

**HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES**

COMPOUND EXCEPTIONS

Generic	Brand	HICL	GCN	Exception/Other

ATTENTION REVIEWERS: THIS GUIDELINE IS TO BE USED FOR DRUGS THAT ARE IDENTIFIED AS COMPOUNDS FOR OPEN OR CLOSED BENEFITS.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

As used in these Guidelines, the word "Formulary" means United States Food and Drug Administration (FDA) approved manufactured drugs covered by Harvard Pilgrim Health Care (HPHC).

1. Is the request for one of the following?

- Magic mouth wash
- All-purpose nipple ointment (also known as APNO) consisting of betamethasone 0.025%, clotrimazole 2.0%. and mupirocin 1.0%
- Medication indicated for fertility or maintenance of pregnancy

If yes, continue to #9.

If no, continue to #2.

2. Is the requested compound being prescribed for cosmetic use?

If yes, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your Prescription Drug Brochure, Harvard Pilgrim does not cover drugs used for cosmetic use. Your provider indicated your compounded drug is being used for a cosmetic condition. Medications that are used for a cosmetic condition are not covered under your prescription drug benefit.

If no, continue to #3.

3. Is the request for one of the following?

- Over-the-counter (OTC) medication(s)
- Medical Food, vitamin or nutritional supplement
- Non-FDA Approved medication(s) (not including bulk powders)
- Non-FDA Approved indication without a compendium supported diagnosis

If yes, continue to #4.

If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

4. Does the request consist of OTC medication(s) for a member 17 years of age or younger?

If yes, defer to HPHC.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your Prescription Drug Brochure, Harvard Pilgrim does not cover over-the-counter (OTC) medications, medical foods, nutritional supplements or vitamins, non-FDA approved medications or non-FDA approved indications without a compendia supported diagnosis. The requested medication is **[a medical food] [a non-FDA approved product] [available over the counter]** and therefore your request was not approved.

5. Is the request for a member 17 years of age or younger?

If yes, **approve until the member reaches their 18th birthday and override the formulary.** Refer to Formulary for applicable quantity limitations or restrictions. Please use status code #057 (without QL) or #056 (with QL) and the approval text provided.

APPROVAL TEXT: Your request has been approved until your 18th birthday **[with a quantity limit of ___ per ___ day supply]** at your highest cost-share tier. Please refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

If no, continue #6.

6. Are there formulary alternatives currently available to treat the member's condition?

If yes, continue to #7.

If no, continue to #9.

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INITIAL CRITERIA (CONTINUED)

7. Has the member had a sufficient trial with at least 2 formulary alternative medications (one formulary alternative is acceptable if only one is available) or is there clinical rationale for not trying at least 2 formulary alternatives (e.g., documented drug allergy, temporary shortage, specific dosage form)?

If yes, continue to #8.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT (if two or more formulary alternatives): Per your health plan's Compound Exceptions guideline, a sufficient trial with at least two formulary alternative medications including oral and **[topical] [injectable] [other]** preparations is required or there must be a clinical reason prohibiting the use of formulary alternatives. Formulary alternatives include, but are not limited to **[formulary alternative(s)]**. Your provider has not submitted information which shows that you have had a sufficient trial with at least two formulary alternatives and therefore your request is not approved.

DENIAL TEXT (if only one formulary alternative): Per your health plan's Compound Exceptions guideline, a sufficient trial with at least one formulary alternative medication is required or there must be a clinical reason prohibiting the use of formulary alternatives. Formulary alternatives include, but are not limited to **[formulary alternative(s)]**. Your provider has not submitted information which shows that you have had a sufficient trial of formulary alternatives and therefore your request is not approved.

8. Does the request meet one of the following for this member's condition?
- Dosage form or route of administration is FDA-approved or compendia supported
 - Provider submitted scientific evidence that supports the use of the requested compound

If yes, continue to #9.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Compound Exceptions guideline, the dosage formulation and/or method of administration must be approved by the Food and Drug Administration (FDA) or there must be scientific evidence to support the use of this compound for your condition prior to approving coverage. Your provider did not submit scientific evidence that supports the use of this medication for your condition and therefore your request is not approved.

9. **Please approve for the requested duration or up to 12 months and override the formulary.** Refer to Formulary for applicable quantity limitations or restrictions. Please use status code #057 (without QL but limited to 12 months) or #056 (with QL) and the approval text provided

APPROVAL TEXT: Your request has been approved for ___ months **[with a quantity limit of ___ per ___ day supply]** at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

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COMPOUND EXCEPTIONS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the requested medication a renewal (determined by utilization within the past 365 days per the member's claim profile)?

If yes, continue to #2.

If no, continue to Initial Criteria.

2. Has the patient experienced improvement while on therapy?

If yes, continue to #3.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Compound Exceptions guideline, authorization for renewal requires documentation of improvement of symptoms while on therapy with _____. Your provider did not indicate that your symptoms have improved with _____ therapy and therefore your request was not approved.

3. **Please approve for the requested duration or up to 12 months and override the formulary.**

Refer to Formulary for applicable quantity limitations or restrictions. Please use status code #057 (without QL but limited to 12 months) or #056 (with QL) and the approval text provided.

APPROVAL TEXT: Your request has been approved for 12 months [with a quantity limit of per day supply] at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

RATIONALE

Compounded medications should be used only when their use is medically necessary. Compounded medications are not covered when there is lack of good scientific evidence of effectiveness or safety for their specific dose, dosage form, combinations and/or mode of administration.

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