

**10-144 Chapter 101
MAINECARE BENEFITS MANUAL
CHAPTER II**

SECTION 60

**MEDICAL SUPPLIES AND
DURABLE MEDICAL EQUIPMENT**

**Established: 06/01/85
Last Updated: 06/13/15**

This Section is Dependent Upon Approval by
the Centers for Medicare and Medicaid Services (CMS)

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60.01 DEFINITIONS

- 60.01-1 **Activities of Daily Living (ADL)** are those activities related to personal care including but not limited to: showering, bowel/bladder management, eating, functional mobility, personal device care (hearing aids, etc.), personal hygiene and toileting.
- 60.01-2 **Adjusted Acquisition Cost** is the lowest price paid to a supplier by an eligible provider for Durable Medical Equipment or medical/surgical supplies after adjustments for quantity discounts, any prompt payment discounts and excluding all associated costs, including but not limited to, shipping, freight, handling and insurance costs. Wheelchair providers need not adjust the price paid to a supplier based on any prompt payment discount.
- 60.01-3 **Department** is the Maine Department of Health and Human Services.
- 60.01-4 **Durable Medical Equipment (DME)** is:
- A. Equipment that can withstand repeated use;
 - B. Primarily used to serve a medical purpose and is medically necessary and reasonable for the treatment of the member's illness or injury or to improve an altered body function. Examples of items that are not primarily used for medical purposes include air conditioners, pools and exercise equipment, and equipment primarily used for the convenience of a caregiver;
 - C. Not generally useful to a person in the absence of illness or injury;
 - D. Appropriate for use in the member's home or place of residence (excluding hospital settings) and is in safe and reasonably good condition and suitable for its intended use.

All four (4) of the above criteria must be met for coverage under this Section. Specific definitions and criteria are provided in the Appendix to this Section.

Home/Environmental modifications do not meet the definition of Medical Supplies or Durable Medical Equipment and are not covered under this Section. These non-covered items include, but are not limited to, ramps or structural or other changes to a building to allow for access, support of equipment, or to attach equipment.

- 60.01-5 **Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF- IID)** is a facility that meets State licensing and Federal certification requirements for ICFs-IID.
- 60.01-6 **Medical Supplies** are those Medical Supplies that are primarily needed to relieve or control a medical condition. Examples of supplies not primarily needed to relieve or

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60.01 **DEFINITIONS** (cont.)

control a medical condition include, but are not limited to, room and underarm deodorants.

60.01-7 **Nursing Facility (NF)** means, a Skilled Nursing Facility (SNF) in the Medicare program or a Nursing Facility (NF) in the MaineCare program which meets State licensing and Federal certification requirements for nursing facilities and has a valid agreement with the Department of Health and Human Services.

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60.01-8 **Prior Authorization (PA)** is the process of obtaining prior approval as to the medical necessity and eligibility for a service.

60.01-9 **Power Mobility Device (PMD)** Includes both integral frame and modular construction type Power Wheelchairs (PWCs) and power operated vehicles (POVs).

60.01-10 **Power Operated Vehicle (POV)** is a chair-like battery powered mobility device for people with difficulty walking due to illness or disability, with integrated seating system, tiller steering, and three or four-wheel non-highway construction.

60.01-11 **Power Wheelchair (PWC)** is a chair-like battery powered mobility device for people with difficulty walking due to illness or disability, with integrated or modular seating system, electronic steering, and four or more wheel non-highway construction.

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60.01-12 **Providers of Medical Supplies and Durable Medical Equipment (DME)** are enrolled MaineCare providers that:

- A. Have executed a MaineCare Provider Agreement with the Department of Health and Human Services and have obtained a provider identification number from the Department;
- B. Provide Medical Supplies and/or DME services to MaineCare members; and
- C. Have a storefront with a commercial address for the sales and service of the supplies and equipment sold, rented or otherwise provided to members, and must have regularly staffed operating hours. Providers must post hours of operation in a visible location for the general public. The storefront must be located in Maine or within fifteen (15) miles of the Maine border in New Hampshire. The provider cannot be solely a sales representative for a manufacturer of DME or Medical Supplies. (Exception will be given to Audiologist operating outpatient services that are not enrolled as a DME dealer).

D. Hearing Aids only: In addition to the requirements above, hearing aids, accessories, and repairs must be provided by an individual licensed by the State of Maine as an Audiologist or as a licensed Hearing Aid Dealer & Fitter.

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60.01 DEFINITIONS (cont.)

The following exceptions apply:

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1. DME and supplies provided to a member who is residing out of state, only for the purposes of meeting an emergency medical need, with Prior Authorization, at the discretion of the Department, taking into account cost effectiveness and medical necessity and only if the item(s) cannot be supplied by a MaineCare enrolled provider;
2. A provider who is the sole provider of a type of cost-effective, medically necessary Durable Medical Equipment may be enrolled only for the purpose of providing that item with Prior Authorization. The provider must warranty the item for parts and labor.
3. The Department reserves the right to issue a request for proposals for provision of any supply or piece of equipment, and the resulting contract may be awarded to an out-of-state provider. The Department may enter into a special purchasing arrangement with one or more vendors capable of providing services to MaineCare members without the vendor having a physical storefront.

60.01-13 Primary Care Provider (PCP) is a provider who has a contract with the Department to provide primary care case management (PCCM) services.

60.02 ELIGIBILITY FOR CARE

Individuals must meet the eligibility criteria as set forth in the MaineCare Eligibility Manual. Some members may have restrictions on the type and amount of services they are eligible to receive.

60.03 DURATION OF CARE

Each Title XIX and XXI member is eligible for as many covered services as are medically necessary and subject to limitations within this Section. The Department reserves the right to request additional information to determine medical necessity or expected therapeutic benefit of prescribed supplies or equipment.

60.04 COVERED SERVICES

A covered service is a service or item for which payment can be made by the Department, and which meets the definitions listed in Section 60.01 and any other criteria or limitations described in this Section.

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60.05 POLICIES AND PROCEDURES

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Face-to-Face Encounter is a mandatory encounter (including encounters through a telehealth system, (as described in Chapter I, § 1.06 of this manual) and other than encounters incidental to services involved) between the member and his or her physician, physician assistant, nurse practitioner or clinical nurse specialist that takes place within the six (6) months prior to a written order for Durable Medical Equipment being given. The written order may be prescribed by the physician, physician assistant, nurse practitioner, or clinical nurse specialist who performed the face-to-face encounter.

The provider of Medical Supplies and/or DME must inform MaineCare members prior to the provision of any medical supply or DME that is not or may not be MaineCare covered, that the member will be responsible for payment. The provider must document this notification in the member's record, in accordance with Chapter I of the MaineCare Benefits Manual.

The Department will not refuse to Prior Authorize (PA) a DME item based solely on a diagnosis, type of illness or condition.

60.05-1 Requirements

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Medical Supplies and Durable Medical Equipment must meet all of the following requirements:

- A. Comply with the criteria in Section 60, including the definitions in Section 60.01;
- B. Be prescribed by a physician or PCP;
- C. Be provided to a member who is not in a hospital, unless necessary for transition to home, in which case the provider must comply with the criteria for emergency rental in this Section;
- D. Have scientifically valid clinical evidence of their efficacy and not be considered investigational or experimental by the Department;
- E. Be approved and defined by the Food and Drug Administration;
- F. Be cost-effective;
- G. Have a warranty that includes parts and labor; and
- H. Be provided by a MaineCare authorized provider of Medical Supplies and Durable Medical Equipment who has a location where members can procure repairs and servicing of items with warranties and guarantees, or meet one of the exceptions outlined in this Section.

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60.05 POLICIES AND PROCEDURES (cont.)

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- I. The Department requires, that for some DME Medical Supplies and medical equipment, providers meet Prior Authorization criteria that are industry recognized criteria utilized by a national company under contract. Providers can view these criteria by accessing the PA portal website which can be found at: <https://mainecare.maine.gov/Default.aspx>, which will include a link to the PA portal.

In cases where the criteria are not met, the Provider/Member may submit additional supporting evidence such as medical documentation, to demonstrate that the requested service is medically necessary.

- J. Durable Medical Equipment Only. The prescribing physician must maintain documentation that includes a statement verifying the date of the Face-to-Face Encounter (see 60.01-5) for that specific piece of Durable Medical Equipment and the name of the Physician, Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist who performed the face-to-face encounter.

60.05-2 Reasonable and Necessary for Treatment

All DME and supplies must be prescribed by and certified as medically necessary by the physician or PCP. Through the PA process, the Department shall determine whether the DME and/or supplies are reasonable for the course of treatment for equipment having a MaineCare allowed amount exceeding \$699.00 (Refer to PA requirements in this Section). In making such a determination, the following factors are to be considered:

- A. The equipment is medically necessary and meets the criteria in this Section;
- B. The equipment serves a different purpose than equipment already available to the member; and the equipment is not an upgrade for currently functioning equipment that meets members' basic needs and already supplied to the member;
- C. The equipment is not more costly than a medically appropriate and realistically feasible alternative plan of care;
- D. The cost of the item is not disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment;
- E. Home/Environmental modifications do not meet the definition of Medical Supplies or Durable Medical Equipment and are not covered under this Section. These items include but are not limited to ramps, structural or other changes to a building, to allow for access or support of equipment or to attach the equipment; and

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60.05 POLICIES AND PROCEDURES (cont.)

- F. Prior to provision, a written document must be submitted indicating, if applicable, the equipment can freely pass through all entryways without the need for modification. It is the responsibility of the provider to submit documentation indicating that necessary modifications or structural changes have occurred prior to the request for authorization.

(Providing all other criteria are met, an exception may be granted for a member who needs a wheelchair during the winter months but is unable to make the necessary home modifications due to the frozen conditions.)

60.05-3 Aesthetic or Deluxe DME

- A. Standard models that are medically necessary and meet the intended purpose will be reimbursed only when they meet all of the guidelines of this Section. Aesthetic or deluxe models or equipment and aesthetic or deluxe features are not reimbursable. Examples of equipment and supplies which are non-reimbursable include such items as: baskets on wheelchairs, sports model wheelchairs, seat elevators, HCPCS Level II L codes that contain the word microprocessor in the description (with the exception of microprocessor controlled knee prostheses), or any piece of equipment or feature that goes beyond the restoration of a basic function.
- B. Stair climbing or gyroscopically guided wheelchairs are considered to be deluxe in nature and are not covered.
- C. Patient lift systems that include track(s) to go from one location to another within the home are considered to be deluxe in nature and are not covered.
- D. The items listed above are examples of those pieces of equipment that have been determined to be aesthetic or deluxe models or equipment and aesthetic or deluxe features and are not meant to be an all-inclusive list.
- E. MaineCare does not “pay toward” deluxe or aesthetic equipment or supplies or allow the member to pay the difference in cost.

60.05-4 Rental and/or Purchase

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The decision to rent or purchase DME lies solely with the Department or its Authorized Entity.

- A. Rental
1. Rental may be made for certain DME at the discretion of the Department.

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2. All rental equipment must receive PA except for emergency equipment. Please refer to Prior Authorization Section regarding emergency equipment. The request for continued Prior Authorization of services must indicate the emergency dates of services.
3. The Department decides when to purchase rented equipment if a member requires its use for an extended period of time. If the Department decides to purchase the rented equipment, the total rental paid to date will be applied to the MaineCare allowed purchase price as listed in the fee schedule or as otherwise set by the Department.
4. Unless otherwise authorized under this Section, rental rates include the cost of servicing, repairs or other maintenance and include replacement parts for defective equipment and disposable items. The Department is not responsible for the cost of repairs (including labor or replacement parts) for rented items or equipment.
5. All rented equipment must be clean and in proper working condition when delivered.

B. Outright Purchase of New DME

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1. The Department may purchase outright any Durable Medical Equipment if the member will be using it for an extended period of time. Once an item is purchased, it becomes the property of the member.
2. The Department reserves the right to purchase the necessary equipment at the lowest price available and to preferentially choose equipment that includes a warranty.
3. All purchased equipment must be new and unused, clean, in proper working condition, free from defects and meet all implied and expressed warranties.

C. Outright Purchase of Used Equipment

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Used equipment will be reimbursed on a prorated basis using the remaining useful life of the equipment based on Generally Accepted Accounting Principles (GAAP) applied to the MaineCare rate of reimbursement. To qualify for payment, a Prior Authorization form must be completed (see Section 60.06). The equipment being reconditioned must not exceed the expense for new equipment.

D. Delivery, Installation, and Member Instructional Time

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60.05 POLICIES AND PROCEDURES (cont.)

The maximum allowable fee for purchase or rental of equipment includes the following:

1. Cost of delivery to the inside of the member's residence and, when appropriate, to the room in which the equipment will be used;
2. Assembly of parts, installation and set-up of the equipment or customized fitting;
3. Instruction to the member or caregivers in the safe and proper use of the equipment or supplies sufficient to ensure that they have demonstrated they can provide necessary service and /or use of the equipment or supplies safely and properly and limitations on replacement.

60.05-5 Emergency DME

In an emergency the Department will reimburse rental of standard DME for up to thirty (30) days, subject to the Prior Authorization requirements in this Section.

If the Department decides to purchase the rented equipment, the total amount paid to date will be applied to the MaineCare allowed purchase price as listed in the fee schedule or as otherwise set by the Department, and can be found at:

<http://www.maine.gov/dhhs/audit/rate-setting/index.shtml>

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60.05-6 Delivery of DME

The reimbursable cost includes delivery, installation, and instruction on use of DME.

60.05-7 Labor

Labor charges are reimbursable for repairs to outright purchased DME only. Such charges are not reimbursed when the DME has a current warranty. Labor charges are not reimbursed for evaluation, assembly, fitting, or other installation on both new and used purchase DME. The Department is not responsible for labor charges for rented DME. Labor is also subject to Prior Authorization requirements of this Section (see Section 60.06).

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60.05-8 Replacement of DME

A. Replacement of all DME is allowed for the following reasons:

1. Irreparable damage or wear that affects the essential performance of the DME;

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2. A change in the member's condition that requires a change of DME. In such cases, the Department requires a current physician's or PCP's order documenting the need for the change; or
3. Repairing the DME (parts and labor) would cost more than sixty (60) percent of the replacement cost of the DME.

B. Additional Rules for Hearing Aids:

1. Members age twenty-one (21) and over, in addition to the criteria above, are eligible to receive one (1) hearing aid or one (1) replacement pair every five (5) years. PA will be required and must meet the criteria specified in section 60.06-2.
2. Members under the age of twenty-one (21), are eligible to receive a replacement hearing aid once per year as medically necessary and as identified and referenced in the MaineCare Benefits Manual, Section 94.

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Replacement will not be allowed in cases of malicious damages, culpable neglect, DME that has been sold, given away, thrown out, or wrongful disposal of DME, by the member or responsible party.

60.05-9 Prosthetics

Providers are responsible to warranty prosthetics for a period of one year to assure proper fit of products purchased by the Department. This will include adjustments, repairs and parts replacement associated with shrinkage, workmanship etc.

60.05-10 Requirements for Medical Supplies for Members Residing in Their Own Home

- A. Covered Medical Supplies may be provided to members residing in their own homes when prescribed by a physician or Primary Care Provider (PCP) and when it meets criteria utilized by the Department. Special rules apply for Medical Supplies provided to members in Nursing Facilities (NF) and Intermediate Care Facilities for individuals with Intellectual Disabilities (ICF-IID)
- B. Providers may not bill for routine Medical Supplies essential for the home health agency to carry out the physician's plan of care for members receiving home health services (see Section 40 of the MaineCare Benefits Manual).
- C. Post-surgical supplies will be covered as long as medically necessary as certified by the physician. Providers may not dispense more than a thirty-four (34) day supply at a time.

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60.05 POLICIES AND PROCEDURES (cont.)

60.05-11 Criteria for Durable Medical Equipment for Members Residing in Their Own Home

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- A. Durable Medical Equipment may be provided to members residing in their own homes when prescribed by a physician or PCP and when it meets criteria outlined in this Section. Special rules apply for equipment provided to members in nursing facilities (NF) and intermediate care facilities for individuals with Intellectual Disabilities (ICF- IID).
- B. Equipment or items that are used primarily for purposes of safety or physical restraint are not covered, including enclosed cribs and beds and barred enclosures. Physical restraints are defined as any physical or mechanical device, material, or equipment, attached or adjacent to the member's body that the member cannot remove easily and which restricts freedom of movement or normal access to one's body.

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- C. Items used for positioning that meet the definition of Medical Supplies or Durable Medical Equipment are not considered restraints and are covered when medically necessary.
- D. All continuous airway pressure (CPAP) devices and all bi-level pressure capability respiratory assist (Bi-PAP) devices will be rented on a three (3) month trial basis to determine appropriateness and member utilization.

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60.05-12 Medical Supplies and DME for Members Residing in a NF or ICF- IID

- A. Some Medical Supplies and DME may be covered for members residing in a NF or an ICF- IID when they are not included in that facility's rate of reimbursement. To be covered under this Section, the items must be prescribed by a physician or PCP and meet all criteria utilized by the Department. Supplies listed in Chapter II, Section 50, ICF- IID Services, as items included in the reimbursement rate for ICF- IID services may not be additionally covered under this Section. Some items require Prior Authorization, see Section 60.06.

Items that may be reimbursed under this Section for members residing in a NF or ICF- IID include

Items that may be reimbursed under this Section for members residing in a NF or ICF- IID include:

1. Wheelchair Amputee kit
2. Apnea monitor, pneumograms and supplies necessary for its use
3. Wheelchair Battery charger
4. Orthotic Braces
5. Colostomy bags and supplies

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6. Compressor nebulizers (hand held)
7. Wheelchair Cushions, special (silicone, etc.)
8. Electro larynx batteries
9. Ileostomy bags and supplies
10. Intermittent positive pressure breathing equipment (IPPB) and supplies
11. Medicated mist equipment room vaporizer
12. Nebulizer, ultrasonic
13. Orthotic devices, except for any device used for restraint
14. Oxygen except for emergency or as needed (prn) use
15. Oxygen cannula and facemasks
16. Oxygen concentrators
17. Oxygen liberators
18. Prosthetic devices - not dental
19. Replacement parts for items on this list
20. Ventilator
21. Ventilator supplies
22. Shoes - orthopedic shoes/lifts made from a mold or cast or with brace attached may be billed only by the orthotist or manufacturer (does not include diabetic shoes).
23. Shoes, diabetic
24. Shoes, with Dennis Brown bar
25. Slings, for extremities all types
26. Splints
27. Stockings, orthopedic, heavy surgical elastic
28. Supports (e.g., orthopedic corsets, cervical collars, etc.)
29. Wheelchairs, specially equipped only
30. Wheelchair batteries
31. Wound vac (rental only) and supplies
32. Hearing Aids

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- B. For purposes of reimbursement, an acute care hospital affiliated with a Nursing Facility through the same corporate structure may be considered a supplier of these items and may bill in conformance with the policies set forth in the ICF- IID. Services (Section 50) and NF Services (Section 67) sections of this Manual, as applicable. Hospitals that bill as a supplier or pharmacy must bill under the appropriate Section (Section 60 for Medical Supplies and Durable Medical Equipment or Section 80 for Pharmacy Services).

60.05-13 Medical Supplies and DME Not Covered for Members in an NF or ICF- IID

The Department will not reimburse DME providers for Medical Supplies and DME provided to MaineCare members residing in a NF or ICF- IID as part of that facility's regular rate of reimbursement. Supplies and equipment provided to members in a NF or ICF- IID as part of the regular rate are listed below and are included for reference only.

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These items may not be billed by either the facility or supplier.

Facilities that serve a special group of the disabled are expected to furnish that equipment which is normally used in their care (e.g. children's wheelchairs) as a part of their reasonable cost.

1. Alcohol, swabs and rubbing
2. Analgesics, non-prescription: a) aspirin: plain buffered and coated suppositories. b) Acetaminophen: tablets, liquids, and suppositories.
3. Antacids, non-prescription: a) aluminium/magnesium hydroxyde (ex. Maalox) b) Aluminium/magnesium hydroxyde with simethicone (ex. Mylanta, Maalox Plus) c) Calcium carbonate tablets (ex. Tums) d) Calcium carbonate/ magnesium hydroxyde tablets (ex. Roloids).
4. Alternating pressure pads, air mattresses, "egg crate" mattresses, gel mattresses
5. Applicators
6. Bandages
7. Band-Aids
8. Basins
9. Beds, standard hospital type, not therapy
10. Bed pans
11. Bed rails
12. Blood pressure equipment
13. Bottles, water
14. Canes
15. Calcium supplements, non-prescription (ex. Tums, Oscal).
16. Catheters
17. Catheter trays, disposable
18. Chairs, standard and geriatric
19. Commodes
20. Corner chair
21. Cotton
22. Cough syrup and expectorants, all non-prescription brands
23. Crutches
24. Cushions (e.g., comfort rings), excluding wheelchair cushions that require mounting hardware
25. Dietary supplements
26. Disinfectants
27. Douche trays, disposable
28. Dressings
29. Enema equipment
30. Enteral feeding, supplies, and equipment.
31. Facility deodorants
32. Gauze bandages, sterile or non-sterile

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33. Glucometers
34. General service supplies such as administration of oxygen and related medications, hand feeding, incontinency care, tray service, and enemas
35. Gloves, sterile or non-sterile
36. Gowns
37. Ice bags
38. Incontinency supplies (full brief- all sizes; bed pad; undergarment liners, disposable or reusable; under pads)
39. Irrigation trays
40. Laundry services, personal (including supplies and equipment)
41. Laxatives, non-prescription: Stool softeners (ex. Docusate sodium liquid or capsule). Bulk: (ex. Psyllium). Stimulants: (ex. Bisacodyl tablets and suppositories; docusate casanthranol, liquid and/or capsule). Enemas: (ex. Saline, phosphate types-except Fleets); oil retention. Misc.: milk of magnesia; glycerin suppositories; lactulose and analogs (when used as a laxative); mineral oil.
42. Lubricants, skin, bath oil
43. Mats – ICF- IID only
44. Ointments and creams, available over the counter, including petroleum jelly and hydrocortisone 0.5%
45. Ophthalmic lubricants, tears and ointments
46. Oxygen, for emergency and prn use only, including portable oxygen and equipment
47. Parenteral solutions, supplies and equipment
48. Pillows
49. Pitchers, water
50. Powders, medicated and baby
51. Prone boards
52. Restraints, poseys, thoracic chest supports, wedge pillows, etc.
53. Sand and water tables – ICF- IID only
54. Sensory stimulation materials– ICF- IID only
55. Sheepskin pads, any size or style
56. Shower chairs
57. Soap, including hypoallergenic
58. Special dietary supplements
59. Specimen containers
60. Sterile I.V. or irrigation solution
61. Stethoscopes
62. Supplies, non-prescription, necessary for the treatment for decubitis
63. Suture sets
64. Swabs, medicated or unmedicated
65. Syringes and needles
66. Tapes
67. Testing materials to be used by staff of facility, not to include materials normally included in psychometric testing – ICF- IID only

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6/13/15 | <ul style="list-style-type: none">68. Thermometers69. Towels, washcloths70. Tongue depressors71. Traction equipment72. Trapezes73. Tub seats74. Tubes, gavage, lavage, etc.75. Under pads76. Urinals77. Urinary drainage equipment and supplies (disposable)78. Velcro strips - ICF- IID only79. Vestibular boards – ICF- IID only80. Vitamins, non-prescription, all brands81. Walkers82. Wheelchairs, standard, including those with removable or adjustable trays, arm and leg rests including elevators, pediatric, "hemi" chairs, reclining wheelchairs, lightweight wheelchairs, high strength light-weight wheelchairs, ultra-light-weight wheelchairs, heavy duty wheelchairs, extra heavy-duty wheelchairs and other manual wheelchairs/base.83. Wipes, rectal medicated84. Routine personal hygiene and grooming items to include, but not be limited to items for shaving, shampooing, bathing, nail clipping (unless specified as a covered service when performed by a podiatrist as covered under the MaineCare Benefits Manual), haircutting or the services of a barber when requested and paid for by the member. Examples of items include but not limited to: combs, lotions, mouthwash, toothbrushes, toothpaste, shampoo (regular, medication and non-tears baby shampoo), sunscreen and tissues. |
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60.06 RESTRICTED SERVICES

Some Medical Supplies and DME have restrictions for coverage, described in this Section:

60.06-1 Physician Provided Supplies

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Physicians may bill for those Medical Supplies needed to perform office procedures, which are above and beyond what is usually included in a normal office visit. Reimbursement is made on the basis of acquisition cost only and may not include any additional markup. Physicians must bill under Chapter II, Section 90, Physician Services of the MaineCare Benefits Manual.

A physician may not be reimbursed for both prescribing and supplying Durable Medical Equipment to the same member, unless the Durable Medical Equipment is otherwise unobtainable or the DME typically requires no maintenance or replacement during the

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period used by a member. If these circumstances do exist, reimbursement to the prescribing physician for also supplying DME shall be on the basis of the acquisition cost of the DME to the physician. The prescribing provider must maintain a copy of the invoice to support such claims. In addition, this policy shall also apply to any entity in which the physician has direct or indirect proprietary interest. All transactions are subject to State and Federal restrictions regarding self-referral.

DME providers may not bill for items delivered to a member in a physician's or PCP's office.

60.06-2 Prior Authorization (PA) Requirements:

Some services and procedures require Prior Authorization in order for MaineCare to provide payment. The Department or its Authorized Entity processes Prior Authorization requests. More information on the PA process is in MaineCare Benefits Manual, Chapter I. Not all of the Medical Supplies and DME that require Prior Authorization are detailed in this Section. Providers should research each item on the MaineCare website to assure it is covered and check whether it requires PA, can be found at:

<https://mainecare.maine.gov/Default.aspx> which includes a link to the PA portal.

The Department reserves the right to require an evaluation by appropriate clinical professionals of its choice before granting PA. The Department requires, that for some DME medical supplies and medical equipment, providers meet Prior Authorization criteria that are industry recognized criteria utilized by a national company under contract by accessing the PA portal website found at: <https://mainecare.maine.gov/Default.aspx> which will include a link to the PA portal.

In cases where the criteria are not met, the Provider/Member may submit additional supporting evidence such as medical documentation, to demonstrate that the requested service is medically necessary.

Providers must make requests for PA on the Department's approved form and get approval prior to the date of service. For prior authorization, contact information and where to send completed prior authorization forms, visit the MaineCare Services website at:

<https://mainecare.maine.gov>.

Proper documentation includes proof of acquisition cost or a price quote from a manufacturer. If a claim is not equal to the exact amount of the Prior Authorization, a subsequent adjustment to the authorization may be made with appropriate documentation. Claims should not be submitted until the adjustment is made. Alternatively, the Department may choose to issue a letter approving the request for Prior Authorization without assigning an approved amount.

Once documentation of Adjusted Acquisition cost is received from the provider, an allowable amount will be assigned by MaineCare staff. A completed Medicare

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Certificate of Medical Necessity Form shall include itemized Adjusted Acquisition cost and usual and customary charges for the equipment being supplied.

The Department reserves the right to request detailed documentation including cost of materials, labor costs and total hours for the manufacture or fabrication of orthotic and prosthetic devices. This information may be estimated prior to the manufacture or fabrication; however, actual costs must be submitted upon completion. Non-compliance may result in denial of payment or recoupment of payments.

The Department requires Prior Authorization (PA) for Medical Supplies and equipment including but not limited to the following:

1. Items with Cost Exceeding \$699.00

Prior authorization (PA) is required for any medical supply costing MaineCare more than \$699.00. The item must be prescribed by a physician or PCP, and be the most cost-effective item available that meets the medical needs of the member.

When determining whether a piece of DME meets the threshold requirement of having MaineCare allowed amount above \$699.00, the cost of all related pieces of equipment must be added together and totaled before applying the criteria. For example, the cost of a wheelchair must be considered to be the sum of the cost of each of its components, including but not limited to: foot plates, wheels, wheel rims, armrests, arm troughs, etc. Should the need arise for an unanticipated component, that item must have PA, regardless of price.

2. Orthotic and Prosthetic DME

Custom molded orthotic and prosthetic items are only covered when the requirements and/or criteria of this Section and other Sections of the MaineCare Benefits Manual, including Section 90, Physician Services, or Section 95, Podiatric Services are also met. All custom made orthotics require Prior Authorization.

a. Orthotic Device: A mechanical device which is intended and fashioned to support or correct any defect or deformity or to improve the function of movable parts of the body and generally known as a "brace" or "orthosis." The orthotic device must be specifically ordered by a physician or PCP and may not be standard equipment used by the general population.

b. Prosthetic device: An artificial substitute for a missing body part (i.e., arm, leg, eye), not including dentures.

3. Rental equipment, Except in Emergency Situations

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Rental equipment requires PA, except in emergency situations. Oxygen is considered a rental.

In an emergency, the Department does not require PA to rent standard equipment for up to thirty (30) days. The Department will pay the rental for this emergency period. In this section, the Department defines emergency as a situation where the member would not otherwise be able to return home from a hospital, rehabilitation facility, or nursing home, or when a physician or PCP determines a member must have the equipment within twenty-four (24) hours.

The provider must request PA authorization within thirty (30) days of providing the equipment if it is necessary to continue the rental beyond thirty (30) days. The Department will deny reimbursement beyond the thirty (30) day emergency period

if the provider does not make this request. The Department will decide, within thirty (30) days of the date the PA is requested, whether to approve, defer, or deny authorization for the rental beyond the thirty (30) day emergency period.

4. Miscellaneous DME

Miscellaneous DME, including those billed under the Healthcare Common Procedure Coding System (HCPCS) code E1399 or any other DME billed under another code, which contains the phrase "miscellaneous," "accessories," "not otherwise specified" or "not otherwise classified" in its description when the MaineCare allowed amount exceeds \$99.99 requires PA.

5. DME Parts

DME parts for member-owned DME previously supplied and covered under MaineCare require PA. For example, a part related to a wheelchair that previously required PA would also require PA. DME parts that fall under warranty will not be covered.

The Department is not responsible for the cost of parts for rented DME.

6. Phototherapy lamps

Such lamps will only be covered when the medical criteria in the Appendix of this rule have been met.

7. Repairs to DME

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Repairs to member-owned DME with a total cost (parts and labor) exceeding sixty percent (60%) of replacement cost require PA, at which time the Department will decide if replacement of the DME is appropriate.

PA is required for any repair if replacement parts, labor, or the combination are over \$699.00 to repair medically necessary DME. The Department reserves the right to request documentation necessary to validate medical necessity before PA is granted.

Reimbursement is not allowed for repair of any DME that is still under warranty.

The Department is not responsible for the costs associated with repairs to rented DME.

8. Outright Purchase of Used Equipment

To qualify for PA, information on the Department's approved PA form or the appropriate Certificate of Medical Necessity (CMN) must indicate that the same warranty is offered on used equipment as on new equipment. The equipment being reconditioned shall not exceed the expense for new equipment.

9. Incontinence supplies

Medically necessary incontinence supplies, that exceed the allowed limits, require PA.

10. Enteral and Parenteral Formula

All enteral and parenteral formulas require PA.

The Department will accept the appropriate Medicare Certificate of Medical Necessity (CMN) in place of the Department's approved PA form. The CMN form must be completed in accordance with Medicare guidelines.

11. Hearing Aids for members age twenty-one (21) and over require Prior Authorization.

12. Other Items Subject to Coverage Limitation

Some items subject to coverage limitations may be covered in excess of the limitation under limited circumstances when prior authorized by the Department. These items include power operated vehicles and wheelchairs, hospital beds, standard mattresses for hospital beds, prosthetic devices to allow functional mobility, nebulizers, respiratory suction pumps, CPAP and Bi-Pap devices and supplies. See Limitations in this Section for additional requirements.

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60.06 RESTRICTED SERVICES (cont.)

60.06-3 Exceptions to Prior Authorization Requirements:

The following exceptions apply to MaineCare Prior Authorization (PA) requirements:

1. A member has received Prior Authorization to reside out of state due to an emergency medical need, is living out-of-state and now requires medically necessary DME or supplies which cannot be supplied by a MaineCare enrolled provider.
2. Prior Authorization for Hearing Aids and accessories are not required for members under the age of twenty-one (21), with the exception of miscellaneous procedure codes which do require Prior Authorization.

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60.06-4 Criteria for Specific Medical Supplies and DME

See Appendix for Specific Criteria for coverage of medical equipment and supplies.

60.07 LIMITATIONS

Changes in technology alone do not necessitate replacement or upgrades in equipment. If it is medically necessary for a member to exceed any of the listed limits, the PCP must submit a request for Prior Authorization (PA) and provide supporting medical documentation to establish the medical necessity. All limits in this Section are based on a twelve month period. Unless specified, limits apply to all members twenty-one (21) years of age and older.

60.07-1 Limitations for Members Twenty-one (21) years of Age and Older

A. Orthopedic shoes and other supportive devices for the feet

Orthopedic shoes and other supportive devices for the feet generally are not covered. However, shoes that are an integral part of a leg brace, and therapeutic shoes such as those furnished to diabetics, are covered.

1. Items classified with HCPCS Level II codes as Orthotic Procedures under the category, Orthopedic Shoes, under the sub-headings, Inserts, (not including Inserts and/or Modifications classified as HCPCS Level II codes as Medical and Surgical Supplies under the category, as described in 60.07-1(A)(4)(b)), Arch Support- Removable-Premolded, Shoe Modifications-Wedges or Shoe Modifications-Heels are limited to two (2) units (meaning 2 shoes or 1 pair) per member per year.
2. Items classified with HCPCS Level II codes as Orthotic Procedures under the category, Orthopedic Shoes, under the sub-heading

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Orthopedic Footwear including the word “shoes” are limited to one (2) units (2 shoes or 1 pair) per year; the same limit applies to all other items under this sub-heading.

3. Items classified with HCPCS Level II codes as Orthotic Procedures under the category, Orthopedic Shoes, under the sub-heading Shoe Modifications-Lifts, are limited to eight (8) units per member per year (units are one (1) inch increments).

4. Items classified with HCPCS Level II codes as Medical and Surgical Supplies under the category:

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Diabetic Shoes, and fittings are limited to two (2) units per member per year (meaning 1 pair or 2 fittings), Modifications and inserts for Diabetic Shoes are limited to a combined total of six (6) units per member per year.

5. Items classified with HCPCS Level II codes as Orthotic Procedures under the category, Orthopedic Shoes, under the sub-heading Abduction and Rotation Bars, excluding the words “abduction rotation bar” are limited to one (2) units (2 shoes or 1 pair) per year.

B. Nebulizers

Nebulizers are limited to one per member every five (5) years.

C. Incontinence Supplies

1. The monthly service limits for diapers and other disposable incontinence products for those who are twenty-one (21) years and older are as follows:

- a. Disposable briefs or pull ons are limited to 8 units per day for adults;
- b. Disposable personal pads, large sized disposable under pads, liners, shields, guards, and undergarments are limited to 1 case (150) -per 36 day period for adults;
- c. Disposable non-sterile gloves are limited to 5 boxes (at 100 per box) or 500 gloves per member per 36 day period for adults.

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2. Incontinence supplies are not covered for children under five (5) years of age and younger. If it is medically necessary for a child age five (5) years

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and younger to use incontinent supplies, then a DME provider may submit a request for Prior Authorization which must include sufficient supporting medical documentation from the PCP (i.e., specific medical exam records and supporting medical literature that shows that the member's medical condition causes incontinence that would not otherwise be normally expected in this age group) to establish the medical necessity and a bowel/bladder training program has failed. The request will be reviewed and decided by the Department or its Authorized Entity.

3. Providers may provide up to a 72-day supply. Members may refuse to accept more than a 36-day supply.

D. Power Mobility Devices (PMD), Power Operated Vehicles and Manual Wheelchairs

Reimbursement for Power Mobility Devices requires PA whether or not the member is eligible for Medicare or other third party insurance. See Power Mobility Device (PMD) guidelines in the Appendix of this rule.

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In the case of motorized wheelchair requests for Medicare/MaineCare dually eligible members, MaineCare will review the request and issue a Prior Authorization decision and the allowable reimbursement rate if approved. The decision must be issued prior to the purchase of any Power Wheelchair or Power Operated Vehicle (POV), and prior to the submission of any claims to Medicare. Any price changes for PWCs and POVs that have received Prior Authorization shall be treated in the same manner as all other price changes on prior authorized equipment.

The following principles apply unless providers can document the need to exceed the established limitation. The Prior Authorization Unit will process requests for exceptions to a limitation:

1. Power Operated Vehicles: Members will be limited to one (1) Power Operated Vehicle (i.e. scooter) every three (3) years, and cannot upgrade to a power wheelchair until the three (3) years have lapsed;
2. Manual or Power Wheelchairs: Members will be limited to one (1) wheelchair (i.e. manual or Power Wheelchair) every five (5) years;
3. Manual or Power Wheelchairs: Members who meet the eligibility requirements for both a prosthetic device necessary to allow functional mobility and a power or manual wheelchair must choose between the prosthetic device and a wheelchair and must sign a letter exercising their choice. A wheelchair will be provided in the interim on a rental basis for those members choosing a prosthetic device. Members may seek Prior

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Authorization for a manual wheelchair in addition to a prosthesis if medically necessary.

4. Regardless of the type, only one wheelchair at a time is reimbursable for each member.
5. Reclining wheelchairs are not medically necessary if sought only for positioning. See Appendix.
6. The member's condition must be such that without use of a wheelchair the member would otherwise be confined to a bed or a chair.
7. The primary purpose is not to allow the member to perform leisure or recreational activities.
8. Reimbursement is allowed for amputee kits for standard wheelchairs in a NF or ICF- IID. Reimbursement for a wheelchair with right or left-handed drive is allowed in case of arm amputee or paralysis.
9. 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.
10. Prior to provision, a written document must be submitted indicating that the equipment can freely pass through all entryways without the need for modification. It is the responsibility of the provider to submit documentation indicating that necessary modifications or structural changes have occurred prior to the request for authorization. (An exception may be granted for a member who needs a wheelchair during the winter months but is unable to make the necessary home modifications due to the frozen conditions.) The provider may not bill the Department for modifications or structural changes, as they are not a MaineCare-covered DME service.
11. If a member-owned PMD meets coverage criteria, medically necessary replacement items, including but not limited to batteries, are covered.
 - a. Reimbursement will not be allowed for repairs or replacement parts for any equipment under warranty.
12. A PMD is considered medically necessary for members who lack the capacity to ambulate a sufficient distance to accomplish essential activities of daily living within the home, defined as inability to ambulate at least one hundred (100) feet. MaineCare does not consider

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inability to climb stairs a medically necessary indication for a PMD. A PMD is not considered medically necessary to elevate a person to eye level or to extend a wheelchair bound person's reach. In addition, inability to navigate rough terrain outside the home is not considered a medically necessary indication for a PMD.

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13. When requesting Prior Authorization for a PMD in a NF or other setting in which there is continuous supervision, the requesting provider must document the member's medical necessity to be independently mobile beyond what can be provided by staff in that setting.
 14. The Department will not approve equipment for purposes other than medical necessity. (Examples: Needs related to vocational school, job or college do not meet the criteria for medical necessity. A PMD will be denied as not medically necessary when it is primarily used to allow a member to perform leisure or recreational activities. A PMD that is generally intended for outdoor use because of size or features is not covered.)
- E. Hospital beds
1. Reimbursement will be limited to one (1) hospital bed every five (5) years.
 2. Reimbursement will be limited to one (1) standard mattress (to fit a hospital bed) every two (2) years.
 3. Trapeze bars attached to bed will be limited to two (2) per lifetime.
 4. Cushioned headrest will be limited to one (1) per year.
- F. Other Limitations for Members Twenty-one (21) years of Age and Older
- a. Pressure Mattress Pads to include Gel and Dry are limited to one (1) per year.
 - b. Sitz bath is limited to one (1) per year.
 - c. Canes are limited to one (1) per year.
 - d. All walkers are limited to one (1) per year.
 - e. All commodes are limited to two (2) per five (5) year period.
 - f. Bath/shower chairs are limited to one (1) per five (5) year period.
 - g. Bath/tub wall rail is limited to two (2) per three (3) year period.
 - h. Raised toilet seat is limited to two (2) per three (3) year period.
 - i. Cough stimulating device is limited to two (2) per year.

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- j. All types of Intermittent Positive Pressure Breathing (IPPB) devices are limited to once per lifetime.
- k. Ultrasonic and Aerosol compressors with Small Volume Nebulizers (SVNEB) are limited to one (1) per year.
- l. Patient lift sling or seat is limited to one (1) per year.
- m. Hydraulic patient lift is limited to two (2) per lifetime.
- n. Transcutaneous Electrical Nerve Stimulator (TENS) units/treatment systems are limited to one (1) per year.
- o. Pneumonic Compression Devices (used to lymphedema and chronic venous insufficiency) are limited to one (1) device per year.
- p. Apnea monitors are limited to one (1) per year.
- q. Respiratory suction pumps
Respiratory suction pumps (home model, portable or stationary, electric), when purchased, are limited to one (1) per member every three (3) years; if paid for on a rental basis, the physician must document therapeutic benefit for renewal after ninety (90) days.
- r. Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airway Pressure (Bi-PAP) devices

To document the need for a CPAP and Bi-PAP device, the Department will accept sleep studies done within the three (3) years preceding the initial request. CPAP and Bi-PAP devices and supplies are limited to the following quantities:

- 1. Oral/nasal mask – 1 per three months
- 2. Oral cushion – 2 per month
- 3. Nasal pillow – 2 per month
- 4. Face mask – 1 per three months
- 5. Nasal appliance – 2 per month
- 6. Head gear – 1 per six months
- 7. Chin strap – 1 per six months
- 8. Tubing – 1 per month
- 9. Filter (disposable) – 2 per month
- 10. Filter (non-disposable) – 1 per six months
- 11. Oral interface – 1 per three months
- 12. Exhalation port – 1 per twelve months
- 13. Water chamber – 1 per month
- 14. Humidifier – 1 per five years
- 15. C-PAP – 1 per five years
- 16. Bi-PAP – 1 per five years

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60.07-2 Limitations for Hearing Aids:

A. Hearing aids shall be purchased from a licensed Audiologist or Hearing Aid Dealer & Fitter, utilizing a vendor contracted with the State of Maine Division of Purchases through the Hearing Aid procurement program found at:

<http://www.maine.gov/purchases/contracts/hearingaids.shtml>

1. Hearing aid accessories are not required to be purchased under contract.
2. Hearing Aids and accessories are covered on the basis of a hearing evaluation when in accordance with medical criteria specified or limited to:
 - a. Hearing Aids only: Adults age twenty-one (21) and over, one (1) hearing aid or one (1) replacement pair every five (5) years. PA will be required and must meet the criteria specified in section 60.06-2 of this chapter.
 - b. Hearing Aids only: Children under the age of twenty-one (21), replacement allowed once per year as medically necessary and as identified and referenced in the MaineCare Benefits Manual, Section 94.05-2.
 - c. Six (6) replacement batteries per month.
3. Back up or spare hearing aids and/or repairs to backup or spare hearing aids are not covered services.

60.08 PROGRAM INTEGRITY

Program Integrity (formerly Surveillance and Utilization Review) requirements are outlined in Chapter I of the MaineCare Benefits Manual.

60.09 REIMBURSEMENT

60.09-1 The reimbursement for “non-miscellaneous” Medical Supplies, Durable Medical Equipment and services, unless provided pursuant to a contract between the Department and the provider (this contract would be in addition to a MaineCare Provider Agreement), shall be the lowest of:

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- A. The maximum MaineCare allowed amount published on the Department’s website, <http://www.maine.gov/dhhs/audit/rate-setting/index.shtml> ;
- B. Medicare’s Allowed amount; or
- C. The provider's usual and customary charge.

60.09-2 Contract with the Department for DME/Medical Supplies

Where the Department has entered into a contract (separate from the MaineCare Provider Agreement) with a manufacturer or provider for the provision of DME/Medical Supplies, the following shall apply:

- A. If the manufacturer/provider serves as a supplier only and does not provide direct services to MaineCare members, the manufacturer/provider shall bill the MaineCare provider who purchases the DME/Medical Supplies, in accordance with normal business practices, and at a price that is contained in the contract with the Department.
- B. After the MaineCare provider who purchases the DME/Medical Supplies has paid the manufacturer/provider, the MaineCare provider can then bill MaineCare following the billing instructions outlined in this Section.

The Department will provide advance written notice to all providers that are required to purchase certain DME items from such manufacturers/providers.

60.09-3 Reimbursement for DME/Medical supplies considered to be “miscellaneous DME/Medical Supplies”

“Miscellaneous DME/Medical Supplies” means those DME/Medical Supplies billed under the Healthcare Common Procedure Coding System (HCPCS) code E1399 or any other DME/Medical Supplies billed under another code, which contains the phrase “miscellaneous,” “accessories,” “not otherwise specified” or “not otherwise classified” in its description. Miscellaneous codes can be used only if there has not been a nationally accepted code assigned to a product/service. Please reference the Healthcare Common Procedure Coding System (HCPCS) guide to identify whether a specific item has been assigned a nationally accepted code before billing the item as Miscellaneous.

Miscellaneous DME/Medical Supplies will be reimbursed as follows:

- A. If there is a Manufacturers’ Suggested Retail Price (MSRP) the reimbursement will be MSRP minus twenty percent (20%). Documentation must be submitted supporting the MSRP.

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60.09 REIMBURSEMENT (cont.)

- B. If there is no listed MSRP, reimbursement will be invoice cost plus thirty percent (30%). Providers will need to submit an invoice for payment.

60.09-4 Rentals, except for oxygen, shall be reimbursed at a monthly rate, for a period not to exceed twelve (12) months, equal to one-twelfth (1/12) of the MaineCare allowable purchase price published on the Department's website:
<http://www.maine.gov/dhhs/audit/rate-setting/index.shtml>

60.09-5 Oxygen supplies and equipment are reimbursed using two different monthly rental rates, one for portable gas or liquid oxygen and one for concentrator or stationary liquid oxygen. The MaineCare amount will be published at least annually and made available to providers on the Department's website: <http://www.maine.gov/dhhs/audit/rate-setting/index.shtml>. MaineCare will follow the 36-month cap on oxygen equipment rentals for members who have both MaineCare and Medicare and will only reimburse for the actual contents (EOB) to track the 36-month limit. When the time limit has passed, then the "content only" codes should be billed.

Claims shall be submitted in accordance with billing instructions provided by the Department, which include information regarding appropriate codes to be used by providers when billing for these services. Oxygen requires annual Prior Authorization. The monthly rental rate is the lowest of:

- A. The maximum MaineCare rental amount published at least annually on the Department's website and made available to providers;
- B. The lowest rental amount paid by Medicare; or
- C. The provider's usual and customary rental charge.
- D. Hearing Aids Trial Period: Following a trial period of at least thirty (30) days, the Audiologist or Hearing Aid Dealer & Fitter will provide written confirmation that the hearing aid meets the member's need and should be purchased.

60.09-6 Any manufacturer's rebate shall be paid to the Treasurer, State of Maine. Providers shall forward or otherwise pay to the Treasurer of the State of Maine all manufacturers' rebates associated with Durable Medical Equipment or Medical Supplies provided to members pursuant to this Section of the MaineCare Benefits Manual.

60.09-7 In accordance with Chapter I of the MaineCare Benefits Manual, it is the responsibility of the provider to seek payment from any other resource that is available for payment of a rendered service prior to billing the MaineCare Program.

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60.09 REIMBURSEMENT (cont.)

Special provisions apply for Power Mobility Devices (PMD):

- A. Prior to the provision of a PMD, providers must submit a request for reimbursement to MaineCare for those members who are dually eligible for MaineCare and Medicare, see Prior Authorization Requirements in this Section;
- B. The total payment will be no more than the established MaineCare allowance for PMDs;
- C. The payment to the provider shall be reduced by any amounts paid by Medicare;
- D. MaineCare's allowance in non-assigned cases shall not be limited by the Medicare determination of medical necessity or allowable reimbursement rate; and
- E. Services initially prior authorized by MaineCare will reflect a reduction in reimbursement equal to the Medicare average payment. Subsequent adjustments will be authorized following a review of all Medicare Explanations of Benefits or written correspondence.

60.09-8 Payment by the Department for any good or service provided shall constitute full payment for the supplies or equipment furnished and no additional charge shall be made to, or on behalf of, the eligible member. Some services and procedures require Prior Authorization in order for MaineCare to provide payment.

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60.10 CO-PAYMENT

Co-payment dispute resolution procedures are described in Chapter I of the MaineCare Benefits Manual.

60.10-1 Co-payment amount

- A. A co-payment will be charged to each MaineCare member receiving items of equipment or supplies. The amount of the co-payment shall not exceed \$3.00 per day for equipment or supplies, according to the following schedule:

MaineCare Payment for Service	Member Co-payment
\$10.00 or less	\$.50
\$10.01 - 25.00	\$1.00
\$25.01 - 50.00	\$2.00
\$50.01 or more	\$3.00

- B. The member shall be responsible for co-payments up to \$30.00 per month whether the co-payment has been paid or not. After the \$30.00 cap has been

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reached the member shall not be required to make additional co-payments and the provider shall receive full MaineCare reimbursement.

- C. Members shall not be charged more than \$3.00 per month for any rental service.
- D. No provider may deny services to a member for failure to pay a co-payment. Providers must rely upon the member's representation that he or she does not have the cash available to pay the co-payment. A member's inability to pay a co-payment does not, however, relieve him/her of liability for a co-payment.
- E. Providers are responsible for documenting the amount of co-payments charged to each member (regardless of whether the member has made payment) and shall disclose that amount to other providers, as necessary, to confirm previous co-payments.

60.10-2 Co-payment exemptions. No co-payment may be imposed with respect to the following services:

- A. All exemptions listed in Chapter I, and
- B. All oxygen and oxygen equipment services.

60.11 BILLING INSTRUCTIONS

- A. Providers must bill in accordance with the Department's "Billing Instructions for Medical Supplies and Durable Medical Equipment."
- B. All claims submitted must include a primary diagnosis code.
- C. Providers may not submit separate claims for DME that is considered to be part of the initially authorized equipment.
- D. Providers may not bill more than a thirty-four (34) day supply at a time unless otherwise specified in this policy.
- E. All claims must be submitted on a CMS 1500 claim form.
- F. A listing of procedure codes included in the Department's fee schedule, can be found at: <http://www.maine.gov/dhhs/audit/rate-setting/index.shtml>

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**Please be advised that there is no Chapter III for this section of policy. For information regarding reimbursement please visit <http://www.maine.gov/dhhs/audit/rate-setting/index.shtml>. For information regarding Prior Authorizations and coding please visit : <https://mainecare.maine.gov/Default.aspx> which

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60.11 BILLING INSTRUCTIONS (cont.)

will contain a link to the HealthPAS portal. Please be advised that only MaineCare providers with a Trading Partners username and password will be able to access the HealthPAS website.

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60.12 APPENDIX I

MEDICAL CRITERIA

The following Appendix provides specific definitions and criteria for Prior Authorization (PA). Unless indicated otherwise, all items in this Appendix require Prior Authorization before reimbursement will be made.

In addition, the Department requires that for some DME Medical Supplies and medical equipment, providers meet Prior Authorization criteria that are industry recognized criteria utilized by a national company under contract by accessing the OMS website, which will include a link to the PA portal. In cases where the criteria are not met, the Provider/Member may submit additional supporting evidence such as medical documentation, to demonstrate that the requested service is medically necessary.

- A. Home Use of Oxygen Criteria
- B. Seat lift mechanisms
- C. Pneumatic Compression Devices (used for lymphedema and chronic venous insufficiency)
- D. Augmentative and Alternative Communication Device (AAC device)
- E. Continuous positive airway pressure (CPAP) and bi-level positive airway pressure (Bi-PAP) devices and supplies
- F. Bone Growth Stimulators
- G. Microprocessor Controlled Knee Prostheses
- H. External Insulin Infusion Pumps
- I. Hospital Beds
- J. Negative Pressure Wound Therapy (NPWT)
- K. Hearing Aids: Amplifying devices that compensate for impaired hearing.

Each eligible member may receive covered services that are medically necessary within the limitations of this section. DHHS reserves the right to request additional information to evaluate medical necessity and may require utilization review for all services reimbursed under Section 60.12(K).

Hearing Aids must be considered medically necessary when prescribed by a qualified MD, DO, PA, or APRN when the following clinical criteria have been met:

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1. Monaural – one (1) hearing aid:

A. MaineCare Members under twenty-one (21) years of age; must

- i. Have an otologic evaluation performed by a primary care provider or otolaryngologist and a clinical audiology evaluation to determine the need for amplification. The sequence of such evaluation is variable depending upon source of referral; and
- ii. Receives a hearing aid orientation that involves instruction in the use and care of the instrument and counseling regarding expectations, limitations, and adjustment to amplification as well as ancillary needs (i.e. auditory rehabilitation, communication therapy, special educational placement, parent/member responsibilities).

B. MaineCare Members twenty-one (21) years of age and older; must

- i. Have an otologic evaluation performed by a primary care provider or otolaryngologist and a clinical audiology evaluation, to determine the need for amplification. The sequence of such evaluation is variable depending upon source of referral; and
- ii. Meet the hearing loss severity criteria of Moderate to Severe: 41-90 dB HL; and
- iii. Obtain Prior Authorization approval.

2. Binaural (2) two hearing aids:

A. MaineCare Members under twenty-one (21) years of age; must;

- i. Have an otologic evaluation performed by a primary care provider or otolaryngologist and a clinical audiology evaluation to determine the need for amplification. The sequence of such evaluation is variable depending upon source of referral; and
- ii. Receives a hearing aid orientation that involves instruction in the use and care of the instrument and counseling regarding expectations, limitations, and adjustment to amplification as well as ancillary needs (i.e. auditory rehabilitation, communication therapy, special educational placement, parent/member responsibilities).

B. Eligible Members twenty-one (21) years of age and older, must;

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- i. Have an otologic evaluation performed by a primary care provider or otolaryngologist and a clinical audiology evaluation to determine the need for amplification. The sequence of such evaluation is variable depending upon source of referral, and
- ii. Obtain Prior Authorization approval, and
- iii. Have documented hearing loss severity criteria of Moderate to Severe: 41-90 dB HL in each ear; and
- iv. Attests to be attending a post-secondary school at any educational level and the prescribing physician has determined that the member will be unable to meet the audiometric requirements to attend school without the use of binaural hearing aids; or
- v. Attests to receiving vocational training and the prescribing physician has determined that the member will be unable to meet the audiometric requirements to attend school without the use of binaural hearing aids; Or
- vi. Report having current employment and the prescribing physician has determined that the member will be unable to meet the audiometric requirements of the job without the use of binaural hearing aids; Or
- vii. Meet the definition of statutory blindness per Federal Regulations §42 CFR 435.530

- C. MaineCare covers the following services using the following MaineCare criteria in addition to using industry recognized criteria utilized by a national company under contract, which can be found at: <https://mainecare.maine.gov/Default.aspx> which will contain a link to the PA portal.

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L. Orthotics & Prosthetics

The Department requires that orthotic or prosthetic services be provided by a licensed occupational therapist, a licensed physical therapist, certified orthotist or prosthetist (American Board for Certification) or an accredited orthotist (Board for Orthotist Certification) when an orthotic or prosthetic device is prior authorized. PA is required for all custom molded orthotics and prosthetics regardless of price using evidence-based criteria and/or may use criteria based on national standards for evaluating what is considered medically necessary.

- III. MaineCare covers the following services only when the Department has granted Prior Authorization using the criteria outlined below:

M Home blood glucose monitors and test strips

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Coverage of home blood glucose monitors is limited to members meeting the following conditions:

1. The member must be diagnosed as a Type I or Type II diabetic; and
2. The member's physician or PCP states that the member is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the member may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the member to assure that the intended effect is achieved. This is permissible if the record is properly documented by the member's physician or PCP; and
3. The device is designed for home rather than clinical use; and
4. (For members with visual impairments only) – In addition to criteria (1 – 3) above, the member's physician or PCP must certify that he or she has a visual impairment severe enough to require use of a special monitoring system designed specifically for use by those with visual impairments.

All diabetic meters and test strips are subject to coverage from the list of preferred meters as indicated on the Department's Preferred Drug List (PDL) in order to be covered without Prior Authorization. Providers should access the PDL on the web at:

<http://www.mainearepdl.org/index.pl/pdffiles/mainecare-pdl>.

Prior Authorization of non-preferred meters and test strips will only be approved after the provider submits documentation of medical necessity showing clinically significant features not available on any of the preferred meters. DME dealers will be required to follow the billing instructions as posted at:

<https://mainecare.maine.gov/Billing%20Instructions/Forms/AllItems.aspx> regarding the need to include the NDC for diabetic testing meters and strips in order for a claim to be payable. Claims without the NDC included or with a non-preferred NDC listed will be rejected for payment unless a Prior Authorization has been obtained prior to supplying the product(s).

As provided under state and federal guidelines, the Department may enter into a special purchasing arrangement with certain vendors of diabetic test strips and meters. Items purchased under a contract with the Department are considered *preferred* products and require special billing procedures. The Department will provide purchasing and billing instructions, in writing to DME providers with respect to these preferred products.

N. Enteral and Parenteral nutritional therapy

Enteral or parenteral nutritional therapy is covered for members who have a chronic illness or trauma that cannot be sustained through oral feeding.

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Coverage for nutritional therapy may be provided to a member that has an inoperative internal body organ or function thereof.

If the coverage requirements for enteral or parenteral nutritional therapy are met, related supplies, equipment, and nutrients are also covered under the conditions in the following paragraphs.

1. Parenteral Nutrition Therapy-Daily parenteral nutrition is considered reasonable and necessary for a member with severe pathology of the alimentary tract, which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the member's general condition.

For parenteral nutrition therapy to be covered, the provider's records must contain a physician's or PCP's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. If the claim involves an infusion pump, sufficient evidence must be maintained to support a determination of medical necessity for the pump. Providers must bill for pumps based on the reasonable charge for the simplest model that meets the medical needs of the member as established by medical documentation.

Nutrient solutions for parenteral therapy are routinely covered for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician or PCP, establishes that the member, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive pre-mixed solutions only under the latter circumstances.

2. Enteral Nutrition Therapy-Enteral nutrition is considered reasonable and necessary for a member with a functioning gastrointestinal tract who, due to pathology in or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes if it can be provided safely and effectively in the home.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the member cannot be maintained with oral feeding. The provider's records must contain a physician's or PCP's

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written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician or PCP) to permit an independent conclusion that the member's condition meets the requirements of the prosthetic device benefit and that

enteral nutrition therapy is medically necessary and are to be reviewed at periodic intervals and additional medical documentation considered necessary is to be obtained as part of this review. Reimbursement is limited to no more than one month's supply of enteral nutrients at any one time.

If the claim involves a pump, sufficient medical documentation must be maintained by the provider to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, and dumping syndrome.

Payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the member as established by medical documentation.

O Cochlear Implant Device

A cochlear implant device is an electronic device, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the member to capture, analyze and code sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are profoundly hearing impaired.

MaineCare coverage of this device is provided for those members who meet all of the guidelines set forth in Physician's policy, Section 90, of the MaineCare Benefits Manual.

P. Intermittent Positive Pressure Breathing (IPPB) Equipment

IPPB equipment requires Prior Authorization that will be granted only when medical necessity is documented by a physician or PCP.

Q. Home Traction

1. The member must have an orthopedic impairment, which requires traction equipment, which prevents ambulation during the period of use, and must meet the following criteria:

- a. The member has failed to respond to routine physical therapy, and
- b. Travel to a facility to receive physical therapy is detrimental to the member's physical health. This must be verified by a physical therapist or a physician or PCP.

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2. The supplier shall provide the following services, which are included in the reimbursement for traction:
 - a. Set-up of traction equipment
 - b. Training of member or caregiver; and
 - c. Maintenance of equipment

R. Apnea Monitor

An apnea monitor is considered necessary for infants if any of the following is present:

1. An infant who has a severe apparent life threatening episode (ALTE) that required mouth-to-mouth resuscitation or vigorous stimulation;
2. Any pre-term infant who has had an episode of apnea;
3. Any infant who has had a sibling who has died of sudden infant death syndrome;
4. A diagnosis of central hypoventilation, gastro esophageal reflux;
5. Any infant with a tracheotomy;
6. Any infant whose mother used cocaine or opiates during pregnancy; or
7. Any infant whose mother is a multiparous adolescent.

S. Incontinence Supplies

All incontinence supplies that exceed the monthly limits require PA. Diapers and incontinence supplies are covered for all members when prescribed by a physician or PCP and the following criteria are met:

1. The member has a medical condition resulting in incontinence and has failed to respond to a bowel/bladder training program or;
2. The medical condition being treated results in incontinence and the member would not benefit from a bowel/bladder training program;

T. Manual Wheelchairs

Manual Wheelchairs (including Standard wheelchairs) are covered if:

- a. Criteria 1, 2, 3, 4, 5 and 6 (below) are met; and

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- b. Criterion 7 or 8 (below) is met.
 - 1. The member has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADL) 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 an MRADL entirely, or
 - b. Places the member at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
 - c. Prevents the member from completing an MRADL within a reasonable time frame; or
 - d. Renders the member unable to ambulate at least one hundred (100) feet.
 - e. The member's condition must be such that without the use of a wheelchair, the member would otherwise be confined to a bed or a chair.
- 2. The member's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker.3. The member's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual wheelchair that is requested.
 - 3. Use of a manual wheelchair will significantly improve the member's ability to participate in MRADLs and the member will use it on a regular basis in the home.
 - 4. The member has not expressed an unwillingness to use a manual wheelchair in the home.
 - 5. Documentation of the member's current height and weight are included in the member's medical record.
 - 6. The member has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair that is provided in the home during a typical day. Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity

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or absence of one or both upper extremities are relevant to the assessment of upper extremity function.

7. The member has a caregiver who is available, willing, and able to provide assistance with the wheelchair.

U. Specialty Wheelchairs

Payment may be made for a specialty wheelchair even though it is more expensive than a standard wheelchair when special circumstances warrant that payment. For example, a narrow wheelchair may be required because of the narrow doorways of a member's home or because of a member's slender build. Such difference in the size of the wheelchair from the standard model is not considered a deluxe feature.

A physician's or PCP's certification or prescription is not required when it can be determined from the information on file or other sources that a specialty wheelchair (rather than a standard one) is needed to accommodate the wheelchair to the place of use or the physical size of the member.

In addition, all criteria for a manual wheelchair must be met. Reclining or tilt-in space wheelchairs are not medically necessary if sought only for positioning and are only covered when the following criteria are met:

1. Tilt-in-space manual or Power Wheelchair

Impairments that would require the use of a tilt-in-space wheelchair

- a. Unable to perform independent effective pressure relief and needs more than additional pressure relief cushion seating.
- b. Excessive extensor tone/spasticity of trunk/lower extremity.
- c. Intermittent bladder catheterization required as part of a bladder management program and unable to independently transfer to bed.
- d. Reduced/low tone and poor trunk/head control with the inability to maintain an upright head or trunk position.

2. Reclining manual or Power Wheelchair.

Impairments that would require the use of a reclining wheelchair.

- a. Unable to perform independent effective pressure relief and needs more than additional cushion seating.

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- b. Recumbent positioning required for intermittent bladder catheterization that is required as part of a bladder management program and unable to independently transfer to bed.
- c. Fixed hip angle
- d. Trunk cast/brace if the reclining option for positioning is due to the limitations placed on the member from the cast or brace.

V. Power Mobility Devices (PMD)

1. General Criteria for All Power Mobility Devices (PMD):

PMDs are covered if a wheelchair is medically necessary and the member is unable to operate a manual wheelchair. All PMDs require Prior Authorization by the Department. Supporting documentation described below must be provided to insure that all coverage requirements are met. The following criteria apply:

- a. A specialist in physical medicine, orthopedic surgery, neurology, or rheumatology must provide an evaluation of the member's medical and physical condition and a prescription for the vehicle to assure that the member requires the vehicle and is capable of using it safely. If the prescription is for a PMD, the documentation should also include a statement indicating the member is able to transfer safely in and out of the PMD, and has adequate trunk stability to safely ride in the PMD. When the Prior Authorization Unit determines that such a specialist is not reasonably accessible, e.g., more than one (1) day's round trip from the member's home, or the member's condition precludes such travel, a prescription from the member's physician or PCP is acceptable with the documentation described above completed by the member's physician. Further, the Department may request an evaluation by an occupational therapist and/or physical therapist in place of the previously listed specialists.
- b. Prior to provision, a provider is required to obtain a written prescription for the PMD, signed and dated by the specialist who performed the evaluation, within 45 days of the evaluation.
- c. Also prior to provision of a PMD, the provider must provide documentation to the Department, signed by the member, indicating that the member has been informed that pursuant to Section 60.07 of these rules—members will be limited to one (1) POV every three (3) years and cannot upgrade to a Power Wheelchair until the three (3) years have lapsed.

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When evaluating the need for a PMD, the Department reserves the right to request a second opinion of its choice from an occupational therapist, physical therapist, physiatrist, physician or PCP concerning medical

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- d. Necessity of the prescribed equipment for any request for Prior Authorization for a PMD.
- e. An itemized list of all necessary parts and cost and usual and customary price shall be provided to the Department, as well as documented medical evidence justifying the need for the prescribed equipment.
- f. All criteria for a manual wheelchair must be met.
- g. The member must have a letter from his or her physician stating that the member's condition is not expected to deteriorate significantly for three (3) years. This only applies to POV's.

Coverage criteria (a-c above) must be met for a PMD or a push-rim activated power assist device to be covered. Additional coverage criteria for specific devices are listed below.

- 2. The member has a mobility limitation that significantly impairs his/her ability to consistently walk, with or without the aid of appropriate assistive devices (such as prostheses, orthoses, canes or walkers) safely and sufficiently to carry out typical mobility related activities of daily living (MRADLs). A mobility limitation is one that:
 - a. Prevents the member from accomplishing an MRADL entirely, or
 - b. Places the member at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
 - c. Prevents the member from completing an MRADL within a reasonable time frame.
- 3. The member's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted assistive device such as an orthosis, cane or walker.
- 4. The member does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair safely and sufficiently to perform typical MRADLs.

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- a. 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.
- b. An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate non-powered accessories.
5. The member is able to:
 - a. Safely transfer to and from a POV, and
 - b. Operate the tiller steering system, and
 - c. Maintain postural stability and position while operating the POV in typical environments of use.
6. The member's mental capabilities (e.g., cognition, judgment) and physical capabilities (e.g., vision) are sufficient for safe mobility using a POV in typical environments of use.
7. The member's home provides adequate access between rooms, maneuvering space and surfaces for the operation of the POV that is provided.
8. The member's weight is less than or equal to the weight capacity of the POV that is provided.
9. Use of a POV will significantly improve the member's ability to participate in typical MRADLs in customary environments of use.
10. The member is willing and able to use a POV.
11. The member is a very active scooter user whose typical daily activities require mobility on smooth, level surfaces (tile or low pile carpet), paved surfaces, thick carpeting or higher than 1" thresholds or transitions between floor surfaces, outdoor environments with steep ramps, hills in the natural environment, or gravel, and grassy surfaces that are not level.
12. The member's typical mobility needs require extended distance travel and may require minimal specialized seating configurations (e.g. non-standard seat size, back angle adjustment).
13. The member has the mental and physical capabilities to safely operate the Power Wheelchair that is provided; or

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14. If the member is unable to safely operate the Power Wheelchair, the member 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
15. The member's weight is less than or equal to the weight capacity of the Power Wheelchair that is provided.
16. The member's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the Power Wheelchair that is provided.
17. Use of a Power Wheelchair will significantly improve the member's ability to participate in typical MRADLs in customary environments of use. For members with severe cognitive and/or physical impairments, participation in MRADLs may require the assistance of a caregiver.
18. The member is willing and able to use a Power Wheelchair.
 - a. Power Operated Vehicle (POV) Coverage Criteria

Group 1 POV – is covered if all of the coverage criteria 1-10 are met. If coverage criteria 1-10 are not met, the individual is not medically eligible for Group 1 POV coverage.

Group 2 POV – is covered if all the coverage criteria 1-10 are met. If coverage criteria 1-11 are not met, the individual is not medically eligible for Group 2 POV coverage.
 - b. Power Wheelchair (PWC) Coverage Criteria

A Power Wheelchair is covered if:

 - (1) Coverage criteria (1)-(3) are met; and
 - (2) The member does not meet coverage criterion (4), (5), or (6) for a POV; and
 - (3) Either criterion (13) or (14) is met; and
 - (4) Criterion (15), (16), (17), and (18) are met; and
 - (5) Any coverage criteria pertaining to the specific wheelchair type (see

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If the PWC will be used in typical environments of use and coverage criteria (1)-(5) are not met but the criteria for a POV are met, payment will be based on the allowance for the least costly medically appropriate alternative. If the PWC will be used in typical environments of use and coverage criteria (1)-(5) are not met and the criteria for a POV are not met, it will be denied as not medically necessary.

c. Additional Power Wheelchair Criteria by Group

- (1) Group 1 PWC or a Group 2 PWC – is covered if all of the coverage criteria (1)-(5) above for a PWC are met and the wheelchair is appropriate for the member's weight.
- (2). Group 2 PWC with a sling/solid seat – is covered if:
 - a. All of the coverage criteria (1)-(5) above for a PWC are met; and
 - b. The member is using a seat and/or back cushion that meets the coverage criteria as defined in the Medicaid Policy Manual. If these coverage criteria are not met, payment will be based on the allowance for the least costly medically appropriate alternative.
- (3) Group 2 Single Power Option PWC – is covered if all of the coverage criteria (1)-(5) above for a PWC are met and if:
 - a. The member 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
 - b. The member meets coverage criteria for a power tilt, power seat elevation, power standing feature or a power recline seating system and the system is being used on the wheelchair.

If a Group 2 Single Power Option PWC is provided and if II (A) or II(B) is not met but the coverage criteria for a PWC are met, payment will be based on the allowance for the least costly medically appropriate alternative Group 2 PWC.

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(4) Group 2 Multiple Power Option PWC – is rarely medically appropriate. Most members that require tilt and recline have diagnoses that are primarily neurological, myopathical in nature or are related to congenital orthopedic deformity and therefore qualify for Group 3 MPO PWCs. However, a Group 2 MPO for members with other diagnoses will be covered if all of the coverage criteria (a)-(e) for a PWC are met and if:

- a. The member meets coverage criteria for a power tilt and recline seating system and the system is being used on the wheelchair; or
- b. The member uses a ventilator which is mounted on the wheelchair.

If a Group 2 Multiple Power Option PWC is provided and if IV(A) is not met but the criteria for another PWC are met, payment will be based on the allowance for the least costly medically appropriate alternative Group 2 PWC

(5) Group 3 PWC with no power options – is covered if:

- a. All of the coverage criteria (1)-(5) for a PWC are met; and
- b. The member’s mobility limitation is due to a neurological condition, myopathy, or congenital skeletal deformity; and

If a Group 3 PWC is provided but all the coverage criteria are not met, payment will be based on the allowance for the least costly medically appropriate alternative.

(6) Group 3 PWC with Single Power Option or with Multiple Power Options is covered if:

- a. Group 3 criteria V (a.) and V (b.) are met; and
- b. The member requires tilt or recline single power options, multi-power options or alternative drive controls.

(7) Group 4 PWC with no power options – is covered if

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- a. The member is a very active Power Wheelchair user that meets all of the coverage criteria (1)-(5) for a PWC are met; and
- b. The member's typical daily activities require mobility over extended distances throughout their day; and
- c. The member's typical daily activities require mobility in accommodated (i.e. level surfaces, carpet) and non-accommodated environments (i.e. uneven surfaces) with obstacles that exceed 2.5" in height; or
- d. The member's typical daily activities require mobility that involves steep inclines (i.e. steep ramps, terrain).

If a Group 4 PWC is provided but all the coverage criteria are not met, payment will be based on the allowance for the least costly medically appropriate alternative.

- (8) Group 4 PWC with Single Power Option or with Multiple Power Options – is covered if:

- a. The Group 4 criteria VII (a) and VII (b) are met and either VII (b) or VII (c); and
- b. The member requires tilt or recline single power options, multi-power options or alternative drive controls.

If Group 4 wheelchairs are provided and medical necessity is not met and coverage criteria for another group are met, payment will be based on the allowance for the least costly medically appropriate alternative.

- (9) Group 5 (Pediatric) PWC with Single Power Option or with Multiple Power Options – is covered if:

- a. All the coverage criteria (1)-(5) for a PWC are met; and
- b. The member is expected to grow in height; and
- c. Group 3 Single Power Option (criteria III[a] and III[b]) or Multiple Power Options (criteria IV[a] and IV[b]) (respectively) are met.

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If a Group 5 PWC is provided but all the coverage criteria are not met, payment will be based on the allowance for the least costly medically appropriate alternative.

(10) Push-rim activated power assist device for a manual wheelchair – is covered if:

- a. All of the criteria for a Power Mobility Device listed in the Basic Coverage Criteria section are met; and
- b. The member has been self-propelling in a manual wheelchair.

If all of the coverage criteria are not met, it will be denied as not medically necessary.

d. Power Mobility Device (PMD) Groups

1. Definitions Related to PWC and POV Groups

Power Mobility Device (PMD) - Include both integral frame and modular construction type Power Wheelchairs (PWCs) and Power Operated Vehicles (POVs).

Power Wheelchair (PWC) - Chair-like battery powered mobility device for people with difficulty walking due to illness or disability, with integrated or modular seating system, electronic steering, and four or more wheel non-highway construction.

Power Operated Vehicle (POV) - Chair-like battery powered mobility device for people with difficulty walking due to illness or disability, with integrated seating system, tiller steering, and three or four-wheel non-highway construction.

Patient Weight Capacity – The terms Standard Duty, Heavy Duty, etc., refer to weight capacity, not performance. For example, the term Group 3 heavy duty Power Wheelchair denotes that the PWC has Group 3 performance characteristics and patient weight handling capacity between 301 and 450 pounds. A device is not required to carry all the weight listed in the class of devices, but must have a patient weight capacity within the range to

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be included. For example, a PMD that has a weight capacity of 400 pounds is coded as a Heavy Duty device.

Portable - A category of devices with lightweight construction or ability to disassemble into lightweight components that allows easy placement into a vehicle for use in a distant location.

Performance Testing - Term used to denote the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) based test parameters used to test PMDs. The PMD is expected to meet or exceed the listed performance and durability figures for the category in which it is to be used when tested. There is no requirement to test the PMD with all possible accessories.

Test Standards - Performance and durability acceptance criteria defined by American National Standards Institute/Rehabilitation Engineering and Assistive Technology Society of North America (ANSI/RESNA) standard testing protocols.

Crash Testing - Successful completion of WC-19 testing. WC-19 is a voluntary industry standard for designing and manufacturing a wheelchair that will be used as a seat in a motor vehicle.

Top End Speed - Minimum speed acceptable for a given category of devices. It is to be determined by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) test for maximum speed on a flat hard surface.

Range - Minimum distance acceptable for a given category of devices on a single charge of the batteries. It is to be determined by the appropriate RESNA test for range.

Obstacle Climb - Vertical height of a solid obstruction that can be climbed using the standing and/or 0.5 meter run-up RESNA test.

Dynamic Stability Incline - The minimum degree of slope at which the PMD in the most common seating and positioning configuration(s) remains stable at the required patient weight capacity. If the PMD is stable at only one configuration, the PMD may have protective mechanisms that prevent climbing inclines in configurations that may be unstable.

Radius Pivot Turn – The distance required for the smallest turning radius of the PMD base. This measurement is equivalent to the “minimum turning radius” specified in the ANSI/RESNA bulletins.

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PWC Basic Equipment Package - Each Power Wheelchair is required to include all these items on initial issue (i.e., no separate billing/payment at the time of initial issue, unless otherwise noted). The statement that an item may be separately billed does not necessarily indicate coverage.

- a. Lap belt or safety belt. Shoulder harness/straps or chest straps/vest may be billed separately.
- b. Battery charger, single mode
- c. Complete set of tires and casters, any type
- d. Leg rests. There is no separate billing/payment if fixed, swing away, or detachable non-elevating leg rests with or without calf pad are provided. Elevating leg rests may be billed separately.
- e. Footrests/foot platform. There is no separate billing/payment if fixed, swing away or detachable footrests or a foot platform without angle adjustment are provided.

There is no separate billing for angle adjustable footplates with Group 1 or 2 PWCs. Angle adjustable footplates may be billed separately with Group 3, 4 and 5 PWCs.

- f. Armrests. There is no separate billing/ payment if fixed, swing away, or detachable non-adjustable height armrests with arm pad are provided. Adjustable height armrests may be billed separately.
- g. Any weight specific components (braces, bars, upholstery, brackets, motors, gears, etc.) as required by patient weight capacity.
- h. Any seat width and depth. Exception: For Group 3 and 4 PWCs with a sling/solid seat/back, the following may be billed separately:
 - (1) For Standard Duty, seat width and/or depth greater than 20 inches;
 - (2) For Heavy Duty, seat width and/or depth greater than 22 inches;

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(3) For Very Heavy Duty, seat width and/or depth greater than 24 inches;

(3) For Extra Heavy Duty, no separate billing

i. Any back width. Exception: For Group 3 and 4 PWCs with a sling/solid seat/back, the following may be billed separately:

(1) For Standard Duty, back width greater than 20 inches;

(2) For Heavy Duty, back width greater than 22 inches;

(3) For Very Heavy Duty, back width greater than 24 inches;

(4) For Extra Heavy Duty, no separate billing

j. Controller and Input Device. There is no separate billing/payment if a non-expandable controller and a

standard proportional joystick (integrated or remote) is provided. An expandable controller, a nonstandard joystick (i.e., non-proportional or mini, compact or short throw proportional), or other alternative control device may be billed separately.

POV Basic Equipment Package - Each POV is to include all these items on initial issue (i.e., no separate billing/payment at the time of initial issue):

- Battery or batteries required for operation
- Battery charger, single mode
- Weight appropriate upholstery and seating system
- Tiller steering
- Non-expandable controller with proportional response to input
- Complete set of tires
- All accessories needed for safe operation

Cross Brace Chair - A type of construction for a Power Wheelchair in which opposing rigid braces hinge on pivot points to allow the device to fold.

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Power Options - Tilt, recline, elevating leg rests, seat elevators, or standing systems that may be added to a PWC to accommodate a patient's specific need for seating assistance.

No Power Options – A category of PWCs that is incapable of accommodating a power tilt, recline, seat elevation, or standing system. If a PWC can only accept power elevating leg rests, it is considered to be a No Power Option chair.

Single Power Option - A category of PWCs with the capability to accept and operate a power tilt or power recline or power standing or, for Groups 3, 4, and 5, a power seat elevation system, but not a combination power tilt and recline seating system. It may be able to accommodate power elevating leg rests, seat elevator, and/or standing system in combination with a power tilt or power recline. A PMD does not have to be able to accommodate all features to qualify for this code. For example, a Power Wheelchair that can only accommodate a power tilt could qualify for this code

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Multiple Power Options - A category of PWCs with the capability to accept and operate a combination power tilt and recline seating system. It may also be able to accommodate power elevating leg rests, a power seat elevator, and/or a power standing system. A PWC does not have to accommodate all features to qualify for this code.

Actuator – A motor that operates a specific function of a power seating system – i.e., tilt, back recline, power sliding back, elevating leg rest(s), seat elevation, or standing.

Proportional Control Input Device - A device that transforms a user's drive command (a physical action initiated by the wheelchair user) into a corresponding and comparative movement, both in direction and in speed, of the wheelchair. The input device shall be considered proportional if it allows for both a non-discrete directional command and a non-discrete speed command from a single drive command movement.

Non-Proportional Control Input Device - A device that transforms a user's discrete drive command (a physical action initiated by the wheelchair user, such as activation of a switch) into perceptually discrete changes in the wheelchair's speed, direction, or both.

Alternative Control Device - A device that transforms a user's drive commands by physical actions initiated by the user to input control

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directions to a Power Wheelchair that replaces a standard proportional joystick. Includes mini-proportional, compact, or short throw joysticks, head arrays, sip and puff and other types of different input control devices.

Non-Expandable Controller - An electronic system that controls the speed and direction of the Power Wheelchair drive mechanism.

Only a standard proportional joystick (used for hand or chin control) can be used as the input device. This system may be in the form of an integral controller or a remotely placed controller. The non-expandable controller:

- (1) May have the ability to control up to 2 power seating actuators through the drive control (for example, seat elevator and single actuator power elevating leg rests).
- (2) May allow for the incorporation of an attendant control.

Expandable Controller - An electronic system that is capable of accommodating one or more of the following additional functions:

- (1) Proportional input devices (e.g., mini, compact, or short throw joysticks, touch pads, chin control, head control, etc.) other than a standard proportional joystick.
- (2) Non-proportional input devices (e.g., sip and puff, head array, etc.)
- (3) Operate 3 or more powered seating actuators through the drive control. An expandable controller may also be able to operate one or more of the following:
 - a) A separate display (i.e., for alternate control devices).
 - b) Other electronic devices (e.g., control of an augmentative speech device or computer through the chair's drive control).
 - c) An attendant control.

Integral Control System - Non-expandable wheelchair control system where the joystick is housed in the same box as the controller. The entire unit is located and mounted near the hand of the user. A direct electrical connection is made from the Integral Control box to the motors and batteries through a high power wire harness.

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Remotely Placed Controller - Non-expandable or expandable wheelchair control system where the joystick (or alternative control device) and the controller box are housed in separate locations. The joystick (or alternative control device) is connected to the controller through a low power wire harness. The separate controller connects directly to the motors and batteries through a high power wire harness.

Sling Seat/Back - Flexible cloth, vinyl, leather or equal material designed to serve as the support for buttocks or back of the user respectively. They may or may not have thin padding but are not intended to provide cushioning or positioning for the user.

Solid Seat/Back - Rigid 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 of the user respectively. 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 Captain's Chair.

Captain's 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, swing-away, or detachable. It may or may not have a headrest, either integrated or separate.

Stadium Style Seat - 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, swing-away, or detachable. It will not have a headrest. Chairs with stadium style seats are billed using the Captain's Chair codes.

Highway Use - Mobility devices that are powered and configured to operate legally on public streets.

Push-rim activated power assist – An option for a manual wheelchair in which sensors in specially designed wheels determine the force that is exerted by the patient on the wheel. Additional propulsive and/or braking force is then provided by motors in each wheel. Batteries are included.

2. Power Operated Vehicle and Power Wheelchair Groups

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There are five PWC Groups and two POV Groups. Groups are divided based on performance. Each group of PMDs has subdivisions based on patient weight capacity, seat type, portability, and/or power seating system capability.

a. Power Operated Vehicle (POV) Groups

All POVs must have the specified components and meet the following requirements:

- Have all components in the POV Basic Equipment Package
- Seat Width: Any width appropriate to weight group
- Seat Depth: Any depth appropriate to weight group
- Seat Height: Any height (adjustment requirements-none)
- Back Height: Any height (minimum back height requirement-none)
- Seat to Back Angle: Fixed or adjustable (adjustment requirements – none)
- Meet the following testing requirements:
 - Fatigue test – 200, 000 cycles
 - Drop test – 6,666 cycles

Group 1 POVs must meet the following requirements:

- Length - less than or equal to 48 inches
- Width - less than or equal to 28 inches
- Minimum Top End Speed - 3 MPH
- Minimum Range - 5 miles
- Minimum Obstacle Climb - 20 mm
- Radius Pivot Turn - less than or equal to 54 inches
- Dynamic Stability Incline - 6 degrees

Group 2 POVs must meet the following requirements:

- Length - less than or equal to 48 inches
- Width - less than or equal to 28 inches
- Minimum Top End Speed - 4 MPH
- Minimum Range - 10 miles
- Minimum Obstacle Climb - 50 mm
- Radius Pivot Turn - less than or equal to 54 inches
- Dynamic Stability Incline - 7.5 degrees

b. Power Wheelchair (PWC) Groups

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All PWCs must have the specified components and meet the following requirements:

- Have all components in the PWC Basic Equipment Package
- Have the seat option listed in the code descriptor
- Seat Width: Any width appropriate to weight group
- Seat Depth: Any depth appropriate to weight group
- Seat Height: Any height (adjustment requirements-none)
- Back Height: Any height (minimum back height requirement-none)
- Seat to Back Angle: Fixed or adjustable (adjustment requirements – none)
- May include semi-reclining back
- Meet the following testing requirements:
 - Fatigue test – 200, 000 cycles
 - Drop test – 6,666 cycles

All Group 1 PWCs must have the specified components and meet the following requirements:

- Standard integrated or remote proportional joystick
- Non-expandable controller
- Incapable of upgrade to expandable controller
- Incapable of upgrade to alternative control devices
- May have cross brace construction

- Accommodates non-powered options and seating systems (e.g., recline-only backs, manually elevating leg rests) (except captains' chairs)
- Length - less than or equal to 40 inches

- Width - less than or equal to 24 inches
- Minimum Top End Speed - 3 MPH
- Minimum Range - 5 miles
- Minimum Obstacle Climb - 20 mm
- Dynamic Stability Incline - 6 degrees

For Group 1 portable wheelchairs the largest single component may not exceed 55 pounds.

All Group 2 PWCs must have the specified components and meet the following requirements:

- Standard integrated or remote proportional joystick
- May have cross brace construction
- Accommodates seating and positioning items (e.g., seat and back cushions, headrests, lateral trunk supports, lateral hip supports, medial thigh supports) (except captain's chairs)
- Length - less than or equal to 48 inches
- Width - less than or equal to 34 inches

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- Minimum Top End Speed - 3 MPH
- Minimum Range - 7 miles
- Minimum Obstacle Climb - 40 mm
- Dynamic Stability Incline - 6 degrees

For Group 2 portable PWCs the largest single component may not exceed 55 pounds.

Group 2 no power option PWCs must have the specified components and meet the following requirements:

- Non-expandable controller
- Incapable upgrade to expandable controller
- Incapable of upgrade to alternative control devices
- Incapable of accommodating a power tilt, recline, seat elevation, standing system

Accommodates non-powered options and seating systems (e.g., recline-only backs, manually elevating leg rests) (except captain's chairs)

Group 2 seat elevator PWCs must have the specified components and meet the following requirements:

- Non-expandable controller
- Incapable of upgrade to expandable controller
- Incapable of upgrade to alternative control devices
- Accommodates only a power seat elevating system

Group 2 single power option PWCs must have the specified components and meet the following requirements:

- Non-expandable controller
- Capable of upgrade to expandable controller
- Capable of upgrade to alternative control devices
- See Single Power Option definition for seating system capability

Group 2 multiple power option PWCs must have the specified components and meet the following requirements:

- Non-expandable controller
- Capable of upgrade to expandable controller
- Capable of upgrade to alternative control devices
- See Multiple Power Options definition for seating system capability
- Accommodates a ventilator

All Group 3 PWCs must have the specified components and meet the following requirements:

- Standard integrated or remote proportional joystick
- Non-expandable controller

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- Capable of upgrade to expandable controller
- Capable of upgrade to alternative control devices
- May not have cross brace construction
- Accommodates seating and positioning items (e.g., seat and back cushions, headrests, lateral trunk supports, lateral hip supports, medial thigh supports) (except captain's chairs)
- Drive wheel suspension to reduce vibration
- Length - less than or equal to 48 inches
- Width - less than or equal to 34 inches
- Minimum Top End Speed - 4.5 MPH
- Minimum Range - 12 miles
- Minimum Obstacle Climb - 60 mm
- Dynamic Stability Incline - 7.5 degrees

All Group 4 PWCs must have the specified components and meet the following requirements:

- Standard integrated or remote proportional joystick
- Non-expandable controller
- Capable of upgrade to expandable controller
- Capable of upgrade to alternative control devices
- May not have cross brace construction
- Accommodates seating and positioning items (e.g., seat and back cushions, headrests, lateral trunk supports, lateral hip supports, medial thigh supports) (except captain's chairs)

- Drive wheel suspension to reduce vibration - Length - less than or equal to 48 inches

- Width - less than or equal to 34 inches
- Minimum Top End Speed - 6 MPH
- Minimum Range - 16 miles
- Minimum Obstacle Climb - 75 mm
- Dynamic Stability Incline - 9 degrees

Group 3 and 4 no power option PWCs must have the specified components and meet the following requirements:

- Incapable of accommodating a power tilt, recline, seat elevation, standing system
- Accommodates non-powered options and seating systems (e.g., recline-only backs, manually elevating leg rests)

Group 3 and 4 single power option PWCs must have the specified components and meet the following requirements:

- See Single Power Option definition for seating system capability

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Group 3 and 4 multiple power option PWCs must have the specified components and meet the following requirements:

- See Multiple Power Options definition for seating system capability
- Accommodates a ventilator

All Group 5 PWCs must have the specified components and meet the following requirements:

- Standard integrated or remote proportional joystick
- Non-expandable controller
- Capable of upgrade to expandable controller
- Capable of upgrade to alternative control devices
- Seat Width: minimum of 5 one-inch options
- Seat Depth: minimum of 3 one-inch options
- Seat Height: adjustment requirements ≥ 3 inches
- Back Height: adjustment requirements minimum of 3 options
- Seat to Back Angle: range of adjustment - minimum of 12 degrees
- Accommodates non-powered options and seating systems
- Accommodates seating and positioning items (e.g., seat and back cushions, headrests, lateral trunk supports, lateral hip supports, medial thigh supports)
- Adjustability for growth (minimum of 3 inches for width, depth and back height adjustment)
- Special developmental capability (i.e., seat to floor, standing, etc.)
- Drive wheel suspension to reduce vibration
- Length - less than or equal to 48 inches
- Width - less than or equal to 34 inches
- Minimum Top End Speed - 4 MPH
- Minimum Range - 12 miles
- Minimum Obstacle Climb - 60 mm
- Dynamic Stability Incline - 9 degrees
- Crash testing - Passed

Group 5 single power option PWC must have the specified components and meet the following requirements:

- See Single Power Option definition for seating system capability

Group 5 multiple power option PWC must have the specified components and meet the following requirements:

- See Multiple Power Options definition for seating system capability
- Accommodates a ventilator

W. Phototherapy for the Treatment of Seasonal Affective Disorder and other conditions

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Phototherapy (high intensity light box therapy or bright light therapy minimum 10,000 lux table top models) for the treatment of documented moderate to severe seasonal affective disorder (SAD) is considered medically necessary when prescribed and administered under the guidance of a qualified mental health professional (physician) when the following clinical criteria have been met:

- a. Major Depressive Episodes with confirmed diagnosis of Bipolar I Disorder or Bipolar Disorder II (including Bipolar Disorder NOS (not otherwise specified)); or
- b. Recurrent Major Depressive Disorder; and
- c. Meets all of the following Diagnostic and Statistical manual (DSM-IV-TR or current) criteria for Seasonal Pattern Specifier, including:
 - i. A regular temporal relationship between the onset of major depressive episodes and a particular time of the year (e.g. winter depression with onset in fall/winter and complete remission in the spring).
 - ii. Substantially increased number of seasonal depressive episodes in the fall/winter, as compared with any non-seasonal depressive episodes.
 - iii. Documented major depressive episodes in the past two (2) years.
 - iv. No association with any psychotic disorder.
 - v. No association with any suicidal ideation.
- d. Is supported by specific medical record documentation and previous treatment attempts (medications, counseling etc.)

Head mounted visors, dawn stimulators and tanning beds for the treatment of seasonal affective disorder (SAD) are not medically necessary and are not covered under this policy.

X. Infusion Pumps Other than Insulin Pumps

An external infusion pump and related enteral or parenteral products/supplies will be covered as medically necessary in the home setting in the following situation: External infusion pumps – other than insulin pumps -- are covered if the Prior Authorization Unit verifies the appropriateness of the therapy and of the prescribed pump for the individual member. A physician's or PCP's prescription and supporting documentation to show medical necessity must be included.

Y. Continuous Glucose Monitor

A Continuous Glucose Monitoring system (CGM) is a U.S. Food and Drug Administration (FDA) approved device that records blood sugar levels throughout the day and night. There are several approved devices that can provide up to 288 blood sugar measurements every 24

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hours. The system is used to measure an average blood sugar for three to seven days (depending on the model you have), while the person with diabetes continues daily activities at home.

1. Members 18 years of age or older and meets ALL of the following:

- a. Diagnosis of diabetes (Type I & II); And
- b. Using insulin analog injections at least 4 times daily or on insulin pump; And
- c. Currently self-monitoring blood glucose at least 4 times daily documented for at least greater than or equal to eight (8) weeks; And
- d. Worked with an endocrinologist or a mid-level provider working with an endocrinologist, And
- e. Meets at least one of the following:
 - i. Failure of 3-7 day diagnostic Continuous Glucose Monitor use to reconcile hypoglycemia and subsequent treatment plan change (documented by scanned glucose meter downloads in the medical record); Or
 - ii. Two or more episodes of severe hypoglycemia per week (blood glucose <55 mg/dl) persisting despite therapy changes over at least the two months proceeding in the request; Or
 - iii. Severe hypoglycemic unawareness with blood glucose <55 mg/dl at least twice monthly over two months or once weekly in the last month (defined as documented Emergency Room (ER) visits, use of glucagon emergency kit, or loss of consciousness); Or
 - iv. Nocturnal hypoglycemia (blood glucose <55 mg/dl) refractory to insulin dose changes at least 2 times per week over the past two months; Or
 - v. Recurrent hypoglycemia seizures (1 or more hypoglycemia seizures in the past year); Or
 - vi. Patient with HgbA1c >7.5 and show compliance with plan of care as determined by endocrinologist to achieve tighter glucose control.

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2. Member is less than 18 years of age and meets ALL of the following:

- a. Diagnosis of Type I diabetes; And
- b. Provide clinical documentation indicating the member is using an insulin pump or multiple or multiple daily shot schedule – three or more shots daily or is a newly diagnosed diabetic member; And
- c. Currently self-monitoring blood glucose testing at least 4 times daily
 - i. Documented for ≥ 8 weeks; Or
 - ii. Patient is ≤ 5 years old and newly diagnosed (within last 60 days)
- d. Documented consistent visits with an endocrinologist
 - i. Every 3 months, over last 6-12 months and at least one (1) in-between phone contact with diabetes educator; Or
 - ii. Newly diagnosed (within last 60 days) and at least 4 visits and 2 calls documented in the last 8 weeks; Or
 - iii. Being discharged from hospital and endocrinologist documents need for immediate CGM
- e. Ordered by an endocrinologist or a (mid-level provider (such as a physician assistant (PA) or nurse practitioner (NP)) working under the direct supervision of the endocrinologist; and
- f. Meets at least one of the following:
 - i. Hypoglycemia unawareness-hypoglycemia requiring assistance from an adult and/or injection Glucagon or visit to ER at least twice within the last year; Or
 - ii. Under six (6) years of age or determined not competent to request assistance due to functional status specifically documented in medical records; Or
 - iii. Nocturnal hypoglycemia refractory to insulin dose changes at least 3 episodes documented in the last 3 months; Or
 - a. Hypoglycemia defined as < 65 for children under 8 years of age
 - b. Defined as < 55 for all others
 - iv. Seizure associated with Hypoglycemia – one or more episode in last 12 months; Or

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v. Difficulty in accomplishing the target A1C, in a setting with a family and member in spite of working closely with endocrinologist and diabetes educator over the last 6 months. Must not be due to documented substantial non-compliance; Or

vi. Patient with HgbA1c >7.5 and highly motivated as determined by endocrinologist to achieve tighter glucose control.

3. ALL ages, Utilization Limits, replacement of the transmitter and/or receiver is allowed only when ALL of the following are met:

- a. The member has successfully utilized long-term CGM as a supplement to self-monitoring of blood glucose, and benefitted from such monitoring (i.e. there is evidence the member has achieved improved glycemic control and/or experienced reduced incidences of hyperglycemia and hypoglycemia); And
- b. Replacement with a comparable device is needed due to a malfunction; And
- c. Since repair estimates are not possible for this equipment, documentation of malfunction is documented by clinical team; And
- d. Must supply documentation that the member is using the CGM as directed by the endocrinologist or a mid-level provider (such as a physician assistant (PA) or nurse practitioner (NP)) working with an endocrinologist, And
- e. Sensors approved for 6 months at a time. Sensors are supplied monthly for 6 months, And
- f. A review of usage is required at month 5 prior to submitting by reauthorization at 6 months, And
- g. Ongoing recommendation for CGM must be provided by an endocrinologist or a mid-level provider (such as a physician's assistant (PA) or nurse practitioner (NP)) working with an endocrinologist