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 or authorized generic) is available:

- Patient has had a clinically significant adverse reaction OR lack of therapeutic response with the generic that was not experienced with the brand and is not otherwise explainable. In some cases another trial with the generic formulation may be required.
- At least one formulary therapeutic alternative was not tolerated or was not efficacious.*
- All generic exception requests require prior authorization and FDA MedWatch Adverse Event report forms to be completed and submitted to Unity Pharmacy Program documenting the adverse reaction or lack of therapeutic response.

*Medications in these categories for the listed indications are exempt from the requirement to use a formulary therapeutic alternative. They are NOT exempt from using the generic equivalent, unless the product is on the Mandatory Substitution Exceptions List.

- Medications on the Mandatory Substitution Exceptions List
- Anticonvulsants, if used for seizures*
- Immunosuppressive agents, if used to prevent organ rejection*
- Beta blockers, if used for heart failure*

Important Information:

- 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.
A. Patient information

1. Patient identifier

2. Age at time of event: ____________________________
   Date of birth: ____________________________
   In confidence ____________________________

3. Sex

   - female ____________________________ lbs
   - male ____________________________ kgs

4. Weight

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)
   - death ____________________________
   - life-threatening ____________________________
   - hospitalization - initial or prolonged ____________________________
   - required intervention to prevent permanent impairment/damage ____________________________
   - disability ____________________________
   - congenital anomaly ____________________________
   - other: ____________________________

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

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

5. Describe event or problem

C. Suspect medication(s)

1. Name (give labeled strength & mfr/lbl, if known)
   #1 ____________________________
   #2 ____________________________

2. Dose, frequency & route used
   #1 ____________________________
   #2 ____________________________

3. Therapy dates (if unknown, give duration)
   #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) ____________________________

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)
   ____________________________

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 # ____________________________

7. Catalog # ____________________________

8. Serial # ____________________________

9. Lot # ____________________________

10. Other # ____________________________

11. Device available for evaluation? (Do not send to FDA)
   - yes ____________________________
   - no ____________________________
   - returned to manufacturer on (mo/day/yr) ____________________________

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

E. Reporter (see confidentiality section on back)

1. Name & address ____________________________

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. ____________________________

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.