

**Compound Drug Products
Effective 2015**

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Coverage Guidelines

Compounded drug products will be covered with prior authorization when the following criteria are met:

- Coverage is provided when the patient has an active authorization for the requested compound with documentation that could be provided to AllWays Health Partners upon request
 - Coverage is provided when the route of administration of the compound is the same as the FDA-approved or compendial supported route of administration for each active ingredient
 - Coverage is provided when the dosing is within guidelines for each active ingredient
 - Coverage is provided in situations where each of the active ingredients in the compound are FDA-approved drugs
 - Coverage is provided when each of the active ingredients in the compound is used for an indication that is FDA-approved
- AND**
- There is a current supply shortage of the commercial product
- OR**
- The patient has a medical need for a dosage form or dosage strength that is not commercially available
- OR**
- The patient had a trial and intolerance to or contraindication to the commercially available product (e.g., allergen/preservative/dye-free, palatable for pediatrics, adverse effects to binders/fillers/other inactive ingredients)
- OR**
- The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness
- AND**

- Coverage is not provided for compounds applied topically (e.g., cream, gels, lotions, ointments) that contain bulk powders OR any ingredient that is not FDA approved for topical use OR any of the following ingredients:
 - Amitriptyline
 - Baclofen
 - Cholestyramine
 - Cyclobenzaprine
 - Dexamethasone (except ophthalmic solution)
 - Flurbiprofen (except ophthalmic solution)
 - Fluticasone propionate
 - Gabapentin
 - Hyaluronate (except ophthalmic solution)
 - Itraconazole
 - Ketamine
 - Ketoprofen
 - Ketorlac (except for ophthalmic solution)
 - Lamotrigine
 - Meloxicam
 - Penlac
 - Sumatriptan
 - Tramadol
- Coverage is not provided in situations where the compound is intended for scar diminishing, cosmetic use, anti-aging, OR contains any of the following ingredients:
 - Coenzyme Q10 (Ubiquinol)
 - Collagenase (Santyl)
 - Naltrexone
 - Resveratrol
- Coverage is provided for additional fills of the compounded drug if patient needs more than 1 fill per month (necessity may include continuation of antibiotic therapy, stability of water-containing formulation is less than a month, dose adjustment)

OR

- Coverage is provided for total parenteral nutrition (TPN) OR for antibiotics or anti-infectives for injectable use

References

1. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf>. Accessed January 2015
2. USP Compounding Standards & Resources. <http://www.usp.org/usp-healthcare-professionals/compounding>. Accessed January 2015.
3. Compounding Quality Act. U.S. Food and Drug Administration. Pharmacy Compounding. Available at: <http://www.gpo.gov/fdsys/pkg/BILLS-113hr3204enr/pdf/BILLS-113hr3204enr.pdf>. Accessed January 2015.
4. Compounded Menopausal Hormone Therapy Questions and Answers. Available at: <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm183088.htm#MenopausalHormoneTherapy>. Accessed January 2015.
5. Drug Information (Drugs@FDA). Available at: <http://www.fda.gov/Drugs/default.htm>. Accessed February 2015.
6. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed February 2015.
7. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed February 2015.



8. Drug Nomenclature Monographs. Route of Administration. Available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071650.htm>. Accessed January 2015.

Review History

N/A

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