

**441—78.10(249A) Durable medical equipment (DME), prosthetic devices and medical supplies.**

**78.10(1) General payment requirements.** Payment will be made for items of DME, prosthetic devices and medical supplies, subject to the following general requirements and the requirements of subrule 78.10(2), 78.10(3), or 78.10(4), as applicable:

*a.* DME, prosthetic devices, and medical supplies must be required by the member because of the member's medical condition.

*b.* The item shall be necessary and reasonable either for the treatment of an illness or injury, or to improve the functioning of a malformed body part. Determination will be made by the Iowa Medicaid enterprise medical services unit.

(1) An item is necessary when it can be expected to make a meaningful contribution to the treatment of a specific illness or injury or to the improvement in function of a malformed body part.

(2) Although an item may be necessary, it must also be a reasonable expenditure for the Medicaid program. The following considerations enter into the determination of reasonableness: Whether the expense of the item to the program would be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the item; whether the item would be substantially more costly than a medically appropriate and realistically feasible alternative pattern of care; and whether the item serves essentially the same purpose as an item already available to the beneficiary.

*c.* A physician's (doctor of medicine, osteopathy, or podiatry), physician assistant's, or advanced registered nurse practitioner's prescription is required to establish medical necessity. The prescription shall state the member's name, diagnosis, prognosis, item(s) to be dispensed, quantity, and length of time the item is to be required and shall include the signature of the prescriber and the date of signature.

For items requiring prior authorization, a request shall include a physician's, physician assistant's, or advanced registered nurse practitioner's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements for the equipment or device are met and the item is medically necessary and reasonable. A request for prior authorization is made using Form 470-5595, Outpatient Prior Authorization Request. See rule 441—78.28(249A) for prior authorization requirements.

*d.* Nonmedical items will not be covered. These include but are not limited to:

(1) Physical fitness equipment, e.g., an exercycle, weights.

(2) First-aid or precautionary-type equipment, e.g., preset portable oxygen units.

(3) Self-help devices, e.g., safety grab bars, raised toilet seats.

(4) Training equipment, e.g., speech teaching machines, braille training texts.

(5) Equipment used for environmental control or to enhance the environmental setting, e.g., room heaters, air conditioners, humidifiers, dehumidifiers, and electric air cleaners.

(6) Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the member, e.g., elevators, stairway elevators and posture chairs.

*e.* The amount payable is based on the least expensive item which meets the member's medical needs. Payment will not be approved for items that serve duplicate functions. EXCEPTION: A second ventilator for which prior authorization has been granted. See 78.10(5) "k" for prior authorization requirements.

*f.* Consideration will be given to rental or purchase based on the price of the item and the length of time it would be required. The decision on rental or purchase shall be made by the Iowa Medicaid enterprise and be based on the most reasonable method to provide the equipment.

(1) The provider shall monitor rental payments up to 100 percent of the purchase price. At the point that total rent paid equals 100 percent of the purchase allowance, the member will be considered to own the item and no further rental payments will be made to the provider.

(2) Payment may be made for the purchase of an item even though rental payments may have been made for prior months. The rental of the equipment may be necessary for a period of time to establish that it will meet the identified need before the purchase of the equipment. When a decision is made to purchase after renting an item, all of the rental payments will be applied to the purchase allowance.

(3) EXCEPTION: Ventilators and oxygen systems shall be maintained on a rental basis for the duration of use.

(4) A deposit shall not be charged by a provider to a Medicaid member or any other person on behalf of a Medicaid member for rental of medical equipment.

g. Payment may be made for necessary repair, maintenance, and supplies for member-owned equipment. No payment may be made for repairs, maintenance, or supplies when the member is renting the item.

h. Replacement of member-owned equipment is covered in cases of loss or irreparable damage or when required because of a change in the member's condition.

i. No allowance will be made for delivery, freight, postage, or other provider operating expenses for DME, prosthetic devices or medical supplies.

j. Reimbursement over the established fee schedule amount is allowed when prior authorization has been obtained. See 78.10(5) "n" for prior authorization requirements.

**78.10(2) Durable medical equipment.** DME is equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of an illness or injury, and is appropriate for use in the home.

a. Durable medical equipment provided in a hospital, nursing facility, or intermediate care facility for persons with an intellectual disability is not separately payable.

**EXCEPTIONS:**

(1) Oxygen services in a nursing facility or an intermediate care facility for persons with an intellectual disability when all of the following requirements and conditions have been met:

1. A Certificate of Medical Necessity for Oxygen, Form CMS-484, or a reasonable facsimile is completed by a physician, physician assistant, or advanced registered nurse practitioner and qualifies the member in accordance with Medicare criteria.

2. Additional documentation shows that the member requires oxygen for 12 hours or more per day for at least 30 days.

3. Oxygen logs must be maintained by the provider. The time between any reading shall not exceed more than 45 days. The documentation maintained in the provider record must contain the following:

- The initial, periodic and ending reading on the time meter clock on each oxygen system, and
- The dates of each initial, periodic and ending reading, and
- Evidence of ongoing need for oxygen services.

4. The maximum Medicaid payment shall be based on the least costly method of oxygen delivery.

5. Oxygen prescribed "PRN" or "as necessary" is not payable.

6. Medicaid payment shall be made for the rental of equipment only. All accessories and disposable supplies related to the oxygen delivery system and costs for servicing and repair of equipment are included in the Medicaid payment and shall not be separately payable.

7. Payment is not allowed for oxygen services that are not documented according to the department of inspections and appeals requirements at 481—subrule 58.21(8).

(2) Speech generating devices for which prior authorization has been obtained. See 78.10(5) "f" for prior authorization requirements.

(3) Wheelchairs for members in an intermediate care facility for persons with an intellectual disability.

b. The types of durable medical equipment covered through the Medicaid program include, but are not limited to:

Automated medication dispenser.

Bathtub/shower chair, bench. See 78.10(5) "g" and "j" for prior authorization requirements.

Commode, shower commode chair. See 78.10(5) "j" for prior authorization requirements.

Decubitus equipment.

Dialysis equipment.

Diaphragm (contraceptive device).

Enclosed bed. See 78.10(5) "a" for prior authorization requirements.

Enuresis alarm system (bed-wetting alarm device) for members five years of age or older.

Heat/cold application device.

Hospital bed and accessories.

Inhalation equipment. See 78.10(5) "c" for prior authorization requirements.

Insulin infusion pump. See 78.10(5) “b” and 78.10(5) “e” for prior authorization requirements.

Lymphedema pump.

Mobility device and accessories. See 78.10(5) “i” for prior authorization requirements.

Neuromuscular stimulator.

Oximeter.

Oxygen, subject to the limitations in 78.10(2) “a” and 78.10(2) “c.”

Patient lift. See 78.10(5) “h” for prior authorization requirements.

Phototherapy bilirubin light.

Protective helmet.

Seat lift chair.

Speech generating device. See 78.10(5) “f” for prior authorization requirements.

Traction equipment.

Ventilator.

c. Coverage of home oxygen equipment and oxygen will be considered reasonable and necessary for members in accordance with Medicare criteria and as shown by supporting medical documentation. The physician, physician assistant, or advanced registered nurse practitioner shall document that other forms of treatment are contraindicated or have been tried and have not been successful and that oxygen therapy is required. EXCEPTION: Home oxygen equipment and oxygen are covered for children through three years of age when prescribed by a physician, physician assistant or advanced registered nurse practitioner. A pulse oximeter reading must be obtained yearly and documented in the provider and physician record.

(1) To identify the medical necessity for oxygen therapy, a Certificate of Medical Necessity for Oxygen, Form CMS-484, or a reasonable facsimile completed by a physician, physician assistant, or advanced registered nurse practitioner, shall qualify the member in accordance with Medicare criteria.

(2) If the member’s condition or need for oxygen services changes, the attending physician, physician assistant, or advanced registered nurse practitioner must adjust the documentation accordingly.

(3) A second oxygen system is not covered by Medicaid when used as a backup for oxygen concentrators or as a standby in case of emergency. Members may be provided with a portable oxygen system to complement a stationary oxygen system, or to be used by itself, with documentation from the physician, physician assistant, or advanced registered nurse practitioner of the specific activities for which portable oxygen is medically necessary.

(4) Payment for oxygen systems shall be made only on a rental basis for the duration of use.

(5) All accessories, disposable supplies, servicing, and repairing of oxygen systems are included in the monthly Medicaid payment for oxygen systems.

(6) Oxygen prescribed “PRN” or “as necessary” is not allowed.

d. Wheelchairs, wheelchair accessories, and wheelchair modifications are covered when they are medically necessary for mobility within the home, nursing facility, or intermediate care facility. Wheelchairs are defined as:

(1) Standard manual wheelchairs. Coverage of a standard manual wheelchair includes the following:

1. Complete set of tires/wheels and casters, any type;
2. Hand rims with or without projections;
3. Weight-specific components required by the patient-weight capacity of the wheelchair;
4. Elevating legrest, lower extension tube and upper hanger bracket;
5. Armrest (detachable, non-adjustable or adjustable) with or without arm pad;
6. Footrest (swingaway, detachable), including lower extension tube(s) and upper hanger bracket;
7. Standard size footplates;
8. Wheelchair bearings;
9. Caster fork, replacement only; and

10. All labor charges involved in the assembly of the wheelchair (including, but not limited to: front caster assembly, rear wheel assembly, ratchet assembly, wheel lock assembly, footrest assembly).

(2) Standard manual wheelchair accessories that are separately billable and require prior authorization include the following:

1. Headrest extensions;

2. One-arm drive attachments;
  3. Positioning accessories;
  4. Specialized skin protection seat and back cushions; and
  5. Anti-rollback devices.
- (3) Standard power wheelchair. Coverage of a standard power wheelchair requires prior authorization and includes the following:
1. Lap belt or safety belt;
  2. Battery charger, single mode;
  3. Complete set of tires/wheels and casters, any type;
  4. Legrests (fixed, swingaway, or detachable non-elevation legrests with or without calf pad);
  5. Footrests/foot platform (fixed, swingaway, detachable footrests or a foot platform without angle adjustment, single adjustable footplate);
  6. Armrests (fixed, swingaway, detachable non-adjustable height armrests with arm pad provided);
  7. Any weight-specific components (braces, bars, upholstery, brackets, motors, gears, etc.) as required by patient-weight capacity of the wheelchair;
  8. Any seat width and depth. For power wheelchairs with a sling/solid seat/back, the following may be billed separately:
    - For standard duty, seat width and/or depth greater than 20 inches;
    - For heavy duty, seat width and/or depth greater than 22 inches;
    - For very heavy duty, seat width and/or depth greater than 24 inches;
    - EXCEPTION: For extra heavy duty, there is no separate billing;
  9. Any back width. For power wheelchairs with a sling/solid seat/back, the following may be billed separately:
    - For standard duty, seat width and/or depth greater than 20 inches;
    - For heavy duty, seat width and/or depth greater than 22 inches;
    - For very heavy duty, seat width and/or depth greater than 24 inches;
    - EXCEPTION: For extra heavy duty, there is no separate billing;
  10. Non-expandable controller or standard proportional joystick (integrated or remote); and
  11. All labor charges involved in the assembly of the wheelchair (including, but not limited to: front caster assembly, rear wheel assembly, ratchet assembly, wheel lock assembly, footrest assembly).
- (4) Standard power wheelchair accessories that are billed separately and require a prior authorization include the following:
1. Shoulder harness/straps or chest straps/vest;
  2. Elevating legrest;
  3. Angle adjustable footplates;
  4. Adjustable height armrests; and
  5. Expandable controller or nonstandard joystick (i.e., non-proportional or mini, compact or short throw proportional, or other alternative control device).
- (5) Customized items are payable with a prior authorization, in accordance with 42 CFR §414.224.
- 78.10(3) Prosthetic devices.** Prosthetic devices mean replacement, corrective, or supportive devices prescribed by a physician (doctor of medicine, osteopathy or podiatry), physician assistant, or advanced registered nurse practitioner within the scope of practice as defined by state law to artificially replace a missing portion of the body, prevent or correct a physical deformity or malfunction, or support a weak or deformed portion of the body. This does not require a determination that there is no possibility that the member's condition may improve sometime in the future.
- a. Prosthetic devices are not covered when dispensed to a member prior to the time the member undergoes a procedure which will make necessary the use of the device.
  - b. The types of prosthetic devices covered through the Medicaid program include, but are not limited to:
    - (1) Artificial eyes.
    - (2) Artificial limbs.
    - (3) Enteral delivery supplies and products. See 78.10(5) "I" for prior authorization requirements.

- (4) Hearing aids. See rule 441—78.14(249A).
  - (5) Orthotic devices. See 78.10(3) “c” for limitations on coverage of cranial orthotic devices.
  - (6) Ostomy appliances.
  - (7) Parenteral delivery supplies and products. Daily parenteral nutrition therapy is considered necessary and reasonable for a member with severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the member’s general condition.
  - (8) Prosthetic shoes, orthopedic shoes. See rule 441—78.15(249A).
  - (9) Tracheotomy tubes.
  - (10) Vibrotactile aids. Vibrotactile aids are payable only once in a four-year period unless the original aid is broken beyond repair or lost. (Cross reference 78.28(5))
- c. Cranial orthotic device. Payment shall be approved for cranial orthotic devices when the device is medically necessary for the postsurgical treatment of synostotic plagiocephaly. Payment shall also be approved when there is documentation supporting moderate to severe nonsynostotic positional plagiocephaly and either:
- (1) The member is 12 weeks of age but younger than 36 weeks of age and has failed to respond to a two-month trial of repositioning therapy; or
  - (2) The member is 36 weeks of age but younger than 108 weeks of age and there is documentation of either of the following conditions:
    - 1. Cephalic index at least two standard deviations above the mean for the member’s gender and age; or
    - 2. Asymmetry of 12 millimeters or more in the cranial vault, skull base, or orbitotragial depth.
- 78.10(4) Medical supplies.** Medical supplies are nondurable items consumed in the process of giving medical care, for example, nebulizers, gauze, bandages, sterile pads, adhesive tape, and sterile absorbent cotton. Medical supplies are payable for a specific medicinal purpose. This does not include food or drugs. However, active pharmaceutical ingredients and excipients that are identified as preferred on the preferred drug list published by the department pursuant to Iowa Code section 249A.20A are covered. Medical supplies shall not be dispensed at any one time in quantities exceeding a 31-day supply for active pharmaceutical ingredients and excipients or a three-month supply for all other items. After the initial dispensing of medical supplies, the provider must document a refill request from the Medicaid member or the member’s caregiver for each refill.
- a. The types of medical supplies and supplies necessary for the effective use of a payable item covered through the Medicaid program include, but are not limited to:
- Active pharmaceutical ingredients and excipients identified as preferred on the preferred drug list published pursuant to Iowa Code section 249A.20A.
- Catheter (indwelling Foley).
  - Colostomy and ileostomy appliances.
  - Colostomy and ileostomy care dressings, liquid adhesive, and adhesive tape.
  - Diabetic supplies (including but not limited to blood glucose test strips, lancing devices, lancets, needles, syringes, and diabetic urine test supplies). See 78.10(5) “e” for prior authorization requirements.
  - Dialysis supplies.
  - Disposable catheterization trays or sets (sterile).
  - Disposable irrigation trays or sets (sterile).
  - Disposable saline enemas (e.g., sodium phosphate type).
  - Dressings.
  - Elastic antiembolism support stocking.
  - Enema.
  - Hearing aid batteries.
  - Incontinence products (for members three years of age and older).
  - Oral nutritional products. See 78.10(5) “m” for prior authorization requirements.
  - Ostomy appliances and supplies.
  - Respirator supplies.

Shoes, diabetic.

Surgical supplies.

Urinary collection supplies.

*b.* Only the following types of medical supplies will be approved for payment for members receiving care in a nursing facility or an intermediate care facility for persons with an intellectual disability when prescribed by the physician, physician assistant, or advanced registered nurse practitioner:

Catheter (indwelling Foley).

Diabetic supplies (including but not limited to lancing devices, lancets, needles and syringes, blood glucose test strips, and diabetic urine test supplies).

Disposable catheterization trays or sets (sterile).

Disposable irrigation trays or sets (sterile).

Disposable saline enemas (e.g., sodium phosphate type).

Ostomy appliances and supplies.

Shoes, diabetic.

**78.10(5) *Prior authorization requirements.*** Prior authorization pursuant to rule 441—79.8(249A) is required for the following medical equipment and supplies (Cross reference 78.28(1)):

*a.* Enclosed beds. Payment for an enclosed bed shall be approved when prescribed for a member who meets all of the following conditions:

(1) The member has a diagnosis-related cognitive or communication impairment that results in risk to safety.

(2) The member's mobility puts the member at risk for injury.

*b.* External insulin infusion pumps. Payment will be approved according to Medicare coverage criteria.

*c.* Vest airway clearance systems. Payment will be approved for a vest airway clearance system when prescribed by a pulmonologist for a member with a diagnosis of a lung disorder if all of the following conditions are met:

(1) Pulmonary function tests for the 12 months before the initiation of the vest demonstrate an overall significant decrease in lung function.

(2) The member resides in an independent living situation or has a medical condition that precludes the caregiver from administering traditional chest physiotherapy.

(3) Treatment by flutter device failed or is contraindicated.

(4) Treatment by intrapulmonary percussive ventilation failed or is contraindicated.

(5) All other less costly alternatives have been tried.

*d.* Rescinded IAB 12/30/20, effective 3/1/21.

*e.* DME rebate agreements. If the department has a current agreement for a rebate with at least one manufacturer of a particular category of diabetic equipment or supplies (by healthcare common procedure coding system (HCPCS) code), prior authorization is required for any equipment or supplies in that category produced by a manufacturer that does not have a current agreement to provide a rebate to the department (other than supplies for members receiving care in a nursing facility or an intermediate care facility for persons with an intellectual disability). Prior approval shall be granted when the member's medical condition necessitates use of equipment or supplies produced by a manufacturer that does not have a current rebate agreement with the department.

*f.* Speech generating device. Payment shall be approved according to Medicare coverage criteria. Form 470-2145, Speech Generating Device System Selection, completed by a speech-language pathologist and a physician's, physician assistant's, or advanced registered nurse practitioner's prescription for a particular device shall be submitted with the request for prior authorization. In addition, documentation from a speech-language pathologist must include information on the member's educational ability and needs, vocational potential, anticipated duration of need, prognosis regarding oral communication skills, prognosis with a particular device, and recommendations. A minimum one-month trial period is required for all devices. The Iowa Medicaid enterprise consultant with expertise in speech-language pathology will evaluate each prior authorization request and make recommendations to the department.

g. Bathtub/shower chair, bench. Payment shall be approved for specialized bath equipment for members whose medical condition necessitates additional body support while bathing.

h. Patient lift, nonstandard. Payment shall be approved for a nonstandard lift, such as a portable, ceiling or electric lifter, when the member meets the Medicare criteria for a patient lift and a standard lifter (Hoyer type) will not work.

i. Power wheelchair attendant control. Payment shall be approved when the member has a power wheelchair and:

(1) Has a sip 'n puff attachment, or

(2) The medical documentation demonstrates the member's difficulty operating the wheelchair in tight space, or

(3) The medical documentation demonstrates the member becomes fatigued.

j. Shower commode chairs. Prior authorization shall be granted when documentation from a physician, physician assistant, advanced registered nurse practitioner, physical therapist or occupational therapist indicates that the member:

(1) Is unable to stand for the duration of a shower or is unable to get in or out of a bathtub, and

(2) Needs upper body support while sitting, and

(3) Needs to be tilted back for safety or pressure relief, if a tilt-in-space chair is requested.

k. Ventilator, secondary. Payment shall be approved according to the Medicare coverage criteria.

l. Enteral products and enteral delivery pumps and supplies. Payment shall be approved according to Medicare coverage criteria. EXCEPTION: The Medicare criteria for permanence is not required.

m. Oral nutritional products. Payment shall be approved when the member is not able to ingest or absorb sufficient nutrients from regular food due to a metabolic, digestive, or psychological disorder or pathology, to the extent that supplementation is necessary to provide 51 percent or more of the daily caloric intake, or when the use of oral nutritional products is otherwise determined medically necessary in accordance with evidence-based guidelines for treatment of the member's condition. Nutritional products consumed orally are not covered for members in nursing facilities or intermediate care facilities for persons with an intellectual disability.

n. Reimbursement over the established Medicaid fee schedule amount. Payment shall be approved for bariatric equipment, pediatric equipment or other specialized medical equipment, supply, prosthetic or orthotic which:

(1) Meets the definition of a code in the current healthcare common procedure coding system (HCPCS), and

(2) Has an established Medicaid fee schedule amount that is inadequate to cover the provider's cost to obtain the equipment or supply.

o. Customized wheelchairs, subject to the requirements of 78.10(2) "d."

This rule is intended to implement Iowa Code sections 249A.3, 249A.4 and 249A.12.

[ARC 7548B, IAB 2/11/09, effective 4/1/09; ARC 8344B, IAB 12/2/09, effective 12/1/09; ARC 8643B, IAB 4/7/10, effective 3/11/10; ARC 8714B, IAB 5/5/10, effective 5/1/10; ARC 8993B, IAB 8/11/10, effective 10/1/10; ARC 9256B, IAB 12/1/10, effective 1/1/11; ARC 0632C, IAB 3/6/13, effective 5/1/13; ARC 0823C, IAB 7/10/13, effective 9/1/13; ARC 1151C, IAB 10/30/13, effective 1/1/14; ARC 4575C, IAB 7/31/19, effective 9/4/19; ARC 4899C, IAB 2/12/20, effective 3/18/20; see Delay note at end of chapter; ARC 5362C, IAB 12/30/20, effective 3/1/21]