PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **COMPOUNDED DRUG PRODUCTS**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 1114-A***

COVERAGE CRITERIA

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

- The request is for any of the following: intraveneous (IV) injection or infusion, anti-infective for injectable use (e.g., antibacterials, antivirals, antifungals), total parenteral nutrition (TPN), leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1mg per 0.2mL kit), pyrimethamine, hydroxyprogesterone, sirolimus for tuberous sclerosis where other dermatological treatments (e.g., laser therapy, surgery, dermabrasion) are inappropriate

OR

- The request is for tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant

OR

- Each of the active ingredients in the compound are FDA-approved drugs
- Each of the active ingredients in the compound are FDA-approved for the indication for which the compound is being prescribed
- The compound route of administration (ROA) is the same as the FDA-approved route of administration for each active ingredient
- The dosage or concentration of each active ingredient in the compound is equal to or below the FDA-approved dosage or concentration
- The request is not for a topical compound or a topical compound kit for use on skin (e.g., cream, gel, lotion, ointment)
- The compound is not intended for anti-aging or cosmetic use, or is not a compound kit, or does not contain a bulk powder or dietary supplement
- The request is not for a hormone therapy compound for menopause or for androgen decline due to aging, (e.g., testosterone, estrogen, progestin, bioidentical hormone)
- 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 is less than a month, dose adjustment)
  AND
  - There is a current supply shortage of the commercially manufactured product
    OR
  - The patient has a medical need for a dosage form or dosage strength that is not available commercially or manufactured
    OR
  - The patient had an intolerance or contraindication to the commercially manufactured product (e.g., allergen or adverse effects due to inactive ingredients)
    OR
  - The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

Products for intraveneous (IV) injection or infusion, anti-infectives for injectable use (e.g., antibacterials, antivirals, antifungals), total parenteral nutrition (TPN), leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1mg per 0.2mL kit)[14,15], pyrimethamine, hydroxyprogesterone, sirolimus for tuberous sclerosis where other dermatological treatments (e.g., laser therapy, surgery, dermabrasion) are inappropriate[14-16], or tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant[14,15], are covered.

Topical compounds and topical compound kits for use on skin (e.g. cream, gel, lotion, ointment) are not covered (except sirolimus for tuberous sclerosis).

Compounds for anti-aging or cosmetic use, or compound kits, or compounds that contain a bulk powder or dietary supplement are not covered.

Hormone therapy compounds (e.g. testosterones, estrogens, progestins, bioidentical hormones) for menopause or for androgen decline due to aging are not covered. The FDA is not aware of any credible scientific evidence to support claims made regarding the safety and effectiveness of compounded bio-identical hormone replacement therapy drugs. In addition, the FDA has not approved any drug containing the hormone estriol.[10-12] There are FDA-approved brand-name and generic manufactured menopausal hormone therapy and hormone replacement therapy products that are available in a variety of strengths and dosage forms (e.g., tablet, patch, gel, injectable, vaginal cream).[11-15]

Compounding does not include mixing or reconstituting commercial products in accordance with the manufacturer's instructions or the product's approved labeling. Bulk ingredients are not FDA-approved products. Compounded drugs are not FDA-approved. The safety or effectiveness of compounded drugs are not verified by the FDA. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed. The FDA does not allow the marketing of compounding drugs that were withdrawn or removed from the market due to lack of safety or effectiveness; or compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products.[1-9]

Pharmaceutical compounding is the combining, mixing, or altering of ingredients to create a customized medication that is not otherwise commercially available and is medically necessary for an individual patient in response to a licensed practitioner's prescription. There may be situations where a compound prescription is necessary due to special patient needs for customized therapies. Health needs that commercially available prescription medicines cannot meet may include:

- drug shortages, the need to access drugs or dosage forms withdrawn from the market, or medication is discontinued by or generally unavailable from pharmaceutical companies
- patient is allergic to certain preservatives, dyes or binders in commercially available medications (e.g., allergen-free medications)
- treatment requires tailored dosage strengths for patients with unique needs (e.g., an infant, non-standard doses, and parenteral nutrition)
- patient cannot ingest the medication in its commercially available form and the medication can be prepared in another form that the patient can ingest.[1-9]

There may be a need to fill the compound prescription more than once per month (necessity may include continuation of antibiotic therapy, stability of water-containing formulation is less than a month, dose adjustment).[6-8]

REFERENCES

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CRITERIA FOR APPROVAL

1	Is this request for ANY of the following: A) intravenous (IV) injection or infusion, B) anti-infective for injectable use, C) total parenteral nutrition (TPN), D) leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1mg per 0.2mL kit), E) pyrimethamine, F) hydroxyprogesterone, G) sirolimus for tuberous sclerosis, where other dermatological treatments, (e.g., laser therapy, surgery, dermabrasion) are inappropriate? [If yes, then no further questions. If no, go to 2.]	Yes	No
2	Is this request for tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant? [If yes, go to 3. If no, go to 4.]	Yes	No
3	Is the patient 12 years of age or older? [No further questions]	Yes	No
4	Is this request for a topical compound or a topical compound kit for use on the skin (e.g., cream, gel, lotion, ointment)? [If yes, then no further questions. If no, go to 5.]	Yes	No
5	Do any of the following apply for the requested compound: A) Intended for anti-aging, B) Intended for cosmetic use, C) Is a compound kit, D) Contains a bulk powder, E) Contains a dietary supplement? [If yes, then no further questions. If no, go to 6.]	Yes	No
6	Is this request for a hormone therapy compound for menopause OR for androgen decline due to aging (e.g., testosterone, estrogen, progestin, bioidentical hormone)? [If yes, then no further questions. If no, go to 7.]	Yes	No
7	Are each of the active ingredients in the compound FDA-approved drugs? [If yes, go to 8. If no, then no further questions.]	Yes	No
8	Are each of the active ingredients in the compound FDA-approved for the indication for which the compound is being prescribed? [If yes, go to 9. If no, then no further questions.]	Yes	No
9	Is the compound route of administration (ROA) the same as the FDA-approved route of administration for each active ingredient? [If yes, go to 10. If no, then no further questions.]	Yes	No
10	Is the dosage or concentration of each active ingredient in the compound equal to or below the FDA-approved dosage or concentration? [If yes, go to 11. If no, then no further questions.]	Yes	No
11	Is there a current supply shortage of the commercially manufactured product? [If yes, go to 15. If no, go to 12.]	Yes	No
12	Does the patient have a medical need for a dosage form or dosage strength that is not available commercially or manufactured? [If yes, go to 15. If no, go to 13.]	Yes	No
13	Has the patient had an intolerance or contraindication to the commercially manufactured product (examples may include allergen or adverse effects due to inactive ingredients)?	Yes	No

[If yes, go to 15. If no, go to 14.]

14	Has the commercial product been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness? [If yes, go to 15. If no, then no further questions.]	Yes	No
15	Does the patient need more than 1 fill per month of the compounded drug (necessity may include continuation of antibiotic therapy, stability is less than a month, dose adjustment)? [No further questions]	Yes	No

Guidelines for Approval			
Duration of Approval 6 Months, remove Fill Limit		**Duration of Approval 6 Months, remove Fill Limit**	
Set 1		**Set 2**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	7	1
		8	2
		9	4
		10	5
		11	6
		15	
Duration of Approval 6 Months, remove Fill Limit		**Duration of Approval 6 Months, remove Fill Limit**	
Set 3		**Set 4**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
7	1	7	1
8	2	8	2
9	4	9	4
10	5	10	5
12	6	13	6
15	11	15	11
			12
Duration of Approval 6 Months, remove Fill Limit			
Set 5			
Yes to question(s)		**No to question(s)**	
7		1	
8		2	
9		4	
10		5	
14		6	
15		11	
		12	
		13	
Duration of Approval 6 Months		**Duration of Approval 6 Months**	
Set 6		**Set 7**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
7	1	7	1
8	2	8	2
9	4	9	4
10	5	10	5
12	6	13	6
	11		11
	15		12
			15

Duration of Approval 6 Months		Duration of Approval 6 Months	
Set 8		**Set 9**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
7	1	7	1
8	2	8	2
9	4	9	4
10	5	10	5
14	6	11	6
	11		15
	12		
	13		
	15		
Duration of Approval 36 Months, remove Fill Limit		**Duration of Approval up to 12 years of age, remove Fill Limit**	
Set 10		**Set 11**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
2	1	2	1
3			3

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	[remove Fill Limit]. Approve, 6 Months	Go to 2	
2.	Go to 3	Go to 4	
3.	[remove Fill Limit]. Approve, 36 Months	[PA approved up to 12 years of age, remove Fill Limit]. Approve, Variable Duration - Specify in Approval Note	
4.	Deny	Go to 5	You do not meet the requirements of your plan. Your plan does not cover this compounded drug when it is for topical use on skin. Your request has been denied based on the information we have. [Short Description: For topical use on skin]
5.	Deny	Go to 6	You do not meet the requirements of your plan. Your plan does not cover this compounded drug when any of the following apply: - You use the drug for anti-aging or cosmetic reasons - The drug is a compound kit - The drug contains a bulk powder or a dietary supplement Your request has been denied based on the information we have. [Short Description: For anti-aging, cosmetic, compound kit, bulk powder, or

			dietary supplement]
6.	Deny	Go to 7	You do not meet the requirements of your plan. Your plan does not cover this compounded drug when you meet all of these conditions: - You use the drug as hormone therapy - You use the drug for menopause or androgen decline due to aging Your request has been denied based on the information we have. [Short Description: For hormone therapy for menopause or androgen decline due to aging]
7.	Go to 8	Deny	You do not meet the requirements of your plan. Your plan covers this drug when each of the active ingredients is an FDA-approved drug. Your request has been denied based on the information we have. [Short Description: Active ingredients are not FDA-approved drugs]
8.	Go to 9	Deny	You do not meet the requirements of your plan. Your plan covers this drug when each of the active ingredients is FDA-approved for the condition being treated. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
9.	Go to 10	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you take or use it by the same route as the FDA-approved route for each active ingredient. Your request has been denied based on the information we have. [Short Description: No approvable route of administration]
10.	Go to 11	Deny	You do not meet the requirements of your plan. Your plan covers this drug when the dosage is at or below the FDA-approved dosage for each active ingredient. Your request has been denied based on the information we have. [Short Description: No approvable dosage]
11.	Go to 15	Go to 12	
12.	Go to 15	Go to 13	
13.	Go to 15	Go to 14	
14.	Go to 15	Deny	You do not meet the requirements of your plan. Your plan covers this compounded drug when one of these conditions applies: - There is a supply shortage of the manufactured drug - You need a form or strength of the manufactured drug that is not available - You tried the manufactured drug and it did not work for you - You cannot take the manufactured drug - The drug manufacturer stopped making the drug for

			reasons other than the lack of safety or the drug not working Your request has been denied based on the information we have. [Short Description: No approvable reason for a compounded drug]
15.	[remove Fill Limit]. Approve, 6 Months	Approve, 6 Months	