

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, weight gain, or weight loss (except for lipase inhibitor drugs for weight loss, with prior authorization as provided in subparagraph (3) below); drugs used for cosmetic purposes or hair growth; drugs used to promote smoking cessation; otherwise covered outpatient drugs if the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or the 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 that 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.

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

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

The fiscal agent shall consider other conditions on an individual basis after review of documentation submitted regarding the need for psychostimulants. Psychostimulants include the following medications: dextroamphetamine, amphetamine mixtures, methamphetamine, methylphenidate, pemoline (Cylert), and modafinil (Provigil). (Cross-reference 78.28(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 single-source histamine H2-receptor antagonists at all dose levels. Single source is defined as the brand-name drug or the innovator of a multiple-source drug. Payment for the single-source histamine H2-receptor antagonist will be authorized only for cases in which there is documentation of a previous trial and therapy failure with at least one multiple-source histamine H2-receptor antagonist.

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

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

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

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

1. Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).
2. Barrett's esophagus.
3. Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses as defined by the histamine H2-receptor antagonist prior authorization guidelines.
4. Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of *Helicobacter pylori* treatment or a negative *Helicobacter pylori* test result.

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

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

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

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

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

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

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

Prior authorization is not required for misoprostol when prescribed concurrently with a nonsteroidal anti-inflammatory drug. Prior authorization is required for any other therapy with misoprostol beyond 90 days. Justification for other therapy will be considered on an individual patient basis. Misoprostol prescribed concurrently with histamine H2-receptor antagonists, sucralfate, or proton pump inhibitors will be considered duplication of therapy. Payment for duplication of therapy will be considered on an individual patient basis after review of submitted documentation of medical necessity. (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 single-source antihistamines including single active ingredient and combination products. Prior authorization is not required for multiple-source antihistamines. Single source is defined as the brand-name drug or the innovator of a multiple-source drug. Patients 21 years of age and older must have received two unsuccessful trials with other covered multiple-source antihistamines unless evidence is provided that the use of these agents would be medically contraindicated, prior to the utilization of single-source antihistamines. Patients 20 years of age and younger must have one unsuccessful trial with another covered multiple-source antihistamine unless evidence is provided that the use of these agents would be medically contraindicated, prior to the utilization of single-source antihistamines. (Cross-reference 78.28(1)“d”(7))

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 erythropoietin prescribed for outpatients for the treatment of anemia. Patients who meet all of the following criteria may receive prior authorization for the use of erythropoietin:

1. Hematocrit less than 30 percent. If renewal of prior authorization is being requested, hematocrit over 36 percent will require dosage reduction or discontinuation. The fiscal agent may consider continuing therapy for higher hematocrit values on an individual basis after review of the evidence provided regarding need for continued therapy. Hematocrit laboratory values must be dated within six weeks of the prior authorization request.
2. Transferrin saturation greater than or equal to 20 percent (transferrin saturation is calculated by dividing serum iron by the total iron binding capacity), ferritin levels greater than or equal to 100 mg/ml, or on concurrent therapeutic iron therapy. Transferrin saturation or ferritin levels must be dated within three months of the prior authorization request.
3. For HIV-infected patients, the endogenous serum erythropoietin level must be less than or equal to 500 mU/ml to initiate therapy.
4. No evidence of untreated GI bleeding, hemolysis, or Vitamin B-12, iron or folate deficiency. (Cross-reference 78.28(1)“d”(10))

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

1. Prevention or treatment of febrile neutropenia in patients with malignancies who are receiving myelosuppressive anticancer therapy.
2. Treatment of neutropenia in patients with malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant.
3. Mobilization of progenitor cells into the peripheral blood stream for leukapheresis collection to be used after myeloablative chemotherapy.
4. Treatment of congenital, cyclic, or idiopathic neutropenia in symptomatic patients.

The fiscal agent may consider other uses on an individual basis after review of the evidence provided regarding the need for therapy with granulocyte colony stimulating factor. (Cross-reference 78.28(1)“d”(11))

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

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

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

The 72-hour emergency supply rule found below and at paragraph 78.28(1)“d” does not apply for drugs used for the treatment of male sexual dysfunction. (Cross-reference 78.28(1)“d”(13))

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

1. The diagnosis requiring therapy.
2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications. (Cross-reference 78.28(1)“d”(14))

Prior authorization is required for narcotic agonist-antagonist nasal sprays for quantities exceeding 10 milliliters (approximately 60 doses) per 30 days. Payment for narcotic agonist-antagonist nasal spray beyond this limit will be considered on an individual basis after review of submitted documentation. For consideration, the diagnosis must be supplied. If the use is for the treatment of migraine headaches, documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications must be provided. (Cross-reference 78.28(1)“d”(15))

Prior authorization is required for isotretinoin therapy.

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

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

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

Prior authorization of isotretinoin therapy for treatment of conditions other than acne will be considered on an individual basis after review of submitted documentation. (Cross-reference 78.28(1)“d”(16))

Prior authorization is required for oral antifungal therapy beyond a cumulative 90 days of therapy per 12-month period per patient. Payment for oral antifungal therapy beyond this limit will be authorized in cases where the patient has a diagnosis of an immunocompromised condition or a systemic fungal infection. Other conditions will be considered on an individual basis after review of submitted documentation. This prior authorization requirement does not apply to nystatin. (Cross-reference 78.28(1)“d”(17))

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

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

Payment for nonparenteral vasopressin derivatives of posterior pituitary hormone products used in the treatment of primary nocturnal enuresis will be authorized for patients who are six years of age or older for periods of six months. Approvals will be granted for subsequent six-month periods only after a drug-free interval to assess the need for continued therapy. (Cross-reference 78.28(1)“d”(18))

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

1. The diagnosis requiring therapy.
2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications. (Cross-reference 78.28(1)“d”(19))

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.

Prior authorization is required for lipase inhibitor drugs for weight loss. Requests must include documentation showing failure of other weight loss programs, a body mass index (BMI) equal to or greater than 30, one or more comorbidity conditions, and a weight management plan including diet and exercise. Prior authorization may be given for up to six months. Additional prior authorizations may be given on an individual basis after review of medical necessity and documented significant weight loss (at least 10 percent) from the individual's weight at the beginning of the previous prior authorization period. (Cross-reference 78.28(1)"d"(20))

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

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

The fiscal agent will consider other conditions on an individual basis after review of submitted documentation. (Cross-reference 78.28(1)"d"(21))

b. Medical and sickroom supplies are payable when ordered by a legally qualified practitioner for a specific rather than incidental use. When a recipient is receiving care in a nursing facility or residential care 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 needles and syringes, blood glucose test strips, and diabetic urine test supplies.

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