Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health	**Submission Date:** 9/1/2020
Policy Number:	**Effective Date:** 12/1/10 **Revision Date:** 8/2020
Policy Name: Compounded Agents	
Type of Submission – Check all that apply: ☐ **New Policy** ☐ **Revised Policy** **X Annual Review – No Revisions**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Updated criteria per P&T annual review. Thank you.	
Name of Authorized Individual (Please type or print): **Natalie Nkurunziza, Pharm.D.**	**Signature of Authorized Individual:** 

AETNA BETTER HEALTH®

Non-Formulary Prior Authorization guideline for Compounded Prescriptions

Authorization guidelines

Compounded drug products will be covered when the following criteria are met:

A. Each active ingredient is FDA-approved (bulk chemicals also known as Active Pharmaceutic Ingredient "API")
B. Each active ingredient is used for an indication that is FDA-approved or compendia supported
C. The final route of administration of the compound is the same as the FDA-approved or compendia supported route of administration of each active ingredient.
   AND
   Either of the following:
   1. If a member has an allergy and requires a medication to be compounded without a certain active ingredient (e.g. dyes, preservatives, fragrances). This situation requires submission of an FDA MedWatch form.
      OR
   2. If a member cannot consume the medication in any of the available formulations and the medication is medically necessary.
      OR
   3. Request is for a formulary antibiotic or anti-infective for injectable use
      OR
   4. Commercial prescription product is unavailable due to a market shortage (or discontinued) and is medically necessary
      OR
   5. Exceptions to the above will be evaluated by the Medical Director

Additional Information:

Compounds are NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**

- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

NOTE: ***All compounds will require authorization and clinical review if total submitted cost exceeds $200.***

Approval Duration:

For market shortages: 3 months

All others: 1 year

Renewals:
For market shortages: 3 months

All others: 1 year

The following compounds are examples of preparations that Aetna considers to be experimental and investigational, because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness.

- Bioidentical hormones and implantable estradiol pellets
- Nasal administration of nebulized anti-infectives for treatment of sinusitis
- Topical Ketamine, Antidepressants
- Topical Anticonvulsants products for use for pain
- Proprietary bases: PCCA Lipoderm Base, PCCA Custom Lipo-Max Cream, Versabase Cream, Versapro Cream, PCCA Pracasil Plus Base, Spirawash Gel Base, Versabase Gel, Lipopen Ultra Cream, Lipo Cream Base, Pentravan Cream/Cream Plus, VersaPro Gel, Versatile Cream Base, PLO Transdermal Cream, Transdermal Pain Base Cream, PCCA Emollient Cream Base, Penderm, Salt Stable LS Advanced Cream, Ultraderm Cream, Base Cream Liposome, Mediderm Cream Base, Salt Stable Cream

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.