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Compound Medications FAQs

NOTE: Effective April 1, 2014, Aetna will resume coverage for compound medications. Such coverage will extend through at least December 31, 2014. Prior to April 1, members can ask their pharmacist to request an override to get coverage for a compound medication. During the remainder of 2014, we will work with Aetna and our members on the various issues regarding compound medications.

Q. Why has the plan coverage for compound medications changed?

A. The plan coverage for *prescription medications* has not changed. Both the retiree and active plans define "prescription drugs" to mean a substance that "may be dispensed only by prescription, and which is required to be labeled, 'Caution: Federal law prohibits dispensing without a prescription.'"

These medications are sometimes called "FDA (Food and Drug Administration) legend drugs."

A compound medication that has an ingredient which is an FDA legend drug is covered by the plan.

Q. But something has changed, because my compound prescriptions were covered last year, and now they are not. Why?

A. There may be a number of reasons:

- your compound medication may not have an FDA legend drug in it
- your compound medication may be experimental or investigational, and therefore the safety or medical efficacy of it is not well-established
- your compound medication may not be medically necessary as defined in the plan document

Also, we now understand that the previous claim administrator, HealthSmart/Envision, interpreted the plan definition of "prescription drug" more liberally than Aetna.

Q. So what happens next?

A. Aetna will resume coverage for compound medications on April 1, 2014.

Q. How did this happen?

A. As a result of a miscommunication or misunderstanding between the State and Aetna last fall, the plan administration of compound medications was not properly transitioned.

Members should know that for a variety of reasons, more and more plan administrators, including Aetna and Envision (the plan's previous pharmacy benefit manager), are recommending against coverage for compound medications. Those reasons need to be thoughtfully considered and conveyed to our members. That did not happen on January 1—instead there was an abrupt change that was disruptive for our members, as well as for Aetna and the Division.

If a coverage change is going to happen, it should happen with appropriate communication, discussion and education.

Q. What happens to compounds that have been denied between January 1, 2014 and March 31, 2014?

A. Aetna will review appeals that were filed for denial of compound medications, and assure that these are reconsidered.

If you have a compound you paid for from January 1st to March 31, 2014, here is what needs to be done to receive reimbursement:

- Obtain a detailed receipt or invoice from your compounding pharmacy that lists all of the ingredients that are in the compounded medication (including quantities and strengths of all ingredients and cost of the medications).
- Complete a pharmacy claim form and submit it to the address on the form. If you paid for more than one compound prescription, you can submit all of your compound prescriptions with one claim form.
- Claim forms can be found here: http://doa.alaska.gov/drb/pdf/ghlb/akcare/aetna/prescriptionDrugClaimForm.pdf
- Aetna will process your claim and mail you a reimbursement check for your out of pocket expense minus your applicable copay or coinsurance.

Q. Are there safety issues with compound medications?

A. Generally speaking, many compound medications have had a good safety record. Compounding pharmacists have a vested interest in ensuring their products are safe. And there are instances when a patient may be allergic to an inactive ingredient or dye in an FDA legend drug, and needs access to a compound medication in order to get medically necessary treatment.

Members should know, however, that the process of compounding medications is not regulated by the FDA. In 2012, hundreds of people contracted fungal meningitis from a compound medication produced by a Massachusetts compounding facility. Over 60 people died as a result. For more information, please see:

(1) Alaska Board of Pharmacy website: http://www.commerce.alaska.gov/dnn/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx

(2) Center for Disease Control website: http://www.cdc.gov/HAI/outbreaks/meningitis.html

For information from the FDA on compounding, please see: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm

Q. What about compound bio-identical hormone replacement therapy?

A. This is an area that requires additional inquiry. Some compound pharmacists contend that bio-identical hormone replacement therapy is "safe."

The following organizations have expressed concerns about the marketing of bio-identical replacement hormone therapy as safe:

The Food and Drug Administration
http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm049312.pdf

The Mayo Clinic
http://www.mayoclinic.org/diseases-conditions/menopause/expert-answers/bioidentical-hormones/FAQ-20058460

The American Congress of Obstetricians and Gynecologists
http://www.acog.org/About_ACOG/News_Room/News_Releases/2009/ACOG_Reiterates_Stance_on_So-Called_Bioidentical_Hormones

The Endocrine Society
https://www.endocrine.org/news-room/press-release-archives/2009/societyreissuespositionstatementonbioidenticalhormones

Members should consult their physician if they have questions.