



## Drug Guide and Clinical Program Updates

Prime Therapeutics® Pharmacy and Therapeutics (P&T) Committee, in association with Blue Cross and Blue Shield of Alabama's Formulary Business Committee, recently approved updates to the Drug Guides and made clinical program changes to select medications. Members will receive a letter from Blue Cross if they are negatively affected by a formulary change that is not a result of a new generic being available.

## Formulary and Clinical Programs - Effective January 1, 2022

Click the links below to view updated formularies and clinical programs. If members have questions about their benefits, they should call the Customer Service number on the back of their Blue Cross member ID card.

- [Standard Prescription Drug Guide Updates](#)
- [Generic Plus Drug Guide Updates](#)
- [High Cost Exclusion Updates](#)
- [Source+Rx 1.0 Prescription Drug List](#)
- [Source+Rx 2.0 Prescription Drug List](#)
- [Source Rx Formulary Updates](#)
- [NetResults Formulary Updates](#)
- Clinical Programs
  - ▶ [Prior Authorization](#)
  - ▶ [Step Therapy](#)
  - ▶ [Quantity Limit](#)

## Effective November 1, 2021, the following initiatives have been implemented:

### Zarxio and Nyvestim

Zarxio and Nyvestim will become the preferred short-acting granulocyte colony stimulating factor (G-CSF) products.

Patients must have failed treatment with, or have a contraindication or intolerance to, both of the preferred G-CSF products prior to consideration of non-preferred products (Neupogen and Granix). **Patients currently receiving non-preferred products will be allowed to complete their existing course of therapy.**

### Paroxysmal Nocturnal Hemoglobinuria

Ultomiris and Empaveli will become the preferred products for Paroxysmal Nocturnal Hemoglobinuria (PNH). Patients must have tried and had an inadequate response, intolerance or contraindication to Ultomiris or Empaveli prior to consideration of Soliris. **Patients currently receiving Soliris will be allowed to continue therapy on this product.**

### Atypical Hemolytic Uremic Syndrome

Ultomiris will become the preferred product for atypical hemolytic uremic syndrome (aHUS). Patients must have tried and had an inadequate response, intolerance or contraindication to Ultomiris prior to consideration of Soliris. **Patients currently receiving Soliris will be allowed to continue therapy on this product.**

## New or Revised Provider-Administered (Medical) Drug Programs

Policy Name	Type of Policy	Coverage Criteria and Changes
Abraxane	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To Uterine CA (carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/de-differentiated carcinoma) added use for patients with locoregional recurrence or distant mets.
Actemra IV	Medical PA	<b>REVISED—Effective 1/1/22</b> – To CRS, specified that use as supportive care for CRS due to blinatumomab therapy is specifically for patients with ALL and for severe CRS and updated all remaining CRS criteria to align with the NCCN 2A recommendations.
Bavencio	Oncology PA	<b>REVISED—Effective 12/1/21</b> – Added criteria for use in patients at least 18 years of age, unless otherwise specified, and subsequently removed the age requirement criteria under all indications except for Merkel cell carcinoma as it can be used in patients at least 12 years of age.
Berinert	Medical PA	<b>REVISED—Effective 1/1/22</b> – To the dosing table, added a statement indicating that patients may self-administer Berinert.
Bevacizumab ONCO	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To breast cancer, added use in patients with inflammatory breast cancer with no response to preoperative systemic therapy. To cervical cancer, added use as second-line therapy for small cell neuroendocrine carcinoma of the cervix.
Cimzia	Medical PA	<b>REVISED—Effective 1/1/22</b> – To PsA, added criteria to indicate that patients with dactylitis need previous t/f of ONE oral DMARD. Also added criteria that patients with axial disease OR active enthesitis only requires t/f of ONE NSAID (instead of two), and that a 4 week trial is needed to confirm adequate t/f on an NSAID. To AS added criteria for t/f of two NSAIDs over 4-weeks in total.
Cinryze	Medical PA	<b>REVISED—Effective 1/1/22</b> – To the universal criteria, added exclusion criteria for use in combination with Orladeyo to keep at parity with the of all of the other HAE prophylaxis policies.
Cyramza	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To NSCLC, updated the overarching criteria for use in recurrent, advanced, or metastatic disease to also exclude use in locoregional recurrence or symptomatic local disease without evidence of disseminated disease and include use in mediastinal lymph node recurrence with prior radiation therapy.
Erbitux	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To SCCHN for very advanced cancers of the head and neck, added combination therapy with carboplatin for nasopharyngeal cancer and also specified that use in combination with platinum-based therapy as subsequent therapy is for non-nasopharyngeal cancer only.
Gazyva	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To B-cell lymphoma, updated verbiage when used as a substitution for rituximab per NCCN.
Ilumya	Medical PA	<b>REVISED—Effective 11/1/21</b> – To PsO, changed duration from 3 months to a 4-week minimum trial of topical agents.
Infliximab	Medical PA	<b>REVISED—Effective 11/1/21</b> – To PsA, updated criteria to indicate that patients with dactylitis need previous trial and failure on an oral DMARD. Also updated PsA to now state that patients with axial disease OR active enthesitis only requires trial and failure of one NSAID and that a 4-week trial is needed to confirm adequate trial and failure on an NSAID.
IVIG	Medical PA	<b>REVISED—Effective 1/1/22</b> – Added new indication for management of CAR T-cell-related toxicity along with the pertinent criteria as per NCCN2A.
Keytruda	Oncology PA	<b>REVISED—Effective 11/1/21</b> – To TNBC, added use as neoadjuvant or adjuvant.
Krystexxa	Medical PA	<b>REVISED—Effective 1/1/22</b> – To the general initial criteria, changed the baseline serum uric acid level from > 8mg/dL to ≥ 8 mg/dL per the pivotal trial.
Kyprolis	Oncology PA	<b>REVISED—Effective 12/1/21</b> – Added systemic light chain amyloidosis indication as per NCCN2A as a single agent or in combination with dexamethasone.
Lemtrada	Medical PA	<b>REVISED—Effective 1/1/22</b> – Added requirement for baseline ECG and additional possible ADRs to the overarching toxicity criteria on renewal based on PI update.
Leuprolide depot	Medical PSCE	<b>REVISED—Effective 11/1/21</b> – Added the compendia supported indication for use as fertility preservation prior to chemotherapy in patients who failed or are not candidates to primary methods of fertility preservation.
Nexvazyme	Medical PA	<b>NEW—Effective 12/1/21</b> – New policy created for Pompe disease.
Nucala	Medical PA	<b>REVISED—Effective 11/1/21</b> – Added FDA-approved expanded indication for use as add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps.

## New or Revised Provider-Administered (Medical) Drug Programs

Policy Name	Type of Policy	Coverage Criteria and Changes
Opdivo	Oncology PA	<b>REVISED—Effective 12/1/21</b> – Added newly approved FDA expanded indication for use as adjuvant treatment in patients with urothelial carcinoma who are at high risk of recurrence after undergoing radical resection.
Orencia	Medical PA	<b>REVISED—Effective 11/1/21</b> – To PsA, updated criteria to indicate that patients with dactylitis need previous trial and failure on an oral DMARD. Also updated PsA to now state that patients with axial disease OR active enthesitis only requires trial and failure of one NSAID, instead of two, and that a 4-week trial is needed to confirm adequate trial and failure on an NSAID.
Pemetrexed	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To NSCLC, removed use for RET positive tumors as first or subsequent line therapy as it is no longer supported by NCCN.
Pepaxto	Oncology PA	<b>REMOVED—Effective 11/1/21</b> – The FDA has pulled the multiple myeloma indication for Pepaxto. This therapy will no longer be available for selection.
Perjeta	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To breast cancer, added criteria for use in inflammatory breast cancer as first-line, subsequent, neoadjuvant, and adjuvant therapy. To CRC primary treatment, excluded use in neoadjuvant therapy.
Ranibizumab	Medical PA	<b>REVISED—Effective 1/1/22</b> – Added the newly FDA-approved biosimilar product, Byooviz, to the policy at full parity with Lucentis. Changed the policy name to Ranibizumab.
Rituximab IV	Medical/ Oncology PA	<b>REVISED—Effective 12/1/21</b> – To oncology indications: ALL- added use as Induction treatment for patients with Ph- disease, ≥ 65 years of age or with substantial comorbidities as per NCCN 2A.
Rylaze	Oncology PA	<b>New—Effective 11/1/21</b> – New policy developed for the treatment of acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL).
Saphnelo	Medical PA	<b>NEW—Effective 12/1/21</b> – New policy created for Systemic Lupus Erythematosus (SLE).
SCIG	Medical PA	<b>REVISED—Effective 1/1/22</b> – Added use in acquired immune deficiency secondary to chronic lymphocytic leukemia to align with IVIG policy.
Simponi ARIA	Medical PA	<b>REVISED—Effective 11/1/21</b> – For PsA, updated criteria: axial disease or active enthesitis, only require a 4-week trial/failure of one NSAID (instead of two) and dactylitis requires a failure of a DMARD (instead of an NSAID). For AS, added at least a 4-week trial is indicated with a trial and failure of NSAIDs.
Soliris	Medical PA	<b>REVISED—Effective 11/1/21</b> – Added a step edit requiring patients to try and fail Ultomiris OR Empaveli prior to consideration of Soliris for PNH. Patients must try and fail Ultomiris prior to consideration of Soliris for atypical hemolytic uremic syndrome (aHUS).
Spinraza	Medical PA	<b>REVISED—Effective 11/1/21</b> – Updated the SMN2 copy number to 3 or fewer based upon the Nurture trial.
Stelara	Medical PA	<b>REVISED—Effective 1/1/22</b> – To PsA, added criteria to indicate that patients with dactylitis need previous t/f of ONE oral DMARD. Also added criteria that patients with axial disease OR active enthesitis only requires t/f of ONE NSAID (instead of two), and that a 4-week trial is needed to confirm adequate t/f on an NSAID.
Synagis	Medical PA	<b>REVISED—Effective 12/1/21</b> – Based on the AAP's 2021 Interim Guidance on the inter-seasonal increase in RSV infections, the Synagis criteria policy was amended to include a length of authorization of coverage if surveillance data from the CDC indicates a high percent of positivity rate in a testing area.
Tivdak	Oncology PA	<b>NEW—Effective 1/1/22</b> – New policy developed for the treatment of metastatic cervical cancer.
Trastuzumab IV	Oncology PA	<b>REVISED—Effective 12/1/21</b> – To breast cancer added criteria for use in inflammatory breast cancer as first-line, subsequent, neoadjuvant, and adjuvant therapy. To CRC primary treatment, excluded use in neoadjuvant therapy.
Ultomiris	Medical PA	<b>REVISED—Effective 1/1/22</b> – Added a requirement to show a beneficial disease response and absence of unacceptable toxicity while on Soliris to switch therapy indication to align all policies (PNH and aHUS).
Uplizna	Medical PA	<b>REVISED—Effective 1/1/22</b> – To general initial criteria, added criteria stating patient must not have received IVIG within 1 month prior to the start of therapy. To universal criteria, added T-cell vaccination therapy to list of examples for other immunosuppressant procedures.
Vivitrol	Medical PA	<b>REVISED—Effective 11/1/21</b> – To universal criteria, added criteria excluding use in patients currently receiving opioid analgesics, with current physiologic opioid dependence, in acute opioid withdrawal, or who have failed the naloxone challenge test or have a positive urine screen for opioids.

\*Post-Service Claims Edit is abbreviated as PSCE

The Prime Therapeutics P&T Committee — consisting of doctors, pharmacists and other healthcare professionals — advises and makes recommendations based on clinical appropriateness. The Blue Cross and Blue Shield of Alabama Formulary Business Committee gives final approval of these clinical recommendations before implementation.

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