BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE:	**12/01/11**
LAST REVIEW DATE:	**02/21/19**
LAST CRITERIA REVISION DATE:	**02/21/19**
ARCHIVE DATE:	

COMPOUNDED MEDICATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

COMPOUNDED MEDICATION (cont.)

Criteria:

- **Criteria for initial therapy:** Compound medication is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Medical necessity or justification for use is submitted with the request by prescriber office

2. Use of the requested compound must
   - follow plan specific benefit design
   - not be used for cosmetic purpose
   - not be considered manufacturing and/or distribution

3. Individual has failure, contraindication or intolerance to a commercially available alternative product used in the same route as the requested compound for the given diagnosis and proposed duration of therapy

4. For ingredient(s) that normally require precertification, all criteria for precertification of the ingredient(s) are met

5. The compound medication must contain at least one FDA-approved federal legend drug

6. The active ingredient(s) in the compound medication is/are FDA-approved or supported by national compendia or peer-reviewed scientific literature for the
   - diagnosis
   - route of delivery
   - therapeutic amounts
   - safety and effectiveness
   - proposed duration of therapy

7. The compound prescription meets **ONE** of the following:
   - Requested compound is not already commercially available in the dosage form, route of administration, or dose requested from any pharmaceutical manufacturer
   - Contains an ingredient(s) that is/are in short supply
   - Compound needs to be prepared without some of the inactive ingredients (such as dyes, preservatives, sugars, flavoring, etc.) that are found in the commercially available product
   - Individual requires a unique dosage form or concentration because individual is unable to take a solid dosage form or dose based on age or weight

8. The compound must not contain **ANY** of the following:
   - Ingredient(s) used for non-FDA approved use for the diagnosis being treated
   - Ingredient(s) that are investigational or experimental
   - Ingredient(s) not FDA approved for compounding
   - Ingredient(s) that has been removed from the market due to safety or effectiveness concerns
   - Ingredient(s) compound for the purpose of convenience only

Initial approval duration: 6 months

COMPOUNDED MEDICATION (cont.)

- **Criteria for continuation of coverage (renewal request):** Compounded medication is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. The individual has benefited from therapy but remains at high risk
  2. The condition has not progressed or worsened while on therapy
  3. The request is for the same compound as originally approved (same dose form, strength, ingredients, etc.)
  4. Individual has been adherent with the medication
  5. Individual has not developed any contraindications or other exclusions to its continued use

  Renewal duration: 12 months

Description:

Compounded medications are medications that contain at least one FDA-approved prescription component and are custom-mixed by a pharmacist or other healthcare professional to create a medication tailored to an individual patient's need. It must contain at least one federal legend drug in therapeutic amounts. A federal legend drug is defined as a medication product whereby federal law prohibits dispensing without a prescription. The compounded medication must not be already commercially available in the dosage form, route of administration, or dose from any pharmaceutical manufacturer. Bulk chemicals, medical food supplements and nutritional additives not approved for dispensing by prescription are not considered federal legend drugs.

Compound prescriptions are only available through the retail pharmacy benefit. Compounded prescriptions are not available through the mail order pharmacy benefit.

Definitions:

National Compendia:

American Hospital Formulary Service
Micromedex/DrugDex
Elsevier Gold Standard's Clinical Pharmacology compendium
United States Pharmacopeia
National Formulary Monograph
Other authoritative reference as identified by the Secretary of the United States Department of Human Health Services

COMPOUNDED MEDICATION (cont.)

Resources:

Food and Drug Administration: Bulk Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act. 503A Lists 1-4. Accessed February 14, 2016

Food and Drug Administration: Bulk Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act. 503B Lists 1-4. Accessed February 14, 2016

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Compounded Medication

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information			
Pharmacy Name:	NPI#:	Pharmacy Phone:	Pharmacy Fax:

Prescription Medication Information (COPY OF ORIGINAL PRESCRIPTION REQUIRED – please attach)			
Final Product Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Ingredients (COPY OF INVOICE REQUIRED for products without a valid NDC – please attach)

Active Drug Ingredient	Strength	NDC	Quantity	X Cost/Unit	= Totals
		Compounding Fee:			
		Total Cost for Compound:			

Method of Compounding (COPY OF RECIPE REQUIRED – please attach) Document any additional information or deviation from recipe below.

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Medical necessity or justification for use is submitted with the request by prescriber office.**

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Pharmacy Prior Authorization Request Form
Compounded Medication

3. ☐ Yes ☐ No **Individual has failure, contraindication or intolerance to a commercially available alternative product used in the same route as the requested compound for the given diagnosis and proposed duration of therapy.**

4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.

Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.

For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.