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Compound Drugs Prior Authorization Policy – Frequently Asked Question

Below is a list of frequently asked questions (FAQs) regarding the state employee plan's new prior authorization process for compound medications. For additional information please contact CVS Caremark at 1-800-318-2572.

Why is the state of Connecticut Employee Plan instituting a Prior Authorization (PA) for compound medications that contain non-FDA approved ingredients?

Topical compounds are not approved by the U.S. Food and Drug Administration (FDA) and utilize ingredients that have not been tested for safety and efficacy in a topical form. The growth in these new medications has been driven, in large part, by the aggressive marketing of out-of-state compound pharmacies. Within the Connecticut state employee plan, the rapid increase in costs for topical compound drugs has raised significant safety concerns. For the Connecticut state employee plan, compound drug claims have increased from \$800,000 in FY 2012 to approximately \$24 million today on an annualized basis.

Will all compound medications subject to the PA be denied?

No. Traditionally compounded medications have been prescribed for patients who need dosage forms or strengths of FDA-approved medications that are not commercially available or formulations free of allergens. In such instances prescriptions used for an indication that is FDA-approved or compendia¹ supported and have a route of administration that is the same as the FDA-approved or compendia supported route of administration for each ingredient will generally be approved through the PA process.

If a compound drug is needed in place of an FDA approved prescription due to an allergy of a non-active ingredient will the medication be covered by the plan?

Compound drugs formulated to avoid intolerance of an inactive ingredient in an FDA approved medication used for an indication that is FDA-approved or compendia supported and that have a route of administration that is the same as the FDA-approved or compendia supported route of administration for each ingredient would be approved through the PA process.

¹ Compendia is a compilation of evidence supported uses of pharmaceutical drugs

I use a compound Hormone Replacement Therapy (HRT). Will my medications continue to be covered?

Compounded HRT medications will be subject to the PA process, but may be covered by the plan in cases in which a provider verifies that a patient has tried and failed FDA-approved HRT medications.

Is the state of Connecticut using CVS Caremark's standard PA process?

No. The State of Connecticut Employee Plan's PA process is customized to retain access to medically-necessary medications.

How long does the typical PA process take?

The typical turnaround time for CVS Caremark to process a PA is 24 to 48 hours from receipt by your provider. There are mechanisms in place to expedite the process when necessary.

What options are available if coverage for my compound medication is denied through the PA process?

If coverage is denied through the PA process you can request an appeal through your provider. The appeals process is detailed in attachment I. The appeal process is tailored to the state plan and seeks to provide an avenue for medically-necessary medications to receive coverage.

What happens if a compound drug subject to the PA is needed urgently?

In the case of an urgent or emergent situation an on call pharmacist is available to process PA requests from your provider 24 hours a day.

Attachment I

Appeals Process

Appeals of initial coverage decisions (Prior Authorization) are typically reviewed by pharmacists and then, by a physician, before a denial is rendered. Appeal decisions are based on the available clinical evidence supporting a physician's proposed use of a drug in a specific patient.

- If a medication is FDA approved for use in patients with the condition the prescriber is treating, these are usually approved at initial review (PA) or by the pharmacist reviewing an appeal.
- If the proposed use is determined to be an “off label” use of the medication, then the appeal will consider whether sufficient published evidence is available to list that proposed use in one of the recognized drug information compendia (e.g. DrugDex). If the off label use is listed in the compendia as effective or probably effective, it may be approved at appeal. For some rare conditions, clinical treatment guidelines and published expert recommendations may be sufficient to approve an appeal request (e.g. mitochondrial disorder treatment with Coenzyme Q).
- If the proposed use is not listed in the compendia or is listed as “not effective” then the appeal is usually denied.
- For compounds, the supporting evidence of the proposed use and its effectiveness must specifically reference the route of administration through the compound. For a topical compound, the FDA labeling, compendia listing, or clinical trials referenced in the appeal must show that the ingredient(s) are effective when applied topically for the proposed indication.
- Appeal requests that do not meet the above levels of clinical evidence above may be denied as investigational or experimental. Under certain circumstances, however, the requested medication (compound) could still be considered medically necessary for a specific patient. Such circumstances might include situations where the patient has a documented trial and failure of all other FDA -approved therapy for a condition and, in the prescriber's opinion, the proposed therapy does not pose more risk than benefit to the patient. There may also be other circumstances (such as hospice care) where coverage of a compound medication can be provided as an override to the formal appeal process where a claim was denied on the basis that it was investigational or experimental.
- Members will retain the right to an external appeal through the Connecticut Insurance Department and are encouraged to contact the Healthcare Advocate for assistance.