Buckeye Health Plan
Medicaid Criteria Updates – Q3 2017

Buckeye Health Plan (BHP) routinely reviews their Prior Authorization (PA) and Medical Necessity (MN) criteria. Decisions on PA and MN criteria content are coordinated with input from pharmacy and medical practitioners, Buckeye Health Plan representatives, and review of current available medical literature and professional standards of practice. Below is the list of changes to the Medicaid criteria this quarter.

For the most current program description you may call Provider Services at 1-866-296-8731 (TTY/TTD 1-800-750-0750) or visit the Buckeye Health Plan website at www.buckeyehealthplan.com

<table>
<thead>
<tr>
<th>Coverage Guideline Policy &amp; Procedure</th>
<th>Status</th>
<th>Revision Summary or Description</th>
</tr>
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<tbody>
<tr>
<td>CP.PMN.13 Dose Optimization</td>
<td>Revised/Reviewed</td>
<td>-Converted to new template</td>
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</table>
| CP.PMN.33 Pregabalin (Lyrica)        | Revised/Reviewed | -Modified trial/failure verbiage and removed age restriction for partial seizures (Lyrica is not proven unsafe or ineffective in pediatric patients) per updated template
|                                     |                | -Separated continued approval criterion II.A.1 into 2 sub-criteria (II.A.1.a and II.A.1.b) to delineate between continuity of care criteria for partial seizure indication and regular criteria for all other covered indications |
| CP.PMN.35 Armodafinil (Nuvigil)     | Revised/Reviewed | -Converted to new template
|                                     |                | -Modified duration of stimulant trial for narcolepsy from ≥ 2 months to ≥ 1 month so that it is consistent with Xyrem policy
|                                     |                | -Added “armodafinil” to requirement related to hypersensitivity to modafinil per PI
|                                     |                | -Removed “Armodafinil will not be approved for concurrent use with benzodiazepines” per new template update, and since this requirement cannot be enforced post-approval without an edit
|                                     |                | -Modified age requirement for MS-related fatigue from ≥18 years to ≥17 years of age per PI (pediatric patients defined as less than 17 years of age) |

Key: PDL=Preferred Drug List  AL=Age Limit  QL=Quantity Limit  ST=Step Therapy  POS=Point Of Sale message

Effective date: 07/10/17
<table>
<thead>
<tr>
<th>Drug Code</th>
<th>Drug Name (Common Name)</th>
<th>Status</th>
<th>Updates</th>
</tr>
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</table>
| CP.PMN.39 | Modafinil (Provigil)   | Revised/Reviewed | - Updated references to reflect current literature search  
- Converted to new template  
- Modified duration of stimulant trial for narcolepsy from ≥ 2 months to ≥ 1 month so that it is consistent with Xyrem policy;  
- Added duration of trial to requirement related to failure of armodafinil for clarity  
- Removed “Modafinil will not be approved for concurrent use with benzodiazepines” per template update, and since this requirement cannot be enforced post-approval without an edit  
- Added “No documentation of hypersensitivity to armodafinil or modafinil” per PI  
- Modified age requirement for SWD and MS-related fatigue from ≥18 years to ≥17 years of age per PI (pediatric patients defined as less than 17 years of age)  
- Updated references to reflect current literature search |
| CP.PMN.42 | Sodium Oxybate (Xyrem) | Revised/Reviewed | - Created separate criteria for diagnosis of narcolepsy with cataplexy and diagnosis of narcolepsy with EDS  
- Narcolepsy with cataplexy: removed requirements related to trial and failure of stimulants and armodafinil/modafinil for narcolepsy with cataplexy since these agents used to treat excessive sleepiness have little effect on cataplexy per American Academy of Sleep Medicine report; modified criteria to require trial and failure of 2 antidepressants, instead of 1 for cataplexy  
- Narcolepsy with EDS: modified criteria to require failure of one CNS stimulant indicated for narcolepsy at up to maximally indicated doses instead of failure of 2 stimulants, one from each class (amphetamine and methylphenidate)  
- Converted to new template  
- Removed requirements related to age restriction and “No concurrent use of sedative hypnotics as evidenced by review of pharmacy claim history” per template update, and since age is not an absolute contraindication per PI and safety concerns are addressed by Xyrem REMS Program  
- Added “documentation of positive response to therapy” for re-auth  
- Updated references |
| CP.PMN.48 | Cyclosporine (Restasis) | Revised/Reviewed | - Converted to new template  
- Removed age criteria as age is not an absolute contraindication per FDA labeling  
- Updated references |
| CP.PMN.49 | Dabigatran (Pradaxa)   | Revised/Reviewed | - Converted to new template  
- Removed age criteria as age is not an absolute contraindication per FDA labeling  
- Updated references |
| CP.PMN.50 | Lurasidone (Latuda)    | Revised/Reviewed | - Converted to new template  
- Removed age criteria as age is not an absolute contraindication per FDA labeling  
- Updated references |
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<tr>
<th>CP.PMN.51 Tetracycline Antibiotics (Solodyn, Doryx, and Oracea)</th>
<th>Retired</th>
<th>Split into individual drug policies (see new policies for Solodyn/Doryx)</th>
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| **CP.PMN.54 Clobazam (Onfi)** | Revised/Reviewed | -Lennox-Gastaut: modified requirement related to treatment failure with clonazepam in conjunction with a PDL anticonvulsant to allow trial and failure of any 2 PDL anti-epileptics for Lennox-Gastaut since a neurologist is involved in the patient’s care; removed requirement that Onfi “must be used as adjunctive therapy with any of the following PDL anticonvulsants: valproic acid (divalproex), lamotrigine, topiramate, or felbamate” since specialist is involved in patient’s care and is better able to select appropriate therapy  
-Created criteria for treatment of intractable/refractory epilepsy (off-label)  
-Converted to new template  
-Removed age restriction per new template update  
-Modified weight-based dose criteria to max dose of drug per new template update  
-Added criteria for continuity of care and documentation of positive response to therapy for re-auth.  
-Updated references |
| **CP.PMN.57 Febuxostat (Uloric)** | Revised/Reviewed | -Modified initial approval duration to 6 months  
-Converted to new template  
-Removed age requirement per updated template  
-Removed requirement for demonstrated adherence and added requirement for documentation of positive response upon re-auth per updated template |
| **CP.PMN.58 Propranolol HCl (Hemangeol)** | Revised/Reviewed | -Removed upper age limit as Hemangeol has demonstrated efficacy in older children per literature review  
-Removed hard stop at 6 months of total treatment and all criteria referencing said hard stop  
-Added criteria to allow continued therapy for recurrence of hemangioma or for those requiring up to 12 consecutive months of treatment per AAP clinical report  
-Converted to new template  
-Updated references |
| **CP.PMN.61 ACEI and ARB Duplicate Therapy** | Revised/Reviewed | -Converted to new template  
-Added duration of 30 days to initial requirement related to continuity of care/heart failure for clarity  
-Specifed approval duration of 3 months for cross-taper for initial and re-auth; limited approval duration for cross-taper to total of 6 months  
Added documentation of positive response to therapy on re-auth  
Updated references |
| **CP.PMN.79 Doxycycline (Doryx, Oracea)** | New | Policy split from CP.PMN.51 Tetracycline Antibiotics (Solodyn, Doryx, Oracea) |

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For acne vulgaris and rosacea, modified criteria related to trial and failure of PDL oral antibiotics to specifically require tetracycline class of antibiotics, one of which must be immediate-release doxycycline, as they are considered first-line for systemic antibiotic therapy; for rosacea, modified criteria to require failure of 2 (instead of 1) oral antibiotics;
- Created criteria sets for other FDA approved indications of Doryx, including malaria prophylaxis;
- Converted to new template;
- Added no documentation of hypersensitivity to tetracyclines per PI;
- Added duration of trial to requirements related to trial and failure of topical therapies for clarity;
- Removed age requirement since tetracycline antibiotics on the PDL are not subjected to age restrictions;
- For acne, modified duration of trial of oral antibiotics from ≥ 6 weeks to ≥ 4 weeks; modified duration of approval for Doryx/Doryx MPC from 16 weeks to 12 weeks since PI does not specify time frame of use and per American Academy of Dermatology, systemic antibiotic use should be limited to shortest possible duration, typically 3 months, to minimize development of bacterial resistance;
- Updated references.

| CP.PMN.80 Minocycline (Solodyn) | New | Policy split from CP.PMN.51 Tetracycline Antibiotics (Solodyn, Doryx, Oracea) to address all indications for the featured drugs;
- Modified criteria related to trial and failure of PDL oral antibiotics to specifically require tetracycline class of antibiotics, one of which must be immediate-release minocycline, as they are considered first-line for systemic antibiotic therapy for acne for ≥ 4 weeks;
- Converted to new template;
- Added no documentation of hypersensitivity to tetracyclines per PI;
- Added duration of trial to requirements related to trial and failure of topical therapies for clarity;
- Removed age requirement since tetracycline antibiotics on the PDL are not subjected to age restrictions;
| Updated references |

| CP.PPA.01 Celecoxib (Celebrex) | Revised/Reviewed | - Converted to new template;
- Added quantity and dosage limit;
- Removed age criteria as age is not an absolute contraindication;
| Updated references |

| CP.PPA.03 Lisdexamfetamine (Vyvanse) | Revised/Reviewed | - Remove criteria of dose of 50 mg to 70 mg within the next 30 days from initial approval criteria for BED because there is no way to verify dose titration occurs in 30 days. Added “Dose of 50 mg to 70 mg requested to treat BED” to the continued approval section;
- Changed requirement of 1 SSRI trial in BED to a trial of Celexa, Zoloft, or Lexapro. These SSRIs show the best outcomes for treatment of BED. |
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- Removed requirement of ≥ 2 week trial for pediatric/adolescent members. A response to the medication should be seen immediately and with a titration to maximum dose, the member would have trialed the medication for a sufficient timeframe.
- Converted to new template
- Removed age criteria as age is not an absolute contraindication per FDA labeling
- Separated continued criteria for clarity
- Updated references

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<th>CP.PPA.06 Oseltamivir (Tamiflu)</th>
<th>Retired</th>
<th>PA requirement removed for all plans. Generic for the capsule now available with expectation for generic for liquid soon</th>
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| CP.PPA.07 Itraconazole (Sporanox) | Revised/Reviewed | - Added 6 week trial of terbinafine for fingernails and 12 week trial of terbinafine for toenail onychomycosis and limited trial to one course instead of 2 courses.  
- Removed requirement of multiple toes and/or fingers involved or member having a diagnosis of diabetes mellitus, peripheral vascular disease, or is immunocompromised for onychomycosis per specialist feedback.  
- Separated approval durations for onychomycosis for fingernails only: 2 months and toenails: 3 months per PI, guideline and clinical pharmacology.  
- Separated initial criteria for oropharyngeal and esophageal candidiasis. Esophageal candidiasis requires a trial of fluconazole only per IDSA guidelines.  
- Added 14 day duration of nystatin or clotrimazole trial and fluconazole trial for oropharyngeal candidiasis per IDSA guideline.  
- Added 21 day duration of fluconazole trial for esophageal candidiasis per IDSA guideline.  
- Changed approval duration from 8 weeks to 4 weeks for oropharyngeal and esophageal candidiasis per IDSA guideline and PI.  
- Changed continued approval duration for oropharyngeal and esophageal candidiasis from 8 weeks to 2 weeks per IDSA guideline and PI.  
- Added Request is for Sporanox capsules for onychomycosis, blastomycosis, histoplasmosis, and aspergillosis. |
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<th>PDL Item</th>
<th>Revised/Reviewed</th>
<th>Changes</th>
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| CP.PPA.10 Toremifene (Fareston) | | - Clarified continued approval duration for blastomycosis, histoplasmosis, and aspergillosis per IDSA guidelines.  
- Added continued approval criteria for onychomycosis.  
- Converted to new template  
- Removed age criteria as age is not an absolute contraindication per FDA labeling  
- Updated references |
| CP.PPA.11 Colchicine (Colcrys) | | - Treatment of gout: added option for failure of NSAID (per ACR guidelines: those with inadequate response to initial therapy should be switched to alternate monotherapy)  
- Prophylaxis of gout:  
- Removed diagnosis of hyperuricemia as colchicine is indicated for gout and does not alter urate levels  
- Added requirement for evidence of active gout and modified serum urate level from 6.5 mg/dL to 6 mg/dL per ACR guideline minimum target  
- Removed requirement for trial/failure of urate lowering therapies (per ACR guidelines: colchicine is 1st line for anti-inflammatory prophylaxis and should be used with or just prior to initiating ULT)  
- Continuation: added requirement for use of ULT; modified approval duration to 6 months  
- Pericarditis: developed criteria set for this off-label indication (per ESC guidelines, which were supported by ACC, and per AHA clinician update: colchicine is a 1st line agent that can be added to conventional NSAID therapy to improve response to therapy, increase remission, and reduce recurrence) Note: the maximum dose enforced in this criteria reflects the available 0.6 mg dosage form and allows up to 2 tablets per day  
- Converted to new template  
- Removed age restriction for FMF per updated template; age restriction is maintained for gout indications per package insert and per age edits currently in place  
- Added quantity limit for gout treatment (max 30 tablets)  
- Continuation: separated into individual criteria sets; added requirement for documentation of positive response for FMF and anti-inflammatory prophylaxis of gout  
- Updated references |
| CP.PPA.15 Milnacipran (Savella) | | - Modified criteria to allow trial and failure of either amitriptyline or cyclobenzaprine (instead of requiring trial of amitriptyline first prior to cyclobenzaprine) if duloxetine is contraindicated due to lack of evidence that one is better than the other |
| CP.PST.08 Mesalamine Oral Therapy | Revised/Reviewed | - Converted to new template  
- Modified age restriction from ≥ 17 years to ≥ 18 years-per PI, use of Savella is not recommended in pediatric population below the age of 18  
- Removed safety requirement related to “no concomitant use of monoamine oxidase inhibitors (MAOI) therapy OR history of MAOI therapy within the past 14 days” per template update  
- Added documentation of positive response to therapy for re-auth  
- Updated references  

| CP.PST.13 Pramlintide (Symlin) | Revised/Reviewed | - Converted to new template  
- Removed age requirement (age is not an absolute contraindication per PI) per updated template  
- Removed verification of diagnosis and requirement for demonstrated adherence upon re-auth since this is a step therapy guideline  
- Added additional examples of mealtime insulin  

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