UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Compounds - TEXAS

Program	Prior Authorization
Medication	Compounds
Markets in Scope	Texas

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 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. **Both** of the following:

a. **One** of the following:

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

-OR-

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

-AND-

b. Coverage for compounds will **NOT** be approved for any of the following:

i. 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-

ii. 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 "iii" below).

-AND-

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

-OR-

iii. Requested compound contains any ingredients when used for cosmetic purposes.

-OR-

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

-AND-

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

-AND-

4. If the drug or drug component is no longer available commercially, it must not have been withdrawn or removed from the market for safety reasons.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 or strength is required for a commercially available product due to patient's specific medical needs.

-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. A compounded oral medication is being requested for patients 12 years of age or younger.

-OR-

e. The drug or drug component is commercially available but is currently on backorder or is in short supply

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) • 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
(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) 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

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.

Program	Prior Authorization - Compounds
Change Control	
Date	Change
1/2018	Texas specific policy created.
10/2019	Annual review. Clarified that bulk powders are included when not included in a compound.