

**State of Maine Department of Health & Human Services
MaineCare/MEDEL Prior Authorization Form
BRAND NAME MEDICATION REQUEST**

Phone: 1-888-445-0497

www.mainearepdl.org

Fax: 1-888-879-6938

Provider must fill all information below. It must be legible, correct and complete or form will be returned.

Member ID #: Patient Name: DOB:
(NOT MEDICARE NUMBER)

Patient Address:

Provider DEA: Provider NPI:

Provider Name: Phone:

Provider Address: Fax:

Pharmacy Name: Rx Address: Rx phone:

(Pharmacy use only): NPI: NABP: NDC:

****THIS FORM IS TO BE USED WHEN THE MEMBER HAS TRIED, AND FAILED OR IS INTOLERANT OF THE PREFERRED MORE COST EFFECTIVE GENERIC FORMULATIONS. ****

| <u>Drug Brand Name</u> | <u>Strength</u> | <u>Dosage</u> <u>Instructions</u> | <u>Quantity</u> | <u>Days Supply</u> <small>(34 retail / 90 mail order)</small> | <u>Refills</u> |
|------------------------|----------------------|--------------------------------------|----------------------|--|----------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | 1 2 3 4 5 |

Has member tried a generic?

- Yes
 - Adverse reaction
 - Inadequate response
 - Other

Details of adverse reaction, inadequate response, or other: (please provide chart notes.)

Is the side effect experienced also listed in the Brand Drug Side Effect Profile? If no please explain.

What other therapeutic alternatives other than the name brand version were tried first?

According to MaineCare Benefits Manual Chapter II (80.07-5), when medically necessary covered brand-name drugs have an A-rated generic equivalent available, the most cost-effective medically necessary version will be approved and reimbursed, since the brand-name and A-rated generic drugs have been determined by the FDA to be chemically and therapeutically equivalent.

The Bureau does not make determinations as to whether or not a generic drug is clinically inferior or inequivalent to its brand version. This is the proper role of the FDA. Providers should submit their reports of generic inequivalence directly to the FDA via the MEDWATCH.

Approvals or denials will be issued based on whether the criteria in the form have been satisfied. If this form is used to submit PA requests for non-preferred brands that involved failing FDA-designated equivalent generics, a denial will almost certainly be issued. If the Department determines however, that the information supplied indicates a highly probable and serious adverse drug effect that is unique to the generic and not to the brand, then it will issue an interim approval after forwarding a report to the FDA, and while awaiting a response back from the FDA.

Pursuant to the MaineCare Benefits Manual, Chapter I, Section 1.16, The Department regards adequate clinical records as essential for the delivery of quality care, such comprehensive records are key documents for post payment review. Your authorization certifies that the above request is medically necessary, meets the MaineCare criteria for prior authorization, does not exceed the medical needs of the member and is supported in your medical records.

Provider Signature: Date of Submission:

***MUST MATCH PROVIDER LISTED ABOVE**

Please complete both pages of this PA request

Provider Help Desk
1 (888) 420-9711

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FAX Completed Form to
1 (888) 879-6938

Revised for submission of brand medically necessary requests for the MaineCare or MEDEL.
Prescriber must have witnessed or have documentation that the manifestation of adverse event(s) is linked to the generic drug
Completion of form does not automatically grant approval.

| A. PATIENT INFORMATION | |
|---|---|
| MEDICAID ID# _____ | DOB ____/____/____ |
| NAME _____ | Sex <input type="checkbox"/> M <input type="checkbox"/> F |
| WEIGHT _____ lbs. | Phone # (____) _____ - _____ |
| Has a generic been tried before? Yes ___ No ___ | |
| Give date: ____/____/____ | Age at time of event: _____ |
| B. ADVERSE EVENT OR INADEQUATE RESPONSE | |
| <input type="checkbox"/> Adverse Event | <input type="checkbox"/> Inadequate response |
| 2. Outcomes Attributed to Adverse Event <i>(Check all that apply)</i> | |
| <input type="checkbox"/> Death: _____ <i>(mo/day/year)</i> | |
| <input type="checkbox"/> Disability | |
| <input type="checkbox"/> Life-threatening event | |
| <input type="checkbox"/> Congenital Anomaly | |
| <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage | |
| <input type="checkbox"/> Hospitalization-Initial or Prolonged | |
| Date of Event (mo/day/yr) | Date of This Report (mo/day/yr) |
| Describe Event or Problem; Relevant History and Tests | |
| | |
| C. SUSPECT MEDICATIONS | |
| Name <i>(Give labeled strength & mfr. Labeler, if known)</i> | |
| | |
| Dose, Frequency & Route Used: | Therapy Dates: |
| | |
| Diagnosis for Use <i>(Indication)</i> | Event Abated After Use Stopped or Dose Reduced? |
| | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| Lot# <i>(If Known)</i> | Exp. Date |
| | Event Reappeared After Reintroduction? |
| | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| NDC # <i>(specify generic manuf.)</i> | |

| D. DEGREE OF CERTAINTY THAT THE ADVERSE REACTION IS DUE TO GENERIC | |
|--|--|
| <p><u>Definite</u>. The reaction follows a reasonable temporal sequence after generic drug exposure or a toxic blood level of the generic drug has been established in body fluids or tissue. The reaction follows a recognized response to the suspected generic drug. The reaction is confirmed by improvement on withdrawing the generic drug and reappears on re-exposure. "Other than drug causes" such as other drugs or toxins or concomitant disease states that can cause similar clinical reactions are ruled out.</p> | |
| <p><u>Probable</u>. The reaction follows a reasonable temporal sequence after generic drug exposure. The reaction follows a recognized response to the suspected generic drug. The reaction is confirmed by withdrawal but not by exposure to the generic drug. The reaction cannot be reasonably explained by known characteristics of the recipient's clinical state.</p> | |
| <p><u>Possible</u>. The reaction follows a temporal sequence after generic drug exposure. The reaction follows a possible recognized pattern to the suspected generic drug. The reaction could be explained by the recipient's clinical state (i.e. other than the suspected generic drug).</p> | |
| <p><u>Doubtful</u>. The reaction is likely to be related to factors other than the suspected generic drug.</p> | |
| <p><u>Negative</u>. The findings clearly eliminate the possibility of a drug reaction caused by the generic version of the drug.</p> | |
| List concomitant medications being taken by patient: | |
| | |
| E. REPORTER | |
| Prescriber's Name _____ | |
| Signature _____ DEA# _____ | |
| Address _____ | |
| | |
| Phone# : (____) _____ - _____ | |
| Fax # : (____) _____ - _____ | |
| Did the prescriber witness the ADR? Yes <input type="checkbox"/> No <input type="checkbox"/> | |
| Has the ADR been reported to the FDA? Yes <input type="checkbox"/> No <input type="checkbox"/> | |
| <p>Please FAX form to GHS at 1-888-879-6938 DO NOT FAX DIRECTLY TO THE FDA</p> | |

Please complete both pages of this PA request