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

78.28(1) Services, procedures, and medications prescribed by a physician (M.D. or D.O.) which are subject to prior approval 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. Drugs require prior authorization as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A. For drugs requiring prior authorization, reimbursement will be made for a 72-hour supply dispensed in an emergency when a prior authorization request cannot be submitted.

b. Automated medication dispenser. (Cross-reference 78.10(2) "*b*") 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.

c. Enteral products and enteral delivery pumps and supplies 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. 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

(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. Preprocedure review by the Iowa Foundation for Medical Care (IFMC) will be required if payment under Medicaid is to be made for certain frequently performed surgical procedures which have a wide variation in the relative frequency the procedures are performed. Preprocedure surgical review applies to surgeries performed in hospitals (outpatient and inpatient) and ambulatory surgical centers. Approval by IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and on the published criteria established by the department and the IFMC. If not so approved by the IFMC, payment will not be made under the program to the physician or to the facility in which the surgery is performed. The criteria are available from IFMC, 3737 Woodland Avenue, Suite 500, West Des Moines, Iowa 50265, or in local hospital utilization review offices.

The "Preprocedure Surgical Review List" shall be published by the department in the provider manuals for physicians, hospitals, and ambulatory surgical centers. (Cross-reference 78.1(19))

g. 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. Prior authorization is required for external insulin infusion pumps and is granted according to Medicare coverage criteria. (Cross-reference 78.10(2) "c")

i. 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. Prior authorization is required for vest airway clearance systems. (Cross-reference 78.10(2) "*c*") 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. 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.

78.28(2) Dental services. Dental services which require prior approval are as follows:

a. The following periodontal services:

(1) Payment for periodontal scaling and root planing will be approved when interproximal and subgingival calculus is evident in X-rays or when justified and documented that curettage, scaling or root planing is required in addition to routine prophylaxis. (Cross-reference 78.4(4) "b")

(2) Payment for pedicle soft tissue graft and free soft tissue graft will be approved when the written narrative describes medical necessity. Payment for other periodontal surgical procedures will be approved after periodontal scaling and root planing has been provided, a reevaluation examination has been completed, and the patient has demonstrated reasonable oral hygiene, unless the patient is unable to demonstrate reasonable oral hygiene because of physical or mental disability or in cases which demonstrate gingival hyperplasia resulting from drug therapy. (Cross-reference 78.4(4)"c")

(3) Payment for pedicle soft tissue graft and free soft tissue graft will be approved when the written narrative describes medical necessity. (Cross-reference 78.4(4) "d")

(4) Payment for periodontal maintenance therapy may be approved after periodontal scaling and root planing or periodontal surgical procedures have been provided. Periodontal maintenance therapy may be approved once per three-month interval for moderate to advanced cases if the condition would deteriorate without treatment. (Cross-reference 78.4(4) "e")

b. Surgical endodontic treatment which includes an apicoectomy, performed as a separate surgical procedure; an apicoectomy, performed in conjunction with endodontic procedure; an apical curettage; a root resection; or excision of hyperplastic tissue will be approved when nonsurgical treatment has been attempted and a reasonable time has elapsed after which failure has been demonstrated. Surgical endodontic procedures may be indicated when:

(1) Conventional root canal treatment cannot be successfully completed because canals cannot be negotiated, debrided or obturated due to calcifications, blockages, broken instruments, severe curvatures, and dilacerated roots.

(2) Correction of problems resulting from conventional treatment including gross underfilling, perforations, and canal blockages with restorative materials. (Cross-reference 78.4(5) "c")

c. The following prosthetic services:

(1) A removable partial denture replacing posterior teeth will be approved when the member has fewer than eight posterior teeth in occlusion or the member has a full denture in one arch, and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one removable partial denture brings eight posterior teeth in occlusion, no additional removable partial denture will be approved. A removable partial denture replacing posterior teeth is payable only once in a five-year period unless the removable partial denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure, and is required to prevent significant dental problems. Replacement of a removable partial denture replacing posterior teeth due to resorption in less than a five-year period is not payable. (Cross-reference 78.4(7) "c")

(2) A fixed partial denture (including an acid etch fixed partial denture) replacing anterior teeth will be approved for members whose medical condition precludes the use of a removable partial denture. High noble or noble metals will be approved only when the member is allergic to all other restorative materials. A fixed partial denture replacing anterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.4(7)"d")

(3) A fixed partial denture (including an acid etch fixed partial denture) replacing posterior teeth will be approved for members whose medical condition precludes the use of a removable partial denture and who have fewer than eight posterior teeth in occlusion or if the member has a full denture in one arch and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one fixed partial denture brings eight posterior teeth in occlusion, no additional fixed partial denture will be approved. High noble or noble metals will be approved only when the member is allergic to all other restorative materials. A fixed partial denture replacing posterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.4(7) "e")

(4) Dental implants and related services will be authorized when the member is missing significant oral structures due to cancer, traumatic injuries, or developmental defects such as cleft palate and cannot use a conventional denture.

d. Orthodontic services will be approved when it is determined that a patient has the most handicapping malocclusion. This determination is made in a manner consistent with the "Handicapping Malocclusion Assessment to Establish Treatment Priority," by J. A. Salzmann, D.D.S., American Journal of Orthodontics, October 1968.

(1) A handicapping malocclusion is a condition that constitutes a hazard to the maintenance of oral health and interferes with the well-being of the patient by causing impaired mastication, dysfunction of the temporomandibular articulation, susceptibility to periodontal disease, susceptibility to dental caries, and impaired speech due to malpositions of the teeth. Treatment of handicapping malocclusions will be approved only for the severe and the most handicapping. Assessment of the most handicapping malocclusion is determined by the magnitude of the following variables:

- 1. Degree of malalignment;
- 2. Missing teeth;
- 3. Angle classification;
- 4. Overjet and overbite;
- 5. Openbite; and
- 6. Crossbite.

(2) A request to perform an orthodontic procedure must be accompanied by an interpreted cephalometric radiograph and study models trimmed so that the models simulate centric occlusion of the patient. A written plan of treatment must accompany the diagnostic aids. Posttreatment records must be furnished upon request of the Iowa Medicaid enterprise medical services unit.

(3) Approval may be made for eight units of a three-month active treatment period. Additional units may be approved by the department's orthodontic consultant if the additional units are found to be medically necessary. (Cross-reference 78.4(8) "a")

e. More than two laboratory-fabricated crowns will be approved in a 12-month period for anterior teeth that cannot be restored with a composite or amalgam restoration and for posterior teeth that cannot be restored with a composite or amalgam restoration or stainless steel crown. (Cross-reference 78.4(3) "d")

f. Endodontic retreatment of a tooth will be authorized when the conventional treatment has been completed, a reasonable time has elapsed, and failure has been demonstrated with a radiograph and narrative history.

78.28(3) Optometric services and ophthalmic materials which must be submitted for prior approval are as follows:

a. A second lens correction within a 24-month period for members eight years of age and older. Payment shall be made when the member's vision has at least a five-tenths diopter of change in sphere or cylinder or ten-degree change in axis in either eye.

b. Visual therapy may be authorized when warranted by case history or diagnosis for a period of time not greater than 90 days. Should continued therapy be warranted, the prior approval process should be reaccomplished, accompanied by a report showing satisfactory progress. Approved diagnoses are convergence insufficiency and amblyopia. Visual therapy is not covered when provided by opticians.

c. Subnormal visual aids where near visual acuity is better than 20/100 at 16 inches, 2M print. Prior authorization is not required if near visual acuity as described above is less than 20/100. Subnormal aids include, but are not limited to, hand magnifiers, loupes, telescopic spectacles or reverse Galilean telescope systems.

For all of the above, the optometrist shall furnish sufficient information to clearly establish that these procedures are necessary in terms of the visual condition of the patient. (Cross-references 78.6(4), 441-78.7(249A), and 78.1(18))

78.28(4) Hearing aids that must be submitted for prior approval are:

a. Replacement of a hearing aid less than four years old (except when the member is under 21 years of age). The department shall approve payment when the original hearing aid is lost or broken beyond repair or there is a significant change in the person's hearing that would require a different hearing aid. (Cross-reference 78.14(7) "d"(1))

b. A hearing aid costing more than \$650. The department shall approve payment for either of the following purposes (Cross-reference 78.14(7) "*d*"(2)):

(1) Educational purposes when the member is participating in primary or secondary education or in a postsecondary academic program leading to a degree and an in-office comparison of an analog aid and a digital aid matched (+/- 5dB) for gain and output shows a significant improvement in either speech recognition in quiet or speech recognition in noise or an in-office comparison of two aids, one of which is single channel, shows significantly improved audibility.

(2) Vocational purposes when documentation submitted indicates the necessity, such as varying amounts of background noise in the work environment and a need to converse in order to do the job and an in-office comparison of an analog aid and a digital aid matched (+/- 5dB) for gain and output shows a significant improvement in either speech recognition in quiet or speech recognition in noise or an in-office comparison of two aids, one of which is single channel, shows significantly improved audibility.

78.28(5) Hospital services which must be subject to prior approval, preprocedure review or preadmission review are:

a. Any medical or surgical procedure requiring prior approval as set forth in Chapter 78 is subject to the conditions for payment set forth although a request form does not need to be submitted by the hospital as long as the approval is obtained by the physician. (Cross-reference 441—78.1(249A))

b. All inpatient hospital admissions are subject to preadmission review. Payment for inpatient hospital admissions is approved when it meets the criteria for inpatient hospital care as determined by the IFMC or its delegated hospitals. Criteria are available from IFMC, 6000 Westown Parkway, Suite 350E,

West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices. (Cross-reference 441-78.3(249A))

c. Preprocedure review by the IFMC is required if hospitals are to be reimbursed for the inpatient and outpatient surgical procedures set forth in subrule 78.1(19). Approval by the IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and the criteria established by the department and IFMC. The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices.

78.28(6) Ambulatory surgical centers are subject to prior approval and preprocedure review as follows:

a. Any medical or surgical procedure requiring prior approval as set forth in Chapter 78 is subject to the conditions for payment set forth although a request form does not need to be submitted by the ambulatory surgical center as long as the prior approval is obtained by the physician.

b. Preprocedure review by the IFMC is required if ambulatory surgical centers are to be reimbursed for surgical procedures as set forth in subrule 78.1(19). Approval by the IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and criteria established by the IFMC and the department. The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices.

78.28(7) Rescinded IAB 6/4/08, effective 5/15/08.

78.28(8) Rescinded IAB 1/3/96, effective 3/1/96.

78.28(9) Private duty nursing or personal care services provided by a home health agency provider for persons aged 20 or under require prior approval and shall be approved if determined to be medically necessary. Payment shall be made on an hourly unit of service.

a. Definitions.

(1) Private duty nursing services are those services which are provided by a registered nurse or a licensed practical nurse under the direction of the member's physician to a member in the member's place of residence or outside the member's residence, when normal life activities take the member outside the place of residence. Place of residence does not include nursing facilities, intermediate care facilities for the mentally retarded, or hospitals.

Services shall be provided according to a written plan of care authorized by a licensed physician. The home health agency is encouraged to collaborate with the member, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment. These services shall exceed intermittent guidelines as defined in subrule 78.9(3). Private duty nursing and personal care services shall be inclusive of all home health agency services personally provided to the member.

Private duty nursing services do not include:

1. Respite care, which is a temporary intermission or period of rest for the caregiver.

2. Nurse supervision services including chart review, case discussion or scheduling by a registered nurse.

3. Services provided to other persons in the member's household.

4. Services requiring prior authorization that are provided without regard to the prior authorization process.

(2) Personal care services are those services provided by a home health aide or certified nurse's aide and which are delegated and supervised by a registered nurse under the direction of the member's physician to a member in the member's place of residence or outside the member's residence, when normal life activities take the member outside the place of residence. Place of residence does not include nursing facilities, intermediate care facilities for the mentally retarded, or hospitals. Payment for personal care services for persons aged 20 and under that exceed intermittent guidelines may be approved if determined to be medically necessary as defined in subrule 78.9(7). These services shall be in accordance with the member's plan of care and authorized by a physician. The home health agency is encouraged to collaborate with the member, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment.

Medical necessity means the service is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent the worsening of conditions that endanger life, cause pain, result in illness or infirmity, threaten to cause or aggravate a disability or chronic illness, and no other equally effective course of treatment is available or suitable for the member requesting a service.

b. Requirements.

(1) Private duty nursing or personal care services shall be ordered in writing by a physician as evidenced by the physician's signature on the plan of care.

(2) Private duty nursing or personal care services shall be authorized by the department or the department's designated review agent prior to payment.

(3) Prior authorization shall be requested at the time of initial submission of the plan of care or at any time the plan of care is substantially amended and shall be renewed with the department or the department's designated review agent. Initial request for and request for renewal of prior authorization shall be submitted to the department's designated review agent. The provider of the service is responsible for requesting prior authorization and for obtaining renewal of prior authorization.

The request for prior authorization shall include a nursing assessment, the plan of care, and supporting documentation. The request for prior authorization shall include all items previously identified as required treatment plan information and shall further include: any planned surgical interventions and projected time frame; information regarding caregiver's desire to become involved in the member's care, to adhere to program objectives, to work toward treatment plan goals, and to work toward maximum independence; and identify the types and service delivery levels of all other services to the member of private duty nursing RN hours, private duty nursing LPN hours, or home health aide hours per day, the number of days per week, and the number of weeks or months of service per discipline. If the member is currently hospitalized, the projected date of discharge shall be included.

Prior authorization approvals shall not be granted for treatment plans that exceed 16 hours of home health agency services per day. (Cross-reference 78.9(10))

78.28(10) Replacement of vibrotactile aids less than four years old shall be approved when the original aid is broken beyond repair or lost. (Cross-reference 78.10(3) "b")

This rule is intended to implement Iowa Code section 249A.4.

[ARC 7548B, IAB 2/11/09, effective 4/1/09; ARC 8714B, IAB 5/5/10, effective 5/1/10]