Arkansas Medicaid Pharmacy Program

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 in accordance with the Code of Federal Regulations, 42 CFR 447.331

The prescriber must determine whether the Medicaid recipient meets the required conditions to override a generic upper limit (GUL) cost of a drug. The prescriber must also complete the required MedWatch (see below) documentation to allow a prior authorization (PA) for a "Brand Medically Necessary" override of the GUL to reimburse at the brand name reimbursement rate.

MedWatch is the Food and Drug Administration (FDA) Safety Information and Adverse Event Reporting Program that allows healthcare professionals to report serious problems that they suspect are associated with certain drugs they prescribe.

The following criteria must be met to override the GUL when calculating the allowable amount of reimbursement:

A. For MedWatch drugs, the following conditions are required for approval of a Brand Medically Necessary override:
    1. 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.

       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 adverse reaction(s) to the generic, allergic reaction(s) to the generic or therapeutic failure of the generic.
        a. Adverse reaction caused by a generic must meet one of the following criteria:
            1. Life threatening
            2. Hospitalization
            3. Disability
            4. Required intervention to prevent impairment or damage
        b. 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.
        c. 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.
    2. The prescriber shall submit documentation to Arkansas Medicaid Pharmacy Unit using the FDA MedWatch Form to support dispensing a brand name medication instead of the generic equivalent.
    3. When a MedWatch drug is approved for a Brand Medically Necessary override, the Arkansas Medicaid Pharmacy Help Desk will contact the pharmacy provider to inform them of the prior authorization number and the date range of the approved PA.

The PA is given for up to one year for MedWatch Drugs.

All prescriptions must be on file for review by auditors from the Division of Medical Services or their designated agents.

If the criteria stated above are met and the pharmacy claim is submitted with a code of "1" in the dispense as written (DAW) field, the prescription will be priced using the EAC price for the specific product dispensed rather than the generic upper limit price.

AND

B. Prescriber must submit to the Arkansas Medicaid Pharmacy Unit 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

1. The MedWatch Patient Information Request Form (DMS-636) may be obtained online at: https://arkansas.magellanrx.com/provider/docs/rxinfo/ptrequest.pdf

2. The FDA MedWatch Form may be obtained online at: https://www.fda.gov/media/76299/download

Prescribers must fax or mail the completed Patient Information Request Form and FDA MedWatch Form to the Arkansas Medicaid Pharmacy Unit at:

Fax: (800) 424-7976

Mail:
Arkansas Medicaid 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 Arkansas Medicaid Pharmacy Unit and approved or denied based on preceding definitions. If it is necessary for the Pharmacy Unit 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. The Arkansas Medicaid Program 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 up to one year.

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.