HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services proposes to amend Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," Iowa Administrative Code.

These amendments expand prior authorization requirements for diabetic equipment and supplies not covered by 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 (such as blood glucose monitors, blood glucose test strips, lancing devices, lancets, or diabetic syringes), prior authorization will be required for any equipment or supplies in that category produced by manufacturers that have not contracted with the Department to provide a rebate. However, this requirement will not apply to supplies for members receiving care in a nursing facility or an intermediate care facility for persons with an intellectual disability. Prior authorization will be granted when medically necessary.

Any interested person may make written comments on the proposed amendments on or before January 2, 2013. Comments should be directed to Harry Rossander, Bureau of Policy Coordination, Department of Human Services, Hoover State Office Building, 1305 East Walnut Street, Des Moines, Iowa 50319-0114. Comments may be sent by fax to (515)281-4980 or by e-mail to policyanalysis@dhs.state.ia.us.

These amendments do not provide for waivers in specified situations because prior authorization may be requested for products from manufacturers without rebate agreements. In addition, requests for the waiver of any rule may be submitted under the Department's general rule on exceptions at 441—1.8(17A,217).

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 249A.4.

The following amendments are proposed.

ITEM 1. Amend subrule 78.10(2) as follows:

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. No change.
- *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" 78.10(5) "d" for prior authorization requirements.

Bedpan.

Blood glucose monitors, subject to the limitation in 78.10(2) "e.". See 78.10(5) "e" for prior authorization requirements.

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" 78.10(5)"a" 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" 78.10(5) "b" and 78.10(5) "e" 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" 78.10(5)"c" for prior authorization requirements.

Walker

Wheelchair—standard and adaptive.

Whirlpool bath.

- c. No change.
- 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.
 - ITEM 2. Amend subrule 78.10(4) as follows:
- **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. 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:

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

Diabetic supplies, other than blood glucose test strips (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.

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 (<u>including but not limited to lancing devices</u>, 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).

- 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.
 - ITEM 3. Adopt the following **new** subrule 78.10(5):
- **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 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.
- 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 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 in 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.
- d. 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 per 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.
- e. Diabetic equipment and supplies. 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.

ITEM 4. Amend paragraph 78.28(1)"k" as follows:

k. Prior authorization is required for 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. The department shall approve payment when a blood glucose monitor or diabetic test strips produced by a manufacturer that does not have a current rebate agreement with the department are medically necessary. Diabetic equipment and supplies. Payment will be approved pursuant to the criteria at 78.10(5) "e."