
From: Ryals, Christopher
Sent: Monday, December 19, 2016 9:28 AM EST
To: \"\Elliott\"\", \"\Arlene; \"\Harris\"\", \"\Shevaun; Arlene.Elliott@ahca.myflorida.com; Shevaun.Harris@ahca.myflorida.com
CC: Sokoloski, Kristin
Subject: FOLLOW UP DUE COB 12/22: Legislative Inquiry: Pharmaceutical Compendia

Arlene and Shevaun – We received the follow up question below from the House.

Can you please provide a response?

Thanks,

Chris

Christa wanted me to follow up on the Compendia information and ask whether the compendia research regarding off-label cross-sex hormones for gender dysphoria was viewed as positive or negative?

From: Elliott, Arlene
Sent: Sunday, December 04, 2016 12:11 PM
To: Sokoloski, Kristin
Cc: Harris, Shevaun; Ryals, Christopher
Subject: Re: PLEASE REVIEW: DRAFT RESPONSE RE: DUE COB 11/29: Legislative Inquiry: Pharmaceutical Compendia

Hi. The prior auth refers to all. I'd rather not add that sentence but keep if you must.

The prior response regarding off label still requires to be medically necessary and until the puberty suppression GAPMS was approved we would be not thought gender dysphoria use was medically necessary. Our reviews from that GAPMS on have to change because most of the research we did find the treatment of G D medically necessary. All of our conclusions say each review has to be individualized. Thanks.

Sent from my iPhone

On Dec 4, 2016, at 10:53 AM, Sokoloski, Kristin <Kristin.Sokoloski@ahca.myflorida.com> wrote:

Shevaun and Arlene – Below is our prior response and the proposed response to the follow up question.

I have a question about our response to the follow up. Is the phrase “Some of the drugs mentioned above require prior authorization” intended to only go with the paragraph beginning “Testosterone cypoinate . . .” or with that AND the paragraph beginning with “Lupron Depot . . .”. Please let me know and let me know if any changes are needed based on this so that I can move this forward. Thanks!

Prior Response;

Consistent with federal law, Florida Medicaid covers all medically necessary services for children under the age of 21 years (child) even if the service is not listed in the Medicaid coverage policy/handbook, fee schedule, or the Florida Medicaid State Plan. If a provider requests a service for a child that is not covered by Florida Medicaid, the Agency (and its contracted health plans) has a process in place for reviewing such requests to make an individualized medical necessity determination. The treating practitioner can submit the request to the Agency's prior authorization vendor (or the enrollee's health plan) for review. States are not required to have the same processes in place for adult Medicaid recipients.

Florida Medicaid does not cover the majority of the services in question for adults. Florida Medicaid covers reproductive hormone suppression therapy (including puberty suppression therapy) for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Children/adolescents diagnosed with gender dysphoria are eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms. Florida Medicaid covers behavioral health assessments/evaluations and individual and group therapy services for adults.

Follow up request:

Per our telephone call, I do not have subscription access to any of the pharmaceutical compendia that CMS authorizes and utilizes for Medicaid/Medicare. I was curious if your group could tell me what compendia they utilize and provide a copy of the compendia recommendations for the specific pharmaceuticals used in pubertal suspension and cross-sex hormone treatment hormones commonly used in treatment for gender dysphoria.

Follow up response:

The Social Security Act section 1861(t)(2)(B)(ii)(I) recognizes the following compendia: American Medical Association Drug Evaluations, United States Pharmacopoeia-Drug Information or its successor publication [amended in Section 6001 (f)(1) of the Deficit Reduction Act of 2005] and American Hospital Formulary Service-Drug Information, Micromedex/DrugDex®.

Lupron Depot, Synarel, and Supprelin LA are drugs approved by the U.S. Food and Drug Administration (FDA) for puberty suppression. The compendia does not address off-label use of treatment for gender dysphoria.

Testosterone cypionate, conjugated estrogens, and ethinyl estradiol are FDA approved for hormone replacement. The compendia addresses off-label use for cross-sex hormone therapy for individuals diagnosed with gender dysphoria.

Some of the drugs mentioned above require prior authorization.

From: Elliott, Arlene

Sent: Friday, December 2, 2016 5:17 PM

To: Harris, Shevaun <Shevaun.Harris@ahca.myflorida.com>; Sokoloski, Kristin <Kristin.Sokoloski@ahca.myflorida.com>

Subject: FW: NEW DRAFT RESPONSE RE: DUE COB 11/29: Legislative Inquiry: Pharmaceutical Compendia

From: Elliott, Arlene
Sent: Friday, December 2, 2016 4:20 PM
To: Harris, Shevaun <Shevaun.Harris@ahca.myflorida.com>
Subject: DRAFT RESPONSE RE: DUE COB 11/29: Legislative Inquiry: Pharmaceutical Compendia

The Social Security Act section 1861(t)(2)(B)(ii)(I) recognizes the following compendia: American Medical Association Drug Evaluations, United States Pharmacopoeia-Drug Information or its successor publication [amended in Section 6001 (f)(1) of the Deficit Reduction Act of 2005] and American Hospital Formulary Service-Drug Information, Micromedex/DrugDex®.

Lupron Depot, Synarel, and Supprelin LA are drugs approved by the U.S. Food and Drug Administration (FDA) for puberty suppression. The compendia does not address off-label use of treatment for gender dysphoria.

Testosterone cypionate, conjugated estrogens, and ethinyl estradiol are FDA approved for hormone replacement. The compendia addresses off-label use for cross-sex hormone therapy for individuals diagnosed with gender dysphoria.

Some of the drugs mentioned above require prior authorization.

Arlene Elliott - AGENCY FOR HEALTH CARE ADMINISTRATOR-SES

Bldg. 3, Rm. 2332A - BUREAU OF MEDICAID POLICY
2727 MAHAN DR TALLAHASSEE, FL 32308
412-4152 (Office)

Arlene.Elliott@ahca.myflorida.com

<image002.png>

<image004.jpg>

Privacy Statement: This e-mail may include confidential and/or proprietary information, and may be used only by the person or entity to which it is addressed. If the reader of this e-mail is not the intended recipient or his or her authorized agent, the reader is hereby notified that any dissemination, distribution or copying of this e-mail is prohibited. If you have received this in error, please reply to the sender and delete it immediately.

From: Ryals, Christopher
Sent: Tuesday, November 22, 2016 1:44 PM
To: Harris, Shevaun <Shevaun.Harris@ahca.myflorida.com>; Elliott, Arlene <Arlene.Elliott@ahca.myflorida.com>
Cc: Ward, Matthew <Matthew.Ward@ahca.myflorida.com>; Reeves, Arabella

<Arabella.Reeves@ahca.myflorida.com>

Subject: DUE COB 11/29: Legislative Inquiry: Pharmaceutical Compendia

Shevaun and Arlene – The Legislative Affairs office received the inquiry below from Tyler Tuszynski with the House Children, Families, & Seniors Subcommittee.

Mr. Tuszynski is requesting information related to the specific pharmaceuticals used in pubertal suspension and cross-sex hormone treatment for gender dysphoria.

Will you please review the request below and provide a response by COB 11/29?

Thanks,

Chris

Request:

Per our telephone call, I do not have subscription access to any of the pharmaceutical compendia that CMS authorizes and utilizes for Medicaid/Medicare. I was curious if your group could tell me what compendia they utilize and provide a copy of the compendia recommendations for the specific pharmaceuticals used in pubertal suspension and cross-sex hormone treatment hormones commonly used in treatment for gender dysphoria.