

Skilled nursing services shall be evaluated based on the complexity of the service and the condition of the patient.

Private duty nursing for persons aged 21 and over is not a covered service. See subrule 78.9(10) for guidelines for private duty nursing for persons aged 20 or under.

78.9(4) *Physical therapy services.* Payment shall be made for physical therapy services when the services relate directly to an active written treatment plan, follow a treatment plan established by the physician after any needed consultation with the qualified physical therapist, are reasonable and necessary to the treatment of the patient's illness or injury, and meet the guidelines defined for restorative, maintenance, or trial therapy as set forth in subrule 78.19(1), paragraphs "a" and "b."

For physical therapy services, the treatment plan shall additionally reflect goals, modalities of treatment, date of onset of conditions being treated, restorative potential, and progress notes.

78.9(5) *Occupational therapy services.* Payment shall be made for occupational therapy services when the services relate directly to an active written treatment plan, follow a treatment plan established by the physician, are reasonable and necessary to the treatment of the patient's illness or injury, and meet the guidelines defined for restorative, maintenance, or trial therapy as set forth in subrule 78.19(1), paragraphs "a" and "c."

For occupational therapy services, the treatment plan shall additionally reflect goals, modalities of treatment, date of onset of conditions being treated, restorative potential, and progress notes.

78.9(6) *Speech therapy services.* Payment shall be made for speech therapy services when the services relate directly to an active written treatment plan, follow a treatment plan established by the physician, are reasonable and necessary to the treatment of the patient's illness or injury, and meet the guidelines defined for restorative, maintenance, or trial therapy as set forth in subrule 78.19(1), paragraphs "a" and "d."

For speech therapy services, the treatment plan shall additionally reflect goals, modalities of treatment, date of onset of conditions being treated, restorative potential, and progress notes.

78.9(7) *Home health aide services.* Payment shall be made for unskilled services provided by a home health aide if the following conditions are met:

a. The service as well as the frequency and duration are stated in a written plan of treatment established by a physician. The home health agency is encouraged to collaborate with the recipient, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment.

b. The recipient requires personal care services as determined by a registered nurse or other appropriate therapist. The services shall be given under the supervision of a registered nurse, physical, speech, or occupational therapist and the registered nurse or therapist shall assign the aide who will provide the care.

c. Services shall be provided on an intermittent basis. "Intermittent basis" for home health agency services is defined as services that are usually two to three times a week for two to three hours at a time. Services provided for four to seven days per week, not to exceed 28 hours per week, when ordered by a physician and included in a plan of care shall be allowed as intermittent services. Increased services provided when medically necessary due to unusual circumstances on a short-term basis of two to three weeks may also be allowed as intermittent services when the home health agency documents the need for the excessive time required for home health aide services.

Home health aide daily care may be provided for persons employed or attending school whose disabling conditions require the persons to be assisted with morning and evening activities of daily living in order to support their independent living.

Personal care services include the activities of daily living, e.g., helping the recipient to bathe, get in and out of bed, care for hair and teeth, exercise, and take medications specifically ordered by the physician, but ordinarily self-administered, and retraining the recipient in necessary self-help skills.

Certain household services may be performed by the aide in order to prevent or postpone the recipient's institutionalization when the primary need of the recipient for home health aide services furnished is for personal care. If household services are incidental and do not substantially increase the time spent by the aide in the home, the entire visit is considered a covered service. Domestic or house-keeping services which are not related to patient care are not a covered service if personal care is not rendered during the visit.

For home health aide services, the treatment plan shall additionally reflect the number of hours per visit and the living arrangement of the recipient, e.g., lives alone or with family.

78.9(8) Medical social services.

a. Payment shall be made for medical social work services when all of the following conditions are met and the problems are not responding to medical treatment and there does not appear to be a medical reason for the lack of response. The services:

- (1) Are reasonable and necessary to the treatment of a recipient's illness or injury.
- (2) Contribute meaningfully to the treatment of the recipient's condition.
- (3) Are under the direction of a physician.
- (4) Are provided by or under the supervision of a qualified medical or psychiatric social worker.
- (5) Address social problems that are impeding the recipient's recovery.

b. Medical social services directed toward minimizing the problems an illness may create for the recipient and family, e.g., encouraging them to air their concerns and providing them with reassurance, are not considered reasonable and necessary to the treatment of the patient's illness or injury.

78.9(9) Home health agency care for maternity patients and children. The intent of home health agency services for maternity patients and children shall be to provide services when the recipients are unable to receive the care outside of their home and require home health care due to a high-risk factor. Routine prenatal, postpartum, or child health care is a covered service in a physician's office or clinic and, therefore, is not covered by Medicaid when provided by a home health agency.

Treatment plans for maternity patients and children shall identify the potential risk factors, the medical factor or symptom which verifies the child is at risk, the reason the recipient is unable to obtain care outside of the home, and the medically related task of the home health agency. If the home health agency is assisting the family to cope with socioeconomic and medical problems, the plan of care shall indicate the involvement of the department's county office and document that the department and the home health agency have agreed that services are in the best interest of the child and are needed to supplement the intervention of the department social worker.

The plan of treatment shall document along with the high-risk factors, the diagnosis, specific services and goals, and the medical necessity for the services to be rendered. A single high-risk factor does not provide sufficient documentation of the need for services.

a. The following list of potential high-risk factors may indicate a need for home health services to prenatal maternity patients:

- (1) Aged 16 or under.
- (2) First pregnancy for a woman aged 35 or over.
- (3) Previous history of prenatal complications such as fetal death, eclampsia, C-section delivery, psychosis, or diabetes.

(4) Current prenatal problems such as hypertensive disorders of pregnancy, diabetes, cardiac disease, sickle cell anemia, low hemoglobin, mental illness, or drug or alcohol abuse.

(5) Sociocultural or ethnic problems such as language barriers, lack of family support, insufficient dietary practices, history of child abuse or neglect, or single mother.

(6) Preexisting disabilities such as sensory deficits, or mental or physical disabilities.

(7) Second pregnancy in 12 months.

(8) Death of a close family member or significant other within the previous year.

b. The following list of potential high-risk factors may indicate a need for home health services to postpartum maternity patients:

(1) Aged 16 or under.

(2) First pregnancy for a woman aged 35 or over.

(3) Major postpartum complications such as severe hemorrhage, eclampsia, or C-section delivery.

(4) Preexisting mental or physical disabilities such as deaf, blind, hemaplegic, activity-limiting disease, sickle cell anemia, uncontrolled hypertension, uncontrolled diabetes, mental illness, or mental retardation.

(5) Drug or alcohol abuse.

(6) Symptoms of postpartum psychosis.

(7) Special sociocultural or ethnic problems such as lack of job, family problems, single mother, lack of support system, or history of child abuse or neglect.

(8) Demonstrated disturbance in maternal and infant bonding.

(9) Discharge or release from hospital against medical advice before 36 hours postpartum.

(10) Insufficient antepartum care by history.

(11) Multiple births.

(12) Nonhospital delivery.

c. The following list of potential high-risk factors may indicate a need for home health services to infants:

(1) Birth weight of five pounds or under or over ten pounds.

(2) History of severe respiratory distress.

(3) Major congenital anomalies such as neonatal complications which necessitate planning for long-term follow-up such as postsurgical care, poor prognosis, home stimulation activities, or periodic development evaluation.

(4) Disabling birth injuries.

(5) Extended hospitalization and separation from other family members.

(6) Genetic disorders, such as Down's syndrome, and phenylketonuria or other metabolic conditions that may lead to mental retardation.

(7) Noted parental rejection or indifference toward baby such as never visiting or calling the hospital about the baby's condition during the infant's extended stay.

(8) Family sociocultural or ethnic problems such as low education level or lack of knowledge of child care.

(9) Discharge or release against medical advice before 36 hours of age.

(10) Nutrition or feeding problems.

d. The following list of potential high-risk factors may indicate a need for home health services to preschool or school-age children:

- (1) Child or sibling victim of child abuse or neglect.
- (2) Mental retardation or other physical disabilities necessitating long-term follow-up or major readjustments in family lifestyle.
- (3) Failure to complete the basic series of immunizations by 18 months, or boosters by 6 years.
- (4) Chronic illness such as asthma, cardiac, respiratory or renal disease, diabetes, cystic fibrosis, or muscular dystrophy.
- (5) Malignancies such as leukemia or carcinoma.
- (6) Severe injuries necessitating treatment or rehabilitation.
- (7) Disruption in family or peer relationships.
- (8) Suspected developmental delay.
- (9) Nutritional deficiencies.

78.9(10) *Private duty nursing or personal care services for persons aged 20 and under.* Payment for private duty nursing or personal care services for persons aged 20 and under 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 recipient's physician to a recipient in the recipient's place of residence or outside the recipient's residence, when normal life activities take the recipient 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 recipient, 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 recipient. Enhanced payment under the interim fee schedule shall be made available for services to children who are technology dependent, i.e., ventilator dependent or whose medical condition is so unstable as to otherwise require intensive care in a hospital.

Private duty nursing or personal care 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 members of the recipient's household.
4. Services requiring prior authorization that are provided without regard to the prior authorization process.
5. Transportation services.
6. Homework assistance.

(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 recipient's physician to a recipient in the recipient's place of residence or outside the recipient's residence, when normal life activities take the recipient 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 recipient's plan of care and authorized by a physician. The home health agency is encouraged to collaborate with the recipient, 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 recipient 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 recipient'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 recipient whether or not the services are reimbursable by Medicaid. Providers shall indicate the expected number 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 recipient 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 78.28(9))

78.9(11) Vaccines. Home health agencies which wish to administer vaccines which are available through the vaccines for children program to Medicaid recipients shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid recipients. Home health agencies may provide vaccines for children clinics and be reimbursed for vaccine administration to provide vaccines for children program vaccines to Medicaid children in other than the home setting.

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

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

78.10(1) General payment requirements. Payment will be made for items of DME, prosthetic devices and sickroom 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 sickroom supplies must be required by the recipient because of the recipient'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 member. Determination will be made by the fiscal agent's medical staff.

(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 member.

(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 fiscal agent, and be based on the most reasonable method to provide the equipment.

(1) The provider shall monitor rental payments up to 150 percent of the purchase price. At the point that total rent paid equals 150 percent of the purchase allowance, the recipient 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 recipient-owned equipment. No payment may be made for repairs, maintenance, or supplies when the recipient is renting the item.

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

i. No allowance will be made for delivery, freight, postage, or other provider operating expenses for DME, prosthetic devices or sickroom 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 Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy, Form HCFA 484, from Medicare or a reasonable facsimile to the Medicaid fiscal agent 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.
- Bedpan.
- 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 recipients 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 recipients 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. Recipients 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.

4. The patient has had a successful trial with an enclosed 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.

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 which are provided for persons unable to communicate their basic needs through oral speech or manual sign language. Payment will be made for the most cost-effective item which meets basic communication needs commensurate with the person'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 supplementation. See 78.10(3) "c" for prior approval requirements.

Orthotic devices.

Ostomy appliances.

Parenteral delivery supplies and products. Daily parenteral nutrition therapy is considered necessary and reasonable for a recipient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the recipient'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 fiscal agent 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 recipient who either has a metabolic or digestive disorder that prevents the recipient 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 recipient'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 recipient's total medical condition that includes a description of the recipient'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 recipient's nutritional status and indicate that the recipient'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 recipient 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 recipient.

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 supplementation of a regular diet shall be approved as medically necessary only when the recipient 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.

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 recipient's total medical condition that includes a description of the recipient'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 recipient's nutritional status and indicate that the recipient'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 recipient.

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 recipient 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.

78.10(4) Sickroom supplies. Sickroom 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. Sickroom supplies are payable for a specific medicinal purpose. This does not include food or drugs. Sickroom supplies are not to be dispensed at any one time for quantities exceeding a three-month supply.

a. Only the following types of sickroom 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 supplies (needles and syringes, blood glucose test strips and diabetic urine test supplies).

Dialysis supplies.

Diapers (for recipients 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 sickroom supplies will be approved for payment for recipients 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).

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

441—78.11(249A) Ambulance service. Payment will be approved for ambulance service if it is required by the recipient's condition and the recipient is transported to the nearest hospital with appropriate facilities or to one in the same locality, from one hospital to another, to the patient's home or to a nursing facility. Payment for ambulance service to the nearest hospital for outpatient service will be approved only for emergency treatment. Ambulance service must be medically necessary and not merely for the convenience of the patient.

78.11(1) Partial payment may be made when an individual is transported beyond the destinations specified, and is limited to the amount that would have been paid had the individual been transported to the nearest institution with appropriate facilities. When transportation is to the patient's home, partial payment is limited to the amount that would have been paid from the nearest institution with appropriate facilities. When a recipient who is a resident of a nursing care facility is hospitalized and later discharged from the hospital, payment will be made for the trip to the nursing care facility where the recipient resides even though it may not in fact be the nearest nursing care facility.

78.11(2) The fiscal agent shall determine that the ambulance transportation was medically necessary and that the condition of the patient precluded any other method of transportation. Payment can be made without the physician's confirmation when:

- a. The individual is admitted as a hospital inpatient or in an emergency situation.
- b. Previous information on file relating to the patient's condition clearly indicates ambulance service was necessary.

78.11(3) When a patient is transferred from one nursing home to another because of the closing of a facility or from a nursing home to a custodial home because the recipient no longer requires nursing care, the conditions of medical necessity and the distance requirements shall not be applicable. Approval for transfer shall be made by the local office of the department of human services prior to the transfer. When such a transfer is made, the following rate schedule shall apply:

- One patient - normal allowance
- Two patients - 3/4 normal allowance per patient
- Three patients - 2/3 normal allowance per patient
- Four patients - 5/8 normal allowance per patient

78.11(4) Transportation of hospital inpatients. When an ambulance service provides transport of a hospital inpatient to a provider and returns the recipient to the same hospital (the recipient continuing to be an inpatient of the hospital), the ambulance service shall bill the hospital for reimbursement as the hospital's DRG reimbursement system includes all costs associated with providing inpatient services as stated in 79.1(5) "j."

78.11(5) In the event that more than one ambulance service is called to provide ground ambulance transport, payment shall be made only to one ambulance company. When a paramedic from one ambulance service joins a ground ambulance company already in transport, coverage is not available for the services and supplies provided by the paramedic.

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

441—78.12(249A) Skilled nursing homes. Rescinded IAB 8/8/90, effective 10/1/90.

441—78.13(249A) Transportation to receive medical care. Payment will be approved for transportation to receive services covered under the program only to the nearest institution or practitioner having appropriate facilities for care of the recipient when the following conditions are met.

78.13(1) The source of the care is located outside the city limits of the community in which the recipient resides; or

78.13(2) The recipient resides in a rural area and must travel to a city to receive necessary care; and

78.13(3) The type of care is not available in the community in which the recipient resides, or the recipient has been referred by the attending physician to a specialist in another community; and

78.13(4) There is no resource available to the recipient through which necessary transportation might be secured free of charge.

78.13(5) Transportation may be of any type and may be provided from any source.

a. When transportation is by car, the maximum payment which may be made will be the actual charge made by the provider for transportation to and from the source of medical care, but not in excess of 20 cents per mile.

b. When public transportation is utilized, the basis of payment will be the actual charge made by the provider of transportation, not to exceed the charge that would be made by the most economical available source of public transportation.

c. In all cases where public transportation is reasonably available to or from the source of care and the recipient's condition does not preclude its use, it must be utilized. When the recipient's condition precludes the use of public transportation, a statement to the effect shall be included in the case record.

78.13(6) In the case of a child too young to travel alone, or an adult or child who because of physical or mental incapacity is unable to travel alone, payment subject to the above conditions shall be made for the transportation costs of an escort. The worker is responsible for making a decision concerning the necessity of an escort and recording the basis for the decision in the case record.

78.13(7) When meals and lodging or other travel expenses are required in connection with transportation, payment will be subject to the same conditions as for a state employee and the maximum amount payable shall not exceed the maximum payable to a state employee for the same expenses in connection with official travel within the state of Iowa.

78.13(8) When the services of an escort are required subject to the conditions outlined above, payment may be made for meals and lodging, when required, on the same basis as for the recipient.

78.13(9) Payment will not be made in advance to a recipient or a provider of medical transportation.

78.13(10) Payment for transportation to receive medical care is made to the recipient with the following exceptions:

a. Payment may be made to the agency which provided transportation if the agency is certified by the department of transportation and requests direct payment by submitting Form 07-350, Purchase Order/Payment Voucher, within 90 days after the trip. Reimbursement for transportation shall be based on a fee schedule by mile or by trip.

b. In cases where the local office has established that the recipient has persistently failed to reimburse a provider of medical transportation, payment may be made directly to the provider.

c. In all situations where one of the department's volunteers is the provider of transportation.

78.13(11) Medical Transportation Claim, MA-3022-1, shall be completed by the recipient and the medical provider and submitted to the local office for each trip for which payment is requested. All trips to the same provider in a calendar month may, at the client's option, be submitted on the same form.

78.13(12) No claim shall be paid if presented after the lapse of three months from its accrual unless it is to correct payment on a claim originally submitted within the required time period. This time limitation is not applicable to claims with the date of service within the three-month period of retroactive Medicaid eligibility on approved applications.

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

441—78.14(249A) Hearing aids. Payment shall be approved for a hearing aid and examinations subject to the following conditions:

78.14(1) Physician examination. The recipient shall have an examination by a physician to determine that the recipient has no condition which would contraindicate the use of a hearing aid. This report shall be made on Form 470-0361, Section A, Report of Examination for a Hearing Aid. The requirement for a physician evaluation shall be waived for recipients 18 years of age and older when the recipient has signed an informed consent statement acknowledging that the recipient:

a. Has been advised that it may be in the recipient's best health interest to receive a medical evaluation from a licensed physician prior to purchase of a hearing aid.

b. Does not wish to receive a medical evaluation prior to purchase of a hearing aid.

78.14(2) Audiological testings. A physician or an audiologist shall perform audiological testing as a part of making a determination that a recipient could benefit from the use of a hearing aid. The audiologist shall report audiological testing on Form 470-0361, Section B. The department shall cover vestibular testing performed by an audiologist only when prescribed by a physician.

78.14(3) Hearing aid evaluation. A physician or an audiologist shall perform a hearing aid evaluation to establish if a recipient could benefit from a hearing aid. The physician or audiologist shall report the hearing aid evaluation on Form 470-0828, Hearing Aid Evaluation/Selection Report. When a hearing aid is recommended for a recipient, the physician or audiologist recommending the hearing aid shall see the recipient at least one time within 30 days subsequent to purchase of the hearing aid to determine that the aid is adequate.

78.14(4) Hearing aid selection. A physician or audiologist may recommend a specific brand or model appropriate to the recipient's condition. When a physician or an audiologist makes a general hearing aid recommendation, a hearing aid dispenser may perform the tests to determine the specific brand or model appropriate to the recipient's condition. The physician, audiologists or hearing aid dispenser shall report the hearing aid selection on Form 470-0828, Hearing Aid Evaluation/Selection Report.

78.14(5) Travel. When a recipient is unable to travel to the physician or audiologist because of health reasons, the department shall make payment for travel to the recipient's place of residence or other suitable location. The department shall make payment to physicians as specified in 78.1(8) and payment to audiologists at the same rate it reimburses state employees for travel.

78.14(6) Purchase of hearing aid. The department shall make payment for the type of hearing aid recommended when purchased from an eligible licensed hearing aid dispenser pursuant to rule 441—77.13(249A). The department shall make payment for binaural amplification when:

- a. A child needs the aid for speech development,
- b. The aid is needed for educational or vocational purposes, or
- c. The aid is for a blind individual.

Payment for binaural amplification shall also be approved where the recipient's hearing loss has caused marked restriction of daily activities and constriction of interests resulting in seriously impaired ability to relate to other people, or where lack of binaural amplification poses a hazard to a recipient's safety.

78.14(7) Payment for hearing aids.

a. Payment for hearing aids shall be acquisition cost plus a dispensing fee covering the fitting and service for six months. The department shall make payment for routine service after the first six months. Dispensing fees and payment for routine service shall not exceed the fee schedule appropriate to the place of service. Shipping and handling charges are not allowed.

b. Payment for ear mold and batteries shall be at the current audiologist's fee schedule.

c. Payment for repairs shall be made to the dealer for repairs made by the dealer. Payment for in-house repairs shall be made at the current fee schedule. Payment shall also be made to the dealer for repairs when the hearing aid is repaired by the manufacturer or manufacturer's depot. Payment for out-of-house repairs shall be at the amount shown on the manufacturer's invoice. Payment shall be allowed for a service or handling charge when it is necessary for repairs to be performed by the manufacturer or manufacturer's depot and this charge is made to the general public.

d. Prior approval.

(1) Payment for the replacement of a hearing aid less than four years old shall require prior approval except when the recipient 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 78.28(4) "a")

(2) Payment for a hearing aid costing more than \$650 shall require prior approval. The department shall approve payment for either of the following purposes (Cross-reference 78.28(4) "b"):

1. Educational purposes when the recipient 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.

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

441—78.15(249A) Orthopedic shoes. Payment shall be approved only for depth or custom-molded orthopedic shoes, inserts, and modifications, subject to the following definitions and conditions.

78.15(1) Definitions.

“*Custom-molded shoe*” means a shoe that:

1. Has been constructed over a cast or model of the recipient’s foot;
2. Is made of leather or another suitable material of equal quality;
3. Has inserts that can be removed, altered, or replaced according to the recipient’s conditions and needs; and
4. Has some form of closure.

“*Depth shoe*” means a shoe that:

1. Has a full length, heel-to-toe filler that when removed provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;
2. Is made from leather or another suitable material of equal quality;
3. Has some form of closure; and
4. Is available in full and half sizes with a minimum of three widths, so that the sole is graded to the size and width of the upper portions of the shoe according to the American Standard last sizing schedule or its equivalent.

“*Insert*” means a foot mold or orthosis constructed of more than one layer of a material that:

1. Is soft enough and firm enough to take and hold an impression during use, and
2. Is molded to the recipient’s foot or is made over a model of the foot.

78.15(2) Prescription. The recipient shall present to the provider a written prescription by a physician, a podiatrist, a physician assistant, or an advanced registered nurse practitioner that includes all of the following:

1. The date.
2. The patient’s diagnosis.
3. The reason orthopedic shoes are needed.
4. The probable duration of need.
5. A specific description of any required modification of the shoes.

78.15(3) Diagnosis. The recipient shall have a diagnosis of an orthopedic, neuromuscular, vascular, or insensate foot condition, supported by applicable codes from the current version of the International Classification of Diseases (ICD). A diagnosis of flat feet is not covered.

a. A recipient with diabetes must meet the Medicare criteria for therapeutic depth and custom-molded shoes.

b. Custom-molded shoes are covered only when the recipient has a foot deformity and the provider has documentation of all of the following:

- (1) The reasons the recipient cannot be fitted with a depth shoe.
- (2) Pain.
- (3) Tissue breakdown or a high probability of tissue breakdown.
- (4) Any limitation on walking.

78.15(4) Frequency. Only two pairs of orthopedic shoes are allowed per recipient in a 12-month period unless documentation of change in size or evidence of excessive wear is submitted. EXCEPTION: School-aged children under the age of 21 may obtain athletic shoes in addition to the two pairs of shoes in a 12-month period.

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

441—78.16(249A) Community mental health centers. Payment will be approved for all reasonable and necessary services provided by a psychiatrist on the staff of a community mental health center. Payment will be approved for services provided by a clinical psychologist, social worker or psychiatric nurse on the staff of the center, subject to the following conditions:

78.16(1) Payment to a community mental health center will be approved for reasonable and necessary services provided to medical assistance recipients by a psychiatrist, psychologist, social worker or psychiatric nurse on the staff of the center under the following conditions:

a. Services must be rendered under the supervision of a board eligible or board certified psychiatrist. All services must be performed under the supervision of a board eligible or board certified psychiatrist subject to the conditions set forth in 78.16(1)“*b*” with the following exceptions:

- (1) Services by staff psychiatrists, or
- (2) Services rendered by psychologists meeting the requirements of the National Register of Health Service Providers in Psychology, or
- (3) Services provided by a staff member, listed in this subrule, performing the preliminary diagnostic evaluation of medical assistance recipients for voluntary admission to one of the state mental health institutes.

b. Supervisory process.

(1) Each patient shall have an initial evaluation completed which shall include at least one personal evaluation interview with a mental health professional, as defined under Iowa Code section 228.1. If the evaluation interview results indicate a need for an interview with a board-eligible or board-certified psychiatrist, then such referral shall be made. This must be accomplished before submission of the first claim for services rendered to that patient.

(2) Ongoing review and assessment of patients’ treatment needs, treatment plans, and the appropriateness of services rendered shall be assured through the peer review process in effect for community mental health centers, as directed by 2002 Iowa Acts, chapter 1120, section 13.

(3) and (4) Rescinded IAB 2/5/03, effective 2/1/03.

78.16(2) The treatment plans for and services rendered to patients of the center shall be evaluated and revised as necessary and appropriate, consistent with the standards of the peer review process described in subparagraph 78.16(1)“*b*”(1).

78.16(3) The peer review process and related activities, as described under subparagraph 78.16(1)“*b*”(1), are not payable as separate services under the Medicaid program. The center shall maintain the results of and information related to the peer review process, and these records shall be subject to audit by the department of human services, its Medicaid fiscal agent, or other department designees, as necessary and appropriate.

78.16(4) Clinical records of medical assistance patients shall be available to the carrier on request. All these records shall be held confidential.

78.16(5) At the time of application for participation in the program the center will be provided with a form on which to list its professional staff. The center shall report acquisitions or losses of professional staff to the carrier within ten days.

78.16(6) Payment to a community mental health center will be approved for day treatment services for persons aged 21 or over if the center is certified by the department for day treatment services, the services are provided on the premises of the community mental health center or satellite office of the community mental health center, and the services meet the standards outlined herein.

a. Community mental health centers providing day treatment services for persons aged 21 or over shall have available a written narrative providing the following day treatment information:

(1) Documented need for day treatment services for persons aged 21 and over in the area served by the program, including studies, needs assessments, and consultations with other health care professionals.

(2) Goals and objectives of the day treatment program for persons aged 21 and over that meet the day treatment program guidelines noted in 78.16(6)“*b*.”

(3) Organization and staffing including how the day treatment program for persons aged 21 and over fits with the rest of the community mental health center, the number of staff, staff credentials, and the staff's relationship to the program, e.g., employee, contractual, or consultant.

(4) Policies and procedures for the program including admission criteria, patient assessment, treatment plan, discharge plan, postdischarge services, and the scope of services provided.

(5) Any accreditations or other types of approvals from national or state organizations.

(6) The physical facility and any equipment to be utilized.

b. Day treatment services for persons aged 21 and over shall be structured, long-term services designed to assist in restoring, maintaining or increasing levels of functioning, minimizing regression, and preventing hospitalization.

(1) Service components include training in independent functioning skills necessary for self-care, emotional stability and psychosocial interactions and training in medication management.

(2) Services are structured with an emphasis on program variation according to individual need.

(3) Services are provided for a period of three to five hours per day, three or four times per week.

c. Payment will be approved for day treatment services provided by or under the general supervision of a mental health professional as defined in rule 441—33.1(225C.230A). When services are provided by an employee or consultant of the community mental health center who is not a mental health professional, the employee or consultant shall be supervised by a mental health professional who gives professional direction and active guidance to the employee or consultant and who retains responsibility for consumer care. The supervision shall be timely, regular, and documented. The employee or consultant shall meet the following minimum requirements:

(1) Have a bachelor's degree in a human services related field from an accredited college or university; or

(2) Have an Iowa license to practice as a registered nurse with two years of experience in the delivery of nursing or human services.

d. Persons aged 18 through 20 with chronic mental illness as defined by rule 441—24.1(225C) can receive day treatment services under this subrule or subrule 78.16(7).

78.16(7) Payment to a community mental health center will be approved for day treatment services for persons aged 20 or under if the center is certified by the department for day treatment services and the services are provided on the premises of the community mental health center or satellite office of the community mental health center. Exception: Field trips away from the premises are a covered service when the trip is therapeutic and integrated into the day treatment program's description and milieu plan.

Day treatment coverage will be limited to a maximum of 15 hours per week. Day treatment services for persons aged 20 or under shall be outpatient services provided to persons who are not inpatients in a medical institution or residents of a group care facility licensed under 441—Chapter 114.

a. Program documentation. Community mental health centers providing day treatment services for persons aged 20 or under shall have available a written narrative which provides the following day treatment program information:

(1) Documented need for day treatment services for persons aged 20 or under in the area served by the program, including studies, needs assessments, and consultations with other health care professionals.

(2) Goals and objectives of the day treatment program for persons aged 20 or under that meet the guidelines noted in paragraphs "c" to "h" below.

(3) Organization and staffing including how the day treatment program for persons aged 20 or under fits with the rest of the community mental health center, the number of staff, staff credentials, and the staff's relationship to the program, e.g., employee, contractual, or consultant.

(4) Policies and procedures for the program including admission criteria, patient assessment, treatment plan, discharge plan, postdischarge services, and the scope of services provided.

(5) Any accreditations or other types of approvals from national or state organizations.

(6) The physical facility and any equipment to be utilized.

b. Program standards. Medicaid day treatment program services for persons aged 20 and under shall meet the following standards:

(1) Staffing shall:

1. Be sufficient to deliver program services and provide stable, consistent, and cohesive milieu with a staff-to-patient ratio of no less than one staff for each eight participants. Clinical, professional, and paraprofessional staff may be counted in determining the staff-to-patient ratio. Professional or clinical staff are those staff who are either mental health professionals as defined in rule 441—33.1(225C,230A) or persons employed for the purpose of providing offered services under the supervision of a mental health professional. All other staff (administrative, adjunctive, support, non-clinical, clerical, and consulting staff or professional clinical staff) when engaged in administrative or clerical activities shall not be counted in determining the staff-to-patient ratio or in defining program staffing patterns. Educational staff may be counted in the staff-to-patient ratio.

2. Reflect how program continuity will be provided.

3. Reflect an interdisciplinary team of professionals and paraprofessionals.

4. Include a designated director who is a mental health professional as defined in rule 441—33.1(225C,230A). The director shall be responsible for direct supervision of the individual treatment plans for participants and the ongoing assessment of program effectiveness.

5. Be provided by or under the general supervision of a mental health professional as defined in rule 441—33.1(225C,230A). When services are provided by an employee or consultant of the community mental health center who is not a mental health professional, the employee or consultant shall be supervised by a mental health professional who gives direct professional direction and active guidance to the employee or consultant and who retains responsibility for consumer care. The supervision shall be timely, regular and documented. The employee or consultant shall have a bachelor's degree in a human services related field from an accredited college or university or have an Iowa license to practice as a registered nurse with two years of experience in the delivery of nursing or human services. Exception: Other certified or licensed staff, such as certified addiction counselors or certified occupational and recreational therapy assistants, are eligible to provide direct services under the general supervision of a mental health professional, but they shall not be included in the staff-to-patient ratio.

(2) There shall be written policies and procedures addressing the following: admission criteria; patient assessment; patient evaluation; treatment plan; discharge plan; community linkage with other psychiatric, mental health, and human service providers; a process to review the quality of care being provided with a quarterly review of the effectiveness of the clinical program; postdischarge services; and the scope of services provided.

(3) The program shall have hours of operation available for a minimum of three consecutive hours per day, three days or evenings per week.

(4) The length of stay in a day treatment program for persons aged 20 or under shall not exceed 180 treatment days per episode of care, unless the rationale for a longer stay is documented in the patient's case record and treatment plan every 30 calendar days after the first 180 treatment days.

(5) Programming shall meet the individual needs of the patient. A description of services provided for patients shall be documented along with a schedule of when service activities are available including the days and hours of program availability.

(6) There shall be a written plan for accessing emergency services 24 hours a day, seven days a week.

(7) The program shall maintain a community liaison with other psychiatric, mental health, and human service providers. Formal relationships shall exist with hospitals providing inpatient programs to facilitate referral, communication, and discharge planning. Relationships shall also exist with appropriate school districts and educational cooperatives. Relationships with other entities such as physicians, hospitals, private practitioners, halfway houses, the department, juvenile justice system, community support groups, and child advocacy groups are encouraged. The provider's program description will describe how community links will be established and maintained.

(8) Psychotherapeutic treatment services and psychosocial rehabilitation services shall be available. A description of the services shall accompany the application for certification.

(9) The program shall maintain a distinct clinical record for each patient admitted. Documentation, at a minimum, shall include: the specific services rendered, the date and actual time services were rendered, who rendered the services, the setting in which the services were rendered, the amount of time it took to deliver the services, the relationship of the services to the treatment regimen described in the plan of care, and updates describing the patient's progress.

c. Program services. Day treatment services for persons aged 20 or under shall be a time-limited, goal-oriented active treatment program that offers therapeutically intensive, coordinated, structured clinical services within a stable therapeutic milieu. Time-limited means that the patient is not expected to need services indefinitely or lifelong, and that the primary goal of the program is to improve the behavioral functioning or emotional adjustment of the patient in order that the service is no longer necessary. Day treatment services shall be provided within the least restrictive therapeutically appropriate context and shall be community-based and family focused. The overall expected outcome is clinically adaptive behavior on the part of the patient and the family.

At a minimum, day treatment services will be expected to improve the patient's condition, restore the condition to the level of functioning prior to onset of illness, control symptoms, or establish and maintain a functional level to avoid further deterioration or hospitalization. Services are expected to be age-appropriate forms of psychosocial rehabilitation activities, psychotherapeutic services, social skills training, or training in basic care activities to establish, retain or encourage age-appropriate or developmentally appropriate psychosocial, educational, and emotional adjustment.

Day treatment programs shall use an integrated, comprehensive and complementary schedule of therapeutic activities and shall have the capacity to treat a wide array of clinical conditions.

The following services shall be available as components of the day treatment program. These services are not separately billable to Medicaid, as day treatment reimbursement includes reimbursement for all day treatment components.

(1) Psychotherapeutic treatment services (examples would include individual, group, and family therapy).

(2) Psychosocial rehabilitation services. Active treatment examples include, but are not limited to, individual and group therapy, medication evaluation and management, expressive therapies, and theme groups such as communication skills, assertiveness training, other forms of community skills training, stress management, chemical dependency counseling, education, and prevention, symptom recognition and reduction, problem solving, relaxation techniques, and victimization (sexual, emotional, or physical abuse issues).

Other program components may be provided, such as personal hygiene, recreation, community awareness, arts and crafts, and social activities designed to improve interpersonal skills and family mental health. Although these other services may be provided, they are not the primary focus of treatment.

(3) Evaluation services to determine need for day treatment prior to program admission. For persons for whom clarification is needed to determine whether day treatment is an appropriate therapy approach, or for persons who do not clearly meet admission criteria, an evaluation service may be performed. Evaluation services shall be individual and family evaluation activities made available to courts, schools, other agencies, and individuals upon request, who assess, plan, and link individuals with appropriate services. This service must be completed by a mental health professional. An evaluation from another source performed within the previous 12 months or sooner if there has not been a change may be substituted. Medicaid will not make separate payment for these services under the day treatment program.

(4) Assessment services. All day treatment patients will receive a formal, comprehensive biopsychosocial assessment of day treatment needs including, if applicable, a diagnostic impression based on the current Diagnostic and Statistical Manual of Mental Disorders. An assessment from another source performed within the previous 12 months may be used if the symptomatology is the same as 12 months ago. If not, parts of the assessment which reflect current functioning may be used as an update. Using the assessment, a comprehensive summation will be produced, including the findings of all assessments performed. The summary will be used in forming a treatment plan including treatment goals. Indicators for discharge planning, including recommended follow-up goals and provision for future services, should also be considered, and consistently monitored.

(5) The day treatment program may include an educational component as an additional service. The patient's educational needs shall be served without conflict from the day treatment program. Hours in which the patient is involved in the educational component of the day treatment program are not included in the day treatment hours billable to Medicaid.

d. Admission criteria. Admission criteria for day treatment services for persons aged 20 or under shall reflect the following clinical indicators:

(1) The patient is at risk for exclusion from normative community activities or residence.

(2) The patient exhibits psychiatric symptoms, disturbances of conduct, decompensating conditions affecting mental health, severe developmental delays, psychological symptoms, or chemical dependency issues sufficiently severe to bring about significant or profound impairment in day-to-day educational, social, vocational, or interpersonal functioning.

(3) Documentation is provided that the traditional outpatient setting has been considered and has been determined not to be appropriate.

(4) The patient's principal caretaker (family, guardian, foster family or custodian) must be able and willing to provide the support and monitoring of the patient, to enable adequate control of the patient's behavior, and must be involved in the patient's treatment. Persons aged 20 or under who have reached the age of majority, either by age or emancipation, are exempt from family therapy involvement.

(5) The patient has the capacity to benefit from the interventions provided.

e. Individual treatment plan. Each patient receiving day treatment services shall have a treatment plan prepared. A preliminary treatment plan should be formulated within 3 days of participation after admission, and replaced within 30 calendar days by a comprehensive, formalized plan utilizing the comprehensive assessment. This individual treatment plan should reflect the patient's strengths and weaknesses and identify areas of therapeutic focus. The treatment goals which are general statements of consumer outcomes shall be related to identified strengths, weaknesses, and clinical needs with time-limited, measurable objectives. Objectives shall be related to the goal and have specific anticipated outcomes. Methods that will be used to pursue the objectives shall be stated. The plan should be reviewed and revised as needed, but shall be reviewed at least every 30 calendar days. The treatment plan shall be developed or approved by a board-eligible or board-certified psychiatrist, a staff psychiatrist, physician, or a psychologist registered either on the "National Register of Health Service Providers in Psychology" or the "Iowa Register of Health Service Providers for Psychology." Approval will be evidenced by a signature of the physician or health service provider.

f. Discharge criteria. Discharge criteria for the day treatment program for persons aged 20 or under shall incorporate at least the following indicators:

(1) In the case of patient improvement:

1. The patient's clinical condition has improved as shown by symptom relief, behavioral control, or indication of mastery of skills at the patient's developmental level. Reduced interference with and increased responsibility with social, vocational, interpersonal, or educational goals occurs sufficient to warrant a treatment program of less supervision, support, and therapeutic intervention.

2. Treatment goals in the individualized treatment plan have been achieved.

3. An aftercare plan has been developed that is appropriate to the patient's needs and agreed to by the patient and family, custodian, or guardian.

(2) If the patient does not improve:

1. The patient's clinical condition has deteriorated to the extent that the safety and security of inpatient or residential care is necessary.

2. Patient, family, or custodian noncompliance with treatment or with program rules exists.

g. *Coordination of services.* Programming services shall be provided in accordance with the individual treatment plan developed by appropriate day treatment staff, in collaboration with the patient and appropriate caretaker figure (parent, guardian, or principal caretaker), and under the supervision of the program director, coordinator, or supervisor.

The program for each patient will be coordinated by primary care staff of the community mental health center. A coordinated, consistent array of scheduled therapeutic services and activities shall comprise the day treatment program. These may include counseling or psychotherapy, theme groups, social skills development, behavior management, and other adjunctive therapies. At least 50 percent of scheduled therapeutic program hours exclusive of educational hours for each patient shall consist of active treatment that specifically addresses the targeted problems of the population served. Active treatment shall be defined as treatment in which the program staff assume significant responsibility and often intervene.

Family, guardian, or principal caretaker shall be involved with the program through family therapy sessions or scheduled family components of the program. They will be encouraged to adopt an active role in treatment. Medicaid will not make separate payment for family therapy services. Persons aged 20 or under who have reached the age of majority, either by age or emancipation, are exempt from family therapy involvement.

Therapeutic activities will be scheduled according to the needs of the patients, both individually and as a group.

Scheduled therapeutic activities, which may include other program components as described above, shall be provided at least 3 hours per week up to a maximum of 15 hours per week.

h. Stable milieu. The program shall formally seek to provide a stable, consistent, and cohesive therapeutic milieu. In part this will be encouraged by scheduling attendance such that a stable core of patients exists as much as possible. The milieu will consider the developmental and social stage of the participants such that no patient will be significantly involved with other patients who are likely to contribute to retardation or deterioration of the patient's social and emotional functioning. To help establish a sense of program identity, the array of therapeutic interventions shall be specifically identified as the day treatment program. Program planning meetings shall be held at least quarterly to evaluate the effectiveness of the clinical program. In the program description, the provider shall state how milieu stability will be provided.

i. Chronic mental illness. Persons aged 18 through 20 with chronic mental illness as defined by rule 441—24.1(225C) can receive day treatment services under this subrule or subrule 78.16(6).

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

441—78.17(249A) Physical therapists. Payment will be approved for the same services payable under Title XVIII of the Social Security Act (Medicare).

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

441—78.18(249A) Screening centers. Payment will be approved for health screening as defined in subrule 84.1(1) for individuals under 21 years of age who are eligible for medical assistance.

78.18(1) Screening centers which wish to administer vaccines which are available through the vaccines for children program to Medicaid recipients shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid recipients. Screening centers shall receive reimbursement for the administration of vaccines to Medicaid recipients.

78.18(2) Payment will be approved for necessary laboratory service related to an element of screening when performed by the screening center and billed as a separate item.

78.18(3) Periodicity schedules for health, hearing, vision, and dental screenings.

a. Payment will be approved for health, vision, and hearing screenings as follows:

- (1) Six screenings in the first year of life.
- (2) Four screenings between the ages of 1 and 2.
- (3) One screening a year at ages 3, 4, 5, and 6.
- (4) One screening a year at ages 8, 10, 12, 14, 16, 18, and 20.

b. Payment for dental screenings will be approved in conjunction with the health screenings up to age 12 months. Screenings will be approved at ages 12 months and 24 months and thereafter at six-month intervals up to age 21.

c. Interperiodic screenings will be approved as medically necessary.

78.18(4) When it is established by the periodicity schedule in 78.18(3) that an individual is in need of screening the individual will receive a notice that screening is due.

78.18(5) When an individual is screened, a member of the screening center shall complete a medical history. The medical history shall become part of the individual's medical record.

78.18(6) Payment will be approved for early and periodic screening, diagnosis and treatment (EPSDT) targeted case management services (hereinafter referred to as EPSDT information and care coordination) for persons under age 21.

EXCEPTION: Payment will not be approved for persons under age 21 who are medically needy recipients as defined at 441—subrule 75.1(35) who are subject to spenddown, or enrolled in a health maintenance organization or foster care.

a. Information and care coordination services shall be provided by a registered nurse or persons with at least a bachelor's degree in health education, social work, counseling, sociology, or psychology. A licensed practical nurse or a paraprofessional may provide the service if the licensed practical nurse or paraprofessional works under the direct supervision of a health professional, such as a registered nurse or person with at least a bachelor's degree in health education, social work, counseling, sociology, or psychology. Payment for information services shall be provided only to designated department of public health agencies.

b. EPSDT information and care coordination services are as follows:

(1) Information activities which are face-to-face visits (including home visits), telephone contacts or written correspondence made for the purpose of promoting preventive health care. Information activities shall be provided to guardians or custodians within 60 days of a determination of Medicaid eligibility for persons under age 21. Activities shall utilize accepted methods for informing guardians or custodians who are illiterate, blind, deaf, or cannot understand the English language. Information activities include:

1. An explanation of the benefits of preventive health care and EPSDT information and care coordination services.

2. A description of services provided in periodic exams.

3. A summary of the periodicity schedule.

4. Information on how EPSDT services can be obtained.

5. Information on the available health resources in the community.

6. Information about other programs which may be of assistance such as head start, child health specialty clinics, women, infants and children (WIC) services, local and area education agencies, local parenting programs, mental health services and social service agencies.

7. A determination of whether the eligible child or youth's legal guardian, and in some cases custodian, wants to participate in care coordination services. At a minimum if the guardian or custodian chooses not to receive the initial screen, the care coordinator will document the decision and recontact the guardian or custodian in a year. If there are children under the age of two, the care coordinator will document the decision and recontact the guardian or custodian within six months if the first decision is not to receive the initial screen.

(2) Care coordination services are defined as ongoing activities which can be face-to-face visits (including home visits), telephone contacts or written correspondence which ensure that EPSDT services are received by children and youth participating in the EPSDT program. Ongoing activities include:

1. Providing the assistance needed to receive early and periodic screenings, and diagnostic and treatment services. Assistance may include, but is not limited to, explaining the necessity for the service, locating needed health care services, scheduling an appointment, arranging transportation, or child care. Arranging transportation or child care does not mean the care coordinator has to transport the recipient or pay for transportation or provide or pay for child care.

2. Authorizing transportation not covered under rule 441—78.13(249A). Payment will be approved for in-town transportation authorized by the EPSDT care coordinator for EPSDT screens, follow-up diagnosis, or treatment services which are not eligible for payment under rule 441—78.13(249A).

3. Establishing and maintaining community linkages with other preventive health care providers in the community such as dentists, primary care physicians, child health centers, WIC, head start, child health specialty clinics, and local and area education agencies must be included in care coordination services.

4. Monitoring to determine that screening and medically necessary diagnostic and treatment services have been received.

5. Maintaining documentation of the care coordination services, including all contacts with and on behalf of recipients; date of care coordination service; name of agency providing care coordination; staff person providing the service; nature, extent, or units of service; and place of service delivery.

6. Notifying the guardian or custodian when the next screening is due.

7. Providing ongoing information about other programs which may be of assistance such as head start; child health specialty clinics; women, infants and children (WIC) services; local and area education agencies; local parenting programs; mental health services and social service agencies.

78.18(7) Payment will be made for persons aged 20 and under for nutritional counseling provided by a licensed dietitian employed by or under contract with a screening center for a nutritional problem or condition of a degree of severity that nutritional counseling beyond that normally expected as part of the standard medical management is warranted. For persons eligible for the WIC program, a WIC referral is required. Medical necessity for nutritional counseling services exceeding those available through WIC shall be documented.

78.18(8) Payment shall be made for dental services provided by a dental hygienist employed by or under contract with a screening center.

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

441—78.19(249A) Rehabilitation agencies.

78.19(1) Coverage of services.

a. General provisions regarding coverage of services.

(1) Services are provided in the recipient's home or in a care facility (other than a hospital) by a speech therapist, physical therapist, or occupational therapist employed by or contracted by the agency. Services provided a recipient residing in a nursing facility or residential care facility are payable when a statement is submitted signed by the facility that the facility does not have these services available. The statement need only be submitted at the start of care unless the situation changes. Payment will not be made to a rehabilitation agency for therapy provided to a recipient residing in an intermediate care facility for the mentally retarded since these facilities are responsible for providing or paying for services required by recipients.

(2) All services must be determined to be medically necessary, reasonable, and meet a significant need of the recipient that cannot be met by a family member, friend, medical staff personnel, or other caregiver; must meet accepted standards of medical practice; and must be a specific and effective treatment for a patient's medical or disabling condition.

(3) In order for a service to be payable, a licensed therapist must complete a plan of treatment every 30 days and indicate the type of service required. The plan of treatment must contain the information noted in subrule 78.19(2).

(4) There is no specific limitation on the number of visits for which payment through the program will be made so long as that amount of service is medically necessary in the individual case, is related to a diagnosed medical impairment or disabling condition, and meets the current standards of practice in each related field. Documentation must be submitted with each claim to support the need for the number of services being provided.

(5) Payments will be made both for restorative service and also for maintenance types of service. Essentially, maintenance services means services to a patient whose condition is stabilized and who requires observation by a therapist of conditions defined by the physician as indicating a possible deterioration of health status. This would include persons with long-term illnesses or a disabling condition whose status is stable rather than posthospital. Refer to 78.19(1)"b"(7) and (8) for guidelines under restorative and maintenance therapy.

(6) Restorative or maintenance therapy sessions must meet the following criteria:

1. There must be face-to-face patient contact interaction.
2. Services must be provided primarily on an individual basis. Group therapy is covered, but total units of service in a month shall not exceed total units of individual therapy. Family members receiving therapy may be included as part of a group.

3. Treatment sessions may be no less than 15 minutes of service and no more than 60 minutes of service per date unless more than 60 minutes of service is required for a treatment session due to the patient's specific condition. If more than 60 minutes of service is required for a treatment session, additional documentation of the specific condition and the need for the longer treatment session shall be submitted with the claim. A unit of treatment shall be considered to be 15 minutes in length.

4. Progress must be documented in measurable statistics in the progress notes in order for services to be reimbursed. Refer to 78.19(1)"b"(7) and (8) for guidelines under restorative and maintenance therapy.

(7) Payment will be made for an appropriate period of diagnostic therapy or trial therapy (up to two months) to determine a patient's rehabilitation potential and establish appropriate short-term and long-term goals. Documentation must be submitted with each plan to support the need for diagnostic or trial therapy. Refer to 78.19(1)"b"(16) for guidelines under diagnostic or trial therapy.

b. Physical therapy services.

- (1) To be covered under rehabilitation agency services, physical therapy services must relate directly and specifically to an active written treatment plan, follow a treatment plan established by the licensed therapist after consultation with the physician, be reasonable and necessary to the treatment of the person's illness, injury, or disabling condition, be specific and effective treatment for the patient's medical or disabling condition, and be of such a level of complexity and sophistication, or the condition of the patient must be such that the services required can be safely and effectively performed only by a qualified physical therapist or under the supervision of the therapist.

(2) A qualified physical therapist assistant may provide any restorative services performed by a licensed physical therapist under supervision of the therapist as set forth in the department of public health, professional licensure division, 645—subrule 200.20(7).*

(3) The initial physical therapy evaluation must be provided by a licensed physical therapist.

(4) There must be an expectation that there will be a significant, practical improvement in the patient's condition in a reasonable amount of time based on the patient's restorative potential assessed by the physician.

(5) It must be demonstrated there is a need to establish a safe and effective maintenance program related to a specific disease state, illness, injury, or disabling condition.

(6) The amount, frequency, and duration of the services must be reasonable.

(7) Restorative therapy must be reasonable and necessary to the treatment of the patient's injury or disabling condition. The expected restorative potential must be practical and in relation to the extent and duration of the treatment. There must be an expectation that the patient's medical or disabling condition will show functional improvement in a reasonable period of time. Functional improvement means that demonstrable measurable increases have occurred in the patient's level of independence outside the therapeutic environment.

(8) Generally, maintenance therapy means services to a patient whose condition is stabilized and who requires observation by a therapist of conditions defined by the physician as indicating a possible deterioration of health status. This includes persons with long-term illnesses or disabling conditions whose status is stable rather than posthospital. Maintenance therapy is also appropriate for individuals whose condition is such that a professionally established program of activities, exercises, or stimulation is medically necessary to prevent deterioration or maintain present functioning levels.

Where a maintenance program is appropriate, the initial evaluation and the instruction of the patient, family members, home health aides, facility personnel, or other caregivers to carry out the program are considered a covered physical therapy service. Payment shall be made for a maximum of three visits to establish a maintenance program and instruct the caregivers. Payment for supervisory visits to monitor the program is limited to two per month for a maximum period of 12 months. The plan of treatment must specify the anticipated monitoring activity of the supervisor.

Beyond evaluation, instruction, and monitoring, maintenance therapy is not reimbursable.

After 12 months of maintenance therapy, a reevaluation is a covered service, if medically necessary. A reevaluation will be considered medically necessary only if there is a significant change in residential or employment situation or the patient exhibits an increase or decrease in functional ability or motivation, clearing of confusion, or the remission of some other medical condition which previously contraindicated restorative therapy. A statement by the interdisciplinary team of a person with developmental disabilities recommending a reevaluation and stating the basis for medical necessity will be considered as supporting the necessity of a reevaluation and may expedite approval.

(Restorative and maintenance therapy definitions also apply to speech and occupational therapy.)

When a patient is under a restorative physical therapy program, the patient's condition is regularly reevaluated and the program adjusted by the physical therapist. It is expected that prior to discharge, a maintenance program has been designed by the physical therapist. Consequently, where a maintenance program is not established until after the restorative program has been completed, it would not be considered reasonable and necessary to the treatment of the patient's condition and would be excluded from coverage.

*Proposed rule 645—201.6(272C), ARC 0990B, IAB 10/3/01.

(9) Hot packs, hydrocollator, infrared treatments, paraffin baths, and whirlpool baths do not ordinarily require the skills of a qualified physical therapist. These are covered when the patient's condition is complicated by other conditions such as a circulatory deficiency or open wounds or if the service is an integral part of a skilled physical therapy procedure.

(10) Gait training and gait evaluation and training constitute a covered service if the patient's ability to walk has been impaired by a neurological, muscular or skeletal condition or illness. The gait training must be expected to significantly improve the patient's ability to walk or level of independence.

Repetitious exercise to increase endurance of weak or unstable patients can be safely provided by supportive personnel, e.g., aides, nursing personnel. Therefore, it is not a covered physical therapy service.

(11) Ultrasound, shortwave, and microwave diathermy treatments are considered covered services.

(12) Range of motion tests must be performed by a qualified physical therapist. Range of motion exercises require the skills of a qualified physical therapist only when they are part of the active treatment of a specific disease or disabling condition which has resulted in a loss or restriction of mobility.

Documentation must reflect the degree of motion lost, the normal range of motion, and the degree to be restored.

Range of motion to unaffected joints only does not constitute a covered physical therapy service.

(13) Reconditioning programs after surgery or prolonged hospitalization are not covered as physical therapy.

(14) Therapeutic exercises would constitute a physical therapy service due either to the type of exercise employed or to the condition of the patient.

(15) Use of isokinetic or isotonic type equipment in physical therapy is covered when normal range of motion of a joint is affected due to bone, joint, ligament or tendon injury or postsurgical trauma. Billing can only be made for the time actually spent by the therapist in instructing the patient and assessing the patient's progress.

(16) When recipients do not meet restorative or maintenance therapy criteria, diagnostic or trial therapy may be utilized. When the initial evaluation is not sufficient to determine whether there are rehabilitative goals that should be addressed, diagnostic or trial therapy to establish goals shall be considered appropriate. Diagnostic or trial therapy may be appropriate for recipients who need evaluation in multiple environments in order to adequately determine their rehabilitative potential. Diagnostic or trial therapy consideration may be appropriate when there is a need to assess the patient's response to treatment in the recipient's environment.

When during diagnostic or trial therapy a recipient has been sufficiently evaluated to determine potential for restorative or maintenance therapy, or lack of therapy potential, diagnostic or trial therapy ends. When as a result of diagnostic or trial therapy, restorative or maintenance therapy is found appropriate, claims shall be submitted noting restorative or maintenance therapy (instead of diagnostic or trial therapy).

At the end of diagnostic or trial therapy, the rehabilitation provider shall recommend continuance of services under restorative therapy, recommend continuance of services under maintenance therapy, or recommend discontinuance of services. Continuance of services under restorative or maintenance therapy will be reviewed based on the criteria in place for restorative or maintenance therapy.

Trial therapy shall not be granted more often than once per year for the same issue. If the recipient has a previous history of rehabilitative services, trial therapy for the same type of services generally would be payable only when a significant change has occurred since the last therapy. Requests for subsequent diagnostic or trial therapy for the same issue would require documentation reflecting a significant change. See number 4 below for guidelines under a significant change. Further diagnostic or trial therapy for the same issue would not be considered appropriate when progress was not achieved, unless the reasons which blocked change previously are listed and the reasons the new diagnostic or trial therapy would not have these blocks are provided.

The number of diagnostic or trial therapy hours authorized in the initial treatment period shall not exceed 12 hours per month. Documentation of the medical necessity and the plan for services under diagnostic trial therapy are required as they will be reviewed in the determination of the medical necessity of the number of hours of service provided.

Diagnostic or trial therapy standards also apply to speech and occupational therapy.

The following criteria additionally must be met:

1. There must be face-to-face interaction with a licensed therapist. (An aide's services will not be payable.)

2. Services must be provided on an individual basis. (Group diagnostic or trial therapy will not be payable.)

3. Documentation of the diagnostic therapy or trial therapy must reflect the provider's plan for therapy and the recipient's response.

4. If the recipient has a previous history of rehabilitative services, trial therapy for the same type of services generally would be payable only when a significant change has occurred since the last therapy. A significant change would be considered as having occurred when any of the following exist: new onset, new problem, new need, new growth issue, a change in vocational or residential setting that requires a reevaluation of potential, or surgical intervention that may have caused new rehabilitative potentials.

5. For persons who received previous rehabilitative treatment, consideration of trial therapy generally should occur only if the person has incorporated any regimen recommended during prior treatment into the person's daily life to the extent of the person's abilities.

6. Documentation should include any previous attempts to resolve problems using nontherapy personnel (i.e., residential group home staff, family members, etc.) and whether follow-up programs from previous therapy have been carried out.

7. Referrals from residential, vocational or other rehabilitation personnel that do not meet present evaluation, restorative or maintenance criteria shall be considered for trial therapy. Documentation of the proposed service, the medical necessity and the current medical or disabling condition, including any secondary rehabilitative diagnosis, will need to be submitted with the claim.

8. Claims for diagnostic or trial therapy shall reflect the progress being made toward the initial diagnostic or trial therapy plan.

c. Occupational therapy services.

(1) To be covered under rehabilitation agency services, occupational therapy services must be included in a plan of treatment, improve or restore practical functions which have been impaired by illness, injury, or disabling condition, or enhance the person's ability to perform those tasks required for independent functioning, be prescribed by a physician under a plan of treatment, be performed by a qualified licensed occupational therapist or a qualified licensed occupational therapist assistant under the general supervision of a qualified licensed occupational therapist as set forth in the department of public health, professional licensure division, rule 645—201.9(148B),* and be reasonable and necessary for the treatment of the person's illness, injury, or disabling condition.

*Proposed rule 645—206.6(272C), ARC 0989B, IAB 10/3/01.

(2) Restorative therapy is covered when an expectation exists that the therapy will result in a significant practical improvement in the person's condition.

However, in these cases where there is a valid expectation of improvement met at the time the occupational therapy program is instituted, but the expectation goal is not realized, services would only be covered up to the time one would reasonably conclude the patient would not improve.

The guidelines under restorative therapy, maintenance therapy, and diagnostic or trial therapy for physical therapy in 78.19(1) "b"(7), (8), and (16) apply to occupational therapy.

(3) Maintenance therapy, or any activity or exercise program required to maintain a function at the restored level, is not a covered service. However, designing a maintenance program in accordance with the requirements of 78.19(1) "b"(8) and monitoring the progress would be covered.

(4) The selection and teaching of tasks designed to restore physical function are covered.

(5) Planning and implementing therapeutic tasks, such as activities to restore sensory-integrative functions are covered. Other examples include providing motor and tactile activities to increase input and improve responses for a stroke patient.

(6) The teaching of activities of daily living and energy conservation to improve the level of independence of a patient which require the skill of a licensed therapist and meet the definition of restorative therapy is covered.

(7) The designing, fabricating, and fitting of orthotic and self-help devices are considered covered services if they relate to the patient's condition and require occupational therapy. A maximum of 13 visits is reimbursable.

(8) Vocational and prevocational assessment and training are not payable by Medicaid. These include services which are related solely to specific employment opportunities, work skills, or work settings.

d. Speech therapy services.

(1) To be covered by Medicaid as rehabilitation agency services, speech therapy services must be included in a plan of treatment established by the licensed, skilled therapist after consultation with the physician, relate to a specific medical diagnosis which will significantly improve a patient's practical, functional level in a reasonable and predictable time period, and require the skilled services of a speech therapist. Services provided by a speech aide are not reimbursable.

(2) Speech therapy activities which are considered covered services include: restorative therapy services to restore functions affected by illness, injury, or disabling condition resulting in a communication impairment or to develop functions where deficiencies currently exist. Communication impairments fall into the general categories of disorders of voice, fluency, articulation, language, and swallowing disorders resulting from any condition other than mental impairment. Treatment of these conditions is payable if restorative criteria are met.

(3) Aural rehabilitation, the instruction given by a qualified speech pathologist in speech reading or lip reading to patients who have suffered a hearing loss (input impairment), constitutes a covered service if reasonable and necessary to the patient's illness or injury. Group treatment is not covered. Audiological services related to the use of a hearing aid are not reimbursable.

(4) Teaching a patient to use sign language and to use an augmentative communication device is reimbursable. The patient must show significant progress outside the therapy sessions in order for these services to be reimbursable.

(5) Where a maintenance program is appropriate, the initial evaluation, the instruction of the patient and caregivers to carry out the program, and supervisory visits to monitor progress are covered services. Beyond evaluation, instruction, and monitoring, maintenance therapy is not reimbursable. However, designing a maintenance program in accordance with the requirements of maintenance therapy and monitoring the progress are covered.

(6) The guidelines and limits on restorative therapy, maintenance therapy, and diagnostic or trial therapy for physical therapy in 78.19(1)“b”(7), (8), and (16) apply to speech therapy. If the only goal of prior rehabilitative speech therapy was to learn the prerequisite speech components, then number “5” under 78.19(1)“b”(16) will not apply to trial therapy.

78.19(2) General guidelines for plans of treatment.

a. The minimum information to be included on medical information forms and treatment plans includes:

(1) The patient’s current medical condition and functional abilities, including any disabling condition.

(2) The physician’s signature and date (within the certification period).

(3) Certification period.

(4) Patient’s progress in measurable statistics. (Refer to 78.19(1)“b”(16).)

(5) The place services are rendered.

(6) Dates of prior hospitalization (if applicable or known).

(7) Dates of prior surgery (if applicable or known).

(8) The date the patient was last seen by the physician (if available).

(9) A diagnosis relevant to the medical necessity for treatment.

(10) Dates of onset of any diagnoses for which treatment is being rendered (if applicable).

(11) A brief summary of the initial evaluation or baseline.

(12) The patient’s prognosis.

(13) The services to be rendered.

(14) The frequency of the services and discipline of the person providing the service.

(15) The anticipated duration of the services and the estimated date of discharge (if applicable).

(16) Assistive devices to be used.

(17) Functional limitations.

(18) The patient’s rehabilitative potential and the extent to which the patient has been able to apply the skills learned in the rehabilitation setting to everyday living outside the therapy sessions.

(19) The date of the last episode of instability or the date of the last episode of acute recurrence of illness or symptoms (if applicable).

(20) Quantitative, measurable, short-term and long-term functional goals.

(21) The period of time of a session.

(22) Prior treatment (history related to current diagnosis) if available or known.

b. The information to be included when developing plans for teaching, training, and counseling include:

(1) To whom the services were provided (patient, family member, etc.).

(2) Prior teaching, training, or counseling provided.

(3) The medical necessity of the rendered services.

(4) The identification of specific services and goals.

- (5) The date of the start of the services.
- (6) The frequency of the services.
- (7) Progress in response to the services.
- (8) The estimated length of time the services are needed.

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

441—78.20(249A) Independent laboratories. Payment will be made for medically necessary laboratory services provided by laboratories that are independent of attending and consulting physicians' offices, hospitals, and critical access hospitals and that are certified to participate in the Medicare program.

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

441—78.21(249A) Rural health clinics. Payment will be made to rural health clinics for the same services payable under the Medicare program (Title XVIII of the Social Security Act). Payment will be made for sterilization in accordance with 78.1(16).

78.21(1) Utilization review. Utilization review shall be conducted of Medicaid recipients who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. Refer to rule 441—76.9(249A) for further information concerning the recipient lock-in program.

78.21(2) Risk assessments. Risk assessments, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed twice during a Medicaid recipient's pregnancy. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. See description of enhanced services at subrule 78.25(3).

Rural health clinics which wish to administer vaccines which are available through the vaccines for children program to Medicaid recipients shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid recipients.

78.21(3) EPSDT care coordination. Payment for EPSDT care coordination services outlined in 78.18(6)“b”(2)“1” to “7” is available to Medipass eligible providers as defined in rule 441—88.41(249A) who accept responsibility for providing EPSDT care coordination services to the Medipass recipients under the age of 21 assigned to them on a monthly basis. All Medipass providers shall be required to complete Form 470-3183, Care Coordination Agreement, to reflect acceptance or denial of EPSDT care coordination responsibility. When the Medipass provider does not accept the responsibility, the Medipass patients assigned to the Medipass provider are automatically referred to the designated department of public health EPSDT care coordination agency in the recipient's geographical area. Acknowledgment of acceptance of the EPSDT care coordination responsibility shall be for a specified period of time of no less than six months. Medipass providers who identify Medipass EPSDT recipients in need of transportation assistance beyond that available according to rule 441—78.13(249A) shall be referred to the designated department of public health agency assigned to the geographical area of the recipient's residence.

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

441—78.22(249A) Family planning clinics. Payments will be made on a fee schedule basis for services provided by family planning clinics. Payment will be made for sterilization in accordance with 78.1(16). Family planning clinics which wish to administer vaccines for Medicaid recipients who receive family planning services at the family planning clinic shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid recipients. Family planning clinics shall receive reimbursement for the administration of vaccines to Medicaid recipients.

441—78.23(249A) Other clinic services. Payment will be made on a fee schedule basis to facilities not part of a hospital, funded publicly or by private contributions, which provide medically necessary treatment by or under the direct supervision of a physician or dentist to outpatients. Payment will be made for sterilization in accordance with 78.1(16).

Utilization review shall be conducted of Medicaid recipients who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. Refer to rule 441—76.9(249A) for further information concerning the recipient lock-in program.

Risk assessments, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed twice during a Medicaid recipient's pregnancy. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. See description of enhanced services at subrule 78.25(3).

Clinics that wish to administer vaccines which are available through the vaccines for children program to Medicaid recipients shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid recipients. Clinics shall receive reimbursement for the administration of vaccines to Medicaid recipients.

441—78.24(249A) Psychologists. Payment will be approved for services authorized by state law when they are provided by the psychologist in the psychologist's office, a hospital, nursing facility, or residential care facility.

78.24(1) Payment for covered services provided by the psychologist shall be made on a fee for service basis.

a. Payment shall be made only for time spent in face-to-face consultation with the client.

b. Time spent with clients shall be rounded to the quarter hour.

78.24(2) Payment will be approved for the following psychological procedures:

a. Individual outpatient psychotherapy or other psychological procedures not to exceed one hour per week or 40 hours in any 12-month period, or

b. Couple, marital, family, or group outpatient therapy not to exceed one and one-half hours per week or 60 hours in any 12-month period, or

c. A combination of individual and group therapy not to exceed the cost of 40 individual therapy hours in any 12-month period.

d. Psychological examinations and testing for purposes of evaluation, placement, psychotherapy, or assessment of therapeutic progress, not to exceed eight hours in any 12-month period.

e. Mileage at the same rate as in 78.1(8) when the following conditions are met:

(1) It is necessary for the psychologist to travel outside of the home community, and

(2) There is no qualified mental health professional more immediately available in the community, and

(3) The recipient has a medical condition which prohibits travel.

f. Covered procedures necessary to maintain continuity of psychological treatment during periods of hospitalization or convalescence for physical illness.

g. Procedures provided within a licensed hospital, residential treatment facility, day hospital, or nursing home as part of an approved treatment plan and a psychologist is not employed by the facility.

78.24(3) Payment will not be approved for the following services:

- a. Psychological examinations performed without relationship to evaluations or psychotherapy for a specific condition, symptom, or complaint.
- b. Psychological examinations covered under Part B of Medicare, except for the Part B Medicare deductible and coinsurance.
- c. Psychological examinations employing unusual or experimental instrumentation.
- d. Individual and group psychotherapy without specification of condition, symptom, or complaint.
- e. Sensitivity training, marriage enrichment, assertiveness training, growth groups or marathons, or psychotherapy for nonspecific conditions of distress such as job dissatisfaction or general unhappiness.

78.24(4) Rescinded IAB 10/12/94, effective 12/1/94.

78.24(5) The following services shall require review by a consultant to the department.

- a. Protracted therapy beyond 16 visits. These cases shall be reviewed following the sixteenth therapy session and periodically thereafter.
- b. Any service which does not appear necessary or appears to fall outside the scope of what is professionally appropriate or necessary for a particular condition.

This rule is intended to implement Iowa Code sections 249A.4 and 249A.15.

441—78.25(249A) Maternal health centers. Payment will be made for prenatal and postpartum medical care and limited care coordination and health education services for persons who are not determined high risk. Payment will be made for enhanced perinatal services for persons determined high risk. These services include additional health education services, nutrition counseling, social services, additional care coordination services, and one postpartum home visit. Maternal health centers shall provide trimester and postpartum reports to the referring physician. Additional prenatal and postpartum reimbursement will be made for persons determined to be high risk. Risk assessments using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed twice during a Medicaid recipient's pregnancy. If the risk assessment reflects a high-risk pregnancy, additional reimbursement shall be provided for the enhanced services related to a high-risk pregnancy.

Maternal health centers which wish to administer vaccines which are available through the vaccines for children program to Medicaid recipients shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid recipients. Maternal health centers shall receive reimbursement for the administration of vaccines to Medicaid recipients.

78.25(1) Prenatal and postpartum medical services shall be provided by a physician, physician assistant, or a nurse practitioner employed by or on contract with the center. Medical services performed by maternal health centers shall be performed under the supervision of a physician. Nurse practitioners and physician assistants performing under the supervision of a physician must do so within the scope of practice of that profession, as defined by Iowa Code chapters 152 and 148C, respectively.

78.25(2) The services provided to a person determined to be low risk include:

- a. Prenatal and postpartum medical care.
- b. Health education which shall include:
 - (1) Importance of continued prenatal care.
 - (2) Normal changes of pregnancy including both maternal changes and fetal changes.
 - (3) Self-care during pregnancy.

- (4) Comfort measures during pregnancy.
- (5) Danger signs of pregnancy.
- (6) Labor and delivery including the normal process of labor, signs of labor, coping skills, danger signs, and management of labor.
- (7) Preparation for baby including feeding, equipment, and clothing.
- (8) Education on the use of over-the-counter drugs.
- (9) Education about HIV protection.
- c. Care coordination services which shall include:
 - (1) Presumptive eligibility.
 - (2) Referral to WIC.
 - (3) Referral for dental services.
 - (4) Referral to physician or midlevel practitioners.
 - (5) Risk assessment.
 - (6) Arrangements for delivery, as appropriate.
 - (7) Arrangements for prenatal classes.
 - (8) Departmental multiprogram application.
 - (9) Hepatitis screen.
 - (10) Referral for eligible services.

78.25(3) Enhanced perinatal services may be provided to a patient who has been determined to have a high-risk pregnancy as documented by Form 470-2942, Medicaid Prenatal Risk Assessment. Enhanced perinatal services may be provided by licensed dietitians; persons with at least a bachelor's degree in social work, counseling, sociology or psychology; physicians; and registered nurses employed by or on contract with the center. An appropriately trained physician or advanced registered nurse practitioner must be involved in staffing the patients receiving enhanced services.

Enhanced services are as follows:

a. Care coordination, the coordination of comprehensive prenatal services, shall be provided by a registered nurse or a person with at least a bachelor's degree in social work, counseling, sociology or psychology and shall include:

(1) Developing an individual plan of care based on the client's needs, including pregnancy and personal and interpersonal issues. This package includes counseling (such as coaching, supporting, educating, listening, encouraging, and feedback), referral, and assistance for other specified services such as mental health.

(2) Ensuring that the client receives all components as appropriate (medical, education, nutrition, psychosocial, and postpartum home visit).

(3) Risk tracking.

b. Education services shall be provided by a registered nurse. Education shall include as appropriate:

(1) Education about high-risk medical conditions.

(2) High-risk sexual behavior.

(3) Smoking cessation.

(4) Alcohol usage education.

(5) Drug usage education.

(6) Environmental and occupational hazards.

c. Nutrition services shall be provided by a licensed dietitian. Nutrition assessment and counseling shall include:

- (1) Initial assessment of nutritional risk based on height, current and prepregnancy weight status, laboratory data, clinical data, and self-reported dietary information.
- (2) Ongoing nutritional assessment.
- (3) Development of an individualized nutritional care plan.
- (4) Referral to food assistance programs if indicated.
- (5) Nutritional intervention.

d. Psychosocial services shall be provided by a person with at least a bachelor's degree in social work, counseling, sociology or psychology. Psychosocial assessment and counseling shall include:

- (1) A psychosocial assessment including: needs assessment, profile of client demographic factors, mental and physical health history and concerns, adjustment to pregnancy and future parenting, and environmental needs.
- (2) A profile of the client's family composition, patterns of functioning and support systems.
- (3) An assessment-based plan of care, risk tracking, counseling and anticipatory guidance as appropriate, and referral and follow-up services.

e. A postpartum home visit within two weeks of the child's discharge from the hospital shall be provided by a registered nurse and shall include:

- (1) Assessment of mother's health status.
- (2) Physical and emotional changes postpartum.
- (3) Family planning.
- (4) Parenting skills.
- (5) Assessment of infant health.
- (6) Infant care.
- (7) Grief support for unhealthy outcome.
- (8) Parenting of a preterm infant.
- (9) Identification and referral to community resources as needed.

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

441—78.26(249A) Ambulatory surgical center services. Ambulatory surgical center services are those services furnished by an ambulatory surgical center in connection with a covered surgical procedure or a covered dental procedure.

Covered surgical procedures shall be those medically necessary procedures that are eligible for payment as physicians' services, under the circumstances specified in rule 441—78.1(249A) and performed on an eligible recipient, that can safely be performed in an outpatient setting as determined by the department upon advice from the department's utilization review and quality assurance firm.

Covered dental procedures are those medically necessary procedures that are eligible for payment as dentists' services, under the circumstances specified in rule 441—78.4(249A) and performed on an eligible recipient, that can safely be performed in an outpatient setting for Medicaid recipients whose mental, physical, or emotional condition necessitates deep sedation or general anesthesia.

The covered services provided by the ambulatory surgical center in connection with a Medicaid-covered surgical or dental procedure shall be those nonsurgical and nondental services covered by the Medicare program as ambulatory surgical center services in connection with Medicare-covered surgical procedures.

78.26(1) Abortion procedures are covered only when criteria in subrule 78.1(17) are met.

78.26(2) Sterilization procedures are covered only when criteria in subrule 78.1(16) are met.

78.26(3) Preprocedure review by the Iowa Foundation for Medical Care (IFMC) is required if ambulatory surgical centers are to be reimbursed for certain frequently performed surgical procedures as set forth under subrule 78.1(19). Criteria are available from IFMC, 3737 Woodland Avenue, Suite 500, West Des Moines, Iowa 50265, or in local hospital utilization review offices. (Cross-reference 78.28(6))

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

441—78.27(249A) Genetic consultation clinics. Rescinded IAB 6/28/00, effective 8/2/00.

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 2003 Iowa Acts, chapter 112, section 3:

a. Prior authorization is required for psychostimulants for recipients 21 years of age or older. Prior approval shall be granted if there is documentation of one of the following:

1. Attention deficit disorder.
2. Attention deficit hyperactivity disorder.
3. Narcolepsy.
4. Adjunctive treatment of major depression.

The fiscal agent shall consider other conditions on an individual basis after review of documentation submitted regarding the need for psychostimulants. Psychostimulants include the following medications: dextroamphetamine, amphetamine mixtures, methamphetamine, methylphenidate, pemoline (Cylert), and modafinil (Provigil). (Cross-reference 78.1(2)“a”(3))

b. Prior approval is required for multiple vitamins, tonic preparations and combinations with minerals, hormones, stimulants, or other compounds which are available as separate entities for treatment of specific conditions. Payment for these vitamins, preparations, or compounds will be approved when there is a specifically diagnosed vitamin deficiency disease or for recipients aged 20 or under if there is a diagnosed disease which inhibits the nutrition absorption process secondary to the disease. (Prior approval is not required for products principally marketed as prenatal vitamin-mineral supplements.) (Cross-reference 78.1(2)“a”(3))

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 recipient who either has a metabolic or digestive disorder that prevents the recipient 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 recipient’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 recipient’s total medical condition that includes a description of the recipient’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 recipient’s nutritional status and indicate that the recipient’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 recipient 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 recipient.

(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. The following drugs require prior approval. For all drugs requiring prior authorization, in the event of an emergency situation when a prior authorization request cannot be submitted and a response received within 24 hours such as after regular working hours or on weekends, a 72-hour supply of the drug may be dispensed and reimbursement will be made. Full therapeutic dose levels and maintenance dose levels for the following drugs are those listed in the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, American Medical Association Drug Evaluations, and the peer-reviewed medical literature. Prior authorization will be granted for 12-month periods per recipient as needed unless otherwise specified. (Cross-reference 78.1(2)“a”(3))

(1) Antiulcer drugs. Prior authorization is required for prescriptions for all single-source histamine H2-receptor antagonists at all dose levels. Single source is defined as the brand-name drug or the innovator of a multiple-source drug. Payment for the single-source histamine H2-receptor antagonist will be authorized only for cases in which there is documentation of a previous trial and therapy failure with at least one multiple-source histamine H2-receptor antagonist.

Prior authorization is required for multiple-source histamine H2-receptor antagonists prescribed at full therapeutic dose levels for longer than a 90-day period or more frequently than one 90-day course of therapy per 12-month period per recipient. Payment for single- or multiple-source histamine H2-receptor antagonists at full therapeutic dose levels beyond the 90-day limit or more frequently than one 90-day course of therapy per patient per 12-month period will be authorized in cases where there is a diagnosis of:

1. Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).
2. Symptomatic gastroesophageal reflux.
3. Symptomatic relapses of duodenal or gastric ulcers not responding to maintenance therapy and with documentation of either failure of *Helicobacter pylori* treatment or a negative *Helicobacter pylori* test result.
4. Barrett's esophagus.
5. Erosive esophagitis.

Other conditions will be considered on an individual patient basis with submitted documentation of medical necessity.

Prior authorization is required for proton pump inhibitor usage longer than 60 days or more frequently than one 60-day course per 12-month period. Payment for proton pump inhibitors beyond the 60-day limit or more frequently than one 60-day course per recipient per 12-month period shall be authorized upon request for those cases in which there is a diagnosis of:

1. Specific hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).
2. Barrett's esophagus.
3. Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses as defined by the histamine H2-receptor antagonist prior authorization guidelines.

4. Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of *Helicobacter pylori* treatment or a negative *Helicobacter pylori* test result.

Proton pump inhibitors prescribed concurrently with histamine H2-receptor antagonists shall be considered duplication of therapy. Payment for duplication of therapy will be considered on an individual basis after review of submitted documentation of medical necessity.

Prior authorization is not required for a cumulative 60 days of therapy with a proton pump inhibitor per 12-month period per recipient. The 12-month period is patient specific and begins 12 months prior to the requested date of prior authorization.

The medical condition of patients receiving continuous long-term treatment with proton pump inhibitors shall be reviewed yearly to determine the need for ongoing treatment.

Prior authorization is required for sucralfate at full therapeutic dose levels for longer than a 90-day period or more frequently than one 90-day course of therapy per patient per 12-month period. Payment for sucralfate at full therapeutic dose levels beyond the 90-day limit or more frequently than a 90-day course per patient per 12-month period will be authorized in cases where there is a diagnosis of:

1. Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).
2. Symptomatic gastroesophageal reflux.
3. Symptomatic relapses of duodenal or gastric ulcers not responding to maintenance therapy and with documentation of either failure of *Helicobacter pylori* treatment or a negative *Helicobacter pylori* test result.
4. Barrett's esophagus.
5. Erosive esophagitis.

Other conditions will be considered on an individual basis with submitted documentation.

Concurrent sucralfate therapy prescribed with histamine H2-receptor antagonists or proton pump inhibitors beyond a 30-day period is considered duplication of therapy. Concurrent sucralfate therapy prescribed with misoprostol is also considered duplication of therapy. Payment for duplication of therapy will be considered on an individual patient basis after review of submitted documentation of medical necessity.

Prior authorization is not required for misoprostol when prescribed concurrently with a nonsteroidal anti-inflammatory drug. Prior authorization is required for any other therapy with misoprostol beyond 90 days. Justification for other therapy will be considered on an individual patient basis. Misoprostol prescribed concurrently with histamine H2-receptor antagonists, sucralfate, or proton pump inhibitors will be considered duplication of therapy. Payment for duplication of therapy will be considered on an individual patient basis after review of submitted documentation of medical necessity.

(2) Antiarthritis drugs. Prior authorization is required for single-source nonsteroidal anti-inflammatory drugs. Requests must document previous trials and therapy failure with at least two multiple-source nonsteroidal anti-inflammatory drugs. Prior authorization for chronic conditions will be issued for a 12-month period. Once a prior authorization has been issued the single-source nonsteroidal anti-inflammatory drug being prescribed may be changed to another single-source product without a new request within the approved time period of 12 months. Patients who have been established on proven therapy with a single-source product prior to October 1, 1992, will not require a prior authorization.

Prior authorization is not required for prescriptions for multiple-source nonsteroidal anti-inflammatory drugs.

(3) Prior authorization is required for single-source benzodiazepines. Requests must document a previous trial and therapy failure with one multiple-source product. Prior authorization will be approved for 12 months for documented:

1. Generalized anxiety disorder.
2. Panic attack with or without agoraphobia.
3. Seizure.
4. Nonprogressive motor disorder.
5. Bipolar depression.
6. Dystonia.

Prior authorization requests will be approved for a three-month period for all other diagnoses related to the use of benzodiazepines. Justification will be considered on an individual patient basis. Patients who have been established on proven therapy with a single-source product prior to October 1, 1992, will not require a prior authorization.

(4) Prior authorization is required for therapy with growth hormones. All of the following criteria must be met for approval for prescribing of growth hormones:

1. Standard deviation of 2.0 or more below mean height for chronological age.
2. No intracranial lesion or tumor diagnosed by MRI.
3. Growth rate below five centimeters per year.
4. Failure of any two stimuli tests to raise the serum growth hormone level above seven nanograms per milliliter.
5. Bone age 14 to 15 years or less in females and 15 to 16 years or less in males.
6. Epiphyses open.

Prior authorization will be granted for 12-month periods per recipient as needed. (Cross-reference 78.1(2)“a”(3))

(5) Prior authorization is required for all prescription topical acne products for the treatment of mild to moderate acne vulgaris. An initial treatment failure of an over-the-counter benzoyl peroxide product, which is covered by the program, is required prior to the initiation of a prescription product, or evidence must be provided that use of these agents would be medically contraindicated. If the patient presents with a preponderance of comedonal acne, tretinoin products may be utilized as first-line agents without prior authorization.

(6) Prior authorization is required for all tretinoin prescription products for those patients over the age of 25 years. Alternatives such as topical benzoyl peroxide (OTC), and topical erythromycin, clindamycin, or oral tetracycline must first be tried (unless evidence is provided that use of these agents would be medically contraindicated) for the following conditions: endocrinopathy, mild to moderate acne (noninflammatory and inflammatory), and drug-induced acne. Prior authorization will not be required for those patients presenting with a preponderance of comedonal acne. Upon treatment failure with the above-mentioned products or if medically contraindicated, tretinoin products will be approved for three months. If tretinoin therapy is effective after the three-month period, approval will be granted for a one-year period. Skin cancer, lamellar ichthyosis, and Darier's Disease diagnoses will receive automatic approval for lifetime use of tretinoin products.

(7) Prior authorization is required for single-source antihistamines including single active ingredient and combination products. Prior authorization is not required for multiple-source antihistamines. Single source is defined as the brand-name drug or the innovator of a multiple-source drug. Patients 21 years of age and older must have received two unsuccessful trials with other covered multiple-source antihistamines unless evidence is provided that the use of these agents would be medically contraindicated, prior to the utilization of single-source antihistamines. Patients 20 years of age and younger must have one unsuccessful trial with another covered multiple-source antihistamine unless evidence is provided that the use of these agents would be medically contraindicated, prior to the utilization of single-source antihistamines.

(8) Rescinded IAB 12/12/01, effective 2/1/02.

(9) Prior authorization is required for all cephalexin hydrochloride monohydrate prescriptions. Treatment failure with cephalexin monohydrate will be required prior to the initiation of a cephalexin hydrochloride monohydrate prescription.

(10) Prior authorization is required for erythropoietin prescribed for outpatients for the treatment of anemia. Patients who meet all of the following criteria may receive prior authorization for the use of erythropoietin:

1. Hematocrit less than 30 percent. If renewal of prior authorization is being requested, hematocrit over 36 percent will require dosage reduction or discontinuation. The fiscal agent may consider continuing therapy for higher hematocrit values on an individual basis after review of the evidence provided regarding the need for continuing therapy. Hematocrit laboratory values must be dated within six weeks of the prior authorization request.

2. Transferrin saturation greater than or equal to 20 percent (transferrin saturation is calculated by dividing serum iron by the total iron binding capacity), ferritin levels greater than or equal to 100 mg/ml, or on concurrent therapeutic iron therapy. Transferrin saturation or ferritin levels must be dated within three months of the prior authorization request.

3. For HIV-infected patients, the endogenous serum erythropoietin level must be less than or equal to 500 mU/ml to initiate therapy.

4. No evidence of untreated GI bleeding, hemolysis, or Vitamin B-12, iron or folate deficiency.

(11) Prior authorization is required for therapy with granulocyte colony stimulating factor. Laboratory values for complete blood and platelet count must be contained as directed by the manufacturer's instructions. The fiscal agent may require dose reduction and discontinuation of therapy based on the manufacturer's guidelines. Payment shall be authorized for one of the following uses:

1. Prevention or treatment of febrile neutropenia in patients with malignancies who are receiving myelosuppressive anticancer therapy.

2. Treatment of neutropenia in patients with malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant.

3. Mobilization of progenitor cells into the peripheral blood stream for leukapheresis collection to be used after myeloablative chemotherapy.

4. Treatment of congenital, cyclic, or idiopathic neutropenia in symptomatic patients.

The fiscal agent may consider other uses on an individual basis after review of the evidence provided regarding the need for therapy with granulocyte colony stimulating factor.

(12) Prior authorization is required for selected brand-name drugs as determined by the department for which there is available an "A" rated bioequivalent generic product as determined by the federal Food and Drug Administration. For prior authorization to be considered, evidence of a treatment failure with the bioequivalent generic drug must be provided. A copy of a completed Med Watch form, FDA Form 3500, as submitted to the federal Food and Drug Administration shall be considered as evidence of a treatment failure. Brand-name drugs selected by the department shall be obtained from those recommended by the Iowa Medicaid drug utilization review commission after consultation with the state associations representing physicians. The list of selected brand-name drugs shall be published in the Medicaid Prescribed Drug Manual and the Physician Manual.

(13) Prior authorization is required for drugs used for the treatment of male sexual dysfunction. For prior authorization to be granted, the patient must:

1. Be 21 years of age or older.
2. Have a confirmed diagnosis of impotence of organic origin or psychosexual dysfunction.
3. Not be taking any medications which are contraindicated for concurrent use with the drug prescribed for treatment of male sexual dysfunction.

Approval for these drugs, with the exception of yohimbine, will be limited to four doses in a 30-day period.

The 72-hour emergency supply rule found above and at 78.1(2)“a”(3) does not apply for drugs used for the treatment of male sexual dysfunction. (Cross-reference 78.1(2)“a”(3))

(14) Prior authorization is required for ergotamine derivatives used for migraine headache treatment for quantities exceeding 18 unit doses of tablets, injections, or sprays per 30 days. Payment for ergotamine derivatives for migraine headache treatment beyond this limit will be considered on an individual basis after review of submitted documentation. For consideration, the following information must be supplied:

1. The diagnosis requiring therapy.
2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.

(15) Prior authorization is required for narcotic agonist-antagonist nasal sprays for quantities exceeding 10 milliliters (approximately 60 doses) per 30 days. Payment for narcotic agonist-antagonist nasal spray beyond this limit will be considered on an individual basis after review of submitted documentation. For consideration, the diagnosis must be supplied. If the use is for the treatment of migraine headaches, documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications must be provided.

(16) Prior authorization is required for isotretinoin therapy.

Payment will be approved for isotretinoin therapy for acne under the following conditions:

1. There are documented trials and therapy failures of systemic antibiotic therapy and topical tretinoin therapy. Documented trials and therapy failures are not required for approval for treatment of acne conglobata.
2. There is a confirmed negative serum pregnancy test, if appropriate.
3. There is a plan for contraception in place, if appropriate.

Initial authorization will be granted for up to 20 weeks. A minimum of two months without therapy is required to consider subsequent authorizations.

Prior authorization of isotretinoin therapy for treatment of conditions other than acne will be considered on an individual basis after review of submitted documentation.

(17) Prior authorization is required for oral antifungal therapy beyond a cumulative 90 days of therapy per 12-month period per patient. Payment for oral antifungal therapy beyond this limit will be authorized in cases where the patient has a diagnosis of an immunocompromised condition or a systemic fungal infection. Other conditions will be considered on an individual basis after review of submitted documentation. This prior authorization requirement does not apply to nystatin.

(18) Prior authorization is required for nonparenteral vasopressin derivatives of posterior pituitary hormone products. Payment for nonparenteral vasopressin derivatives of posterior pituitary hormone products will be authorized for the following diagnoses:

1. Diabetes insipidus.
2. Hemophilia A.
3. Von Willebrand's disease.

Payment for nonparenteral vasopressin derivatives of posterior pituitary hormone products used in the treatment of primary nocturnal enuresis will be authorized for patients who are six years of age or older for periods of six months. Approvals will be granted for subsequent six-month periods only after a drug-free interval to assess the need for continued therapy.

(19) Prior authorization is required for serotonin 5-HT₁-receptor agonists for quantities exceeding 18 unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT₁-receptor agonists beyond this limit will be considered on an individual basis after review of submitted documentation. For consideration, the following information must be supplied:

1. The diagnosis requiring therapy.
2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.

(20) Prior authorization is required for lipase inhibitor drugs for weight loss. Requests must include documentation showing failure of other weight loss programs, a body mass index (BMI) equal to or greater than 30, one or more comorbidity conditions, and a weight management plan including diet and exercise. Prior authorization may be given for up to six months. Additional prior authorizations may be given on an individual basis after review of medical necessity and documented significant weight loss (at least 10 percent) from the individual's weight at the beginning of the previous prior authorization period. (Cross-reference 78.1(2)"a"(3))

(21) Prior authorization is required for therapy with palivizumab. Payment for palivizumab shall be authorized for patients who meet one of the following criteria:

1. Patient is less than 24 months of age at start of therapy and has chronic lung disease requiring medication or oxygen within the last six months.
2. Patient is less than 12 months of age at start of therapy with a gestational age of less than or equal to 28 weeks.
3. Patient is less than 6 months of age at start of therapy with a gestational age between 28 weeks and 31 weeks.
4. Patient is less than 6 months of age at start of therapy with a gestational age of 32 weeks to 35 weeks and has at least one additional risk factor.

The fiscal agent will consider other conditions on an individual basis after review of submitted documentation.

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 prescription for a particular device shall be submitted to request prior approval. (Cross-reference 78.10(3)"c"(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. 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.

(4) The patient has had a successful trial with an enclosed 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 supplementation of a regular diet. (Cross-reference 78.10(2) "c") The department shall approve payment when the recipient 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.

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.

(1) The documentation shall include:

1. A statement of the recipient's total medical condition that includes a description of the recipient'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 recipient's nutritional status and indicate that the recipient'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 recipient, if the request includes oral supplementation of a regular diet.

(2) 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 recipient 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.

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.