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 diagnosis, prognosis, and length of time the item is to be required.

For items requiring prior approval, 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 approval is made on Form 470-0829, Request for Prior Authorization. See rule 441—78.28(249A) for prior approval 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 patient, e.g., elevators, stairway elevators and posture chairs.

e. The amount payable is based on the least expensive item which meets the patient's medical needs. Payment will not be approved for duplicate items.

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 will be maintained on a rental basis for the duration of use.

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.

78.10(2) *Durable medical equipment.* DME is equipment which 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 will not be provided in a hospital, nursing facility, or intermediate care facility for the mentally retarded except when a Medicaid-eligible resident of a nursing facility medically needs oxygen for 12 or more hours per day for at least 30 days or more. Medicaid will provide payment to medical equipment and supply dealers to provide oxygen services in a nursing facility when all of the following requirements and conditions have been met:

(1) A physician's, physician assistant's, or advanced registered nurse practitioner's prescription documents that a resident of a nursing facility requires oxygen for 12 hours or more per day and the provider and physician, physician assistant, or advanced registered nurse practitioner jointly submit Certificate of Medical Necessity, Form CMS-484, from Medicare or a reasonable facsimile to the Iowa Medicaid enterprise with the monthly billing. The documentation submitted must contain the following:

1. The number of hours oxygen is required per day;
2. The diagnosis of the disease requiring continuous oxygen, prognosis, and length of time the oxygen will be needed;
3. The oxygen flow rate and concentration; the type of system ordered, i.e., cylinder gas, liquid gas, or concentrator;
4. A specific estimate of the frequency and duration of use; and
5. The initial reading on the time meter clock on each concentrator, where applicable.

Oxygen prescribed "PRN" or "as necessary" is not allowed.

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

(3) Medicaid payment shall be made for the rental of equipment only. All accessories and disposable supplies related to the oxygen delivery system, servicing and repairing of equipment are included in the Medicaid payment.

(4) Oxygen logs must be maintained by the provider. When random postpayment review of these logs indicates less than an average of 12 hours per day of oxygen was provided over a 30-day period, recoupment of the overpayment may occur.

(5) Payment will be made for only one mode of oxygen even if the physician's, physician assistant's, or advanced registered nurse practitioner's prescription allows for multiple modes of delivery.

(6) Payment will not be made for oxygen that is not documented according to department of inspections and appeals 481—subrule 58.21(8).

b. Only the following types of durable medical equipment can be covered through the Medicaid program:

Alternating pressure pump.

Automated medication dispenser. See 78.10(2)*"d"* for prior authorization requirements.

Bedpan.

Blood glucose monitors, subject to the limitation in 78.10(2)*"e."*

Blood pressure cuffs.

Cane.

Cardiorespiratory monitor (rental and supplies).

Commode.
Commode pail.
Crutches.
Decubitus equipment.
Dialysis equipment.
Diaphragm (contraceptive device).
Enclosed bed. See 78.10(2)*"d"* for prior authorization requirements.
Enuresis alarm system (bed-wetting alarm device) for members five years of age or older.
Hospital bed.
Hospital bed accessories.
Inhalation equipment.
Insulin infusion pump. See 78.10(2)*"d"* for prior authorization requirements.
Lymphedema pump.
Neuromuscular stimulator.
Oximeter.
Oxygen, subject to the limitations in 78.10(2)*"a"* and 78.10(2)*"c."*
Patient lift (Hoyer).
Phototherapy bilirubin light.
Pressure unit.
Protective helmet.
Respirator.
Resuscitator bags and pressure gauge.
Seat lift chair.
Suction machine.
Traction equipment.
Urinal (portable).
Vaporizer.
Ventilator.
Vest airway clearance system. See 78.10(2)*"d"* for prior authorization requirements.
Walker.
Wheelchair—standard and adaptive.
Whirlpool bath.

c. Coverage of home oxygen equipment and oxygen will be considered reasonable and necessary only for members with significant hypoxemia, as shown by medical documentation. The physician's, physician assistant's, or advanced registered nurse practitioner's prescription shall document that other forms of treatment have been tried and have not been successful, and that oxygen therapy is required.

(1) To identify the medical necessity for oxygen therapy, the supplier and a physician, physician assistant, or advanced registered nurse practitioner shall jointly submit Medicare Form B-7401, Physician's Certification for Durable Medical Equipment, or a reasonable facsimile. The following information is required:

1. A diagnosis of the disease requiring home use of oxygen;
2. The oxygen flow rate and concentration;
3. The type of system ordered, i.e., cylinder gas, liquid gas, or concentrator;
4. A specific estimate of the frequency and duration of use; and
5. The initial reading on the time meter clock on each concentrator, where applicable.

Oxygen prescribed "PRN" or "as necessary" is not allowed.

(2) If the patient'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 (doctor of medicine or osteopathy), physician assistant, or advanced registered nurse practitioner of the medical necessity for portable oxygen for specific activities.

(4) Payment for concentrators shall be made only on a rental basis.

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

d. Prior authorization is required for the following medical equipment and supplies (Cross-reference 78.28(1)):

(1) Enclosed beds. Payment for an enclosed bed will be approved when prescribed for a patient who meets all of the following conditions:

1. The patient has a diagnosis-related cognitive or communication impairment that results in risk to safety.
2. The patient's mobility puts the patient at risk for injury.
3. The patient has suffered injuries when getting out of bed.

(2) External insulin infusion pumps. Payment will be approved according to Medicare coverage criteria.

(3) Vest airway clearance systems. Payment will be approved for a vest airway clearance system when prescribed by a pulmonologist for a patient 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 of lung function.
2. The patient 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.

(4) Automated medication dispenser. Payment will be approved for an automated medication dispenser when prescribed for a member who meets all of the following conditions:

1. The member has a diagnosis indicative of cognitive impairment or age-related factors that affect the member's ability to remember to take medications.
2. The member is on two or more medications prescribed to be administered more than one time a day.
3. The availability of a caregiver to administer the medications or perform setup is limited or nonexistent.
4. Less costly alternatives, such as medisets or telephone reminders, have failed.

(5) Blood glucose monitors and diabetic test strips produced by a manufacturer that does not have a current agreement to provide a rebate to the department for monitors or test strips provided through the Medicaid program. Prior approval shall be granted when the member's medical condition necessitates use of a blood glucose monitor or diabetic test strips produced by a manufacturer that does not have a current rebate agreement with the department.

e. Blood glucose monitors are covered through the Medicaid program only if:

(1) The monitor is produced by a manufacturer that has a current agreement to provide a rebate to the department for monitors provided through the Medicaid program; or

(2) Prior authorization based on medical necessity is received pursuant to rule 441—79.8(249A) for a monitor produced by a manufacturer that does not have a current rebate agreement with the department.

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 patient's condition may improve sometime in the future.

a. Prosthetic devices are not covered when dispensed to a patient prior to the time the patient undergoes a procedure which will make necessary the use of the device.

b. Only the following types of prosthetic devices shall be covered through the Medicaid program:

Artificial eyes.

Artificial limbs.

Augmentative communications systems provided for members unable to communicate their basic needs through oral speech or manual sign language. Payment will be made for the most cost-effective item that meets basic communication needs commensurate with the member's cognitive and language abilities. See 78.10(3)*"c"* for prior approval requirements.

Enteral delivery supplies and products. See 78.10(3)*"c"* for prior approval requirements.

Hearing aids. See rule 441—78.14(249A).

Oral nutritional products. See 78.10(3)*"c"* for prior approval requirements.

Orthotic devices. See 78.10(3)*"d"* for limitations on coverage of cranial orthotic devices.

Ostomy appliances.

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.

Prosthetic shoes. See rule 441—78.15(249A).

Tracheotomy tubes.

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(8))

c. Prior approval is required for the following prosthetic devices:

(1) Augmentative communication systems. Form 470-2145, Augmentative Communication System Selection, completed by a speech pathologist and a physician's, physician assistant's, or advanced registered nurse practitioner's prescription for a particular device shall be submitted to the Iowa Medicaid enterprise medical services unit to request prior approval. Information requested on the prior approval form includes a medical history, diagnosis, and prognosis completed by a physician, physician assistant, or advanced registered nurse practitioner. In addition, a speech or language pathologist needs to describe current functional abilities in the following areas: communication skills, motor status, sensory status, cognitive status, social and emotional status, and language status. Also needed from the speech or language pathologist is information on educational ability and needs, vocational potential, anticipated duration of need, prognosis regarding oral communication skills, prognosis with a particular device, and recommendations. The department's consultants with expertise in speech pathology will evaluate the prior approval requests and make recommendations to the department. (Cross-reference 78.28(1)*"c"*)

(2) Enteral products and enteral delivery pumps and supplies. Daily enteral nutrition therapy shall be approved as medically necessary only for a member who either has a metabolic or digestive disorder that prevents the member from obtaining the necessary nutritional value from usual foods in any form and cannot be managed by avoidance of certain food products or has a severe pathology of the body that does not allow ingestion or absorption of sufficient nutrients from regular food to maintain weight and strength commensurate with the member's general condition.

A request for prior approval shall include a physician's, physician assistant's, or advanced registered nurse practitioner's written order or prescription and documentation to establish the medical necessity

for enteral products and enteral delivery pumps and supplies pursuant to the above standards. The documentation shall include:

1. A statement of the member's total medical condition that includes a description of the member's metabolic or digestive disorder or pathology.

2. Documentation of the medical necessity for commercially prepared products. The information submitted must identify other methods attempted to support the member's nutritional status and indicate that the member's nutritional needs were not or could not be met by regular food in pureed form.

3. Documentation of the medical necessity for an enteral pump, if the request includes an enteral pump. The information submitted must identify the medical reasons for not using a gravity feeding set.

Examples of conditions that will not justify approval of enteral nutrition therapy are: weight-loss diets, wired-shut jaws, diabetic diets, milk or food allergies (unless the member is under five years of age and coverage through the Women, Infant and Children's program is not available), and the use of enteral products for convenience reasons when regular food in pureed form would meet the medical need of the member.

Basis of payment for nutritional therapy supplies shall be the least expensive method of delivery that is reasonable and medically necessary based on the documentation submitted.

(3) Oral nutritional products. Payment for oral nutritional products shall be approved as medically necessary only 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.

A request for prior approval shall include a physician's, physician assistant's, or advanced registered nurse practitioner's written order or prescription and documentation to establish the medical necessity for oral supplementation pursuant to these standards. The documentation shall include:

1. A statement of the member's total medical condition that includes a description of the member's metabolic, digestive, or psychological disorder or pathology.

2. Documentation of the medical necessity for commercially prepared products. The information submitted must identify other methods attempted to support the member's nutritional status and indicate that the member's nutritional needs were not or could not be met by regular food in pureed form.

3. Documentation to support the fact that regular foods will not provide sufficient nutritional value to the member.

Examples of conditions that will not justify approval of oral supplementation are: weight-loss diets, wired-shut jaws, diabetic diets, milk or food allergies (unless the member is under five years of age and coverage through the Women, Infant and Children's program is not available), supplementation to boost calorie or protein intake by less than 51 percent of the daily intake, and the absence of severe pathology of the body or psychological pathology or disorder.

d. 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 photographic evidence supporting moderate to severe nonsynostotic positional plagiocephaly and either:

(1) The member is between 3 and 5 months of age and has failed to respond to a two-month trial of repositioning therapy; or

(2) The member is between 6 and 18 months 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. Medical supplies are not to be dispensed at any one time for quantities exceeding a three-month supply. 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. Only the following types of medical supplies and supplies necessary for the effective use of a payable item can be purchased through the medical assistance program:

Catheter (indwelling Foley).

Colostomy and ileostomy appliances.

Colostomy and ileostomy care dressings, liquid adhesive, and adhesive tape.

Diabetic blood glucose test strips, subject to the limitation in 78.10(4)*"c."*

Diabetic supplies, other than blood glucose test strips (needles, syringes, and diabetic urine test supplies).

Dialysis supplies.

Diapers (for members aged four and above).

Disposable catheterization trays or sets (sterile).

Disposable irrigation trays or sets (sterile).

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

Disposable underpads.

Dressings.

Elastic antiembolism support stocking.

Enema.

Hearing aid batteries.

Respirator supplies.

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 the mentally retarded when prescribed by the physician, physician assistant, or advanced registered nurse practitioner:

Catheter (indwelling Foley).

Colostomy and ileostomy appliances.

Colostomy and ileostomy care dressings, liquid adhesive and adhesive tape.

Diabetic supplies (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).

c. Diabetic blood glucose test strips are covered through the Medicaid program only if:

(1) The strips are produced by a manufacturer that has a current agreement to provide a rebate to the department for test strips provided through the Medicaid program, or

(2) Prior authorization is received pursuant to rule 441—79.8(249A) for test strips produced by a manufacturer that does not have a current rebate agreement with the department, based on medical necessity.

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]