Effective date: 12/04/17

Buckeye Health Plan
Medicaid Criteria Updates – Q4 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

Coverage Guideline/Policy & Procedure	Status	Revision Summary Description
CP. PHAR.108 Omacetaxine (Synribo)	Revised/Reviewed	Changed approval durations from 3/6 months to 6/12 months Added age Added NCCN recommended uses of previously diagnosed with chronic phase CML and has progressed to accelerated phase CML and history of T315I mutation.
CP.PHAR.109 Tesamorelin (Egrifta)	Revised/Reviewed	Removed member is not presently receiving therapy with growth hormone, insulin-like growth factors or any of their analogs; It was part of the exclusion criteria in the pivotal study but is not list as a contraindications and does not meet our current safety policy. Removed Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma and Active malignancy (either newly diagnosed or recurrent) and/or receiving treatment for a malignancy per updated safety policy.
CP.PHAR.121 Nivolumab (Opdivo)	Revised/Reviewed	Updated off-label usage requirements for RCC, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, and urothelial carcinoma to reflect off-label NCCN recommendations for use. Consolidated criteria under

		NSCLC as the FDA approved use aligns with NCCN recommendations for use. Added age limit ≥ 12 years. Added coverage criteria for the new FDA-approved indication of MSI-H/dMMR colorectal cancer and for the NCCN-recommended off-label usages of malignant pleural mesothelioma and small cell lung cancer.
CP.PHAR.126 Ibrutinib (Imbruvica)	Revised/Reviewed	Converted to new template. Added new FDA approved indication: cGVHD. Increased continued approval duration from 6 to 12 months. Created criteria for hairy cell leukemia per NCCN guidelines/compendium. Added Appendix B: General Information.
CP.PHAR.149 Intrathecal Baclofen (Gablofen, Lioresal)	Revised/Reviewed	Added age restriction per PI; Removed "baclofen will not be compounded with other medications" and requirement related to hypersensitivity to baclofen per safety approach. Re-auth: added requirement of positive response to therapy.
CP. PHAR.150 Mecasermin (Increlex)	Revised/Reviewed	Added age and max dose. Updated new criteria to be in line with new safety guidance.
CP.PHAR.151 Levoleucovorin (Fusilev)	Revised/Reviewed	Converted to new template. All indications: Removed allergy contraindication as it constitutes a hypersensitivity reaction. Modified leucovorin criteria to allow for clinically significant adverse effects. Added max dose criteria. Following MTX: Added age limit as safety and efficacy have not been established in patients < 6 years. For impaired elimination/accidental overdose, decreased continued approval duration from 3 months to 1 month as these events do not occur chronically and are typically managed on an inpatient basis. For sarcomas, increased approval duration from 1/3 months to 6/12 months (MTX regimens used in bone cancers are dosed on a schedule through 45 weeks after surgery per MTX's PI, while the NCCN guidelines do not indicate a limit on treatment duration). CRC: Added NCCN off label recommended uses. Increased approval duration from 3/6 months to 6/12 months per new standard. Added megaloblastic and pernicious anemias as diagnoses not covered per PI.
CP.PHAR.152 Laronidase (Aldurazyme)	Revised/Reviewed	Policy converted to newer template; added age restriction.
CP.PHAR.153 Eliglustat (Cerdelga)	Revised/Reviewed	Added age restriction. Added requirement for presence of symptoms. Added max dose to re-auth criteria. Removed criteria related to cardiac disease and renal/hepatic impairment as those conditions do not represent CI or BBW. Added examples of what can constitute a positive response to therapy. Added monotherapy requirement for re-auth requests in addition to the initial criteria. Added appendix B.

CP.PHAR.154 Imiglucerase (Cerezyme)	Revised/Reviewed	Added age restriction. Modified requirement for presence of one of the following: anemia, thrombocytopenia, bone disease, or hepatomegaly or splenomegaly to require the presence of symptoms since other GD1 manifestations may be present which can also indicate need for initiation of enzyme replacement therapy (ERT). Added ERT monotherapy requirement for re-auth requests in addition to the initial criteria. Added appendix B.
CP.PHAR.155 Cysteamine (Cystagon, Procysbi)	Revised/Reviewed	Policy converted to newer template. Age restriction added. Reasons to discontinue removed from continuation criteria.
CP.PHAR.156 Idursulfase (Elaprase)	Revised/Reviewed	Policy converted to newer template. Added age restriction.
CP.PHAR.157 Taliglucerase Alfa (Elelyso)	Revised/Reviewed	Added age restriction. Added requirement for presence of symptoms. Added examples of what can constitute a positive response to therapy. Added ERT monotherapy requirement for re-auth requests in addition to the initial criteria. Added appendix B.
CP.PHAR.158 Agalsidase Beta (Fabrazyme)	Revised/Reviewed	Policy converted to newer template. Age restriction added. Added general information appendix.
CP.PHAR.159 Sebelipase Alfa (Kanuma)	Revised/Reviewed	Added age restriction and max dose criteria. Added examples of what may constitute positive response to therapy.
CP.PHAR.160 Alglucosidase Alfa (Lumizyme)	Revised/Reviewed	Added max dose criteria. Added examples of what may constitute positive response to therapy.
CP.PHAR.161 Galsulfase (Naglazyme)	Revised/Reviewed	Policy converted to newer template. Age restriction added. Added appendix B.
CP.PHAR.162 Elosulfase Alfa (Vimizim)	Revised/Reviewed	Policy converted to newer template. Age restriction reinstated. Added appendix B.
CP.PHAR.163 Velaglucerase Alfa (VPRIV)	Revised/Reviewed	Added age restriction. Added requirement for presence of symptoms. Added examples of what can constitute a positive response to therapy. Added ERT monotherapy requirement for re-auth requests in addition to the initial criteria. Added appendix B.
CP.PHAR.164 Miglustat (Zavesca)	Revised/Reviewed	Added age restriction. Added requirement for presence of symptoms. Removed severe renal impairment (not a CI or BBW) and reasons to discontinue per new safety strategy. Added examples of what can constitute a positive response to therapy. Added appendix B.
CP.PHAR.169 Vigabatrin (Sabril)	Revised/Reviewed	Added criteria of Abnormal electroencephalogram (EEG) confirming diagnosis of infantile spasms; Extended approval durations from 3/6 months to 6/12 months. Removed age criteria in continued approval for infantile spasms, as it is already criteria for initial approval.

CP.PHAR.170 Degarelix Acetate (Firmagon)	Revised/Reviewed	Age and dosing added. Positive therapeutic response examples added. Prostate cancer FDA/NCCN (categories 1 and 2A) indications listed separately. Breast cancer removed as an off label indication per NCCN. Safety information removed (hypersensitivity).
CP.PHAR.171 Goserelin Acetate (Zoladex)	Revised/Reviewed	Age and dosing added to oncology criteria; age added to gynecology criteria. Positive therapeutic response examples added for oncology and endometriosis criteria. Oncology FDA/NCCN (categories 1 and 2A) indications listed separately. Endometriosis step therapy edited from estrogen/progestin OC to OC or depot contraceptive or progestin. Total approval duration increased from 6 to 12 months. Specialist requirement added for endometriosis, DUB. Safety information removed with the exception of pregnancy; pregnancy added for breast cancer per expert recommendation.
CP.PHAR.172 Histrelin Acetate (Vantas, Supprelin LA)	Revised/Reviewed	Age and dosing added to prostate cancer. FDA/NCCN (categories 1 and 2A) indications listed separately. Positive therapeutic response examples added. Specialist requirement added for CPP. Safety information removed (hypersensitivity).
CP.PHAR.173 Leuprolide Acetate (Eligard, Lupaneta Pack, Lupron Depot, Lupron Depot-Ped)	Revised/Reviewed	Age and dosing added to oncology criteria; age added to gynecology criteria. Positive therapeutic response examples added to oncology and endometriosis criteria. Oncology FDA/NCCN (categories 1 and 2A) indications listed separately. Pelvic pain criteria deleted with direction to suspected endometriosis if appropriate. Endometriosis step therapy edited from estrogen/progestin OC to OC or depot contraceptive or progestin. Total approval duration increased from 6 to 12 months. Concomitant iron therapy and specific time period within which surgery must be performed are removed from fibroid criteria. Total approval duration increased from 3 to 6 months. Specialist requirement added for endometriosis, fibroids, CPP. Safety information removed with exception of pregnancy.
CP.PHAR.174 Nafarelin Acetate (Synarel)	Revised/Reviewed	Pelvic pain criteria deleted. Age added to endometriosis; endometriosis step therapy edited from estrogen/progestin OC to OC or depot contraceptive or progestin. Total approval duration increased from 6 to 12 months. Positive therapeutic response examples added. Specialist requirement added for endometriosis, CPP. Safety information removed with exception of pregnancy.
CP.PHAR.175 Triptorelin Pamoate (Trelstar, Triptodur)	Revised/Reviewed	Age and dosing added for prostate cancer; positive therapeutic response examples added. Prostate cancer FDA/NCCN (categories 1 and 2A) indications listed separately. New drug/indication added: Triptodur/CPP. Safety information removed (hypersensitivity).

CP.PHAR.201 Belatacept (Nulojix)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Initial approval duration extended to 6 months.
CP.PHAR.210 Ivacaftor (Kalydeco)	Revised/Reviewed	Removed the requirement of specific gene mutations, G551D, G1244E, G1349D, G178R, G551S, R117H, S1251N, S1255P, S549N, or S549R, there are now over 20 gene mutation susceptible to Kalydeco. Appendix B added. Added maximum dose for pediatric patients.
CP.PHAR.241 Abatacept (Orencia)	Revised/Reviewed	Added new indication for PsA Revised criteria for confirmation of RA diagnosis per 2010 ACR Criteria. Removed safety requirements per updated CPAC Safety Precaution in PA Policies approach.
CP.PHAR.246 Canakinumab (Ilaris)	Revised/Reviewed	All indications: Added age limits per FDA labeling. Except for SJIA, modified specialist requirement to remove physician experienced in the management of the relevant diagnosis since this is too general and not evaluable or enforceable. Changed initial approval durations from the duration of 1 dose + buffer time to the standard 6 months for all indications except CAPS (changed to 3 months). SJIA: Removed requirement for trial/failure of NSAID as it not a first line therapy recommended by the SJIA guidelines. Note: Safety criteria was applied according to the safety guidance discussed at CPAC. An exception was made to require TB screening for all patients prior to treatment to ensure that proper risk reduction measures are taking, though this is not specifically addressed in boxed warning.
CP.PHAR.263 Tocilizumab (Actemra)	Revised/Reviewed	SJIA: Removed requirement for trial/failure of NSAID as it not a first line therapy recommended by the SJIA guidelines. GCA: Added age requirement as safety and efficacy have not been established in pediatric populations.
CP.PHAR.288 Eteplirsen (Exondys 51)	Reviewed	Performed literature search: no new efficacy data is available to support use of Exondys 51 in DMD.
CP.PHAR.290 Aripiprazole Long-Acting Injections (Abilify Maintena, Aristada)	Revised/Reviewed	Converted to new template. Added age restriction. Removed requirements related to hypersensitivity to aripiprazole and history of dementia-related psychosis per safety approach. Removed “Therapeutic plan includes initial concomitant use of oral antipsychotic therapy as appropriate” since requirement is subjective and specialist is involved in care. Increased initial approval duration from 3 to 6 months. Added new FDA approved indication for Abilify Maintena: bipolar I disorder. Re-auth: updated to include bipolar disorder; modified to allow continuation of therapy for covered indications; removed “Therapeutic plan includes appropriate concomitant use of oral aripiprazole if

		there were missed or delayed doses of Abilify Maintena or Aristada". Added dementia-related psychosis under section III.
CP.PHAR.291 Paliperidone Long-Acting Injections (Invega Sustenna, Invega Trinza)	Revised/Reviewed	Converted to new template. Added age restriction per PI. Removed requirements related to hypersensitivity to either paliperidone or risperidone and history of dementia-related psychosis per safety approach. Removed "therapeutic plan includes initial concomitant use of oral antipsychotic therapy as appropriate" since requirement is subjective and specialist is involved in care. Increased initial approval duration from 3 to 6 months. Re-auth: combined criteria sets and updated to allow continuation of therapy for schizophrenia and schizoaffective disorder. Added dementia-related psychosis under section III.
CP.PHAR.292 Olanzapine Long-Acting Injection (Zyprexa Relprevv)	Revised/Reviewed	Converted to new template. Added age restriction per PI/safety approach. Removed "Therapeutic plan includes initial concomitant use of oral antipsychotic therapy as appropriate" since requirement is subjective and specialist is involved in care. Removed requirements related to history of dementia-related psychosis and Alzheimer's disease per safety approach Increased initial approval duration from 3 to 6 months. Re-auth: updated to allow continuation of therapy for schizophrenia; removed reasons to discontinue per safety approach. Added dementia-related psychosis and Alzheimer's disease under section III.
CP.PHAR.293 Risperidone Long-Acting Injection (Risperdal Consta)	Revised/Reviewed	Converted to new template. Added age restriction per PI. Removed requirements related to hypersensitivity to either risperidone or paliperidone and history of dementia-related psychosis per safety approach. Increased initial approval duration from 3 to 6 months. Re-auth: updated to allow continuation of therapy for schizophrenia and bipolar disorder. Added dementia-related psychosis under section III.
CP.PHAR.294 Osimertinib (Tagrisso)	Revised/Reviewed	Converted to new template. Initial: added age restriction per PI/safety approach; modified max dose requirement to include QL; increased approval duration from 3 to 6 months. Re-auth: added requirement for positive response to therapy; removed requirement related to reasons to discontinue per safety approach-retained no disease progression or unacceptable toxicity as examples of positive response; added max dose; increased approval duration from 6 to 12 months. Updated references.
CP.PHAR.295 Sargramostim (Leukine)	Revised/Reviewed	Updated template and references. Added age, max dose, and continued approval section
CP.PHAR.296 Pegfilgrastim (Neulasta)	Revised/Reviewed	Updated template and references. Removed off-label use.

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

CP. PHAR.297 Filgrastim (Neupogen), Filgrastim-sndz (Zarxio), Tbo-filgrastim (Granix)	Revised/Reviewed	Updated template and references. Added continued therapy criteria for severe chronic neutropenia. For AML: changed wording from myelosuppressive chemotherapy from non-myeloid leukemia to induction or consolidation chemotherapy for acute myeloid leukemia per indication.
CP.PHAR.298 Afatinib (Gilotrif)	Revised/Reviewed	Converted to new template. NSCLC: Removed criteria for off-label NCCN use in HER2+ disease as it is a category 2B recommendation. Added criteria for the FDA approved indication of metastatic squamous NSCLC progressing after platinum-based chemotherapy. Added age limit as safety and efficacy have not been established in pediatric patients. Added max dose criteria. Increased approval duration from 3/6 months to 6/12 months per new standard. Head and neck cancers: Removed criteria for this off-label NCCN use as it is a category 2B recommendation. Re-auth: Added requirement for positive response to therapy. Removed reasons to discontinue per new safety strategy. Added max dose criteria.
CP.PHAR.299 Gefitinib (Iressa)	Revised/Reviewed	Updated references and template. Changed approval duration from 3/6 months to 6/12 months. Updated policy with new safety strategy and added age.
CP.PHAR.300 Bezlotoxumab (Zinplava)	Reviewed	Updated template (age, max dose) and references.
CP.PHAR.302 Ixazomib (Ninlaro)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.
CP.PHAR.303 Brentuximab Vedotin (Adcetris)	Revised/Reviewed	Age and dosing added. Safety information removed. NCCN recommended uses added separately.
CP.PHAR.304 Irinotecan Liposome (Onivyde)	Revised/Reviewed	Age and dosing added. Hypersensitivity and reasons to discontinue removed. NCCN recommended uses added separately.
CP.PHAR.305 Obinutuzumab (Gazyva)	Revised/Reviewed	Age and dosing added. Safety information removed. NCCN recommended uses added separately. HCPCS code updated.
CP.PHAR.306 Ofatumumab (Arzerra)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Added criteria for NCCN 2A rating and above recommended off-label use: Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.

CP.PHAR.307 Bendamustine (Bendeka, Treanda)	Revised/Reviewed	Age and dosing added. Safety information removed. NCCN recommended uses added separately. Removed HCPCS code for bevacizumab. Removed ICD-10-CM codes.
CP.PHAR.308 Elotuzumab (Empliciti)	Revised/Reviewed	Converted to new template. Added age restriction as safety and effectiveness have not been established in pediatric patients per PI/safety approach. Added max dose criteria for both FDA and off-label NCCN uses. Increased initial/continued approval from 3/6 months to 6/12 months, respectively. Added Appendix B: Examples of Myeloma Therapy per NCCN guidelines for multiple myeloma.
CP.PHAR.309 Carfilzomib (Kyprolis)	Revised/Reviewed	Age and dosing added. Safety information removed. NCCN recommended uses added separately.
CP.PHAR.310 Daratumumab (Darzalex)	Reviewed	Policy converted to new template. Annual review – no clinical changes.
CP.PHAR.311 Belinostat (Beleodaq)	Revised/Reviewed	Age and dosing added NCCN recommended uses added separately.
CP.PHAR.312 Blinatumomab (Blincyto)	Revised/Reviewed	Dosing added. Safety information removed. NCCN recommended uses added separately.
CP.PHAR.313 Pralatrexate (Folotyn)	Revised/Reviewed	Age and dosing added. Safety information removed. NCCN recommended uses added separately.
CP.PHAR.314 Romidepsin (Istodax)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively. Removed Stage I-IIA from Cutaneous T-Cell Lymphoma NCCN criteria due to NCCN 2B rating for stage I-IIA with blood involvement.
CP.PHAR.315 Vincristine Sulfate Liposome Injection (Marqibo)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.
CP.PHAR.316 Cabazitaxel (Jevtana)	Revised/Reviewed	Converted to new template. Added age restriction as safety and effectiveness have not been established in pediatric patients per PI/safety approach. Removed requirement related to history of severe hypersensitivity reaction to cabazitaxel per safety approach. Added max dose per PI. Increased initial/continued approval from 3/6 months to 6/12 months, respectively. Re-auth: Added requirement that member is responding positively to therapy. Removed reasons to discontinue per safety approach-

		maintained no disease progression or unacceptable toxicity as examples of positive response to therapy.
CP.PHAR.317 Cetuximab (Erbitux)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Criteria with NCCN 2B rating recommendations removed. Added criteria for NCCN 2A or above off-label indications for NSCLC, penile cancer, and squamous cell skin cancer. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.
CP.PHAR.318 Eribulin Mesylate (Halaven)	Revised/Reviewed	Removed requirement for negative history of congenital long QT syndrome and added an age limit for all covered indications, per the PA policy on safety precautions. Removed coverage of uterine sarcoma, as it is an NCCN 2b-rated recommendation. Changed approval duration periods from 3/6 months to 6/12 months
CP.PHAR.319 Ipilimumab (Yervoy)	Revised/Reviewed	Added age limit of ≥ 12 years per package labeling. Added coverage criteria for small cell lung cancer. Previously the off-label diagnosis was covered, but without any coverage requirements. Added off-label NCCN recommended uses for malignant pleural mesothelioma and brain metastases from melanoma. For Continued Therapy, removed requirement to check for safety-related reasons to discontinue therapy, per the PA Policy for Safety Precautions.
CP.PHAR.320 Necitumumab (Portrazza)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.
CP.PHAR.321 Panitumumab (Vectibix)	Revised/Reviewed	Converted to new template, adding age limit and removing safety requirements per the PA Policy on Safety Precautions. Updated diagnosis requirement to KRAS and NRAS to reflect updated FDA indication. Removed coverage of the following off-label usages which have NCCN 2b recommendations: 1) as adjuvant therapy, and 2) as a single agent in rectal cancer patients who are not appropriate for intensive therapy. Changed approval durations from 3/6 months to 6/12 months.
CP.PHAR.323 Perixafor (Mozobil)	Revised/Reviewed	Age added. Safety information removed. NCCN recommended uses added separately.
CP.PHAR.324 Temsirolimus (Torisel)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene

		Medical Affairs. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively. Added criteria for NCCN 2A and above recommended off-label uses: Endometrial cancer and soft tissue sarcoma.
CP.PHAR.325 Ziv-aflibercept (Zaltrap)	Revised/Reviewed	Added age limit and removed safety-related criteria per the PA Policy for Safety Precautions. Changed 3/6 month approval durations to 6/12 months.
CP.PHAR.326 Olaratumab (Lartruvo)	Revised/Reviewed	Policy converted to new template. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Added criteria for NCCN 2A and above recommended off-label use: Uterine sarcoma. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.
CP.PHAR.328 Asfotase Alfa (Strensiq)	Revised/Reviewed	Policy converted to new template. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively. Prescriber requirement added.
CP.PHAR.329 Siltuximab (Sylvant)	Reviewed	Updated references and template.
CP.PHAR.330 Brentuximab Vedotin (Adcetris)	Reviewed	Updated references and template.
CP.PHAR.332 Pasireotide (Signifor LAR)	Revised/Reviewed	Updated references and new template. Changed initial approval duration from 3 to 6 months
CP.PHAR.74 Erlotinib (Tarceva)	Revised/Reviewed	Updated approval duration to 6 and 12 months; Added NCCN compendium use for pancreatic cancer; Added max dose; Added criteria for off-label uses of Bone cancer – chordoma; Central nervous system cancers-Brain Metastases; and Kidney cancer per NCCN guidelines and compendium. Removed criteria for vulvar cancer since it is a 2b category and only 1 and 2b categories are addressed in the policy. Removed reasons to discontinue per new safety strategy.
CP.PHAR.79 Lapatinib (Tykerb)	Revised/Reviewed	Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Central nervous system cancer off-label use criteria added per NCCN 2A recommendation. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively
CP.PHAR.81 Pazopanib (Votrient)	Revised/Reviewed	Converted policy to new template. Added age limit as safety and efficacy have not been established in pediatric populations. Removed the following safety criteria: hepatotoxicity (although it is a BBW, the action to mitigate risk is limited to withholding the drug); hemoptysis, cerebral hemorrhage, clinically significant gastrointestinal

		hemorrhage, or an arterial thromboembolic event in the past 6 months (they are not absolute contraindications or BBW); and all reasons to discontinue per new safety strategy. Added requirement for positive response to therapy. Added max dose criteria for STS and continued therapy. Increased approval durations from 3/6 months to 6/12 months.
CP.PHAR.82 Collagenase Clostridium Histolyticum (Xiaflex)	Revised/Reviewed	Converted to new template. Dupuytren's and Peyronie's: Added age restriction as safety and effectiveness of Xiaflex in pediatric patients < 18 years old have not been established and removed requirement related to history of hypersensitivity to Xiaflex per safety approach. Modified approval duration to allow up to 2 injections within a 3 month period. Peyronie's disease: Removed requirements related to completion of training for use of Xiaflex and contraindication related to plaques that involve the penile urethra since Xiaflex is available for the treatment of Peyronie's disease only through Xiaflex REMS program.
CP.PHAR.83 Vorinostat (Zolinza)	Revised/Reviewed	Updated references and added max dose and changed 3/6 approval duration to 6/12 month approval duration
CP.PHAR.92 Tetrabenazine (Xenazine)	Revised/Reviewed	Policy converted to new template. Added age limit as safety and efficacy has not been established in pediatric populations. Removed the following contraindications: actively suicidal or untreated/inadequately treated depression (cannot be objectively confirmed) and hepatic impairment (requires clinical judgment; adverse reaction is not predictable per PI [safety and efficacy of increased exposure to Xenazine is unknown]). Modified DDI contraindication to include acceptable time of last use (MAOI > 14 days ago, reserpine > 20 days ago). Removed reasons to discontinue per new safety strategy. Increased approval durations from 3/6 months to 6/12 months.
CP.PHAR.XX Daunorubicin/Cytarabine (Vyxeos)	New	Policy created.
CP.PHAR.XX Pegaspargase (Oncaspar)	New	Policy created.
CP.PHAR.XX Testosterone Pellet (Testopel)	New	Policy created.
CP.PMN.08 Lidocaine Transdermal (Lidoderm)	Revised/Reviewed	Converted to new template. Post-herpetic neuralgia: Removed requirement related to failure of topical lidocaine gel/ointment or capsaicin-per AAN guidelines, magnitude of benefit for topical capsaicin is below the level that is

		considered clinically important in treatment of chronic pain/lower efficacy, or limited strength of evidence than lidocaine patch. Diabetic neuropathy (off-label): Modified criterion related to failure of either a TCA or SNRI to require both agents since level of recommendation for TCA and SNRI (level B) is higher than Lidoderm patch (level C) per AAN guidelines. Member ≥ 65 years exempted from TCA trial as this is a high risk medication in this age group. Re-auth: Added a requirement that member is responding positively to therapy. Increased approval duration from 6 to 12 months. Updated references.
CP.PMN.11 Oral Antiemetics (5-HT3 Antagonists)	Revised/Reviewed	Converted to new template; added age restriction; separated chemo-induced from radiation-induced nausea vomiting in the Initial Approval section; specified which agents are FDA-approved or NCCN-supported for use for which indications (previously all agents were covered for all indications). Changed auth duration for radiation-induced nausea vomiting from 72 hours to 48 hours based on Zuplenz dosing recommendations.
CP.PMN.12 Clozapine ODT (Fazaclo)	Revised/Review	Added age and appendix C-black box warning information Changed requirement of failure of 2 atypical antipsychotics to failure of risperidone ODT or solution. Most atypical antipsychotics are available in tablet formulation and a member that cannot use regular tablets would not be able to trial two antipsychotics.
CP.PMN.16 Request for Medically Necessary Drug not on the PDL	Revised/Review	Converted to new template. Initial IA2c: Modified one month to 30 days. Continued approval: Added requirement that member is responding positively to therapy.
CP.PMN.17 Droxidopa (Northera)	Revised/Reviewed	Added age and Appendix B, black box warning. Updated references.
CP.PMN.27 Linezolid (Zyvox)	Revised/Reviewed	Converted to new template. Modified title of IA and IIA from “Infections Caused by Susceptible Gram-positive Bacteria” to “All FDA Approved Indications” per PI. Removed language specifying “Isolated pathogen is VRE” since VRE is gram-positive and policy covers gram positive bacteria. Modified criteria to allow for cases in which obtaining C&S report is not feasible per documentation from the provider. Clarified requirement related to failure of PDL antibiotics by specifying 2 PDL antibiotics, provided 2 appropriate PDL antibiotics are available to which the pathogen is susceptible and/or are indicated for member’s diagnosis. Added DDI contraindication related to MAOI per PI/safety approach. Modified initial approval duration from “Up to 14 day supply” to “Duration of request or 28 days (whichever is less)”.

CP.PMN.29 Olanzapine ODT (Zyprexa Zydis)	Revised/Reviewed	Converted to new template. All indications: Added age limits based on established safety and efficacy per PI. Schizophrenia: Changed requirement of failure of 2 atypical antipsychotics to failure of PDL risperidone ODT or oral solution. Most atypical antipsychotics are available in tablet formulation, and members who cannot use regular olanzapine tablets would likely not be able to trial two other antipsychotics. Bipolar: Removed requirement for failure of 2 atypical antipsychotics for same rationale noted above. Unlike above, risperidone is not added as a required trial as it is not indicated for depressive episodes of bipolar disorder. MDD: Removed the following: "treatment-resistant" from diagnosis language, trial/failure of antidepressants, and requirement for concurrent fluoxetine because regular olanzapine tablets (non-ODT) are available on the PDL without any limitation. Re-auth: Removed MDD from COC criteria as it is not a diagnosis eligible for COC.
CP.PMN.44 Pyrimethamine (Daraprim)	Revised/Reviewed	Converted to new template. Daraprim is no longer indicated for malaria as of 06/2017; updated policy to reflect this. Continued therapy: Corrected CD4 requirement from < 200 cells/mm3 to ≤ 200 cells/mm3 per guidelines.
CP.PMN.53 No Custom Criteria/Off-Label Use Policy	Revised/Reviewed	Converted to new template. Added criteria for labeled use without custom criteria. Added initial approval criteria for off-label use to align with off-label use policy & procedures. Allowed COC for listed disease states in continued approval.
CP.PMN.59 Quantity Limit Override	Reviewed	Converted to new template. Updated verbiage.
CP.PMN.64 Quetiapine ER (Seroquel XR)	Revised/Review	Converted to new template. All indications: Added age limits based on established safety and efficacy per PI. Schizophrenia and bipolar: Removed requirement that trialed antipsychotics must be generic to give credit to members who have tried branded products. Re-auth: Removed MDD from COC criteria as it is not a diagnosis eligible for COC. Removed the following from schizophrenia and bipolar disorder Per SDC guidance: Failure of a ≥ 4 week trial of one additional PDL atypical antipsychotic indicated for schizophrenia at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;

CP.PMN.67 Sacubitril/Valsartan (Entresto)	Revised/Reviewed	Converted to new template. Added age restriction and contraindications related to DDI per PI/safety approach. Modified max dose requirement to include specific quantity limit. Updated references.
CP.PMN.68 Brexpiprazole (Rexulti)	Revised/Reviewed	Converted to new template. Added age restriction per PI/safety approach. Updated max dose requirement to include specific QL. Schizophrenia: Modified requirement related to trial and failure of 3 atypical antipsychotics to 2 atypical antipsychotics since aripiprazole is available on the PDL as a generic and criteria require an additional trial of aripiprazole prior to approval of Rexulti. Removed requirement that trialed antipsychotics must be generic to give credit to members who have tried branded products. Re-auth: Removed MDD from COC criteria since the diagnosis is not eligible for COC.
CP.PMN.70 Ivabradine (Corlanor)	Revised/Reviewed	Converted to new template. Added age restriction and DDI contraindication as the interactions are severe per PI/safety approach; Modified max dose requirement to include specific quantity limit. Updated references.
CP.PMN.71 Linaclotide (Linzess)	Revised/Reviewed	Converted to new template. Updated max dose requirement to include specific QL. Added a requirement that member is responding positively to therapy on re-auth.
CP.PMN.72 Metformin ER (Glumetza)	Revised/Reviewed	Converted to new template. Initial: Added requirement related to contraindications per PI (severe renal impairment) in accordance with safety approach. Continued approval: Added requirement that member is responding positively to therapy. Updated references.
CP.PMN.73 Lifitegrast (Xiidra)	Revised/Reviewed	Added age and quantity limit; verified references.
CP.PMN.74 Granisetron Transdermal System (Sancuso)	Revised/Reviewed	Added age per PI. Verified and updated references.
CP.PMN.75 Tazarotene (Tazorac)	Reviewed	Updated template and updated references.
CP.PMN.76 Calcifediol (Rayaldee)	Reviewed	Updated template and references.
CP.PPA.17 Aripiprazole (Abilify) for Oral Use	Revised/Reviewed	Schizophrenia: Modified trial/failure requirement from 3 antipsychotics to 2 antipsychotics as aripiprazole is available as a generic and on the PDL. Removed requirement that trialed antipsychotics must be generic to give credit to members who have tried branded products. Bipolar: Modified trial/failure requirement from lithium AND valproate to lithium OR valproate as aripiprazole is available as a generic and on the PDL. Removed requirement that trialed antipsychotics must be generic to give credit to members who have tried branded products.

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

		Autism: Removed prescriber requirement as autism can be managed by physicians other than mental health providers (e.g., developmental pediatricians, neurologists, primary care doctor). Re-auth: Removed MDD, autism, and Tourette's from COC criteria as they are diagnoses which are not eligible for COC.
CP.PPA.20 Methadone (Dolophine)	Revised/Reviewed	Converted to new template. Modified initial/continued approval duration from "Duration of request or 12 months (whichever is less) to "Duration of request or 3 months (whichever is less)" to match the approval duration in the Narcotic Analgesics policy (CP.PPA.12). Initial: Added age restriction per PI and safety approach. Continued approval: Added requirement related to positive response to therapy. Updated references.
CP.PPA.21 Glucagon-like Peptide-1 Receptor Agonists for Diabetes	Revised/Reviewed	Removed requirement for A1c ≥ 6.5%. Added alternate pathway to approval with metformin at doses of ≥ 1500 mg and A1c > 7%. Modified trial requirement for non-PDL requests from 2 PDL GLP-1 agonists to 1 PDL GLP-1 agonist. Modified initial approval duration to 12 months. Removed requirement for positive to response to therapy to allow for automatic renewal. Updated appendix B.
CP.PPA.XX Isotretinoin	New	Policy created from CP.PST.06 which was retired.
CP.PST.05 Exemestane (Aromasin)	Revised/Reviewed	Converted to new template. Added age limit as safety and efficacy have not been established in pediatric populations. Added anastrazole as an example of a core PDL aromatase inhibitor (does not require ST).
CP.PST.17 Atomoxetine (Strattera)	New	New step therapy policy created – replaces CP.PMN.01
CP.PST.06 Isotretinoin	Retired	Replaced with new CP.PPA. policy
CP.PST.16 Sedative Hypnotics	Retired	

Based on Q4 P&T 2017