ARC 0649C

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," and Chapter 79, "Other Policies Relating to Providers of Medical and Remedial Care," Iowa Administrative Code.

The purposes of these amendments are to:

• Provide clarifying language.

• Rename "augmentative communication device" as "speech generating device" and reclassify the device from the prosthetics category to the medical equipment category consistent with Medicare classification.

• Reclassify oral nutrition from the prosthetics category to the medical supply category consistent with the classification in the healthcare common procedure coding system (HCPCS).

• Add coverage for bath chairs, nonstandard patient lifters, power wheelchair attendant control, a secondary ventilator, and wheelchairs for members in an intermediate care facility for persons with an intellectual disability.

• Lower the age limit for incontinence products from four years of age to three years of age.

• Allow for reimbursement over the established Medicaid fee schedule amounts for some items.

• Add a prior authorization requirement for shower commode chairs.

Exceptions to policy have routinely been granted according to established criteria for bath chairs, nonstandard patient lifters, power wheelchair attendant control, a secondary ventilator, wheelchairs for members in an intermediate care facility for persons with an intellectual disability, incontinence products for children between three and four years of age, and reimbursement over established Medicaid fee schedule amounts.

Given the complex coverage criteria and the cost for shower commode chairs, authorization prior to the delivery of this item is more efficient than review of a submitted claim.

Any interested person may make written comments on the proposed amendments on or before April 9, 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 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(1) as follows:

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. and *b.* No change.

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, ~~and~~ 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 ~~approval~~ 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 ~~approval~~ authorization is made on Form 470-0829, Request for Prior Authorization. See rule 441—78.28(249A) for prior ~~approval~~ authorization requirements.

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

(1) to (5) No change.

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

e. The amount payable is based on the least expensive item which meets the ~~patient's~~ member's medical needs. Payment will not be approved for ~~duplicate~~ 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) and (2) No change.

(3) EXCEPTION: Ventilators ~~will~~ 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. to *i.* No change.

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.

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

78.10(2) *Durable medical equipment.* DME is equipment ~~which~~ 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 ~~will not be~~ provided in a hospital, nursing facility, or intermediate care facility for persons with ~~mental retardation~~ an intellectual disability is not separately payable. ~~EXCEPTION: Medicaid will provide payment to medical equipment and supply dealers to provide oxygen services in a nursing facility or an intermediate care facility for persons with mental retardation 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 the member has significant hypoxemia as defined by Medicare and evidenced by supporting medical documentation and the member requires oxygen for 12 hours or more per day for at least 30 days. Oxygen prescribed "PRN" or "as necessary" is not allowed. The documentation maintained in the provider record 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.~~

~~(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).~~

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. ~~Only the following~~ The types of durable medical equipment ~~can be~~ covered through the Medicaid program include, but are not limited to:

~~Alternating pressure pump.~~

Automated medication dispenser. See 78.10(5)*"d"* for prior authorization requirements.

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

~~Bedpan.~~

~~Blood glucose monitors. See 78.10(5)*"e"* for prior authorization requirements.~~

~~Blood pressure cuffs.~~

~~Cane.~~

~~Cardiorespiratory monitor (rental and supplies).~~

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

~~Commode pail.~~

~~Crutches.~~

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.
~~Hospital bed 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 ~~(Hoyer)~~. See 78.10(5)*"h"* for prior authorization requirements.
Phototherapy bilirubin light.
~~Pressure unit.~~
Protective helmet.
~~Respirator.~~
~~Resuscitator bags and pressure gauge.~~
Seat lift chair.
Speech generating device. See 78.10(5)*"f"* for prior authorization requirements.
~~Suction machine.~~
Traction equipment.
~~Urinal (portable).~~
~~Vaporizer.~~
Ventilator.
~~Vest airway clearance system. See 78.10(5)*"e"* 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 in accordance with ~~significant hypoxemia as defined by~~ Medicare criteria and as shown by supporting medical documentation. The ~~physician's, physician assistant's, or advanced registered nurse practitioner's prescription~~ 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 ~~at one year of age and at two years of age~~ yearly and documented in the provider and physician record.

(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:~~ 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.

~~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~~ 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 ~~(doctor of medicine or osteopathy)~~, physician assistant, or advanced registered nurse practitioner of the ~~medical necessity for portable oxygen for specific activities~~ specific activities for which portable oxygen is medically necessary.

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

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

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

ITEM 3. Amend subrule 78.10(3) as follows:

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~~ member's condition may improve sometime in the future.

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

b. ~~Only the following~~ The types of prosthetic devices ~~shall be~~ covered through the Medicaid program include, but are not limited to:

(1) Artificial eyes.

(2) Artificial limbs.

~~(3) 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.~~

~~(4)~~ (3) Enteral delivery supplies and products. See ~~78.10(3)*"c"*~~ 78.10(5)*"l"* for prior ~~approval~~ authorization requirements.

~~(5)~~ (4) Hearing aids. See rule 441—78.14(249A).

~~(6) Oral nutritional products. See 78.10(3)*"c"* for prior approval requirements. Nutritional products consumed orally are not covered for members in nursing facilities or intermediate care facilities for the mentally retarded.~~

~~(7)~~ (5) Orthotic devices. See 78.10(3)~~*"d"*~~*"c"* for limitations on coverage of cranial orthotic devices.

~~(8)~~ (6) Ostomy appliances.

~~(9)~~ (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.

~~(10)~~ (8) Prosthetic shoes, orthopedic shoes. See rule 441—78.15(249A).

~~(11)~~ (9) Tracheotomy tubes.

~~(12)~~ (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(4))

~~*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. Nutritional products consumed orally are not covered for members in nursing facilities or intermediate care facilities for the mentally retarded. 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.*~~ *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 ~~photographic evidence~~ documentation supporting moderate to severe nonsynostotic positional plagiocephaly and either:

(1) The member is ~~between 3 and 5 months~~ 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 ~~between 6 and 18 months~~ 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.

ITEM 4. 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~~ The types of medical supplies and supplies necessary for the effective use of a payable item ~~can be purchased~~ covered through the ~~medical assistance~~ 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.

~~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.

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).

~~Colostomy and ileostomy appliances.~~

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

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.

ITEM 5. Amend subrule 78.10(5) as follows:

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~~ shall be approved when prescribed for a ~~patient~~ member who meets all of the following conditions:

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

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

~~(3) The patient has suffered injuries when getting out of bed.~~

b. No change.

c. Vest airway clearance systems. Payment will be approved for a vest airway clearance system when prescribed by a pulmonologist for a ~~patient~~ 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 ~~patient~~ 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. and *e.* No change.

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.

ITEM 6. Amend rule 441—78.28(249A), catchwords, as follows:

441—78.28(249A) List of medical services and equipment requiring prior ~~approval~~ authorization, preprocedure review or preadmission review.

ITEM 7. Amend subrule 78.28(1) as follows:

78.28(1) Services, procedures, and medications prescribed by a physician ~~(M.D. or D.O.)~~, physician assistant, or advanced registered nurse practitioner which are subject to prior ~~approval~~ authorization or preprocedure review are as follows or as specified in the preferred drug list published by the department pursuant to Iowa Code ~~Supplement~~ section 249A.20A:

a. No change.

b. Automated medication dispenser. ~~(Cross-reference 78.10(2)*"b"*)~~ Payment ~~will~~ shall be approved ~~for an automated medication dispenser when prescribed for a member who meets all of the following conditions:~~ pursuant to the criteria at 78.10(5)*"d."*

~~(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.~~

c. Enteral products and enteral delivery pumps and supplies. Payment shall be approved pursuant to the criteria at 78.10(5)*"l."* ~~require prior approval. 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. (Cross-reference 78.10(3)*"c"*(2))

(1) 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.

(2) 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.

(3) 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.

d. Rescinded IAB 5/11/05, effective 5/1/05.

e. Speech generating device. Payment shall be approved pursuant to the criteria at 78.10(5)*"f."* Augmentative communication systems, which are provided to persons unable to communicate their basic needs through oral speech or manual sign language, require prior approval. Form 470-2145, Augmentative Communication System Selection, completed by a speech pathologist and a physician's prescription for a particular device shall be submitted to request prior approval. (Cross-reference 78.10(3)*"e"*(1))

(1) Information requested on the prior authorization form includes a medical history, diagnosis, and prognosis completed by a physician. 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.

(2) 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.

(3) The department's consultants with an expertise in speech pathology will evaluate the prior approval requests and make recommendations to the department.

f. No change.

g. Enclosed beds. Payment shall be approved pursuant to the criteria at 78.10(5)*"a."* Prior authorization is required for enclosed beds. (Cross-reference 78.10(2)*"c"*) The department shall approve payment for an enclosed bed 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.

h. No change.

i. Oral nutritional products. Payment shall be approved pursuant to the criteria at 78.10(5)*"m."* Prior authorization is required for oral nutritional products. (Cross-reference 78.10(2)*"c"*) The department shall approve payment for oral nutritional products 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.~~

~~(1) A request for prior approval shall include a written order or prescription from a physician, physician assistant, or advanced registered nurse practitioner and documentation to establish the medical necessity for oral nutritional products 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, if the request includes oral supplementation of a regular diet.~~

~~(2) Examples of conditions that will not justify approval of oral nutritional products are: weight-loss diets, wired-shut jaws, diabetic diets, and milk or food allergies (unless the member is under five years of age and coverage through the Special Supplemental Nutrition Program for Women, Infants, and Children is not available).~~

j. Vest airway clearance system. Payment shall be approved pursuant to the criteria at 78.10(5)*"c."* ~~Prior authorization is required for vest airway clearance systems. (Cross-reference 78.10(2)*"e"*) The department shall approve payment for a vest airway clearance system when prescribed by a pulmonologist for a patient with a medical diagnosis related to a lung disorder if all of the following conditions are met:~~

~~(1) Pulmonary function tests for the 12 months before 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.~~

k. No change.

l. Reimbursement over the established Medicaid fee schedule amount. Payment shall be approved pursuant to the criteria at 78.10(5)*"n."*

m. Bathtub/shower chair, bench. Payment shall be approved pursuant to the criteria at 78.10(5)*"g."*

n. Patient lift, nonstandard. Payment shall be approved pursuant to the criteria at 78.10(5)*"h."*

o. Power wheelchair attendant control. Payment shall be approved pursuant to the criteria at 78.10(5)*"i."*

p. Shower commode chair. Payment shall be approved pursuant to the criteria at 78.10(5)*"j."*

q. Ventilator, secondary. Payment shall be approved pursuant to the Medicare coverage criteria.

ITEM 8. Amend subrule 79.1(4) as follows:

79.1(4) *Durable medical equipment, prosthetic devices, medical supply dealers.* Fees for durable medical appliances, prosthetic devices and medical supplies are developed from several pricing sources and are based on pricing appropriate to the date of service; prices are developed using prior calendar year price information. The average wholesale price from all available sources is averaged to determine the fee for each item. Payment for used equipment will be no more than 80 percent of the purchase allowance. For supplies, equipment, and servicing of standard wheelchairs, standard hospital beds, enteral nutrients, and enteral and parenteral supplies and equipment, the fee for payment shall be the lowest price for which the devices are widely and consistently available in a locality. Reimbursement over an established Medicaid fee schedule amount may be allowed pursuant to the criteria at 441—paragraph 78.10(5)*"n."*