**Criteria for Approval:**

1. The total prescription ingredient cost is $\geq 200$; **OR**  
   a. At least one prescription ingredient in the compounded product is on BCBSNC’s prior review list; **AND**
2. The compounded product contains at least one prescription ingredient; **AND**
3. Costs associated with prescription drug ingredients in the compounded product will be covered if approved by the Food & Drug Administration (FDA) for medical use in the United States; **AND**
4. Costs associated with ingredients which are non-FDA approved will not be covered; **AND**
5. The active prescription medication component(s) are in therapeutic amounts, based on scientific literature or national compendia*; **AND**
6. The compounded product is not a copy of any commercially available FDA-approved drug product; **AND**
7. The use for which the compounded product is being prescribed is supported by FDA approval of the active ingredient(s), or is supported by adequate medical and scientific evidence in the medical literature* for that diagnosis and for the method or route of delivery; **OR**
8. If any prescription ingredient in the compounded product is on BCBSNC’s prior review list, the patient must meet the criteria designated for that prescription ingredient; **AND**
9. Costs associated with ingredients which are over the counter (OTC) medications will not be covered; **AND**
10. The compound will not be used for cosmetic purposes; **AND**
11. The compound does not contain investigational or experimental drugs as defined in the BCBSNC Corporate Medical Policy Investigational (Experimental) Services; **AND**
12. The compound does not contain medications which have been withdrawn or removed from the market for safety purposes; **AND**
13. The compound is not being created for convenience only.  
   a. Exceptions include:
      i. Patients that cannot swallow or have trouble swallowing and require administration with an oral liquid, or administration by topical, rectal or other appropriate non-oral routes; **OR**
      ii. Patients who have sensitivity to dyes, preservatives, or fillers in commercial products and require allergy-free medications as documented in the medical record; **OR**
      iii. Children who require prescription medications for which there are no liquid formulations available.

**Duration of Approval:** 1095 days (3 years)
* Please note: Medical and scientific evidence is defined as any ONE of the following:

1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff; OR
2. Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institute of Health’s Nations Library of Medicine for indexing in index Medicus, Excerpta Medicus (EMBASE), Medline, or MEDLARS database Health Services Technology Assessment Research (STAR); OR
3. Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act (42 U.S.C. 1395x); OR
4. The following standard reference compendia; OR
   a. The American Hospital Formulary Service Drug Information (AHFS-DI)
   b. Micromedex’s DrugDex
   c. National Comprehensive Cancer Network (NCCN) Drug & Biological Compendia; OR
5. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
   a. Agency for Healthcare Research and Quality,
   b. National Institutes of Health,
   c. National Cancer Institute,
   d. National Academy of Sciences,
   e. Center for Medicare and Medicaid Services,
   f. Any national board recognized by the National Institutes of Health for evaluating the medical value of health services.

**BCBSNC “Off-Label” Requirements**
The FDA is responsible for approving medications for use based on clinical data proving the medication is safe and effective for that specific use. BCBSNC’s prior review and quantity limitations programs follow FDA-approved uses for these drugs. However, BCBSNC recognizes that in many cases, “off-label” (non-FDA approved) uses of prescription drugs may be acceptable. In determining the acceptability of off-label uses, BCBSNC utilizes several sources of clinical information including but not limited to 1) nationally recognized clinical references including American Hospital Formulary Service Drug Information and Micromedex; 2) the results of at least two randomized controlled clinical studies that support a specific off-label use, and that are published in peer-reviewed professional medical journals; and 3) consultations with internal and external physician experts regarding community standards. Additional searches for current supporting medical literature may be performed utilizing standard electronic databases.
Non-formulary Exception Criteria

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

a) Request must be for an FDA approved indication; AND

b) Patient must have a trial and failure of up to TWO formulary medications or a clinical contraindication/intolerance to those medications not tried.

Policy Implementation/Update Information:

May 2020: Criteria update: Removed section addressing compounds of chloroquine phosphate or hydroxychloroquine sulfate.
March 2020: Criteria update: Added section to address compounds of chloroquine phosphate or hydroxychloroquine sulfate utilizing bulk ingredients.
October 2019: Criteria change: Costs associated with OTC or non-FDA approved ingredients will not be covered; reformatted criteria.
February 2017: Clarification added on over the counter products. Over the counter medications are a benefit exclusion outlined in the members benefit booklet and therefore excluded from coverage in a compound.
September 2012: Policy Originated

Non-Discrimination and Accessibility Notice

Discrimination is Against the Law

- Blue Cross and Blue Shield of North Carolina (“Blue Cross NC”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.
- Blue Cross NC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Blue Cross NC:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified 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 Customer Service **1-888-206-4697**, TTY and TDD, call **1-800-442-7028**.

- If you believe that Blue Cross NC 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:
  
  ➢ Blue Cross NC, PO Box 2291, Durham, NC 27702, Attention: Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office, Telephone **919-765-1663**, Fax **919-287-5613**, TTY **1-888-291-1783** civilrightscoordinator@bcbsnc.com

- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.


- This Notice and/or attachments may have important information about your application or coverage through Blue Cross NC. Look for key dates. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call Customer Service **1-888-206-4697**.

**ATTENTION:** If you speak another language, language assistance services, free of charge, are available to you. Call 1-888-206-4697 (TTY: 1-800-442-7028).

**ATENCIÓN:** Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-888-206-4697 (TTY: 1-800-442-7028).

**注意：**如果您講廣東話或普通話，您可以免費獲得語言援助服務。請致電 1-888-206-4697 (TTY：1-800-442-7028）。

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