

**Utilization Management Policy Name:** Restricted Access - Essential

**Restricted Product(s):**

- Branded products without generic equivalents marked as both Prior Review and Restricted Access on the formulary publication

•	Prior Review
•	Restricted Access
	Quantity Limits
	ACA
	Limited Distribution

**Rationale:**

These products can be used in attempts to treat conditions that have not been validated by the FDA. This program ensures that members are receiving this medication for conditions that have the appropriate evidence to support its use. Other products, such as generic therapeutic equivalents, treat the same condition at a lower cost for members.

**Criteria Summary:**

FDA approved use/Medical necessity; trial of effective and lower cost agent

**Criteria for Approval of Restricted Product(s):**

1. The requested medication is being used for an FDA approved indication; **AND**
2. Medication and/or dose are medically necessary and appropriate for treating the condition; **AND**
3. The prescribing provider must certify to BCBSNC that up to TWO available therapeutic equivalent alternative non-restricted access medications (or medically appropriate medications, if no therapeutic equivalents exist) for treatment of the same condition:
  - a. Have been detrimental to the member's health OR have been ineffective in the treatment of the disease or condition; **AND**
  - b. In the prescribing provider's opinion, are likely to be detrimental to the member's health OR ineffective in treating the disease or condition again; **OR**
4. The member has a documented intolerance or contraindication to the non-restricted access medications that have not been tried; **AND**
5. Members seeking coverage for hormone therapy, related to Gender Identity Dysphoria are also subject to the following medical necessity criteria:
  - a. The member has satisfied criteria points 2-4 of the Restricted Access Utilization Management Criteria (above); **AND**
  - b. The member has the desire to live and be accepted as a member of the opposite sex; **AND**
  - c. The gender identity dysphoria is not a symptom of a mental disorder or a chromosomal abnormality; **AND**

- d. The gender identity dysphoria causes clinical or social distress or impairment in social, occupational, or other important areas of functioning; **AND**
- e. The member is 18 years of age or older and the new gender identity has been present for at least 24 months; **OR**
- f. The member is under the age of 18 years of age; **AND**
  - i. The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This requirement must be demonstrated by living in their new gender while:
    - 1. Maintaining part- or full-time employment; or
    - 2. Functioning as a student in an academic setting; or
    - 3. Functioning in a community-based volunteer activity as applicable. (For those candidates not meeting this criteria, see item 3. below.); **OR**
  - ii. The treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria; **AND**
  - iii. **Letter of medical necessity are provided which include:**
    - 1. One of the letters must be from a behavioral health professional with an appropriate degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., psychiatric physician assistant, Psy.D, or psychiatric nurse practitioner under the supervision of a psychiatrist) who is capable of adequately evaluating if the candidate has any co-morbid psychiatric conditions.
    - 2. One of the letters must be from the candidate's established physician or behavioral health provider. The letter or letters must document the following:
    - 3. Whether the author of the letter is part of a gender identity dysphoria treatment team and/or follows WPATH Standards of Care or Endocrine Society Guidelines for the Treatment of Transsexual Persons (2009) for evaluation and treatment of gender identity dysphoria; and
    - 4. The initial and evolving gender, sexual, and other psychiatric diagnoses (if applicable); and
    - 5. The duration of their professional relationship including the type evaluation that the candidate underwent; and
    - 6. The eligibility criteria that have been met by the candidate according to the above Standards of Care; and
    - 7. The physician or mental health professional's rationale for hormone therapy; and
    - 8. The degree to which the candidate has followed the treatment and experiential requirements to date and the likelihood of future compliance; and
    - 9. The extent of participation in psychotherapy throughout the 12 month real-life trial, (if such therapy is recommended by a treating medical or behavioral health practitioner) and
    - 10. That during the 12 month, real-life experience (for candidates not meeting the 12 month candidate criteria as noted in 6 and 7, the letter should still comment on the candidates ability to function and experience in the desired gender role), persons other than the treating therapist were aware of the candidate's experience in the desired gender role and could attest to the candidate's ability to function in the new role.

**Duration of approval is set by utilization management criteria up to 1095 days (3 years)**

**Policy Implementation/Update Information:** Originated: January, 2017; Last updated: April 2019

Apr 2019: Duration of approval updated to 1095 days (3 years) or lesser of utilization management criteria duration of approval

Mar 2018: Removed reference to Basic Open Formulary

Feb 2017: Placed letter of medical necessity requirement for GID only on those under the age of 18.

Jan 2017: Original utilization management criteria issued.

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