



Effective date: 03/05/18

Buckeye Health Plan Medicaid Criteria Updates – Q1 2018

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 Criteria Guideline	Status	Applicable Business	Revision Summary Description
CP.PHAR.366 Acalabrutinib (Calquence®)	New	Commercial HIM Medicaid	Policy created
CP.PHAR.367 Letemovir (Prevymis®)	New	Commercial HIM Medicaid	Policy created
CP.PHAR.368 Pemetrexed (Alimta®)	New	Medicaid	Policy created
CP.PMN.89 Amantadine ER (Gocovri®)	New	Commercial HIM Medicaid	Policy created
CP.PMN.90 Benznidazole	New	Commercial HIM Medicaid	Policy created
CP.PMN.93 Dextromethorphan-Quinidine (Nuedexta®)	New	Commercial HIM	Policy created

Preferred Drug List (PDL) Updates – Q4 2017

		Medicaid	
CP.PMN.95 Fluticasone Propionate (Xhance®)	New	Commercial HIM Medicaid	Policy created
CP.PMN.103 Secnidazole (Solosec®)	New	Commercial HIM Medicaid	Policy created
CP.PMN.108 Latanoprostene Bunod (Vyzulta®)	New	Commercial HIM Medicaid	Policy created
CP.PST.14 GLP-1 receptor agonists	New	HIM Medicaid	Policy created
CP.PST.18 DPP-4 inhibitors	New	HIM Medicaid	Policy created
CP.PST.19 SGLT2 inhibitors	New	HIM Medicaid	Policy created
CP.PHAR.14 Hydroxyprogesterone caproate (Makena®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Combined policies for Medicaid and commercial - Medicaid: removed contraindications following the safety guidance - No significant changes from previous corporate approved policy - References reviewed and approved
CP.PHAR.115 Pegloticase (Krystexxa®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - No significant changes - Policies combined for Medicaid and Commercial lines of business - References reviewed and updated.
CP.PHAR.165 Ferumoxytol (Feraheme®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - No significant changes - Converted to the new template - Dosing added - References reviewed and updated.
CP.PHAR.166 Ferric Gluconate (Ferrlecit®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - No significant changes - Converted to the new template - Dosing added - References reviewed and updated.

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CP.PHAR.167 Iron Sucrose (Venofer®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - No significant changes - Converted to the new template - Dosing added - References reviewed and updated
CP.PHAR.177 Ecallantide (Kalbitor®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Medicaid and commercial business - No significant changes from previously approved corporate policy - Medicaid: added specialist requirement, removed “Other types of angioedema have been ruled out” from part of diagnosis due to its subjective nature, while specialist has been added - Added age limit - References reviewed and updated.
CP.PHAR.178 Icatibant (Firazyr®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Medicaid, HIM and commercial lines of business - No significant change from previously approved corporate policy - HIM/Medicaid: added specialist requirement, removed “Other types of angioedema have been ruled out” from part of diagnosis due to its subjective nature, while specialist has been added - Added age limit - References reviewed and updated
CP.PHAR.179 Romiplostim (Nplate®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Commercial lines of business. New policy for Marketplace line of business. - No significant changes from previous corporate approved policy - Added age restriction per PI as safety and effectiveness in pediatric patients (< 18 years) have not been established. - Commercial: added requirements related to specialist involvement, insufficient response to corticosteroids and immunoglobulins, splenectomy (unless member has contraindications to surgery), and platelet count or active bleed; re-auth: added platelet count < 400 x 10⁹/L within the last 90 days; modified initial/continued approval duration from 6 months or to member’s renewal period (whichever is longer)/LOB to 6/12 months.

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			<ul style="list-style-type: none"> - Medicaid: Removed “other causes (e.g., myelodysplastic syndrome) of thrombocytopenia has been ruled out with documentation supporting that ITP is not due to any other causes” since specialist is involved in care - References reviewed and updated
CP.PHAR.180 Eltrombopag (Promacta®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Commercial lines of business. New policy for Marketplace line of business. - No significant change from previous corporate approved policy - Added age restriction per PI. - Commercial: for chronic ITP-added requirements related to specialist involvement, insufficient response to corticosteroids and immunoglobulins, splenectomy (unless member has contraindications to surgery), platelet count, and active bleed; for hepatitis-C associated thrombocytopenia, added requirements related to specialist involvement, concomitant use with interferon-based therapy, and platelet count; for aplastic anemia, added requirements related to specialist involvement and platelet count; modified initial approval duration from LOB to 6 months. On re-auth, added requirements related to platelet count < 400 x 10⁹/L within the last 90 days, and for hepatitis C-associated thrombocytopenia, continuation of antiviral therapy; additional positive therapeutic response examples added; modified continued approval duration from LOB to 12 months, or 6 months for hepatitis C associated thrombocytopenia - References reviewed and updated.
CP.PHAR.181 Hemin (Panhematin®)	No Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - No significant changes - References reviewed and updated.
CP.PHAR.192 Epoprostenol (Flolan®, Veletri®)	No Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for commercial and Medicaid. - No significant changes from previous corporate approved policy - Medicaid: removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated.

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CP.PHAR.193 Iloprost (Ventavis®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for commercial, HIM and Medicaid - No significant changes from previous corporate approved policy. - Medicaid/HIM: removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated
CP.PHAR.194 Macitentan (Opsumit®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for commercial, HIM and Medicaid - No significant changes from previous corporate approved policy. - Medicaid/HIM: removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated
CP.PHAR.195 Riociguat (Adempas®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for commercial, HIM and Medicaid - No significant changes from previous corporate approved policy. - Medicaid/HIM: removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated
CP.PHAR.197 Sildenafil (Revatio®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for commercial, HIM and Medicaid - No significant changes from previous corporate approved policy. - Medicaid/HIM: removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated.
CP.PHAR.198 Tadalafil (Adcirca®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for commercial, HIM and Medicaid - No significant changes from previous corporate approved policy. - Medicaid/HIM: removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated.
CP.PHAR.199 Trepstinil (Orenitram®, Remodulin®, Tyvaso®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for commercial, HIM and Medicaid - No significant changes from previous corporate approved policy. - Medicaid/HIM: removed WHO/NYHA classifications from initial criteria since specialist is involved in care - References reviewed and updated.

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CP.PHAR.210 Ivacaftor (Kalydeco®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid, Marketplace, and Commercial lines of business. - No significant changes. - References reviewed and updated.
CP.PHAR.213 Lumacaftor-ivacaftor (Orkambi®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Commercial lines of business. - No significant changes from previous corporate approved policy - Commercial: Added age requirement per FDA labeling. Modified max dose criteria to be age-specific - References reviewed and updated.
CP.PHAR.214 Desmopressin (DDAVP®, Stimate®)	No Significant Clinical Change(s)	HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Medicaid and HIM lines of business - No significant changes - Converted to new template - Marketplace policy included Stimate, therefore Stimate remains in policy - Added age limit for diabetes insipidus - - References reviewed and updated
CP.PHAR.215 Factor VIII	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> -No significant changes. -References reviewed and updated.
CP.PHAR.216 Factor VIII-von Willebrand_Human	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Converted to new template - No significant changes -References reviewed and updated.
CP.PHAR.217 Anti-inhibitor Coagulant Complex (Feiba®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - No significant changes - Converted to new template - References reviewed and updated.
CP.PHAR.220 Factor VIIa Recombinant (NovoSeven® RT)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - No significant changes - Converted to new template - References reviewed and updated.

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CP.PHAR.221 Factor XIII Human (Corifact®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - No significant changes -Converted to new template - References reviewed and updated.
CP.PHAR.222 Factor XIIIa_Recombinant (Tretten®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - No significant changes - Converted to new template - Referenced reviewed and updated.
CP.PHAR.223 Reslizumab (Cinqair®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Combined Medicaid and Commercial policies - No significant changes from previously approved corporate policy - Removed smoking cessation program requirements from existing Medicaid policy as this cannot be enforced. - Added “Acute bronchospasm or status astmaticus” to section III as indications for which coverage is not authorized per PI References reviewed and updated
CP.PHAR.234.Ferric Carboxymaltose (Injectafer®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - No significant changes - Converted to the new template - Dosing added - References reviewed and updated.
CP.PHAR.235 Atezolizumab (Tecentriq®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - Converted to new template - No significant changes - Added continuation of therapy for all covered indications - References reviewed and updated
CP.PHAR.288 Eteplirsen (Exondys 51®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for Centene Medicaid, Marketplace, and Commercial lines of business. - No significant changes. - References reviewed and updated.
CP.PHAR.300 Bezlotoxumab (Zinplava®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: -Combined for Medicaid and commercial lines of business. - No significant change from previously approved corporate policy - Age added per safety guidance endorsed by Centene Medical Affairs

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			- References reviewed and updated.
CP.PHAR.301 Erwinia Asparaginase (Erwinaze®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: -No significant changes -Converted to the new template and added dosing -Combined FDA approved criteria and NCCN recommendations, FDA indication covers both -References reviewed and updated
CP.PHAR.329 Siluximab (Sylvant®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - No significant changes - References reviewed and updated.
CP.PHAR.330 Protein C Concentrate Human (Ceprotrin®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: - No significant changes - Converted to the new template - References reviewed and updated.
CP.PHAR.331 Deflazacort (Emflaza®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Policies combined for Centene Medicaid and Commercial lines of business - No significant changes from previous corporate approved policy - Medicaid: Removed time period in which prednisone trial must have occurred. - References reviewed and updated.
CP.PHAR.336 Dupilumab (Dupixent®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: - Policies combined for HIM, Medicaid and commercial - No significant changes - References were reviewed and updated.
CP.PHAR.341 Deutetrabenazine (Austedo®)	No Significant Clinical Change(s)	Commercial Medicaid	Policies combined for Centene Medicaid and Commercial lines of business.
CP.PHAR.350 Rucaparib (Rubraca®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - No significant clinical changes - Added Age ≥18 years per PI - Updated Appendix B with additional acceptable prior treatment regimens based on NCCN Ovarian Cancer guidelines. - References reviewed and updated

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CP.PHAR.40 Octreotide Acetate (Sandostatin®, Sandostatin LAR Depot®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Medicaid and Commercial lines of business -Specialist added for oncology indications -Requests for non-oncology off-label indications and any oncology off-label indications not outlined above are directed to the off-label use policies referenced in Section I.F. - Positive therapeutic response examples (diarrhea, flushing, disease progression, unacceptable toxicity) are removed as they are not amenable to objective measurement. -References updated.
CP.PMN.05 rifapentine (Priftin®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> -No significant changes -References reviewed and updated.
CP.PMN.07 Levalbuterol (Xopenex®)	No Significant Clinical Change(s)	HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Marketplace lines of business - No significant changes from previous corporate approved policy - Medicaid: modified QL of inhalation solution from 3 vials/day to 4 vials (12 mL)/day - References reviewed and updated.
CP.PMN.12 Clozapine orally disintegrating tablet (Fazaclo®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - No significant changes - References reviewed and updated.
CP.PMN.15 Asenapine (Saphris®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for commercial, HIM and Medicaid lines of business - No significant change from previous corporate approved policy - HIM: changed from failure of 1 atypical antipsychotic to failure of 2 for treatment of bipolar disorder. - References reviewed and updated.
CP.PMN.20 Aspirin-dipyridamole (Aggrenox®)	No Significant Clinical Change(s)	HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Marketplace lines of business. - No significant changes from previous corporate approved policy

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			<ul style="list-style-type: none"> - HIM: Removed criterion directing requests for the branded product to the generic product since the branded product is not on formulary. - References reviewed and updated.
CP.PMN.21 Becaplermin (Regranex®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - No significant changes. - Age added per safety guidance endorsed by Centene Medical Affairs. - References reviewed and updated.
CP.PMN.29 Olanzapine ODT (Zyprexa Zydis®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - No significant changes. - References reviewed and updated.
CP.PMN.30 Paliperidone (Invega®)	No Significant Clinical Change(s)	HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policy combined for HIM and Medicaid. -No significant change from previously approved corporate policy -Age added per safety guidance endorsed by Centene Medical Affairs. -References reviewed and updated.
CP.PMN.32 Iloperidone (Fanapt®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid, HIM and commercial lines of business. - No significant change from previously approved corporate policy - Age added per safety guidance endorsed by Centene Medical Affairs. - References reviewed and updated.
CP.PMN.34 Ranolazine (Ranexa®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Medicaid and commercial -No significant clinical changes from previously approved corporate policy - Commercial: added the requirement of first line generic agent trial -Age added -References reviewed and updated.
CP.PMN.50 Lurasidone (Latuda®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid, Marketplace and Commercial lines of business - No significant changes from previous corporate approved policy

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			<ul style="list-style-type: none"> - Age added per safety guidance endorsed by Centene Medical Affairs - Removed diagnosis of metabolic syndrome from Centene commercial bipolar criteria - References reviewed and updated
CP.PMN.52 Omega-3-Acid Ethyl Esters (Lovaza®)	No Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Age added - No significant changes - References reviewed and updated.
CP.PMN.64 Quetiapine ER (Seroquel XR®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Centene Medicaid, Marketplace and Commercial lines of business - No significant changes - References reviewed and updated.
CP.PMN.68 Brexpiprazole (Rexulti®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid, marketplace and commercial lines of business - No significant change from previous corporate approved policy - HIM: added trial of aripiprazole - Commercial: added trial of aripiprazole as requirement for schizophrenia and increased overall drug trials from 2 drugs to 3. For depression changed from 2 trials of atypical antipsychotics to 3 trials of antidepressants and a trial of aripiprazole.
CP.PMN.77 Ezetimibe-Simvastatin (Vytorin®)	No Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid and commercial lines of business [CP.CPA.62 Pitavastatin (Livalo), Ezetimibe/Simvastatin (Vytorin 10/10 mg) and CP.CPA.169 (Vytorin 10/80 mg)]. Retired Livalo from CP.CPA.62 (previously combined with Vytorin 10/10)-refer to CP.CPA.190 Formulary Exceptions policy. - No significant changes from previous corporate approved policy - Age added per safety guidance endorsed by Centene Medical Affairs. - Commercial: removed “One of the following (a or b): a. Failure to achieve NCEP goals; b. Failure of one generic formulary statin unless contraindicated or clinically significant adverse effects are

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			<p>experienced” and replaced it with the use of high-, moderate-, or low-intensity statin for 3 months; added adherence to statin therapy as a requirement; updated policy provides a pathway to approval for patients with HeFH and ASCVD with involvement of a specialist.</p> <ul style="list-style-type: none"> - Medicaid: for HoFH, HeFH, ASCVD, and re-auth- updated to allow use of the 10/80-mg dose of Vytorin in patients who have been taking simvastatin 80 mg for 12 months or more. - References reviewed and updated.
CP.PMN.78 Ezetimibe (Zetia®)	No Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - No significant changes - Age added per safety guidance endorsed by Centene Medical Affairs. - Added “unless contraindicated” to requirement related to adherence to statin therapy - References reviewed and updated.
CP.PMN.91 Cariprazine (Vraylar®)	No Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policy generated from existing commercial policy – CP.CPA.221 - No significant change from previously approved corporate policy - New for Medicaid - Age added for schizophrenia per safety guidance endorsed by Centene Medical Affairs.
CP.PMN.92 CNS Stimulants	No Significant Clinical Change(s)	Commercial Medicaid	<p>New policy created</p> <ul style="list-style-type: none"> - Policies created from existing Medicaid and Commercial lines of business policies for CNS Stimulants - No significant changes from previous corporate approved policy - Age requirement is new for the Centene Commercial and changed requirement from failure of 2 methylphenidate products to failure of 1 methylphenidate and 1 amphetamine - References reviewed and updated.
CP.PMN.94 Etidronate (Didronel®)	No Significant Clinical Change(s)	Medicaid	<p>New policy created</p> <ul style="list-style-type: none"> - Split from CP.PMN.43 – oral bisphosphonates - No significant changes from previous corporate approved policy - References reviewed and updated.

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CP.PMN.96 Ibandronate Oral (Boniva®)	No Significant Clinical Change(s)	Medicaid	New policy created <ul style="list-style-type: none"> - Split from CP.PMN.43 – oral bisphosphonates - No significant changes from previous corporate approved policy - References reviewed and updated
CP.PMN.97 Opioid Analgesics	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Added Oxycontin-specific criteria adapted from CP.PPA.04, which will be retired; Oxycontin is programmed with a QL of 2/day - Change name from CP.PPA.12 to CP.PMN.97 - Change the requirement for approval for long term use to require 90 days of opioid use in 120 days from 84 in 120 days to align with edit programming - No significant changes - References reviewed.
CP.PMN.98 Pimecrolimus (Elidel®)	No Significant Clinical Change(s)	Commercial HIM	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for HIM and Commercial lines of business. - Renaming to PMN due to multiple line of business usage - References reviewed and updated.
CP.PMN.99 Prasterone (Intrarosa®)	No Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Commercial and Medicaid lines of business -No significant changes - Added age limit. - Added specific formulary alternative vaginal estrogens. - Added example of what constitutes a response to therapy for reauthorization - References reviewed and updated.
CP.PMN.100 Risedronate (Actonel®, Atelvia®)	No Significant Clinical Change(s)	Commercial HIM Medicaid	New policy created <ul style="list-style-type: none"> - Policy split from existing oral bisphosphonate policy for all lines for business - No significant change from previous corporate approved policy. - Combined policy for Medicaid, market place and commercial lines of business. - References reviewed and updated.
CP.PMN.101 Rivastigmine (Exelon®)	No Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - No significant changes - Policy number changes from CP.PPA.22 to CP.PMN.101

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			<ul style="list-style-type: none"> - Age added per safety guidance endorsed by Centene Medical Affairs - Referenced reviewed and updated
CP.PMN.105 Tavaborole (Kerydin®)	No Significant Clinical Change(s)	Commercial Medicaid	<p>New policy created</p> <ul style="list-style-type: none"> - Policy split from CP.CPA.54 Efinaconazole (Jublia), Tavaborole (Kerydin) for Centene commercial line of business-retired. - New policy for Medicaid line of business. - Age added per safety guidance endorsed by Centene Medical Affairs. - Specified duration of trial of oral terbinafine for toenail onychomycosis per PI and a timeframe of within the past 12 months - References reviewed and updated.
CP.PMN.106 Tiludronate (Skelid®)	No Significant Clinical Change(s)	Medicaid	<p>New policy created</p> <ul style="list-style-type: none"> - Split from CP.PMN.43 – oral bisphosphonates. - No significant changes from previous corporate approved policy. - References reviewed and updated.
CP.PMN.107 Topical Immunomodulators	No Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policy changed from CP.PPA to CP.PMN. - Changed authorization duration limits from 3/6 months to 6/12 months - Removed restriction against coverage for vitiligo - References reviewed and updated.
CP.PMN.109 Suvorexant (Belsomra®)	No Significant Clinical Change(s)	HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - No significant changes - Existing HIM policy (HIM.PA.22), new policy for Medicaid - Added age and references reviewed and updated.
CP.PST.08 Mesalamine Oral Therapy	No Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - No significant changes. - References reviewed and updated.
CP.PHAR.01 Omalizumab (Xolair®)	Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Converted to new template - Combined Medicaid and commercial policies. - New policy for HIM line of business. - Removed smoking cessation program requirements from existing Medicaid policy as this cannot be enforced. - Added “Acute

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			bronchospasm or status asthmaticus” to section III as indications for which coverage is not authorized per PI. For CIU, modified length of trials from 4 to 2 weeks each - References reviewed and updated
CP.PHAR.100 Axitinib (Inlyta®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Policies combined for Medicaid and Commercial lines of business. - Age, specialist and dosing added. - Renal cell carcinoma: definition of “advanced” removed given the additional requirement of a prior systemic therapy. - References reviewed updated.
CP.PHAR.101 Mifepristone (Korlym®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Policies combined for Medicaid and Commercial lines of business. - Age added. “Adherence to an anti-diabetic regimen” is removed due to verification challenge. - The following contraindications are removed due to verification challenge: history of unexplained vaginal bleeding; endometrial hyperplasia with atypia or endometrial carcinoma. - “Dose does not exceed 1200 mg/day or 20 mg/kg per day, whichever is less” is edited to “Dose does not exceed 1200 mg/day”. - - References reviewed and updated.
CP.PHAR.111 Cabozantinib (Cabometyx®, Cometriq®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Combined Medicaid and commercial policies. - Removed safety requirement for hemorrhage and hemoptysis per CPAC safety guidance endorsed by medical affairs - For RCC, modified redirection to apply only for clear cell histology, requiring NCCN Category 1 recommended alternatives. - Added off-label use for RCC with non-clear cell histology and NSCLC - References reviewed and updated.
CP.PHAR.114 Teduglutide (Gattex®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Policies combined for Medicaid and Commercial lines of business. - Age added - Preferencing for Zorptive added

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			<ul style="list-style-type: none"> - The following criteria are removed given the 12-month PN requirement: colonoscopy; PN \geq 3 times per week; use of antimotility and antisecretory agents. - “Consecutive” removed from the 12-month PN requirement. - Initial duration is increased from 6 to 12 months to allow more time for therapeutic response; continued therapy duration is increased from 6 to 12 months. - References reviewed and updated.
CP.PHAR.119 Ramucirumab (Cyramza®)	Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Age, dosing, specialist added. - NCCN recommendations removed for lung and colon cancer. - References reviewed and updated.
CP.PHAR.121 Nivolumab (Opdivo®)	Significant Clinical Change(s)	Medicaid	<p>New indication addition:</p> <ul style="list-style-type: none"> - Added coverage criteria for the new FDA-approved indication of hepatocellular carcinoma.
CP.PHAR.125 Palbociclib (Ibrance®)	Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Converted to new template - Added prescriber specialty requirement; - Added max dosing criteria; - Added criteria for off-label use for soft tissue sarcoma. - References reviewed and updated.
CP.PHAR.168 Corticotropin (H.P. Acthar®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Combined Medicaid and commercial policies. - Removed indications not supported by well-designed clinical trials as noted in Appendix C - West syndrome – removed EEG requirement to confirm diagnosis; added neurologist prescriber requirement. - MS- approval duration reduced to one month for initial as this medication is not indicated to used chronically and for continued approval for MS was referred to the initial criteria - References reviewed and updated.
CP.PHAR.184 Aflibercept (Eylea®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid and commercial lines of business <p>For Medicaid:</p>

			<ul style="list-style-type: none"> - Added bevacizumab redirection except for members with baseline visual acuity worse than 20/50 due to clinical superiority of Eylea - Moved initial and continued therapy criterion “not used concomitantly with other VEGF therapies” to section III. Diagnoses/indications NOT authorized. - Added specialist requirement - Removed criteria checking for contraindications (ocular infections) due to its ophthalmic nature and addition of specialist requirement - Added age limit following safety guidance endorsed by Medical Affairs - References reviewed and updated.
CP.PHAR.185 Pegaptanib (Macugen®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid and commercial <p>For Medicaid:</p> <ul style="list-style-type: none"> - Added bevacizumab redirection - Added specific documentation of positive response to therapy required for continued approval - Added “not used concomitantly with other VEGF therapies” to section III. Diagnoses/indications NOT authorized. - Added specialist requirement - Removed criteria checking for contraindications (ocular infections) due to its ophthalmic nature and addition of specialist requirement - Added age limit following safety guidance - - References reviewed and updated.
CP.PHAR.186 Ranibizumab (Lucentis®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid and commercial - Added fluorescein angiography as an acceptable documentation for positive response to therapy <p>Medicaid:</p> <ul style="list-style-type: none"> - Added specialist requirement - Removed criteria checking for contraindications (ocular infections) due to its ophthalmic nature and addition of specialist requirement - Moved initial and continued therapy criterion “not used concomitantly with other VEGF therapies” to section III. Diagnoses/indications NOT authorized. - Added bevacizuamb redirection

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			<ul style="list-style-type: none"> - Added age limit - References reviewed and updated
CP.PHAR.187 Verteporfin (Visudyne®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid and commercial lines of business <p>For Medicaid:</p> <ul style="list-style-type: none"> - Added specialist requirement - Removed fluorescein angiography for diagnosis due to addition of specialist - Added age limit - Expanded VEGF requirement for AMD and pathologic myopia specifically to bevacizumab or other VEGF inhibitors - Added redirection to Lucentis for mCNV due to clinical superiority - Removed allowed indication for occult CNV per limitation of use - References reviewed and updated.
CP.PHAR.188 Teriparatide (Forteo®)	Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for commercial and Medicaid. - Converted to new template. - Removed criteria for evidence of diagnosis. Removed member characteristic requirements for gender and type of osteoporosis. - Added specialist requirement. Modified age requirement. Modified trial and failure requirements to a bisphosphonate (alendronate is preferred) - Removed requirement regarding admin of last dose of Reclast. - Modified approval duration to 6 months (initial) and 12 months (continuation). - Defined positive response in continued therapy criteria - References reviewed and updated.
CP.PHAR.189 Ibandronate injection (Boniva®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for commercial and Medicaid - Removed criteria for evidence of diagnosis - Modified trial and failure requirements to a bisphosphonate - Removed requirement regarding admin of last dose of Reclast - Removed hypocalcemia monitoring requirement - Added definition for positive response to therapy - References reviewed and updated.

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CP.PHAR.190 Ambrisentan (Letairis®)	Significant Clinical Change(s)	HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for HIM and Medicaid. - Converted to new template - Removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated.
CP.PHAR.191 Bosentan (Tracleer®)	Significant Clinical Change(s)	HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for HIM and Medicaid - Converted to new template - Removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated.
CP.PHAR.196 Selexipag (Uptravi®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for HIM and Medicaid - Converted to new template - Removed WHO/NYHA classifications from initial criteria since specialist is involved in care. - References reviewed and updated.
CP.PHAR.200 Mepolizumab (Nucala®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review <ul style="list-style-type: none"> - Combined Medicaid and Commercial policies. - Removed smoking cessation program requirements from existing Medicaid policy as this cannot be enforced. - Added “Acute bronchospasm or status asthmaticus” to section III as indications for which coverage is not authorized per PI. - References reviewed and updated.
CP.PHAR.202 C1 Esterase Inhibitors (Berinert®, Cinryze®, Haegarda®, Ruconest®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: Policies combined for commercial and Medicaid. <ul style="list-style-type: none"> - Added Haegarda into the policy. - Medicaid: added specialist requirement, removed “Other types of angioedema have been ruled out” from part of diagnosis due to its subjective nature, while specialist has been added; removed qualifying descriptions of “abdominal, facial, or laryngeal attacks” for Berinert as there is no evidence that there is lack of efficacy in other forms of HAE; added short-term prophylaxis for plasma-derived C1 esterase inhibitors according to AOW treatment guidelines.

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			- References reviewed and updated.
CP.PHAR.203 Cosyntropin (Cortrosyn®)	Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Modified max dose criteria from 0.125 mg to 0.25 mg for age ≤ 2 years since 0.125 is not a true max per labeling, plus partial vials cannot be dispensed so a dose of 0.125 is unenforceable post-approval. References reviewed and updated.
CP.PHAR.204 Trabectedin (Yondelis®)	Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Initial: Added age requirement as safety and efficacy have not been established in pediatric patients. - Removed criteria around specific FDA/NCCN uses that are under the purview of the provider, and added prescriber requirement to ensure appropriate use. - Require that use be for palliative therapy or for metastatic or unresectable disease - Re-auth: Added COC for STS. Modified requirement for no disease progression or unacceptable toxicity to requirement for positive response to therapy. - Both: Added max dosing criteria. - References reviewed and updated
CP.PHAR.206 Carglumic acid (Carbaglu®)	Significant Clinical Change(s)	Medicaid HIM	1Q18 annual review: <ul style="list-style-type: none"> - Added HIM line of business to criteria. - Removed requirement for confirmation that Carbaglu is prescribed to treat acute or chronic hyperammonemia as this is characteristic of the condition itself - - References reviewed and updated.
CP.PHAR.207 Glycerol phenylbutyrate (Ravicti®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Converted to new template - Removed dietary protein restriction requirements as this cannot be confirmed - References reviewed and updated.
CP.PHAR.208 Sodium phenylbutyrate (Buphenyl®)	Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Converted to new template. - Removed dietary protein restriction requirements as this cannot be confirmed References reviewed and updated

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CP.PHAR.209 Aztreonam (Cayston®)	Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Initial: Modified age restriction from ≥ 7 to ≥ 6 years per ATS guideline recommendations. - Removed baseline FEV requirement. - Added Appendix C: General Information - References reviewed updated.
CP.PHAR.211 Tobramycin	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Commercial lines of business. - Medicaid: Removed baseline FEV requirement. - Commercial: Added requirement for no concurrent/alternating use with aztreonam. - Added Appendix B: General Information - References reviewed and updated
CP.PHAR.212 Dornase alfa (Pulmozyme®)	Significant Clinical Change(s)	HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Medicaid: Removed initial requirement that therapeutic plan includes concomitant use of standard CF therapies as this is non-specific. - HIM: policy revised to apply to this line of business - References review and updated
CP.PHAR.218 Factor IX_Human Recombinant	Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Converted to new template - Added Idelvion to the policy under the same coverage criteria as the other recombinant factor IX agents. - Specified routine prophylaxis indication is only for certain agents, per package labeling for those agents. - Added age limit for AlphaNine per package labeling - References reviewed and updated.
CP.PHAR.219 Factor IX Complex Human	Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Converted to new template - Changed auth limit for Profilnine to 18 years, per PI - References reviewed and updated
CP.PHAR.224 Enoxaparin (Lovenox®).	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Combined policies for Medicaid and commercial lines of business - Section I.A., Venous Thrombosis, is changed to “Thrombosis and Thromboembolism” so as not to restrict to venous thrombi. Section

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			<p>I.A criteria are edited to encompass CHEST guidelines for neonates and children (seen primarily under implantable devices), and the criteria is collapsed to maximize consistency across the Lovenox, Fragmin and Arixtra policies.</p> <ul style="list-style-type: none"> - Per specialist recommendation an additional indication is added for short-term prophylaxis to or from oral anticoagulation. <p>Continuation criteria added for pregnancy.</p> <ul style="list-style-type: none"> - References reviewed and updated.
CP.PHAR.225 Dalteparin (Fragmin®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Combined policies for Medicaid and commercial lines of business - Section I.A., Venous Thrombosis, is changed to “Thrombosis and Thromboembolism” so as not to restrict to venous thrombi. Section I.A criteria are edited to encompass CHEST guidelines for neonates and children (seen primarily under implantable devices), and the criteria is collapsed to maximize consistency across the Lovenox, Fragmin and Arixtra policies. - Per specialist recommendation an additional indication is added for short-term prophylaxis to or from oral anticoagulation. <p>Continuation criteria added for pregnancy.</p> <ul style="list-style-type: none"> - References reviewed and updated.
CP.PHAR.226 Fondaparinux (Arixtra®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Combined policies for Medicaid and commercial lines of business - Section I.A., Venous Thrombosis, is changed to “Thrombosis and Thromboembolism” so as not to restrict to venous thrombi. Section I.A criteria are edited to encompass CHEST guidelines for neonates and children (seen primarily under implantable devices), and the criteria is collapsed to maximize consistency across the Lovenox, Fragmin and Arixtra policies. - Per specialist recommendation an additional indication is added for short-term prophylaxis to or from oral anticoagulation. <p>Continuation criteria added for pregnancy.</p> <ul style="list-style-type: none"> - References reviewed and updated.
CP.PHAR.289 Buprenorphine Implant (Probuphine®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for commercial and Medicaid lines of business. - Commercial: removed requirement that member is not using concurrent opioid medications (including tramadol) from initial

			<p>approval criteria; re-auth: added requirements related to absence/presence of opioid use since last approval.</p> <ul style="list-style-type: none"> - Medicaid: added age restriction as safety and effectiveness of Probuphine have not been established in children or adolescents < 16 years of age; removed “No evidence or reports of illicit opioid use (confirmed with at least one random urine drug screen within the last 3 months), significant withdrawal symptoms, significant desire/need to use illicit opioids, hospitalizations, emergency room visits or crisis interventions for addiction or mental health issues, and non-adherence to clinic visits or drug abuse counseling as recommended”; removed requirement for participation in drug abuse counseling to shift the responsibility of appropriate monitoring and use to the prescriber; added requirement for medical justification to support why oral (e.g., sublingual, buccal) formulations of buprenorphine cannot be continued; re-auth: removed that if a supplemental buprenorphine containing product was prescribed, it was prescribed only intermittently rather than on an ongoing basis - References reviewed and updated.
CP.PHAR.298 Afatinib (Gilotrif®)	Significant Clinical Change(s)	HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Marketplace lines of business. - Initial: Added age requirement as safety and efficacy have not been established in pediatric patients. - Removed criteria around specific FDA/NCCN uses that are under the purview of the provider, and added prescriber requirement to ensure appropriate use. - Re-auth: Added COC for NSCLC. Removed criteria around use after disease progression on Gilotrif since it is not objective and is under the purview of the provider - References reviewed and updated.
CP.PHAR.327 Nusinersen (Spinraza®)	Significant Clinical Change(s)	Commercial Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> -Policies combined for Medicaid and commercial - Expanded indication to SMA types 1-3 with SMN2 copies up to 4. - References reviewed and updated

<p>CP.PHAR.333 Avelumab (Bavencio®)</p>	<p>Significant Clinical Change(s)</p>	<p>Medicaid</p>	<p>1Q18 annual review: - Specialist added to MCC and UC. - Age added to MCC. - Dose added to UC; -“Locally advanced or metastatic” removed given inclusion of criteria requiring progression following platinum-based chemotherapy - NCCN bladder cancer use delineating “as a single agent” removed. - References reviewed and updated.</p>
<p>CP.PHAR.334 Ribociclib (Kisqali®, Kisqali Femara®)</p>	<p>Significant Clinical Change(s)</p>	<p>Commercial Medicaid</p>	<p>1Q18 annual review: - Combined with CP.CPA.222. Converted to new template Added requirement for prescriber specialty - Added criteria for off-label use in men - References reviewed and updated.</p>
<p>CP.PHAR.345 Abaloparatide (Tymlos®)</p>	<p>Significant Clinical Change(s)</p>	<p>Commercial HIM Medicaid</p>	<p>1Q18 annual review: - Combined Medicaid and commercial policies - New policy for HIM - Removed criteria for evidence of diagnosis - Added specialist requirement - Modified age requirement to include pediatric members with closed epiphyses - Modified trial and failure requirements to a bisphosphonate (oral or IV acceptable) - Modified approval duration to 6 months (initial) and 12 months (continuation) - Defined positive response in continued therapy criteria - References reviewed and updated.</p>
<p>CP.PHAR.43 Sapropterin (Kuvan®)</p>	<p>Significant Clinical Change(s)</p>	<p>Medicaid</p>	<p>1Q18 annual review: - The diagnostic description “BH4 responsive” in relation to PKU is deleted as it may not be determined until after a therapeutic trial. - Use in conjunction with a Phe-restricted diet is removed. - Initial approval duration increased from 2 to 3 months to allow adequate time for follow-up. Continuation criteria that refers to an increase in dietary Phe tolerance or improvement in neuropsychiatric symptoms is deleted leaving reduction of Phe levels per the PI. - References reviewed and updated.</p>

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CP.PHAR.52 Interferon Gamma-1b (Actimmune®)	Significant Clinical Change(s)	Commercial HIM Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Combined Medicaid and Commercial policies. - New policy for HIM line of business. - Removed diagnostic confirmatory tests and replaced with specialty prescriber requirement - References reviewed and updated
CP.PHAR.59 Zoledronic Acid (Reclast®, Zometa®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Converted to new template. - Modified diagnoses and removed requirements for evidence of diagnoses for Reclast indications - Removed contraindication of hypocalcemia - Modified approval duration of 24 months to apply only to postmenopausal osteoporosis prevention - Removed requirements for calcium and vitamin D supplementation - Added definitions for positive response to therapy. Added requirement for continuation of standard antineoplastic therapy for multiple myeloma and bone metastases - Modified approval duration for other diagnoses/indications to 6 months - References reviewed and updated.
CP.PHAR.61 Cinacalcet (Sensipar®)	Significant Clinical Change(s)	Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Included calcium acetate as the required formulary alternative phosphate binder. - Removed the requirement for parathyroidectomy (medical procedure) - Converted to new template - References reviewed and updated.
CP.PHAR.63 Everolimus (Afinitor®, Afinitor Disperz®)	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: <ul style="list-style-type: none"> - Combined Medicaid and Commercial policies - Removed dose form requirement by indication, no clinical difference expected (dosing is equivalent for SEGA indication) - For RCC, included list of first line therapies per NCCN guidelines. - For breast cancer, removed compendium supported use after tamoxifen as this was removed from the 1.2017 NCCN guideline update.

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			<ul style="list-style-type: none"> - Added the following off-label NCCN compendium supported uses: GIST, lymphoplasmacytic lymphoma, osteosarcoma, endometrial carcinoma - References reviewed and updated.
CP.PHAR.74 Erlotinib (Tarceva®)	Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Centene Medicaid, Marketplace and Commercial lines of business - Added age to FDA approved indications - For Medicaid NSCLC/ Pancreatic Cancer: replaces specific disease conditions with general language to ensure coverage of both NCCN recommended uses and FDA approved uses - References reviewed and updated
CP.PHAR.80 Vandetanib (Caprelsa®)	Significant Clinical Change(s)	HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid and HIM lines of business - Added non-small cell lung cancer as a covered off-label indication per NCCN 2A recommendation. - Added oncologist and age limit restrictions. - Added requirement of prior trials of lenvatinib and sorafenib for non-medullary thyroid carcinoma; removed requirement for prior trial of iodine. - Extended reauthorization duration from 6 months to 12 months. - Allowed for Continuation of Care requirements for reauthorization - References reviewed and updated
CP.PHAR.91 Vemurafenib (Zelboraf®)	Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> -Policies combined for Centene Medicaid, Marketplace and Commercial lines of business. -Added oncologist and age limit requirements for the melanoma indication. Added off-label usages per NCCN recommendations, including new coverage for thyroid carcinoma and brain metastases (2A recommendations). -Changed Approval Durations for Medicaid and HIM from 3/6 months to 6/12 months. -Added Erdheim-Chester disease as a new FDA-approved indication
CP.PHAR.93 Bevacizumab (Avastin®)	Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined from Medicaid and commercial - Specialist involvement in care added to all indications

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			<ul style="list-style-type: none"> - Added specific criteria for off-label uses for ophthalmic indications - Added allowable off-label oncology indications as reflected in the NCCN compendium - References reviewed and updated
CP.PHAR.94 Alpha-1 Proteinase Inhibitors	Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Combined existing policies for Medicaid and commercial business - Medicaid: removed requirement for supportive measures (avoidance of cigarette smoking and vaccinations) due to lack of actionability and objectivity; - Medicaid: protective threshold value per nephelometry changed from 57 mg/dL to 50 mg/dL per American Thoracic Society 2003 guidelines. - Medicaid: added “If the member has an AAT level >11 umol/L, then the member must have one of the high-risk phenotypes (i.e. PiZZ, PiZnull, Pi(null, null), or one of a few rare phenotypes [e.g. Pi(Malton, Malton)]” to allow treatment before clinical deterioration due to definite diagnosis; - Added prescriber requirement due to the complexity of disease diagnosis and management; - Changed minimally significant change in FEV from 120 mL to 100 mL per ATC guidelines and specialist feedback -References reviewed and updated.
CP.PHAR.96 Naltrexone (Vivitrol®)	Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Removed requirement related to participation in psychosocial treatment while on Vivitrol from initial and continued approval criteria. - Modified initial approval duration from 6 to 12 months. - References reviewed and updated.
CP.PHAR.97 Eculizumab (Soliris®)	Significant Clinical Change(s)	Commercial Medicaid	Added generalized myasthenia gravis indication and criteria for approval.
CP.PHAR.98 Ruxolitinib (Jakafi®)	Significant Clinical Change(s)	Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Removed request for bloodwork. - Removed NCCN off-label use for myelofibrosis. - References reviewed and updated.

CP.PHAR.369 Alectinib (Alecensa®)	Significant Clinical Change(s)	Commercial Medicaid	Policy created for Centene Medicaid and updated for commercial lines of business. Age and specialist requirements added. Labeled indication is updated to include either first- or second-line ALK tyrosine kinase inhibitor therapy for ALK-positive metastatic NSCLC.
CP.PMN.04 Non-Calcium Phosphate Binders	Significant Clinical Change(s)	Commercial Medicaid	1Q18 annual review: - Combined Medicaid and commercial non-calcium phosphate binder policies - Added trial duration of 4 weeks per guideline recommendations for monitoring frequency - Added additional requirement for trial of generic Fosrenol or generic Renvela - References reviewed and updated
CP.PMN.22 Brand Name Override	Significant Clinical Change(s)	Medicaid	1Q18 annual review: - Modified to require trial of 2 generic drugs across the board, and moved examples of what constitutes failure to Appendix C. - Added that drug trials must be of an adequate duration. - Removed that one of the trials must have occurred in the last 90 days. - Added maximum dosing requirement. - Added requirement for clinical rationale as to why the brand name product would be expected to benefit the patient when the generics did not. - References reviewed and updated
CP.PMN.24 Ciclopirox (Penlac®)	Significant Clinical Change(s)	Medicaid	1Q18 annual review: - Converted to new template. Removed laboratory testing related to confirmation of diagnosis and requirement that member is immunocompetent; modified dosing requirement of terbinafine 250 mg/day to “at up to maximally indicated doses” and specified a time frame of trial within the past 12 months. - Re-auth: removed requirement that member has not used ciclopirox daily ≥48 weeks as this would be difficult to verify objectively; modified approval duration from “up to 48 weeks total” to 48 weeks. - References reviewed and updated.

<p>CP.PMN.25 Efinaconazole (Jublia®)</p>	<p>Significant Clinical Change(s)</p>	<p>Commercial Medicaid</p>	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Centene Medicaid and Commercial lines of business. - Added age restriction as safety and effectiveness in pediatrics have not been established; specified a timeframe of within the past 12 months for oral terbinafine trial; - Commercial: specified duration of trial of oral terbinafine for toenail onychomycosis per PI; added QL. - Medicaid: Removed laboratory testing related to confirmation of fungal infection; re-auth: removed requirement that member has not used Jublia daily \geq48 weeks as this would be difficult to verify objectively; modified approval duration from “up to 48 weeks total” to 48 weeks. - References reviewed and updated.
<p>CP.PMN.57 Febuxostat (Uloric®)</p>	<p>Significant Clinical Change(s)</p>	<p>HIM Medicaid</p>	<p>1Q18 annual review:</p> <p>Policies combined for HIM and Medicaid;</p> <ul style="list-style-type: none"> - Added age limit following the safety guidance endorsed by Medical Affairs; - Added drug interactions with azathioprine and mercaptopurine following the safety guidance - References reviewed and updated.
<p>CP.PMN.62 Tedizolid (Sivextro®)</p>	<p>Significant Clinical Change(s)</p>	<p>HIM Medicaid</p>	<p>1Q18 Annual Review: policies combined for Medicaid and HIM lines of business.</p> <ul style="list-style-type: none"> - Removed language specifying that isolated pathogen is VRE or MRSA since VRE & MRSA are gram-positive and policy now covers gram positive bacteria per indication. - 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 formulary antibiotics by specifying 2 formulary antibiotics, provided 2 appropriate formulary antibiotics are available to which the pathogen is susceptible and/or are indicated for member’s diagnosis. - Age added per safety guidance endorsed by Centene Medical Affairs - References reviewed and updated.

<p>CP.PMN.67 Sacubitril and valsartan (Entresto®)</p>	<p>Significant Clinical Change(s)</p>	<p>Commercial HIM Medicaid</p>	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Centene Medicaid, Marketplace and Commercial lines of business. - No significant change from previous corporate approved policy. - Commercial: added age restriction as safety and effectiveness in pediatric patients have not been established; modified LVEF from < 40% to ≤ 35% per PARADIGM-HF clinical trial; added contraindications related to DDI per PI; updated re-auth to allow COC for heart failure. Added requirement for positive response to therapy. - Marketplace and Medicaid: added age restriction and contraindications related to DDI per PI (Marketplace only); removed “previously tolerated an ACEI or ARB at therapeutic doses for ≥ 30 days” since specialist is involved in care - References reviewed and updated.
<p>CP.PMN.71 Linaclotide (Linzess®)</p>	<p>Significant Clinical Change(s)</p>	<p>HIM Medicaid</p>	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for Medicaid and marketplace lines of business - Removed duration and timeframe of trial related to laxative use since they are available OTC and may not be verifiable via claims history - Medicaid: modified initial approval duration from 6 to 12 months for both indications - References reviewed and updated.
<p>CP.PMN.81 Buprenorphine-naloxone (Suboxone®, Bunavail®, Zubsolv®)</p>	<p>Significant Clinical Change(s)</p>	<p>Medicaid</p>	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Removed XDEA number (DATA2000 waiver) as a requirement since prescription use of these products is limited under the Drug Addiction Treatment Act. - Removed criteria related to participation in drug abuse counseling and urine drugs screens (e.g., submission of at least 2 negative random urine drug screens) to shift the responsibility of appropriate monitoring and use to the prescriber. - Removed requirement related to adherence to therapy on re-auth and added requirement for positive response to therapy. Modified generalized dosing requirement to include specific max dose of each drug

<p>CP.PMN.82 Buprenorphine (Subutex®)</p>	<p>Significant Clinical Change(s)</p>	<p>Commercial HIM Medicaid</p>	<p>-References reviewed and updated.</p> <p>1Q18 annual review: - Policies combined for Centene Medicaid, Marketplace and Commercial lines of business. - Commercial: Removed requirement that member is not using concurrent opioid medications (including tramadol). Added member has experienced clinically significant adverse effects or contraindication(s) to buprenorphine/naloxone (e.g., Suboxone) as an approvable condition. Modified max dose from 32 mg/day to 24 mg/day per PI. Changed initial approval duration from LOB to 12 months. Re-auth: added requirement related to absence/presence of opioid use since last approval; modified continued approval duration from LOB to “duration of request or 12 months (whichever is less).” Added pain management as a diagnosis for which coverage is not authorized. - Medicaid and Marketplace: Removed XDEA number (DATA2000 waiver) as a requirement since prescription use of this product is limited under the Drug Addiction Treatment Act. Removed criteria related to participation in drug abuse counseling and urine drugs screens (e.g., submission of at least 2 negative random urine drug screens) to shift the responsibility of appropriate monitoring and use to the prescriber. Removed requirement related to adherence to therapy on re-auth and added requirement for positive response to therapy. - Marketplace: Removed breastfeeding as an approvable condition-per SAMHSA/CSAT clinical guidelines, Suboxone is not contraindicated in breastfeeding. Removed requirement related to adherence to therapy on re-auth and added requirement for positive response to therapy. - References reviewed and updated.</p>
<p>CP.PMN.87 Plecanatide (Trulance®)</p>	<p>Significant Clinical Change(s)</p>	<p>Commercial Medicaid</p>	<p>1Q18 annual review: - Policies combined for Medicaid and commercial lines of business. - Modified criterion to require trial of all 3 different laxatives recommended per ACG (bulk-forming, polyethylene glycol, and stimulant) and removed stool softeners as an option since there is</p>

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			<p>little evidence to support the use of such agents in chronic constipation.</p> <ul style="list-style-type: none"> - Updated max dose requirement to include QL of 1 tablet/day. - Modified initial approval from 6 to 12 months - References reviewed and updated.
CP.PMN.102 Rolapitant (Varubi®)	Significant Clinical Change(s)	HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Added trial of aprepitant (Emend) since it's generically available. - Added Medicaid line of business as new criteria <p>References reviewed and updated.</p>
CP.PMN.104 Tasimelteon (Hetlioz®)	Significant Clinical Change(s)	Commercial HIM Medicaid	<p>1Q18 annual review:</p> <ul style="list-style-type: none"> - Policies combined for HIM and commercial; - Medicaid line of business was added to criteria - Added specialist requirement - Added trial and failure of melatonin - Removed diagnosis with “confirmed by at least 14 days of documentation of progressively shifting sleep-wake times” due to added specialist requirement - References reviewed and updated
CP.PMN.01 Atomoxetine (Strattera®)	Retire	Medicaid	Policy has been replaced by step therapy policy CP.PST.17
CP.PPA.05 Topical Immunomodulators	Retire	Medicaid	Replaced by CP.PMN.107 Topical Immunomodulator
CP.PPA.17 Aripiprazole (Abilify®)	Retire	Medicaid	PA will be removed in 1Q2018
CP.PPA.21 GLP-1	Retire	Medicaid	Replaced by CP.PST.14 GLP-1 receptor agonists (converted to electronic step therapy)
CP.PPA.22 Rivastigmine (Exelon®)	Retire	Medicaid	Replaced by CP.PMN.101 Rivastigmine (Exelon®)
CP.PPA.23 Dipeptidyl Peptidase-4 (DDP-4) Inhibitors	Retire	Medicaid	Replaced by CP.PST.18 DPP-4 inhibitors (converted to electronic step therapy)
CP.PPA.24 Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors	Retire	Medicaid	Replaced by CP.PST.19 SGLT2 inhibitors (converted to electronic step therapy)

Based on Q1 P&T 2018

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

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