1. **Background:**
Compounded medications can provide a unique route of delivery for certain patient-specific conditions and administration requirements. Compounded medications should be produced for a single individual and not produced on a large scale. A dollar threshold may be used to identify compounds which require Notification and must meet the criteria below in order to be covered. Drugs included in the compound must be a covered product.

2. **Coverage Criteria:**

A. **Authorization** for compounds and bulk powders will be approved based on all of the following criteria:

1. The requested drug component is a covered medication

   -AND-

2. The requested drug component is to be administered for an FDA-approved indication

   -AND-

3. If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

   -AND-

4. If the drug component is no longer available commercially it must not have been withdrawn for safety reasons

   -AND-

5. **One** of the following:

   a. A unique vehicle is required for topically administered compounds

   -OR-
b. A unique dosage form is required for a commercially available product due to patient’s age, weight or inability to take a solid dosage form.

-OR-

c. A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

-AND-

6. Coverage for compounds and bulk powders will NOT be approved for any of the following:

a. Requested compound contains any of the following ingredients which are available as over-the-counter products:

(1) Cetyl Myristoleate
(2) Coenzyme Q10
(3) Methylcobalamin
(4) Hyaluronic Acid
(5) Nicotinamide
(6) Methyltetrahydrofolate
(7) Ibuprofen
(8) Lipoic acid
(9) Beta Glucan
(10) Ubiquinol
(11) Chrysin
(12) Glutathione
(13) Lactobacillus
(14) Vitamin E
(15) Ascorbic Acid
(16) Melatonin
(17) Pyridoxal-5-Phosphate (Vitamin B6)
(18) Loperamide
(19) Dextromethorphan
(20) Dehydroepiandrosterone
(21) Pregnenolone
(22) Biotin
(23) L-Glutamine
(24) Serotonin
(25) Aloe vera
(26) Sodium butyrate
(27) L-Isoleucine
(28) Vitamin D3
(29) Ginseng
(30) Phosphatidylerine
(31) Resveratrol
(32) Methionine
(33) Naproxen
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>34</td>
<td>Carnosine L</td>
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<tr>
<td><strong>-OR-</strong></td>
<td><strong>-OR-</strong></td>
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<tr>
<td>b. For topical compound preparations (e.g. creams, ointments, lotions or gels to be applied to the skin for transdermal, transcutaneous or any other topical route), requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:</td>
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<tr>
<td>(1)</td>
<td>Ketamine</td>
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<tr>
<td>(2)</td>
<td>Gabapentin</td>
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<tr>
<td>(3)</td>
<td>Flurbiprofen (topical ophthalmic use not included)</td>
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<tr>
<td>(4)</td>
<td>Ketoprofen</td>
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<tr>
<td>(5)</td>
<td>Morphine</td>
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<td>(6)</td>
<td>Nabumetone</td>
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<td>(7)</td>
<td>Oxycodone</td>
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<tr>
<td>(8)</td>
<td>Cyclobenzaprine</td>
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<td>(9)</td>
<td>Baclofen</td>
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<td>(10)</td>
<td>Tramadol</td>
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<td>(11)</td>
<td>Hydrocodone</td>
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<tr>
<td>(12)</td>
<td>Meloxicam</td>
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<td>(13)</td>
<td>Amitriptyline</td>
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<td>(14)</td>
<td>Pentoxifylline</td>
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<td>(15)</td>
<td>Orphenadrine</td>
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<td>(16)</td>
<td>Piroxicam</td>
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<td>(17)</td>
<td>Levocetirizine</td>
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<td>(18)</td>
<td>Amantadine</td>
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<td>(19)</td>
<td>Oxytocin</td>
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<td>(20)</td>
<td>Sumatriptan</td>
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<tr>
<td>(21)</td>
<td>Chorionic gonadotropin (human)</td>
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<td>(22)</td>
<td>Clomipramine</td>
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<tr>
<td>(23)</td>
<td>Dexamethasone</td>
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<td>(24)</td>
<td>Hydromorphone</td>
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<td>(25)</td>
<td>Methadone</td>
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<td>(26)</td>
<td>Papaverine</td>
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<tr>
<td>(27)</td>
<td>Mefenamic acid</td>
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<td>(28)</td>
<td>Promethazine</td>
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<td>(29)</td>
<td>Succimer DMSA</td>
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<td>(30)</td>
<td>Tizanidine</td>
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<td>(31)</td>
<td>Apomorphine</td>
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<td>(32)</td>
<td>Carbamazepine</td>
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<td>(33)</td>
<td>Ketorolac</td>
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<tr>
<td>(34)</td>
<td>Dimercaptopropane-sulfonate</td>
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<td>(35)</td>
<td>Dimercapto succinic acid</td>
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<tr>
<td>(36)</td>
<td>Duloxetine</td>
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<tr>
<td>(37)</td>
<td>Fluoxetine</td>
</tr>
</tbody>
</table>
c. Requested compound contains topical fluticasone. Topical fluticasone will NOT be approved unless:

(1) Topical fluticasone is intended to treat a dermatologic condition. Scar treatments are considered cosmetic and will not be covered (refer to criteria “c” below).

-AND-

(2) Patient has a contraindication to all commercially available topically fluticasone formulations

-OR-

d. Requested compound contains leuprolide when prescribed for off-label use (refer to leuprolide criteria)

-OR-

e. Requested compound contains any of the following ingredients when used for cosmetic purposes:
   (1) Hydroquinone
   (2) Acetyl hexapeptide-8
   (3) Tocopheryl Acid Succinate
   (4) PracaSil TM-Plus
   (5) Chrysaderm Day Cream
   (6) Chrysaderm Night Cream
   (7) PCCA Spira-Wash
   (8) Lipopen Ultra
   (9) Versapro
   (10) Fluticasone
   (11) Mometasone
   (12) Halobetasol
   (13) Betamethasone
   (14) Clobetasol
   (15) Triamcinolone
   (16) Minoxidil
   (17) Tretinoin
   (18) Dexamethasone
   (19) Spironolactone
   (20) Cycloserine
   (21) Tamoxifen
   (22) Sermorelin
   (23) Mederma Cream
   (24) PCCA Cosmetic HRT Base
   (25) Sanare Scar Therapy Cream
   (26) Scarin Cream
   (27) Apothederm
   (28) Stera Cream
(29) Copasil  
(30) Collagenase  
(31) Arbutin Alpha  
(32) Nourisil

-OR-

f. Requested compound contains cholestyramine when prescribed for off-label use. (FDA labeled uses include: hypercholesterolemia, coronary artery atherosclerosis, and pruritus associated with biliary obstruction)

-OR-

g. Requested compound contains any of the following ingredients which are on the FDA’s Do Not Compound List:
   (1) 3,3′,4′,5-tetrachlorosalicylanilide  
   (2) Adenosine phosphate  
   (3) Adrenal cortex  
   (4) Alatrofloxacan mesylate  
   (5) Aminopyrine  
   (6) Astemizole  
   (7) Azaribine  
   (8) Benoxaprofen  
   (9) Bithionol  
   (10) Camphorated oil  
   (11) Carbetapentane citrate  
   (12) Casein, iodinated  
   (13) Cerivastatin sodium  
   (14) Chlormadinone acetate  
   (15) Chloroform  
   (16) Cisapride  
   (17) Exfenfluramine hydrochloride  
   (18) Diamthazole dihydrochloride  
   (19) Dibromsalan  
   (20) Dihydristreptomycin sulfate  
   (21) Dipyrrone  
   (22) Encainide hydrochloride  
   (23) Etretinate  
   (24) Fenfluramine hydrochloride  
   (25) Flosequinan  
   (26) Glycerol, iodinated  
   (27) Grepafloxacin  
   (28) Mepazine  
   (29) Metabromsalan  
   (30) Methapyrilene  
   (31) Methopholine  
   (32) Methoxyflurane  
   (33) Mibefradil dihydrochloride  
   (34) Nomifensine maleate  
   (35) Novobiocin sodium
Authorization will be issued for 12 months

a For Kentucky, requests for therapeutic food, formulas, supplements, low-protein modified food products, vitamins, nutritional supplements and amino acid-based elemental medical formula for the treatment of inborn errors of metabolism, genetic conditions, mitochondrial disease, food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic disorders, or short-bowel syndrome may be approved through review by UnitedHealthcare Pharmacy. Please note there is a plan year cap of twenty five thousand dollars ($25,000) for therapeutic foods, formulas and supplements, and a separate cap for each plan year of four thousand dollars ($4,000) on low-protein modified foods. Each cap shall be subject to annual inflation adjustments based on the consumer price index.
3. **Additional Clinical Rules:**
   - Supply limits, Step Therapy and/or Prior Authorization may be in place.

4. **References:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Notification - Compounds and Bulk Powders</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td><strong>Change</strong></td>
</tr>
<tr>
<td>7/2013</td>
<td>Topical use section updated to include all medications that are not FDA approved for topical use. Reformatted to standard.</td>
</tr>
<tr>
<td>10/2013</td>
<td>Added the following to the list of compound ingredients that are not covered: ibuprofen, lipoic acid, beta glucan, ubiquinol, chrysin, glutathione, lactobacillus, vitamin E, ascorbic acid, melatonin, meloxicam, amitriptyline, pentoxifylline, orphenadrine, piroxicam, acetyl hexapeptide-8, tocopheryl acid succinate, PracaSil TM-Plus, Chrysaderm Day Cream, Chrysaderm Night Cream, PCCA Spira-Wash and Lipopen Ultra.</td>
</tr>
<tr>
<td>11/2013</td>
<td>Added criteria for topical fluticasone.</td>
</tr>
<tr>
<td>2/2014</td>
<td>Added criteria for cholestyramine.</td>
</tr>
<tr>
<td>4/2014</td>
<td>Added pyridoxal-5-phosphate (Vitamin B6) and loperamide to list of ingredients that will not be coverage as they are available OTC. Added levocetirizine, amantadine, oxytocin, sumatriptan and chorionic gonadotropin to list of ingredients that will not be covered for topical use. Added Versapro to list of ingredients that will not be covered for cosmetic use.</td>
</tr>
<tr>
<td>10/2014</td>
<td>Added Dextromethorphan, Dehydroepiandrosterone, Pregnenolone, Biotin, L-Glutamine, Serotonin, Aloe vera, Sodium butyrate, L-Isoleucine and Vitamin D3 to the list of ingredients that will not be covered as they are available OTC. Added Clomipramine, Dexamethasone, Hydromorphone, Methadone, Papaverine, Mefenamic acid, Promethazine, Succimer DMSA, Tizanidine, Apomorphine, Carbamazepine, Ketorolac, Dimercaptopropane-sulfonate and Dimercaptosuccinic acid to the list of ingredients that will not be covered for topical use. Added Fluticasone, Mometasone, Halobetasol, Betamethasone, Clobetasol, Triamcinolone, Minoxidil, Tretinoin, Dexamethasone, Spironolactone, Cycloserine, Tamoxifen and Sermorelin to the list of ingredients that will not be covered for cosmetic use. Removed criterion that a similar commercially available product is not available.</td>
</tr>
<tr>
<td>4/2015</td>
<td>Updated criteria to reflect that if any drug ingredient of the compound requires prior authorization and/or step therapy, that clinical criteria must also be met. Added ginseng, phosphatidylserine and resveratrol to the ingredients that will not be covered as they are available OTC. Added Mederma Cream, PCCA Cosmetic HRT Base, Sanare Scar</td>
</tr>
<tr>
<td>Date</td>
<td>Changes</td>
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<tr>
<td>7/2015</td>
<td>Added to the criteria ingredients that should not be compounded as they reside on the FDA’s Do Not Compound List. Clarified language around commercially available products.</td>
</tr>
<tr>
<td>4/2016</td>
<td>Added criteria to allow for coverage when patient has an allergy to the commercially available product. Added methionine and naproxen to ingredients that will not be covered as they are available OTC. Added Apothederm to the list of ingredients that will not be covered for cosmetic use.</td>
</tr>
<tr>
<td>10/2016</td>
<td>Removed language that a unique dosage form is required and the commercially available product is excluded. Added Kentucky state mandate language. Added carnosine L to the ingredients that will not be covered as they are available OTC. Added duloxetine and fluoxetine to the ingredients that will not be covered for topical use. Added Stera cream, Copasil, collagenase, arbutin alpha, and Nourisil to the list of ingredients that will not be covered for cosmetic use.</td>
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</tbody>
</table>