Pharmacy News

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BlueCross BlueShield of Alabama

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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. 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 makes final approval of these clinical recommendations before implementation.

The following drugs may have coverage changes that affect what a member will be required to pay at the time of purchase. Members will receive a letter if they are negatively affected by a formulary change that is not a result of a new generic being available.

Prescription Drug Guide Updates – Effective January 1, 2019 (unless otherwise noted)

Brand Name (generic name if available)	Therapeutic Class	Description of Change	Additional Comments
BYDUREON (BCISE, VIAL, PEN)	Antidiabetic Medication	Move from Tier 2 to Tier 3	
BYETTA	Antidiabetic Medication	Move from Tier 2 to Tier 3	
COMPLERA	Antiretrovirals	Move from Tier 2 to Tier 3	Mylan authorized generic will continue to be covered
COPAXONE	Multiple Sclerosis	Move from Tier 2 to Tier 3	
FULPHILA	Hematological Medications	Addition to Tier 2	
NUCYNTA ER	Pain Relievers	Move from Tier 2 to Tier 3	
OXYCONTIN	Pain Relievers	Non-covered	
PRALUENT	Cardiovascular Medications	Non-covered	
RETACRIT	Hematological Medications	Addition to Tier 2	
STRIBILD	Antiretrovirals	Move from Tier 2 to Tier 3	
SUPRAX	Anti-Infective Agents	Move from Tier 2 to Tier 3	
TRULICITY	Antidiabetic Medication	Addition to Tier 2	
YONSA	Anticancer Medication	Addition to Tier 2	

The Prescription Drug Guide is updated quarterly. Please visit AlabamaBlue.com/pharmacy for the most up-to-date information

Note: Coverage is subject to each member's specific benefits. Group-specific policies will supersede these policies when applicable. Please refer to the member's benefit plan.

Generic Plus Drug Guide Updates – Effective January 1, 2019 (unless otherwise noted)

Brand Name (generic name if available)	Therapeutic Class	Description of Change	Additional Comments
COPAXONE	Multiple Sclerosis	Non-covered	Mylan-authorized generic will continue to be covered
FULPHILA	Hematological Medication	Addition to Tier 2	
OXYCONTIN	Pain Reliever	Non-covered	
RETACRIT	Hematological Medication	Addition to Tier 2	
SUPRAX	Anti-Infective Agent	Move from Tier 2 to Tier 3	
YONSA	Anti-cancer Medication	Addition to Tier 2	

For a complete listing of generic and preferred brand alternatives, please refer to the Generics Plus Drug Guide located in the Pharmacy section of the Blue Cross website, **AlabamaBlue.com/pharmacy**.

Note: Coverage is subject to each member's specific benefits. Group-specific policies will supersede these policies when applicable. Please refer to the member's benefit plan

Clinical Program Updates – Effective January 1, 2019 (unless otherwise noted)

The following medication dispensing limits (DL), prior authorization (PA), predetermination (PD) and/or step therapy (ST) programs have been added or revised:

New or Revised Pharmacy PA or ST Programs

Policy Name	Type of Policy	Coverage Criteria and Changes
Ampyra	PADL	**REVISED** – Addition of Dalfampridine 10mg tablet ER, First generic for Ampyra. If approved, a dispensing limit of 2 tablets/day will apply.
Androgen/Anabolic Steroid	PADL	**REVISED** – First generics for Androgel 1.62% available and must be tried prior to branded product. If approved, a dispensing limit of 30 packets (1.25 gm/day0/30 days, 60 packets (5 gm/day)/ 30 days and 2 bottles/ 30 days will apply.
Atypical Antipsychotics	STDL	**REVISED** – Addition of Perseris (risperidone ER) for susp subcutaneous prefilled syringe, 90 mg and 120 mg. If approved, a dispensing limit of 1 injection/30 days will apply to all strengths.

Biologic Immunomodulators	PADL	**REVISED** • Addition of prerequisites and length of therapy trial (to ensure adequate time had elapsed for clinical response/failure) for prerequisites according to clinical practice guidelines o Indications with prerequisites not previously required: ankylosing spondylitis, hidradenitis suppurative • Requires 3 months trial of preferred agents – time frame for clinical response to be consistent • Addition of specialist or consultation of specialist – to concerns of inappropriate staging/diagnosis and/or starting biologics without assessing for conventional agents first • Enbrel 25 mg/0.25 syringe QL decrease to 4 syringes/28 days; dose optimize, no need for 8 syringes if 50 mg syringe is available. Per Enbrel label, to achieve pediatric doses other than 25 mg or 50 mg, use reconstituted Enbrel lyophilized powder • Reduce QL for Xeljanz 5mg from 4 tablets daily to 2 tablets daily to dose optimize since Xeljanz 10 mg is now available
CFTR	PADL	**REVISED** – Addition of Orkambi (lumacaftor/ivacaftor) oral granules packet, 100-125 mg and 150-188 mg. Indicated for the treatment of cystic fibrosis in patients age two years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. If approved, a dispensing limit of 60 packets/30 days will apply to all strengths.
CGRP	PADL	**REVISED** – Addition of Ajovy (fremanezumab-vfrm) subcutaneous solution prefilled syringe 225mg/1.5mL and Emgality (galcanezumab-gnlm) inj, 120 mg/mL indicated for the preventive treatment of migraine in adults. If approved, a dispensing limit for Ajovy of 3 syringes/90 days and for Emgality of 1 auto injector per month will apply.
HAE	PADL	**REVISED** – Addition of Takhzyro (lanadelumab-flyo) 300 mg/2 mL. Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 yrs and older. If approved, a dispensing limit of 4 mLs/28 days will apply.
Immune Globulins	PA	**REVISED** – Addition of Panzyga (immune globulin [human]) ifas IV soln, 1 gm/10 mL, 2.5 gm/25 mL, 5 gm/50 mL, 10 gm/100 mL, 20 gm/200 mL, and 30 gm/300 mL. Indicated for the treatment of primary humoral immunodeficiency (PI) in patients two years of age and older and treatment of chronic immune thrombocytopenia (ITP) in adults.
Injectable Atopic Dermatitis	PADL	**REVISED** – Addition of Dupixent (dupilumab) prefilled syringe, 200 mg/2 mL. Indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. If approved, a dispensing limit of two syringes (2.280 mL)/28 days will apply.

Jynarque	PADL	**NEW** - Jynarque (tolvaptan) 45 mg/15 mg blister card, 60 mg/30 mg blister card and 90 mg/30 mg blister card tablets are targets in this new program. The intent of this program is to encourage appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines. Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). If approved, a dispensing limit for 45 mg of 56 tablets (4 blister cards) / 28 days, 60 mg of 56 tablets (4 blister cards) / 28 days and 90 mg 56 tablets (4 blister cards) / 28 days will apply.
Lucemyra	PADL	**NEW** - Lucemyra (lofexidine) 0.18 mg tablets is a target in this new program. The intent of this program is to appropriately select patients according to product labeling and/or clinical guidelines, and to direct use to more cost-effective clonidine. Indicated for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. If approved, a dispensing limit of 228 tablets (2 x 96 count bottles and 1 x 36 count bottle) / 6 months will apply.
Opioids ER	PADL	**REVISED** – Addition of Morphine sulfate ER capsules 40 mg, first generic for Kadian. If approved, a dispensing limit of 2 capsules/day will apply.
Oral PAH	PADL	**REVISED** – Addition of tadalafil 20 mg tablets, first generic for Adcirca. If approved, a dispensing limit of 60 tablets/30 days will apply.
Oral Tetracyline Derivates	ST	**REVISED** – Addition of Minolira (minocycline ER) tablets 105 mg and 135 mg. Indicated for the treatment of only inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 12 years of age and older.
SA Oncology	PADL	**REVISED** – Addition of Lenvima (lenvatinib) capsule therapy pack, 4 mg (4 mg daily dose) and 4 mg (12 mg daily dose). Indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC), in combination with everolimus for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy, and treatment of patients with unresectable hepatocellular carcinoma (HCC). If approved, a dispensing limit for 4 mg of 30 capsules/30 days and 12 mg of 90 capsules/30 days will apply.
SA Oncology	PADL	**REVISED** – Addition of Copiktra (duvelsib) capsule, 15 mg and 25 mg. Indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies. Relapsed or refractory follicular lymphoma after at least two prior systemic therapies. If approved, a dispensing limit of 2 capsules/day will apply for all strengths.
SA Oncology	PADL	**REVISED** – Addition of Vizimpro (dacomitinib) tabs, 15 mg, 30 mg, 45 mg indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deleltion or exon 21 L858R substitution mutations as detected by an FDA-approved test. If approved, a dispensing limit of 1 tablet/day will apply for all strengths.

SA Oncology	PADL	**REVISED** – Addition of Talzenna (talazoparib tosylate) capsule, 0.25 mg and 1 mg. Indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer. If approved, a dispensing limit for 0.25 mg of 3 capsules/day and for 1 mg of 1 capsule/day will apply.
SA Oncology	PADL	**REVISED** – Addition of Lorbrena (lorlatinib) tablet 25 mg and 100 mg. Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or alectinib as the first ALK inhibitor therapy for metastatic disease; or ceritinib as the first ALK inhibitor therapy for metastatic disease. If approved, a dispensing limit for 25 mg of 3 tablets/day and for 100 mg of 1 tablet/day will apply.
Thrombopoietin Receptor Agonists	PADL	**REVISED** – Addition of Mulpleta (lusutrombopag) tablets 3 mg. Indicated for treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. If approved, a dispensing limit for 25 mg of 3 tablets/day and for 100 mg of 1 tablet/day will apply.

New or Revised Dispensing Limits

Brand Name (generic if available)	Strength	Dispensing Limit	New or Revised
Amphetamine	5 mg 10 mg	3 tablets/day 6 tablets/day	Revised
Delstrigo (doravirine, lamivudine, and tenofovir disoproxil fumarate)	100/300/300 mg	1 tablet/day	Revised
Nevirapine suspension	50 mg/5 mL	1200ml/30 days	Revised
Pifeltro (doravirine)	100 mg	1 tablet/day	Revised
Tadalafil	2.5 mg 5 mg 10 mg 20 mg	30 tablets/month 30 tablets/month 6 tablets/month 6 tablets/month	Revised
Vardenafil	2.5 mg 5 mg 10 mg 20 mg	30 tablets/month 30 tablets/month 6 tablets/month 6 tablets/month	Revised
Xarelto (rivaroxaban)	2.5 mg	2 tablets/day	Revised
Xelpros (latanoprost)	0.005%	2.5 mL/30 days	Revised
Xofluza (baloxavir marboxil)	20 mg (40 mg dose) 40 mg (80 mg dose)	2 boxes (4 capsules)/120 days 2 boxes (4 capsules)/120 days	Revised
Xyosted (testosterone enanthate)	50 mg/0.5 mL 75 mg/0.5 mL 100 mg/0.5 mL	4 pens (=2 mL) per 28 days 4 pens (=2 mL) per 28 days 4 pens (=2 mL) per 28 days	Revised

Clinical Program Updates – Effective January 1, 2019

New or Revised Provider-Administered (Medical) Drug Programs

Policy Name	Type of Policy	Coverage Criteria and Changes
Botulinum Toxin	Medical PA	**REVISED – Effective 1/1/19** – Criteria for all indications without a level 2a support or FDA approved indication was removed. **The following diagnoses have been removed from coverage criteria:** • Botox - Palmer hyperhidrosis – no compendium support - Esophageal achalasia – level 2b - Chronic anal fissures – level 2b - Focal limb dystonia; laryngeal dystonia; torsion dystonia – guideline supported and level 2b - Lower urinary tract symptoms due to benign prostatic hyperplasia – level 2b • Dysport - Hemifacial spasm – level 2b • Myobloc - Oromandibular dystonia – no compendium support - Sialorrhea- level 2b **Addition of indication with level 2a support** • Dysport - Blepharospasm – level 2a **Clarified specific accepted diagnoses based off clinical studies listed in FDA label/compendium evidence:** • Upper limb spasticity associated with stroke • Lower limb spasticity associated with cerebral palsy, stroke • Excessive drooling associated with Parkinson's **Matched requirements for use in migraine to that of CGRP:** • Defined qualifications for chronic migraine • Required use of at least two traditional migraine prophylaxis classes • Restrict concurrent therapy of Botulinum toxin and CGRP • Require specialist or consultation of specialist
Colony Stimulating Factors	Medical and Oncology PA	**REVISED – Effective 11/1/18** - Nivestym was added to the medical policy criteria for coverage.
Darzalex	Oncology PA	**REVISED – Effective 11/19/18 –** Added criteria for newly-diagnosed multiple myeloma patients that are ineligible for stem cell transplant when used in combination with bortezomib, melphalan and prednisone. Added criteria for relapsed or refractory disease following two prior lines of therapy when used in combination with pomalidomide and dexamethasone. Investigational criteria added to policy statement.

Healthcare Provider Administered Biologic Immunomodulator	Medical PA	**NEW – Effective 11/1/18 –** This new policy combined the Infusible Biologics and the Infliximab and Infliximab Biosimilars policies into one. Revisions made to the infliximab program agents are as follows: • Removed Hep B requirement • Added required length of trial to prerequisite agents • For RA, require patient to take in combination with MTX (or another DMARD) or have an intolerance/contraindication/hypersensitivity; expanded to alternative DMARDs in case MTX is not appropriate • For diagnosis of granulomatosis with polyangiitis (GPA), guidelines suggest either cyclophosphamide or rituximab as first line and try the other agent if the first trial failed; second/third line recommendations are oral immunosuppressants (AZA, MTC, or mychophenolate) for duration of 3 months to see clinical benefit, requires use in combination with corticosteroid • Addition of specialist or consultation with specialist • Formation of anti-drug antibodies is prevalent with infliximab, which results in patients who initially responded to drug therapy to have decrease response (notable in diagnoses of CD and UC). Policy requires patient to have tried lower doses (titrated up to dose requested) and lost clinical response • Length of approval shortened for CD to 14 weeks (previously 16 weeks)
Hereditary Angioedema	Medical PA	**REVISED – Effective 1/1/19 –** Takhzyro is added to the medical policy criteria for coverage.
Imfinzi	Oncology PA	**REVISED – Effective 12/2/18 –** Added criteria for consolidation therapy for unresectable stage III non-small cell lung cancer.
Immune Globulins	Medical and Oncology PA	**REVISED – Effective 1/1/19 –** Panzyga is added to the medical policy criteria for coverage.
Synagis	Medical PA	**REVISED – Effective 1/1/19** – Synagis season defined as 10/1/18-4/30/19. Added the intent of the requested agent is to prevent serious lower respiratory tract disease due to RSV; exclusion criteria is added if patient has already had a confirmed RSV infection.

Non-Coverage of Select Prescription Drugs

Blue Cross and Blue Shield of Alabama and Prime Therapeutics evaluate drugs to be included on our formulary based on the drug's clinical safety, efficacy and uniqueness. Blue Cross's formulary is designed to provide sufficient options to treat patients who require pharmacologic treatment. As a result, Blue Cross may determine that select medications are not covered on the formulary when those decisions are supported by clinical rationale.

Drugs may not be covered on the formulary for the following reasons:

- The medication has safety or efficacy concerns.
- The medication has been shown to have excessive adverse effects and/or safer alternatives.
- The medication has an over-the-counter (OTC) alternative and/or ingredients.
- The medication is considered a cost outlier with lower cost alternatives available.

Beginning January 1, 2019, the following drugs will no longer be covered on the formulary. Impacted members will receive notification of this change.

- Carafate
- Cleocin
- Nascobal
- Oxycontin and oxycodone ER
- Praluent