quality of life measures. Due to the variety of devices used, outcome measures and lengths of follow-up, a quantitative meta-analysis of multiple studies could not be performed. The authors concluded that there was a lack of evidence supporting any one airway clearance technique or device over another, and that adequately powered RCTs with long-term follow-up were needed.

Randomized Controlled Trials

Overall, RCTs are underpowered have not found clear advantages of one oscillatory device over another.[3,4] Details on studies with a minimum of one year follow-up are as follows:

McIlwaine (2013) published an RCT comparing two types of oscillatory devices.[5] This study differed from previous trials, because it had a larger sample size (n=107) and the primary outcome measure was a clinically meaningful outcome, i.e., the number of pulmonary exacerbations requiring an antibiotic. In addition, the study was conducted over a relatively long time period (one year), was a multicenter trial, and was not industry-funded, although industry did donate devices. The study included individuals over six years of age with clinically stable cystic fibrosis; age ranged from 6 to 47 years. Patients were randomized to perform either positive expiratory pressure (PEP) using a face mask (n=51) or high frequency chest wall oscillation (HFCWO) using the inCourage system (n=56) for one year. After randomization, there was a two-month washout period (without knowledge of treatment group assignment). Eight patients in each arm dropped out after randomization and before treatment, and another three patients dropped out during the intervention phase. A total of 88 of 107 (82%) randomized patients completed the study. By the end of one year, there were 49 exacerbations requiring antibiotics in the PEP group and 96 in the HFCWO group; the difference between groups was statistically significant, favoring PEP (p=0.007). The time to first pulmonary exacerbation was 220 days in the PEP group and 115 days in the HFCWO group (p=0.02). There was not a statistically significant difference in pulmonary measures, including FEV1. Limitations of this study were that patients were not blinded and there was nearly a 20% drop-out rate. The trial was stopped early without enrolling the expected number of patients and, thus, may have been underpowered to detect clinically significant differences between groups.

Sontag and colleagues conducted a multicenter randomized trial with 166 adults and children with cystic fibrosis.[6] Patients were assigned to receive treatment with P/PD (n=58), the Flutter® device (n=51), or the Vest (n=57). Investigators planned to evaluate participants on a quarterly basis for 3 years. However, dropout rates were high and consequently the trial ended early; 35 (60%), 16 (31%) and 5 (9%) patients withdrew from the postural drainage, Flutter®, and Vest groups, respectively. Fifteen patients withdrew in the first 60 days (11 of these on the day of randomization) and the remainder after 60 days. The most common reasons for withdrawal after 60 days were moved or lost to follow-up (n=13), and lack of time (n=7). At study termination, patients had a final assessment; the length of participation ranged from 1.3 to 2.8 years. An intention-to-treat (ITT) analysis found no significant differences between treatment groups in the modeled rate of decline for FEV1 predicted or forced vital capacity (FVC%) predicted. The small sample size and high dropout rate greatly limit the conclusions that might be drawn from this study.

Section Summary

A number of RCTs and a systematic review (SR) have been published. RCTs had mixed findings and limitations such as small sample sizes and large dropout rates. The SR identified

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35 RCTs comparing oscillatory devices with another recognized airway clearance techniques; some were published only as abstracts. Study findings could not be pooled due heterogeneity in design and outcome measures. The SR concluded that additional RCTs are needed that are adequately powered and have long-term follow-up.

BRONCHIECTASIS

Systematic Reviews

Lee (2015) published a Cochrane review on airway clearance techniques for treating bronchiectasis.[7] Seven RCTs comparing airway clearance techniques with sham or an alternative treatment were identified.[8-14] One hundred and five total patients were included; sample sizes ranged from 8 to 37. All studies, except one (N=37), were crossover trials. Five trials used a PEP device, one used HFCWO, and one used postural drainage. The investigators did not pool study findings due to heterogeneity among studies. Primary outcomes of interest to the Cochrane reviewers were exacerbations, hospitalizations for bronchiectasis, and quality of life (QOL). Only one trial, a crossover study with 20 patients, reported exacerbations. This trial, published by Murray (2009), did not find a statistically significant difference at 12 weeks in the number of exacerbations (there were five exacerbations with the oscillating PEP device vs seven without the oscillating PEP device; p=0.48).[10] Cough-related QOL was significantly better after 12 weeks of any airway clearance technique compared with no airway clearance. Three studies reported QOL outcomes. The Murray trial found significantly better health-related quality of life (HRQOL) with a PEP device compared with control, though a study by Svenningen did not. The third study, by Nicolini, used HFCWO and found significantly better HRQOL with the oscillatory device than with control.[11] The Cochrane reviewers noted that the studies were not blinded and that patient-reported QOL measures may have been subject to bias.

Randomized Controlled Trials

RCTs evaluating HFCWO or IPV devices for bronchiectasis were not identified.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Systematic Reviews

Systematic reviews evaluating HFCWO or IPV devices for chronic obstructive pulmonary disease were not identified.

Randomized Controlled Trials

Goktalay (2013) published a study that included 50 patients with stage 3-4 COPD who were hospitalized for COPD exacerbations.[15] Patients were randomized to receive five days of treatment with medical therapy plus HCFWO using the Vest Airway Clearance System (n=25) or medical therapy-only (n=25). At day five, outcomes, including FEV1, scores on the MMRC dyspnea scale and the six-minute walk test, did not differ significantly between groups. This was a short-term study and included hospitalized patients who may not be similar to COPD patients treated on an outpatient basis.

Chakrovorty (2011) published a randomized cross-over study evaluating use of high-frequency chest wall oscillation in patients with moderate to severe COPD and mucus hypersecretion.[16] Patients received HFCWO or conventional treatment, in random order, for four weeks, with a

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two-week wash-out period between treatments. Thirty patients enrolled in the study and 22 (73%) completed the trial; eight patients withdrew due to COPD exacerbations. The primary outcome was quality of life which was measured with the St. George's Respiratory Questionnaire (SGRQ). Only one out of four dimensions of the SGRQ (the symptom dimension) improved after HFCWO compared to before treatment, with a decrease in the mean score from 72 to 64 (p=0.02). None of the four dimensions of the SGRQ improved after conventional treatment. There were no significant differences in secondary outcomes such as FEV1 or FVC after either treatment compared to before treatment. The study was limited by small sample size, the relatively high drop-out rate, and lack of intention to treat analysis.

RESPIRATORY CONDITIONS RELATED TO NEUROMUSCULAR DISORDERS

A 2014 Cochrane review on nonpharmacologic management of respiratory morbidity in children with severe global developmental delay addressed airway clearance techniques.[17] The review included RCTs and nonrandomized comparative studies. Three studies were identified on HFCWO (one RCT, two pre-post) and one on PEP (pre-post). Sample sizes ranged from 15 and 28 patients.

The RCT, published by Yuan (2010), compared HCFWO to standard chest physical therapy in 28 patients with cerebral palsy or neuromuscular disease attending a pediatric pulmonary clinic.[18] Both groups were instructed to perform the assigned treatment for 12 minutes three times a day for the study period (mean, five months). Twenty-three (82%) of 28 patients completed the study; all five dropouts were in the HCFWO group. The authors noted that the trial was exploratory and was not powered to detect statistically significant findings on of the primary outcomes (e.g., incidence and duration of acute respiratory infection requiring inpatient or patient antibiotics, adverse effects of treatment). There were no statistically significant differences between groups on primary outcomes. For example, four patients required inpatient intravenous antibiotics in the standard physical therapy group and none in the HCFWO group (p=0.09). In addition, seven patients required oral antibiotics in the standard physical therapy group and three in the HFCWO group (p=NS). No therapy-related adverse events were reported in either group. No subsequent RCTs published after their Cochrane review was identified on oscillatory devices in children with neuromuscular diseases.

In addition to the pediatric studies included in the Cochrane review, one RCT, published by Lange (2006) was identified on HFCWO in adults with amyotrophic lateral sclerosis (ALS).[19] The trial included 46 patients with probable or definite ALS with respiratory conditions as evidenced by score on the ALS Functional Rating Scale (ALSFRS) respiratory subscale between 6 and 11 (the subscale range, 0 [complete ventilator support] to 12 [normal]). Patients were randomized to 12 weeks of HCFWO or usual care. The primary end points were measures of pulmonary function after 12 weeks. Data were available for 35 (76%) of 46 patients at 12 weeks. There were no statistically significant between-group differences in pulmonary measures (FVC predicted, capnography, oxygen saturation, or peak expiratory flow). There was also no significant difference in the ALSFRS respiratory subscale score (worsening) at 12 weeks. Of symptoms assessed as secondary outcomes, there was significantly less breathlessness and night cough in the HCFWO group than in the usual care group, and groups did not differ significantly on other symptoms, including noise of breathing, suction frequency, suction amount, day cough, and nocturnal symptoms.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF CHEST PHYSICIANS

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The 2006 guidelines from the American College of Chest Physicians (ACCP) recommended (level of evidence; low) that in patients with cystic fibrosis, devices designed to oscillate gas in the airway, either directly or by compressing the chest wall, can be considered as an alternative to chest physiotherapy.[20]

CYSTIC FIBROSIS FOUNDATION

In April 2009, the Cystic Fibrosis Foundation (CFF) published guidelines on airway clearance therapies based on a SR of evidence.[21] They recommend airway clearance therapies for all patients with cystic fibrosis but state that no therapy has been demonstrated to be superior to others (level of evidence, fair; net benefit, moderate; grade of recommendation, B). They also issued a consensus recommendation that the prescribing of airway clearance therapies should be individualized based on factors such as age and patient preference.

SUMMARY

HIGH-FREQUENCY CHEST WALL OSCILLATION DEVICES (HFCWO) AND INTRAPULMONARY PERCUSSIVE VENTILATION (IPV) DEVICES

There is enough research to show that high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices improve health outcomes for people with cystic fibrosis or chronic diffuse bronchiectasis. Therefore, HFCWO and IPV may be considered medically necessary when the policy criteria are met.

There is not enough research to show that high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices are a medically necessary alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis, in any other clinical situations. Therefore, HFCWO and IPV are considered not medically necessary as an alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis when the policy criteria are not met.

There is not enough research to show that high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices improve health outcomes as an adjunct to chest physical therapy or for people with chronic obstructive pulmonary disease (COPD) and respiratory conditions associated with neuromuscular disorders. Therefore, the use of HCWO and IPV devices as an adjunct to chest physical therapy or for patients with chronic obstructive pulmonary disease (COPD) and respiratory conditions associated with neuromuscular disorders is considered investigational.

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CODES

NOTES:

- Devices have codes specific to their technology, e.g., IPV is reported by E0481.
- Oscillatory positive expiratory pressure (OPEP) are not reviewed by this policy and may be considered medically necessary. They are reported by E0484 and S8185.

Codes	Number	Description
CPT	None	
HCPCS	A7025	High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each
	A7026	High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each
	E0481	Intrapulmonary percussive ventilation system and related accessories
	E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

Date of Origin: *May 2011*

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Programmable Pneumatic Compression Pumps

Effective: June 1, 2019

Next Review: April 2020
Last Review: April 2019

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Compression pumps may be used to reduce swelling, help circulation, and prevent blood clot formation in immobilized patients.

MEDICAL POLICY CRITERIA

Note: This policy addresses only single- or multi-chamber programmable pumps described by HCPCS code E0652. This policy does *not* address single- or multi-chamber non-programmable pumps, which are considered a standard of care for the treatment of lymphedema, prevention of venous thromboembolism in high risk patients, and chronic venous insufficiency.

I. Single- or multi-chamber programmable pneumatic compression (lymphedema) pumps applied to the limb (HCPCS code E0652) may be considered **medically necessary** for the treatment of lymphedema when any of the following are met:

   A. Lack of adequate clinical response after use of a single- or multi-chamber non-programmable pneumatic compression pump; or

   B. There is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression with single- or multi-chamber non-

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programmable pneumatic compression pumps, including but not limited to significant scarring, fibrosis, or anatomic variations.

II. Single- or multi-chamber programmable pneumatic compression pumps are considered **not medically necessary** when criterion I is not met.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of unique characteristics that prevent satisfactory pneumatic compression with single- or multi-chamber non-programmable lymphedema pumps or documentation of a lack of adequate clinical response of a non-programmable pump.

CROSS REFERENCES

None

BACKGROUND

Multi-chamber programmable pneumatic compression pumps may be used to lessen the accumulation of fluids in the arms, legs or trunk, to treat chronic venous insufficiency, or to prevent blood clot formation in immobile patients. Similar in action to the way a blood pressure cuff inflates and deflates, these devices provide air compression to segmented sleeves that are wrapped around the limbs or trunk. These multi-chambered sleeves can be individually adjusted to allow different pressures (gradient pressure) in each segment.

EVIDENCE SUMMARY

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as selection bias (e.g., noncomparability of treatment groups) and observation bias (e.g., the placebo effect).

SYSTEMATIC REVIEWS

Ezzo (2015) published a systematic review (SR) that included six randomized or quasi-randomized trials that were divided into three categories based on similar design.[1] Only one study[2] included compression therapy using pneumatic pumps. This quasi-randomized, controlled trial (RCT) compared compression sleeve plus manual lymphedema drainage (MLD) to compression sleeve plus intermittent pneumatic pump in 24 women with post-mastectomy

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arm lymphedema. Both groups reported a statistically significant improvement in sensations of heaviness compared to baseline. Volume reduction was statistically better in the MLD group than in the pneumatic pump group, though no significant difference was found for percent reduction, strength, or range of motion. Adverse effects were not reported. The limitations of the included study were the lack of assessor blinding, the small patient population, and the short-term follow-up period of four weeks. In addition, this study was published in 1998 and may not reflect the outcomes from newer technologies.

RANDOMIZED CONTROLLED TRIALS

No high quality RCTs were identified that compared the effectiveness of multi-chamber programmable pneumatic compression pumps with either single compartment or multi-chamber non-programmable pneumatic compression pumps.

NON-RANDOMIZED COMPARATIVE STUDIES

Data on the effectiveness of pneumatic compression devices is limited. The evidence consists primarily of small non-randomized studies for a variety of single and multi-chamber pumps.[3-5] Evidence from these studies does not permit conclusion about the effectiveness and safety of these pumps due to methodological limitations including but not limited to the following:

- Non-random allocation of treatment which may introduce selection or response bias.
- Lack of blinding may bias treatment effect estimates.
- Lack of appropriate comparison groups which does not permit conclusions on the efficacy of multi-chamber programmable pumps compared to other available pumps.
- Variable pump protocols limit effective analysis across studies because it is difficult to determine whether a treatment effect is related to the pump type or protocol used.
- Small study populations which limit the ability to rule out the role of chance as an explanation of findings.
- Variable patient baseline characteristics such as severity of conditions (e.g., lymphedema) which may bias treatment effect estimates.

ADVERSE EVENTS

Concerns about damage to remaining intact lymphatics caused by too high pump pressures have been reported; however, these concerns are not well quantified in the literature.

PRACTICE GUIDELINE SUMMARY

SOCIETY FOR VASCULAR SURGERY AND AMERICAN VENOUS FORUM

The Society for Vascular Surgery and the American Venous Forum performed a systematic review and published a 2014 guideline on the management of venous ulcers. The guideline included the following statement on pneumatic compression: “We suggest use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy.[6] The recommendation is based on Grade - 2; Level of Evidence - C (Very weak recommendations; Other alternatives may be reasonable).

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SUMMARY

It appears that single- or multi- chamber programmable pneumatic compression pumps may improve health outcomes for some people with lymphedema. Clinical guidelines based on research recommend the use of single- or multi-chamber programmable pneumatic compression pumps in certain situations. Therefore, single- or multi-chamber programmable pneumatic compression pumps may be considered medically necessary to treat lymphedema when policy criteria are met.

There is not enough research to show that single- or multi-chamber programmable pneumatic compression pumps improve health outcomes in patients with lymphedema when policy criteria are not met. Therefore, single- or multi-chamber programmable pneumatic compression pumps are considered not medically necessary when policy criteria are not met.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
	E0671	Segmental gradient pressure pneumatic appliance, full leg

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Codes	Number	Description
	E0672	Segmental gradient pressure pneumatic appliance, full arm
	E0673	Segmental gradient pressure pneumatic appliance, half leg

Date of Origin: *November 2009*

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