

**Regence BlueCross BlueShield of Oregon · Regence BlueShield
Regence BlueCross BlueShield of Utah · Regence BlueShield of Idaho
Independent licensees of the Blue Cross and Blue Shield Association**

Medication Policy Manual

Policy No: dru116

Topic: Non-Formulary Medications, Medical
Exception Criteria for Closed Pharmacy Benefit
Designs

Date of Origin: April 2005

Revised/Effective Date: January 9, 2009

Next Review Date: January 2010

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

DESCRIPTION

This policy applies only to "closed" pharmacy benefit design contracts where prior authorization needs to be approved for coverage of a non-formulary or non-preferred medication. Non-formulary or non-preferred means those self-administered medications not listed in the Regence formulary/preferred medication list.

PLEASE NOTE: This policy does NOT apply to "open" or "tiered" pharmacy benefit design contracts where non-formulary or non-preferred medications are covered (typically at a higher copayment than formulary or preferred) either with or without prior authorization.

There are not exceptions to the copayment structure for closed pharmacy benefits. Specific prior authorization criteria in drug-specific policies take precedence over the general criteria listed in this policy.

Policy/Criteria

- I. A non-formulary or non-preferred medication may be prior authorized for coverage if there is a Regence medication policy and those criteria are met.

- II. A non-formulary or non-preferred medication for which there is no medication-specific policy may be prior authorized for coverage under closed benefit designs that require coverage of a non-formulary or non-preferred medication when one of the following criteria in A, B or C below is met:

- A. For non-formulary or non-preferred medications that do not have a generic available:

Treatment with at least two formulary/preferred medication alternatives was contraindicated, ineffective or not tolerated. If only one alternative is available, only that treatment must have been contraindicated, ineffective or not tolerated.

Formulary/preferred medication alternatives are defined as those alternatives specific to the non-formulary/non-preferred alternative listed on the Alternatives to Non-Formulary page of the www.regencerx.com web site. (<http://www.regencerx.com/learn/alternatives/index.html>)

OR

- B. A non-formulary or non-preferred medication for which there is a generic equivalent available:
 - 1. The generic equivalent was either ineffective or not tolerated.

AND

- 2. The provider submits a completed FDA MedWatch form (Appendix 1) documenting the intolerance or lack of efficacy of the generic product. The completed form will be faxed to the FDA for reporting of adverse events and product problems.

OR

- C. There is no formulary/preferred or generic medication available.

III. Limitations and Authorization Period

Authorization may be renewed as defined in the specific medication policy or at least annually to confirm continued eligibility.

Position Statement

The Regence Formulary/Preferred Medication List

- A formulary/preferred medication list is a group of generic and selected brand-name medications that is established, reviewed and updated routinely by an external group of physicians and pharmacists called the Pharmacy and Therapeutics Committee.
- The criteria for evaluating and selecting medications for the formulary/preferred medication list are based on published scientific evidence and include efficacy (a medication's ability to treat a condition or prevent a disease), safety (the incidence of side effects and medication interactions), outcomes (clinical value of the product), and cost-effectiveness all relative to other available treatment options.
- Medications that provide significant medical value, based on a rigorous review of both published and unpublished scientific data, are included on the formulary/preferred medication list when their benefit is worth their cost.
- There is at least one or more medication available on the formulary/preferred medication list (either as a generic or preferred brand) for any condition that is a covered benefit.
- Formulary/preferred medication choices are reviewed at least annually and regularly as new data become available. Medications may be removed from the formulary/preferred medication list when the brand name becomes generically available or when they are no longer cost-effective relative to other existing or newer products that come to market.

Generic Medications

- A generic medication is an identical copy of a brand name medication in dosage, safety, strength, route of administration, quality, performance and intended use. ^[1]
- The FDA requires that generic manufacturers: ^[1]
 - * Adhere to the same stringent manufacturing standards and requirements as brand manufacturers for assuring quality, strength, purity and stability of medication products.
 - * Scientifically prove that their generic medication works the same way and in the same amount of time as the reference brand version (i.e., demonstrate bioequivalence).
- Since generics have the same active ingredients and are shown to work the same way in the body, they have the same efficacy, safety, and risk-benefit profile as their brand-name counter-parts. ^[1]

- As a result, the majority of FDA-approved generic medications may be considered therapeutically interchangeable with their brand name reference products.

FDA MedWatch

- The FDA MedWatch Program is designed to maintain the safety and post-marketing surveillance of all FDA-regulated medications. ^[2]
- The FDA uses the MedWatch Program to: ^[2]
 - * Report medication adverse events and product quality problems.
 - * Maintain effective and quality medication products on the market.
- Healthcare professionals have the clinical responsibility to report serious adverse events or product quality problems associated with a medication to the FDA MedWatch Program.
- MedWatch reports filed by healthcare professionals serve as the basis that may prompt further regulatory actions to improve product safety and protect the public health, such as updating a product's labeling information, sending out a "Dear Health Care Professional" letter, or re-evaluating an approval decision. ^[2]

References

1. Federal Food and Drug Administration. Center for Drug Evaluation and Research (CDER). Generic drugs: questions and answers. http://www.fda.gov/cder/consumerinfo/generics_q&a.htm (accessed January 2, 2007).
2. Federal Food and Drug Administration MedWatch Reporting Program. <http://www.fda.gov/medwatch/index.html> (accessed January 2, 2007).
3. Federal Food and Drug Administration Adverse Event Reporting System (AERS). <http://www.fda.gov/cder/aers/default.htm> (accessed January 2, 2007).

Cross References

Non-Preferred Medications, Medical Exception Criteria for Tiered Benefit Designs with Tier Copay Exceptions, dru125

Medication Policy Manual Introduction, dru150

Off-Label Use of FDA-Approved Drugs, dru031

Codes	Number	Description
None		

Appendix 1: FDA MedWatch (Voluntary) Form & Instructions

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

MEDWATCH

For VOLUNTARY reporting of
adverse events, product problems and
product use errors

The FDA Safety Information and
Adverse Event Reporting Program

Page ____ of ____

FDA USE ONLY	
Triage unit sequence #	

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION			
1. Patient Identifier <small>In confidence</small>	2. Age at Time of Event, or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ lb or ____ kg
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR			
Check all that apply:			
1. <input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input type="checkbox"/> Product Use Error <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death: _____ <input type="checkbox"/> Disability or Permanent Damage <small>(mm/dd/yyyy)</small>			
<input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect			
<input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events)			
<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
3. Date of Event (mm/dd/yyyy)		4. Date of this Report (mm/dd/yyyy)	
5. Describe Event, Problem or Product Use Error			
6. Relevant Tests/Laboratory Data, Including Dates			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)			
C. PRODUCT AVAILABILITY			
Product Available for Evaluation? (Do not send product to FDA)			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: _____ <small>(mm/dd/yyyy)</small>			

D. SUSPECT PRODUCT(S)			
1. Name, Strength, Manufacturer (from product label)			
#1 _____			
#2 _____			
2. Dose or Amount		Frequency	Route
#1 _____		_____	_____
#2 _____		_____	_____
3. Dates of Use (if unknown, give duration) from/to (or best estimate)			5. Event Abated After Use Stopped or Dose Reduced?
#1 _____			#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2 _____			#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
4. Diagnosis or Reason for Use (Indication)			8. Event Reappeared After Reintroduction?
#1 _____			#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2 _____			#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
6. Lot #	7. Expiration Date		
#1 _____	#1 _____		
#2 _____	#2 _____		
9. NDC # or Unique ID			
E. SUSPECT MEDICAL DEVICE			
1. Brand Name			
2. Common Device Name			
3. Manufacturer Name, City and State			
4. Model #	Lot #	5. Operator of Device	
Catalog #	Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Health Professional	
Serial #	Other #	<input type="checkbox"/> Lay User/Patient	
		<input type="checkbox"/> Other: _____	
6. If Implanted, Give Date (mm/dd/yyyy)		7. If Explanted, Give Date (mm/dd/yyyy)	
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input type="checkbox"/> No			
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor			
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS			
Product names and therapy dates (exclude treatment of event)			
G. REPORTER (See confidentiality section on back)			
1. Name and Address			
Phone #		E-mail	
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation	4. Also Reported to:	
		<input type="checkbox"/> Manufacturer	
		<input type="checkbox"/> User Facility	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>		<input type="checkbox"/> Distributor/Importer	

FORM FDA 3500 (10/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: <http://www.fda.gov/medwatch/report/consumer/instruct.htm>

Report adverse events, product problems or product use errors with:

- Medications (*drugs or biologics*)
- Medical devices (*including in-vitro diagnostics*)
- Combination products (*medication & medical devices*)
- Human cells, tissues, and cellular and tissue-based products
- Special nutritional products (*dietary supplements, medical foods, infant formulas*)
- Cosmetics

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization - initial or prolonged
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (*or both*)

Other methods of reporting:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone
- www.fda.gov/medwatch/report.htm -- To report online

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves a serious adverse event with a vaccine call 1-800-822-7967 to report.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The public reporting burden for this collection of information has been estimated to average 36 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

*Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002*

*Please DO NOT
RETURN this form
to this address.*

*OMB statement:
"An agency may not conduct or sponsor, and a
person is not required to respond to, a collection of
information unless it displays a currently valid
OMB control number."*

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FORM FDA 3500 (10/05) (Back)

Please Use Address Provided Below -- Fold in Thirds, Tape and Mail

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use \$300

BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

