MaineCare Services
An Office of the
Department of Health and Human Services
John E. Baldacci, Governor Brenda M. Harvey, Commissioner

Department of Health and Human Services
MaineCare Services
442 Civic Center Drive
11 State House Station
Augusta, Maine 04333-0011
Tel: (207) 287-2674; Fax: (207) 287-2675
TTY: 1-800-423-4331

June 23, 2009

TO: Interested Parties

FROM: Anthony Marple, Director, MaineCare Services

SUBJECT: Final Rule: Ch. 101, MaineCare Benefits Manual, Chapter II, Section 60, Medical Supplies and Durable Medical Equipment

The adopted rules reflect changes to this section to repeal and replace Section 60 in order to clarify the policy and to achieve legislatively mandated cost savings. Proposed changes include new language under Limitations, additional prior authorization requirements, and new language to clarify that items procured under a contract with the Department must be purchased, billed and reimbursed according to the terms of the contract. There will be a change to reimbursement methodology: with the exception of wheelchair providers, DME providers must deduct any prompt payment discounts when determining the acquisition cost of DME. This Section has been totally replaced due to extensive formatting changes proposed, including a thorough restructuring of the Appendix. The adopted rules reflect changes to repeal and replace Section 60 in order to clarify the policy and to achieve legislatively mandated cost savings. Proposed changes include new language under Limitations, additional prior authorization requirements, and new language to clarify that items procured under a contract with the Department must be purchased, billed and reimbursed according to the terms of the contract. This Section has been totally replaced due to extensive formatting changes, including a thorough restructuring of the Appendix.

Changes made to the Section 60 proposed rule due to comments received include: incontinent supplies only require Prior Authorization if the limits are exceeded; the limit for respiratory suction pumps was changed to one (1) every three (3) years; the time to obtain a written prescription for a Power Mobility Device was changed to 45 days; sleep studies for CPAP and Bi-Pap done within the last three (3) years will be accepted; the term "adaptive aid equipment" was removed from the examples of items that are not primarily used for medical purposes; language was added to clarify the policy on rental of oxygen for MaineCare members who also have Medicare; language that a warranty must include parts and labor was clarified; language concerning limits on orthopedic shoes was clarified; language was added to clarify that only examples were given and not limits on medically necessary conditions for hospital beds; limits for incontinent supplies for members under 21 were removed; language was updated for "Augmentative and Alternative Communication Device (AAC device)"; and with the exception of wheelchair providers, DME providers must deduct any prompt payment discounts when determining the acquisition cost of DME. Language was changed to "generally not covered" in regards to aesthetic or deluxe models or equipment. The dollar amount of medical supplies requiring Prior Authorization was changed to $499.00. Additional format and other non-substantive changes were made in response to legal review.

A public hearing was held on May 6, 2009. The comment deadline was May 18, 2009.

Rules and related rulemaking documents may be reviewed at and printed from the Office of MaineCare Services website at http://www.maine.gov/dhhs/oms/rules/provider_rules_policies.html or, for a fee,

interested parties may request a paper copy of rules by calling 207-287-9368. For those who are deaf or hard of hearing and have a TTY machine, the TTY number is 1-800-423-4331.

A copy of the public comments and Department responses can be viewed at and printed from the Office of MaineCare Services website or obtained by calling 207-287-9368 or TTY: (207) 287-1828 or 1-800-423-4331.

If you have any questions regarding the policy, please contact your Provider Relations Specialist at 624-7539, option 8 or 1-800-321-5557, extension option 8 or TTY: (207)287-1828 or 1-800-423-4331.

Notice of Agency Rule-making Adoption

AGENCY: Department of Health and Human Services, Office of MaineCare Services

CHAPTER NUMBER AND TITLE: Ch. 101, MaineCare Benefits Manual, Chapter II, Section 60, Medical Supplies and Durable Medical Equipment

ADOPTED RULE NUMBER:

CONCISE SUMMARY: The adopted rules reflect changes to repeal and replace Section 60 in order to clarify the policy and to achieve legislatively mandated cost savings. Proposed changes include new language under Limitations, additional prior authorization requirements, and new language to clarify that items procured under a contract with the Department must be purchased, billed and reimbursed according to the terms of the contract. This Section has been totally replaced due to extensive formatting changes, including a thorough restructuring of the Appendix.

Changes made to the Section 60 proposed rule based on the State budget include: increasing the markup of the acquisition cost of DME to 40% from 30%, and DME providers must deduct any prompt payment discounts when determining the acquisition cost of DME. Several additional changes were made to clarify the Section 60 proposed rule due to comments received and legal review, such as; sleep studies for CPAP and Bi-Pap done within the last three (3) years will be accepted; limits for incontinent supplies for members under 21 were removed; and the time to obtain a written prescription for a Power Mobility Device was changed to 45 days.

The adopted rule does not impose an economic burden on municipalities or counties. The adopted rules are not expected to increase reporting, record keeping, or other administrative costs or skills necessary for reporting or recording for small businesses.

See http://www.maine.gov/dhhs/oms/rules/provider_rules_policies.html for rules and related rulemaking documents.

EFFECTIVE DATE: July 1, 2009

AGENCY CONTACT PERSON: Darrell S. Wood, Health Planner
AGENCY NAME: Division of Policy and Performance
ADDRESS: 442 Civic Center Drive
11 State House Station
Augusta, Maine 04333-0011
TELEPHONE: (207)-287-6348, FAX: (207) 287-9369
TTY: 1-800-423-4331 or 207-287-1828 (Deaf/Hard of Hearing)

SECTION 60	MEDICAL SUPPLIES AND DURABLE MEDICAL EQUIPMENT	Established: 06/01/85 Last Updated:07/01/09

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

60.01-6 **Power Mobility Device (PMD)** Includes both integral frame and modular construction type power wheelchairs (PWCs) and power operated vehicles (POVs).

60.01 **DEFINITIONS (cont.)**

60.01-7 **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.

60.01-8 **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.

60.01-9 **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 store 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, within fifteen (15) miles of the Maine border in New Hampshire, or within five (5) miles of the Maine border in Canada. The provider cannot be solely a sales representative for a manufacturer of DME or medical supplies. The following exceptions apply:

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.

60.01-10 **Primary Care Provider (PCP)** is a provider who has a contract with the Department to provide primary care case management (PCCM) services.

SECTION 60	MEDICAL SUPPLIES AND DURABLE MEDICAL EQUIPMENT	Established: 06/01/85 Last Updated:07/01/09

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.

60.05 POLICIES AND PROCEDURES

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

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;

60.05 **POLICIES AND PROCEDURES (cont)**

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.

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 an adjusted acquisition cost exceeding $499.00. (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 pattern 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

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 **POLICIES AND PROCEDURES (cont)**

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. Generally, aesthetic or deluxe models or equipment and aesthetic or deluxe features are not reimbursable. Examples of equipment and supplies which are generally 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, 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

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

A. Rental

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

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, fifty percent (50%) of the total rental paid to date will be applied to the MaineCare allowed purchase price and the total paid by the Department shall not exceed one hundred and sixty (160) percent of the adjusted acquisition cost.

60.05 **POLICIES AND PROCEDURES (cont)**

4. Unless otherwise authorized under this Section, rental rates include the cost of servicing, repairs, or other maintenance and includes replacement parts for defective equipment and disposable items.

5. All rented equipment must be clean and in proper working condition when delivered.

B. Outright Purchase of New DME

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

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. The equipment being reconditioned must not exceed the expense for new equipment.

D. Delivery, Installation, and Member Instructional Time

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 **POLICIES AND PROCEDURES (cont)**

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.

The Department decides when to purchase rented DME if a member requires its use for an extended period of time. If the Department decides to purchase the rented DME, fifty percent (50%) of the total amount authorized will be applied to the MaineCare allowed

purchase price, the total paid by the Department shall not exceed one hundred and sixty (160) percent of the adjusted acquisition cost.

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. Labor is also subject to prior authorization requirements of this Section.

60.05-8 Replacement of DME

Replacement of DME is allowed for the following reasons:

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

B. 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

C. Repairing the DME (parts and labor) would cost more than sixty-five (65) percent of the replacement cost of the DME.

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 **POLICIES AND PROCEDURES (cont)**

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 Department criteria as defined in this Section. Special rules apply for medical supplies provided to members in Nursing Facilities (NF) and Intermediate Care Facilities for persons with Mental Retardation (ICF-MR).

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.

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

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 persons with mental retardation (ICF-MR).

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.

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.

60.05-12 Medical Supplies and DME For Members Residing in a NF or ICF-MR

A. Some medical supplies and DME may be covered for members residing in a NF or an ICF-MR 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 defined in this Section. Supplies listed in Chapter II, Section 50, ICF-MR Services, as items included in the reimbursement rate for ICF-MR services may

60.05 **POLICIES AND PROCEDURES (cont)**

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-MR 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
6. Compressor nebulizers (hand held)
7. Wheelchair Cushions, special (silicone, etc.)
8. Electrolarynx 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

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-MR 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

60.05 **POLICIES AND PROCEDURES (cont)**
60.06

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 a NF or ICF-MR

The Department will not reimburse DME providers for Medical Supplies and DME provided to MaineCare members residing in a NF or ICF-MR as part of that facility's

regular rate of reimbursement. Supplies and equipment provided to members in a NF or ICF-MR as part of the regular rate are listed below and are included for reference only. 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) aluminum/magnesium hydroxide (ex. Maalox) b) Aluminum/magnesium hydroxide with simethicone (ex. Mylanta, Maalox Plus) c) Calcium carbonate tablets (ex. Tums) d) Calcium carbonate/ magnesium hydroxide tablets (ex. Rolaids).
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. Combs
20. Commodes
21. Corner chair
22. Cotton
23. Cough syrup and expectorants, all non-prescription brands
24. Crutches
25. Cushions (e.g., comfort rings)

60.05 **POLICIES AND PROCEDURES (cont)**

26. Dietary supplements
27. Disinfectants
28. Douche trays, disposable
29. Dressings
30. Enema equipment
31. Enteral feeding, supplies and equipment.
32. Facility deodorants
33. Gauze bandages, sterile or non-sterile
34. Glucometers
35. General service supplies such as administration of oxygen and related medications, hand feeding, incontinency care, tray service, and enemas
36. Gloves, sterile or non-sterile
37. Gowns
38. Ice bags
39. Incontinency supplies (full brief- all sizes; bed pad; undergarment liners, disposable or reusable; under pads)
40. Irrigation trays
41. Laundry services, personal (including supplies and equipment)
42. 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.
43. Lotions, emollient
44. Lubricants, skin, bath oil
45. Mats – ICF-MR only
46. Mouth wash
47. Ointments and creams, available over the counter, including petroleum jelly and hydrocortisone 0.5%
48. Ophthalmic lubricants, tears and ointments
49. Oxygen, for emergency and prn use only, including portable oxygen and equipment
50. Parenteral solutions, supplies and equipment
51. Pillows
52. Pitchers, water
53. Powders, medicated and baby
54. Prone boards
55. Restraints, poseys, thoracic chest supports, wedge pillows, etc.
56. Sand and water tables – ICF-MR only
57. Sensory stimulation materials– ICF-MR only
58. Shampoo, regular, medicated and no-tears baby shampoo
59. Sheepskin
60. Shower chairs
61. Soap, including hypoallergenic
62. Special dietary supplements
63. Specimen containers

60.05 **POLICIES AND PROCEDURES (cont)**

64. Sterile I.V. or irrigation solution
65. Stethoscopes
66. Sunscreen
67. Supplies, non-prescription, necessary for the treatment for decubitis
68. Suture sets
69. Swabs, medicated or unmedicated
70. Syringes and needles
71. Tapes
72. Testing materials to be used by staff of facility, not to include materials normally included in psychometric testing – ICF-MR only
73. Thermometers
74. Tissues
75. Toothbrushes
76. Toothpaste
77. Towels, washcloths
78. Tongue depressors
79. Traction equipment
80. Trapezes
81. Tub seats
82. Tubes, gavage, lavage, etc.
83. Under pads
84. Urinals
85. Urinary drainage equipment and supplies (disposable)
86. Velcro strips - ICF-MR only
87. Vestibular boards – ICF-MR only
88. Vitamins, non-prescription, all brands
89. Walkers
90. Wheelchairs, standard, including those with removable or adjustable arms and leg rests including elevators, pediatric, "hemi" chairs, reclining wheelchairs
91. Wipes, rectal medicated
92. 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.

60.06 **RESTRICTED SERVICES**

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

60.06-1 Physician Provided Supplies

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

60.06 **RESTRICTED SERVICES (cont)**

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 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:

1. Some services and procedures require prior authorization in order for MaineCare to provide payment. The Department or its Authorized Agent 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. This site is: (http://www.maine.gov/bms/providerfiles/codes.htm).

   The Department reserves the right to require an evaluation by appropriate clinical professionals of its choice before granting PA.

   The Department requires prior authorization (PA) for medical supplies and equipment including but not limited to the following:

2. Items Having an Adjusted Acquisition Cost Exceeding $499.00

   Prior authorization (PA) is required for any medical supply having an adjusted acquisition cost exceeding $499.00. 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 an adjusted acquisition cost above $499.00, the adjusted acquisition cost of all related pieces of equipment must be added together and totaled before applying the criteria. For example, the adjusted acquisition cost of a

60.06 **RESTRICTED SERVICES (cont)**

wheelchair must be considered to be the sum of the adjusted acquisition 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.

3. 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. Only 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.

4. Rental equipment, Except in Emergency Situations

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.

60.06 **RESTRICTED SERVICES (cont)**

5. 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 adjusted acquisition cost exceeds $99.99 requires PA.

6. DME Parts

DME parts for 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.

7. Seasonal affective disorder lamps

Such lamps will only be covered when evidence of severe, depressive seasonal affective disorder and an appropriate diagnosis is documented by a physician.

8. Power Mobility Devices (PMD)

Power Mobility Devices require 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.

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 will 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.

9. Repairs to DME

Repairs to DME with a total cost (parts and labor) exceeding sixty-five percent (65%) 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 $499.00 to repair medically necessary DME. In addition, PA is required when any DME has been repaired three (3) times in any twelve (12) month

60.06 **RESTRICTED SERVICES (cont)**

period. 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.

10. 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.

11. Incontinence supplies

Incontinence supplies for members age 21 and over require PA, and there are limits for adults.

12. Enteral and Parenteral Supplies

All enteral and parenteral supplies 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.

13. 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.

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.

60.06 **RESTRICTED SERVICES (cont)**

60.06-4 Procedure to Request Prior Authorization

Providers must make requests for PA on the Department's approved form and get approval prior to the date of service.

Completed PA forms must be sent to: Division of Health Care Management
Prior Authorization Unit
State House Station #11
Augusta, Maine 04333-0011

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 CMN 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.

60.06-5 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.

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.

60.07 LIMITATIONS (cont)

1. Items classified with HCPCS Level II codes as Orthotic Procedures under the category, Orthopedic Shoes, under the sub-headings, Inserts, 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 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, Diabetic Shoes, Fitting and Modifications are limited to two (2) 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

Incontinence supplies are limited to the quantities detailed in the Appendix of this Section. Additional quantities require PA.

60.07-2 Limitations for All MaineCare Members

A. Power Mobility Devices (PMD)

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

60.07 LIMITATIONS (cont)

1. 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. Members will be limited to one (1) wheelchair (i.e. manual or power wheelchair) every five (5) years;

3. Members who meet the eligibility requirements for both a prosthetic device necessary to allow functional mobility and a 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 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.

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-MR and will allow a wheelchair with right or left-handed drive 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 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.

60.07 **LIMITATIONS (cont)**

11. Reimbursement will not be allowed for repairs or replacement parts for any equipment under warranty.

12. If a member-owned PMD meets coverage criteria, medically necessary replacement items, including but not limited to batteries, are covered.

13. 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 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.

14. When requesting prior authorization for a PMD in a NF or other setting in which there is continuous supervision, the requesting provider will need to document the member's medical necessity to be independently mobile beyond what can be provided by staff in that setting.

15. 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.)

B. Hospital beds

1. Members will be limited to one (1) hospital bed every five (5) years;

2. Members will be limited to one (1) standard mattress (to fit a hospital bed) every five (5) years;

C. 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.

D. CPAP and Bi-PAP devices

60.07 **LIMITATIONS (cont)**

For CPAP and Bi-PAP purposes the Department will accept sleep studies done within the last three (3) years of the initial request regardless of the payor.

CPAP and Bi-PAP devices and supplies are limited to the quantities provided in the Appendix of this Section.

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 medical supplies, durable medical equipment and services, except for orthotics and prosthetics, rentals, and oxygen obtained under a contract with the Department, shall be the lowest of:

A. The maximum MaineCare amount published at least annually on the Department's website, http://www.maine.gov/bms/providerfiles/codes.htm and made available to providers;

B. The adjusted acquisition cost (AC) plus forty percent (40%) mark up of acquisition cost (AC*.40), with total mark up not to exceed two thousand dollars ($2,000);

Adjusted acquisition cost for purposes of this Section is the lowest price paid to a supplier by an eligible provider for durable medical equipment, medical/surgical supplies after deductions 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.

The Department may at any time require proof of the acquisition cost to the eligible provider. Such proof shall be in the form of a receipted invoice;

C. The provider's usual and customary charge; or

D. The manufacturer's suggested retail price for any medical supply or durable medical equipment (including replacement parts).

60.09-2 In addition to the requirements contained within these rules, providers seeking reimbursement for medical supplies and/or DME covered under a contract with the Department must adhere to the policies and procedures outlined in the contract. If the contractor serves as a supplier only and does not provide direct services to MaineCare members, the contractor shall bill a MaineCare-enrolled provider in accord with normal business practices and will be reimbursed by the provider at the agreed upon contract

60.09 **REIMBURSEMENT (cont)**

price(s). After the provision of a covered service to a MaineCare member, the DME provider will then bill MaineCare following the billing instructions outlined in this Section. Payment shall be the lowest of the following:

A. The maximum MaineCare amount published at least annually on the Department's website, http://www.maine.gov/bms/providerfiles/codes.htm and made available to providers;

B. Except as provided below, adjusted acquisition cost (AC) plus forty percent (40%) mark up of acquisition cost (AC*.40), with total mark up not to exceed two thousand dollars ($2000); or

C. The provider's usual and customary charge.

Reimbursement will not be made when purchased from another supplier unless extenuating circumstances exist (e.g., the contractor does not supply a particular item which has been deemed medically necessary by the Department, or none of the available items meet the member's specific medical needs), in which case, reimbursement may be sought through the prior authorization process. The Department will provide advance notification to all providers that are required to purchase items from such a contractor.

60.09-3 The amount of payment for custom molded orthotics and prosthetics shall be ninety-four (94) percent of the lowest of:

A. The maximum MaineCare amount published at least annually on the Department's website, http://www.maine.gov/bms/providerfiles/codes.htm and made available to providers;

B. The lowest amount paid by Medicare;

C. The provider's usual and customary charge; or

D. The manufacturer's suggested retail price (including replacement parts).

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/bms/providerfiles/codes.htm.

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/oms/provider_index.html. 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 (oxygen) after that time. The Department will refer to Medicare's Explanation of Benefits

60.09 **REIMBURSEMENT (cont)**

(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.

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.

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 **REIMBURSEMENT (cont)**

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.

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 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

60.10 **CO-PAYMENT (cont)**

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.

APPENDIX

MEDICAL CRITERIA

A. Specific Definitions and Criteria for Prior Authorization

Unless indicated otherwise, all items in this Appendix require prior authorization before reimbursement will be made.

1. **Home Use of Oxygen Criteria**

a. General – Coverage of home oxygen and oxygen equipment is considered reasonable and necessary only for members with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections b, c, and d. This section also includes special coverage criteria for portable oxygen systems.

b. Medical documentation – Initial claims and renewals for oxygen services must include a completed Department approved prior authorization form and/or a Certificate of Medical Necessity form for Oxygen to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's or PCP's prescription or other medical documentation. The treating physician's or PCP's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each member must receive optimum therapy before long-term home oxygen therapy is ordered.

Medical and prescription information on this form can be completed only by the treating physician, the PCP, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. The form must be signed by the physician or PCP. Although hospital discharge coordinators and medical social workers may assist in arranging for prescribed home oxygen, they do not have the authority to prescribe the services. The prescription for home oxygen must be updated at least annually by the treating physician or PCP.

A physician's or PCP's PA form or certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the member's record. This documentation may be in the form of a prescription written by the member's attending physician who has recently examined the member (normally within a month of the start of therapy) and must specify:

1. A diagnosis of the disease requiring home use of oxygen;

Home use of oxygen Criteria (cont.)

2. The oxygen flow rate; and

3. An estimate of the frequency, duration of use (e.g., two (2) liters per minute, ten (10) minutes per hour, twelve (12) hours per day), and duration of need (e.g., six (6) months or lifetime).

   NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the member.

c. The attending physician or PCP must specify the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed form (currently HCFA-484.) In addition, the supplier or prescriber may use the space in section C for written confirmation of additional details of the physician's or PCP's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the non-continuous use of oxygen as appropriate. The prescriber must confirm this information with his or her signature on the form.

   New medical documentation written by the member's attending physician or PCP must be submitted to the Prior Authorization Unit in support of revised oxygen requirements when there has been a change in the member's condition and need for oxygen therapy exists, and annually at a minimum.

   The Department reserves the right to conduct periodic, continuing medical necessity reviews on members whose conditions warrant these reviews and on members with indefinite or extended periods of necessity.

   The Prior Authorization Unit may also request documentation of the results of a repeat arterial blood gas or oximetry study.

d. Laboratory Evidence – Initial claims or renewals for oxygen therapy must also include the results of a blood gas study except for paragraph (c) above that has been ordered and evaluated by the attending physician or PCP. This is usually in the form of a measurement of the partial pressure of oxygen (PO^2) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending physician or PCP and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services. When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these requirements. This prohibition does not extend to the results of blood gas tests conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are

Home use of oxygen Criteria (cont.)

performed must be specified in writing and submitted with the request for prior authorization i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are an existing physician or PCP and/or hospital records that reflect the member's medical condition. If more than one arterial blood gas test is performed during the member's hospital stay, the test result obtained closest to, but no earlier than two (2) days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those members whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be during a period of an acute illness or an exacerbation of their underlying disease.

The Prior Authorization Unit may accept an attending physician's or PCP's statement of recent hospital test results for a particular member, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that the member has undergone a major change in his or her condition relevant to home use of oxygen. If the Prior Authorization Unit has reason to believe that there has been a significant change in the member's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

An overnight oximetry study may be set up by the DME provider. The unit must have the capacity to download the oximetry study information. The results must be interpreted by an objective third party i.e. the requesting physician or a qualified contracted entity. The requesting provider must submit a written and signed interpretation of the report.

Physician ordered positive airway devices such as CPAP, BiPAP or Ventilators do not require laboratory evidence (oxygen saturations or ABG's) if the oxygen is ordered only to be bled into the system.

e. Health Conditions – Coverage is available for members with significant hypoxemia in the chronic stable state if: 1) the attending physician or PCP has determined that the member has a health condition outlined in subsection (e)(1) below; 2) the member meets the blood gas evidence requirements specified in subsection (e) (3) below; and 3) the member has appropriately tried other alternative treatment measures without complete success. (See above, subsection (1)(b) of this Appendix.)

1. Conditions for Which Oxygen Therapy May Be Covered

a. A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, whether of known or

Home use of oxygen Criteria (cont.)

unknown etiology; cystic fibrosis bronchiectasis; widespread pulmonary neoplasm; or

b. Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2. Conditions for Which Oxygen Therapy Is Not Covered

a. Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;

b. Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;

c. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. (There is no evidence that increased PO^2 improves the oxygenation of tissues with impaired circulation); or

d. Terminal illnesses that do not affect the lungs.

3. Covered Oxygen Measurements

If the member has a condition specified in subsection A(1)(e)(1), the Prior Authorization Unit must review the medical documentation and laboratory evidence that has been submitted for a particular member (see subsections A(1)(b) and (c)) and determine if coverage is available under one of the three group categories outlined below.

a. Group I – Except as modified in subsection A(1)(e), coverage is provided for members with significant hypoxemia evidenced by any of the following:

1. An arterial PO^2 at or below fifty-five (55) mm Hg (millimeters of mercury), or an arterial oxygen saturation at or below eighty-eight (88) percent, taken at rest, breathing room air.

Home use of oxygen Criteria (cont.)

2. An arterial PO^2 at or below fifty-five (55) mm Hg, or an arterial oxygen saturation at or below eighty-eight (88) percent, taken during sleep for a member who demonstrates an arterial PO^2 at or above fifty-six (56) mm Hg, or an arterial oxygen saturation at or above eighty-nine (89) percent, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO^2 more than ten (10) mm Hg, or decrease in arterial oxygen saturation more than five (5) percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.

3. An arterial PO^2 at or below fifty-five (55) mm Hg or an arterial oxygen saturation at or below eighty-eight (88) percent, taken during exercise for a member who demonstrates an arterial PO^2 at or above fifty-six (56) mm Hg, or an arterial oxygen saturation at or above eighty-nine (89) percent, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the member was breathing room air.

b. Group II – Except as modified in subsection A(1)(e), coverage is available for members whose arterial PO^2 is fifty-six to fifty-nine (56-59) mm Hg or whose arterial blood oxygen saturation is eighty-nine (89) percent, if there is evidence of:

1. Dependent edema suggesting congestive heart failure;

2. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than three (3) mm in standard leads II, III, or AVFL); or

3. Erythrocythemia with a hematocrit greater than fifty-six (56) percent.

c. Group III – Except as modified in subsection A(1)(e), the provider must apply a rebuttable presumption that a home program of oxygen

Home use of oxygen Criteria (cont.)

use is not medically necessary for members with arterial PO^2 levels at or above sixty (60) mm Hg, or arterial blood oxygen saturation at or above ninety (90) percent. In order for claims in this category to be reimbursed, the Prior Authorization Unit's reviewing professional needs to review any documentation submitted in rebuttal of this presumption and grant specific approval.

d. Variable Factors That May Affect Blood Gas Values – In reviewing the arterial PO^2 levels and the arterial oxygen saturation percentages specified in subsections e(3)(a), (b) and (c) above, variations in oxygen measurements that may result from such factors as the member's age, the altitude level, or the member's decreased oxygen carrying capacity may be considered.

e. Portable Oxygen Systems – A member meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or (2) to use in addition to a stationary oxygen system. A portable oxygen system is covered for a particular member if:

1. The request for PA meets the requirements specified in subsections A(1) (a) through (e), as appropriate; and

2. The medical documentation indicates that the member is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for members who qualify for oxygen solely based on blood gas studies obtained during sleep.

2. **Seat lift mechanisms**

Reimbursement may be made for the rental or purchase of a medically necessary seat lift mechanism when prescribed by a physician or PCP for a member with severe arthritis of the hip or knee and members with muscular dystrophy or other neuromuscular diseases, when it has been determined the member can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift mechanism, the evidence must show that the item is included in the physician's or PCP's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the member's condition, and that the severity of the condition is such that the alternative would be chair or bed confinement.

Coverage of seat lift mechanisms is limited to those types which operate smoothly, can be controlled by the member, and effectively assist a member in standing up and sitting down without other assistance. The type of lift that operates by a spring release mechanism with a sudden, catapult-like motion and jolts the member from a seated to a standing position is

2. **Seat lift mechanisms (cont)**

excluded from coverage. The payment for units, which incorporate a recliner feature along with the seat lift mechanism, is limited to the amount payable for a seat lift mechanism without this feature.

3. **Home blood glucose monitors and test strips**

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.mainecarepdl.org/index.pl/pdlfiles/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. Beginning on this same date, DME dealers will be required to follow the billing instructions as posted at: http://www.maine.gov/dhhs/bms/providerfiles/provider_billing_manuals.htm 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.

4. **Infusion pumps**

Continuous subcutaneous insulin infusion pumps (CSII), an external infusion pump and related drugs/supplies will be covered as medically necessary in the home setting in the following situation:

1. Treatment of Type I diabetes. In order to be covered, members must meet criteria (a) or (b):

   a. The member has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e. at least three (3) injections per day), with frequent self-adjustments of insulin dose for at least six (6) months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least four (4) times per day during the two (2) months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:

      i. Glycosylated hemoglobin level (HbAlc) > seven (7) percent
      ii. History of recurring hypoglycemia
      iii. Wide fluctuations in blood glucose before mealtime
      iv. Dawn phenomenon with fasting blood sugars frequently exceeding two hundred (200) mg/dl
      v. History of severe glycemic excursions

   b. The member with Type I diabetes has been on a pump prior to enrollment and has documented frequency of glucose self-testing an average of at least four (4) times per day during the month prior enrollment.

      Type I diabetes needs to be documented by a fasting C-peptide level < = one hundred and ten (110) percent of the lower limit of normal of the laboratory's measurement method.

      Continued coverage of the insulin pump would require that the member has been seen and evaluated by the treating physician or PCP at least every 3 months. The pump must be ordered by, and follow-up care of the member must be managed by, a physician or PCP who manages multiple members with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.

      Subcutaneous insulin infusion pumps will continue to be denied as not medically necessary and unreasonable for all Type II diabetics including insulin-requiring Type II diabetics.

2. Insulin syringe filling devices for the visually impaired (e.g. Count-a-dose) are covered with adequate documentation maintained demonstrating visual impairment.

4. **Infusion pumps (cont)**

3. Other uses of external infusion pumps are covered if the Prior Authorization Unit verifies the appropriateness of the therapy and of the prescribed pump for the individual member.

NOTE: Payment may also be made to the appropriate provider for drugs necessary for the effective use of an external infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the member's treatment.

5. **Pneumatic Compression Devices (used for lymphedema and chronic venous insufficiency)**

Pneumatic compression devices consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary among devices. Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers.

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from an impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition, which may be due such causes as Milroy's Disease and congenital anomalies. Secondary lymphedema, which is much more common, results from the destruction of or damage to formerly functioning lymphatic channels, such as surgical removal of lymph nodes or post radiation fibrosis, among other causes.

Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the member has undergone a four (4) -week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

Chronic Venous Insufficiency with venous stasis ulcers

Chronic Venous Insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the member has one or more venous stasis ulcer(s), which have failed to heal after a six (6) month trial of conservative therapy, directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

5. **Pneumatic Compression Devices (used for lymphedema and chronic venous insufficiency) (cont)**

General coverage criteria

Pneumatic compression devices are covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the member's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use and ongoing monitoring of use and response to treatment.

6. **Continuous positive airway pressure (CPAP) and bi-level positive airway pressure (Bi-PAP) devices and supplies**

CPAP/ Bi-PAP are non-invasive techniques for providing low levels of air pressure from a flow generator. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

a. The use of CPAP/ Bi-PAP devices is covered when ordered and prescribed by the licensed treating physician to be used in adult members with OSA if either of the following criteria using the Apnea-Hypopnea Index (AHI) is met:

AHI = 15 events or more per hour; or

AHI = 5 - 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia or documented hypertension, ischemic heart disease or history of stroke.

The AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of two (2) hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e. the AHI may not be extrapolated or projected).

b. 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 if the equipment and treatment will continue. Determining factors for continued coverage shall be based on, but not limited to, the following:

1. For the rental/trial period the device must be capable of recording and storing three (3) consecutive months worth of measurable, objective compliance data; and the compliance data reported to the Department for review when requested.

2. The three (3) month downloaded data and physician documentation from the rental period will be reviewed to determine the utilization of the equipment, member comfort level with the ongoing use of equipment and the success of

6. **Continuous positive airway pressure (CPAP) and bi-level positive airway pressure (Bi-PAP) devices and supplies (cont)**

the equipment to decide if the purchase, continued rental or change in equipment is warranted. The Department requires documentation in support of all of the above to continue treatment beyond the three (3) month rental period.

c. CPAP and Bi-PAP devices and supplies are limited as follows:

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

Physician ordered positive airway devices such as CPAP, BiPAP or Ventilators do not require laboratory evidence (oxygen saturations or ABG's) if the oxygen is ordered only to be bled into the system.

7. **Hospital beds**

a. General Requirements for Coverage of Hospital Beds – A physician's or PCP's prescription, and such additional documentation as the Prior Authorization Unit may consider necessary, including medical records, physician's and PCP's reports, must establish the medical necessity for a hospital bed due to one of the following reasons:

1. The member's condition requires positioning of the body; e.g., to alleviate pain, promote good body alignment, prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed; or

2. The member's condition requires special attachments that cannot be fixed and used on an ordinary bed.

7. **Hospital beds (cont)**

b. Physician's or PCP's Prescription – The physician's or PCP's prescription, which must accompany the request for prior authorization, and supplementing documentation when required, must establish that a hospital bed is medically necessary. If the stated reason for the need for a hospital bed is the member's condition requires positioning, the prescription or other documentation must describe the medical condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the condition that necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is that the member's condition requires special attachments to a bed, the prescription must describe the member's condition and specify the attachments that require a hospital bed.

c. Variable Height Feature – In well-documented cases, the Prior Authorization Unit may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered. The following are some examples of these medically necessary conditions:

Severe arthritis and other injuries to lower extremities; e.g., fractured hip. The condition requires the variable height feature to assist the member to ambulate by enabling the member to place his or her feet on the floor while sitting on the edge of the bed;

Severe cardiac conditions. The condition requires the variable height feature to avoid the strain of "jumping" up or down;

Spinal cord injuries, including quadriplegia and paraplegia members, multiple-limb amputees, and members who have had a stroke. For those members who are able to transfer from bed to a wheelchair, with or without help, or other severely debilitating diseases and conditions, if the variable height feature is required to assist the member to ambulate.

d. Electric-Powered Hospital Bed Adjustments – Electric-powered adjustments to lower and raise head and foot may be covered when the Prior Authorization Unit determines that the member's condition requires frequent change in body position and/or there may be an immediate need for a change in body position (i.e., no delay can be tolerated) and the member can operate the controls and cause the adjustments. Exceptions may be made to this last requirement in cases of spinal cord injury and members with brain damage.

e. Side Rails – If the member's condition requires bed side rails, they may be covered when an integral part of, or an accessory to, a hospital bed.

8. **Enteral and Parenteral nutritional therapy**

There are members who, because of chronic illness or trauma, cannot be sustained through oral feeding. They must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

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.

a. 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.

Since the alimentary tract of such a member does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the member until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the member in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the member's home.

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.

8. **Enteral and Parenteral nutritional therapy (cont)**

Payment will be on the basis of the reasonable charge for more expensive pre-mixed solutions only under the latter circumstances.

b. 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 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.

9. **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 an 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.

10. **Negative Pressure Wound Therapy (NPWT)**

MaineCare covers NPWT when the following criteria are met:

10. **Negative Pressure Wound Therapy (NPWT) (cont)**

a. The treatment must be reasonable and medically necessary.

b. The Department requires prior authorization for initial (the first month) coverage of NPWT. The PA can be extended monthly for an additional three (3) months. After four months, a new PA is required.

c. For coverage to continue, a licensed medical professional (physician, physician's assistant, registered nurse, licensed practical nurse, or physical therapist) licensed to provide wound care and/or assess wounds must, on a regular basis, directly assess the wound(s) being treated, supervise or directly perform the dressing changes, and at least monthly, document changes in the ulcer's dimensions and characteristics.

d. The Department will deny continued coverage if the treating PCP documents that adequate wound healing (improvement in the surface area of the wound or depth of the wound) has occurred, or any measurable degree of wound healing has failed to take place over the prior month.

e. MaineCare covers the NPWT pump (portable or stationary), on a monthly rental basis only. If more than one pump is required, the PCP must document medical necessity for the additional pump(s).

f. MaineCare covers the necessary NPWT supplies, including the canister and dressings. Providers must purchase the supplies monthly. The Department does not require prior authorization unless the monthly total acquisition cost exceeds four hundred and ninety-nine dollars ($499.00).

g. The PCP must document treatment already completed, including, but not limited to, evaluation, care, and wound measurements. The PCP must also document that a comprehensive wound therapy program has been tried or considered and ruled out, including:

1. application of dressings to maintain a moist wound environment, and

2. debridement of necrotic tissue, and

3. evaluation and provision of adequate nutritional status.

h. For Stage III or IV pressure ulcers:

1. The member must have been appropriately turned and positioned, and

2. A group 2 support surface mattress or group 3 support surface mattress must be used for pressure ulcers on the pelvis or posterior trunk, and

10. **Negative Pressure Wound Therapy (NPWT) (cont)**

3. The licensed medical professional must assure that the member's moisture and incontinence is properly managed.

i. For neuropathic ulcers:

1. The member has participated in a comprehensive diabetes management program, and

2. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.

j. For venous insufficiency ulcers:

1. Compression bandages and/or garments have been consistently applied, and

2. Leg elevation and ambulation have been encouraged.

k. MaineCare will not cover NPWT if the following are present:

1. necrotic tissue with eschar in the wound (unless debridement has been attempted),

2. cancer in the wound,

3. untreated osteomyelitis in the vicinity of the wound, or

4. a fistula to a body cavity or organ in the vicinity of the wound.

11. **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.

12. **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.

13. **Augmentative and Alternative Communication Device (AAC device)**

a. Definition

An augmentative and alternative communication device (AAC device) is a total functional communication system of an individual including a communicative technique, a symbol set, or system and communication/interaction behavior. The AAC device encompasses all techniques, which aid communication with some type of physical object or device. These include methods that use communication boards, charts, and mechanical or electrical aids, or computerized devices. The purpose of an AAC device is to enhance communication skills and interaction behavior that are necessary to have an idea expressed and understood.

The AAC device is designed to meet the individual needs of the member. The AAC device may include spoken and or printed words as output, pictures, symbols, traditional orthography (written) and sign language. The AAC device is complex and, therefore, must be coordinated with an overall plan of service.

This plan shall identify and assess the physical, cognitive, intellectual, linguistic, sensory, and communication needs of the member. Both short and long-term management plans shall be developed.

The following criteria need to be met during the life of the plan: The establishment of a monitoring mechanism to ensure cost containment and accountability; the maintenance of equipment; and the identification of advocates to promote the access and continuity of these services.

b. Coverage

1. Coverage for an AAC device shall be based on communication necessity that is determined by the nature and severity of the member's expressive communication disorder. The determination for coverage shall be based upon an overall plan of care established by a physician or PCP. The plan of care must identify and assess the environmental, physical, cognitive, intellectual, linguistic, sensory, and communication needs of the member. The Department reserves the right to request an evaluation from another physician or PCP, and may require that the physician be board certified as a neurologist, physiatrist, or ear, nose and throat specialist. In addition, the Department may request an evaluation from an audiologist,

2. In order to assure that there is a full and adequate augmentative and alternative communication assessment and management of the member with a severe expressive communication disorder, a referral must be made to a licensed speech-language pathologist who is familiar with augmentative communication device/systems. The evaluation/ assessment performed by the licensed speech-language pathologist will include but is not limited to the following criteria:

13. **Augmentative and Alternative Communication Device (AAC device) (cont)**

a. language comprehension;
b. expressive language capabilities;
c. oral motor speech status;
d. the appropriate symbol set or system;
e. the member's use of pragmatics in communication and assessment of communicative interest;
f. communication needs including the need to enhance conversation, writing and signaling emergency, basic care and related needs and writing impairments; and
g. the member's environment.

The speech-language pathologist shall identify what other AAC devices have been evaluated and tested and shall select the AAC device needed by the member. The appropriate device is based on a medical rationale for the request of a particular device, and on a comparative analysis of equipment available and the member's ability to use the equipment. The pathologist shall provide a written plan for review, monitoring, and maintenance of the communicator. A speech-language pathologist shall re-evaluate the member's need as part of a request for replacement or improvement of an AAC device.

The Department may request a second opinion from another speech-language pathologist.

3. In addition to the referral to a licensed speech-language pathologist, an evaluation by an occupational therapist or a physical therapist is required.

a. Occupational therapist. An occupational therapist must be licensed as such in the state or province in which services are provided;

b. Physical therapist. A physical therapist must be licensed as such in the state or province in which services are provided.

The evaluation performed by the occupational therapist registered or physical therapist shall include an assessment of the member's motor skills and the member's physical ability to relate to the AAC device. The assessment shall also identify the member's mobility status and the optimum seating and physical positioning of the member.

The Department may request an evaluation by a licensed psychologist. If an evaluation is requested, it shall include an assessment of the member's cognitive abilities by a psychologist who is skilled in evaluating people who are non-speaking.

13. **Augmentative and Alternative Communication Device (AAC device) (cont)**

The periodicity of re-evaluation will be established by the speech-language pathologist with input from the member, family, and/or caregivers as appropriate. Changes in technology alone do not necessitate replacement or upgrades in equipment.

c. Purchase or Rental Arrangements

The Department reserves the right to purchase or rent all AAC devices.

Prior to purchase, rental or lease arrangements, the review by the licensed speech-language pathologist must be consistent with the physician's or PCP's overall plan of care. The review must include a statement by the speech-language pathologist of the member's progress, prognosis, and continued plan of care, as well as provide instruction to the person, as needed, to maximize his or her communication skills with the particular augmentative communication device.

d. Prior Authorization

All of the following information must be documented for prior authorization by the member's physician or PCP:

1. Name, birth date, MaineCare ID number;
2. Written referral from a physician or PCP to a licensed speech-language pathologist who has demonstrated expertise with AAC devices;
3. Physical assessment of any hearing or visual loss, muscular disorder, or motor weaknesses to include motor speech problems, laryngectomy or glossectomy (removal of the tongue), missing limbs, aphasia, and head injuries or any other physical disability;
4. Current intellectual/communication level;
5. Current cognitive level;
6. Status of current speech/language treatment; and
7. A copy of the warranty of the equipment, a statement identifying the availability of maintenance and a statement of the acquisition cost of the equipment.

The Department reserves the right to request a second opinion covering communicative necessity of prescribed equipment on any request for prior authorization for an AAC device.

13. **Augmentative and Alternative Communication Device (AAC device) (cont)**

The Department will approve an AAC device based only on communicative necessity.

14. **Home Traction**

a. 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:

1. The member has failed to respond to routine physical therapy, and
2. 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.

b. The supplier shall provide the following services, which are included in the reimbursement for traction:

1. Set-up of traction equipment
2. Training of member or caregiver; and
3. Maintenance of equipment

15. **Bone Growth Stimulator**

MaineCare covers spinal bone growth stimulators (electrical osteogenesis stimulators) when there is failed spinal fusion at least nine months after the last surgery; subsequent to multilevel spinal fusion surgery; or subsequent to spinal fusion surgery where previous spinal surgery at the same site failed.

MaineCare covers bone growth stimulators (electrical osteogenesis stimulators) when there is a nonunion of a long bone fracture, failed fusion of a non-spinal joint, or congenital pseudarthrosis.

For both spinal and non-spinal bone growth stimulators, the physician or PCP must document the date of the injury, the dates of medical and surgical treatment, radiographic evidence, and the expected outcome of the devices. Prior authorization is required.

16. **Apnea Monitor**

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

a. An infant who has a severe apparent life threatening episode (ALTE) that required mouth-to-mouth resuscitation or vigorous stimulation;
b. Any pre-term infant who has had an episode of apnea;
c. Any infant who has had a sibling who has died of sudden infant death syndrome;

16. **Apnea Monitor (cont)**

d. A diagnosis of central hypoventilation, gastroesophageal reflux;
e. Any infant with a tracheotomy;
f. Any infant whose mother used cocaine or opiates during pregnancy; or
g. Any infant whose mother is a multiparous adolescent.

17. **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:

a. The member has a medical condition resulting in incontinence and has failed to respond to a bowel/bladder training program or;
b. The medical condition being treated results in incontinence and the member would not benefit from a bowel/bladder training program;
c. The monthly service limits for diapers and other disposable incontinence products for those members who are 21 years of age and older are as follows:

1. Disposable briefs are limited to 248 units per month for adults;
2. Disposable personal pads, liners, shields, guards and undergarments are limited to 93 units per month for adults;
3. Large sized disposable underpads are limited to 93 units per month for adults.
4. Disposable non-sterile gloves are limited to 4 boxes (at 100 per box) or 400 gloves per member per month for adults.
5. Disposable wipes are covered if the member is receiving incontinence products paid for by MaineCare. Disposable wipes are limited to 4 boxes (at 100 per box) or 400 disposable wipes per member per month for adults.

18**.** **Manual Wheelchairs**

1. Manual Wheelchairs (including Standard wheelchairs) are covered if:

a) Criteria A, B, C, D, and E (below) are met; and

b) Criterion F or G (below) is met.

A) 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.

18. **Manual Wheelchairs (cont)**

A mobility limitation is one that:

1) Prevents the member from accomplishing an MRADL entirely, or

2) Places the member at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or

3) Prevents the member from completing an MRADL within a reasonable time frame; or

4) Renders the member unable to ambulate at least one hundred (100) feet.

B) The member's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker.

C) The member's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual wheelchair that is requested.

D) 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.

E) The member has not expressed an unwillingness to use a manual wheelchair in the home.

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

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

19. **Specially Sized Wheelchairs**

Payment may be made for a specially sized 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 specially-sized 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.

20. **Power Mobility Devices (PMD)**

A. 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.

d. 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 necessity of the prescribed equipment for any request for prior authorization for a PMD.

e. An itemized list of all necessary parts and adjusted acquisition 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.

20. **Power Mobility Devices (PMD) (cont)**

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.

A) 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:

1. Prevents the member from accomplishing an MRADL entirely, or

2. Places the member at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or

3. Prevents the member from completing an MRADL within a reasonable time frame.

B) 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.

C) The member does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair safely and sufficiently to perform typical MRADLs.

1. 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.

2. An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate non-powered accessories.

D) The member is able to:

1. Safely transfer to and from a POV, and

2. Operate the tiller steering system, and

3. Maintain postural stability and position while operating the POV in typical environments of use.

20. **Power Mobility Devices (PMD) (cont)**

E) 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.

F) The member's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the POV that is provided.

G) The member's weight is less than or equal to the weight capacity of the POV that is provided.

H) Use of a POV will significantly improve the member's ability to participate in typical MRADLs in customary environments of use.

I) The member is willing and able to use a POV.

J) 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, curbs or gravel, and grassy surfaces that are not level.

K) 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)

L) The member has the mental and physical capabilities to safely operate the power wheelchair that is provided; or

M) 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

N) The member's weight is less than or equal to the weight capacity of the power wheelchair that is provided.

O) The member's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the power wheelchair that is provided.

P) 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.

Q) The member is willing and able to use a power wheelchair.

20. **Power Mobility Devices (PMD) (cont)**

1. Power Operated Vehicle (POV) Coverage Criteria

Group 1 POV – is covered if all of the coverage criteria (A-I) is met. If coverage criteria A-I is not met, the individual is not medically eligible for Group 1 POV coverage.

Group 2 POV – is covered if all the coverage criteria (A-K) is met. If coverage criteria A-K is not met, the individual is not medically eligible for Group 2 POV coverage.

2. Power Wheelchair (PWC) Coverage Criteria

A power wheelchair is covered if:

a. Coverage criteria (A-C) are met; and

b. The member does not meet coverage criterion D, E, or F for a POV; and

c. Either criterion L or M is met; and

d. Criterion N, O, P, and Q are met; and

e. Any coverage criteria pertaining to the specific wheelchair type (see below) are met.

If the PWC will be used in typical environments of use and coverage criteria (a)-(e) 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 (a)-(e) are not met and the criteria for a POV are not met, it will be denied as not medically necessary.

Additional Power Wheelchair Criteria by Group

1. Group 1 PWC or a Group 2 PWC – is covered if all of the coverage criteria (a)-(e) 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 (a)-(e) 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.

20. **Power Mobility Devices (PMD) (cont)**

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 (a)-(e) 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.

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 (a)-(e) 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.

20. **Power Mobility Devices (PMD) (cont)**

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

   A. The member is a very active power wheelchair user that meets all of the coverage criteria (a)-(e) 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, curbs) 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, hilly 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 (D) 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:

20. **Power Mobility Devices (PMD) (cont)**

A. All the coverage criteria (a)-(e) 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.

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.

B. 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

20. **Power Mobility Devices (PMD) (cont)**

devices, but must have a patient weight capacity within the range to 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.

20. **Power Mobility Devices (PMD) (cont)**

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.

1. Lap belt or safety belt. Shoulder harness/straps or chest straps/vest may be billed separately.
2. Battery charger, single mode
3. Complete set of tires and casters, any type
4. Leg rests. There is no separate billing/payment if fixed, swingaway, or detachable non-elevating leg rests with or without calf pad are provided. Elevating leg rests may be billed separately.
5. Footrests/foot platform. There is no separate billing/payment if fixed, swingaway, 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.
6. Armrests. There is no separate billing/ payment if fixed, swingaway, or detachable non-adjustable height armrests with arm pad are provided. Adjustable height armrests may be billed separately.
7. Any weight specific components (braces, bars, upholstery, brackets, motors, gears, etc.) as required by patient weight capacity.
8. Any seat width and depth. Exception: For Group 3 and 4 PWCs with a sling/solid seat/back, the following may be billed separately:
   a. For Standard Duty, seat width and/or depth greater than 20 inches;
   b. For Heavy Duty, seat width and/or depth greater than 22 inches;
   c. For Very Heavy Duty, seat width and/or depth greater than 24 inches;
   d. For Extra Heavy Duty, no separate billing

9. Any back width. Exception: For Group 3 and 4 PWCs with a sling/solid seat/back, the following may be billed separately:
   a. For Standard Duty, back width greater than 20 inches;
   b. For Heavy Duty, back width greater than 22 inches;
   c. For Very Heavy Duty, back width greater than 24 inches;
   d. For Extra Heavy Duty, no separate billing

10. 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., nonproportional or mini, compact or short throw proportional), or other alternative control device may be billed separately.

20. **Power Mobility Devices (PMD) (cont)**

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.

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.

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

20. **Power Mobility Devices (PMD) (cont)**

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 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:

a. 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).
b. 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:

a. Proportional input devices (e.g., mini, compact, or short throw joysticks, touch pads, chin control, head control, etc.) other than a standard proportional joystick.
b. Non-proportional input devices (e.g., sip and puff, head array, etc.)
c. 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:
    1. A separate display (i.e., for alternate control devices).
    2. Other electronic devices (e.g., control of an augmentative speech device or computer through the chair's drive control).
    3. 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

20. **Power Mobility Devices (PMD) (cont)**

is made from the Integral Control box to the motors and batteries through a high power wire harness.

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 Captains Chair.

Captains Chair - A one or two-piece automotive-style seat with rigid frame, cushioning material in both seat and back sections, covered in cloth, vinyl, leather or equal as upholstery, and designed to serve as a complete seating, support, and cushioning system for the user. It may have armrests that can be fixed, 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 Captains 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.

20. **Power Mobility Devices (PMD) (cont)**

2. Power Operated Vehicle and Power Wheelchair Groups

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

20. **Power Mobility Devices (PMD) (cont)**

b. Power Wheelchair (PWC) Groups

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 crossbrace 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 crossbrace construction
- Accommodates seating and positioning items (e.g., seat and back cushions, headrests, lateral trunk supports, lateral hip supports, medial thigh supports) (except captains chairs)
- Length - less than or equal to 48 inches
- Width - less than or equal to 34 inches
- Minimum Top End Speed - 3 MPH

20. **Power Mobility Devices (PMD) (cont)**

- 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 captains 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
- Capable of upgrade to expandable controller
- Capable of upgrade to alternative control devices

20. **Power Mobility Devices (PMD) (cont)**

- May not have crossbrace construction
- Accommodates seating and positioning items (e.g., seat and back cushions, headrests, lateral trunk supports, lateral hip supports, medial thigh supports) (except captains 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 crossbrace construction
- Accommodates seating and positioning items (e.g., seat and back cushions, headrests, lateral trunk supports, lateral hip supports, medial thigh supports) (except captains 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

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

20. **Power Mobility Devices (PMD) (cont)**

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