

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION, AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDICAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

<u>CITATION</u>	Medical and Remedial	<u>Prescribed drugs, and Prosthetic Devices; and Eyeglasses</u>
42 CFR	Care and Services	<u>Prescribed by a Physician Skilled in Diseases of the Eye or by</u>
440.120	Item 12.a.	<u>an Optometrist</u>

Item 12.a. Prescribed drugs are limited as follows:

Vendor payments are made for prescribed medications and/or supplies. The medications must be prescribed by a practitioner authorized to prescribe under State law. The National Drug Code (NDC) must be shown on each pharmaceutical claim form for reimbursement of prescription drugs subject to rebates from manufacturers as prescribed by mandatory federal law and regulations.

A. Program Coverage

Coverage of drugs shall be limited to specific drug products authorized for reimbursement by therapeutic category and listed by generic name, strength/unit, NDC, and brand name. Those drug products subject to mandatory coverage as a result of a rebate agreement with the federal government shall be covered until written notice is received from the Centers for Medicare and Medicaid Services (CMS) that coverage will be terminated. Providers will be given prior notice of any termination as required under federal regulations.

The list of covered drug products shall be maintained in the Services Manual of the Medicaid Program of Louisiana.

B. Prior Authorization with Preferred Drug List (PDL)

Effective June 10, 2002, as authorized by LA R.S. 46:153.3(B)(2)(a), and pursuant to 42 USC §1396r-8, a prior authorization process is established. This process utilizes a preferred drug list (PDL) for selected therapeutic classes. Drugs included on the PDL are automatically prior authorized. Drugs in these classes that are not included on the PDL shall require prescribers to obtain prior authorization.

Providers will be notified of the drugs selected for placement on the PDL by therapeutic classes prior to implementation of the prior authorization process and as additional drugs are subsequently added to the list. Lists of covered drug products, including those that require prior authorization, will be maintained in either the Prescription Drug Services Manual, other designated service provider manuals, on the Louisiana Medicaid web site, or provider notices.

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The prior authorization process provides for a turnaround response by either telephone or other telecommunications device within twenty-four (24) hours receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two (72) hour supply of medication as mandated by LA R.S. 46:153.3(B)(2)(a), and pursuant to 42 USC s1396r-8.

The Pharmaceutical and Therapeutics Committee will make recommendations to the Department regarding drugs to be subject to the prior authorization. The composition of and appointment to the Pharmaceutical and Therapeutics Committee complies with LA R.S. 46:153.3(D) and 42 USC s1396r-8. The Committee is appointed by the Governor and approved by the Senate.

The Pharmaceutical and Therapeutics Committee was established by State law in 2001 to advise the Department of Health and Hospitals (DHH) regarding the prescription drug program. The Committee reviews monographs on selected therapeutic drug classes or individual drugs and makes recommendations to the DHH for inclusion either on the Preferred Drug List (PDL) or on the Non-Preferred Drug List (NPDL).

Drugs on the PDL do not require prior authorization, and drugs on the NPDL require authorization. The monographs include clinical data, utilization data, therapeutic information relative to populations (i.e. elderly and pediatric use), multiple source availability (generic and innovator products) and relative cost information (state and federal rebate information is confidential). The Medicaid Pharmacy Benefits Management Program staff compiles the Committee's recommendations along with staff comments and/or additional information as necessary and submits them to the DHH Secretary for consideration.

C. Drugs for Full Benefit Dual Eligibles

Effective January 1, 2006, the Louisiana Medicaid agency will not reimburse any drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B which would entitle the eligible to receive drug benefits under the Medicare Prescription Drug Benefit, Part D. The only drugs covered for the full-benefit dual eligible by Louisiana Medicaid are those subject to restriction under Section 1927(d) (2) of the Social Security Act.

D. Medicaid Coverage of Drugs Restricted Under Section 1927(d) (2) of the Social Security Act

The Medicaid Program will provide coverage for the following drugs which may be excluded or otherwise restricted under the provisions of Section 1927(d)(2) of the Social Security Act. When Medicare Part B or Part D plans reimburse for these drugs, the Medicaid agency will not pay.

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- Agents when used for anorexia, weight loss, or weight gain
Some.
Xenical only

- Agents when used to promote fertility
Some.
Vaginal progesterone when used for high-risk pregnancy to prevent premature births

- Agents when used for cosmetic purposes or hair growth
Some.
Accutane

- Agents when used for symptomatic relief of cough and colds
Some.
Prescription Antihistamine and Antihistamine/Decongestant Combination Products

- Prescription vitamins and mineral products, except prenatal vitamins and fluoride.
Some.
Vitamin A Injection
Vitamin B Injection
Vitamin D (prescription only)
Vitamin K (prescription only)
Vitamin B12 Injection
Folic Acid (prescription only)
Niacin (prescription only)
Vitamin B6 Injection
Vitamin B1 Injection
Multivitamin (prescription only)
Magnesium Injection
Calcium Injection
Urinary PH modifiers (Phosphorous, specifically K Phos Neutral and Phospha Neutral)

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AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION, AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDICAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

- Nonprescription drugs
Some.
OTC antihistamines and antihistamine/decongestant combinations
Miralax
Insulin
 - Experimental drugs
None.
 - Compounded prescriptions
None
 - Vaccines
Some.
Influenza vaccine
 - Medications which are included in the reimbursement to a facility
None.
 - DESI drugs
None.
 - Covered outpatient drugs when the manufacturer seeks to require as a condition of sale
None.
 - Drugs for erectile dysfunction
Some.
When used for the treatment of conditions, or indications approved by the FDA, other than erectile dysfunction.
- E. **Monthly Prescription Limit.** Effective February 1, 2011, a monthly prescription limit is established.
1. The program will pay for a maximum of four prescriptions per calendar month for Medicaid recipients.

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LIMITATIONS ON THE AMOUNT, DURATION, AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

2. The following federally mandated recipient groups are exempt from the four prescriptions per calendar month limitations:
 - a. Persons under 21 years of age;
 - b. Persons who are residents of long-term care institutions, such as nursing homes and ICF-DD facilities; and
 - c. Pregnant women.
3. The four prescriptions per month limit can be exceeded when the prescriber determines an additional prescription is medically necessary.
4. Pharmacists and prescribers are required to maintain documentation to support the override of a prescription limitation.

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AMLUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION, AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDICAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

- I. **Parenteral Nutrition Therapy.** Parenteral nutrition is covered for a recipient with permanent, severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. Parenteral Nutrition Therapy is the introduction of nutrients by some means other than through the gastrointestinal tract, in particular intravenous, subcutaneous, intramuscular, or intramedullary injection. Intravenous nutrition is also referred to as TPN (Total Parenteral Nutrition) or Hyperalimentation Therapy.

Parenteral Nutrition Therapy must be prior authorized and approved by the Prior Authorization unit (PAU).

II. **Supplemental Drug Rebates**

- A. As authorized by LA R.S. 46:153.3 (B)(2)(a) the State Supplemental Drug Rebate program is effective April 1, 2002.
- B. The state negotiates supplemental rebates from manufacturers that are in addition to those mandated by Title XIX of the Social Security Act.

SUPERSEDES TN# 05-13

- C. The Department is in compliance with Section 1927 of the Social Security Act. Based on the requirements for Section 1927, the state has the following policies for drug rebate agreements:

STATE <u>Louisiana</u>	A
DATE REC'D <u>12-23-05</u>	
DATE APPVD <u>4-14-06</u>	
DATE EFF <u>1-1-06</u>	
HCFA 179 <u>05-40</u>	

1. The drug file permits coverage of participating manufacturers' drugs.
2. The program is in compliance with reporting for state utilization information and restrictions to coverage.

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE OF LOUISIANA
AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES
PROVIDED

Attachment 3.1-A
Item 12.a. Page 5

LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED
MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

3. Rebate agreements between the state and a drug manufacturer that are separate from the drug rebate agreements of Section 1927 are approved by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any state supplemental rebates collected.
 4. Manufacturers are allowed to audit utilization data.
 5. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
 6. The Department will utilize the same processes to resolve State Supplemental rebate issues as it uses to resolve federal rebate disputes and as outlined in CMS' *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program*.
- D. The Department is also in compliance with R.S. 44:4 as amended by Act 124 of The First Extraordinary Session of the 2002 Legislature relative to the confidentiality of supplemental rebate information contained in the records of the Department and its agents.
- E. A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on April 8, 2002 and entitled "Supplemental Rebate Agreement" was previously authorized by CMS on April 25, 2002.
- F. CMS has authorized the state of Louisiana to enter into *The Optimal PDL Solution (TOP\$)*. This Supplemental Drug Rebate Agreement was submitted to CMS on November 5, 2013, and has been authorized by CMS effective October 1, 2013.

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LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

III. Limits on Allowable Cost

Provider reimbursement limits on cost as established under Attachment 4.19-B must be followed. These limits neither supercede or contravene State anti-substitution laws. Pharmacists shall not be authorized or required to dispense drugs in violation of State Law.

IV. Recipient Co-Payments

Effective for dates of service July 13, 1995 and after, the Department of Health and Hospitals, Bureau of Health Services Financing, imposes a co-payment requirement in the Pharmacy Program as reflected on Attachment 4.18-A, Page 1.

In accordance with Federal regulations the following provisions apply: 1) the provider may not deny services to any eligible individual on account of the individual's inability to pay the co-payment amount. However, this service statement does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the co-payment. Providers shall not waive the recipient co-payment liability. Departmental monitoring and auditing will be conducted to determine provider compliance. Violators of this policy will be subject to a penalty such as suspension from the Medicaid program.

STATE <u>Louisiana</u>	A
DATE RECD <u>6-10-02</u>	
DATE APP'VD <u>1-8-03</u>	
DATE EFF <u>6-10-02</u>	
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