

Uniform Medical Plan coverage limits

Updates effective 10/1/2020

The benefit coverage limits listed below apply to these UMP plans:

- Uniform Medical Plan (UMP) Classic (PEBB)
- UMP Consumer-Directed Health Plan (UMP CDHP) (PEBB)
- UMP Plus–Puget Sound High Value Network (UMP Plus–PSHVN) (PEBB)
- UMP Plus–UW Medicine Accountable Care Network (UMP Plus–UW Medicine ACN) (PEBB)

- UMP Achieve 1 (SEBB)
- UMP Achieve 2 (SEBB)
- UMP High Deductible Plan (SEBB)
- UMP Plus–Puget Sound High Value Network (UMP Plus–PSHVN) (SEBB)
- UMP Plus–UW Medicine Accountable Care Network (UMP Plus–UW Medicine ACN) (SEBB)

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](#).**

Uniform Medical Plan Pre-authorization List

The Uniform Medical Plan (UMP) Pre-authorization List includes services and supplies that require pre-authorization or notification for UMP members.

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	<ul style="list-style-type: none"> 20974, 20975, 20979, E0747, E0748, E0749, E0760
Continuous Glucose Monitoring	HTCC decision	<ul style="list-style-type: none"> A9277, A9278, K0554, S1030, S1031
Implantable Drug Delivery System	HTCC decision	<ul style="list-style-type: none"> C1772, C1889, C1891, C2626, E0782, E0783, E0785, E0786 Effective September 1, 2020: 62350, 62351, 62360, 62361, and 62362 will require pre-authorization from Regence. Codes are subject to HTCC Decision and coverage criteria.
Insulin Infusion Pumps, Automated Insulin Delivery and Artificial Pancreas Device Systems	Regence Medical Policy DME77	<ul style="list-style-type: none"> E0784, E0787, S1034
Microprocessor-Controlled Lower Limb Prosthetics	HTCC decision	<ul style="list-style-type: none"> L5856, L5857, L5858 <p>Use Regence Medical Policy DME81 in addition to the HTCC to review requests regarding "functional level 2" and "experienced user exceptions".</p>
Myoelectric Prosthetic and Orthotic Components for the Upper Limb	Regence Medical Policy DME80	<ul style="list-style-type: none"> L6026, L6693, L6715, L6880, L6881, L6882, L6925, L6935, L6945, L6955, L6965, L6975, L7007, L7008, L7009, L7045, L7180, L7181, L7190, L7191
Noninvasive Ventilators in the Home Setting	Regence Medical Policy DME87	<ul style="list-style-type: none"> E0466 Note: Due to the COVID-19 pandemic, pre-authorization

		requirements for noninvasive ventilators will be suspended until August 1, 2020
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions	Regence Medical Policy DME45	<ul style="list-style-type: none"> E0481, E0483
Power Wheelchairs: Group 3	Regence Medical Policy DME37	<ul style="list-style-type: none"> K0848, K0849, K0850, K0851, K0852, K0853, K0854, K0855, K0856, K0857, K0858, K0859, K0860, K0861, K0862, K0863, K0864
Stents, Drug Coated or Drug-Eluting (DES)	HTCC decision	Refer to Cardiac Stenting in the Surgery section.

Power Wheelchairs: Group 3

Effective: October 1, 2020

Next Review: July 2021

Last Review: August 2020

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

Power wheelchairs are battery powered mobility devices with integrated or modular seating system, electronic steering and four or more wheel non-highway construction.

MEDICAL POLICY CRITERIA

Note: This policy only addresses Group 3 power wheelchairs (HCPCS codes K0848-K0864).

- I. Group 3 power wheelchairs may be considered **medically necessary** when both of the following Criteria (A. and B.) are met:
 - A. All of the following general Criteria (1. – 12.) are met:
 1. The patient has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a PT or OT, or practitioner who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features; and
 2. The patient has a mobility limitation that significantly impairs their ability to participate in one or more mobility-related activities of daily living (MRADLs)

such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. A mobility limitation is one that:

- a. Prevents the member from accomplishing a MRADL entirely, or
 - b. Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform a MRADL, or
 - c. Prevents the member from completing MRADLs within a reasonable time frame.
3. Use of a power wheelchair will significantly improve the patient's ability to participate in MRADLs and the patient will use it in the home. For patients with severe cognitive and/or physical impairments, participation in MRADLs may require the assistance of a caregiver; and
 4. The patient does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform MRADLs during a typical day. Notes: Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function; and
 5. The underlying condition is not reversible and the length of need is more than 3 months; and
 6. The patient's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker; and
 7. The patient is not a candidate for a power operated vehicle; and
 8. The patient has the mental (e.g., cognition, judgment) and physical (e.g., vision) capabilities to safely operate the power wheelchair that is provided, in the home setting; or if the patient is unable to safely operate the power wheelchair, the patient has a caregiver who is unable to adequately propel an optimally configured manual wheelchair, but is available, willing, and able to safely operate the power wheelchair that is provided; and
 9. The patient's weight is less than or equal to the weight capacity of the PWC that is provided and greater than or equal to 95% of the weight capacity of the next lower weight class, i.e., a Heavy Duty PWC is covered for a patient weighing 285 – 450 pounds; a Very Heavy Duty PWC is covered for a patient weighing 428 – 600 pounds; an Extra Heavy Duty PWC is covered for a patient weighing 570 pounds or more; and
 10. The patient's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the power wheelchair that is provided; and
 11. The patient has not expressed an unwillingness to use a power wheelchair in the home; and
 12. Any coverage criteria pertaining to the specific wheelchair type (see below) are met.
- B. Any of the following Group 3 power wheelchairs may be considered **medically necessary** when all of Criteria A. above are met:

1. A Group 3 PWC with no power options (K0848-K0855) when the patient's mobility limitation is due to a neurological condition, myopathy, or congenital skeletal deformity.
 2. A Group 3 PWC with single power option (K0856-K0860) or multiple power option (K0861-K0864) when **both** of the following (a. and b.) are met:
 - a. The patient's mobility limitation is due to a neurological condition, myopathy, or congenital skeletal deformity; and
 - b. Any one of the following are met:
 - i. The patient requires a drive control interface other than a hand or chin-operated standard proportional joystick (examples include but are not limited to head control, sip and puff, switch control); or
 - ii. The patient uses a ventilator which is mounted on the wheelchair; or
 - iii. The patient has a power tilt or a power recline seating system and the system is being used on the wheelchair and one of the following are met:
 - a.) The patient is at high risk for development of a pressure ulcer and is unable to perform a functional weight shift; or
 - b.) The patient utilizes intermittent catheterization for bladder management and is unable to independently transfer from the wheelchair to bed; or
 - c.) The power seating system is needed to manage increased tone or spasticity.
- II. Group 3 power wheelchairs are considered **not medically necessary** when the above criteria are not met, including but not limited to the following:
- A. The patient is capable of ambulation within the home but requires a wheelchair for movement outside the home; or
 - B. The primary benefit of the wheelchair is to allow the patient to perform leisure or recreational activities; or
 - C. The patient has been approved for a power operated vehicle (POV); or
 - D. The accessory is used for the convenience of the patient or caregiver and is not necessary for performance of mobility related activities of daily living (MRADLs); or
 - E. The underlying condition is reversible and the length of need is less than 3 months (e.g., following lower extremity surgery which limits ambulation).

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

POLICY GUIDELINES

APPROPRIATE POPULATIONS

Group 3 power wheelchairs are reserved for the severely impaired patient afflicted with diseases such as: Amyotrophic Lateral Sclerosis (ALS), spinal cord injuries resulting in quadriplegia, stroke (CVA) with hemiplegia, late stage Parkinson's, late stage Multiple Sclerosis (MS), cerebral palsy, or Muscular Dystrophy.^[1]

A group 3 power wheelchair would not be appropriate for a beneficiary who has diabetes with peripheral neuropathy. Peripheral neuropathy affects the nerves. It is not a primary neurological condition but rather a symptom of another disease. The Power Mobility Device LCD specifically states that the patient must have a neurological condition; therefore, the beneficiary with peripheral neuropathy does not meet coverage criteria for a group 3 power wheelchair.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- Medical records and chart notes pertinent to the PWC request, including history of the present condition(s) and past medical history relevant to mobility needs. Required information includes:
 - Date of face-to-face examination by the treating practitioner, with signed and dated documentation;
 - Elements of the face-to-face should include:
 - Mobility limitation and how it interferes with the performance of ADLs (the physical examination should focus on body systems responsible for ambulatory difficulty or impact on ambulatory ability);
 - Explanation of why a cane, walker, manual wheelchair, or POV (scooter) is unable to meet the mobility needs in the home; and,
 - If the member has the physical and mental abilities to operate a power wheelchair safely in the home.
 - The underlying condition, and whether or not it is reversible.
 - Ambulation-limiting symptoms and the diagnoses responsible for them;
 - Medications or other treatment for these symptoms;
 - Progression of ambulation difficulty over time;
 - Other diagnoses that may relate to ambulatory problems;
 - How far the beneficiary can walk without stopping and the pace of ambulation;
 - What ambulatory assistance (e.g., cane, walker, wheelchair, caregiver) currently used. If the prior mobility device is not a POV, provide details regarding the physical and functional changes that now require the use of a power mobility device;
 - Ability to stand up from a seated position without assistance; and,
 - Description of the home setting and the ability to perform activities of daily living in the home.
 - Length of need
- Physical examination relevant to mobility needs;

- Weight and height;
- Cardiopulmonary examination;
- Musculoskeletal examination (i.e., arm and leg strength and range of motion);
- Neurological examination (i.e., gait, balance and coordination); and,
- Clearly distinguish the beneficiary's abilities and needs within the home from any additional needs for use outside the home.

CROSS REFERENCES

None

BACKGROUND

Wheelchairs can be described in HCPCS coding with one code for the wheelchair base and then additional codes for wheelchair options and accessories. The decision for a particular wheelchair base may be influenced by the chair's intended use, the patient's size or level of disability, or based on specific features that will be incorporated into the chair (for example, a heavy-duty base with additional electronics features may be needed to support a power tilt and/or recline option.)

The following is a list of wheelchair bases and their characteristics:

POWER WHEELCHAIRS (PWCS)

Power wheelchairs are battery powered mobility devices with integrated or modular seating system, electronic steering and four or more wheel non-highway construction. PWCs are divided into six performance-based groups as listed in Table 1.^[2] This policy only addresses Group 3 PWCS:

Table 1. Power Wheelchairs: Six Performance-based Groups

CHAIR/ HCPCS	GROUP 1 K0813-16	GROUP 2 K0820-K0843	GROUP 3 K0848-K0864	GROUP 4 K0868-K0886	GROUP 5 K0890-K0891	GROUP 6 K0898-99
Length	40 inches	48 inches	48 inches	48 inches	48 inches	NA
Width	≤24 inches	≤34 inches	≤34 inches	≤34 inches	≤34 inches	NA
Obstacle Height	20 mm	40 mm	60 mm	75 mm	60 mm	NA
Minimum Top End Speed-Flat	3 MPH	3 MPH	4.5 MPH	6 MPH	4 MPH	NA
Range	5 miles	7 miles	12 miles	16 miles	12 miles	NA
Obstacle height or obstacle climb denotes the vertical height of a solid obstruction that can be climbed.						
Minimum top end speed denotes the minimum speed on a flat hard surface that is acceptable for a given category of devices.						
Range denotes the minimum distance acceptable for a given category of devices on a single charge of the batteries.						
The above six PWC groups are subdivided based on patient weight capacity, seat type, portability and/or power seating system capability.						

There are four weight capacity groups. Those listed in Table 2. represent patient weight handling capacity and are not intended to reflect performance.

Table 2. Weight Capacity Groups

Standard Duty	Heavy Duty	Very Heavy Duty	Extra Heavy Duty
Up to and including 300 pounds	301-450 pounds	451-600 pounds	601 pounds or more

Table 3. Seat Types

Sling Seat/Back-Flexible	Solid Seat/ Back-Rigid	Captains Chair	Stadium Style Seat
Cloth, vinyl, leather or equal material designed to serve as the support for buttocks or back. They may or may not have thin padding but are not intended to provide cushioning or positioning for the user.	Metal or plastic material usually covered with cloth, vinyl, leather or equal material, with or without some padding material designed to serve as the support for the buttocks or back. They may or may not have thin padding but are not intended to provide cushioning or positioning for the user. PWCs with an automotive-style back and a solid seat pan are considered as a solid seat/back system, not a Captains Chair.	A one or two-piece automotive-style seat with rigid frame, cushioning material in both seat and back sections, covered in cloth, vinyl, leather or equal as upholstery, and designed to serve as a complete seating, support, and cushioning system for the user. It may have armrests that can be fixed, swingaway, or detachable. It may or may not have a headrest, either integrated or separate.	A one or two piece stadium-style seat with rigid frame and cushioning material in both seat and back sections, covered in cloth, vinyl, leather or equal as upholstery, and designed to serve as a complete seating, support, and cushioning system for the user. It may have armrests that can be fixed, swingaway, or detachable. It does not have a headrest. Chairs with stadium style seats are billed using the Captains Chair HCPCS codes.

Portable denotes a PWC that is built of lightweight construction or can be disassembled into lightweight components that allow easy placement into a vehicle for use in a distant location.

Power options that may be added to a PWC to include power tilt, recline, elevating legrests, seat elevators or standing systems. There are three categories of PWCs based on the capability to accept and operate these power options:

- No-power-options PWCs are incapable of accommodating any power options
- Single power option PWCs have the capability to accept and operate only one power accessory at a time on the base.
- Multiple power option PWCs have the capability to accept and operate more than one power accessory at a time on the base.

Pediatric PWCs are uniquely sized for use with very small individuals and have the capability for extensive growth through frame adjustments (not just seating) and special features to address developmental issues (e.g., seat to floor placement, standing capability).

Each power wheelchair base code is intended to include all of the following Basic Equipment Package items on initial issue:

- Lap belt or safety belt (E0978)
- Battery charger single mode (E2366)
- Complete set of tires and casters, any type

- Legrests: Fixed, swingaway, or detachable nonelevating leg rests with or without calf pad (E0995)
- Footrests: Fixed, swingaway, or detachable nonelevating foot rests/plates or foot platform without angle adjustment for any PWC or angle adjustable footplates with Group 1 or 2 PWCs (K0037, K0040, K0041, K0042, K0043, K0044, K0045, K0052)
- Fixed, swingaway, or detachable nonadjustable height armrests (E0994, K0015, K0019) with arm pad (K0019)
- Upholstery for seat and back of proper strength and type for patient weight capacity of the power wheelchair (E0981, E0982)
- Weight specific components per patient weight capacity
- Any seat width and depth or back width except for Group 3 or 4 PWCs with a sling/solid seat/back
- Controller and Input Device.

SUMMARY

Group 3 power wheelchairs may improve overall health outcomes for some people with mobility limitations. According to the U.S. Centers for Medicare & Medicaid Services, Group 3 power wheelchairs are considered reasonable and medically necessary for specific populations when certain situations exist. Therefore, Group 3 power wheelchairs may be considered medically necessary when policy criteria are met. In all other situations, Group 3 power wheelchair use does not change management and does not improve health outcomes. Therefore, Group 3 power wheelchairs are not medically necessary when policy criteria are not met.

REFERENCES

1. Noridian Healthcare Solutions. Group 3 Power Wheelchair Requirements. Last updated Jun 19, 2019. [cited 8/19/2020]; Available from: <https://med.noridianmedicare.com/web/jddme/dmepos/pmds/group-3-power-wheelchair-requirements>
2. U.S. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA): Power Mobility Devices - Policy Article (A52498). Revision Effective Date 01/01/2020. [cited 08/19/2020]; Available from: <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52498&ver=40&LCDId=33789&Date=&DocID=L33789&bc=iAAAABAAQAAA&>
3. U.S. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Power Mobility Devices (L33789) For services performed on or after 01/01/2020 [cited 08/19/2020]; Available from: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33789&ver=31&Date=&DocID=L33789&bc=iAAAABAAqAAA&>

CODES

NOTE: This policy only addresses Group 3 PWC (HCPCS codes K0848-K0864).

Codes	Number	Description
CPT	None	
HCPCS	K0848	Power wheelchair, group 3 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
	K0849	Power wheelchair, group 3 standard, captains chair, patient weight capacity up to and including 300 pounds
	K0850	Power wheelchair, group 3 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
	K0851	Power wheelchair, group 3 heavy duty, captains chair, patient weight capacity 301 to 450 pounds
	K0852	Power wheelchair, group 3 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
	K0853	Power wheelchair, group 3 very heavy duty, captains chair, patient weight capacity 451 to 600 pounds
	K0854	Power wheelchair, group 3 extra heavy duty, sling/solid seat/back, patient weight capacity 601 pounds or more
	K0855	Power wheelchair, group 3 extra heavy duty, captains chair, patient weight capacity 601 pounds or more
	K0856	Power wheelchair, group 3 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
	K0857	Power wheelchair, group 3 standard, single power option, captains chair, patient weight capacity up to and including 300 pounds
	K0858	Power wheelchair, group 3 heavy duty, single power option, sling/solid seat/back, patient weight 301 to 450 pounds
	K0859	Power wheelchair, group 3 heavy duty, single power option, captains chair, patient weight capacity 301 to 450 pounds
	K0860	Power wheelchair, group 3 very heavy duty, single power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
	K0861	Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
	K0862	Power wheelchair, group 3 heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
	K0863	Power wheelchair, group 3 very heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
	K0864	Power wheelchair, group 3 extra heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 601 pounds or more

Date of Origin: July 2019

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

Effective: September 1, 2020

Next Review: June 2021

Last Review: July 2020

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

Note: 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 oscillatory positive expiratory pressure (OPEP) devices may be considered **medically necessary**.
- II. 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:
 - 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.
- III. 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.
- IV. 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
- 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.

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.

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

Device	Manufacturer	FDA number
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

This evidence review is focused on HFCWO and IPV devices. 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 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:

Mcllwaine (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 have been published. RCTs had mixed findings and limitations such as small sample sizes and large dropout rates. The systematic review identified 35 RCTs comparing oscillatory devices with another recognized airway clearance techniques; some were published only as abstracts. Study findings could not be pooled due to heterogeneity in design and outcome measures. The systematic review 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 Svenning (2013)^[13] 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

Additional 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 HFCWO 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 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 HFCWO 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 HFCWO 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 HFCWO group ($p=0.09$). In addition, seven patients required oral antibiotics in the standard physical therapy group and three in the HFCWO group. 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 (ALSFERS) respiratory subscale between 6 and 11 (the subscale range, 0 [complete ventilator support] to 12 [normal]). Patients were randomized to 12 weeks of HFCWO 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 ALSFERS respiratory subscale score (worsening) at 12 weeks. Of symptoms assessed as secondary outcomes, there was significantly less breathlessness and night cough in the HFCWO 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

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 systematic review of the 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

OSCILLATORY POSITIVE EXPIRATORY PRESSURE (OPEP)

There is enough research to show that oscillatory positive expiratory pressure (OPEP) devices improve health outcomes. Clinical practice guidelines based on research recommend the use of OPEP devices. Therefore, oscillatory positive expiratory pressure devices may be considered medically necessary.

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 HFCWO 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 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
	E0484	Oscillatory positive expiratory pressure device, nonelectric, any type, each
	S8185	Flutter device

Date of Origin: May 2011

Insulin Infusion Pumps, Automated Insulin Delivery and Artificial Pancreas Device Systems

Effective: April 1, 2020

Next Review: October 2020

Last Review: February 2020

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

An external insulin infusion pump is typically used to deliver insulin into patients with diabetes mellitus. Automated insulin delivery systems (including but not limited to artificial pancreas devices) monitor glucose levels and automatically adjust the delivery of insulin to help achieve tight glucose control.

MEDICAL POLICY CRITERIA

Note: This policy is does not address stand-alone continuous glucose monitors (CGM) which may be considered medically necessary.

- I. An *automated insulin delivery system* (including artificial pancreas devices) may be considered **medically necessary** for diabetes mellitus when either of the following criteria are met:
 - A. The patient has type 1 diabetes mellitus and all of the following criteria (1. – 3.) are met:

1. The device is approved by the Food and Drug Administration (FDA) and the patient meets the FDA approved age requirements for the device (see Policy Guidelines); and
 2. Glycated hemoglobin level (Hemoglobin A1c or HbA1c) between 5.8% and 10.0%; and
 3. Used insulin pump therapy for more than 6 months.
- B. Patient has gestational diabetes or preconception/pregnancy related suboptimal glycemic control (e.g., erratic blood sugars, ketoacidosis, or symptomatic hypoglycemia).
- II. An *external insulin infusion pump* may be considered **medically necessary** for diabetes mellitus when either of the following criteria are met:
- A. Patients with type 1 or 2 diabetes mellitus when all of the following criteria (1. and 2.) are met:
1. The patient has been performing insulin injections every day with self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump and either of the following are met:
 - a. A healthcare provider documents that the patient has a frequency of glucose self-testing an average of at least 3 times per day during the 2 months prior to initiation of the insulin pump; or
 - b. A healthcare provider documents the use of a continuous glucose monitor.
 2. The patient meets one or more of the following criteria:
 - a. Glycated hemoglobin level (HbA1c) greater than 7%; or
 - b. History of recurring hypoglycemia; or
 - c. Wide fluctuations in blood glucose before mealtime; or
 - d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
 - e. History of severe glycemic excursions.
- B. Patients has gestational diabetes or preconception/pregnancy related suboptimal glycemic control (e.g., erratic blood sugars, ketoacidosis, or symptomatic hypoglycemia).
- III. A replacement for all or part of the *external insulin pump* or FDA-approved *automated insulin delivery system* (including artificial pancreas device systems) may be considered **medically necessary** when both of the following criteria (A. and B.) are met:
- A. The pump is no longer able to perform its basic function due to one or more of the following:
1. Device is out of the warranty period; or
 2. Damage or wear; or

3. The device can no longer meet the patient's medical needs due to a significant change in the patient's medical condition (e.g., larger insulin reservoir needed).
 - B. The current device cannot be repaired or adapted adequately to meet the patient's medical needs.
- IV. The use of an *external insulin infusion pump* is considered **not medically necessary** when Criterion II. is not met.
- V. A replacement for all or part of the *external insulin pump* or FDA-approved *automated insulin delivery system* (including artificial pancreas device systems) that does not meet Criterion III. is considered **not medically necessary**.
- VI. The use of an *automated insulin delivery system* (including artificial pancreas device systems) is considered **investigational** when Criterion I. is not met including but not limited to a device that is not approved by the FDA.

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

POLICY GUIDELINES

FDA-Approved Automated Insulin Delivery Systems (Artificial Pancreas Device Systems)

Device	Age Indication	Manufacturer
MiniMed™ 530G System ^a (open-loop, LGS)	≥16 years	Medtronic
MiniMed™ 630G System with SmartGuard™ ^b (open-loop, LGS):		Medtronic
○ MiniMed™ 630G with Guardian™ Sensor 3	≥14 years	
○ MiniMed™ 630G with Enlite™ Sensor	≥16 years	
MiniMed™ 670G System ^c (hybrid closed-loop, LGS or PLGM)	≥7 years	Medtronic

^a MiniMed 530G System consists of the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump, Enlite™ Sensor, Enlite™ Sertter, the MiniLink Real-Time System, the Bayer Contour NextLink glucose meter, CareLink® Professional Therapy Management Software for Diabetes, and CareLink® Personal Therapy Management Software for Diabetes (at time of approval).

^b MiniMed 630G System with SmartGuard™ consists of the following devices: MiniMed 630G Insulin Pump, Enlite® Sensor, One-Press Sertter, Guardian® Link Transmitter System, CareLink® USB, Bayer's CONTOUR® NEXT LINK 2.4 Wireless Meter, and Bayer's CONTOUR® NEXT Test Strips (at time of approval).

^c MiniMed 670G System consists of the following devices: MiniMed 670G Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Sertter, and the Contour NEXT Link 2.4 Glucose Meter (at time of approval).

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- Automated insulin delivery system (artificial pancreas device system)
 - History and physical

- Age of patient
- Name and type of device requested
- Documented use of insulin pump for more than 6 months
- When applicable, documentation of gestational diabetes or preconception/pregnancy related suboptimal glycemic control (e.g., erratic blood sugars, ketoacidosis, or symptomatic hypoglycemia)
- External insulin infusion pumps
 - History and physical
 - Name and type of device requested
 - Medical record documentation stating both of the following:
 - The patient has been performing insulin injections every day with self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump; and
 - There is documented frequency of glucose self-testing an average of at least 3 times per day during the 2 months prior to initiation of the insulin pump OR a healthcare provider documents the use of a continuous glucose monitor with documentation of one or more of the following: glycated hemoglobin level (HbA1c) greater than 7%; history of recurring hypoglycemia; wide fluctuations in blood glucose before mealtime; dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; and/or history of severe glycemic excursions
 - When applicable, documentation of gestational diabetes or preconception/pregnancy related suboptimal glycemic control (e.g., erratic blood sugars, ketoacidosis, or symptomatic hypoglycemia)
- Replacement and upgrades
 - History and physical
 - Name and type of device requested
 - Documentation of specifically why pump is no longer able to perform its basic function
 - Documentation that the current device cannot be repaired or adapted adequately to meet the patient's needs

CROSS REFERENCES

[Medication Policy Manual](#), Note: Do a find (Ctrl+F) and enter name in the find bar to locate the appropriate policy.

BACKGROUND

Maintenance of a target blood glucose and target glycated hemoglobin (HbA1c < 7%), a marker which is used as a proxy for average blood glucose, is now considered standard of care for diabetic patients. Also known as tight diabetic control, this strategy is intended to prevent severe hypoglycemic events and lower the risk of cardiovascular disease mortality

associated with uncontrolled glycemia.^[1] In order to achieve tight glucose control, several devices may be used individually or in combination which includes but is not limited to continuous glucose monitors, insulin pumps, and more recently artificial pancreas device systems. The Food and Drug Administration (FDA) describes the basic design of an artificial pancreas device system (APDS) as a CGM linked to an insulin pump with the capability to automatically stop, reduce, or increase insulin infusion based on specified thresholds of measured interstitial glucose. The APDS components are designed to communicate with each other to automate the process of maintaining blood glucose concentrations at or near a specified range or target and to minimize the incidence and severity of hypoglycemic and hyperglycemic events. An APDS control algorithm is embedded in software in an external processor or controller that receives information from the CGM and performs a series of mathematical calculations. Based on these calculations, the controller sends dosing instructions to the infusion pump.

Different APDS types are currently available for clinical use. Sensor augmented pump therapy (SAPT) with low glucose suspend (LGS) (suspend on low) may reduce the likelihood or severity of a hypoglycemic event by suspending insulin delivery temporarily when the sensor value reaches (reactive) a predetermined lower threshold of measured interstitial glucose. Low glucose suspension (LGS) automatically suspends basal insulin delivery for up to two hours in response to sensor-detected hypoglycemia.

A sensor augmented pump therapy with predictive low glucose management (PLGM) (suspend before low) suspends basal insulin infusion with the prediction of hypoglycemia. Basal insulin infusion is suspended when sensor glucose is at or within 70 mg/dL above the patient-set low limit and is predicted to be 20 mg/dL above this low limit in 30 minutes. In the absence of a patient response, the insulin infusion resumes after a maximum suspend period of two hours. In certain circumstances, auto-resumption parameters may be used.

When a sensor value is above or predicted to remain above the threshold, the infusion pump will not take any action based on CGM readings. Patients using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give premeal bolus insulin to control their glucose levels.

A control-to-range system reduces the likelihood or severity of a hypoglycemic or hyperglycemic event by adjusting insulin dosing only if a person's glucose levels reach or approach predetermined higher and lower thresholds. When a patient's glucose concentration is within the specified range, the infusion pump will not take any action based upon CGM readings. Patients using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give premeal bolus insulin to control their glucose levels.

A control-to-target system sets target glucose levels and always tries to maintain these levels. This system is fully automated and requires no interaction from the user (except for calibration of the CGM). There are two subtypes of control-to-target systems: insulin-only and bihormonal (e.g., glucagon). There are no systems administering glucagon marketed in the United States.

An APDS may also be referred to as a "closed-loop" system. A closed-loop system has automated insulin delivery and continuous glucose sensing and insulin delivery without patient intervention. The systems utilize a control algorithm that autonomously and continually increases and decreases the subcutaneous insulin delivery based on real-time sensor glucose levels. There are no completely closed-loop insulin delivery systems marketed in the United

States.

A hybrid closed-loop system also uses automated insulin delivery with continuous basal insulin delivery adjustments. However, at mealtime, the patient enters the number of carbohydrates they are eating for the insulin pump to determine the bolus meal dose of insulin. A hybrid system option with the patient administration of a premeal or partial premeal insulin bolus can be used in either control-to-range or control-to-target systems.

REGULATORY STATUS

There are several APDS devices approved by the Food and Drug Administration (FDA). These systems are regulated by the FDA as class III device systems.

The MiniMed® 530G System includes a threshold suspend or LGS feature.^[2] The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is at or below a preset threshold within the 60- to 90-mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If patients respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If patients fail to respond, the pump automatically suspends action for two hours, and then insulin therapy resumes.

The MiniMed® 630G System with SmartGuard™, which is similar to the 530G, includes updates to the system components including waterproofing.^[3] The threshold suspend feature can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value. The MiniMed 630G System with SmartGuard™ is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the values provided by the MiniMed 630G system. The device is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard™ Suspend on Low alarm to take measures to prevent or treat hypoglycemia themselves.

The MiniMed® 670G System is a hybrid closed-loop insulin delivery system consisting of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm and the SmartGuard Hybrid Closed Loop.^[4] The system includes an LGS feature that suspends insulin delivery; this feature either suspends delivery on low-glucose levels or suspends delivery before low-glucose levels, and has an optional alarm (manual mode). Additionally, the system allows semiautomatic basal insulin-level adjustment (decrease or increase) to preset targets (automatic mode). As a hybrid system; basal insulin levels are automatically adjusted, but the patient needs to administer premeal insulin boluses. The CGM component of the MiniMed 670G System is not intended to be used directly for making manual insulin therapy adjustments; rather it is to provide an indication of when a glucose measurement should be taken.

On June 21, 2018, the FDA approved the t:slim X2 Insulin Pump with Basal-IQ Technology (PMA P180008) for individuals who are six years of age and older. The System consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile CGM (Continuous Glucose Monitor), as well as the Basal-IQ Technology. The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the System as the receiver for a therapeutic CGM.

The t:slim X2 Insulin Pump running the Basal-IQ Technology can be used to suspend insulin delivery based on CGM sensor readings. Introduction into clinical care is planned for summer 2019.

There are many insulin pumps on the market that are approved by the FDA. Insulin infusion pumps that are FDA approved include but are not limited to the Omnipod® System and the Omnipod DASH™ System. FDA 510(k) Product Code: LZG.

EVIDENCE SUMMARY

EXTERNAL INSULIN INFUSION PUMP

Randomized controlled trials have evaluated insulin pumps with various functionalities including a low glucose suspend (LGS) feature.^[5-10] Results of these studies have demonstrated that insulin infusion pumps may, in carefully selected patient populations, control blood glucose to near-normal levels.

ARTIFICIAL PANCREAS DEVICE SYSTEMS

The key clinical outcomes regarding the clinical utility of artificial pancreas device systems (APDSs) relate to their ability to improve morbidity and mortality associated with clinically significant, severe, and acute hypoglycemia or hyperglycemic events.

Low Glucose Suspend Devices

A TEC Assessment (2013) reviewed studies that reported on the use of APDSs in patients with type 1 or type 2 diabetes taking insulin who were 16 years and older.^[11] It included studies that compared an APDS containing an LGS feature with the best alternative treatment in the above population, had at least 15 patients per arm, and reported on hypoglycemic episodes. A single trial met the inclusion criteria, and the TEC Assessment indicated that, although the trial results were generally favorable, the study was flawed, and further research is needed. Reviewers concluded that there was insufficient evidence to draw conclusions about the impact of an APDS, with an LGS feature, on health outcomes.

Randomized Controlled Trials

The single trial assessed in the TEC Assessment was the in-home arm of the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, reported by Bergenstal et al (2013).^[9] This industry-sponsored trial used the Paradigm Veo insulin pump. A total of 247 patients were randomized to an experimental group, in which a continuous glucose monitor with the LGS feature was used (n=121), or a control group, which used the continuous glucose monitor but not the LGS feature (n=126). Key eligibility criteria were 16-to-70 years old, type 1 diabetes, and HbA1c levels between 5.8% and 10.0%. In addition, patients had to have more than 6 months of experience with insulin pump therapy and at least 2 nocturnal hypoglycemic events (≤ 65 mg/dL) lasting more than 20 minutes during a 2-week run-in phase. The randomized intervention phase lasted three months. Patients in the LGS group were required to use the feature at least between 10 PM and 8 AM. The threshold value was initially set at 70 mg/dL and could be adjusted to between 70 mg/dL and 90 mg/dL. Seven patients withdrew early from the trial; all 247 were included in the intention-to-treat analysis. The primary efficacy outcome was the area under the curve (AUC) for nocturnal hypoglycemia events. This was calculated by multiplying the magnitude (in milligrams per deciliter) and duration (in minutes) of each qualified hypoglycemic event. The primary safety outcome was change in HbA1c levels.

The primary end point, mean (standard deviation [SD]) AUC for nocturnal hypoglycemic events, was 980 (1200) mg/dL/min in the LGS group and 1568 (1995) mg/dL/min in the control group. The difference between groups was statistically significant ($p < 0.001$), favoring the intervention group.

Similarly, the mean AUC for combined daytime and nighttime hypoglycemic events (a secondary outcome) significantly favored the intervention group ($p < 0.001$). Mean (SD) AUC values were 798 (965) mg/dL/min in the intervention group and 1164 (1590) mg/dL/min in the control group. Moreover, the intervention group experienced fewer hypoglycemic episodes (mean, 3.3 per patient-week; $SD = 2.0$) than the control group (mean, 4.7 per patient-week; $SD = 2.7$; $p < 0.001$). For patients in the LGS group, the mean number of times the feature was triggered per patient was 2.08 per 24-hour period and 0.77 each night (10 PM-8 AM). The median duration of nighttime threshold suspend events was 11.9 minutes; 43% of events lasted for less than five minutes, and 19.6% lasted more than two hours. In both groups, the mean sensor glucose value at the beginning of nocturnal events was 62.6 mg/dL. After four hours, the mean value was 162.3 mg/dL in the LGS group and 140.0 mg/dL in the control group.

Regarding safety outcomes and adverse events, change in HbA1c level was minimal, and there was no statistically significant difference between groups. Mean HbA1c levels decreased from 7.26 to 7.24 mg/dL in the LGS group and from 7.21 to 7.14 mg/dL in the control group. During the study period, there were no severe hypoglycemic events in the LGS group and four events in the control group (range of nadir glucose sensor values in these events, 40-76 mg/dL). There were no deaths or serious device-related adverse events.

Before reporting on in-home findings, the ASPIRE researchers (Garg et al [2012]) published data from the in-clinic arm of the study.^[12] This randomized crossover trial included 50 patients with type 1 diabetes who had at least three months of experience with an insulin pump system. After a 2-week run-in period to verify and optimize basal rates, patients underwent two in-clinic exercise sessions to induce hypoglycemia. The LGS feature on the insulin pump was turned on in one session and off in the other session, in random order. When on, the LGS feature was set to suspend insulin delivery for two hours when levels reached 70 mg/dL or less. The goal of the study was to evaluate whether the severity and duration of hypoglycemia were reduced when the LGS feature was used. The study protocol called for patients to start exercise with glucose levels between 100 mg/dL and 140 mg/dL and to use a treadmill or stationary bicycle until their plasma glucose levels were 85 mg/dL or less. The study outcome (duration of hypoglycemia) was defined as the period of time glucose values were lower than 70 mg/dL and above 50 mg/dL, and hypoglycemia severity was defined as the lowest observed glucose value. A successful session was defined as an observation period of 3 to 4 hours and with glucose levels above 50 mg/dL. Patients who did not attain success could repeat the experiment up to three times.

The 50 patients attempted 134 exercise sessions; 98 of them were successful. Duration of hypoglycemia was significantly shorter during the LGS-on sessions (mean, 138.5 minutes; $SD = 68$) than the LGS-off sessions (mean, 170.7 minutes; $SD = 91$; $p = 0.006$). Hypoglycemia severity was significantly reduced in the LGS-on group. The mean (SD) lowest glucose level was 59.5 (72) mg/dL in the LGS-on group and 57.6 (5.7) mg/dL in the LGS-off group ($p = 0.015$). Potential limitations of the Garg study included evaluation of the LGS feature in a research setting and short assessment period.

A second RCT evaluated the in-home use of the Paradigm Veo System.^[13] The trial by Ly et al (2013) in Australia was excluded from the 2013 TEC Assessment due to the inclusion of children and adults and lack of analyses stratified by age group (the artificial pancreas system approved in the United States at the time of the review was only intended for individuals ≥ 16 years). The Ly trial included 95 patients with type 1 diabetes between 4 and 50 years of age (mean age, 18.6 years; $>30\%$ of sample <18 years old) who had used an insulin pump for at least 6 months. In addition, participants had to have an HbA1c level of 8.5% or less and have impaired awareness of hypoglycemia (defined as a score of at least four on the modified Clarke questionnaire). Patients were randomized to six months of in-home use of the Paradigm Veo System with automated insulin suspension when the glucose sensor reached a preset threshold of 60 mg/dL or to continued use of an insulin pump without the LGS feature. The primary study outcome was the combined incidence of severe hypoglycemic events (defined as hypoglycemic seizure or coma) and moderate hypoglycemic events (defined as an event requiring assistance from another person). As noted, findings were not reported separately for children and adults.

The baseline rate of severe and moderate hypoglycemia was significantly higher in the LGS group (129.6 events per 100 patient-months) than in the pump-only group (20.7 events per 100 patient-months). After 6 months of treatment, and controlling for the baseline hypoglycemia rate, the incidence rate per 100 patient-months was 34.2 (95% confidence interval [CI], 22.0 to 53.3) in the pump-only group and 9.6 (95% CI, 5.2 to 17.4) in the LGS group. The incidence rate ratio was 3.6 (95% CI, 1.7 to 7.5), which was statistically significant favoring the LGS group. Although results were not reported separately for children and adults, the trialists conducted a sensitivity analysis in patients younger than 12 years (15 patients in each treatment group). The high baseline hypoglycemia rates could be explained in part by two outliers (children ages 9 and 10 years). When both children were excluded from the analysis, the primary outcome was no longer statistically significant. The incidence rate ratio for moderate and severe events excluding the two children was 1.7 (95% CI, 0.7 to 4.3). Mean HbA1c levels (a secondary outcome) did not differ between groups at baseline or at 6 months. Change in HbA1c levels during the treatment period was -0.06% (95% CI, -0.2% to 0.09%) in the pump-only group and -0.1% (95% CI, -0.3% to 0.03%) in the LGS group; the difference between groups was not statistically significant.

Prospective Studies

Gómez et al (2017) published the results of a cohort of 111 type 1 diabetic individuals with documented hypoglycemia and hypoglycemia unawareness who received a sensor-augmented insulin pump with LGS therapy.^[14] Participants used a combination system with the Medtronic Paradigm 722 or Paradigm Veo pump connected to the MiniMed CGM device. At a mean follow-up of 47 months (SD=22.7), total daily insulin dose was reduced (mean difference, -0.22 U/kg; 95% CI, -0.18 to -0.26 U/kg; $p<0.001$). HbA1c levels were reduced from a baseline value of 8.8% (SD=1.9%) to 7.5% (SD=1.0%) at five months (mean difference, -1.3%; 95% CI, -1.09% to -1.50%; $p<0.001$) and 7.1% (SD=0.8%; mean difference, -1.7%; 95% CI, -1.59% to -1.90%; $p<0.001$). At baseline, 80% of subjects had had at least one episode of hypoglycemic awareness compared with 10.8% at last follow-up ($p<0.001$). Episodes of severe hypoglycemia decreased from 66.6% to 2.7% ($p<0.001$).

Retrospective Studies

Agrawal et al (2015) retrospectively analyzed use of the threshold suspend feature associated with the Paradigm Veo System in 20,973 patients, most of whom were treated outside of the United States.^[15] This noncontrolled descriptive analysis provided information on the safety of the device when used in a practice setting. The threshold suspend feature was enabled for 100% of the time by 14,673 (70%) patients, 0% of the time by 2249 (11%) patients, and the remainder used it intermittently. The mean (SD) setting used to trigger suspension of insulin was a sensor glucose level of 62.8 (5.8) mg/dL. On days when the threshold suspend feature was enabled, there was a mean of 0.82 suspend events per patient day. Of these, 56% lasted for 0 to 5 minutes, and 10% lasted the full two hours. (Data on the length of the other 34% of events were not reported.) On days when the threshold suspend feature was on, sensor glucose values were 50 mg/dL or less 0.64% of the time compared with 2.1% of sensor glucose values 50 mg/dL or less on days when the feature was off. Reduction in hypoglycemia was greatest at night. Sensor glucose percentages equivalent to 17 minutes per night occurred when the threshold suspend feature was off vs glucose percentages equivalent to five minutes per night when the threshold suspend feature was on. Data on the use of the device has suggested fewer and shorter hypoglycemic episodes. The length and severity of hypoglycemic episodes were not fully discussed in this article.

SECTION SUMMARY

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a low glucose suspend feature, the evidence includes two randomized controlled trials (RCTs) conducted in home settings. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Primary eligibility criteria of the key RCT, the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, were ages 16-to-70 years old, type 1 diabetes, glycated hemoglobin levels between 5.8% and 10.0%, and at least two nocturnal hypoglycemic events (≤ 65 mg/dL) lasting more than 20 minutes during a 2-week run-in phase. Both trials required at least six months of insulin pump use. Both RCTs reported significantly less hypoglycemia in the treatment group than in the control group. In both trials, primary outcomes were favorable for the group using an artificial pancreas system; however, findings from one trial were limited by nonstandard reporting of hypoglycemic episodes, and findings from the other trial were no longer statistically significant when two outliers (children) were excluded from analysis. The RCT limited to adults showed an improvement in the primary outcome (AUC for nocturnal hypoglycemic events). AUC is not used for assessment in clinical practice, but the current technology does allow user and provider review of similar trend data with a CGM.

Results from the ASPIRE study suggested that there were increased risks of hyperglycemia and potential DKA in subjects using the threshold suspend feature. This finding may be related to whether or not actions are taken by the user to assess glycemic status, etiology of the low glucose (activity, diet or medication) and to resume insulin infusion. Both retrospective and prospective observational studies have reported reductions in rates and severity of hypoglycemic episodes in automated insulin delivery system users.

The evidence is sufficient that the magnitude of reduction for hypoglycemic events in the T1D population is likely to be clinically significant. Limitations of the published evidence preclude determining the effects of the technology on overall glycemic control as assessed by HbA1c and other parameters and thus, net health outcomes. Patient selection criteria considering FDA label and inclusion criteria in the evidence include: age 14 and older; glycated

hemoglobin level between 5.8% and 10.0%; used insulin pump therapy for more than six months; and at least two documented nocturnal hypoglycemic events in a 2-week period.

Hybrid Closed-loop Insulin Delivery Systems

Systematic Review

Karageorgiou (2019) published a systematic review and network meta-analysis evaluating the efficacy of closed-loop systems in glycemic control for non-adults with type 1 diabetes mellitus.^[16] The meta-analysis included 25 studies (N=504). The closed-loop system group spent a significantly higher percentage of time in a target glycemic range and the mean glucose was also decreased in the closed-loop system group (MD: 3.01%, 95% CI [1.68-4.34%]). Overall the closed-loop system showed better outcomes compared to standard insulin pumps for non-adults.

Prospective Studies

Bergenstal et al (2016) published a prospective single-arm study on the safety of the hybrid closed-loop system in patients with type 1 diabetes.^[17] It included 124 patients ages 14-to-75 years old who had type 1 diabetes for at least two years, had HbA1c levels less than 10.0%, and who had used an insulin pump for at least six months. There was an initial run-in period at baseline for patients to learn how to use the device followed by a 3-month period of device use. The study period included a 6-day hotel stay with a 1-day period of frequent sampling of venous blood glucose levels to verify device accuracy. The primary safety end points were the incidence of severe hypoglycemia and diabetic ketoacidosis and the incidence of device-related and serious adverse events.

There were no episodes of severe hypoglycemia or ketoacidosis during the study. A total of 28 device-related adverse events occurred, all of which could be resolved at home. There were four serious adverse events, one case each of appendicitis, bacterial arthritis, worsening rheumatoid arthritis, and *Clostridium difficile* diarrhea. There were also a number of predefined descriptive end points (but no statistically powered efficacy end points). The device was in the closed-loop mode for a median of 97% of the study period. Mean (SD) HbA1c levels were 7.4% (0.9%) at baseline and 6.9% (0.6%) at the end of the study, and the percentage of sensor glucose values within the target range was 66.7% at baseline and 72.2% at the end of the study.

A multicenter pivotal trial published by Garg et al (2017) evaluated the safety of Medtronic's hybrid closed-loop system, using methods similar to those of Bergenstal (NCT02463097) and employing the same device (MiniMed 670G).^[18] Of 129 subjects, 124 completed the trial; 30 were adolescents (age range, 14-21 years) and 94 were adults (age range, 22-75 years), all of whom had type 1 diabetes for at least two years before the study, and used insulin pump therapy for six months or more. A three month study period was preceded by a run-in period for subjects to be more familiar with the equipment, and the sensor glucose values were confirmed by an extended hotel stay (6-day/5-night with daily exercise). In both the adolescent and adult cohorts, the trial found improvements during the study phase over the run-in phase, with an increased percentage of glucose values in the favorable range (for adults, a mean improvement of 68.8% to 73.8%; for adolescents, a mean improvement of 60.4% to 67.2%; $p < 0.001$ for both cohorts). Similarly, the authors reported a decrease in the percentage of values outside of the target range (< 70 mg/dL or > 180 mg/dL): for adults, time spent below the target range decreased from 6.4% to 3.4% ($p < 0.001$); time above the range decreased from

24.9% to 22.8% ($p=0.01$). For both cohorts, HbA1c levels showed a significant reduction between baseline and the end of study: for adults, the mean decreased from 7.3% to 6.8% ($p<0.001$), while for adolescents, the mean decreased from 7.7% to 7.1% ($p<0.001$). Secondary outcomes, which included a reduction of nocturnal hyperglycemia and hypoglycemia, increase in mean overall body weight, and a reduction of basal insulin, were favorable for the study phase, compared with the run-in phase; measurements from the hotel stay verified the in-home glucose values. However, there were several limitations in the trial, including its nonrandomized design, the exclusion of individuals who had recently experienced diabetic ketoacidosis or severe hypoglycemia, and the interaction between subjects and site personnel. Additionally, most of the adult cohort were already using CGM, and baseline HbA1c levels were lower than average for both cohorts; both baseline characteristics potentially limit the generalizability of the results.

One type of hybrid insulin delivery system employs a predictive algorithm to keep the patient's glucose levels within a specific range or zone, only increasing or decreasing insulin levels if the device detects that glucose levels are going to fall outside the defined zone. Forlenza et al (2017) published a randomized controlled crossover trial comparing the efficacy of a zone model predictive control algorithm with that of sensor-augmented pump therapy; the trial included 20 subjects (19 completed), all with type 1 diabetes and having at least three months treatment with a subcutaneous insulin infusion pump.^[19] The six week, in-home study was divided into 2-week blocks, with two randomized groups alternating treatment between an artificial pancreas system (DiAs web monitoring) or sensor-augmented pump therapy (Dexcom Share); subjects in both arms reported glucose values and, if applicable, sensor failure. For several primary end points, which included percentage of time in the target glucose range (70-180 mg/dL) and reduction in hypoglycemia (<70 mg/dL), the algorithm-controlled artificial pancreas system was found to be superior to the sensor-augmented pump therapy (71.6 vs 65.2%, $p=0.008$; 1.3 vs 2%, $p=0.001$, respectively); however, while the mean glucose value was lower in the artificial pancreas system than in the control group, the difference between them was not significant ($p=0.059$). Measurements of nocturnal hypoglycemia were consistent with day-to-day findings. For the secondary end point (safety of both systems after extended wear), the study found that the mean glucose did not change between the first and seventh day of wear. A limitation of the trial was its use of remote monitoring of subjects; also, the trialists noted that, given the marked difference in outcomes between responders and nonresponders, an error might have occurred in setting basal rates. The remainder of the review is focused on additional studies that recently evaluated HCL systems in children and adolescents with T1D.

The RCT by Tauschman, et al (2018) evaluated individuals with uncontrolled T1D as reflected in mean Hb1c <8 %.^[20] Approximately, 50% of the subjects were between 6-21 years of age and 25% are 6-12 years old. Both groups achieved a reduction in HbA1c but were statistically greater in the HCL group compared to the control group. The investigators reported that the HbA1c improvements were not different among children, adolescents, and adults (data not shown in tables). No severe hypoglycemic events were reported consistent with decrease in time spent with glucose <70 mg/dl.

Abraham et al (2018) reported the results of a six month, multicenter, RCT in children and adolescents with T1D comparing use of an insulin pump with suspend before low or predictive low-glucose management (PLGM) with sensor-augmented insulin pump therapy (SAPT) alone.^[21] At six months, significant reductions were seen in day and night hypoglycemia and

number of hypoglycemic events <63mg/dl lasting longer than 20 minutes. There were no differences in HbA1c at six months in either group.

Forlenza et al (2019) reported the data and analysis of the supplemental information filed with the FDA to support the expanded indication for the MiniMed 670G system to children 7-13 years of age.^[22] The nonrandomized, single arm multicenter study reported the day and night use of the automated insulin delivery and PLGM for three months in the home setting. There were no serious adverse events and use of the system was associated with reduction in HbA1c and increased time in target glucose range.

Wood et al (2018) reported an in-clinic evaluation of a 7-13 year-old cohort of the 670G pivotal trial that was designed to evaluate the performance characteristics of the device when activity induced hypoglycemic patterns were used to set individual device parameters for ongoing use by the study participant.^[23] The suspend before low prevention capability was confirmed in 97.5% of patients experiencing a sensor glucose of ≤ 55 mg/dl.

Messer et al (2018) reported on a subanalysis of the adolescent and young adult participants in the 670G pivotal trial to better characterize the carbohydrate input and insulin bolus determination features of the device over a three-month period.^[24] Participants successfully utilized the device without significant changes in total daily dose of insulin but improved percentage time in range (70-180 mg/dl).

SECTION SUMMARY

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a hybrid closed-loop insulin delivery system, the evidence includes a multicenter pivotal trial using devices cleared by the Food and Drug Administration, supplemental data and analysis for expanded indications and more recent studies focused on children and adolescents. Three crossover RCTs using a similar first generation device approved outside the United States have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of the three crossover RCTs assessing a related device conducted outside the United States, two found significantly better outcomes (ie, time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the device than with standard care and the other had mixed findings (significant difference in time spent in nocturnal hypoglycemia and no significant difference in time spent in preferred glycemic range). For the US regulatory registration pivotal trial, the primary outcomes were safety and not efficacy. Additional evidence from device performance studies and clinical studies all demonstrate reductions in time spent in various levels of hypoglycemia, improved time in range (70-180mg/dl), rare diabetic ketoacidosis and few device related adverse events. The evidence is sufficient that the magnitude of reduction for hypoglycemic events in the T1D population is likely to be clinically significant. The variation in the definition of primary and secondary outcomes in the study design and conduct of the published evidence are limitations that preclude determining the effects of the technology on net health outcomes. Reduction in the experience of hypoglycemia and inappropriate awareness of hypoglycemia and glycemic excursions were identified as important acute clinical outcomes in children, adolescents and adults and are related to the future risk for end organ complications. Patient selection criteria considering FDA label and inclusion criteria in the evidence include: age seven and older; glycated hemoglobin level between 5.8% and 10.0%; used insulin pump therapy for more than 6 months; and at least two documented nocturnal hypoglycemic events in a 2-week period.

PRACTICE GUIDELINE SUMMARY

AMERICAN DIABETES ASSOCIATION

The American Diabetes Association has released multiple publications on controlling type 1 diabetes as outlined below.

Date	Title	Publication Type	Recommendation	Level of Evidence
2020	Standards of Medical Care in Diabetes	Guideline standard ^[25]	<p>Use of technology should be individualized based on a patient’s needs, desires, skill level, and availability of devices. Nonprofit websites can offer advice for providers and patients to determine the suitability of various options.</p> <p>Insulin pump therapy may be considered as an option for all adults, children, and adolescents with type 1 diabetes who are able to safely manage the device.</p> <p>Automated insulin delivery systems may be considered in children (B) and adults with type 1 diabetes to improve glycemic control. (A)</p> <p>Sensor-augmented pump therapy with automatic low glucose suspend may be considered for adults and children with type 1 diabetes to prevent/mitigate episodes of hypoglycemia.</p>	<p style="text-align: center;">E</p> <p style="text-align: center;">A</p> <p style="text-align: center;">B</p> <p style="text-align: center;">B</p>

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND THE AMERICAN COLLEGE OF ENDOCRINOLOGY

The American Association of Clinical Endocrinologists and American College of Endocrinology (2018) published a joint position statement on the integration of insulin pumps and continuous glucose monitoring in patients with diabetes.^[26] The statement emphasized the use of continuous glucose monitoring and insulin pump therapy for type 1 diabetes patients who are not in glycemic target ranges despite intensive attempts at self-blood glucose monitoring and multiple insulin injection therapy.

In 2014, the American Association of Clinical Endocrinologists and the American College of Endocrinology published a joint position statement for insulin pump management.^[27] The consensus statement was developed by evaluating the current evidence, and when

evidence from randomized controlled trials lacked, by consensus of a task force of experts. The summary of recommendations states that data support CSII for basal-bolus insulin therapy in patients with type 1 diabetes mellitus (T1DM), when selection is based on a comprehensive evaluation of the patient's knowledge of diabetes management principles. Specific patient selection recommendations include the ideal CSII candidate as follows:

- A patient with T1DM or intensively managed insulin-dependent type 2 diabetes mellitus
- Currently performing ≥ 4 insulin injections and ≥ 4 self-monitored blood glucose (SMBG) measurements daily
- Motivated to achieve optimal blood glucose control
- Willing and able to carry out the tasks that are required to use this complex and time-consuming therapy safely and effectively
- Willing to maintain frequent contact with their health care team

SUMMARY

There is enough research to show that the use of an external insulin infusion pump or FDA-approved automated insulin delivery system (artificial pancreas device) improves health outcomes for select patients with diabetes mellitus or preconception/pregnancy related suboptimal glycemic control. Clinical practice guidelines based on research recommend these devices in certain populations and clinical scenarios. Therefore, the use of an external insulin infusion pump or an FDA-approved automated insulin delivery system (artificial pancreas device) may be considered medically necessary when policy criteria are met.

There is not enough research to show that an insulin pump or FDA-approved automated insulin delivery system (artificial pancreas device) improve health outcomes in all other situations. No clinical practice guidelines based on research recommend these devices for patients not addressed in the policy criteria. Therefore, the use of an external insulin infusion pump or FDA-approved automated insulin delivery system (artificial pancreas device) is investigational when the policy criteria are not met.

All or part of an insulin pump or automated insulin delivery system (artificial pancreas device) may warrant replacement or upgrade when the current device is no longer able to perform its basic function and cannot be repaired or adapted adequately to meet the patient's medical needs. Therefore, a replacement or upgrade may be considered medically necessary when policy criteria are met. A replacement or upgrade is considered not medically necessary when the device is adequately functioning and can meet the patient's medical needs.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	A9999	Miscellaneous DME supply or accessory, not otherwise specified
	E0784	External ambulatory infusion pump, insulin
	E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
	E1399	Durable medical equipment, miscellaneous
	S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
	S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
	S1036	Transmitter; external, for use with artificial pancreas device system
	S1037	Receiver (monitor); external, for use with artificial pancreas device system

Date of Origin: September 2000

NOTE: This policy has been revised. The revised policy will be effective January 1, 2021. To view the revised policy, [click here](#).

Medical Policy Manual

Durable Medical Equipment, Policy No. 80

Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Effective: October 1, 2020

Next Review: June 2021

Last Review: September 2020

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

- 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; 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.

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 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
- 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.

- 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.
- 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.

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 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 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 (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 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.

There is enough research to show that myoelectric upper limb prostheses do not improve health outcomes when policy criteria are not met. Therefore, 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
	L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
	L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device

Codes	Number	Description
	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	Elbow, wrist, hand device, powered, with single or double upright(s), any type joint(s), includes microprocessor, sensors, all components and accessories
	L8702	Elbow, wrist, hand, finger device, powered, with single or double upright(s), any type joint(s), includes microprocessor, sensors, all components and accessories

Date of Origin: June 2010

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

Effective: January 1, 2020

Next Review: September 2020

Last Review: December 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

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

- 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.

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

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 to 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

Gailey published a 2012 randomized, within-subject crossover study that 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

Two comparative trials of the microprocessor-controlled ankle from the same investigators investigated the Proprio Foot. Its use was evaluated 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. These results were also compared with 11 matched controls with intact limbs.^[9] 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 four preferred the ESR prosthesis.

In another small study of seven amputees and seven intact controls, Herr (2012) 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 (2011) 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 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

A 2017 clinical practice guideline from the Department of Veterans Affairs and the Department of Defense (VA/DoD) included the following recommendation with a weak strength of evidence:^[12]

We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces.

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. The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management program:^[13]

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.
- 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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14. 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	L2006	Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated
	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)
	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

Noninvasive Ventilators in the Home Setting

Effective: October 1, 2020

Next Review: July 2021

Last Review: August 2020

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

Noninvasive ventilation (NIV) assistance or noninvasive positive pressure ventilation (NPPV) uses a nasal mask, face mask, or mouthpiece, connected to a ventilator to provide ventilation support during sleep or intermittently throughout the day.

MEDICAL POLICY CRITERIA

Notes: This policy only addresses home ventilators with a *noninvasive* interface (HCPCS code E0466). It does not address the use of other types of home ventilators, including those with an *invasive* interface (HCPCS E0465) or a multi-function home ventilator (HCPCS E0467).

- I. Use of a noninvasive ventilator in the home setting may be considered **medically necessary** when both of the following criteria are met (A. and B.):
 - A. The device is being requested to treat any of the following indications:
 1. Neuromuscular disease, or
 2. Thoracic restrictive disease, or

- 3. Chronic respiratory failure consequent to chronic obstructive pulmonary disease.
 - B. There is sufficient documentation in the medical record to support the condition is life-threatening where interruption of respiratory support would quickly lead to serious harm or death.
- II. Use of a noninvasive ventilator in the home setting is considered **not medically necessary** when Criterion I. is not met, including but not limited to the following situations:
 - A. The patient's condition is such that treatment may be adequately provided by a bilevel positive airway pressure device; or
 - B. Severity of the patient's condition is not severe and life-threatening.

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

POLICY GUIDELINES

VENTILATOR WITH NOINVASIVE INTERFACES

The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-03) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators (E0465, E0466) are covered for the following conditions:

“[N]euromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.”

Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These ventilator-related disease groups overlap conditions described in this Respiratory Assist Devices LCD used to determine coverage for bi-level PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bi-level PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.

Ventilators fall under the Frequent and Substantial Servicing (FSS) payment category, and payment policy requirements preclude FSS payment for devices used to deliver continuous and/or intermittent positive airway pressure, regardless of the illness treated by the device. (Social Security Act 1834(a)(3)(A)) This means that products currently classified as HCPCS code E0465 or E0466 when used to provide CPAP or bi-level PAP (with or without backup rate) therapy, regardless of the underlying medical condition, shall not be paid in the FSS payment category. A ventilator is not eligible for reimbursement for any of the conditions described in this RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Claims for ventilators used to provide CPAP or bi-level CPAP therapy for conditions described in this RAD policy will be denied as not reasonable and necessary.

General principles of correct coding require that products assigned to a specific HCPCS code only be billed using the assigned code. Thus, using the HCPCS codes for CPAP (E0601) or bi-level PAP (E0470, E0471) devices for a ventilator (E0465, E0466) used to provide CPAP or bi-level PAP therapy is incorrect coding. Claims for ventilators billed using the CPAP or bi-level PAP device HCPCS codes will be denied as incorrect coding.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- All chart notes and medical records pertinent to the request (e.g., supporting documentation of neuromuscular disease, thoracic restrictive disease, and/or chronic respiratory failure consequent to COPD).
- Documentation must demonstrate that the condition is life-threatening where interruption of respiratory support would quickly lead to serious harm or death.

CROSS REFERENCES

1. [Phrenic Nerve Stimulation for Central Sleep Apnea](#), Surgery, Policy No. 212

BACKGROUND

This policy is based on the Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-03) in Chapter 1, Part 4, Section 280.1; and Local Coverage Determination (LCD): Respiratory Assist Devices (L33800).^[1,2]

NONINVASIVE VENTILATORS

Ventilators, also known as respirators, are medical devices used to mechanically assist with a patients' breathing. Mechanical ventilation is often categorized by the interface used, such as a tracheostomy tube for invasive ventilation, or a mask for non-invasive ventilation. Non-invasive ventilation (NIV) assistance or non-invasive positive pressure ventilation (NPPV) uses a nasal mask, face mask, or mouthpiece, connected to a ventilator to provide ventilation support during sleep or intermittently throughout the day. In the hospital setting, a trial of NPPV may be attempted prior to invasive treatment. Ventilation support rests the lung muscles and improves breathing performance during the day. At night, ventilation may be used to treat sleep-associated hypoventilation. If use is at night only, this is referred to as nocturnal NPPV. If use is intermittent, this may be referred to as "Mouthpiece" or "Sip and Puff" ventilation. Supplemental oxygen may also be added to this type of system.

In recent decades, NPPV has been used for treatment in the home setting. BPAP are portable pressure-limited ventilators, which are more commonly used than portable volume-limited ventilators. In some populations, efficacy is similar with both types of devices according to comparative studies, thus the portable pressure-limited ventilators are usually preferred over portable volume-limited ventilators, because of lower cost, better portability, and often greater comfort.^[3]

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved numerous portable home ventilators through the 510(k) process. A non-exhaustive list of examples includes the following:

- Trilogy™ (Philips Respironics)
- Newport® (Newport Medical Instruments)
- IVent (GE Healthcare)
- Puritan™ (Covidien)
- LTV® (Carefusion)

FDA Product Code: CBK.

SUMMARY

There is enough research to show that use of a noninvasive ventilator in the home setting improves health outcomes for patients with neuromuscular disease, thoracic restrictive disease, or chronic respiratory failure consequent to chronic obstructive pulmonary disease. Clinical guidelines based on research recommend noninvasive ventilators for use in the home setting for these populations. Therefore, the use of a noninvasive ventilator in the home setting may be considered medically necessary when policy criteria are met.

In all other situations, the use of a noninvasive ventilator in the home setting is not associated with improvements in health outcomes. Therefore, the use of a noninvasive ventilator in the home setting is considered not medically necessary when policy criteria are not met.

REFERENCES

1. U.S. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1). Version number: 2. Publication Number 100-3. Implementation Date 7/5/2005. [cited 08/07/2020]; Available from: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&DocID=280.1&bc=qAAAABAAAA&>
2. U.S. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Respiratory Assist Devices (L33800). For services performed on or after 01/01/2020. [cited 08/07/2020]; Available from: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33800&ver=13&Date=&DocID=L33800&bc=iAAAABAAAA&>
3. Noridian Healthcare Solutions. Correct Coding and Coverage of Ventilators - Revised April 2019. [cited 07/01/2019]; Available from: <https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2019/correct-coding-and-coverage-of-ventilators-revised-april-2019>
4. UpToDate. Types of noninvasive nocturnal ventilatory support in neuromuscular and chest wall disease. Topic 5114 Version 16.0. Literature review current through: July 2020. | This topic last updated: June 05, 2020. [cited 08/07/2020]; Available from:

<https://www.uptodate.com/contents/types-of-noninvasive-nocturnal-ventilatory-support-in-neuromuscular-and-chest-wall-disease>

CODES

NOTE: Home ventilator codes requiring prior authorization are listed on the “Commercial Pre-authorization List” web page. Home ventilators not listed on the pre-authorization website do not require prior approval. There may be codes related to home ventilator systems that are not included in this medical policy.

Codes	Number	Description
CPT	None	
HCPCS	E0466	Home ventilator, any type, used with non-invasive interface, (e.g., mask, chest shell)

Date of Origin: July 2019