

Utilization Management Policy Name: Medical Necessity Prior Authorization – Net Results

Application:

This policy addresses the coverage of drugs not explicitly documented on the Net Results Drug list and covered under the pharmacy benefit. If approved, these drugs will be covered at tier 4 for traditional drugs and tier 5 for [specialty drugs](#)

These drugs will reject for reimbursement at the pharmacy prior to authorization and will have the following message delivered to the pharmacy at point of sale: *“PA for medical necessity required for coverage”*

Rationale:

Drugs not explicitly documented on the Net Results drug list are subject to review for medical necessity.

The intent is that a drug subject to Medical Necessity review be the only clinically reasonable option for the patient. These drugs have been selected for review based on having therapeutically equivalent alternatives that are safe, effective, and at a lower overall price for patient.

I. Drugs with Brand Name Alternatives

Medical Necessity PA Required	Alternatives
Alogliptin, Nesina, Onglyza, Tradjenta	Januvia
Kazano, Oseni, Segluromet, Steglujan, Jentaduetto/ Jentaduetto XR, Kombiglyze XR, Invokamet/ Invokamet XR	Glyxambi, Janumet/ Janumet XR, Synjardy/ Synjardy XR, Xigduo XR
Byetta, Adlyxin	Ozempic, Trulicity, Victoza, Bydureon, Rybelsus
Basaglar	Levemir, Toujeo, Tresiba, Semglee (insulin glargine-yfgn)
Seebri, Tudorza	Incruse, Spiriva, Atrovent
Proventil, Xopenex, albuterol HFA (authorized generic Ventolin HFA), ProAir Digihaler, ProAir HFA, ProAir Respiclick	Ventolin HFA, albuterol HFA (generic ProAir HFA), albuterol HFA (generic Proventil HFA)
Aerospan, Alvesco, Armonair, Pulmicort	Flovent, Qvar, Arnuity, Asmanex
Airduo, Bevespi, Duaklir, fluticasone/salmeterol (Advair generic), Utibron, Wixela	Advair Diskus (brand), Advair HFA, Anoro, Breo, Dulera, Stiolto, Symbicort, Trelegy, Combivent, fluticasone/salmeterol (AirDuo authorized generic)

Criteria for Approval of Product(s) above (item I):

1. The patient has demonstrated a trial and failure of up to TWO of the associated alternatives listed; **OR**
2. The patient has a clinical contraindication/intolerance to all the drugs that have not been trialed; **OR**
3. The provider submits a written explanation that the alternative drugs are/will be harmful to the patient based on their unique clinical scenario and the unique characteristics of the alternative drugs.

II. Products with Brand Name Alternatives

Medical Necessity PA Required	Alternatives
Roche, including but not limited to Accu-Chek products Abbott, including but not limited to FreeStyle products LifeScan, including but not limited to OneTouch products Other	Ascensia Contour Next products
Freestyle Libre (and supplies)	Dexcom G7, G6 and G5 (and supplies)

Criteria for Approval of Product(s) above (item II):

1. The patient satisfies the drug specific criteria found by searching the product name or “Glucose Test Strips and Disk” here:
www.bcbsnc.com/umdruug

III. Specialty Products and Products with Detailed Requirements

The drugs have detailed criteria regarding diagnosis and standards of medical care in addition to the use of alternatives. These criteria are to ensure the safe and effective use.

Condition	Medical Necessity PA Required	Alternatives
Multiple Sclerosis	Aubagio, Bafiertam, Copaxone, Extavia, Gilenya, Tecfidera, Vumerity	Avonex, Betaseron, dimethyl fumarate (generic Tecfidera), fingolimod (generic Gilenya), glatiramer acetate (generic Copaxone or Glatopa), Kesimpta, Mavenclad, Mayzent, Plegridy, Rebif, teriflunomide (generic Aubagio), Zeposia

Chronic Hepatitis C	ledipasvir-sofosbuvir (Harvoni authorized generic), sofosbuvir-velpatasvir (Epclusa authorized generic), Viekira Pak, Zepatier	Epclusa, Harvoni, Mavyret, Sovaldi, Vosevi
Rheumatoid Arthritis	Abrilada, Hadlima, Hulio, Hyrimoz, Idacio, Kineret, Olumiant, Simponi 50mg/ml, Yusimry	Actemra, Amjevita, Cimzia, Cyltezo, Enbrel, Humira, Kevzara, Oencia, Rinvoq, Xeljanz, Xeljanz XR
Psoriasis	Abrilada, Hadlima, Hulio, Hyrimoz, Idacio, Siliq, Simponi 50mg/ml, Taltz, Yusimry	Amjevita, Cimzia, Cosentyx, Cyltezo, Enbrel, Humira, Otezla, Skyrizi, Stelara, Tremfya
Inflammatory bowel diseases	Abrilada, Hadlima, Hulio, Hyrimoz, Idacio, Yusimry	Amjevita, Cimzia, Cyltezo, Humira, Simponi 100mg/ml, Stelara, Xeljanz, Xeljanz XR
Growth Hormone	Humatrope, HumatroPen, Nutropin, Nutropin AQ, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, Sogroya, Skytrofa, Zomacton, Zorbtive	Genotropin, Genotropin MiniQuick, Norditropin, Nordiflex, Norditropin Flexpro
Rapid/short acting Insulin	Afrezza, Admelog, Apidra, Humulin, Humalog, Insulin Aspart, Insulin Aspart FlexPen, Insulin Aspart 70/30	Fiasp, Humulin R U-500, Novolin, Novolog

Criteria for Approval of Product(s) above (item III):

1. The patient satisfies the drug specific criteria found by searching the drug name here: www.bcbsnc.com/umdruk

IV. Brand Name Drugs with Substitutable Generics or Interchangeable Biosimilars: (Brand Name products that have FDA approved A-Rated generics or interchangeable biosimilars)

Note: drugs that have a narrow therapeutic index (NTI) are not subject to authorization.

Criteria for Approval of Product(s) above (item IV):

1. The patient satisfies the drug specific criteria found by searching the drug name here: www.bcbsnc.com/umdruk **if present; AND**

2. The patient had a sub-therapeutic or intolerant response (therapeutic failure) to an inactive ingredient of the generic or interchangeable biosimilar product; **OR**
3. The generic or interchangeable biosimilar Drug is on shortage based on nationally recognized references such as Food and Drug Administration or The Academy of Health-System Pharmacy (ASHP); **OR**
4. The provider submits a written statement that demonstrates a patients specific, clinical reason for which the generic or interchangeable biosimilar version cannot be used, and the brand name is required (to be evaluated by Blue Cross NC Clinical Review).

V. Contraceptive medication/device (item V)

1. The patient's attending provider recommends the non-preferred version of the prescribed contraceptive based on a determination of medical necessity.

VI. Drugs not addressed in items I-V

Criteria for Approval of Product(s) above (item VI):

1. The drug is a self-administered medication (does not require a health care provider for administration); **AND**
2. The patient satisfies the drug specific criteria found by searching the drug name here: www.bcbsnc.com/umdrug **AND**
3. The drug is being used for an FDA approved indication; **AND**
4. The member has tried and failed:
 - a. TWO unrestricted drugs for the same condition in a drug class that contains THREE or more drugs; **OR**
 - b. ONE unrestricted drug for the same condition in a drug class that contains TWO drugs; **OR**
 - c. The patient has a contraindication/clinical intolerance to the other all drugs in the class that they have not trialed.

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

Quantity Limitations:

Drug specific Quantity limits and Exception Criteria found by searching the drug name here: www.bcbsnc.com/umdrug

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other Drugs and doses have been tried and failed).

References: all information referenced is from FDA package insert unless otherwise noted below.

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.

July 2023: Criteria update: Updated preferred specialty products for Multiple Sclerosis, Rheumatoid Arthritis, Psoriasis, and Inflammatory bowel diseases. Removed Migraine category from policy.

April 2023: Criteria change: Dexcom G7, fingolimod (generic Gilenya), added to preferred products. Gilenya (brand) moved to MN PA required. Genotropin moved to preferred products.

August 2022: Criteria change: Added criteria regarding requests for contraceptive medications/devices.

April 2022: Criteria updated: Removed Lantus from policy due to release of interchangeable biosimilar Semglee. Updated section IV to include interchangeable biosimilar products.

January 2022: Criteria updated: Moved Ajoyv and Orencia to preferred products.

October 2021: Criteria change: Removed Qtern from alternatives, Removed Daklinza and Viekira XR (obsolete products). Changed duration of approval to 365 days.

July 2021: Criteria change: Invokana, Invokamet, Invokamet XR moved to MN PA required.

April 2021: Criteria change: Moved Copaxone to MN PA required. Brand name drugs with suitable generics must meet criteria if present AND have a sub-therapeutic or intolerant response to an inactive ingredient of the generic product. Added Kesimpta and Bafiertam to policy.
January 2021: Criteria update: Moved Onglyza, Segluromet, ProAir HFA, ProAir Respiclick, Tecfidera, Vumerity to MN PA required.
July 2020: Criteria update: Albuterol HFA (generic ProAir and generic Proventil HFA), Kevzara, Xeljanz XR, Zeposia, Vumerity, Simponi 100mg/ml moved/added to alternatives section.
June 2020: Criteria update: Duration of approval is set by utilization management criteria up to 1095 days (3 years).
April 2020: Criteria update: Addition of Freestyle Libre to Products with Brand Name Alternatives section.
March 2020: Criteria update: Added albuterol (generic ProAir HFA) to the policy and clarified albuterol (authorized generics) language.
January 2020: Original utilization management criteria issued.