Mass General Brigham
Health Plan

Compounded Drugs
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria is met:

1. Each active ingredient in the compounded drug is FDA-approved or national compendia supported for the condition being treated.
2. The therapeutic amounts are supported by the national compendia or two peer-reviewed literature for the condition being treated in the requested route of delivery.
3. If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must also be met.
4. The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (refer to Appendix).
5. The patient has tried and failed therapy or had an intolerance to two FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless ONE of the following criteria are met:
    1. Member has a contraindication to commercially available products.
    2. One or no other therapeutic alternatives are commercially available.
    3. Prepared in a strength not commercially available or currently in short supply.
    4. Prepared in a different dosage form for a member who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).
    5. Member has an allergy or sensitivity to inactive ingredients (e.g., dyes, preservatives, sugars, etc.) that are found in commercially available products.
6. The compounded drug must not be used for a cosmetic purpose.

7. If the compound is subject to the drug-specific/targeted compound program, the member meets all the applicable drug-specific criteria for all the targeted ingredient(s) used in the requested compound product (See below for drug-specific/targeted compound program).

For diclofenac compounds:

1. Member is 18 years of age or older.
2. Member has a diagnosis of one of the following:
    a. Osteoarthritis
    b. Rheumatoid arthritis
    c. Mild to moderate pain
    d. Pain due to minor strains, sprains, or contusions
    e. Migraine
    f. Primary dysmenorrhea
    g. Actinic keratosis
    h. Ankylosing spondylitis
    i. Inflammatory disorder of the eye
    j. Photophobia
    k. Pain in the eye
3. The final dosage form will be for oral, topical, or ophthalmic use.
4. The final dosage form and strength of the diclofenac ingredient is not commercially available.
5. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).

For flurbiprofen compounds:

1. Member is 18 years of age or older.
2. Member has a diagnosis of one of the following:
    a. Osteoarthritis
    b. Rheumatoid arthritis
    c. Intraoperative miosis inhibition
3. The final dosage form will be for oral or ophthalmic use.
4. The final dose is not commercially available.
5. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).

For fluticasone compounds:

1. Member is 3 months of age or older.
2. Member has a diagnosis of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis.
3. The final dose is not commercially available.

4. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).
5. The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

For gabapentin compounds:

1. Member is 3 years of age or older.
2. Member must have one of the following diagnoses:
    a. Partial seizures
    b. Postherpetic neuralgia
    c. Restless leg syndrome (RLS)
3. The final dosage form will be for oral use.
4. The requested dose is not commercially available.
5. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).

For ketamine compounds:

1. Member is 16 years of age or older.
2. ONE of the following:
    a. Member is requiring ketamine for conscious sedation prior to a diagnostic or surgical procedure that do not require skeletal muscle relaxation.
    b. Member is requiring ketamine for the induction of anesthesia prior to the administration of other general anesthetic agents.
    c. Member is requiring ketamine as a supplement to low-potency anesthetic agents, such as nitrous oxide.
3. The final dosage form will be for injection.
4. The requested dose is not commercially available.
5. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).
6. The requested dose does not exceed the concentration limit of 100mg/ml (According to the prescribing information, 100mg/ml product must be diluted prior to administration).

For ketoprofen compounds:

1. Member is 18 years of age or older.
2. Member has a diagnosis of ONE of the following:
    a. Osteoarthritis
    b. Rheumatoid arthritis
    c. Acute pain

    d. Primary dysmenorrhea
3. The final dosage form will be for oral use.
4. The final dose is not commercially available.
5. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).

For levocetirizine compounds:

1. Member is 6 months of age or older.
2. Member has a diagnosis of ONE of the following:
    a. Seasonal or perennial allergic rhinitis
    b. Uncomplicated skin manifestations of chronic idiopathic urticaria
3. The final dosage form will be for oral use.
4. The final dose is not commercially available.
5. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).

For mometasone compounds:

1. Member is 2 years of age or older.
2. Member has a diagnosis of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis.
3. The final dose is not commercially available.
4. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).
5. The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

For Acyclovir ointment 5% compounds:

1. Member is 18 years of age or older.
2. Member has a diagnosis of ONE of the following:
    a. Management of initial genital herpes
    b. Limited non-life-threatening mucocutaneous herpes simplex virus infection in immunocompromised patients
3. The final dose is not commercially available.
4. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).

For Doxepin cream 5% compounds:

1. Member is 18 years of age or older.
2. Requested medication will be used for treatment of moderate pruritis with atopic dermatitis or lichen simplex chronicus.
3. The final dose is not commercially available.
4. The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially available).

Limitations

1. Approvals will be granted for 6 months.

Appendix

Table 1: Drugs that were withdrawn from the market due to safety or effectiveness	
3,3',4',5-tetrachlorosalicylanilide	Methoxyflurane
Adenosine phosphate	Mibefradil dihydrochloride
Adrenal cortex	Nitrofurazone
Alatrofloxacin mesylate	Nomifensine maleate
Aminopyrine	Novobiocin
Astemizole	Ondansetron hydrochloride
Azaribine	Oxyphenisatin
Benoxaprofen	Oxyphenisatin acetate
Bithionol	Pemoline
Bromfenac sodium	Pergolide mesylate
Bromocriptine mesylate	Phenacetin
Butamben	Phenformin hydrochloride
Camphorated oil	Phenylpropanolamine
Carbetapentane citrate	Pipamazine
Casein, iodinated	Polyethlene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl
Cerivastatin sodium	
Chloramphenicol	Potassium arsenite
Chlormadinone acetate	Potassium chloride
Chloroform	Povidone
Cisapride	Propoxyphene
Cobalt	Rapacuronium bromide
Dexfenfluramine hydrochloride	Reserpine
Diamthazole dihydrochloride	Rofecoxib
Dibromsalan	Sibutramine hydrochloride
Diethylstilbestrol	Sparteine sulfate
Dihydrostreptomycin sulfate	Sulfadimethoxine
Dipyrone	Sulfathiazole
Encainide hydrochloride	Suprofen

Esmolol hydrochloride Etretinate Fenfluramine hydrochloride Flosequinan Gatifloxacin Gelatin Glycerol, iodinated Gonadotropin, chorionic Grepafloxacin Mepazine Metabromsalan Methamphetamine hydrochloride Methapyrilene	Sweet spirits of nitre Tegaserod maleate Temafloxacin hydrochloride Terfenadine Tetracycline Ticrynafen Tribromsalan Trichloroethane Troglitazone Trovafloxacin mesylate Urethane Valdexocib Vinyl chloride Zirconium Zomepirac sodium

References
N/A

Review History
01/10/2024 – Created for Jan P&T; adopted Optum Compounded Drugs guidelines. Effective 01/01/2024.