UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1014-18
Program	Prior Authorization/Notification
Medication	Compounds and Bulk Powders
P&T Approval Date	1/2012, 02/2013, 04/2013, 07/2013, 10/2013, 11/2013, 2/2014, 4/2014, 10/2014, 4/2015, 7/2015, 4/2016, 10/2016, 10/2017, 10/2018, 10/2019, 5/2020, 1/2021, 3/2022, 3/2023, 3/2024, 4/2025, 6/2025
Effective Date	7/1/2025

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.

Claims for patients under the age of 6 will process automatically for First-Lansoprazole, First-Omeprazole, and Omeprazole + Syrspend SF compounding kits.

2. Coverage Criteria[a]:

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 such as bulk powder formulations of cholestyramine or nystatin when the powder formulation requested is not the commercially available FDA approved product):

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 If the drug component is no longer available commercially it must not have been withdrawn for safety reasons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

   a. A unique vehicle is required

   -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. 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) Phosphatidylserine
(31) Resveratrol
(32) Methionine
(33) Naproxen
(34) Carnosine L
(35) Arnica LG

-OR-

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:

(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)

-OR-

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 "e" 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 is for cosmetic use or 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) 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

-OR-

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

-OR-

g. Requested compound contains nystatin when prescribed for an off-label use.

-OR-

h. 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) 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

Authorization will be issued for 12 months

B. **Authorization** for the compounding kits **First-Lansoprazole ,First-Omeprazole** and **Omeprazole + Syrspend SF** will be approved based on **all** of the following criteria:

1. The requested drug component in the compounding kit is to be administered for an FDA-approved indication

-AND-

2. **One** of the following:

a. A unique dosage form is required for a covered commercially available product due to the patient's age, weight or inability to take a solid dosage form.

-OR-

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

Authorization will be issued for 12 months

C. **Authorization** for compounded oral budesonide for the treatment of eosinophilic esophagitis will be approved based on the following criteria (all other indications refer to general criteria in Section A):

1. Compounded oral budesonide is requested for the treatment of eosinophilic esophagitis

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.

* For appeals only: An injectable product which is intended to be used for a route of administration typically covered on the pharmacy benefit (e.g. topical, intranasal, oral) will be considered a compound for the purposes of this clinical pharmacy program.

3. Additional Clinical Rules:

- Supply limits, Step Therapy and/or Prior Authorization 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 https://www.federalregister.gov/d/2014-15371
2. FDA Drug Shortages. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages3. ASHP Current Drug Shortages. Available at: https://www.ashp.org/Drug-Shortages/Current-Shortages

Program	Prior Authorization/Notification - 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 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.
10/2017	Added criteria for First-Lansoprazole and First-Omeprazole. Added Arnica LG to the ingredients that will not be covered as they are available OTC. 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.
10/2018	Annual review. No changes.
10/2019	Annual review. Clarified that bulk powders are included when not included in a compound. Added criteria for nystatin powder.
5/2020	Updated to allow coverage of a compound when there is a shortage of the commercially available product. Clarified that compounds for cosmetic use will not be covered.
1/2021	Added Omeprazole Syrspend + SF compounding kit to criteria. Removed note that First Omeprazole and First Lansoprazole are typically excluded from coverage.
3/2022	Added note that injectable products intended for use with a route of administration typically covered under the pharmacy benefit may be reviewed with these criteria. Updated requirement that a unique vehicle is needed and removed specifically for a topical product.
3/2023	Annual review. No changes.
3/2024	Annual review. No changes.
4/2025	Annual review. Updated references.
6/2025	Oral budesonide added to criteria.