



Generic Substitution Policy Prior Authorization Criteria

FORMULARY STATUS: Varies

APPROVAL LIMITS: Indefinite

QUANTITY LIMITS: Same as apply to generic formulation

CRITERIA FOR COVERAGE of Brand name medication when FDA approved generic equivalent (A rated) is available:

- Patient has had not otherwise explainable clinically significant adverse reactions with the generic that were not experienced with the brand or has not had therapeutic response with the generic that was experienced with the brand that is not otherwise explainable. In some cases another trial with the generic formulation may be required.
- Prior authorization and FDA MedWatch Adverse Event report forms are completed and submitted to Unity Pharmacy Programs documenting the adverse reaction or lack of therapeutic response.
- Information provided by member requests for exceptions to the policy will need to be supplemented by supporting documentation from the prescribing practitioner which will be requested by pharmacy program staff.
- Medications on the Mandatory Substitution Exceptions List are exempt from this policy.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

FDA Use Only

Triage unit sequence #

Page ____ of ____

A. Patient information

1. Patient identifier	2. Age at time of event: or _____ Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
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In confidence

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death _____ (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 _____

#2 _____

2. Dose, frequency & route used

#1 _____

#2 _____

3. Therapy dates (if unknown, give duration from/to (or best estimate))

#1 _____

#2 _____

4. Diagnosis for use (indication)

#1 _____

#2 _____

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 _____

#2 _____

7. Exp. date (if known)

#1 _____

#2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1 _____

#2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: _____

5. Expiration date (mo/day/yr)

6. model # _____

catalog # _____

serial # _____

lot # _____

other # _____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address

phone # _____

2. Health professional? yes no

3. Occupation

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box.

PLEASE TYPE OR USE BLACK INK



Mail to: **MEDWATCH**
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178