Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Transgender Services***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***December 2016***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO	*Products*: [ ] Small [ ] Indiv. [ ] Large	*Exchange*: [ ] Shop [ ] Indiv.	[x] All
OTHER	[x] Self-funded/ASO			

PURPOSE

The purpose of this policy is to define the prior authorization process for testosterone products and LHRH agents.

DEFINITIONS

Gender Dysphoria (previously referred to as transsexualism or Gender Identity Disorder) – refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and their sex assigned at birth.

In the United States, the American Psychiatric Association (APA) permits a diagnosis of gender dysphoria if the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, (DSM-5) are met. The criteria are:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six month's duration, as manifested by at least two of the following:
    - A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics; or

- A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender; or
- A strong desire for the primary and/or secondary sex characteristics of the other gender; or
- A strong desire to be of the other gender or some alternative gender different from one's assigned gender; or
- A strong desire to be treated as the other gender or some alternative gender different from one's assigned gender; or
- A strong conviction that one has the typical feelings and reactions of the gender or some alternative gender different from one's assigned gender; and

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Gender Identity – the sense one has of being male or female.

Gender Identity Disorder (GID) – a significant incongruence between gender identity and physical phenotype, the observable traits of the person. This term has been replaced in the current DSM-V with Gender Dysphoria described above.

Gender Nonconformity – refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex.

Gender Confirmation Surgery – refers to surgical procedures to reshape the body to remove characteristics that are incompatible with a person's sense of gender identity or/and to resemble those of the non-natal gender.

Male to Female (MtF) gender confirmation surgeries include orchiectomy, penectomy, penile inversion vaginoplasty, labiaplasty, and breast augmentation.
Female to Male (FtM) gender confirmation surgeries include mastectomy, oophorectomy, salpingoophorectomy, hysterectomy, vaginectomy, metoidioplasty, phalloplasty, and scrotoplasty.

Informed consent - refers to a person's consent to a proposed medical intervention after receiving relevant information. The information that is legally required includes: diagnosis, nature and purpose of the proposed intervention, risks and consequences of the proposed treatment, probability that the treatment will be successful, feasible treatment alternatives and prognosis if the treatment is not given.

Luteinizing Hormone Releasing Hormone (LHRH) Agents – agents such as leuprolide (Lupron®) or histrelin acetate (Supprelin LA®) utilized to suppress puberty for relief of gender dysphoria, as well as to improve psychological and physical outcomes.

LHRH agents may be used with cross-sex hormones, up to the time of sex confirmation surgery.

Qualified Mental Health Professional (according to World Professional Association for Transgender Health) – must have all of the following characteristics:

- Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; and
- Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; and
- Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; and
- Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; and
- Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

Sex Confirmation Surgery – is part of gender confirmation surgery and refers only to the reconstruction of the genitals.

Tanner Stages (Sexual Maturity Rating) – staging system consisting of systematized descriptions of the development of secondary sexual characteristics, including breast changes in females, genital changes in males, and pubic hair in both males and females.

Tanner Stage	Boys – Development of External Genitalia	Girls – Breast Development	Boys and Girls – Pubic Hair
Stage 1	Prepubertal		
Stage 2	Enlargement of scrotum and testes; scrotal skin reddens and changes in texture	Breast bud stage with elevation of breast and papilla; enlargement of areola	Sparse growth of long, slightly pigmented hair, straight or curled, at base of penis or along labia

Stage 3	Enlargement of penis (length at first); further growth of testes	Further enlargement of breast and areola; no separation of their contour	Darker, coarser and more curled hair, spreading sparsely over junction of pubes
Stage 4	Enlargement of penis (length at first); further growth of testes	Areola and papilla form a secondary mound above level of breast	Hair adult in type, but covering smaller area than in adult; no spread to medial surface of thighs
Stage 5	Adult genitalia	Mature stage: projection of papilla only, related to recession of areola	Adult female in type and quantity, with horizontal upper border

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective product:

1. LHRH Agents:

- Must be prescribed and monitored by or in consultation with a pediatric endocrinologist or clinician with specialized training in transgender health care
- Member must be an adolescent
- Member must have persistent (at least 6 months), well-documented diagnosis of gender dysphoria as outlined in Definitions Section, and as evidenced by chart documentation and/or a letter of medical necessity and diagnosed by a qualified mental health professional (see Definitions Section).

  - Documentation must be submitted to support the diagnosis, as well as confirm that the condition is not a result of another mental disorder, or other conditions. Documentation must indicate both of the following:
    - The desire to live and be accepted as a member of the opposite sex, typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment; and
    - The gender dysphoria causes distress or impairment in social, educational, occupational, or other important areas of functioning
- Must have experienced puberty to at least Tanner Stage 2
- Must have gender dysphoria that emerged or worsened with onset of puberty
- If the member has significant medical or mental health issues present, they must be reasonably well-controlled. Documentation (if applicable) of the presence and nature of any significant medical or mental health conditions, and documentation that they are reasonably well-controlled is required.
- Must have adequate psychological, medical, and social support available during treatment
- Documentation that the member can demonstrate adequate knowledge and understanding of the expected outcomes of pubertal suppression.
- Documentation that the adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. When parental consent cannot be obtained, exceptions are reviewed on a case by case basis.

2. Testosterone Products:

- Must be 16 years of age or older
- Must be prescribed and monitored by or in consultation with an endocrinologist or a clinician trained in transgender health care
- Member must have persistent (at least 6 months), well-documented diagnosis of gender dysphoria as outlined in Definitions Section, and as evidenced by chart documentation and/or a letter of medical necessity and diagnosed by a qualified mental health professional (see Definitions Section).
  - Documentation must be submitted to support the diagnosis, as well as confirm that the condition is not a result of another mental disorder, or other conditions. Documentation must indicate both of the following:

    - The desire to live and be accepted as a member of the opposite sex, typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment; and
    - The gender dysphoria causes distress or impairment in social, educational, occupational, or other important areas of functioning
- If the member has significant medical or mental health issues present, they must be reasonably well-controlled. Documentation (if applicable) of the presence and nature of any significant medical or mental health conditions, and documentation that they are reasonably well-controlled is required.
- Member must have an initial mental health evaluation; continued psychotherapy is recommended.
- Documentation that the member can demonstrate adequate knowledge and understanding of the expected outcomes of cross-sex hormone treatment, as well as the medical and social risks and benefits of sex confirmation.
- Documentation that the adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. When parental consent cannot be obtained, exceptions are reviewed on a case by case basis.

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis, depending upon diagnosis, to determine the Medical Necessity for continuation of therapy.

- For LHRH Agents:
    - Must submit documentation that member has been assessed by prescriber at least every 3 to 6 months for response to treatment, compliance, side effects (through regular monitoring of parameters such as height, weight, sitting height, Tanner stage, FH, FSH, estradiol/testosterone levels, renal/liver function, lipids, glucose, insulin, glycosylated hemoglobin, bone density, bone age, etc), and discussion of treatment plan (e.g. hormone therapy, sex confirmation surgery).
    - LHRH agents are covered only for use in adolescents and are not covered following sex confirmation surgery.
- For testosterone: must submit documentation that member has been assessed by prescriber every 3-6 months for response to treatment, compliance, side effects (through regular monitoring of parameters such as height, weight, sitting height,

Tanner stage, FH, FSH, estradiol/testosterone levels, renal/liver function, lipids, glucose, insulin, glycosylated hemoglobin, bone density, bone age, etc), and discussion of treatment plan (e.g. hormone therapy, sex confirmation surgery).

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• LHRH: 6 months or until time of sex confirmation surgery • Testosterone: 6 months
Reauthorization	1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. The World Professional Association for Transgender Health (WPATH). Standards of care for the health of transsexual, transgender, and gender nonconforming people. 7th version. http://www.wpath.org/uploaded_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf. Accessed June 29, 2015
2. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society Practice Guideline. J Clin Endocr Metab 2009;94(9):3132-3154
3. Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. J Clin Endocrinol Metab. 2014;99(12):4379-89
4. Smith KP, Madison CM, Milne NM, et al. Gonadal suppressive and cross-sex hormone therapy for gender dysphoria in adolescents and adults. *Pharmacotherapy* 2014;34(12):1282-1297

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New policy	*12/16*
Annual Review	*02/17, 02/18*