



## 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. All information is online at [AlabamaBlue.com/pharmacy](http://AlabamaBlue.com/pharmacy). 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.

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.

## Clinical Program Updates – Effective January 1, 2020

### Growth Hormone – Preferred Product Strategy Change

The preferred growth hormone for Blue Cross will change from Omnitrope to Norditropin. Norditropin offers the lowest net cost solution. Members currently taking Omnitrope will be required to switch to the new preferred product effective January 1, 2020.

### Autoimmune – Preferred Product Strategy Change

The autoimmune drug, Simponi, will change from preferred to non-preferred. Current utilizers of Simponi will be able to continue their treatment without disruption. They will be grandfathered until the end of their current prior authorization (PA). Once their PA expires and they are required to renew their PA, they will be granted continued access to Simponi. Depending on their benefits, some members may see an increase in cost-share due to a tier change.

The following autoimmune therapy drugs are newly added preferred products:

- Skyrizi (currently in effect)
- Tremfya (currently in effect)
- Rinvoq (effective January 1, 2020)

### Laxatives – Preferred Product Strategy Change

Effective January 1, 2020, Blue Cross will change the preferred product for laxatives to exclude current high-cost, branded alternatives. The drugs listed below will be added to your drug list as the new preferred products for laxatives. They offer the lowest net cost solution.

- Symproic
- Trulance

To view which laxative medications will be removed from or remain on your drug list, please contact your Blue Cross Representative.

### Opioid cDUR Program – New Cumulative Opioid Dose Safety Edit

In our continuing effort to decrease opioid misuse among our members, Blue Cross and Blue Shield of Alabama will implement a new cumulative opioid dose safety edit in the pharmacy claims system.

- Members will be required to obtain additional prescriber justification for continued coverage of opioids if they exceed a defined opioid dose threshold for a 180-day period. The defined dose threshold will be 300 morphine milligram equivalents (MMEs).
- If a member visits their pharmacy for a prescription refill of their opioid medication and the member exceeds the 300 MME dose threshold, the member's prescriber will need to request prior authorization before coverage is granted.
- Prescribers will be notified before a member experiences a rejection to allow for continuity of care.

In 2017- 2019, Blue Cross and Blue Shield of Alabama's opioid management strategies resulted in a 12 percent decrease in opioid use by its members. We firmly believe implementing the opioid dose safety edit will add to our effort to help fight the growing opioid epidemic.

## Formulary Updates

Click the links below to view updated formularies effective January 1, 2020. If a member has 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 – Standard and Generics Plus](#)
- [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](#)
- Medical Drug Updates

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

Policy Name	Type of Policy	Coverage Criteria and Changes
<b>Abraxane</b>	Oncology PA	REVISED – Effective 12/1/19 – Policy updated to include indication for the treatment of advanced or metastatic small bowel adenocarcinoma.
<b>Avastin</b>	Oncology PA	REVISED – Effective 12/1/19 – Policy updated with indication for the treatment of advanced or metastatic small bowel adenocarcinoma; clarified subsequent therapy for colorectal cancer, added monotherapy option for continued maintenance after responding to atezolizumab-based quadruple therapy in non-small cell lung cancer; removed combination therapy with irinotecan from recurrent anaplastic glioma; and removed use in mixed mullerian ovarian tumors.
<b>Bavencio</b>	Oncology PA	REVISED – Effective 12/1/19 Policy updated to include use in relapsed/ metastatic disease with clear cell histology.
<b>Bendamustine (Treanda and Bendeka)</b>	Oncology PA	REVISED – Effective 12/1/19 – Updated criteria for Non-Hodgkin’s lymphoma for treatment of high-grade lymphoma B-cell lymphomas or DLBCL when used in combination with rituximab and polatuzumab after 2 or more therapies; clarified for histologic transformation of follicular or marginal zone lymphomas bendamustine may be used after multiple lines of chemoimmunotherapy for indolent or transformed disease.
<b>Bendamustine RTD (Belrapzo)</b>	Oncology PA	REVISED – Effective 12/1/19 – Updated criteria for Non-Hodgkin’s lymphoma for treatment of high-grade lymphoma B-cell lymphomas or DLBCL when used in combination with rituximab and polatuzumab after 2 or more therapies; clarified for histologic transformation of follicular or marginal zone lymphomas bendamustine may be used after multiple lines of chemoimmunotherapy for indolent or transformed disease.
<b>Berinert, Cinryze, Firazyr, Haegarda, Kalbitor, Ruconest, Takhzyro</b>	Medical PA	REVISED – Effective 1/1/20 – Updated the diagnostic criteria for HAE-I to more closely align with 2017 WAO/EAACI guideline that acquired angioedema is ruled out as an additional alternative to patient having a family history.
<b>Blinicyto</b>	Oncology PA	REVISED – Effective 12/1/19 – Policy updated for use in relapsed/refractory disease for Ph-positive patients that are TKI intolerant or refractory.
<b>Bortezomib</b>	Oncology PA	REVISED – Effective 12/1/19 – Updated policy to include treatment of relapsed/refractory pediatric ALL.

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

Policy Name	Type of Policy	Coverage Criteria and Changes
<b>Botox</b>	Medical PA	<p>REVISED – Effective 1/1/20 –</p> <ul style="list-style-type: none"> <li>For migraines: Added requirement for trial and failure of cGRP prior to approval for Botox.</li> <li>For Cervical Dystonia: Added step through Dysport AND Xeomin prior to Botox.</li> <li>For Upper Limb Spasticity (Stroke): Added step through Dysport AND Xeomin prior to Botox.</li> <li>For Lower Limb Spasticity (stroke): Added step through Dysport prior to Botox.</li> <li>For Blepharospasm: Added step through Xeomin prior to Botox.</li> <li>For Sialorrhea: Added step through Xeomin prior to Botox.</li> </ul>
<b>Cinqair</b>	Medical PA	<p>REVISED – Effective 1/1/20 – Definition of an exacerbation requiring corticosteroid use, combined previous criteria to now require at least 2 exacerbations in the previous year and daily oral steroid use per ERS/ATS guidelines. Added leukotriene modifiers as an example of a controller medication per GINA guidelines.</p>
<b>Darzalex</b>	Oncology PA	<p>REVISED – Effective 11/1/19 – Added expanded FDA approved indication for the treatment of newly diagnosed multiple myeloma.</p>
<b>Dysport</b>	Medical PA	<p>REMOVED – Effective 1/1/20 – Precertification will no longer be required.</p>
<b>Entyvio</b>	Medical PA	<p>REVISED – Effective 1/1/20 – Renewal criteria for the treatment of UC, added additional parameters of response such as the normalization of CRP and FC (useful when no endoscopic results), per the 2019 ACG UC guidelines. Per NCCN, limited use for the treatment of immunotherapy-related diarrhea or colitis to severe disease only.</p>
<b>Fasenra</b>	Medical PA	<p>REVISED – Effective 1/1/20 – To definition of an exacerbation requiring corticosteroid use, combined previous criteria to now require at least 2 exacerbations in the previous year and daily oral steroid use per ERS/ATS guidelines. Added leukotriene modifiers as an example of a controller medication per GINA guidelines.</p>
<b>Gazyva</b>	Oncology PA	<p>NEW – Effective 12/1/19 – Updated policy to include first line treatment of CLL/SLL with del (17p)/TP53 when used in combination with venetoclax; used in combination with venetoclax or chlorambucil in frail patients or those ≥ 65 years or younger with significant comorbidities without del (17p)/TP53.</p>
<b>Immune Globulins, IV</b>	Medical and Oncology PA	<p>REVISED – Effective 1/1/20 – Use in the management of immune-checkpoint inhibitor toxicity, added use for the treatment of severe inflammatory arthritis that is refractory to at least 2 weeks of corticosteroid therapy (per NCCN 2A).</p> <ul style="list-style-type: none"> <li>To solid organ transplant and acquired immune deficiency in ALL/CLL/MM in renewal criteria, clarified verbiage to indicate that patient is at a decreased risk of infection as a result of being on therapy and thereby necessitating further treatment. To CIDP, removed criteria requiring CSF analysis as not supported by the guidelines.</li> </ul>
<b>Keytruda</b>	Oncology PA	<p>REVISED – Effective 11/1/19 – Added expanded FDA approved indication for esophageal cancer as subsequent therapy; added treatment of small bowel adenocarcinoma to MSI-H cancers; updated indications for treatment of squamous cell carcinoma of the head and neck.</p>
<b>Kymriah</b>	Oncology PA	<p>REVISED – Effective 1/1/20 – Removed criteria for CD19 negativity.</p>
<b>Mvasi</b>	Oncology PA	<p>REVISED – Effective 12/1/19 – Policy updated with indication for the treatment of advanced or metastatic small bowel adenocarcinoma; clarified subsequent therapy for colorectal cancer, added monotherapy option for continued maintenance after responding to atezolizumab-based quadruple therapy in non-small cell lung cancer; removed combination therapy with irinotecan from recurrent anaplastic glioma.</p>

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

Policy Name	Type of Policy	Coverage Criteria and Changes
Myobloc	Medical PA	<p>REVISED – Effective 1/1/20 –</p> <ul style="list-style-type: none"> <li>For Cervical Dystonia: Added step through Dysport AND Xeomin prior to Myobloc.</li> <li>For Upper Limb Spasticity: Added step through Dysport AND Xeomin prior to Myobloc.</li> <li>For Sialorrhea: Added step through Xeomin prior to Myobloc.</li> </ul>
Nucala	Medical PA	<p>REVISED – Effective 1/1/20 – Added expanded age limit for eosinophilic severe asthma to include patients aged 6-11 years and dosing of 40mg every 4 weeks (SDV only). To severe asthma, updated definition of an exacerbation requiring corticosteroid use, combined previous criteria to now require at least 2 exacerbations in the previous year and daily oral steroid use per ERS/ATS guidelines. Also added leukotriene modifiers as an example of a controller medication per GINA guidelines. To EGPA, added examples of an objective measure/tool to align with renewal criteria and changed classification criteria for eosinophils to &gt;10% per ACR classification.</p>
Ocrevus	Medical PA	<p>REVISED – Effective 11/1/19 – Updated use for the treatment of relapsing MS to include active secondary progressive disease and CIS per FDA expanded approval.</p>
Onpattro	Medical PA	<p>REVISED – Effective 1/1/20 – Added that it must not be used in combination with other TTR reducing agents (inotersen, tafamidis, etc.).</p>
Opdivo	Oncology PA	<p>REVISED – Effective 12/1/19 – policy updated with indication for the treatment of small bowel adenocarcinoma that is dMMR/MSI-H; added use for subsequent therapy in colorectal cancer; added indication for use in classical Hodgkin's Lymphoma for patients that are not eligible for transplant.</p>
Orencia	Medical PA	<p>REVISED – Effective 11/1/19 – removed previous failure with oral glucocorticoids and replaced it with failure to an oral DMARD per the 2019 ACR guideline for JIA.</p>
Soliris	Medical PA	<p>REVISED – Effective 11/1/19 – Added FDA-approved expanded indication in the treatment of neuromyelitis optica spectrum disorder (NMOSD) and its dosing.</p>
Spravato	Medical PA	<p>REVISED – Effective 11/1/19 – Clarified duration and defined failure of trial of 2 anti-depressants from different classes required; clarified trial of antidepressant augmentation therapy criteria; clarified that if the patient previously tried ECT, TMS, VNS or DBS they must not have failed the trial and that the patient is not receiving concomitant ECT, VNS, TNS or DBS for coverage of Spravato; expanded the list of baseline assessment rating scales that can be used for depression rating.</p>
Tecentriq	Oncology PA	<p>REVISED – Effective 12/1/19 – policy updated to include indication for small cell lung cancer for use as single-agent maintenance therapy.</p>
Testopel	Medical PA	<p>REVISED – Effective 10/1/19 – Added trial and failure to a 3 or more month trial with an intramuscular testosterone product before approval of Testopel for delayed puberty and primary or secondary hypogonadism in males. Added restriction that product is not to be used for age-related/late-onset hypogonadism.</p>
Trogarzo	Medical PA	<p>REVISED – Effective 11/1/19 – Added baseline viral load of at least 1000 copies/mL and explicitly defined failure of 1 drug from each class.</p>
Tysabri	Medical PA	<p>REVISED – Effective 11/1/19 – Updated use for the treatment of relapsing MS to include active secondary progressive disease and CIS per FDA-expanded approval.</p>
Velcade	Oncology PA	<p>REVISED – Effective 12/1/19 – Updated policy to include treatment of relapsed/refractory pediatric ALL.</p>

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

Policy Name	Type of Policy	Coverage Criteria and Changes
Vivitrol	Medical PA	REVISED – Effective 11/1/19 – Clarified Vivitrol not to be used in Child-Pugh C hepatic insufficiency; clarified lack of adherence to oral therapy is required prior to approval for alcohol dependence; added that patient has or is anticipated to have adherence issues to oral naltrexone for opioid dependence; added to renewal: abstinence is confirmed on urine drug screen, adherence to comprehensive management program, and continued administration is necessary to prevent relapse; added that compounded naltrexone products are not covered.
Xeomin	Medical PA	REMOVED – Effective 1/1/20 – Precertification will no longer be required.
Xolair	Medical PA	REVISED – Effective 1/1/20 – Per an NCCN 2a recommendation, added use for checkpoint inhibitor therapy related toxicity and for systemic mastocytosis.
Yervoy	Oncology PA	REVISED – Effective 12/1/19 – Updated policy to include treatment of small bowel adenocarcinoma that is dMMR/MSI-H; added use in central nervous system cancers when used as initial therapy in patients with asymptomatic or stable disease.
Yescarta	Oncology PA	REVISED – Effective 1/1/20 – Removed criteria for CD19 negativity.
Yondelis	Oncology PA	NEW – Effective 11/1/19 – New policy created with indications for the treatment of liposarcoma, leiomyosarcoma (including uterine leiomyosarcoma), and soft tissue sarcoma.
Zolgensma	Medical PA	REVISED – Effective 11/8/19 – Removed the requirement that the patients with 3 copies of the SMN2 gene to also have the absence of the c.859G>C single base substitution modification in exon 7; removed requirement that patient must have a baseline anti-AAV9 antibody titer of ≤ 1:50 measured by ELISA; added requirement that patient has not previously been administered Zolgensma.

## Medical Drug Category Changes in Coverage - Botulinum Toxins

Effective January 1, 2020, several changes will be made that will affect coverage of these provider-administered drugs. A summary of these changes is included below.

Botox medical policy changes:

### Migraine Treatment

- All new requests for Botox to treat migraines will require the trial and failure of a calcitonin gene-related peptide (CGRP) inhibitor as well as an oral prophylactic medication before treatment with Botox will be approved.
- Any patients currently receiving Botox for migraines will be allowed to continue therapy with Botox.

### Non-Migraine Treatment

- Several non-migraine indications will require an additional step through both Xeomin and Dysport prior to approval of Botox based on FDA approved indications. See medical policy for details.
- Any patients currently receiving Botox for non-migraine indications where these step requirements are added will be allowed to continue therapy with Botox if their provider attests that member is at risk if therapy is changed.

### Myobloc Medical Policy Changes

- Several indications will require an additional step through Xeomin and Dysport prior to approval of Myobloc based on FDA-approved indications. See medical policy for details.
- Any patients currently receiving Myobloc for indications where these step requirements are added will be allowed to continue therapy with Mobloc if their provider attests that the member is at risk if therapy is changed.

### Xeomin and Dysport Medical Policy Changes

- Precertification for Xeomin and Dysport will no longer be required effective January 1, 2020.
- Claims for FDA-approved indications will be allowed to process without precertification based on member benefits.

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