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CROSS-SEX HORMONE THERAPY
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: ~~{DATE}~~ May 20, 2022
To: ~~Beth Kidder, Interim Deputy Secretary for Medicaid~~ Ashley Peterson
From: Bureau of Medicaid Policy
Subject: ~~Cross-Sex Hormone Therapy~~

PURPOSE

~~In order for~~For the use of cross-sex hormone therapy to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of cross-sex hormone therapy must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in Rule 59G-1.035,F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of cross-sex hormone therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that cross-sex hormone therapy is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

RECOMMENDATION

This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards and is supported in compendia as off-label use. There are clinical guidelines that have been published for the use of cross-sex hormones by the Endocrine Society, September 2009 and the World Professional Association for Transgender Health (WPATH 7th version). These guidelines are considered standards of care for transgender patients and provide parameters to determine the diagnosis of gender dysphoria, at what age to start treatment of cross-sex hormone therapy, and monitoring parameters that should be in place during treatment.

Commented [GS1]: Newest guidelines published April Dec 2016
Hormone therapy for transgender patients - PMC (nih.gov)

Commented [GS2]: Cross-Sex hormones are usually recommended at the age of sixteen.

Veteran's Administration, Centers for Medicaid and Medicare, many commercial and Medicaid plans have protocols in place to provide access of the use of cross-sex hormone therapy in transgender patients.

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REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in Rule 59G-1.035, F.A.C., based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A ~~high-level~~high-level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g., Food and Drug Administration).
- Evidence based clinical practice guidelines.
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and
- Consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are ~~no~~not exclusively male or female hormones that have been identified. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns.

Cross-Sex Hormone Therapy

Cross-sex hormone therapy assists transgender patients to reflect the desired sex through physical changes. This is accomplished by increasing the testosterone in assigned females at birth, in conjunction with suppressing the estrogen in their bodies. Assigned males at birth will have their testosterone levels suppressed while their estrogen levels will be increased.

Currently, there are drugs approved by the FDA that increases testosterone in men with hypogonadism and increase estrogen in women for various approved indications in addition to men with advanced prostate cancer (Analytics, 2016). Estrogen and testosterone are the medications mainly used in cross-sex hormone therapy. Female to Male (FTM) patients, are prescribed testosterone, unless contraindicated. Male to Female patients, are prescribed estrogen, unless contraindicated (Levine, 2013). Anti-androgen agents may be used in conjunction with cross-sex hormone therapy, such as: progestins, gonadotropin releasing hormone agonists, spironolactone, or 5-alpha reductase inhibitors**.**

Testosterone has a variety of available formulations: ~~buccal~~ oral, intramuscular (IM), topical, transdermal, and ~~intranasal~~ subcutaneous. ~~The oral formulation of testosterone is not available in the United States~~. FTM patients most commonly use transdermal/topical, or IM routes of

Commented [GS3]: Cross-Sex Hormone therapy remains the same. (Table 1 and 2 of article)

Commented [GS4]: Testosterone current formulations are include subcutaneous now. (Parental and Implant). Oral Testosterone Undecanoate is now available in the U.S. (Tlando and Jatenzo).

Table 1 of article

administration because it provides better hormone levels. Estrogen also has various formulations available: transdermal, ~~vaginal, spray~~, oral, subcutaneous, and intramuscular. The most common route of administration for (MTF): oral, IM or transdermal (Tangpricha, 2016). For the purposes of this report, an analysis is being performed on the use of cross-sex hormone therapy concentrating on testosterone and estrogen.

Commented [GS5]: Estrogen current formulations include: Oral, Parental (SubQ, IM), Transdermal and SubQ implant. No mention of vaginal or spray formulations.

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved testosterone for hypogonadism in men and estrogen is approved in women for various indications (see below) and for men with advanced prostate cancer:

Testosterone (testosterone cypionate, testosterone enanthate, testosterone undecanoate)

- Indications for use: Primary hypogonadism or hypogonadotropic hypogonadism in men
- Off Label Use: various doses used in clinical trials, including testosterone cypionate 200mg IM every 2 weeks for gender identity disorder female- to male transsexual (Analytics, 2016)

- Possible side effects of testosterone FTM therapy: acne, polycythemia, dyslipidemia, transaminitis, weight gain, hypertension and mood lability. After 6 to 8 weeks of hormone treatment of testosterone, deepening of the voice occurs and is irreversible (Gibson et al., 2010)

Testosterone options for transgender men

Route	Formulation	Dosing
Oral (not available in United States)	Testosterone undecanoate	160–240 mg/day
Parental (subcutaneous, intramuscular)	Testosterone enanthate, cypionate	50–200 mg/week 100–200 mg/10–14 days
Implant (subcutaneous)	Testopel®	75 mg/pellet
Transdermal	Testosterone gel (1%)	2.5–10 g/day
	Testosterone patch	2.5–7.5 mg/day

- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/#:~:text=for%20some%20patients.-,Table%201,2.5%E2%80%937.5%20mg/day,-Open%20in%20a

Estrogen (conjugated estrogens, esterified estrogens, estradiol, estradiol acetate, estradiol cypionate, estradiol valerate)

- Indications for use: Advanced prostate cancer- androgen dependent men, metastatic breast cancer, lower than normal estrogen levels in women,

prevention of osteoporosis (postmenopausal~~),vulvovaginal~~), vulvovaginal atrophy (menopausal), and moderate to severe menopausal vasomotor symptoms

- ~~o~~ Off Label use: Conjugated estrogens, 17-beta estradiol and ethinyl estradiol may be effective in changing the physical external appearance for male to female transsexuals (Analytics, 2016)

Estrogen and anti-androgen options for transgender women

Route	Formulation	Dosing
Oral	Estradiol	2–4 mg daily
Parental (subcutaneous, intramuscular)	Estradiol valerate	5–30 mg every 2 weeks
Transdermal	Estradiol	0.1–0.4 mg twice weekly
Anti-androgens	Progesterone	20–60 mg PO daily
	Medroxyprogesterone acetate	150 mg IM every 3 months
	GnRH agonist (leuprolide)	3.75–7.5 mg IM monthly
	Histrelin implant	50 mg implanted every 12 months
	Spironolactone	100–200 mg PO daily
	Finasteride	1 mg PO daily

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/#:~:text=profiles%20(14).-,Table%202,1%20mg%20PO%20daily,-Open%20in%20a

- Side effects of estrogen in MTF therapy: decreased facial and body hair, fat redistribution, decreased spontaneous erections, softened skin, growth of breast tissue, and growth plate closure, increased risk of thromboembolic disease, liver dysfunction, cholelithiasis, hypertension, and hyperprolactinemia. Breast development will begin almost immediately upon estrogen administration, will proceed in a cyclical fashion, and will be as large as can be expected after approximately two years of treatment.

LITERATURE REVIEW

Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria (GD) (formally referred to as gender identity disorder) as an individual's affective or cognitive discontent with their assigned gender at birth. GD refers to the ***distress*** that may accompany the incongruence between the individual's experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as the individual ages or enters different developmental stages. Both categories require marked incongruence between the individual's experienced or expressed

gender and their assigned gender of at least a six months' duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning (Association, 2014)

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys, games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy. Studies have shown that ~~the majority of~~most children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty *(Moller et al., 2009; Wallien & Cohen-Kettenis, 2008; and Drummond et al., 2008).*

Commented [GS6]: Still valid per article "Gender Dysphoria in Children" published November 2018
Gender Dysphoria in Children | American College of Pediatricians (acpeds.org)

For the 20% of children who persist in their feelings of gender dysphoria, clinicians may begin to explore alternative treatment approaches beyond psychotherapy after the onset of puberty, including medical interventions such as the use of gonadotropin releasing hormone (GnRH) analogs to suppress puberty. It is generally introduced in children who have reached a minimum of Tanner Stage 2 (a scale used to determine physical development in children, adolescents and adults based on external primary and secondary sex characteristics) which is usually at the age of 12-16 (Cohen-Kettenis et al.2011). Other drugs, such as progestins and antiandrogens (spironolactone and 5-alpha reductase inhibitors) have been used to suppress physical changes in puberty. In addition to puberty suppression therapy, a physician may also begin to prescribe cross-sex hormones, though the latter does not generally begin until the ages of 16-18 (de Vries et al. 2011).

Cross-sex hormone therapy is the primary medical intervention sought by transgender people**.** Exogenous hormones have a clear impact on fertility. Patients must be informed and counseled regarding options for fertility and evaluation of medical conditions that can be exacerbated by hormone depletion, prior to treatment with sex hormones of the desired sex in both adolescents and adults. The patient must be made aware of the possibility of infertility/sterilization with the use of cross-sex hormone therapy. Fertility preservation options may include sperm, oocyte, embryo, ovarian tissue or testicular tissue cryopreservation. Transgender patients who undergo fertility preservation or assisted reproduction should be informed of the lack of data on outcomes. The use of cross-sex therapy alone does not guarantee prevention of pregnancy, if sexually active contraception is required. Testosterone is a teratogen and is contraindicated in pregnancy. The effects of ~~long term~~long-term exogenous testosterone and estrogen are unclear, but the possible side effects should be addressed (Francisco, Center, and Information, 2016)

It is important to note that most of the literature reviewed in development of this analysis concluded that more systematic research is required to determine the long-term efficacy of medical treatment for adolescents with gender dysphoria (Kaltiala-Heino et al. 2015; Jarin et al. 2016; Lee et al. 2016, March et al. 2015; Vance et al. ~~2014; Vrouenraets~~2014; Vrouenraets et al 2015)

Clinical Outcome

No perspective, randomized, controlled trials were located that have evaluated the safety and efficacy of the use of cross-sex hormones to produce physical effects in transgender patients. The current information used has been derived primarily from observational study or has been extrapolated from the use of hormones for the approved FDA indications (Tangpricha, 2016).

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of cross-sex hormone therapy. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Recommendations from The Endocrine Society Guidelines are as follows:

- We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology.
- Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in pre-pubertal children with GID
- We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (~~e.g.~~e.g., GnRH analog treatment) and cross-sex hormone treatment before they start hormone treatment.
- We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.
- We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 year, using a gradually increasing dose schedule of cross-sex steroids.
- We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes.
- We suggest that treatment with GnRH analogs be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion
- Baseline labs and scheduled routine monitoring for known risks throughout adulthood
- Maintain physiologic levels of appropriate sex hormones in the range of the desired gender and monitor for known risks of gender-appropriate sex hormones
- Lifetime continuation of cross-sex hormone therapy usually required unless medically ~~contraindicated (~~contraindicated (Hembree et al., 2009)

WPATH Version 7 Standard of Care recommendations for Cross-Sex Hormone therapy:

- Persistent, well-documented gender ~~dysphoria;~~dysphoria.
- Capacity to make a fully informed decision and to consent for ~~treatment;~~treatment.
- If significant medical or mental health concerns are present, they must be reasonably well controlled.
- Mental health professional competent in diagnosing and treating ordinary problems of children and adolescents; trained in childhood and adolescent developmental psychopathology; and must meet the competency requirements for mental health professionals working with adults.

- A staged process of physical interventions of adolescents is recommended to allow the adolescents and their parents to assimilate fully the effects of earlier interventions: fully reversible interventions (~~i.e.~~i.e., GnRH analogues, spironolactone, progestins) partially reversible interventions (~~i.e.~~i.e., hormone therapy to masculinize or feminize the body, cross-sex hormones) and irreversible interventions (surgical procedures).
- Adolescents may be eligible to begin feminizing/masculinizing hormone therapy preferably with parental consent at 16.
- Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (Hembree et al., 2009). The hormone regimen is adjusted to account for emotional, somatic and mental development that occurs throughout adolescence.

Possible risk Factors associated with Cross-Sex Hormone therapy:

- Adolescents undergoing partially reversible cross-gender hormone therapy should be monitored for progress in transition and for any potential medical complications.

- MTF patients started on estrogen might develop deep venous thrombosis, prolactinomas, hypertension, hypertriglyceridemia, cardiovascular disease, type 2 diabetes, liver disease, and decreased libido and are at increased risk of breast cancer. Spironolactone can lead to hyperkalemia and decreased blood pressure.

- FTM patients receiving testosterone may develop hyperlipidemia, polycythemia, male pattern baldness, acne, cardiovascular disease, hypertension, type 2 diabetes, breast cancer, cervical cancer, ovarian cancer, uterine cancer, destabilization of certain psychiatric disorders (~~i.e.~~i.e., bipolar, schizoaffective disorders (Hembree et al.,2009; Tangpricha, 2016)

Monitoring for FTM on hormone therapy:

- Monitor for virilizing and adverse effects every 3 months for first year and then every 6 – 12 months.
- Monitor serum testosterone at follow-up visits with a practical target in the male range (300 – 1000 ng/dl). Peak levels for patients taking parenteral testosterone can be measured 24 – 48 h after injection. Trough levels can be measured immediately before injection.
- Monitor hematocrit and lipid profile before starting hormones and at follow-up visits.
- Bone mineral density (BMD) screening before starting hormones for patients at risk for osteoporosis. Otherwise, screening can start at age 60 or earlier if sex hormone levels are consistently low.
- FTM patients with cervixes or breasts should be screened appropriately. ***(~~site~~Site reference)***
- Monitor renal function, liver function ~~tests fasting~~tests fasting glucose, insulin, hemoglobin A1C, bone density and bone age.
- FTM patients should have axillary lymph nodes examined (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005).

Monitoring for MTF on hormone therapy:

- Monitor for feminizing and adverse effects every 3 months for first year and then every 6– 12 months.
- Monitor serum testosterone and estradiol at follow-up visits with a practical target in the female range (testosterone 30 – 100 ng/dl; E2 <200 pg/ml).
- Monitor prolactin and triglycerides before starting hormones and at follow-up visits.
- Monitor potassium levels if the patient is taking spironolactone.
- Bone mineral density screening before starting hormones for patients at risk for osteoporosis. Otherwise, start screening at age 60 or earlier if sex hormone levels are consistently low.
- MTF patients should be ~~be~~ advised to do breast self-exams and be screened for breast and prostate cancer appropriately. Breast ~~self-exams~~self-exams should be advised (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005).

COVERAGE POLICY

Federal Regulations

Federal regulations for Medicaid specify that a state may limit coverage of a drug with respect to the treatment of a specific disease or condition for an identified population (if any) based on the drug's labeling, if it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary. In addition, states may exclude a drug when the prescribed use of the drug is not for a medically accepted indication, either approved by the FDA or supported by information from the appropriate compendia. These guidelines apply to a state's administration of its Medicaid prescribed drug benefit in both managed care and non-managed care delivery systems.

States are also required to implement a drug use review program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results. The program is required to assess data on drug use against predetermined standards, consistent with the following:

- Compendia, consisting of the following:
    1. American Hospital Formulary Service Drug ~~Information;~~Information.
    2. United States Pharmacopeia-Drug Information (or its successor publications); and
    3. the DRUGDEX Information System; and
- The peer-reviewed medical literature.

Federal law requires states to provide services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. This is known as the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the Social Security Act, codified in Title 42 of the United States Code 1396d (a). As such, services for recipients under the age of 21 years exceeding any coverage limitations specified within a state's policies maybe approved, if medically necessary.

Florida Medicaid

In order to be reimbursed by Florida Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with section 1927(k) (6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency for Health Care Administration (Agency).

The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows:

1. Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication **AND**
2. Phase III clinical studies published in peer review journals to support the non-FDA approved use **AND**
3. Usage supported by publications in peer reviewed medical literature **and** one or more citations in at least one of the following compendia:
   a. American Hospital Formulary Service Drug Information (AHFS)
   b. United States Pharmacopeia-Drug Information (or its successor publications)
   c. DRUGDEX Information System

Florida Medicaid covers hormone 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. Testosterone and estrogen are not FDA approved for cross-sex hormone therapy in patients with gender dysphoria. However, DRUGDEX Information System's compendia addresses off-label use of testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol in the use of cross-sex hormone therapy.

Children/adolescents diagnosed with gender dysphoria are also 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.

Health plans contracted to provide services under the Florida Medicaid Statewide Medicaid Managed Care program are required to cover all prescription drugs listed in the Agency's Medicaid Preferred Drug List (PDL). In addition, the health plan's prior authorization criteria and protocols may not be more restrictive than those used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan and those posted on the Agency website.

Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Medical necessity in the State of Florida must meet the following conditions:

1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe ~~pain;~~pain.
2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not ~~in excess of~~more than the patient's ~~needs;~~needs.
3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or ~~investigational;~~investigational.

4. Be reflective of the level of service that can be safely furnished, and for which ~~no~~not equally effective and more conservative or less costly treatment is available statewide; and
5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

If a service exceeds the coverage described within a Florida Medicaid policy or the associated fee schedule, a request (along with all supporting documentation) may be submitted to the Agency or its designee for review.

Federal

CMS implemented a new rule by the Department of Health and Human Services implements Section 1557 of the Affordable Care Act (ACA), "Nondiscrimination in Health Programs and Activities." This rule applies to all health programs that receive federal funding or assistance, including state Medicaid agencies, as well as most health insurance issuers. Effective July 18, ~~2016~~2016, are other provisions including provisions related to discrimination based on gender identity, pregnancy, or transgender status. Individuals must be provided equal access to health services without discrimination related to gender or identity. Entities can still review for medical necessity ~~as long as~~if the review is not discriminatory towards these individuals and utilizes a neutral rule or principal. Categorical exclusion or limits on services related to gender transition are discriminatory as well.

Medicare

Transgender beneficiaries can use hormone therapy, which are coverable under the Medicare Part D prescription drug benefit program. The *Medicare Benefit Policy Manual*, Chapter 15, page 15, subsection 50.4.2, discusses the unlabeled use of a drug. The policy states that "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." Medicare provides a special billing code (condition code 45) when gender mis-match claims may be a problem (http://www.transequality.org/sites/default/files/docs/kyr/MedicareAndTransPeople.pdf)

Veteran's Administration

Veteran's Administration Pharmacy Benefits Management has criteria for adult transgender men testosterone replacement therapy in as well as adult transgender women estrogen replacement therapy.
http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender_Cross_Sex_Hormone_Therapy_in_FtM_Female_to_Male_CFU.pdf

http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender_Cross_Sex_Hormone_Therapy_in_MtF_Male_to_Female_CFU.pdf

State Medicaid Programs

All state Medicaid programs cover hormone therapy for the approved FDA indications and when the criteria for off-label use are met. Some state Medicaid programs are also adopting coverage policies that allow for reimbursements of cross-sex therapy in adolescents diagnosed with gender dysphoria. This report highlights the coverage policies for some Medicaid programs that do cover the service, as follows:

1. Colorado Medicaid covers behavioral health services, GnRH analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, physical therapy and ~~pre~~pre- and post-operative care.
2. Maryland Medicaid covers cross-sex hormone therapy for recipients 18 and older.
3. Rhode Island Medicaid covers behavioral health services, pharmacological and hormonal therapy to delay physical changes of puberty, and pharmacological and hormonal therapy that is non-reversible and produces masculinization or feminization. Some services require prior authorization.
4. Washington State Medicaid covers behavioral health services, puberty suppression therapy, hormonal therapy, and gender reassignment surgery. They have had policy in place since February 2014 regarding access to care.
5. California, New York and Massachusetts are obligated to pay for gender transition.
6. Oregon covers cross-sex hormone therapy for adolescents and adults who meet eligibility and readiness criteria.
7. Montana covers cross-sex hormone therapy for transgender recipients. Testosterone requires a prior authorization to ensure treatment is for appropriate diagnoses.
8. Indiana covers cross-sex hormone therapy for gender dysphoria recipients.
9. Illinois removed gender restrictions on estradiol and testosterone in 04/01/2015 based on the Endocrine Society recommendations.

Commented [GS7]: Colorado also covers physical therapy, hormone therapy, and surgical procedures
Gender-Affirming Care Billing Manual | Colorado Department of Health Care Policy & Financing

Private Insurers:
The following private insurers have criteria in place to access medications for cross-sex hormone therapy:

Moda Health ~~Plan Inc~~Plan Inc, Gender Reassignment Medical Necessity:
https://www.modahealth.com/pdfs/med_criteria/GenderReassignment.pdf

Fallonhealth: Transgender Services Clinical Coverage Criteria
http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=20&ved=0ahUKEwjeharT6ubOAhVH5iYKHZYfAIg4ChAWCF8wCQ&url=http%3A%2F%2Fwww.fchp.org%2Fproviders%2Fmedical-management%2F~%2Fmedia%2FFiles%2FProviderPDFs%2FMedicalPolicies%2FTransgenderServices.ashx&usg=AFQjCNHGumXLS82ivBfVGHDP6bXEeJOdbQ

Blue regence Transgender Services Policy
http://blue.regence.com/trgmedpol/medicine/med153.pdf

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

Cross-sex hormone therapy may be considered a health service that is consistent with generally accepted professional medical standards for the approved FDA indications (i.e., hypogonadism, hypoestrogenism) and for off-label use when supported by citations in at least one of the compendia. Since Florida Medicaid already provides coverage of hormone therapy in the FDA approved indications and for use in treating the conditions cited in the compendia, no further policy coverage analyses are needed to supplement this report on this point.

Based upon the available published literature, cross-sex hormone therapy should be considered a health service that is consistent with generally accepted professional medical standards in the treatment of gender dysphoria. Most of the studies published thus far on the use of cross-sex hormone therapy in gender dysphoric children/adolescents have concluded that further systematic research is required to determine the long-term safety and efficacy of this approach. The guidelines for transgender patients in the Endocrine Society and WPATH are controversial because they are based primarily on expert opinion rather than scientific data, given the paucity of the outcomes data on the effects of mental health and medical interventions (Vance, Ehrensaft, and ~~Rosenthal, 2014~~Rosenthal, 2014). However, the standards of care for cross-sex hormone therapy seem to be consistent in the approach with diagnosis, monitoring and dosing of the transgender patients. Indeed, hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people (American Medical Association, 2008; Anton, 2009; Tangpricha, 2016) Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults. The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (Hembree et al., 2009). As the research on this topic continues to evolve, more conclusive evidence may emerge that supports the long-term efficacy and effectiveness of this treatment approach.

EPSDT Considerations:

Clinical guidelines from the Endocrine Society and WPATH recommend this therapy for certain adolescents, albeit based upon weak evidence. In certain circumstances, the risks of not treating an adolescent may be worse than the potential long-term consequences of treatment. Moreover, it is noted extensively in the literature that adolescents contending with gender

dysphoria often experience a myriad of emotional, physical, and societal challenges. Unresolved, the distress can manifest into a host of behavioral health problems including depression, anxiety, and suicidal ideation and self-mutilation. Florida pays for services for children when they protect life and /or prevent significant disability or harm, in accordance with the state's medical necessity definition.

Testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol have documented off-label use in DRUGDEX. Because of this supporting documentation in the compendia, the off-label criteria could be used to evaluate each patient on a ~~case by case~~case-by-case basis. This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards. Consistent with EPSDT requirements, the request can be evaluated on an individualized basis to determine if the service is medically necessary (~~e.g.~~e.g., it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation) to ensure that all less invasive interventions have been exhausted, and to ensure that this treatment approach presents as the best alternative given the adolescent's psychological state and presenting signs and symptoms.

REFERENCES

1. Unger C. A. (2016). Hormone therapy for transgender patients. *Translational andrology and urology*, *5*(6), 877–884. https://doi.org/10.21037/tau.2016.09.04

____ Concur **____ Do Not Concur**

Comments:

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Signature Date

Deputy Secretary for Medicaid (or designee)