UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Compounds and Bulk Powders

Program	Prior Authorization
Medication	Compounds and Bulk Powders
Markets in Scope	Arizona, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	7/2013
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

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 prior authorization and must meet the criteria below in order to be approved. 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 (includes bulk powders requested as a single ingredient when the powder formulation requested is not the commercially available FDA approved product):

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 If the drug component is no longer available commercially it must not have been withdrawn for safety reasons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. **<u>One</u>** 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

   -OR-

   d. There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP Current Drug Shortages tracking log

-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

-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 Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology • United States Pharmacopoeia-National Formulary (USP-NF)

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
(29) Succimer DMSA
(30) Tizanidine
(31) Apomorphine
(32) Carbamazepine
(33) Ketorolac
(34) Dimercaptopropane-sulfonate
(35) Dimercaptosuccinic acid
(36) Duloxetine
(37) Fluoxetine
(38) Bromfenac (topical ophthalmic use not included)
(39) Nepafenac (topical ophthalmic use not included)

Example compounds 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) Apothederm
(28) Stera Cream
(29) Copasil
(30) Collagenase
(31) Arbutin Alpha
(32) Nourisil
(33) Freedom Cepapro
(34) Freedom Silomac Andydrous
(35) Retinaldehyde
(36) Apothederm

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) Defenfluramine 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. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

1. Food and Drug Administration (2014, July 02). Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety and Effectiveness. Retrieved from http://federalregister.gov/a/2014-15371
2. FDA Drug Shortages. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA. Available at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_SearchResults.cfm
3. ASHP Current Drug Shortages. Available at: https://www.ashp.org/Drug-Shortages/Current-Shortages

Program	Prior Authorization - Compounds and Bulk Powders
Change Control	
Date	Change
7/2013	Topical use section updated to include all medications that are not FDA approved for topical use. Reformatted to standard.
10/2013	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.
11/2013	Added criteria for topical fluticasone.
2/2014	Added criteria for cholestyramine.
4/2014	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.
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 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.
4/2015	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.
7/2015	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.
4/2016	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.
10/2016	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.
12/2016	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.
4/2017	Added approval for compendia supported uses in addition to FDA approved indications.
10/2017	Added bromfenac and nepafenac to the ingredients that will not be covered for topical use. Added Freedom Cepapro, Silomac Anhydrous, Retinaldehyde and Apothederm to the list of ingredients that will not be covered for cosmetic use.
7/2018	Removed "refer to criteria "e" below" since there is no longer criteria "e" in the policy
10/2019	Annual review. Clarified that bulk powders are included when not included in a compound.
5/2020	Updated to allow coverage of a compound when there is a shortage of the commercially available product.