

Clinical Guidelines and Coverage Criteria for the Treatment of Gender Dysphoria

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1. POLICY STATEMENT

Amida Care complies with 18 NYCRR 505.2(I) coverage guidelines for the management of hormone therapy (HT) and gender affirming surgery (GAS) for the treatment of gender dysphoria (GD). The following guidelines aid in establishing practices and coverage regulations consistent with the New York State Medicaid Regulations for Transgender Related Care and Services and are guided by the WPATH Standards of Care. Amida Care will follow all the provisions of NYS DOH's "Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria."

2. SCOPE

Coverage for treatment of gender dysphoria is subject to the terms, conditions and limitations of the applicable benefit plan and may be governed by state and/or federal mandates. Medically necessary treatment for an individual with a diagnosis of gender dysphoria may include ANY of the following services, when services are available in the benefit plan:

- Behavioral health services, including but not limited to, counseling for gender dysphoria and related psychiatric conditions (e.g., anxiety, depression)
- Hormonal therapy, including but not limited to androgens, anti-androgens, GnRH analogues, estrogens, and progestins
- Laboratory testing to monitor prescribed hormonal therapy
- Age-related, gender-specific services, including but not limited to preventive health, as appropriate to the individuals biological anatomy (e.g., cancer screening [e.g., cervical, breast, prostate]; treatment of a prostate medical condition)
- Gender affirmation and related surgery (see Appendix 8.1)
- Procedures that change the patient's physical appearance to more closely align with secondary sex characteristics to those of the patient's identified gender shall be covered if it is demonstrated that such surgery, service, or procedure is medically necessary to treat a particular patient's gender dysphoria, and prior approval is received.

3. GENDER DYSPHORIA

Gender Dysphoria is defined as clinically significant discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth and the associated gender role and/or primary and secondary sex characteristics [DSM 5]. Gender dysphoria can affect people of all genders, and is not limited to people with binary gender identities.

4. COVERAGE PROCEDURES

4.1. Gender Affirming Hormone Therapy

Hormone therapy, whether or not in preparation for gender reassignment surgery, shall be covered as follows:

- Testosterone requires prior authorization for members with gender dysphoria diagnosis.
- The following do not require a prior authorization:
 - treatment with gonadotropin-releasing hormone agents (pubertal suppressants), based upon a determination by a qualified medical professional that a member is eligible and ready for such treatment, i.e., that the member:
 - o meets the criteria for a diagnosis of gender dysphoria

- has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria
- does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment; has adequate psychological and social support during treatment
- demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment
- treatment with cross-sex hormones for members who are sixteen years of age and older, based upon a determination of medical necessity made by a qualified medical professional;
- members who are under sixteen years of age who meet treatment criteria shall be covered in specific cases if medical necessity is demonstrated and prior approval is received. [18 NYCRR 505.2_Section 505.2 - Physicians' services]

4.2. GENDER AFFIRMING SURGERY

Gender affirming procedures shall be covered for an individual who is eighteen (18) years of age or older and has letters from two qualified New York State licensed health professionals who have independently assessed the individual and are recommending the individual for the surgery.

4.2.1. LETTERS OF SUPPORT FOR DIAGNOSIS OF GENDER DYSPHORIA

- One of these letters must be from a psychiatrist, psychologist, nurse practitioner, psychiatric nurse practitioner, or licensed clinical social worker with whom the member has an established and ongoing relationship.
- The other letter may be from a psychiatrist, psychologist, nurse practitioner, physician, psychiatric nurse practitioner, or licensed clinical social worker acting within the scope of his or her practice, who has only had an evaluative role with the member.
- The *totality* of the referral letters together must establish the following and must be written within 12 months at the time of surgery request:
 - Member has persistent and well-documented gender dysphoria;
 - has received hormone therapy appropriate to the member's gender goals, which shall be for a minimum of twelve (12) months in the case of an member seeking genital surgery, unless such therapy is medically contraindicated or the member is otherwise unable to take hormones;
 - Hormone therapy is necessary if it is appropriate to the member's gender goals recommended by the member's treating provider, clinically appropriate for the type of surgery requested, not medically contraindicated, and the member is otherwise able to take hormones. Ref 18 NYCRR 505.2(l)(2); (3)(i)(b);
 - has lived for twelve (12) months in a gender role congruent with the member's gender identity, and has received mental health counseling, as deemed medically necessary, during that time; there is no requirement that mental health counseling be provided continuously for twelve (12) months prior to surgery. [Ref 18 NYCRR 505.2(I)(3)(i)(c)]
 - has no other significant medical or mental health conditions that would be a contraindication to gender affirmation surgery, or if so, that those are reasonably wellcontrolled prior to surgery;
 - has the capacity to make a fully informed decision and to consent to the treatment.

4.2.2. BIOPSYCHOSOCIAL NEEDS ASSESSEMENT

Amida Care strongly encourages the completion of a Biopsychosocial Needs Assessment (BNA) by the primary care provider for initial requests for genital surgery and may require the BNA for procedures not included in 18 NYCRR 505.2(I), paragraph 4. The BNA is a comprehensive evaluation of the member's unique clinical and psychosocial profile, when determining the appropriateness of gender affirming surgery. Due to the increased care coordination provided in the Special Needs Plan (SNP) Model of Care (MOC); this assessment aids Amida Care, the Primary Care Provider (PCP) and the member in identifying any supportive services that may be required before and/or after surgery to ensure a positive health outcome. The BNA shall not be a barrier to coverage determinations.

5. COVERAGE RESTRICTIONS

For members under eighteen (18) years of age coverage be made in specific cases if medical necessity is demonstrated and prior approval is received.

Coverage is not available for:

- services rendered outside of the five (5) boroughs of New York City or as prescribed in the Medicaid Managed Care Model Contract.
- services received via an out of network provider when prior authorization is not received and service is otherwise available within the coverage area
- surgeries, services, or procedures that are purely cosmetic, i.e., that enhance a patient's appearance but are not medically necessary to treat the patient's underlying gender dysphoria.
- Cryopreservation, storage, and thawing of reproductive tissue, and all related services and charges
- Reversal of genital and/or breast surgery
- Reversal of surgery to revise secondary sex characteristics
- Reversal of any procedure resulting in sterilization

6. AUTHORIZATION AND UTILIZATION MANAGEMENT (UM)

Amida Care's UM department follows all New York State Medicaid regulatory guidelines as indicated in the MEDICAID MANAGED CARE/ FAMILY HEALTH PLUS/ HIV SPECIAL NEEDS PLAN MODEL CONTRACT - March 1, 2014, Appendix F. The guidelines ensure that all service authorization determinations for requested services (i.e. hormone therapy and surgery for the treatment of gender dysphoria) are determined as fast as the enrollee's condition requires.

The following apply to determinations regarding requests for surgery for the treatment of gender dysphoria:

- Amida Care performs administrative prior authorizations only for the following procedures included in 18 NYCRR 505.2(I), paragraph 4: reduction mammoplasty, mastectomy, hysterectomy, salpingectomy, oophorectomy, vaginectomy, urethroplasty, metoidioplasty, phalloplasty, scrotoplasty, penectomy, orchiectomy, vaginoplasty, labiaplasty, clitoroplasty, and/or placement of a testicular prosthesis. penile prosthesis, breast augmentation and electrolysis when required for vaginoplasty or phalloplasty.
- In order to perform medical necessity review for procedures not included in the above list (18 NYCRR 505.2(I), paragraph 4) Amida Care requires medical documentation of the specific procedures being requested. This documentation may include but is not limited to: completed fax submission form, clinical

documentation from the requester, a completed Biopsychosocial need assessment that indicates services being requested.

- 3. Prior to issuing an adverse determination, Amida Care will provide for at least one attempt to conduct a peer to peer consultation with the ordering provider.
- 4. Amida Care will ensure that at least one clinical peer involved in adverse determinations and plan appeals have clinical expertise in the treatment of gender dysphoria.
 - 1. In the case of an adverse determination or upheld denial on appeal, ensure the notice of decision includes:
 - 1.1. If the decision is administrative, the specific benefit coverage criteria that has not been met or other specific reason for denial
 - 1.2. If the decision is regarding medical necessity/utilization review, the clinical rationale specifying;
 - 1.2.1. How the documentation provided does not support the enrollee's diagnosis of gender dysphoria, or
 - 1.2.2. How the documentation provided does not support the medical necessity of the proposed treatment for the enrollee's gender dysphoria, or
 - 1.2.3. There was not enough information to make a decision, and, for initial adverse determinations, what specific information would be necessary for review on appeal.
 - 2. For procedures that require specific anatomical/body part size, shape, feature, presentation or assessment as part of those procedures' service coverage criteria, Amida Care will accept the member's treating provider's determination of the member's anatomical/body part size, shape, feature, presentations and/or assessment; Amida Care does not include the evaluation of photographic documentation in the administrative prior authorization processes of procedures that require specific anatomical/body part size, shape, feature, presentation or assessment as part of those procedures' service coverage criteria.

7. REFERENCES

WPATH Standards of Care v7 (PDF) 2011 [wpath.org]

New York State Department of Health, 2017 DOH Medicaid Updateshttps://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-01.htm#transgender

505.2 Physicians' services. (a) General policies. <u>https://regs.health.ny.gov/book/export/html/53608</u> Public Health Law, Sections 201 and 206 and Social Services Law, Sections 363-a and 365-a(2)

American Psychiatric Association,

Diagnostic and Statistical Manual of Mental Disorders (DSM), American Psychiatric Association. (2013). Gender Dysphoria. In Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition ed.). Washington, DC: American Psychiatric Publishing Inc.

DOI 10.1007/978-88-470-5696-1_4 Chapter The DSM-5 Diagnostic Criteria for Gender Dysphoria Publisher: Springer-Verlag Italia, Editors: Trombetta C, Liguori G, Bertolotto M

Diagnostic and Statistical Manual of Mental Disorders

MEDICAID MANAGED CARE/ FAMILY HEALTH PLUS/ HIV SPECIAL NEEDS PLAN MODEL CONTRACT March 1, 2014 <u>https://www.health.ny.gov/health_care/managed_care/docs/medicaid_managed_care_fhp_hiv-</u> <u>snp_model_contract.pdf</u>

8. APPENDIX

8.1.Gender Affirming surgery authorization requirements

Service	(2) Supporting Letters*	HRT Requirement	Other Requirements	Notes
Breast Augmentation (BA)	Yes	24 months	N/A	The member has completed a minimum of 24 months of hormone therapy, during which time breast growth has been negligible; or hormone therapy is medically contraindicated; or the patient is otherwise unable to take hormones
BA Revision	Yes	No	Requires supporting documentation from surgeon that indicates the need for revision	Original supporting letters are sufficient to support diagnosis of gender dysphoria
Body contouring	Yes	No	Requires clinical documentation establishing service is medically necessary and not cosmetic	
Chest Masculinization (mastectomy)	Yes	No	N/A	
Electrolysis – Pre Op	Yes	No	N/A	
Electrolysis – Facial	Yes	No	Requires clinical documentation establishing service is medically necessary and not cosmetic	
Facial Feminization Surgery (FFS)	Yes	No	Requires supporting documentation that indicates specific type of FFS procedures requested	
Hysterectomy/ oopherectomy/ salpingectomy	Yes	No	N/A	
Metoidioplasty	Yes	12 months	N/A	
Orchiectomy	Yes	12 months	N/A	

Service	(2) Supporting Letters*	HRT Requirement	Other Requirements	Notes
Penectomy	Yes	12 months	N/A	
Phalloplasty*	Yes	12 months	Recommends completed BNA	
Phalloplasty Revision	Yes	No	Supporting documentation from surgeon that indicates the need for revision	Original supporting letters are sufficient to support diagnosis of gender dysphoria
Penile prosthesis	Yes	No	N/A	
Scrotoplasty	Yes	No	N/A	
Silicone Removal	Yes	No	N/A	
Tracheal Shave	Yes	No	N/A	
Testicular prosthesis	Yes	No	N/A	
Urethroplasty	Yes	No	N/A	
Vaginectomy	Yes	12 months	N/A	
Vaginoplasty*	Yes	12 months	Recommends completed BNA	
Labiaplasty	Yes	12 months	N/A	
Clitoroplasty	Yes	12 months	N/A	
Vaginoplasty Revision	Yes	12 months	Supporting documentation from surgeon that indicates the need for revision	Original supporting letters are sufficient to support diagnosis of gender dysphoria
Voice Modification Surgery	Yes	No	Requires supporting documentation that indicates procedures requested are medically necessary	
Voice and Communication Training	Yes	No	Requires supporting documentation that indicates procedures requested are medically necessary	

8.2. BIOPSYCHOSOCIAL NEEDS ASSESSEMENT

Patient Name:	DOB:	
Name on Mediciad	Card, if different:	
Primary Care Provid	der: PCP	Location:
Patient Informatio	<u>on</u>	
Sex Assigned at Birt	/oman □ Trans Man □ Non-binary □ Other: th: □ Male □ Female □ Intersex Sex on Insur □English □Spanish □Other: Languag	
Medical History:		
Co-occurring medical conditions, medications, hospitalizations, pain management etc	,	
Behavioral Health:		
Mental Health / Substance Abuse		
Supportive Services:		
Case workers, friends & family, caregivers, home health aids, etc		

Prerequisites for Surgery

- Major medical and mental health conditions are reasonably controlled
- □ Surgery referral process explained in language patient can understand
- □ Two referral letters written by a New York State licensed physician, psychiatrist, psychologist, psychiatric nurse practitioner, physician, or clinical social worker (**LCSW**, not LMSW)
 - □ One written by a New York State licensed psychiatrist, psychologist, or psychiatric nurse practitioner who has an ongoing relationship with the patient.
 - □ The second letter written by a New York State licensed psychiatrist, psychologist, psychiatric nurse practitioner, physician, or clinical social worker (**LCSW**, not LMSW).
 - □ Combined content of letters must establish that member:
 - \square Has a persistent and well-documented case of gender dysphoria
 - □ Has received hormone therapy appropriate to the individual's gender goals unless hormone therapy is medically contraindicated or not clinically appropriate for the type of surgery requested:
 - \Box 12 months for genital surgery
 - \square 24 months with negligible breast growth for MTF breast augmentation
 - □ Has lived for 12 months in a gender role congruent with the individual's gender identity, and has received mental health counseling, as deemed medically necessary, during that time
 - □ Has no other significant medical or mental health conditions that would contraindicate gender reassignment surgery, or if so, that those conditions are reasonably well-controlled prior to surgery
 - \Box Has the capacity to make a fully informed decision and to consent to treatment

. Patient Education	
\square Patient has been educated on surgical procedure	e in language they can understand
\square Patient has been made aware of long term impa	ct of genital surgery on long-term reproductive capacity
\square Patient has realistic expectations of surgery	
. Support Systems	
\square Patient has supports in place to assist with ADLs	during recovery phase.
\square Patient has people/resources that will provide er	motional and social support during recovery
. Financial	
\square Any anticipated changes in income/ability has be	een accounted for, including sex work if applicable
floor Patient has a plan to pay for food, rent, medical $ floor$	supplies and other expenses during recovery
. Medical History and Care Compliance	
\exists If major medical conditions are present, they are	e well controlled.
\exists Patient is adherent to medications with no issues	es to report
There is clear communication between mental h	nealth, medical, and surgical members of treatment team
. Behavioral Health	
\exists Mental health benefits of surgery outweigh the r	risks
\exists Necessary supports are in place to manage MH s	symptoms that may arise as a result of surgery
Patient is not currently using substances	
] Patient has a plan to cut down or discontinue sul	bstance use:
Housing	
☐ Patient has stable housing	
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