RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
INTERIM SECRETARY

October 6, 2016

Melissa Vergeson, Director
Florida Department of Health
Children's Medical Services Managed Care Plan
4052 Bald Cypress Way, BIN A-06
Tallahassee, FL 32399-1707

Dear Ms. Verguson:

The purpose of this letter is to address the Children's Medical Services (CMS) Plan's determination of coverage under the Medicaid Act's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirements for medically necessary services to an enrollee under the age of 21 years. The CMS Plan must establish and maintain a utilization management system to monitor utilization of medically necessary services, including an automated service authorization system for denials, service limitations, and reductions of authorization. The CMS Plan must not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the enrollee's diagnosis, type of illness, or condition. (Attachment I, Section II.D.20.)

In an authorization review dated January 7, 2016, the CMS Plan issued a Notice of Prior Authorization Determination (Notice) for coverage of Supprelin LA (request 0917477). The CMS Plan did not authorize coverage of Supprelin LA and did not issue a notice of action for the denied service as required by Attachment II, Section VII.G.6.a. of the contract. In its Notice, the CMS Plan stated, "Please be advised patient's age exceeds max age limit for this request. Please refer to web site for specific drug criteria and preferred alternatives." The enrollee filed a request for Medicaid Fair Hearing in response to the denied pharmacy claim. In its Statement of Matters filed in the Fair Hearing, the CMS Plan included several additional documents, including the Agency for Health Care Administration's (Agency) rules for experimental and investigational procedures and Rule 59G-1.035, Determining Generally Accepted Professional Medical Standards, Florida Administrative Code.

The Statement of Matters arises from several factual errors. For example, Supprelin LA is not an experimental drug; the Food and Drug Administration has approved Supprelin LA for treatment of central precocious puberty in both sexes. Supprelin LA is also approved to treat other conditions, as specified in the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System. However, Supprelin LA is not authorized or specified in these compendia for use in treating individuals diagnosed with gender dysphoria. This means that the CMS Plan denied Supprelin LA based solely on the Agency's criteria, which were not developed for this particular application of the drug. Given that this medication was prescribed for purposes outside of the approved indications, referring the treating physician to the Agency Web site could not provide "preferred alternatives."

The CMS Plan must ensure that all decisions to deny a service authorization request or limit a service in amount, duration, or scope that is less than requested, must be determined using the acceptable standards of care, state and federal laws, the Agency's medical necessity definition,

Pl. Trial Ex. 258

and clinical judgment of a licensed physician, psychiatrist, or dentist (as appropriate) or other professional as approved by the Agency. (Attachment I, Section VII.G.4.b.) The CMS Plan may utilize a national standardized set of criteria (e.g., Interqual*) or other evidence-based guidelines approved by the Agency to approve services. Such criteria and guidelines must not **solely** be used to deny, reduce, suspend or terminate a service; it may only be used as evidence of generally accepted medical practices which support the basis of a medical necessity determination.

The CMS Plan must develop a process for authorization of any medically necessary EPSDT service to enrollees under the age of 21 years when:

(1) The service is not listed in the service-specific Medicaid Coverage and Limitations Handbook, Coverage Policy, or fee schedule, or is not a covered service of the plan; or

(2) The amount, frequency, or duration of the service exceeds the limitations specified in the service-specific handbook or the corresponding fee schedule. (Attachment I, Section VII.G.1.d.)

The CMS Plan must notify the provider and give the enrollee written notice of any decision to deny a service authorization request, or to authorize a service in an amount, duration or scope that is less than requested. (Attachment I, Section VII.G.5.a.) In addition, the CMS Plan must mail the enrollee a written notice of action using the template provided by the Agency. (Attachment I, Section VII.G.6.a.) Finally, the CMS plan must provide the notice of action for standard service authorization decisions that deny or limit services no more than seven days following the request for service. (Attachment I, Section VII.G.6.b.(3))

Based on these facts, the CMS Plan must rescind the Notice of Prior Authorization Determination for request 0917477 and conduct a medical necessity review of the enrollee's request in compliance with the plan's contract with the Agency. For additional reference, the CMS Plan may use the Agency's Puberty Suppression Therapy - Generally Accepted Professional Medical Standards (GAPMS) Determination Report with Recommendation (attached to this letter). As a result of this review on puberty suppression therapy, the Agency has developed Drug Utilization Review Criteria for Pubertal Suppression with Gonadotropin-Releasing Hormone Analog Agent for Gender Dysphoria, which is also included with this letter.

Sincerely,

Lucinda Coverston
Contract Manager

LC/dp
Attachments; GAPMS Analysis