PreferredOne®

Department of Origin: Pharmacy	**Effective Date:** 12/06/2023
Approved by: Pharmacy and Therapeutics Subcommittee	**Date Approved:** 12/06/2023
Pharmacy Clinical Policy Document: Gender Dysphoria Treatment; Gonadotropin Releasing Hormone Analogues	**Replaces Effective Clinical Policy Dated:** 5/24/2023
Reference #: PC/G002	**Page:** 1 of 6

PURPOSE:
The intent of this Gender Dysphoria Treatment; Gonadotropin Releasing Hormone Analogues Pharmacy Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

This policy refers to the following gonadotropin releasing hormone analog (GnRH analog) drug products:

Camcevi (leuprolide mesylate)
Eligard (leuprolide acetate (for depot suspension))
Fensolvi® (leuprolide acetate)
Firmagon® (degarelix)
Leuprolide
Lupron Depot® (leuprolide acetate)
Lupron Depot-PED® (leuprolide acetate)
Supprelin® LA (histrelin acetate)
Trelstar® (triptorelin pamoate)
Triptodur® (triptorelin)
Zoladex® (goserelin acetate)

GUIDELINES:
Medical Necessity Criteria - Must satisfy one the following: I - III

I. Prior to initiation of GnRH analogues used as *puberty suppressing* hormonal therapy in the treatment of gender dysphoria, the following minimum criteria must be met: A - D

   A. Diagnosis of *gender dysphoria*, according to the current DSM (i.e., DSM-5) criteria, by a *qualified mental health professional* with expertise in child and adolescent psychiatry; and

   B. Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in *gender dysphoria* hormone therapy; and

   C. The adolescent must have reached Tanner Stage 2 or above (see Attachment A); and

   D. A letter from the prescriber and/or formal documentation stating all of the following: 1-4

      1. Patient has experienced pubertal changes that have resulted in an increase of their *gender dysphoria* that has significantly impaired psychological or social functioning; and

      2. Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed; and

3. Both of the following: a and b
   a. Current enrollment, attendance, and active participation in psychological and social support treatment program; and
   b. Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment; and

4. Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies.

II. Prior to initiation of GnRH analogues used as adjunct for gender-affirming hormonal therapy for transgender adults, the following minimum criteria must be met: A - F

A. Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5) criteria, by a mental health professional; and

B. Medication is prescribed by, or in consultation with, an endocrinologist or a medical provider experienced in transgender hormone therapy; and

C. Gonads (i.e., testes, ovaries) have not been removed and are functional (e.g., hormone producing); and

D. Patient is currently receiving hormonal gender reassignment therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender; and

E. Inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, LH, or gonadotropins (e.g., menses, testosterone);and

F. A letter from the prescriber and/or formal documentation stating all of the following:1-4

1. Transgender patient has identified goals of gender-affirming hormone therapy; and

2. Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed; and

3. Both of the following: a and b
   a. Current enrollment, attendance, and active participation in psychological and social support treatment program; and
   b. Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment; and

4. Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies.

III. Continuation request – Allow up to an additional 12 months

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description.

DEFINITIONS:
Gender dysphoria or gender identity disorder
Is defined as evidence of a strong and persistent cross-gender identification, which is the desire to be, or the insistence that one is of the other gender. Persons with this disorder experience a sense of discomfort and inappropriateness regarding their anatomic or genetic sexual characteristics.

Gender reassignment
Refers to the hormonal and surgical reassignment of gender dysphoric persons.

Gonadotropin releasing hormone (GnRH) analogues (agonists and antagonists)
Synthetic drugs similar to natural GnRH. There are two main types: agonists and antagonists.

- Agonists stimulate the pituitary gland to secrete follicle stimulating hormone (FSH), luteinizing hormone (LH) secretion. Unlike natural GnRH, which is secreted in a pulsatile manner, synthetic agonists have a constant pharmacokinetic action. They are usually administered via nasal spray or via injection
- Antagonists also suppress FSH and LH production, but unlike agonists, they do so without the initial stimulation. Antagonists are usually injected.

Hormonal gender reassignment
Refers to the administration of androgens (male hormones) to genetic females and estrogens and/or progesterones (female hormones) to genetic males for the purpose of effecting somatic changes (softening of skin, hair growth, breast development etc.) in order to more closely approximate the physical appearance of the other gender.

Puberty suppression
Refers to the administration of GnRH analogues to suppress estrogen or testosterone production and consequently delay the physical changes of puberty.

- Adolescents with male genitalia should be treated with GnRH analogues, which stop luteinizing hormone secretion and therefore testosterone secretion. Alternatively, they may be treated with progestins (such as medroxyprogesterone) or other medications (such as spironolactone) that block testosterone secretion and/or neutralize testosterone action.
- Adolescents with female genitalia should be treated with GnRH analogues, which stop the production of estrogens and progesterone. Alternatively, they may be treated with progestins (such as medroxyprogesterone). Continuous oral contraceptives (or depot medroxyprogesterone) may be used to suppress menses.

Qualified mental health professional:
The following are the minimum credentials for mental health professionals who work with adults presenting with gender dysphoria:

- A master's degree or its equivalent in a clinical behavioral science field
- Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Diseases for diagnostic purposes
- Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria
- Documented supervised training and competence in psychotherapy or counseling
- Knowledge about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria
- Continuing education in assessment and treatment of gender dysphoria

The following are desired credentials but are not required:

- Cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients, e.g. knowledgeable about community, advocacy and public policy issues relevant to these clients and their families
- Knowledge about sexuality, sexual health concerns, and the assessment and treatment of sexual disorders

BACKGROUND:
Gender dysphoria or gender identity disorder is not the same condition that occurs in patients suffering from genetic or hormonal abnormalities, or ambiguous genitalia.

Prior Authorization: Yes, per network provider agreement - up to 12 months. This is subject to the member's contract benefits.

CODING:
When billed with the following ICD-10 diagnosis codes:
F64.0 transsexualism
F64.1 dual role transvestism
F64.2 gender identify disorder of childhood
F64.8 other gender identity disorders
F64.9 gender identify disorder, unspecified
Z87.890 personal history of sex reassignment status

HCPCS - 2023
J1675 injection, histrelin acetate, 10mcg
J1950 Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J1951 Injection, leuprolide acetate for depot suspension (Fensolvi), 0.25 mg
J1952 Injection, leuprolide, Camcevi, 1 mg
J1954 Injection, leuprolide depot, Lutrate, 7.5 mg
J3315 Injection, triptorelin pamoate, 3.75 mg
J3316 Injection, triptorelin, extended-release, 3.75 mg
J9155 Injection, degarelix, 1 mg
J9202 Goserelin acetate implant, per 3.6 mg
J9217 Leuprolide acetate (for depot suspension), 7.5 mg
J9218 Leuprolide acetate, per 1 mg
J9219 Leuprolide acetate implant, 65 mg
J9226 Histrelin implant (Supprelin LA), 50 mg

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Clinical Policy: MP/C002 Cosmetic Procedures/Treatments
4. Minnesota Statute 363A.17 Business Discrimination
5. World Professional Association for Transgender Health. Standards of care for the health of transgender and gender diverse people. 8th Version. 2022. Retrieved from https://www.wpath.org/publications/soc. Accessed 10-12-23.
6. Rafferty, J., AAP Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescences, Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. *Pediatrics*. 2018;142(4):e20182162.
7. Biro FM, Chan YM. Normal puberty. (Topic 5849, Version 49.0; last updated: 02/02/23) In: Hoppin AG, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2022. www.uptodate.com. Accessed 10-12-23.
8. Mahfouda BA, Moore JK, Franz CP, et al. Puberty Suppression in Transgender Children and Adolescents. *The Lancet Diabetes Endocrinol* 2017;5816-26.

DOCUMENT HISTORY:

Created Date: (Previously MC/G014) 02/22/22
Reviewed Date: 2/22/2023, 10/14/2023
Revised Date:

PreferredOne®

Department of Origin: Pharmacy	**Effective Date:** 12/06/2023
Approved by: Pharmacy and Therapeutics Subcommittee	**Date Approved:** 12/06/2023
Pharmacy Clinical Policy Document: Gender Dysphoria Treatment; Gonadotropin Releasing Hormone Analogues	**Replaces Effective Clinical Policy Dated:** 5/24/2023
Reference #: PC/G002	**Page:** 6 of 6

Attachment A – Sexual maturity rating (Tanner stages) of secondary sexual characteristics

Boys - Development of external genitalia
Stage 1: Prepubertal
Stage 2: Enlargement of scrotum and testes; scrotal skin reddens and changes in texture
Stage 3: Enlargement of penis (length at first); further growth of testes
Stage 4: Increased size of penis with growth in breadth and development of glans; testes and scrotum larger, scrotal skin darker
Stage 5: Adult genitalia
Girls - Breast development
Stage 1: Prepubertal
Stage 2: Breast bud stage with elevation of breast and papilla; enlargement of areola
Stage 3: Further enlargement of breast and areola; no separation of their contour
Stage 4: Areola and papilla form a secondary mound above level of breast
Stage 5: Mature stage: projection of papilla only, related to recession of areola
Boys and girls - Pubic hair
Stage 1: Prepubertal (the pubic area may have vellus hair, similar to that of forearms)
Stage 2: Sparse growth of long, slightly pigmented hair, straight or curled, at base of penis or along labia
Stage 3: Darker, coarser and more curled hair, spreading sparsely over junction of pubes
Stage 4: Hair adult in type, but covering smaller area than in adult; no spread to medial surface of thighs
Stage 5: Adult in type and quantity, with horizontal upper border

Retrieved from Biro FM, Chan YM. Normal puberty. (Topic 5849, Version 49.0; last updated: 02/02/23) In: Hoppin AG, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2022. www.uptodate.com. Accessed 04-12-23.

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013).

ဟသျှဉ်ဟသး– နမ့်ကတိ၊ ကညီ ကျိာ်အယိ, နမၤန့် ကျိာ်အတ်မၤစၢၤလ၊ တလၫ်ဘူဉ်လၫ်စ့၊ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013).

ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).