

Compound Management Program FAQs for Members

What are compounds and are they FDA approved?

According to the FDA, compounding is the practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient. The active ingredients within the compound are FDA approved, but the FDA does not approve the quality, safety and efficacy of the compound with multiple ingredients.

What are the alternatives?

Only your medical provider and you can determine a suitable alternative since it is often difficult to determine the condition for which a compounded medication is being prescribed. Ask your doctor if an FDA-approved drug is available and appropriate for your treatment.

What are the members' appeals rights and how long will it take to get a decision?

Appeals would go through the same appeals process that the client currently has in place. Express Scripts recommends that you contact your physician to try a commercially available FDA approved alternative. Obtaining an alternative will likely take less time than maneuvering through the appeals process.

Can I appeal the exclusion decision and if so how?

Express Scripts recommends that you contact your physician to try a commercially available FDA approved alternative. If you've tried all the alternatives, then you can appeal to obtain the compound Express Scripts will handle and review your appeal and inform you of the decision. You may also continue therapy and pay out of pocket for your current medication.

My pharmacist prepares my bio-identical hormones. Will these continue to be covered?

Yes – most hormone replacement therapies are still available via compounding. Due to the FDA's warning of estriol's lack of safety and efficacy data, we have included this product in the Exclusion List. Express Scripts will continue to monitor the class of medications.

Why would my physician prescribe a compounded medication instead of something that is already on the market?

Only you and your doctor can decide what is the best medication option for you. Physicians make therapy choices based on a variety of factors. Furthermore, these compounded products are not evaluated or verified for safety or efficacy by the FDA.

The compounded medication that I have been using works really well for me. What are my options?

You may appeal the coverage exclusion. You may also pay out of pocket.

Why isn't my compound covered anymore?

At the recommendation of our Pharmacy Benefit Manager, the plan no longer covers certain compounded medication products that have little or no proven clinical value [in relation to their high cost]. **Furthermore, these compounded products are not evaluated or verified for safety or efficacy by the FDA.**

Isn't this a change in my benefit? How can you change my benefit in the middle of a plan year?

The benefit reserves the right to update coverage as allowed by plan guidelines.

Who decided to exclude these compounded medications?

The list of excluded compound medications was put together and recommended by our pharmacy benefit manager, Express Scripts.

What will be excluded?

Over 1,000 products are currently excluded and the list is subject to change at the discretion of Express Scripts. The best option would be to ask your provider if an FDA approved product is available to treat your condition and appropriate for your treatment.

Why has my benefit been changed?

Compounded medications that are combined or mixed by pharmacists are not approved by the FDA and there is no way to confirm their quality, safety or effectiveness so as the plan sponsor we are excluding these targeted agents from the plan benefit.

If my provider prescribed this compounded medication and feels it is best for me and it was covered before, what changed, why won't it continue to be covered?

Only you and your provider can determine your therapy however these compounded medications are **not FDA approved** and have not been evaluated for safety or efficacy. Perhaps you can discuss other therapy options for commercially available FDA approved alternatives with your provider.

My colleague is also receiving a compound medication and told me that his/her compounded medication is not being excluded, how was this list determined?

Express Scripts is our pharmacy benefit manager and helped the Health and Welfare Fund determine the list and reviewed high cost products which were lacking in clinical evidence for safety and efficacy. Typically, there are commercially available FDA approved medications to treat the conditions for which the high cost compounded medication was prescribed.

Will pediatric compounds still be covered?

Yes. If a child needs to obtain an adult medication in a lesser dose and/or cannot swallow tablets, the pharmacist can compound the medication into a dosage form that the child can take.