

## OFFICIAL NOTICE

**DMS-2002-O-7**  
**DMS-2002-E-5**  
**DMS-2002-KK-11**  
**DMS-2002-Q-8**  
**DMS-2002-R-15**

**TO:** Health Care Provider – Certified Nurse-Midwives,  
Dental, Nurse Practitioners, Pharmacy and Physicians

**DATE:**

**SUBJECT:** Prescription Drug Program Requirement for  
Documentation of Medical Necessity for Brand Name  
Drugs with a Generic Upper Limit

Effective for claims with dates of service on or after October 15, 2002, the Arkansas Department of Human Services is amending the conditions required to override the Generic Upper Limit cost on brand name drugs when a generic equivalent is available. The requirements are attached which outline introduction, definition and procedure.

If you need this material in an alternative format, such as large print, please contact our Americans with Disabilities Act Coordinator at (501) 682-8307 (voice) or at (501) 682-6789 and 1-877-708-8191 (TDD).

**If you have questions regarding this notice, please contact the EDS Provider Assistance Center at In-State WATS 1-800-457-4454, or locally and Out-of-State at (501) 376-2211.**

Thank you for your participation in the Arkansas Medicaid Program.

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Ray Hanley, Director

*Arkansas Medicaid provider manuals (including update transmittals), official notices and remittance advice (RA) messages are available for downloading from the Arkansas Medicaid website: [www.medicaid.state.ar.us](http://www.medicaid.state.ar.us).*

# Documentation of Medical Necessity for Brand Name Drugs with a Generic Upper Limit

## Introduction

In order for the Arkansas Medicaid Prescription Drug Program (Program) to increase patient safety, decrease unnecessary expenditures, and assist in monitoring drug products, effective for claims on or after October 15, 2002, the following conditions are required to override the Generic Upper Limit (GUL) cost when computing the allowable amount of reimbursement for a prescription:

- The Prescriber shall establish that the recipient's condition meets the definition provided for the medical necessity of dispensing any brand name drug when a generic equivalent is available.
- The Prescriber shall submit additional documentation using the FDA MedWatch form to support dispensing a Brand-Name medication instead of the generic equivalent--with the exception of carbamazepine, primidone, valproic acid and warfarin.

## Definition

In the context of this policy, Brand Medically Necessary is defined as the necessity to prescribe and dispense a Brand-Name medication when use of a generic product has resulted in a) Adverse Reaction(s) to the generic, b) Allergic Reaction(s) to the generic, or c) Therapeutic Failure of the generic.

- Adverse reaction caused by a generic must meet one of the following criteria:
  - a. Life Threatening
  - b. Hospitalization
  - c. Disability
  - d. Required intervention to prevent impairment or damage
- Allergic reaction is defined as when an allergen is present in a generic drug that is not present in a brand drug resulting in a hypersensitive reaction.
- Therapeutic failure is defined as, clinical failure due to the recipient's suboptimal plasma drug concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.

## General Requirements for All Drugs with GULs

As required by the Code of Federal Regulations, 42 CFR 447.331, all prescriptions for drugs with GULs are required to have, in the prescriber's own handwriting, "Brand Medically Necessary" in order for the pharmacy to receive payment exceeding the upper limit established by the Program. The prescription with the necessary documentation is to be provided to the pharmacy provider to alert the pharmacist to the possibility of a Brand Medically Necessary prior authorization for a MedWatch drug, or for the need of a prior authorization for a non-MedWatch drug. The pharmacy will transmit a DAW of 1 to indicate the prescription has the necessary documentation to override the Generic Upper Limit on a drug and reimburse at the Brand-Name reimbursement rate. The pharmacy will be responsible for maintaining on file the original prescription with the "Brand Medically Necessary" documentation.

**I. Prior Authorization Requirements for drugs requiring MedWatch documentation:**

1. The Prescriber shall establish the medical necessity for dispensing the brand name drug using the FDA MedWatch form for one of the following reasons:

**a) Adverse Reaction(s) to the generic:**

Prescriber must submit to the EDS Pharmacy Help Desk a completed FDA MedWatch form documenting that the adverse reaction to a generic caused one or more of the following criteria:

- a. Life Threatening
- b. Hospitalization
- c. Disability
- d. Required intervention to prevent impairment or damage

**b) Allergic Reaction(s) to the generic:**

Prescriber must submit to the EDS Pharmacy Help Desk a completed FDA MedWatch form documenting that the recipient's experience of allergic reaction to a generic product of one or more manufacturers. The dates and clinical details with the names of specific companies and the generic versions involved must be included.

**c) Therapeutic Failure(s) of the generic:**

Prescriber must submit to the EDS Pharmacy Help Desk a completed FDA MedWatch Form documenting the clinical failure due to recipient's suboptimal drug plasma concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.

**AND**

2. Prescriber must submit to the EDS Pharmacy Help Desk the completed MedWatch Patient Information Request Form (DMS-636) to allow processing of the Brand-Name product. This will assist in the consolidation of patient/physician/pharmacy and drug information identification.

**Submitting MedWatch Documentation for Review**

The FDA MedWatch forms may be obtained online at:

<http://www.FDA.gov/medwatch/safety/3500.pdf>.

Prescribers must mail or fax completed FDA MedWatch Forms and patient information request to EDS at:

Fax:  
(501) 372-2971

Mail:  
EDS Pharmacy Unit  
P. O. Box 8036  
Little Rock, AR 72203

The Arkansas Medicaid Program may forward the completed MedWatch forms to the FDA. Requests will be reviewed by the EDS Pharmacy Help Desk and approved or denied based on preceding definitions. If it is necessary for the EDS Pharmacy Help Desk to have further correspondence with the prescriber, the status of the prior authorization will be pending until contact is made with the prescriber and a decision is made as to the status of the request. EDS will notify the prescribing and dispensing providers, by the close of the following business day, excluding weekends and holidays, of approval, denial, or additional documentation by way of the MedWatch Patient Information Request Form (DMS-636). Prescribers may appeal denied prior authorization requests by contacting the Pharmacists at the office of Division of Medical Services.

Recipients will be notified by mail of the denied Brand Medically Necessary prior authorization. Approved MedWatch Prior Authorizations will be established for one year at the pharmacy provider named on the MedWatch Patient Information Request form (DMS-636). The EDS Pharmacy Help Desk will contact the pharmacy provider to determine the NDC the pharmacy will be dispensing. The pharmacy provider will then be informed of the prior authorization number and date range. The pharmacy will be responsible for maintaining on file the original prescription with the “Brand Medically Necessary” documentation. Renewal of a MedWatch Prior Authorization will require the prescriber to resubmit a letter and a MedWatch Patient Information Request form (DMS-636). A renewal does not require a resubmission of a MedWatch form.

## **II. Prior Authorization Requirements for drugs\* not requiring MedWatch Documentation:**

FDA MedWatch form completion will not be required for recipients being treated with the following drug products:

- Carbamazepine
- Primidone
- Valproic Acid
- Warfarin

*\*Drugs may be added or deleted to the list of drugs not requiring a MedWatch Prior Authorization.*

As required by the Code of Federal Regulations, 42 CFR 447.331, all prescriptions for drugs with GULs are required to have in the prescriber’s own handwriting, “Brand Medically Necessary” in order for the pharmacy to receive payment exceeding the Generic Upper Limit established by the Program. The prescription with the necessary documentation is to be provided to the pharmacy provider to alert the provider of the need for a prior authorization for a non MedWatch drug. It is the responsibility of the Pharmacist to obtain this documentation on all “Brand Medically Necessary” prescriptions in order to submit DAW 1 code to override the GUL. The pharmacy will establish a Prior Authorization through the Voice Response System and transmit a DAW code of 1 to override the Generic Upper Limit if the prescription has the required notation. The pharmacy will be responsible for maintaining on file the original prescription with the “Brand Medically Necessary” notation.

**Arkansas Medicaid Prescription Drug Program  
MedWatch Patient Information Request Form**

Prescribers must mail or fax completed FDA MedWatch Forms and patient information request to EDS at:  
**Fax:** (501) 372-2971    **Mail:** EDS Pharmacy Unit, P. O. Box 8036, Little Rock, AR 72203  
FDA MedWatch is available at: <http://www.FDA.gov/medwatch/safety/3500.pdf>

<b>Recipient Name:</b>	_____
<b>Recipient Medicaid Number:</b>	_____
<b>Date of Birth:</b>	_____

<b>Prescriber Name:</b>	_____
<b>Prescriber Medicaid Number:</b>	_____
<b>Office Phone Number:</b>	_____
<b>Office Fax Number:</b>	_____
<b>Pharmacy Name:</b>	_____
<b>Pharmacy Phone Number:</b>	_____
<b>Pharmacy Fax Number:</b>	_____

<b>Brand Name/Strength of Drug:</b>	_____
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<b>Completed MedWatch Form Attached?</b>	<b>YES</b>	<b>NO</b>
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<b>Prescriber Signature:</b>	_____
<b>Date:</b>	_____

**All fields are required to be populated in order to process the request.**

**PA Status**             **Approved**             **Denied**             **Pending**

**Dates Approved**            \_\_\_\_\_ **to** \_\_\_\_\_

**Additional Comments:**

*Carbamazepine, Primidone, Valproic Acid, and Warfarin do NOT require MedWatch documentation as part of their Prior Authorization requirements.*