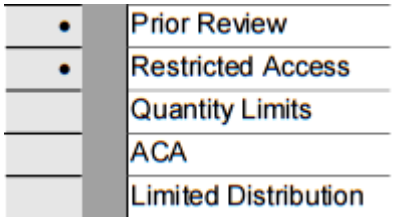
Utilization Management Policy Name: Restricted Access - Essential

Restricted Product(s):

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



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 patient is 18 years of age or older; **AND**
        i. The patient has persistent, well-documented gender dysphoria; **AND**
        ii. The patient has the capacity to make a fully informed decision and to consent for treatment; **AND**
        iii. Mental health concerns, if present, are reasonably well controlled; **OR**
    b. The patient is under the age of 18 years of age; **AND**
        i. ALL of the following
            1. A qualified mental health provider* has confirmed:
                a. The persistence of gender dysphoria; **AND**
                b. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment; **AND**

c. The patient has sufficient mental capacity to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment; **AND**

2. The patient has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility); **AND**
3. The patient has given informed consent and the parents or other caretakers, or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process; **AND**

ii. The treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria **(medical record documentation required)**.

Duration of approval is set by utilization management criteria up to 365 days (1 year)

Policy Implementation/Update Information:

Dec 2021: Criteria change: Updated gender dysphoria criteria.
Oct 2021: Criteria change: Duration of approval updated to 365 days (1 year) or lesser or utilization management criteria duration of approval.
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.