Criteria for Approval:

1. ONE of the following:
    a. If the requested medication is currently being used to treat a seizure related or refractory psychiatric disorder, the patient must be stabilized on current regimen, or the provider states that the patient's condition is too critical to try other medications **(medical record documentation required)**; **OR**
    b. The request is for a contraceptive medication/device; **AND**
        i. The patient's attending provider recommends the non-preferred version of the prescribed contraceptive based on a determination of medical necessity; **OR**
    c. The requested medication is being used for an FDA approved indication; **AND**
        i. The medication and/or dose are medically necessary and appropriate for treating the condition; **AND**
        ii. ONE of the following:
            1. If the requested product is a brand medication with an FDA approved A-rated generic equivalent or interchangeable biosimilar:
                a. The patient had a documented life-threatening side effect that required medical intervention to the generic or interchangeable biosimilar product that is not anticipated with the requested product; **AND**
                    i. The prescriber completed and submitted an FDA MedWatch Adverse Event Reporting Form **(The prescriber must provide a copy of the completed MedWatch form. Authorization will not be considered unless the form is completed and submitted to the FDA)**; **AND**
                b. ONE of the following**:**
                    i. ALL formulary alternative medications FDA approved for the treatment of the same condition have been detrimental to the patient's health OR have been ineffective in the treatment of the disease or condition; **AND**
                        1. In the prescribing provider's opinion, are likely to be detrimental to the patient's health OR ineffective in treating the disease or condition again; **OR**
                    ii. The patient has a documented intolerance or contraindication to all untrialed formulary alternative medications FDA approved for the treatment of the same condition; **OR**
                    iii. The provider has addressed all formulary alternatives that have not been tried as clinically inappropriate (e.g., expected side effects, conflicting disease states, similar mechanisms of action); **AND**

2. If the requested product is a generic medication or a brand medication without a FDA approved A-rated generic equivalent or interchangeable biosimilar:
    a. All formulary alternative medications FDA approved for treatment of the same condition have been detrimental to the patient's health OR have been ineffective in the treatment of the disease or condition; **AND**
        i. In the prescribing provider's opinion, are likely to be detrimental to the patient's health OR ineffective in treating the disease or condition again; **OR**
    b. The patient has a documented intolerance or contraindication to all formulary alternative medications FDA approved for the treatment of the same condition; **OR**
    c. The provider has addressed all formulary alternatives that have not been tried as clinically inappropriate (e.g., expected side effects, conflicting disease states, similar mechanisms of action); **OR**

d. The requested medication is being used for a non-FDA approved indication; **AND**
    i. The patient's diagnosis is clinically supported by at least one of the following:
        1. DrugDex (recommendation rating Class I, Class IIa or Class IIb); **OR**
        2. NCCN (category 1 or 2A); **AND**
    ii. The medication and/or dose are medically necessary and appropriate for treating the condition; **AND**
    iii. The requested medication is treating a chronic, disabling, or life-threatening disease; **AND**
    iv. ONE of the following:
        1. If the requested product is a brand medication with an FDA approved A-rated generic equivalent or interchangeable biosimilar:
            a. The patient had a documented life-threatening side effect that required medical intervention to the generic or interchangeable biosimilar product that is not anticipated with the requested product; **AND**
                i. The prescriber completed and submitted an FDA MedWatch Adverse Event Reporting Form **(The prescriber must provide a copy of the completed MedWatch form. Authorization will not be considered unless the form is completed and submitted to the FDA)**; **AND**
            b. ONE of the following**:**
                i. All formulary alternative medications FDA approved for treatment of the same condition have been detrimental to the patient's health OR have been ineffective in the treatment of the disease or condition; **AND**
                    1. In the prescribing provider's opinion, are likely to be detrimental to the patient's health OR ineffective in treating the disease or condition again; **OR**

ii. The patient has a documented intolerance or contraindication to all formulary alternative medications FDA approved for the treatment of the same condition; **OR**
iii. The provider has addressed all formulary alternatives that have not been tried as clinically inappropriate (e.g., expected side effects, conflicting disease states, similar mechanisms of action); **AND**

2. If the requested product is a generic medication or a brand medication without an FDA approved A-rated generic equivalent or interchangeable biosimilar:
   a. All formulary alternative medications FDA approved for treatment of the same condition have been detrimental to the patient's health OR have been ineffective in the treatment of the disease or condition; **AND**
      i. In the prescribing provider's opinion, are likely to be detrimental to the patient's health OR ineffective in treating the disease or condition again; **OR**
   b. The patient has a documented intolerance or contraindication to all formulary alternative medications FDA approved for the treatment of the same condition; **OR**
   c. The provider has addressed all formulary alternatives that have not been tried as clinically inappropriate (e.g., expected side effects, conflicting disease states, similar mechanisms of action); **AND**

2. If the requested product is a non-standard formulation (e.g. chew, concentrate, elixir, film, granule, liquid, orally disintegrating tablet (ODT), powder, sprinkle, suspension, syrup) for which an unrestricted standard formulation (e.g. tablet/capsule) is available:
   a. The patient is 11 years of age or younger; **OR**
   b. ALL of the following:
      i. The provider attests that the patient is unable to take the requested product in a standard formulation; **AND**
      ii. The patient is not taking any other medication in a standard dosage form; **AND**
      iii. If a patient is using an enteral feeding tube, the tablet/capsule formulation cannot be crushed for administration (via nationally recognized organization such as the Institute for Safe Medication Practices[1]); **AND**
3. Medications being considered for a formulary exception must meet any applicable utilization management requirements if they are in the same therapeutic class as formulary medications that require such authorization; **AND**
4. Medical documentation may be required to support the criteria above.

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

Note: If criteria are met, the non-formulary medication will be approved allowing the prescription to process as a covered medication at the appropriate co-payment.

References:

https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

October 2024: Criteria update: Updated criteria to include brand medications with any A-rated generic equivalent.
August 2022: Criteria update: Added criteria regarding requests for contraceptive medications/devices.
April 2022: Criteria update: Medications with interchangeable biosimilars available require a completed FDA MedWatch Adverse Reporting Form to be considered for coverage.
March 2022: Criteria update: Clarification of policy to include the following: “the provider has addressed all formulary alternatives that have not been tried as clinically inappropriate (e.g., expected side effects, conflicting disease states, similar mechanisms of action)”
October 2021: Criteria change: A trial and failure of ALL available therapeutic equivalent alternative non-restricted access or medically appropriate medications required. Criteria for non-standard formulation products added. Products with unrestricted generic equivalents require a completed FDA MedWatch Adverse Reporting Form to be considered for coverage. Coverage for non-FDA approved indication criteria added. Decreased length of approval to one year.
April 2019: Duration of approval updated to 1095 days (3 years) or lesser of utilization management criteria duration of approval
January 2017: Original utilization management criteria issued.