Clinical Pharmacy Program Guidelines for Compounds and Bulk Powders

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<th>Program</th>
<th>Prior Authorization</th>
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<td>Medication</td>
<td>Compounds and Bulk Powders</td>
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<tr>
<td>Issue Date</td>
<td>7/2013</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>4/2017</td>
</tr>
<tr>
<td>Effective Date</td>
<td>6/2017</td>
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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. One of the following:
      a. The requested drug component is to be administered for an FDA-approved indication

     -OR-

      b. The use of this drug is supported by information from the appropriate compendia of current literature*.

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 If the drug component is no longer available commercially it must not have been withdrawn for safety reasons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

   -OR-

b. 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 “e” below).

   -AND-

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

   -OR-

c. Requested compound contains any ingredients when used for cosmetic purposes.
-OR-

d. Requested compound contains any ingredient(s) which are on the FDA’s Do Not Compound List.

Authorization will be issued for 12 months

*Compendia of Current Literature:  • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologies Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology • United States Pharmacopoeia-National Formulary (USP-NF) • United States Pharmacopoeia Drug Information (USP DI)

APPENDIX

Example topical compound preparations (e.g. creams, ointments, lotions or gels to be applied to the skin for transdermal, transcutaneous or any other topical route) that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

(1) Ketamine
(2) Gabapentin
(3) Flurbiprofen (topical ophthalmic use not included)
(4) Ketoprofen
(5) Morphine
(6) Nabumetone
(7) Oxycodone
(8) Cyclobenzaprine
(9) Baclofen
(10) Tramadol
(11) Hydrocodone
(12) Meloxicam
(13) Amitriptyline
(14) Pentoxifylline
(15) Orphenadrine
(16) Piroxicam
(17) Levocetirizine
(18) Amantadine
(19) Oxytocin
(20) Sumatriptan
(21) Chorionic gonadotropin (human)
(22) Clomipramine
(23) Dexamethasone
(24) Hydromorphone
(25) Methadone
(26) Papaverine
(27) Mefenamic acid
(28) Promethazine
Example compound(s) that contain ingredients 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. Scarcin Cream
27. Apotheaderm
28. Stera Cream
29. Copasil
30. Collagenase
31. Arbutin Alpha
32. Nourisil

Example ingredients on the FDA’s Do Not Compound List:

1. 3,3′,4′,5′-tetrachlorosalicylanilide
2. Adenosine phosphate
3. Adrenal cortex
4. Alatrofloxacin 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) Dihydrostreptomycin sulfate
(21) Dipyrone
(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
(36) Oxyphenisatin acetate
(37) Oxyphenisatin
(38) Pemoline
(39) Pergolide mesylate
(40) Phenacetin
(41) Phenformin hydrochloride
(42) Phenylpropanolamine
(43) Pipamazine
(44) Potassium arsenite
(45) Propoxyphene
(46) Rapacuronium bromide
(47) Rofecoxib
(48) Sibutramine hydrochloride
(49) Sparteine sulfate
(50) Sulfadimethoxine
(51) Sweet spirits of nitre
(52) Tegaserod maleate
(53) Temafloxacin hydrochloride
(54) Terfenadine
(55) Ticrynafen
(56) Tribromsalan
(57) Trichloroethane
(58) Troglitazone
(59) Trovafloxacin mesylate:
(60) Urethane
(61) Valdecoxib
(62) Zomepirac sodium

3. References:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<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>
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<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 chiorionic 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>
</tbody>
</table>
| 10/2014 | 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 Dimercapto succinic 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
<table>
<thead>
<tr>
<th>Date</th>
<th>Changes Description</th>
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<tbody>
<tr>
<td>4/2015</td>
<td>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 Therapy Cream, and Scarcin Cream to the ingredients that will not be covered for cosmetic use.</td>
</tr>
<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 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>
</tr>
<tr>
<td>12/2016</td>
<td>Moved examples of drugs not approved for topical use, cosmetic use, and FDA’s do not compound list to the appendix. Removed statements about leuprolide and cholestyramine since both pertain to off-label use and this would be covered elsewhere in the criteria.</td>
</tr>
<tr>
<td>4/2017</td>
<td>Added approval for compendia supported uses in addition to FDA approved indications.</td>
</tr>
</tbody>
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