

NOTICE OF RULE ADOPTION—FINAL RULE

**STATE OF MISSISSIPPI
OFFICE OF THE GOVERNOR
DIVISION OF MEDICAID**

Miss. Division of Medicaid
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Specific Legal Authority Authorizing the promulgation of
Rule: Miss Code Ann. §43-13-121(1972), as amended

Reference to Rules repealed, amended or suspended by the
Proposed Rule :
Provider Policy Manual Update Section 31

Date Rule Proposed:

Explanation of the Purpose of the Proposed Rule and the reason(s) for proposing the rule:
AP 2006-43. This Provider Policy Manual Updates Sections 31.12, 31.13, 31.15, 31.24 regarding
Pharmacy - Prior authorization, Over the Counter (OTC) Drugs, Tobacco Cessation, and Preferred
Drug List, respectively.

The Agency Rule Making Record for this rule including any written comments received during the comment period and the record of any oral proceeding is available for public inspection by contacting the Agency at the above address.

An oral proceeding was held on this rule:

Date:
Time:
Place:

An oral proceeding was not held on this rule.

The Agency has considered the written comments and the presentations made in any oral proceedings, and

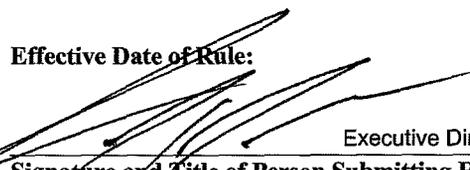
This rule as adopted is without variance from the proposed rule.

This rule as adopted differs from the proposed rule as there are minor editorial changes which affect the form rather than the substance of the rule.

The rule as adopted differs from the proposed rule. The differences however are:
Within the scope of the matters in the Notice of Proposed Rule Adoption, the logical outgrowth of the contents of the Notice of Proposed Rule Adoption and the comments submitted in response thereto, and
The Notice of Proposed Rule Adoption provided fair warning that the outcome of the proposed rule adoption could be the rule in question.

The entire text of the Proposed Rule including the text of any rule being amended or changed is attached.

Effective Date of Rule:



Executive Director
Signature and Title of Person Submitting Rule for Filing

Division of Medicaid State of Mississippi Provider Policy Manual	New: Revised: X Current:	Date: Date: 06/01/05 11/01/06
Section: Pharmacy	Section: 31.12	
Subject: Prior Authorization	Pages: 127	Cross Reference:

DOM requires prior authorization of certain covered drugs that have been approved by the Food and Drug Administration (FDA) for specific medical conditions. The approval criteria are recommended by DOM's Pharmacy and Therapeutics Committee and are based on information from the FDA, manufacturers, and medical literature. The prior authorization process is managed through the DOM Pharmacy Benefits Manager.

Prescription Drugs Requiring Prior Authorization

These prescription drugs were chosen based on the high potential for misuse and/or abuse. Prior authorization allows DOM to ensure that these prescription drugs are used responsibly and as they are intended. The following drugs/drug classes require prior authorization:

- ~~Actiq~~
- ~~Cox-2 Inhibitors~~
- Enbrel
- Enteral Nutrition
- ~~Erectile Dysfunction Oral Agents~~
- Immunosuppressants
- ~~Neurontin (brand name only)~~
- Oral Sustained Release Opioid Agonists (brand name only)
- ~~Proton Pump Inhibitors~~
- Synagis
- Xenical

Prior Authorization Process

Processes related to prior authorization for prescription drugs must be handled according to the procedures set forth by the Pharmacy Benefits Manager.

Refer to Section 1.11 Retrospective DUR Information for information related to the Pharmacy Benefits Manager.

Actiq (Oral Transmucosal Fentanyl Citrate)

Actiq is indicated for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid-tolerant are those who are taking at least 60 mg morphine/day, 50 mcg transdermal fentanyl/ hour, or an equianalgesic dose of another opioid for a week or longer.

Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, Actiq is contraindicated in the management of acute or postoperative pain. This product must not be used in opioid non-tolerant patients.

The FDA recommends Actiq to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

The appropriate dosing and safety of Actiq in opioid-tolerant children with breakthrough cancer pain have not been established below the age of sixteen (16) years.

DOM covers Actiq when the following criteria are met:

1. Management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy.
2. Diagnosis of cancer (ICD-9 codes 141.0-208)

Actiq is contraindicated for those patients with one or more of the following:

- Hypersensitivity to opiates
- Respiratory depression/ hypoxia/ hypercarbia
- Severe asthma or COPD
- Paralytic ileus
- Treatment of acute or postoperative pain
- Treatment of opioid non-tolerant patients
- Use in children below the age of sixteen (16) years

Cox-2 Inhibitors

DOM covers ~~Cox-2 Inhibitors and/or brand name Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) when the following criteria are met:~~

1. ~~The beneficiary must have a diagnosis of one of the following:~~
 - a. ~~Osteoarthritis (OA)~~
 - b. ~~Rheumatoid Arthritis (RA)~~
 - c. ~~Degenerative Joint Disease (DJD)~~
 - d. ~~Systemic Lupus Erythematosus (SLE)~~
 - e. ~~Other joint related diagnosis~~
 - f. ~~Primary dysmenorrhea~~
 - g. ~~Familial adenomatous polyposis~~

2. ~~The beneficiary must have received and failed to adequately respond to a 30-day trial of each of two prior NSAIDS or COX-2 within the past 6-month period prior. (May be generic, OTC, or brand name.)~~

3. ~~For Cox-2 Inhibitors, the beneficiary must not have a documented diagnosis of one of the following:~~
 - a. ~~GI ulcer disease~~
 - b. ~~GERD~~
 - c. ~~Diverticulitis~~
 - d. ~~Anticoagulation therapy~~
 - e. ~~Other diagnosis in which bleeding could occur with NSAID therapy~~

~~NOTE: Generic and DOM covered over the counter products in these classes do not require prior authorization.~~

Enteral Nutrition

Enteral nutrition is used as a nutritional replacement for patients who are unable to get enough nutrients in their diet. These formulas are taken by mouth or through a feeding tube and are used by the body for energy and to form substances needed for normal body functions.

DOM covers enteral nutrition when the following criteria are met:

1. For beneficiaries age 21 and over, the requested enteral nutritional must be the sole source of nutrition.
2. For beneficiaries under the age of 21, specialized feeding must constitute more than 50% of nutritional needs. A qualifying diagnosis is required.
3. The unique composition of the formula must contain nutrients the beneficiary is unable to obtain from food.
4. The composition of the formula must represent an integral part of treatment of the specified diagnosis and/or condition.
5. It must be documented that the beneficiary is unable to tolerate nutrients orally to sufficiently maintain life. The beneficiary is either unable to take oral nutrition or unable to tolerate oral intake.
6. Consideration is not given to accommodate psychological or behavioral conditions, food preferences, allergies, loss of appetite, or non-compliance with a specialized diet.

Documentation to support coverage of enteral nutrition must be maintained in the beneficiary's medical record. Documentation must include the following:

- a. Specific diagnosis related to the beneficiary's inability to take or eat regular food
- b. For oral feedings, list economic alternatives that have been tried. For beneficiaries age 21 and over, also list laboratory values for albumin or total protein.
- c. Amount needed per day
- d. Duration of treatment
- e. Height, current weight, and recent weight loss
- f. Specific prescription identifying levels of individual nutrient(s) that is required in increased or restricted amounts.

A prior authorization for enteral nutrition is for the nutritional product only and does not include supplies necessary to administer the nutrient.

Please note that Medicare must be billed first if the beneficiary is dually-eligible for Medicare and Medicaid.

Enteral nutritional replacements are not covered for residents in a long-term care facility, i.e. nursing home, ICF MR, etc. as these products are included in facilities' per diem rate.

Etanercept/Enbrel

DOM covers Etanercept/Enbrel when the following criteria are met on the **initial request**:

1. The beneficiary has a diagnosis of Rheumatoid Arthritis (RA).
2. The beneficiary has failed trials of at least one NSAID and one local/oral steroid without success.
3. The beneficiary has failed a trial of a least one prior DMARD and is currently on or has failed the second DMARD. Other DMARDs include:
 - a. Gold
 - b. Penicillamine
 - c. Plaquenil (Hydroxychloroquine)
 - d. Methotrexate (Rheumatrex)
 - e. Sulfasalazine

DOM covers Etanercept/Enbrel for **renewal requests** with documentation of demonstrated effectiveness.

Erectile Dysfunction Oral Agents

DOM covers erectile dysfunction oral agents when the following criteria are met:

1. The beneficiary must be male and 21 or older.
2. The beneficiary must be male from birth.
3. The beneficiary must have a diagnosis of one of the following:
 - a. Spinal Cord injury
 - b. Diabetic neuropathy
 - c. Prostatectomy
 - d. Irreversible neurological damage due to TURP
 - e. Cardiovascular disease (CHD, PVD, HTN)
4. The beneficiary must not be receiving nitrates, in any form, or other drugs contraindicated with recommended oral erectile dysfunction treatment.

Coverage is limited to one prescription of no more than two units, total, per month for this entire drug category.

Immunosuppressants

DOM covers immunosuppressants when the following criteria are met:

1. The beneficiary must have a diagnosis of one of the following:
 - a. Kidney, liver or heart allogenic transplant
 - b. Rheumatoid arthritis
 - c. Psoriasis
 - d. Nephrotic Syndrome
 - e. Stevens-Johnson Syndrome

2. Documentation must reflect that blood levels are monitored regularly.

The FDA recommends that the prescriber be experienced in managing post-transplant patients on immunosuppressant therapy.

Please note that Medicare must be billed first if the beneficiary is dually-eligible for Medicare and Medicaid.

Neurontin

DOM covers Neurontin when the following criteria are met:

1. The beneficiary must have a diagnosis of:

- Partial/partial complex seizures
- Post-Herpetic Neuralgia
- Diabetic Neuropathy of the lower extremities*
- Treatment of Amyotrophic Lateral Sclerosis, (ALS)**

** Supported by several comparative clinical trials*

*** Granted orphan drug status by the FDA*

2. Corresponding clinical information must be in beneficiary's medical chart and be retrievable.

Generic gabapentin is exempt from prior authorization.

Approval **may** be granted for up to six months.

Oral Sustained Release Opioid Agonists (Brand name only)

Patients appropriate for oral sustained release (SR) opioid agonists have chronic, severe pain that has not responded to alternative pain management choices, such as schedule II opioid agonists, physical therapy, cognitive behavioral techniques and/or medical techniques.

DOM covers oral SR opioid agents when the following criteria are met:

1. The beneficiary must have a diagnosis of one of the following:
 - a. Cancer (ICD-9 codes 141.0-208)
 - b. Arthropathies (ICD-9 codes 715.01-715.9)
 - c. Spinal neurological disorders (ICD-9 codes 720-725)
 - d. Other ICD-9 codes with supporting documentation
2. If the beneficiary does not have a diagnosis noted above, the prescriber must provide additional medical justification for the absence of alternative therapies in debilitated patients.
3. The beneficiary must have no contraindications such as:
 - a. Hypersensitivity to opiates
 - b. Respiratory depression/ hypoxia/hypercarbia
 - c. Severe asthma or COPD
 - d. Paralytic Ileus

The daily dosage intervals of oral sustained-release opioid agonists should not exceed manufacturer guidelines or FDA requirements.

For opioid dependent patients, the prescriber must provide documentation of a titration-weaning schedule.

Proton Pump Inhibitors

DOM covers proton pump inhibitors also known as anti-secretory therapy when the following criteria are met:

1. The beneficiary must have a diagnosis of one of the following:
 - a. Heartburn
 - b. H. Pylori
 - c. Gastroesophageal Reflux Disease (GERD)
 - d. Esophagitis
 - e. Peptic Ulcer Disease (PUD)
 - f. Gastric Ulcer
 - g. Barrett's Esophagus
 - h. Zollinger-Ellison Syndrome
 - i. Laryngopharyngeal Reflux (LPR)
 - j. Other Hypersecretory condition (diagnosis with medical justification attached to the request)
2. The beneficiary must have failed two (2) 30-day trials of Antacids, H2-Antagonists, or other PPI. Multiple antacids will be considered as one trial only.
3. The beneficiary must have documentation of testing supporting the diagnosis.

NOTE: DOM covered over-the-counter products in this class do not require prior authorization.

Palvizumab (Synagis)

DOM covers Synagis when a beneficiary meets the criteria in one of the four following categories:

- Category 1 Prematurity of \leq 28 weeks gestation
Age: \leq 1 year old
- Category 2 Prematurity of 29-32 weeks gestation
Age: \leq 6 months at the start of Respiratory Syncytial Virus (RSV) Season
- Category 3 Prematurity of \leq 35 weeks gestation
Age: 0-2 years old
Diagnosis: Chronic Lung Disease (CLD) and ongoing medical treatment for CLD (supplemental oxygen, steroids, bronchodilators or diuretics) within the last 6 months
- Category 4 33-35 weeks gestation
Age: Birth- 6 months old during RSV season
Risk factors as noted below are present and documented
No diagnosis of CLD is required.

Extending beyond age two years may be considered on an individual basis when supported by clinical documentation of extreme necessity.

Prior authorization will end at age two (last day of child's birthday month).

Prior authorization is granted during RSV season only (usually October through March).

RSV Risk Factors:

One of the following is considered sufficient:

- Hemodynamically significant Congenital Heart Disease (simple, small Atrial Septal Defects (ASD), Ventricular Septal Defects (VSD), and Patent Ductus Arteriosus (PDA) are not eligible).
- Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)
- Chronic lung disease requiring medical treatment within the past 6 months (e.g. diuretics, systemic steroids, oxygen on a continuous basis, bronchodilators or ventilation-dependent,

Or

Must have two of the following:

- Exposure to tobacco smoke in the home
- School age siblings
- Multiple birth
- Day care
- Severe neuromuscular disease
- Congenital airway abnormalities

Xenical

DOM covers Xenical when the following criteria are met:

1. A beneficiary must be at least 21 years of age.
2. For the initial request, a beneficiary must have all of the following criteria:
 - a. A diagnosis of diabetes, hypertension, or hyperlipidemia
 - b. A Body Mass Index (BMI) of 35 or greater
 - c. Documentation in medical record of prior physician supervised exercise/diet regimen
 - d. Has planned adjunctive therapy
 - e. Has been educated and understands risks/adverse reaction/complications
 - f. Have no contraindications such as Chronic Malabsorption Syndrome, Hypothyroidism, Cholestasis, or Hypersensitivity to Xenical or to any of its components.
3. For 1st renewal request, the beneficiary must have documentation of 7% body weight or greater within 3 months.
4. For subsequent renewals, the beneficiary must have documentation of no weight gain.