

1 . Criteria

Product Name: Standard criteria for compound medications	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Evidence in the compendia of current literature (e.g. AHFS, Micromedex, current accepted guidelines, etc.) that show the safety, efficacy, and improvement in net health outcomes concerning this compound therapy when compared to existing therapy for the medical condition being treated. (Articles must be submitted with PA request)</p> <p style="text-align: center;">AND</p> <p>2 - The patient must not have a clinical contraindication to any component of the requested product</p> <p style="text-align: center;">AND</p> <p>3 - Drugs prescribed must be for purposes that are medically necessary</p> <p style="text-align: center;">AND</p> <p>4 - Each of the active ingredients in the compound must be used for an indication that is FDA-approved or compendia supported.</p> <p style="text-align: center;">AND</p> <p>5 - The route of administration of the compound must be the same as the FDA-approved or compendia supported route of administration for each active ingredient</p> <p style="text-align: center;">AND</p>	

6 - The dosing must be within guidelines for each active ingredient

AND

7 - The compound must contain at least 1 formulary prescription medication

AND

8 - Each of the active ingredients in the compound are FDA-approved drugs

AND

9 - One of the following:

- There is a current supply shortage of the commercial product
- The patient has a medical need for a dosage form or strength that is not commercially available
- The patient had a trial and intolerance or contraindication to the commercially available product
- The commercially available product has been discontinued by the manufacturer for reasons other than lack of safety or effectiveness

AND

10 - If there are FDA-approved therapies or other standard therapies for the medical condition being treated, such therapies must have been tried and failed or been contraindicated for the patient. (Medication usage must be documented in patient's medical records)

AND

11 - For compounds of an oral liquid formulation of a solid dosage form, all of the following:

- It must contain only 1 prescription product
- It may or may not also contain OTC products
- The patient must be unable to take the solid dosage form or there is no corresponding dose available in the solid dosage form

- There must not be a commercially available liquid formulation of the product in the same strength

AND

12 - Request for compound drug coverage can not be approved for one of the following:

12.1 Request is for a compounded bioidentical hormone product for hormone replacement therapy

OR

12.2 The compound is being used for cosmetic use, medical (wound) dressing, topical emollient, anti-aging, or convenience

OR

12.3 Request is for oral vancomycin compound and it is being compounded with anything other than vancomycin injectable

OR

12.4 Compounds to be applied topically (ie, cream, gel, lotion, ointment, solution) which contain bulk powders, or any ingredient that is not FDA-approved for topical use, or any of the following ingredients:

12.4.1 Amitriptyline *Baclofen *Cholestyramine *Cyclobenzaprine *Dexamethasone (except ophthalmic solution) *Flurbiprofen (except ophthalmic solution) *Fluticasone propionate *Gabapentin *Hyaluronate (except ophthalmic solution) *Itraconazole *Ketamine *Ketoprofen *Ketorolac (except ophthalmic solution) *Lamotrigine *Meloxicam *Penlac *Sumatriptan *Tramadol **Compounds which contain any of the following ingredients: **Androstanolone Powder **Androstenediol (Bulk) Powder **Androstenedione (Bulk) Powder **Androsterone (Bulk) Powder **Dienestrol (Bulk) Powder **Dihydrotestosterone Propionate Powder **Epitestosterone (Bulk) Powder **Estradiol Benzoate (Bulk) Powder **Estradiol Cypionate (Bulk) Powder **Estradiol Micronized Powder **Estradiol Powder **Estradiol Valerate (Bulk) Powder **Estril Micronized Powder **Estrogens, Conjugated Powder **Estrone Crystals **Estrone Powder **Estropipate (Bulk) Powder **Ethinyl Estradiol Powder **Hydroxyprogesterone Caproate (Bulk) Powder **Medroxyprogesterone Acetate Micronized (Bulk) Powder **Medroxyprogesterone Micronized Powder **Methyltestosterone Powder **Norethindrone (Bulk) Powder **Norethindrone Acetate Powder **Progesterone Micronized Powder (excluding progesterone suppositories) **Progesterone Powder (excluding

progesterone suppositories) **Testosterone Cypionate Powder **Testosterone Decanoate (Bulk) Powder **Testosterone Enanthate (Bulk) Powder **Testosterone Isocaproate (Bulk) Powder **Testosterone Phenylpropionate (Bulk) Powder **Testosterone Powder
**Testosterone Propionate Powder