CHAPTER 78
AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL SERVICES

[Prior to 7/1/83, Social Services[770] Ch 78]
[Prior to 2/11/87, Human Services[498]]

441—78.1(249A) Physicians' services. Payment will be approved for all medically necessary services and supplies provided by the physician including services rendered in the physician's office or clinic, the home, in a hospital, nursing home or elsewhere.

Payment shall be made for all services rendered by a doctor of medicine or osteopathy within the scope of this practice and the limitations of state law subject to the following limitations and exclusions:

78.1(1) Payment will not be made for:

a. Drugs dispensed by a physician or other legally qualified practitioner (dentist, podiatrist, therapeutically certified optometrist, physician assistant, or advanced registered nurse practitioner) unless it is established that there is no licensed retail pharmacy in the community in which the legally qualified practitioner's office is maintained. Payment will not be made for biological supplies and drugs provided free of charge to practitioners by the state department of public health. Rate of payment shall be established as in subrule 78.2(2), but no professional fee shall be paid.

b. Routine physical examinations. A routine physical examination is an examination performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint, or injury. No payment will be made for these examinations unless:

(1) The examination is required as a condition of employment or training and is approved by the department.

(2) The examination is required for an initial certification or period of recertification of the need for nursing care.

(3) The examination is in connection with early and periodic screening, diagnosis, and treatment for persons under age 21, as specified in rules 441—78.18(249A) and 441—84.3(249A).

(4) The examination is required of a child or disabled adult for attendance at school or camp. These examinations shall include all components necessary to meet all early and periodic screening, diagnosis and treatment requirements as set forth in rules 441—78.18(249A) and 441—84.3(249A).

(5) The examination is in connection with the prescription of birth control medications and devices.

(6) The examination is for a pap smear which is allowed as preventive medicine services.

(7) The examination is for well baby care or a routine physical examination for a child under six years of age. These examinations shall include all components necessary to meet all early and periodic screening, diagnosis and treatment requirements as set forth in rules 441—78.18(249A) and 441—84.3(249A).

(8) The examination is an annual routine physical examination for a child in foster care for whom the department assumes financial responsibility. These examinations shall include all components necessary to meet all early and periodic screening, diagnosis and treatment requirements as set forth in rules 441—78.18(249A) and 441—84.3(249A).

c. Treatment of certain foot conditions as specified in 78.5(2)*"a," "b,"* and *"c."*

d. Acupuncture treatments.

e. Rescinded 9/6/78.

f. Unproven or experimental medical and surgical procedures. The criteria in effect in the Medicare program shall be utilized in determining when a given procedure is unproven or experimental in nature.

g. Charges for surgical procedures on the "Outpatient/Same Day Surgery List" produced by the Iowa Foundation for Medical Care or associated inpatient care charges when the procedure is performed in a hospital on an inpatient basis unless the physician has secured approval from the hospital's utilization review department prior to the patient's admittance to the hospital. Approval shall be granted only when inpatient care is deemed to be medically necessary based on the condition of the patient or when the surgical procedure is not performed as a routine, primary, independent procedure. The "Outpatient/Same Day Surgery List" shall be published by the department in the provider manuals for hospitals and physicians. The "Outpatient/Same Day Surgery List" shall be developed by the Iowa Foundation for Medical Care, and shall include procedures which can safely and effectively be performed in a doctor's office or on an outpatient basis in a hospital. The Iowa Foundation for Medical Care may add, delete, or modify entries on the "Outpatient/Same Day Surgery List."

78.1(2) Payment will be made for drugs and supplies when prescribed by a legally qualified practitioner (physician, dentist, podiatrist, therapeutically certified optometrist, physician assistant, or advanced registered nurse practitioner) as provided in this rule.

a. Prescription drugs.

(1) Subject to subparagraphs (2) and (3), payment will be made for prescription drugs marketed by manufacturers that have signed a Medicaid rebate agreement with the Secretary of Health and Human Services in accordance with Public Law 101-508.

(2) Notwithstanding subparagraph (1), payment is not made for: drugs if the prescribed use is not for a medically accepted indication as defined by Section 1927(k)(6) of the Social Security Act, drugs used to cause anorexia or weight gain, drugs used for cosmetic purposes or hair growth, drugs used to promote smoking cessation, covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or manufacturer's designee, drugs described in Section 107(c)(3) of the Drug Amendments of 1962, identical, similar or related drugs (within the meaning of Section 310.6(b)(1) of Title 21 of the Code of Federal Regulations (DESI drugs), and drugs which are prescribed for an individual for fertility purposes. Exceptions may be made to allow payment for fertility drugs if prescribed for a use which meets the definition of a medically accepted indication as described previously in this subparagraph.

(3) Payment will be made for certain drugs only when prior approval is obtained from the fiscal agent and when prescribed for treatment of specified conditions as follows. Prior authorization will be granted for 12-month periods per recipient as needed unless otherwise specified.

Payment for amphetamines and combinations of amphetamines with other therapeutic agents and amphetamine-like sympathomimetic compounds used for obesity control, including any combination of these compounds with other therapeutic agents, will be provided when there is a diagnosis of narcolepsy, hyperkinesis in children, or senile depression but not for obesity control. (Cross-reference 78.28(1)*"a"*)

Payment for multiple vitamins, tonic preparations and combinations thereof with minerals, hormones, stimulants, or other compounds which are available as separate entities for treatment of specific conditions 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 78.28(1)*"b"*)

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 is required for prescriptions for all histamine H2-receptor antagonists, and sucralfate, at full therapeutic dose levels that exceed a 90-day supply for therapy at that dose level. Prior authorization is not required for prescriptions for maintenance doses of these drugs or for a 90-day supply at full therapeutic dose levels per 12-month period per recipient.

Sucralfate prescribed concurrently with histamine H2-receptor antagonists for a period exceeding 30 days will be considered duplicative and inappropriate.

The following conditions will be considered justification for continued use of full therapeutic doses of histamine H2-receptor antagonists beyond the 90-day limitation:

1. Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).
2. Symptomatic gastroesophageal reflux (not responding or failure by maintenance therapy).
3. Symptomatic relapses (duodenum or gastric ulcer) on maintenance therapy.
4. Barretts Esophagus.

Other conditions will be considered on an individual patient basis.

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. Barretts 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 duplicative and inappropriate.

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 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 will be considered duplicative and inappropriate. (Cross-reference 78.28(1)*"d"*(1))

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. (Cross-reference 78.28(1)*"d"*(2))

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. (Cross-reference 78.28(1)*"d"*(3))

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 78.28(1)*"d"*(4))

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. (Cross-reference 78.28(1)*"d"*(5))

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. (Cross-reference 78.28(1)*"d"*(6))

Prior authorization is required for all nonsedating antihistamines. Patients 21 years of age and older must have received two unsuccessful trials with other covered antihistamines (chlorpheniramine or diphenhydramine) unless evidence is provided that the use of these agents would be medically contraindicated, prior to the utilization of the nonsedating antihistamines. Patients 20 years of age and younger must have received one unsuccessful trial with another covered antihistamine (chlorpheniramine or diphenhydramine) unless evidence is provided that the use of these agents would be medically contraindicated, prior to the utilization of the nonsedating antihistamines. (Cross-reference 78.28(1)*"d"*(7))

Prior authorization is required for all dipyridamole prescriptions outside the hospital setting. Dipyridamole will only be approved if aspirin is medically contraindicated in a patient. (Cross-reference 78.28(1)*"d"*(8))

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. (Cross-reference 78.28(1)*"d"*(9))

Prior authorization is required for epoetin prescribed for outpatients for the treatment of anemia. Patients who meet the following criteria may receive prior authorization for the use of epoetin:

1. Hematocrit less than 30 percent.
2. Transferrin saturation greater than 20 percent (transferrin saturation is calculated by dividing serum iron by the total iron binding capacity), or ferritin levels greater than 100 mg/ml.
3. Laboratory values must be current to within three months of the prior authorization request.
4. For AZT treated patients endogenous serum erythropoetin level needs to be greater than 500 mU/ml.
5. Patient should not have a demonstrated gastrointestinal bleed.
6. Exceptions may be made if the patient does not meet criteria "2," but is on aggressive oral iron therapy (i.e., twice or three times per day dosing). The prior authorization for this exception would be for a limited time. (Cross-reference 78.28(1)*"d"*(10))

Prior authorization is required for filgrastim prescribed for outpatients whose conditions meet the following indications for use:

1. Decrease the incidence of infection due to severe neutropenia caused by myelosuppressive anticancer therapy. For this indication the following criteria apply: Filgrastim therapy can continue until the postnadir, absolute neutrophil count is greater than 10,000 cells per cubic millimeter and routine CBC and platelet counts are required twice per week.
2. Decrease the incidence of infection due to severe neutropenia in AIDS patients on zidovudine. For this indication, the following criteria apply: Evidence of neutropenic infection exists or absolute neutrophil count is below 750 cells per cubic millimeter, filgrastim is adjusted to maintain absolute neutrophil count of approximately 1000 cells per cubic millimeter, and routine CBC and platelet counts are required once per week. (Cross-reference 78.28(1)*"d"*(11))

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.

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.

b. Medical and sickroom supplies are payable when ordered by a legally qualified practitioner for a specific rather than incidental use. No payment will be approved for medical and sickroom supplies for a recipient receiving care in a Medicare-certified skilled nursing facility. When a recipient is receiving care in a nursing facility or residential care facility which is not a Medicare-certified skilled nursing facility, payment will be approved only for the following supplies when prescribed by a legally qualified practitioner:

(1) Colostomy and ileostomy appliances.
(2) Colostomy and ileostomy care dressings, liquid adhesive and adhesive tape.
(3) Disposable irrigation trays or sets.
(4) Disposable catheterization trays or sets.
(5) Indwelling Foley catheter.
(6) Disposable saline enemas.
(7) Diabetic supplies including disposable or reusable needles and syringes, testape, clinitest tablets, and clinistix.

c. Prescription records are required for all drugs as specified in Iowa Code sections 155.33, 155.34 and 204.308. For the purposes of the medical assistance program, prescriptions for medical supplies are required and shall be subject to the same provisions.

d. When it is not therapeutically contraindicated, the legally qualified practitioner shall prescribe a quantity of medication sufficient for a 30-day supply. Maintenance drugs in the following therapeutic classifications for use in prolonged therapy may be prescribed in 90-day quantities:

(1) Oral contraceptives
(2) Cardiac drugs
(3) Hypotensive agents
(4) Vasodilating agents
(5) Anticonvulsants
(6) Diuretics
(7) Anticoagulants
(8) Thyroid and antithyroid agents
(9) Antidiabetic agents

e. All physicians who administer vaccines which are available through the vaccines for children program to Medicaid recipients shall enroll in the vaccines for children program. Vaccines available through the vaccines for children program shall be obtained from the department of public health for Medicaid recipients. Physicians shall, however, receive reimbursement for the administration of these vaccines to Medicaid recipients.

f. The following nonprescription drugs are payable:

Acetaminophen Tablets 325 mg, 500 mg
Acetaminophen Elixir 120 mg/5 ml
Acetaminophen Elixir 160 mg/5 ml
Acetaminophen Solution 100 mg/ml
Acetaminophen Suppositories 120 mg
Aspirin Tablets 325 mg, 650 mg, 81 mg (chewable)
Aspirin Tablets, Enteric Coated 325 mg, 650 mg, 81 mg
Aspirin Tablets, Buffered 325 mg
Bacitracin Ointment 500 units/gm
Benzoyl Peroxide 5%, Cleanser, Lotion, Cream, Gel
Benzoyl Peroxide 10%, Cleanser, Lotion, Cream, Gel
Chlorpheniramine Maleate Tablets 4 mg
Diphenhydramine Hydrochloride Capsules 25 mg
Diphenhydramine Hydrochloride Liquid 6.25 mg/5 ml, 12.5 mg/5 ml
Ferrous Sulfate Tablets 300 mg, 325 mg
Ferrous Sulfate Elixir 220 mg/5 ml
Ferrous Sulfate Drops 75 mg/0.6 ml
Ferrous Gluconate Tablets 300 mg, 325 mg
Ferrous Gluconate Elixir 300 mg/5 ml
Ferrous Fumarate Tablets 300 mg, 325 mg
Guaifenesin 100 mg/5 ml with Dextromethorphan 10 mg/5 ml Liquid
Meclizine Hydrochloride Tablets 12.5 mg, 25 mg
Miconazole Nitrate Cream 2% Topical and Vaginal
Miconazole Nitrate Vaginal Suppositories, 100 mg
Niacin (Nicotinic Acid) Tablets 25 mg, 50 mg, 100 mg, 250 mg, 500 mg
Pediatric Oral Electrolyte Solutions
Permethrin Liquid 1%
Pseudoephedrine Hydrochloride Tablets 30 mg, 60 mg
Pseudoephedrine Hydrochloride Liquid 30 mg/5 ml
Salicylic Acid Liquid 17%
Senokot Granules, 326 mg/tsp for children aged 20 and under
Senokot Tablets, 187 mg for children aged 20 and under
Sodium Chloride Solution 0.9% for inhalation with metered dispensing valve 90 ml, 240 ml
Tolnaftate 1% Cream, Solution, Powder

Nonprescription multiple vitamin and mineral products specifically formulated and recommended for use as a dietary supplement during pregnancy and lactation.

With prior authorization, nonprescription multiple vitamins and minerals under the conditions specified in subparagraph 78.1(2)*"a"*(3).

Insulin.

Oral solid forms of the above-covered items shall be prescribed and dispensed in a minimum quantity of 100 units per prescription or the currently available consumer package size except when dispensed via a unit dose system. When used for maintenance therapy, all of the above-listed items may be prescribed and dispensed in 90-day quantities.

78.1(3) Payment will be approved for injections provided they are reasonable, necessary, and related to the diagnosis and treatment of an illness or injury. When billing for an injection, the legally qualified practitioner must specify the brand name of the drug and the manufacturer, the strength of the drug, the amount administered, and the charge of each injection. When the strength and dosage of the drug is not included, payment will be made based on the customary dosage. The following exclusions are applicable.

a. Payment will not be approved for injections when they are considered by standards of medical practice not to be specific or effective treatment for the particular condition for which they are administered.

b. Payment will not be approved for an injection when administered for a reason other than the treatment of a particular condition, illness, or injury. When injecting an amphetamine or legend vitamin, prior approval must be obtained as specified in 78.1(2)*"a"*(3).

c. Payment will not be approved when injection is not an indicated method of administration according to accepted standards of medical practice.

d. Allergenic extract materials provided the patient for self-administration shall not exceed a 90-day supply.

e. Payment will not be approved when an injection is determined to fall outside of what is medically reasonable or necessary based on basic standards of medical practice for the required level of care for a particular condition.

f. Payment will not be approved for vaccines which are available through 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.

78.1(4) For the purposes of this program, cosmetic, reconstructive, or plastic surgery is surgery which can be expected primarily to improve physical appearance or which is performed primarily for psychological purposes or which restores form but which does not correct or materially improve the bodily functions. When a surgical procedure primarily restores bodily function, whether or not there is also a concomitant improvement in physical appearance, the surgical procedure does not fall within the provisions set forth in this subrule. Surgeries for the purpose of sex reassignment are not considered as restoring bodily function and are excluded from coverage.

a. Coverage under the program is generally not available for cosmetic, reconstructive, or plastic surgery. However, under certain limited circumstances payment for otherwise covered services and supplies may be provided in connection with cosmetic, reconstructive, or plastic surgery as follows:

(1) Correction of a congenital anomaly; or

(2) Restoration of body form following an accidental injury; or

(3) Revision of disfiguring and extensive scars resulting from neoplastic surgery.

(4) Generally, coverage is limited to those cosmetic, reconstructive, or plastic surgery procedures performed no later than 12 months subsequent to the related accidental injury or surgical trauma. However, special consideration for exception will be given to cases involving children who may require a growth period.

b. Cosmetic, reconstructive, or plastic surgery performed in connection with certain conditions is specifically excluded. These conditions are:

(1) Dental congenital anomalies, such as absent tooth buds, malocclusion, and similar conditions.

(2) Procedures related to transsexualism, hermaphroditism, gender identity disorders, or body dysmorphic disorders.

(3) Cosmetic, reconstructive, or plastic surgery procedures performed primarily for psychological reasons or as a result of the aging process.

(4) Breast augmentation mammoplasty, surgical insertion of prosthetic testicles, penile implant procedures, and surgeries for the purpose of sex reassignment.

c. When it is determined that a cosmetic, reconstructive, or plastic surgery procedure does not qualify for coverage under the program, all related services and supplies, including any institutional costs, are also excluded.

d. Following is a partial list of cosmetic, reconstructive, or plastic surgery procedures which are not covered under the program. This list is for example purposes only and is not considered all inclusive.

(1) Any procedure performed for personal reasons, to improve the appearance of an obvious feature or part of the body which would be considered by an average observer to be normal and acceptable for the patient's age or ethnic or racial background.

(2) Cosmetic, reconstructive, or plastic surgical procedures which are justified primarily on the basis of a psychological or psychiatric need.

(3) Augmentation mammoplasties.

(4) Face lifts and other procedures related to the aging process.

(5) Reduction mammoplasties, unless there is medical documentation of intractable pain not amenable to other forms of treatment as the result of increasingly large pendulous breasts.

(6) Panniculectomy and body sculpture procedures.

(7) Repair of sagging eyelids, unless there is demonstrated and medically documented significant impairment of vision.

(8) Rhinoplasties, unless there is evidence of accidental injury occurring within the past six months which resulted in significant obstruction of breathing.

(9) Chemical peeling for facial wrinkles.

(10) Dermabrasion of the face.

(11) Revision of scars resulting from surgery or a disease process, except disfiguring and extensive scars resulting from neoplastic surgery.

(12) Removal of tattoos.

(13) Hair transplants.

(14) Electrolysis.

(15) Sex reassignment.

(16) Penile implant procedures.

(17) Insertion of prosthetic testicles.

e. Coverage is available for otherwise covered services and supplies required in the treatment of complications resulting from a noncovered incident or treatment, but only when the subsequent complications represent a separate medical condition such as systemic infection, cardiac arrest, acute drug reaction, or similar conditions. Coverage shall not be extended for any subsequent care or procedure related to the complication that is essentially similar to the initial noncovered care. An example of a complication similar to the initial period of care would be repair of facial scarring resulting from dermabrasion for acne.

78.1(5) The legally qualified practitioner's prescription for medical equipment, appliances, or prosthetic devices shall include the patient's diagnosis and prognosis, the reason the item is required, and an estimate in months of the duration of the need. Payment will be made in accordance with rule 78.10(249A).

78.1(6) Payment will be approved for the examination to establish the need for orthopedic shoes in accordance with rule 78.15(249A).

78.1(7) No payment shall be made for the services of a private duty nurse.

78.1(8) Payment for mileage shall be the same as that in effect in part B of Medicare.

78.1(9) Payment will be approved for visits to patients in nursing facilities subject to the following conditions:

a. Payment will be approved for only one visit to the same patient in a calendar month. Payment for further visits will be made only when the need for the visits is adequately documented by the physician.

b. When only one patient is seen in a single visit the allowance shall be based on a follow-up home visit. When more than one patient is seen in a single visit, payment shall be based on a follow-up office visit. In the absence of information on the claim, the carrier will assume that more than one patient was seen, and payment approved on that basis.

c. Payment will be approved for mileage in connection with nursing home visits when:

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

(2) There are not physicians in the community in which the nursing home is located.

d. Payment will be approved for tasks related to a resident receiving nursing facility care which are performed by a physician's employee who is a nurse practitioner, clinical nurse specialist, or physician assistant as specified in subrule 81.13(13)*"e."* On-site supervision of the physician is not required for these services.

78.1(10) Payment will be approved in independent laboratory when it has been certified as eligible to participate in Medicare.

78.1(11) Rescinded, effective 8/1/87.

78.1(12) Payment will be made on the same basis as in Medicare for services associated with treatment of chronic renal disease including physician's services, hospital care, renal transplantation, and hemodialysis, whether performed on an inpatient or outpatient basis. Payment will be made for deductibles and coinsurance for those persons eligible for Medicare.

78.1(13) Payment will be made to the physician for services rendered by auxiliary personnel employed by the physician and working under the direct personal supervision of the physician, when such services are performed incident to the physician's professional service.

a. Auxiliary personnel are nurses, physician's assistants, psychologists, social workers, audiologists, occupational therapists and physical therapists.

b. An auxiliary person is considered to be an employee of the physician if the physician:

(1) Is able to control the manner in which the work is performed, i.e., is able to control when, where and how the work is done. This control need not be actually exercised by the physician.

(2) Sets work standards.

(3) Establishes job description.

(4) Withholds taxes from the wages of the auxiliary personnel.

c. Direct personal supervision in the office setting means the physician must be present in the same office suite, not necessarily the same room, and be available to provide immediate assistance and direction.

Direct personal supervision outside the office setting, such as the recipient's home, hospital, emergency room, or nursing facility, means the physician must be present in the same room as the auxiliary person.

Advanced registered nurse practitioners certified under board of nursing rules 655—Chapter 7 performing services within their scope of practice are exempt from the direct personal supervision requirement for the purpose of reimbursement to the employing physicians. In these exempted circumstances, the employing physicians must still provide general supervision and be available to provide immediate needed assistance by telephone. Advanced registered nurse practitioners who prescribe drugs and medical devices are subject to the guidelines in effect for physicians as specified in rule 441—78.1(249A).

A physician assistant licensed under board of physician assistant examiners' professional licensure rules 645—Chapter 325 is exempt from the direct personal supervision requirement but the physician must still provide general supervision and be available to provide immediate needed assistance by telephone. Physician assistants who prescribe drugs and medical devices are subject to the guidelines in effect for physicians as specified in rule 441—78.1(249A).

d. Services incident to the professional services of the physician means the service provided by the auxiliary person must be related to the physician's professional service to the recipient. If the physician has not or will not perform a personal professional service to the recipient the clinical records must document that the physician assigned treatment of the recipient to the auxiliary person.

78.1(14) 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 physician 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.

78.1(15) The certification of inpatient hospital care shall be the same as that in effect in part A of Medicare. The hospital admittance record is sufficient for the original certification.

78.1(16) No payment will be made for sterilization of an individual under the age of 21 or who is mentally incompetent or institutionalized. Payment will be made for sterilization performed on an individual who is aged 21 or older at the time the informed consent is obtained and who is mentally competent and not institutionalized when all the conditions in this subrule are met.

a. The following definitions are pertinent to this subrule:

(1) Sterilization means any medical procedure, treatment, or operation performed for the purpose of rendering an individual permanently incapable of reproducing and which is not a necessary part of the treatment of an existing illness or medically indicated as an accompaniment of an operation on the genital urinary tract. Mental illness or retardation is not considered an illness or injury.

(2) Hysterectomy means a medical procedure or operation to remove the uterus.

(3) Mentally incompetent individual means a person who has been declared mentally incompetent by a federal, state or local court of jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

(4) Institutionalized individual means an individual who is involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or an individual who is confined under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.

b. The sterilization shall be performed as the result of a voluntary request for the services made by the person on whom the sterilization is performed.

c. The person shall be advised prior to the receipt of consent that no benefits provided under the medical assistance program or other programs administered by the department may be withdrawn or withheld by reason of a decision not to be sterilized.

d. The person shall be informed that the consent can be withheld or withdrawn any time prior to the sterilization without prejudicing future care and without loss of other project or program benefits.

e. The person shall be given a complete explanation of the sterilization. The explanation shall include:

(1) A description of available alternative methods and the effect and impact of the proposed sterilization including the fact that it must be considered to be an irreversible procedure.

(2) A thorough description of the specific sterilization procedure to be performed and benefits expected.

(3) A description of the attendant discomforts and risks including the type and possible effects of any anesthetic to be used.

(4) An offer to answer any inquiries the person to be sterilized may have concerning the procedure to be performed. The individual shall be provided a copy of the informed consent form in addition to the oral presentation.

f. At least 30 days and not more than 180 days shall have elapsed following the signing of the informed consent except in the case of premature delivery or emergency abdominal surgery which occurs not less than 72 hours after the informed consent was signed. The informed consent shall have been signed at least 30 days prior to the expected delivery date for premature deliveries. Consent shall be obtained on Form XIX (PHY-3), Consent Form, and shall be attached to the claim for payment.

g. The information in paragraphs "*b*" through "*f*" shall be effectively presented to a blind, deaf, or otherwise handicapped individual and an interpreter shall be provided when the individual to be sterilized does not understand the language used on the consent form or used by the person obtaining consent. The individual to be sterilized may have a witness of the individual's choice present when consent is obtained.

h. Form XIX (PHY-3), Consent Form, shall be signed by the individual to be sterilized, the interpreter, when one was necessary, the physician, and the person who provided the required information.

i. Informed consent shall not be obtained while the individual to be sterilized is:

(1) In labor or childbirth, or

(2) Seeking to obtain or obtaining an abortion, or

(3) Under the influence of alcohol or other substance that affects the individual's state of awareness.

j. Payment will be made for a medically necessary hysterectomy only when it is performed for a purpose other than sterilization and only when one or more of the following conditions is met:

(1) The individual or representative has signed an acknowledgment that she has been informed orally and in writing from the person authorized to perform the hysterectomy that the hysterectomy will make the individual permanently incapable of reproducing, or

(2) The individual was already sterile before the hysterectomy, the physician has certified in writing that the individual was already sterile at the time of the hysterectomy and has stated the cause of the sterility, or

(3) The hysterectomy was performed as a result of a life-threatening emergency situation in which the physician determined that prior acknowledgment was not possible and the physician includes a description of the nature of the emergency.

78.1(17) Abortions. Payment for an abortion or related service is made when Form XIX (PHY-4) is completed for the applicable circumstances and is attached to each claim for services. Payment for an abortion is made under one of the following circumstances:

a. The physician certifies that the pregnant woman's life would be endangered if the fetus were carried to term.

b. The physician certifies that the fetus is physically deformed, mentally deficient or afflicted with a congenital illness and the physician states the medical indication for determining the fetal condition.

c. The pregnancy was the result of rape reported to a law enforcement agency or public or private health agency which may include a family physician within 45 days of the date of occurrence of the incident. The report shall include the name, address, and signature of the person making the report. Form XIX (PHY-4) shall be signed by the person receiving the report of the rape.

d. The pregnancy was the result of incest reported to a law enforcement agency or public or private health agency including a family physician no later than 150 days after the date of occurrence. The report shall include the name, address, and signature of the person making the report. Form XIX (PHY-4) shall be signed by the person receiving the report of incest.

78.1(18) Payment and procedure for obtaining eyeglasses, contact lenses, and visual aids, shall be the same as described in 441—78.6(249A). (Cross-reference 78.28(3))

78.1(19) 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 the IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and the published criteria established by the IFMC and the department. 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, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, 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. The "Preprocedure Surgical Review List" shall be developed by the department with advice and consultation from the IFMC and appropriate professional organizations and will list the procedures for which prior review is required and the steps that must be followed in requesting such review. The department shall update the "Preprocedure Surgical Review List" annually. (Cross-reference 78.28(1)"*e.*")

78.1(20) Transplants.

a. Payment will be made only for the following organ and tissue transplant services:

(1) Kidney, cornea, skin, and bone transplants.

(2) Allogeneic bone marrow transplants for the treatment of leukemia, aplastic anemia, severe combined immunodeficiency disease (SCID), or Wiskott-Aldrich syndrome.

(3) Autologous bone marrow transplants for treatment of the following conditions: acute leukemia in remission with a high probability of relapse when there is no matched donor; resistant non-Hodgkin's lymphomas; lymphomas presenting poor prognostic features; recurrent or refractory neuroblastoma; or advanced Hodgkin's disease when conventional therapy has failed and there is no matched donor.

(4) Liver transplants for persons with extrahepatic biliary artesia or any other form of endstage liver disease, except that coverage is not provided for persons with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Liver transplants require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1)*"f."*)

Covered liver transplants are payable only when performed in a facility which meets the requirements of 78.3(10).

(5) Heart transplants. Artificial hearts and ventricular assist devices, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplants, are not covered. Heart-lung transplants are not covered.

Heart transplants require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1)*"f."*) Covered heart transplants are payable only when performed in a facility which meets the requirements of 78.3(10).

(6) Lung transplants. Lung transplants for persons having end-stage pulmonary disease. Lung transplants require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1)*"f."*) Covered transplants are payable only when performed in a facility which meets the requirements of 78.3(10). Heart-lung transplants are not covered.

b. Donor expenses incurred directly in connection with a covered transplant are payable. Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery. Expenses of searching for a donor are not covered.

c. All transplants must be medically necessary and meet other general requirements of this chapter for physician and hospital services.

d. Payment will not be made for any transplant not specifically listed in paragraph *"a."*

78.1(21) Utilization review. Utilization review shall be conducted of Medicaid recipients who access more than 24 outpatient visits in any 12-month period from physicians, family and pediatric nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. For the purposes of utilization review, the term "physician" does not include a psychiatrist. Refer to rule 441—76.9(249A) for further information concerning the recipient lock-in program.

78.1(22) 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. Enhanced services include care coordination, health education, social services, nutrition education, and a postpartum home visit. Additional reimbursement shall be provided for obstetrical services related to a high-risk pregnancy. (See description of enhanced services at subrule 78.25(3).)

78.1(23) 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.

78.1(24) Rescinded IAB 10/8/97, effective 12/1/97.

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

441—78.2(249A) Retail pharmacies.

78.2(1) Payment will be approved for the following when ordered by a legally qualified practitioner (physician, dentist, or podiatrist, therapeutically certified optometrist, physician assistant, or advanced registered nurse practitioner):

a. Drugs and devices subject to the same conditions as specified in subrule 78.1(2).

b. Medical and sickroom supplies when ordered by a legally qualified practitioner for a specific rather than incidental use subject to the same conditions as specified in paragraph 78.1(2)*"b."*

c. Rental or purchase of medical equipment and appliances subject to the same conditions as specified in rule 78.10(249A).

d. Nonprescription drugs as specified in 78.1(2)*"f."*

78.2(2) Rescinded, effective July 1, 1987.

78.2(3) The pharmacist shall dispense the lowest cost item in stock which meets the requirements of the practitioner as shown on the prescription.

78.2(4) Prescription records are required for all drugs as specified in Iowa Code sections 155.33, 155.34, and 204.308. For the purposes of the medical assistance program, prescriptions for medical supplies are required and shall be subject to the same provisions. All prescriptions shall be available for audit by the department of human services.

78.2(5) Payment will be approved for pharmaceutical agents when ordered by a therapeutically certified optometrist, in accordance with Iowa Code chapter 154 regulating the practice of optometry.

78.2(6) Consultation. In accordance with Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990), a pharmacist shall offer to discuss with each Medicaid recipient or the caregiver of a recipient presenting a prescription, information regarding the use of the medication. The consultation is not required if the person refuses the consultation. Standards for the content of the consultation shall be found in rules of the Iowa board of pharmacy examiners.

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

441—78.3(249A) Inpatient hospital services. Payment for inpatient hospital admission is approved when it meets the criteria for inpatient hospital care as determined by the Iowa Foundation for Medical Care (IFMC). All cases are subject to random retrospective review and may be subject to a more intensive retrospective review if abuse is suspected. In addition, transfers, outliers, and readmissions within 31 days are subject to random review. Readmissions to the same facility due to premature discharge shall not be paid a new DRG. Selected admissions and procedures are subject to a 100 percent review before the services are rendered. Medicaid payment for inpatient hospital admissions and continued stays are approved when the admissions and continued stays are determined to meet the criteria for inpatient hospital care. (Cross-reference 78.28(5)) The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices. No payment will be made for waiver days.

See rule 441—78.31(249A) for policies regarding payment of hospital outpatient services.

If the recipient is eligible for inpatient or outpatient hospital care through the Medicare program, payment will be made for deductibles and coinsurance applicable in that program.

The DRG payment calculations include any special services required by the hospital, including a private room.

78.3(1) Payment for Medicaid-certified physical rehabilitation units will be approved for the day of admission but not the day of discharge or death.

78.3(2) No payment will be approved for private duty nursing.

78.3(3) Certification of inpatient hospital care shall be the same as that in effect in part A of Medicare. The hospital admittance records are sufficient for the original certification.

78.3(4) Services provided for intestinal or gastric bypass surgery for treatment of obesity requires prior approval, which must be obtained by the attending physician before surgery is performed.

78.3(5) Payment will be approved for drugs provided inpatients subject to the same provisions specified in 78.1(2)*"a"*(2) and (3). The basis of payment for drugs administered to inpatients is through the DRG reimbursement. Payment will be approved for drugs and supplies provided outpatients subject to the same provisions specified in 78.1(2). The basis of payment for drugs provided outpatients is through the APG reimbursement. Hospitals which wish to administer vaccines which are available through the vaccines for children program to Medicaid children 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.

78.3(6) Payment for nursing care provided by a hospital shall be made to those hospitals which have been certified by the department of inspections and appeals as meeting the standards for a nursing facility.

78.3(7) Payment for inpatient hospital tests for purposes of diagnosis and treatment shall be made only when the tests are specifically ordered for the diagnosis and treatment of a particular patient's condition by the attending physician or other licensed practitioner acting within the scope of practice as defined by law, who is responsible for that patient's diagnosis or treatment.

78.3(8) Rescinded IAB 2/6/91, effective 4/1/91.

78.3(9) Payment will be made for sterilizations in accordance with 78.1(16).

78.3(10) Payment will be approved for organ and tissue transplant services, as specified in subrule 78.1(20). Kidney, cornea, skin, bone, allogeneic bone marrow, autologous bone marrow, heart, liver, and lung transplants are covered as specified in subrule 78.1(20). Lung transplants are payable at Medicare-designated lung transplant centers only. Heart and liver transplants are payable when performed at facilities that meet the following criteria:

a. Recipient selection and education.

(1) *Selection.* The transplant center must have written criteria based on medical need for transplantation for final facility selection of recipients. These criteria should include an equitable, consistent and practical protocol for selection of recipients. The criteria must be at least as strict as those specified by Medicare.

(2) *Education.* The transplant center will provide a written plan for recipient education. It shall include educational plans for recipient, family and significant others during all phases of the program. These phases shall include:

Intake.

Preparation and waiting period.

Preadmission.

Hospitalization.

Discharge planning.

Follow-up.

b. Staffing and resource commitment.

(1) *Transplant surgeon.* The transplant center must have on staff a qualified transplant surgeon.

The surgeon must have received at least one year of training at a transplant center approved by the American Society of Transplant Surgeons under the direction of an experienced transplant surgeon and must have had at least two years of experience in all facets of transplant surgery specific to the surgeon's specialty. This experience must include management of recipients' presurgical and postsurgical care and actual experience as a member of a transplant team at the institution. The transplant surgeon will have an understanding of the principles of and demonstrated expertise in the use of immunosuppressive therapy.

The transplant surgeon will be certified by the American Board of Thoracic Surgery or equivalent for heart transplants and the American Board of Surgery or equivalent for liver transplants.

The transplant surgeon will be the defined leader of a stable, established transplant team that has a strong commitment to the transplant program.

(2) *Transplant team.* The transplant team will be clearly defined with leadership and corresponding responsibilities of all team members identified.

The team should consist of:

A surgeon director.

A board-certified internist or pediatrician with training and expertise in organ transplantation medicine and clinical use of immunosuppressive regimens.

The transplant center will assume responsibility for initial training and continuing education of the transplant team and ancillary personnel. The center will maintain records that demonstrate competency in achieving, maintaining and improving skills in the distinct areas of expertise of each of the team members.

(3) *Physicians.* The transplant center will have on staff or available for consultation physicians with the following areas of expertise:

Anesthesiology.
Cardiology.
Dialysis.
Gastroenterology.
Hepatology.
Immunology.
Infectious diseases.
Nephrology.
Neurology.
Pathology.
Pediatrics.
Psychiatry.
Pulmonary medicine.
Radiology.
Rehabilitation medicine.

Liaison with the recipient's permanent physician is established for the purpose of providing continuity and management of the recipient's long-term care.

(4) *Support personnel and resources.* The center must have a commitment of sufficient resources and planning for implementation and operation of the transplant program. Indicators of the commitment will include the following:

Persons with expertise in the following areas available at the transplant center:

Anesthesiology.

Blood bank services.

Cardiology.

Cardiovascular surgery.

Dialysis.

Dietary services.

Gastroenterology.

Infection control.

Laboratory services (pathology, microbiology, immunology, tissue typing, and monitoring of immunosuppressive drugs).

Legal counsel familiar with transplantation laws and regulations.

Nursing service department with staff available who have expertise in the care of transplant recipients, especially in managing immunosuppressed patients and hemodynamic support.

Respiratory therapy.

Pharmaceutical services.

Physical therapy.

Psychiatry.

Psycho-social.

The center will have active cardiovascular, medical, and surgical programs with the ability and willingness to perform diagnostic and evaluative procedures appropriate to transplants on an emergency and ongoing basis.

The center will have designated an adequate number of intensive care and general service beds to support the transplant center.

(5) *Laboratory.* Each transplant center must have direct local 24-hour per day access to histocompatibility testing facilities. These facilities must meet the Standards for Histocompatibility Testing set forth by the Committee on Quality Assurance and Standards of the American Society for Histocompatibility and Immunogenetics (ASHI). As specified by ASHI, the director of the facility shall hold a doctoral degree in biological science, or be a physician, and subsequent to graduation shall have had four years' experience in immunology, two of which were devoted to formal training in human histocompatibility testing, documented to be professionally competent by external measures such as national proficiency testing, participation in national or international workshops or publications in peer-reviewed journals. The laboratory must successfully participate in a regional or national testing program.

c. Experience and survival rates.

(1) *Experience.* Centers will be given a minimum volume requirement of 12 heart or 12 liver transplants that should be met within one year. Due to special considerations such as patient case mix or donor availability, an additional one year conditional approval may be given if the minimum volume is not met the first year.

For approval of an extrarenal organ transplant program it is highly desirable that the institution: 1. has available a complete team of surgeons, physicians, and other specialists with specific experience in transplantation of that organ, or 2. has an established approved renal transplant program at that institution and personnel with expertise in the extrarenal organ system itself.

(2) *Survival rates.* The transplant center will achieve a record of acceptable performance consistent with the performance and outcomes at other successful designated transplant centers. The center will collect and maintain recipient and graft survival and complication rates. A level of satisfactory success and safety will be demonstrated with bases for substantial probability of continued performance at an acceptable level.

To encourage a high level of performance, transplant programs must achieve and maintain a minimum one-year patient survival rate of 70 percent for heart transplants and 50 percent for liver transplants.

d. Organ procurement. The transplant center will participate in a nationwide organ procurement and typing network.

Detailed plans must exist for organ procurement yielding viable transplantable organs in reasonable numbers, meeting established legal and ethical criteria.

The transplant center must be a member of the National Organ Procurement and Transplant Network.

e. Maintenance of data, research, review and evaluation.

(1) *Maintenance of data.* The transplant center will collect and maintain data on the following:

Risk and benefit.

Morbidity and mortality.

Long-term survival.

Quality of life.

Recipient demographic information.

These data should be maintained in the computer at the transplant center monthly.

The transplant center will submit the above data to the United Network of Organ Sharing yearly.

(2) *Research.* The transplant center will have a plan for and a commitment to research.

Ongoing research regarding the transplanted organs is required.

The transplant center will have a program in graduate medical education or have a formal agreement with a teaching institution for affiliation with a graduate medical education program.

(3) *Review and evaluation.* The transplant center will have a plan for ongoing evaluation of the transplantation program.

The transplant center will have a detailed plan for review and evaluation of recipient selection, preoperative, operative, postoperative and long-term management of the recipient.

The transplant center will conduct concurrent ongoing studies to ensure high quality services are provided in the transplantation program.

The transplant center will provide information to members of the transplant team and ancillary staff regarding the findings of the quality assurance studies. This information will be utilized to provide education geared toward interventions to improve staff performance and reduce complications occurring in the transplant process.

The transplant center will maintain records of all quality assurance and peer review activities concerning the transplantation program to document identification of problems or potential problems, intervention, education and follow-up.

f. Application procedure. A Medicare-designated heart, liver, or lung transplant facility needs only to submit evidence of this designation to the Medicaid fiscal agent. The application procedure for other heart and liver facilities is as follows:

(1) An original and two copies of the application must be submitted on 8½ by 11 inch paper, signed by a person authorized to do so. The facility must be a participating hospital under Medicaid and must specify its provider number, and the name and telephone number of a contact person should there be questions regarding the application.

(2) Information and data must be clearly stated, well organized and appropriately indexed to aid in its review against the criteria specified in this rule. Each page must be numbered.

(3) To the extent possible, the application should be organized into five sections corresponding to each of the five major criteria and addressing, in order, each of the subcriteria identified.

(4) The application should be mailed to the Medicaid fiscal agent.

g. Review and approval of facilities. An organized review committee will be established to evaluate performance and survival statistics and make recommendations regarding approval as a designated transplant center based on acceptable performance standards established by the review organization and approved by the Medicaid agency.

There will be established protocol for the systematic evaluation of patient outcome including survival statistics.

Once a facility applies for approval and is approved as a heart or liver transplant facility for Medicaid purposes, it is obliged to report immediately to the department any events or changes which would affect its approved status. Specifically, a facility must report any significant decrease in its experience level or survival rates, the transplantation of patients who do not meet its patient selection criteria, the loss of key members of the transplant team, or any other major changes that could affect the performance of heart or liver transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicaid coverage of heart or liver transplants performed at the facility.

78.3(11) Payment will be approved for inpatient hospital care rendered a patient in connection with dental treatment only when the mental, physical, or emotional condition of the patient prevents the dentist from providing this necessary care in the office.

78.3(12) Payment will be approved for an assessment fee as specified in 441—paragraphs 79.1(16)*"a"* and *"r"* to determine if a medical emergency exists.

Medical emergency is defined as a sudden or unforeseen occurrence or combination of circumstances presenting a substantial risk to an individual's health unless immediate medical treatment is given.

The determination of whether a medical emergency exists will be based on the patient's medical condition including presenting symptoms and medical history prior to treatment or evaluation.

78.3(13) Payment for patients in acute hospital beds who are determined by IFMC to require the skilled nursing care level of care shall be made at the average rate of all facilities participating in the skilled nursing program with the rate being adjusted January 1 each year. This rate is effective *(a)* as of the date of notice by IFMC that the lower level of care is required or *(b)* for the days IFMC determines in an outlier review that the lower level of care was required.

78.3(14) Payment for patients in acute hospital beds who are determined by IFMC to require nursing facility level of care shall be made at the statewide average Medicaid nursing facility rate with the rate being adjusted January 1 each year. This rate is effective *(a)* as of the date of notice by IFMC that the lower level of care is required or *(b)* for the days IFMC determines in an outlier review that the lower level of care was required.

78.3(15) Payment for inpatient hospital charges associated with surgical procedures on the "Outpatient/Same Day Surgery List" produced by the Iowa Foundation for Medical Care shall be made only when attending physician has secured approval from the hospital's utilization review department prior to admittance to the hospital. Approval shall be granted when inpatient care is deemed to be medically necessary based on the condition of the patient or when the surgical procedure is not performed as a routine, primary, independent procedure. The "Outpatient/Same Day Surgery List" shall be published by the department in the provider manuals for hospitals and physicians. The "Outpatient/Same Day Surgery List" shall be developed by the Iowa Foundation for Medical Care, and shall include procedures which can safely and effectively be performed in a doctor's office or on an outpatient basis in a hospital. The Iowa Foundation for Medical Care may add, delete or modify entries on the "Outpatient/Same Day Surgery List."

78.3(16) Payment will be made for medically necessary skilled nursing care when provided by a hospital participating in the swing bed program certified by the department of inspections and appeals and approved by the U.S. Department of Health and Human Services. Payment shall be at the average rate per patient day paid during the previous calendar year for routine skilled nursing services furnished by Iowa facilities participating in the Medicaid skilled payment program.

78.3(17) Rescinded IAB 8/9/89, effective 10/1/89.

78.3(18) Preprocedure review by the IFMC is required if hospitals are to be reimbursed for certain frequently performed surgical procedures as set forth under subrule 78.1(19). Criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices. (Cross-reference 78.28(5))

78.3(19) Rescinded IAB 10/8/97, effective 12/1/97.

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

441—78.4(249A) Dentists. Payment will be made for medical and surgical services furnished by a dentist to the extent these services may be performed under state law either by doctors of medicine, osteopathy, dental surgery or dental medicine and would be covered if furnished by doctors of medicine or osteopathy. Payment will also be made for the following dental procedures:

78.4(1) *Preventive services.* Payment shall be made for the following preventive services:

a. Oral prophylaxis, including necessary scaling and polishing, is payable only once in a six-month period except for persons who, because of physical or mental disability, need more frequent care. Documentation supporting the need for oral prophylaxis performed more than once in a six-month period must accompany the claim.

b. Topical application of fluoride is payable once in a six-month period and only when preceded by an oral prophylaxis. (This does not include the use of fluoride prophylaxis paste as fluoride treatment.)

c. Pit and fissure sealants are payable for placement on first and second permanent molars only. Reimbursement for sealants is restricted to work performed on children through 15 years of age for first and second permanent molars. Payment will be approved for only one application per tooth in a child's lifetime.

78.4(2) *Diagnostic services.* Payment shall be made for the following diagnostic services:

a. An initial oral examination is payable once per patient per dentist.

b. A periodic oral examination is payable once in a six-month period.

c. A complete mouth radiograph survey consisting of a minimum of 14 periapical films and bitewing films is a payable service once in a five-year period, except when medically necessary to evaluate development, and to detect anomalies, injuries and diseases. Complete mouth radiograph surveys are not payable under the age of six. A panographic-type radiography with bitewings is considered the same as a complete mouth radiograph survey.

d. Supplemental bitewing films are payable only once in a 12-month period.

e. Single periapical films are payable when necessary.

f. Intraoral radiograph, occlusal.

g. Extraoral radiograph.

h. Posteroanterior and lateral skull and facial bone radiograph, survey film.

i. Temporomandibular joint radiograph.

j. Cephalometric film.

k. Diagnostic casts are payable only for orthodontic cases or when requested by the fiscal agent's dental consultant.

78.4(3) *Restorative services.* Payment shall be made for the following restorative services:

a. Treatment of dental caries is payable in those areas which require immediate attention. Restoration of incipient or nonactive carious lesions are not payable. Carious activity may be considered incipient when there is no penetration of the dento-enamel junction as demonstrated in diagnostic radiographs.

b. Amalgam alloy, silicate, acrylic or composite resin-type filling materials are payable benefits of the program.

c. Composite resin- or plastic-type fillings on posterior teeth are payable benefits only as Class V restorations, i.e., facial (buccal) surfaces and, as Class I restorations, i.e., occlusal surfaces. Class I restorations are reimbursable only once in a two-year period.

d. Two crowns utilizing nonprecious materials, other than stainless steel, are payable per patient in a 12-month period. Two gold crowns are payable in a 12-month period when patients are allergic to all other restoration material. Stainless steel crowns may be payable when a more conservative procedure would not be serviceable.

e. Cast post and core, steel post and composite or amalgam in addition to a crown is payable when a tooth is functional and the integrity of the tooth would be jeopardized by no post support.

f. Payment as indicated will be made for the following restorative procedures:

(1) Amalgam or acrylic buildups are considered part of the preparation for the completed restoration.

(2) One, two, or more restorations on one surface of a tooth shall be paid as a one-surface restoration, i.e., mesial occlusal pit and distal occlusal pit of a maxillary molar or mesial and distal occlusal pits of a lower bicuspid.

(3) Occlusal lingual groove of a maxillary molar that extends from the distal occlusal pit and down the distolingual groove will be paid as a two-surface restoration. This restoration and a mesial occlusal pit restoration on the same tooth will be paid as one, two-surface restoration.

(4) Class III restorations will be payable as a one-surface restoration.

(5) A two-surface anterior composite restoration will be payable as a one-surface restoration if it involved the lingual surface.

(6) Tooth preparation, temporary restorations, cement bases, pulp capping, impressions, local anesthesia and inhaled anesthesia are included in the restorative fee and may not be billed separately.

(7) Pin retention will be paid on a per-tooth basis and in addition to the final restoration.

(8) More than four surfaces on an amalgam restoration will be reimbursed as a "four-surface" amalgam.

(9) An amalgam restoration is not payable following a sedative filling in the same tooth unless the sedative filling was placed more than 30 days previously.

78.4(4) *Periodontal services.* Payment may be made for the following periodontal services:

a. Periodontal scaling performed in the presence of gingival inflammation (gross debridement) is payable once every 24 months.

b. Periodontal scaling and root planing is payable once in a 24-month period and when prior approval has been received. A request for approval must be accompanied by a plan for treatment, a completed copy of a periodontic probe chart which exhibits pocket depths, history and radiograph(s). Payment for periodontal scaling and root planing will be approved when interproximal and subgingival calculus is evident in X-rays or when justified and documented that curettage, scaling or root planing is required in addition to routine prophylaxis. (Cross-reference 78.28(2)*"c"*(1))

c. Periodontal surgical procedures which include gingivoplasty, osseous surgery, osseous allograft, pedicle soft tissue graft, and free soft tissue graft are payable services when prior approval has been received. A request for approval must be accompanied by a plan for treatment, a completed copy of a periodontal probe chart which exhibits pocket depths, history and radiograph(s). Payment for these surgical procedures will be approved after periodontal scaling and root planing have been provided, a reevaluation examination has been completed, and the patient has demonstrated reasonable oral hygiene, unless the patient is unable to demonstrate reasonable oral hygiene because of physical or mental disability or in cases which demonstrate gingival hyperplasia resulting from drug therapy. (Cross-reference 78.28(2)*"c"*(2))

d. Periodontal maintenance therapy which includes oral prophylaxis, measurement of pocket depths and limited root planing and scaling is a payable service when prior approval has been received. A request for approval must be accompanied by a periodontal treatment plan, a completed copy of a periodontal probe chart which exhibits pocket depths, periodontal history and radiograph(s). Payment for periodontal maintenance therapy may be approved after periodontal scaling and root planing or periodontal surgical procedures have been provided. Periodontal maintenance therapy may be approved once per three-month interval for moderate to advanced cases if the condition would deteriorate without treatment. (Cross-reference 78.28(2)*"a"*(3))

e. Payment as indicated will be made for the following periodontal services:

(1) Periodontal scaling and root planing, gingivoplasty, osseous surgery will be paid per quadrant.

(2) Gingivoplasty will be paid per tooth.

(3) Osseous allograft will be paid as a single site if one site is involved, or if more than one site is involved, payment will be made for multiple sites.

78.4(5) *Endodontic services.* Payment shall be made for the following endodontic services:

a. Root canal treatments on permanent anterior and posterior teeth when extensive posttreatment restorative procedures are not necessary and when missing teeth do not jeopardize the integrity or function of the dental arches.

b. Vital pulpotomies. Cement bases, pulp capping, and insulating liners are considered part of the restoration and may not be billed separately.

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

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

(2) Correction of problems resulting from conventional treatment including gross underfilling, perforations, and canal blockages with restorative materials. (Cross-reference 78.28(2)*"d"*)

78.4(6) *Oral surgery—medically necessary.* Payment shall be made for medically necessary oral surgery services furnished by dentists to the extent that these services may be performed under state law either by doctors of medicine, osteopathy, dental surgery or dental medicine and would be covered if furnished by doctors of medicine or osteopathy, as defined in rule 441—78.1(249A). These services will be reimbursed in a manner consistent with the physician's reimbursement policy. The following surgical procedures are also payable when performed by a dentist:

a. Extractions, both surgical and nonsurgical.

b. Impaction (soft tissue impaction, upper or lower) that requires an incision of overlying soft tissue and the removal of the tooth.

c. Impaction (partial bony impaction, upper or lower) that requires incision of overlying soft tissue, elevation of a flap, removal of bone and removal of the tooth.

d. Impaction (complete bony impaction, upper or lower) that requires incision of overlying soft tissue, elevation of a flap, removal of bone and section of the tooth for removal.

e. Root recovery (surgical removal of residual root).

f. Oral antral fistula closure (or antral root recovery).

g. Surgical exposure of impacted or unerupted tooth for orthodontic reasons, including ligation when indicated.

h. Surgical exposure of impacted or unerupted tooth to aid eruption.

i. General anesthesia and intravenous sedation are payable services when the extensiveness of the procedure indicates it or there is a concomitant disease or impairment which warrants its use.

j. Routine postoperative care is considered part of the fee for surgical procedures and may not be billed separately.

k. Payment may be made for postoperative care where need is shown to be beyond normal follow-up care or for postoperative care where the original service was performed by another dentist.

78.4(7) *Prosthetic services.* Payment may be made for the following prosthetic services:

a. An immediate denture and a first-time complete denture including six months' postdelivery care. An immediate denture and a first-time complete denture are payable when the denture is provided to establish masticatory function. An immediate denture or a first-time complete denture is payable only once following the removal of teeth it replaces. A complete denture is payable only once in a five-year period except when the denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure and is required to prevent significant dental problems.

b. A removable partial denture replacing anterior teeth, including six months' postdelivery care. A removable partial denture replacing anterior teeth is only payable once in a five-year period unless the removable partial denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure and is required to prevent significant dental problems.

c. A removable partial denture replacing posterior teeth including six months' postdelivery care when prior approval has been received. A removable partial denture replacing posterior teeth shall be approved when the recipient has fewer than eight posterior teeth in occlusion or the recipient has a full denture in one arch, and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one removable partial denture brings eight posterior teeth in occlusion, no additional removable partial denture will be approved. A removable partial denture replacing posterior teeth is payable only once in a five-year period unless the removable partial denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure and is required to prevent significant dental problems. (Cross-reference 78.28(2)*"c"*(1))

d. A fixed partial denture (including an acid etch fixed partial denture) replacing anterior teeth when prior approval has been received. A fixed partial denture (including an acid etch fixed partial denture) replacing anterior teeth shall be approved for recipients whose medical condition precludes the use of a removable partial denture. High noble or noble metals shall be approved only when the recipient is allergic to all other restorative materials. A fixed partial denture replacing anterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.28(2)*"c"*(2))

e. A fixed partial denture (including an acid etch fixed partial denture) replacing posterior teeth when prior approval has been received. A fixed partial denture (including an acid etch fixed partial denture) replacing posterior teeth shall be approved for the recipient whose medical condition precludes the use of a removable partial denture and who has fewer than eight posterior teeth in occlusion or if the recipient has a full denture in one arch and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one fixed partial denture brings eight posterior teeth in occlusion, no additional fixed partial denture will be approved. High noble or noble metals will be approved only when the recipient is allergic to all other restorative materials. A fixed partial denture replacing posterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.28(2)*"c"*(3))

f. Obturator for surgically excised palatal tissue or deficient velopharyngeal function of cleft palate patients.

g. Chairside relines are payable only once per prosthesis every 12 months.

h. Laboratory processed relines are payable only once per prosthesis every 12 months.

i. Tissue conditioning is a payable service twice per prosthesis in a 12-month period.

j. Two repairs per prosthesis in a 12-month period are payable.

k. Adjustments to a complete or removable partial denture are payable when medically necessary after six months' postdelivery care.

78.4(8) *Orthodontic procedures.* Payment may be made for the following orthodontic procedures:

a. When prior approval has been given for orthodontic services to treat the most handicapping malocclusions in a manner consistent with "Handicapping Malocclusion Assessment to Establish Treatment Priority," by J.A. Salzmann, D.D.S., American Journal of Orthodontics, October 1968.

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

A request to perform an orthodontic procedure must be accompanied by an interpreted cephalometric radiograph and study models trimmed so that the models simulate centric occlusion of the patient. A written plan of treatment must accompany the diagnostic aids. Posttreatment records must be furnished upon request of the fiscal agent.

Approval may be made for eight units of a three-month active treatment period. Additional units may be approved by the fiscal agent's orthodontic consultant if found to be medically necessary. (Cross-reference 78.28(2)*"d"*)

b. Space management services shall be payable when there is too little dental ridge to accommodate either the number or the size of teeth and if not corrected significant dental disease will result.

c. Tooth guidance for a limited number of teeth or interceptive orthodontics is a payable service when the total cost of treatment does not exceed $125. Pretreatment records are not required.

78.4(9) *Treatment in a hospital.* Payment will be approved for dental treatment rendered a hospitalized patient only when the mental, physical, or emotional condition of the patient prevents the dentist from providing necessary care in the office.

78.4(10) *Treatment in a nursing facility.* Payment will be approved for dental treatment provided in a nursing facility. When more than one patient is examined during the same nursing home visit, payment will be made by the Medicaid program for only one visit to the nursing home.

78.4(11) *Office visit.* Payment will be approved for an office visit for care of injuries or abnormal conditions of the teeth or supporting structure when treatment procedures or exams are not billed for that visit.

78.4(12) *Office calls after hours.* Payment will be approved for office calls after office hours in emergency situations. The office call will be paid in addition to treatment procedures.

78.4(13) *Drugs.* Payment will be made for drugs dispensed by a dentist only if there is no licensed retail pharmacy in the community where the dentist's office is located. If eligible to dispense drugs, the dentist should request a copy of the Prescribed Drugs Manual from the fiscal agent. Payment will not be made for writing prescriptions.

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

441—78.5(249A) Podiatrists. Payment will be approved only for certain podiatric services.

78.5(1) Payment will be approved for the following orthotic appliances and treatment of nail pathologies:

a. Durable plantar foot orthotic.

b. Plaster impressions for foot orthotic.

c. Molded digital orthotic.

d. Shoe padding when appliances are not practical.

e. Custom molded space shoes for rheumatoid arthritis, congenital defects and deformities, neurotropic, diabetic and ischemic intractable ulcerations and deformities due to injuries.

f. Rams horn (hypertrophic) nails.

g. Onychomycosis (mycotic) nails.

78.5(2) Payment will be made for the same scope of podiatric services available through Part B of Title XVIII (Medicare) except as listed below:

a. Treatment of flatfoot. The term "flatfoot" is defined as a condition in which one or more arches have flattened out.

b. Treatment of subluxations of the foot are defined as partial dislocations or displacements of joint surfaces, tendons, ligaments, or muscles of the foot. Surgical or nonsurgical treatments undertaken for the sole purpose of correcting a subluxated structure in the foot as an isolated entity are not covered.

Reasonable and necessary diagnosis of symptomatic conditions that result from or are associated with partial displacement of foot structures is a covered service. Surgical correction in the subluxated foot structure that is an integral part of the treatment of a foot injury or is undertaken to improve the function of the foot or to alleviate an induced or associated symptomatic condition is a covered service.

c. Routine foot care. Routine foot care includes the cutting or removal of corns or callouses, the trimming of nails and other hygienic and preventive maintenance care in the realm of self-care such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of both ambulatory and bedfast patients and any services performed in the absence of localized illness, injury, or symptoms involving the foot.

d. Orthopedic shoes. Payment will not be made for orthopedic shoes or for any device to be worn in or attached to orthopedic shoes or other types of shoes when provided by the podiatrist. Payment will be made to the podiatrist for the examination including tests to establish the need for orthopedic shoes.

78.5(3) Prescriptions are required for drugs and supplies as specified in rule 78.1(2)*"c."* Payment shall be made for drugs dispensed by a podiatrist only if there is no licensed retail pharmacy in the community where the podiatrist's office is located. If eligible to dispense drugs, the podiatrist should request a copy of the Prescribed Drugs Manual from the fiscal agent. Payment will not be made for writing prescriptions.

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

441—78.6(249A) Optometrists. Payment will be approved for medically necessary services and supplies provided by the optometrist within the scope of practice of optometry and the limitations of state law, subject to the following limitations and exclusions. Covered optometric services include a professional component and materials. The specific codes to be used in billing for covered services are described in the Optometric Services Manual.

78.6(1) *Payable professional services are:*

a. Eye examinations. The coverage of eye examinations depends on the purpose of the examination. Services are covered if the exam is the result of a complaint or symptom of an eye disease or injury. Routine eye examinations are covered once in a 12-month period. These services are rendered in the optometrist's office or clinic, the home, a skilled nursing facility, an intermediate care facility, or other appropriate setting. Payment for mileage shall be subject to the same approval and payment criteria as those in effect for Medicare Part B. The following levels of service are recognized for optometric examinations:

(1) Intermediate examination. A level of optometric or ophthalmological services pertaining to medical examination and evaluation, with initiation or continuation of a diagnostic and treatment program.

(2) Comprehensive examination. A level of optometric or ophthalmological services pertaining to medical examination and evaluation, with initiation or continuation of a diagnostic and treatment program, and a general evaluation of the complete visual system.

b. Medical services. Payment will be approved for medically necessary services and supplies within the scope of practice of the optometrist, including services rendered in the optometrist's office or clinic, the home, a skilled nursing facility, an intermediate care facility or other appropriate setting. Payment for mileage shall be subject to the same approval and payment criteria as those in effect for Medicare Part B.

c. Auxiliary procedures. The following auxiliary procedures and special tests are payable when performed by an optometrist. Auxiliary procedures and special tests are reimbursed as a separate procedure only when warranted by case history or diagnosis.

(1) Serial tonometry. Single tonometry is part of the intermediate and comprehensive exams and is not payable as a separate procedure as is serial tonometry.

(2) Gonioscopy.

(3) Extended ophthalmoscopy. Routine ophthalmoscopy is part of the intermediate and comprehensive examination and is not payable as a separate procedure. Generally, extended ophthalmoscopy is considered to be part of the comprehensive examination and, if performed in conjunction with that level of service, is not payable as a separate procedure.

(4) Visual fields. Gross visual field testing is part of general optometric services and is not reported separately.

(5) External photography.

(6) Fundus photography.

(7) Retinal integrity evaluation.

d. Single vision lens service, verification and subsequent service. When lenses are necessary, the following enumerated professional and technical optometric services are to be provided:

(1) Ordering of corrective lenses.

(2) Verification of lenses after fabrication.

(3) Adjustment and alignment of completed lens order.

e. Multifocal lens service.

(1) Ordering of corrective lenses.

(2) Verification of lenses after fabrication.

(3) Adjustment and alignment of completed lens order.

f. Frame service. When a new frame is necessary, the following enumerated professional and technical optometric services are to be provided:

(1) Selection and styling.

(2) Sizing and measurements.

(3) Fitting and adjustment.

(4) Readjustment and servicing.

g. Frame service when only lenses are provided.

h. Repairs. The service fee shall not exceed the dispensing fee for a replacement frame.

i. Fitting of contact lenses when required following cataract surgery or documented keratoconus or for treatment of acute or chronic eye disease.

78.6(2) *Ophthalmic materials.* Ophthalmic materials which are provided in connection with any of the foregoing professional optometric services shall provide adequate vision as determined by the optometrist and meet the following standards:

a. Corrected curve lenses, unless clinically contraindicated, manufactured by reputable American manufacturers.

b. Standard plastic, plastic and metal combination, or metal frames manufactured by reputable American manufacturers, if available.

c. Prescription standards according to the American National Standards Institute (ANSI) standards and tolerance.

78.6(3) *Reimbursement.* The reimbursement for allowed ophthalmic material is subject to a fee schedule established by the department or to actual laboratory cost as evidenced by an attached invoice. All fees shall be reviewed annually by the department.

a. Materials payable by fee schedule are:

(1) Lenses, single vision and multifocal.

(2) Frames.

(3) Case for glasses.

b. Materials payable at actual laboratory cost as evidenced by an attached invoice are:

(1) Contact lenses.

(2) Schroeder shield.

(3) Ptosis crutch.

(4) Protective lenses for a person with only one eye even if a corrective lens is not required.

(5) Subnormal visual aids.

78.6(4) *Prior authorization.* Prior authorization is required for the following:

a. A second lens correction within a 24-month period. Approval shall be given when the recipient's vision has at least a five-tenths diopter of change in sphere or cylinder or ten degree change in axis in either eye. (Cross-reference 78.28(3))

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

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

78.6(5) *Noncovered services.* Noncovered services include, but are not limited to, the following services:

a. Glasses with cosmetic gradient tint lenses or other eyewear for cosmetic purposes.

b. Glasses for protective purposes including glasses for eye safety, sunglasses, or glasses with photogray lenses. An exception to this is in 78.6(3)*"b"*(4).

c. A second pair of glasses or spare glasses.

d. Cosmetic surgery and experimental medical and surgical procedures.

e. Contact lenses if vision is correctable with noncontact lenses.

78.6(6) *Therapeutically certified optometrists.* Therapeutically certified optometrists may provide services and employ pharmaceutical agents in accordance with Iowa Code chapter 154 regulating the practice of optometry. A therapeutically certified optometrist is an optometrist who is licensed to practice optometry in this state and who is certified by the board of optometry examiners to employ the agents and perform the procedures provided by the Iowa Code.

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

441—78.7(249A) Opticians. Payment will be approved only for certain services and supplies provided by opticians.

78.7(1) Payment will be made for the following services when prescribed by a physician (MD or DO) or an optometrist (OD):

a. A dispensing fee only when the recipient is provided with a new pair of glasses.

b. Dispensing of contact lenses when required following cataract surgery or documented keratoconus. Payment for contact lenses shall be the actual laboratory cost as evidenced by an attached invoice.

c. Preparation and fitting of artificial eye.

d. Ophthalmic materials which are provided according to the prescription provided by a professional physician or optometrist shall meet the following standards:

(1) Corrected curve lenses, unless clinically contraindicated, manufactured by reputable American manufacturers.

(2) Standard plastic, plastic metal combination, or metal frames manufactured by reputable American manufacturers.

(3) Prescription standards according to the American Optometric Association standards and tolerances.

e. Payment for single vision lenses shall be $15.05 per pair, bifocal vision lenses shall be $26.19 per pair, trifocal vision lenses shall be $32.88 per pair, and aphakia lenses shall be $52.38 per pair. Payment for lenses with a correction of plus or minus six diopters or more shall be an additional $8.92 per pair. One lens shall be one-half the per pair price. All fees shall be reviewed annually.

f. Payment for a total frame shall be at cost not to exceed $13.37 and payment for replacement parts for frames shall be at cost not to exceed $8.92.

g. Repairs or replacement of frames, lenses or component parts. Payment will be approved for service in addition to materials. Payment will be approved for replacement of glasses when the original glasses have been lost or damaged beyond repair. When the glasses no longer adequately correct the recipient's vision, payment will be approved for lenses only. Lens fee shall be the same as 78.7(1)*"e."* Service fees shall not exceed the dispensing fee.

h. Schroeder shield.

i. Ptosis crutch.

j. Case for glasses not to exceed $1.06.

78.7(2) When prior approval is obtained from the fiscal agent by the physician or optometrist, payment for the following services shall be made:

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

b. A second lens correction within a 24-month period. Approval shall be given when the recipient's vision has at least a five-tenths diopter of change in sphere or cylinder or ten degree change in axis in either eye.

78.7(3) Noncovered services include but are not limited to the following services:

a. Glasses with cosmetic gradient tint lenses or other eyewear for cosmetic purposes.

b. Glasses for protective purposes including glasses for eye safety, sunglasses, or glasses with photogray lenses.

c. Any service related to a noncovered service.

d. A second pair of glasses or spare glasses.

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

441—78.8(249A) Chiropractors. Payment will be made for the same chiropractic procedures payable under Title XVIII of the Social Security Act (Medicare).

78.8(1) *Covered services.* Chiropractic manipulative therapy (CMT) eligible for reimbursement is specifically limited by Medicaid to the manual manipulation (i.e., by use of the hands) of the spine for the purpose of correcting a subluxation demonstrated by X-ray. Subluxation means an incomplete dislocation, off-centering, misalignment, fixation, or abnormal spacing of the vertebrae.

78.8(2) *Indications and limitations of coverage.*

a. The subluxation must have resulted in a neuromusculoskeletal condition set forth in the table below for which CMT is appropriate treatment. The symptoms must be directly related to the subluxation that has been diagnosed. The mere statement or diagnosis of "pain" is not sufficient to support the medical necessity of CMT. CMT must have a direct therapeutic relationship to the patient's condition. No other diagnostic or therapeutic service furnished by a chiropractor is covered under the Medicaid program.

ICD-9	CATEGORY I	ICD-9	CATEGORY II	ICD-9	CATEGORY III
307.81	Tension headache	353.0	Brachial plexus lesions	721.7	Traumatic spondylopathy
721.0	Cervical spondylosis without myelopathy	353.1	Lumbosacral plexus lesions	722.0	Displacement of cervical intervertebral disc without myelopathy
721.2	Thoracic spondylosis without myelopathy	353.2	Cervical root lesions, NEC	722.10	Displacement of lumbar intervertebral disc without myelopathy
721.3	Lumbosacral spondylosis without myelopathy	353.3	Thoracic root lesions, NEC	722.11	Displacement of thoracic intervertebral disc without myelopathy
723.1	Cervicalgia	353.4	Lumbosacral root lesions, NEC	722.4	Degeneration of cervical intervertebral disc
724.1	Pain in thoracic spine	353.8	Other nerve root and plexus disorders	722.51	Degeneration of thoracic or thoracolumbar intervertebral disc
724.2	Lumbago	719.48	Pain in joint (other specified sites, must specify site)	722.52	Degeneration of lumbar or lumbosacral intervertebral disc
724.5	Backache, unspecified	720.1	Spinal enthesopathy	722.81	Post laminectomy syndrome, cervical region

ICD-9	CATEGORY I	ICD-9	CATEGORY II	ICD-9	CATEGORY III
784.0	Headache	722.91	Calcification of intervertebral cartilage or disc, cervical region	722.82	Post laminectomy syndrome, thoracic region
		722.92	Calcification of intervertebral cartilage or disc, thoracic region	722.83	Post laminectomy syndrome, lumbar region
		722.93	Calcification of intervertebral cartilage or disc, lumbar region	724.3	Sciatica
		723.0	Spinal stenosis in cervical region		
		723.2	Cervicocranial syndrome		
		723.3	Cervicobrachial syndrome		
		723.4	Brachial neuritis or radiculitis, NOC		
		723.5	Torticollis, unspecified		
		724.01	Spinal stenosis, thoracic region		
		724.02	Spinal stenosis, lumbar region		
		724.4	Thoracic or lumbosacral neuritis or radiculitis		
		724.6	Disorders of sacrum, ankylosis		
		724.79	Disorders of coccyx, coccygodynia		
		724.8	Other symptoms referable to back, facet syndrome		
		729.1	Myalgia and myositis, unspecified		
		729.4	Fascitis, unspecified		
		738.40	Acquired spondylolisthesis		
		756.12	Spondylolisthesis		

ICD-9 CATEGORY I	ICD-9 CATEGORY II	ICD-9 CATEGORY III
	846.0 Sprains and strains of sacroiliac region, lumbosacral (joint; ligament)	
	846.1 Sprains and strains of sacroiliac region, sacroiliac ligament	
	846.2 Sprains and strains of sacroiliac region, sacrospinatus (ligament)	
	846.3 Sprains and strains of sacroiliac region, sacrotuberous (ligament)	
	846.8 Sprains and strains of sacroiliac region, other specified sites of sacroiliac region	
	847.0 Sprains and strains, neck	
	847.1 Sprains and strains, thoracic	
	847.2 Sprains and strains, lumbar	
	847.3 Sprains and strains, sacrum	
	847.4 Sprains and strains, coccyx	

b. The neuromusculoskeletal conditions listed in the table in paragraph *"a"* generally require short-, moderate-, or long-term CMT. A diagnosis or combination of diagnoses within Category I generally requires short-term CMT of 12 per 12-month period. A diagnosis or combination of diagnoses within Category II generally requires moderate-term CMT of 18 per 12-month period. A diagnosis or combination of diagnoses within Category III generally requires long-term CMT of 24 per 12-month period. For diagnostic combinations between categories, 28 CMTs are generally required per 12-month period. If the CMT utilization guidelines are exceeded, documentation supporting the medical necessity of additional CMT must be submitted with the Medicaid claim form or the claim will be denied for failure to provide information.

c. CMT is not a covered benefit when:

(1) The maximum therapeutic benefit has been achieved for a given condition.

(2) There is not a reasonable expectation that the continuation of CMT would result in improvement of the patient's condition.

(3) The CMT seeks to prevent disease, promote health and prolong and enhance the quality of life.

78.8(3) *Documenting X-ray.* An X-ray must document the primary regions of subluxation being treated by CMT.

The documenting X-ray must be taken at a time reasonably proximate to the initiation of CMT. An X-ray is considered to be reasonably proximate if it was taken no more than 12 months prior to or 3 months following the initiation of CMT. X-rays need not be repeated unless there is a new condition. No X-ray is required for pregnant women and for children aged 18 and under.

The X-ray films shall be labeled with the patient's name and date the X-rays were taken and shall be marked right or left. The X-ray shall be made available to the department or its duly authorized representative when requested. A written and dated X-ray report, including interpretation and diagnosis, shall be present in the patient's clinical record.

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

441—78.9(249A) Home health agencies. Payment shall be approved for medically necessary home health agency services prescribed by a physician in a plan of home health care provided by a Medicare-certified home health agency which has provided the surety bond required in rule 441—77.9(249A) for the home health agency's fiscal year.

The number of hours of home health agency services shall be reasonable and appropriate to meet an established medical need of the recipient that cannot be met by a family member, significant other, friend, or neighbor. Services must be medically necessary in the individual case and be related to a diagnosed medical impairment or disability.

The recipient need not be homebound to be eligible for home health agency services; however, the services provided by a home health agency shall only be covered when provided in the recipient's residence with the following exception. Private duty nursing and personal care services for persons aged 20 and under as described at 78.9(10)*"a"* may be provided in settings other than the recipient's residence when medically necessary.

Medicaid recipients of home health agency services need not first require skilled nursing care to be entitled to home health aide services.

Further limitations related to specific components of home health agency services are noted in subrules 78.9(3) to 78.9(10).

Payment shall be made on an encounter basis. An encounter is defined as separately identifiable hours in which home health agency staff provide continuous service to a recipient.

Payment for supplies shall be approved when the supplies are incidental to the patient's care, e.g., syringes for injections, and do not exceed $15 per month. Dressings, durable medical equipment, and other supplies shall be obtained from a durable medical equipment dealer or pharmacy. Payment of supplies may be made to home health agencies when a durable medical equipment dealer or pharmacy is not available in the recipient's community.

Payment may be made for restorative and maintenance home health agency services.

Payment may be made for teaching, training, and counseling in the provision of health care services.

Treatment plans for these services shall additionally reflect: to whom the services are to be provided (patient, family member, etc.); prior teaching training, or counseling provided; medical necessity for the rendered service; identification of specific services and goals; date of onset of the teaching, training, or counseling; frequency of services; progress of recipient in response to treatment; and estimated length of time these services will be needed.

The following are not covered: services provided in the home health agency office, homemaker services, well child care and supervision, and medical equipment rental or purchase.

Services shall be authorized by a physician, evidenced by the physician's signature and date on a plan of treatment.

78.9(1) *Treatment plan.* A plan of treatment shall be completed prior to the start of care and at a minimum reviewed every 62 days thereafter. The plan of care shall support the medical necessity and intensity of services to be provided by reflecting the following information:

a. Place of service.
b. Type of service to be rendered and the treatment modalities being used.
c. Frequency of the services.
d. Assistance devices to be used.
e. Date home health services were initiated.
f. Progress of recipient in response to treatment.
g. Medical supplies to be furnished.
h. Recipient's medical condition as reflected by the following information, if applicable:
(1) Dates of prior hospitalization.
(2) Dates of prior surgery.
(3) Date last seen by a physician.
(4) Diagnoses and dates of onset of diagnoses for which treatment is being rendered.
(5) Prognosis.
(6) Functional limitations.
(7) Vital signs reading.
(8) Date of last episode of instability.
(9) Date of last episode of acute recurrence of illness or symptoms.
(10) Medications.
i. Discipline of the person providing the service.
j. Certification period (no more than 62 days).
k. Estimated date of discharge from the hospital or home health agency services, if applicable.
l. Physician's signature and date. The date of the signature shall be within the certification period.

78.9(2) *Supervisory visits.* Payment shall be made for supervisory visits two times a month when a registered nurse acting in a supervisory capacity provides supervisory visits of services provided by a home health aide under a home health agency plan of treatment or when services are provided by an in-home health care provider under the department's in-home health-related care program as set forth in 441—Chapter 177.

78.9(3) *Skilled nursing services.* Skilled nursing services are services that when performed by a home health agency require a licensed registered nurse or licensed practical nurse to perform. Situations when a service can be safely performed by the recipient or other nonskilled person who has received the proper training or instruction or when there is no one else to perform the service are not considered a "skilled nursing service." Skilled nursing services shall be available only on an intermittent basis. Intermittent services for skilled nursing services shall be defined as a medically predictable recurring need requiring a skilled nursing service at least once every 60 days, with an attempt to have a predictable end. Daily visits that are reasonable and necessary and show an attempt to have a predictable end shall be covered for up to three weeks. Coverage of additional daily visits beyond the initial anticipated time frame may be appropriate for a short period of time, based on the medical necessity of service. Medical documentation shall be submitted justifying the need for continued visits, including the physician's estimate of the length of time that additional visits will be necessary. Daily skilled nursing visits which are ordered for an indefinite period of time and designated as daily skilled nursing care do not meet the intermittent definition and shall be denied.