**Effective date: 08/01/18**

# Buckeye Health Plan
# Medicaid Criteria Updates – Q2 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 |
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| **Clinically Significant Change(s)** | | | |
| CP.PHAR.05 Hyaluronate Derivatives | Clinically Significant Change(s) | Commercial Medicaid | 2Q 2018 annual review: policies combined for commercial and Medicaid lines of business; Commercial: modified failure of glucocorticoid injections to partial response requirement; Commercial and Medicaid: modified NSAID trial duration to 4 weeks, added requirement that member must not have coexistent active inflammatory arthritis other than OA or history of total knee arthroplasty in the targeted knee; added Durolane; references reviewed and updated. |
| CP.PHAR.55 Somatropin (Human Growth Hormone) | Clinically Significant Change(s) | HIM Medicaid | 2Q 2018 annual review: added HIM; removed requirements regarding contraindications; removed requirements for ruling out alternative of diagnoses; neonatal hypoglycemia: removed brain MRI and random GH measurement requirement; GHD, small for gestational age: removed requirements for open epiphyses, evidence of growth failure via appendix C, defined central nervous system pathology documented by MRI or CT; Prader-Willi syndrome: removed requirements for closed epiphyses, rGH will be titrated to maintain normal range IGF-1 level for age and sex |

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| | | | matched controls, ruling out of contraindications, untreated severe sleep apnea, and active psychosis; CKD: removed requirements for open epiphyses, evidence of growth failure per appendix C, dx of CKD via Structural or functional abnormalities of the kidney for ≥ 3 months, GFR < 60 mL/min per 1.73 m2 for ≥ 3 months, occurrence of both together of any duration, member does not have a functioning renal allograft; SBS: removed requirements for member's SBS therapeutic plan requires specialized nutritional support; changed approval duration from 3 months to 4 weeks; HIV-related wasting or cachexia: removed requirement for ruling out alternate causes of cachexia, unexplained loss of > 10% body weight from baseline, treatment with therapies other than rhGH have been suboptimal; added requirements for trial of appetite stimulants or anti-nausea tx as well as trial of testosterone and anabolic steroid in males; continued tx: removed documentation of adherence to therapy; removed examples of positive response criteria if not mandatory and objective; for Adult GHD: corrected peak GH level ≤ 5 µg/mL to ≤ 5 µg/L; aligned labs required for diagnosis with 2009 AACE guidelines; for Child/adolescent GHD: corrected peak GH level ≤ 10 µg/L to 10; GH use in children: added requirement for documentation of baseline height for initial approval. |
| CP.PHAR.58 Denosumab (Prolia, Xgeva) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q2018 annual review: policies combined for commercial and Medicaid lines of business; added HIM line of business to the policy.<br>Commercial: combined CP.CPA.170 (Xgeva) and CP.CPA.202 (Prolia); added age and requirement for no concomitant use of Prolia/Xgeva; modified approval duration from length of benefit to 6 months or to the member's renewal date, whichever is longer; allowed COC for oncology related indications on re-auth; Osteoporosis: added specialist or failure of an on oral bisphosphonate requirement; Hypercalcemia: added lab requirement for albumin-corrected calcium > 12.5 mg/dL<br>Medicaid: All indications: removed requirements related to pregnancy (for Prolia) and hypocalcemia monitoring; allowed COC for oncology related indications on re-auth; Osteoporosis: Modified diagnosis criterion by removing requirement for evidence of diagnosis; removed requirements pertaining to Reclast; added specialist requirement as an option in lieu of bisphosphonate trial; Prostate and breast cancer treatments: removed T-score and risk factors; Criteria added for new FDA indication: multiple myeloma; references reviewed and updated. |

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| CP.PHAR.64 Topotecan (Hycamtin®) | Clinically Significant Change(s) | HIM-Medical Benefit Medicaid | 2Q 2018 annual review: HIM added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; added age; removed lab requirements pertaining to baseline neutrophil and platelet counts; off-label NCCN recommended uses (e.g., bone cancer, CNS cancers, etc.): updated to include only category 2A (removed 2b); added requirement that request is for the injectable formulation, added dosing statement and initial approval duration of 6 months; references reviewed and updated. |
| CP.PHAR.65 Imatinib mesylate (Gleevec®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: added Commercial and HIM lines of business; added age; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; off-label CNS/NSCLC, Kaposi sarcoma added; references reviewed and updated. |
| CP.PHAR.72 Dasatinib (Sprycel®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: HIM and Commercial lines of business added; off-label GIST added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated. |
| CP.PHAR.75 Bexarotene (Targretin®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: Commercial and HIM lines of business added; added age; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated. |
| CP.PHAR.84 Abiraterone (Zytiga®) | Clinically Significant Change(s) | Commercial HIM Medicaid | Criteria added for new FDA indication: castration-sensitive prostate cancer. |
| CP.PHAR.90 Crizotinib (Xalkori®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: policies combined for Commercial and Medicaid; added HIM line of business; age added; minimum dose removed; off-label NSCLC recurrent disease added; off-label ALCL added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated. |
| CP.PHAR.105 Bosutinib (Bosulif®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q2018 annual review: off-label ALL added; references updated. |
| CP.PHAR.116 Pomalidomide (Pomalyst®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: policies combined for Commercial and Medicaid; HIM line of business added; added age and COC; summarized NCCN and |

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| | | | FDA approved uses for improved clarity; added specialist involvement in care; off-label Kaposi sarcoma and amyloidosis added; references updated. |
| CP.PHAR.200 Mepolizumab (Nucala) | Clinically Significant Change(s) | Commercial Medicaid | Criteria added for new FDA indication: treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EPGA). |
| CP.PHAR.227 Pertuzumab (Perjeta®) | Clinically Significant Change(s) | HIM Medicaid | 2Q 2018 annual review: added HIM line of business; age and COC added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; breast cancer FDA labels updated: neoadjuvant treatment with trastuzumab and docetaxel replaced with trastuzumab and chemotherapy; adjuvant treatment added; ejection fraction and number of cycles restrictions removed; references reviewed and updated. |
| CP.PHAR.229 Ado-Trastuzumab Emtansine (Kadcyla®) | Clinically Significant Change(s) | Commercial Medicaid | 2Q 2018 annual review; policies combined for Commercial and Medicaid; age, and COC added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; off-label NSCLC added; references reviewed and updated. |
| CP.PHAR.236 Darbepoetin alfa (Aranesp®) | Clinically Significant Change(s) | HIM Medicaid | 2Q 2018 annual review: HIM added; removed subjective criteria across all indications since specialist requirement is added; added age where relevant approval duration modified to allow no less than 6 months for initial/continued approval; anemia associated with MDS/MF: clarified that the lab for serum EPO should be current (within the past 3 months); added requirement for positive response to therapy on re-auth; references reviewed and updated. |
| CP.PHAR.237 Epoetin Alfa (Epogen and Procrit) | Clinically Significant Change(s) | HIM Medicaid | 2Q 2018 annual review: HIM added; removed subjective criteria across all indications since specialist requirement is added; added age where relevant approval duration modified to allow no less than 6 months for initial/continued approval; clarified that the lab for serum EPO should be current (within the past 3 months) for MDS; added requirement for positive response to therapy on re-auth; added criteria for MF-associated anemia; references reviewed and updated. |
| CP.PHAR.238 Methoxy polyethylene glycol-epoetin beta (Mircera®) | Clinically Significant Change(s) | HIM Medicaid | 2Q 2018 annual review: HIM added; removed subjective criteria across all indications since specialist requirement is added; added age where relevant approval duration modified to allow no less than 6 months for initial/continued approval; clarified that the lab for serum EPO should be current (within the past 3 months) for MDS; added requirement for positive |

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| | | | response to therapy on re-auth; added criteria for MF-associated anemia; references reviewed and updated. |
| CP.PHAR.258 Mitoxantrone (Novantrone®) | Clinically Significant Change(s) | Medicaid | 2Q 2018 annual review: approval durations modified from 3 months to 6 months and removed LVEF requirement for MS; oncology: criteria added; references reviewed and updated. |
| CP.PHAR.272 Sonidegib (Odomzo®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review; policies combined for HIM and Medicaid; Commercial line of business added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated. |
| CP.PHAR.289 Buprenorphine (Probuphine®, Sublocade®) | Clinically Significant Change(s) | Commercial Medicaid HIM-Medical Benefit | Added criteria for Sublocade to policy. |
| CP.PHAR.298 Afatinib (Gilotrif®) | Clinically Significant Change(s) | Commercial HIM Medicaid | New indication: updated FDA approved indication and approval criteria to allow coverage for the following uncommon EGFR mutations: L861Q, G719X, and S768I for metastatic NSCLC with sensitizing EGFR mutation; added NCCN 2A recommended off-label use for central nervous system cancer with brain metastases; references reviewed and updated. |
| CP.PHAR.360 Olaparib (Lynparza) | Clinically Significant Change(s) | Commercial HIM Medicaid | Add new indication for treatment of gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer. |
| CP.PMN.04 Non-Calcium Phosphate Binders | Clinically Significant Change(s) | Commercial, Medicaid | Criteria added for new indication for Auryxia: for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis. |
| CP.PMN.33 Pregabalin (Lyrica®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: policies combined for commercial, HIM, and Medicaid lines of business; added age requirement; Commercial: diabetic neuropathy and neuropathic pain associated with spinal cord injury: added criteria requiring failure of gabapentin, TCA, and SNRI; Fibromyalgia: added requirements for failure of gabapentin, duloxetine, and cyclobenzaprine or TCA; Postherpetic neuralgia: specified duration and strength of gabapentin trial; added criteria requiring failure of TCA and SNRI ; Seizures: added specialist requirement; added criteria pertaining to failure of gabapentin used as adjunctive therapy, and failure of 2 anticonvulsants indicated for partial seizures; re-auth: added language to allow continuation of therapy for members currently receiving Lyrica for partial onset seizures; HIM: fibromyalgia: removed “with symptoms present |

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| | | | for at least 3 month" from the diagnosis since this is a subjective; Medicaid: for all indications: extended initial approval duration from 6 to 12 months; Neuropathic pain (not associated with DPN): modified diagnosis to specify neuropathic pain associated with spinal cord injury; HIM/Medicaid: Combined diabetic neuropathy, neuropathic pain associated with spinal cord injury, and postherpetic neuralgia into one criteria set; fibromyalgia: removed requirement that one of the trials must have occurred within the past 90 days, unless contraindicated or intolerant; added off-label indication: generalized anxiety disorder; added dental pain, essential tremor, and social phobia as indications for which coverage is not authorized; references reviewed and updated. |
| CP.PMN.87 Plecanatide (Trulance®) | Clinically Significant Change(s) | Commercial Medicaid | 2Q 2018 annual review: criteria added for new FDA indication: IBS-C; approval duration for CIC and continuation therapy modified to 12 months for commercial; references reviewed and updated. |
| CP.PMN.117 Naproxen and esomeprazole magnesium (Vimovo®) | Clinically Significant Change(s) | Commercial Medicaid | Policy created: replaces CP.CPA.168 Vimovo; Medicaid line of business added. |
| CP.PMN.120 Ibuprofen and Famotidine (Duexis) | Clinically Significant Change(s) | Commercial Medicaid | Policy created: replaces CP.CPA.23 Duexis for commercial; Medicaid line of business added |
| CP.PMN.122 Celecoxib (Celebrex®) | Clinically Significant Change(s) | Commercial HIM, Medicaid | 2Q 2018 annual review: polices combined for Medicaid, HIM, and commercial lines of business; reference number changed from PPA to PMN; Medicaid: Added age and max dose; increased approval duration from 3/12 to 12/12; HIM: removed specific diagnoses; added age; decreased trials from 3 (meloxicam & 2 NSAIDs) to 2 (meloxicam & 1 NSAID); added a path to approval for those with high risk for gastroduodenal damage (>65 years, current steroid or anticoagulant use, or prior bleed); Commercial: added age; changed trial of 2 NSAIDs to meloxicam and 1 NSAID; references reviewed and updated. |
| CP.PMN.123 Colchicine (Colcrys®) | Clinically Significant Change(s) | HIM Medicaid | 2Q 2018 annual review: no significant changes, reference number changed from PPA to PMN; HIM added; removed classification of pericarditis indication; removed requirement of clinical evidence of gout; references reviewed and updated. |
| CP.PMN.124 Itraconazole (Sporanox®, Onmel®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: policies combined for Medicaid, Commercial, and HIM; added Onmel to policy; added age; added 3 months trial of |

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| | | | voriconazole for aspergillosis per IDSA; added criteria for hematologic malignancy; references reviewed and updated. |
| CP.PMN.125 Milnacipran (Savella®) | Clinically Significant Change(s) | Commercial HIM Medicaid | 2Q2018 annual review: polices combined for Medicaid, HIM, and Commercial lines of business; Medicaid & HIM: Added off-label criteria for depression; changed from trial of 2 antidepressants to trial of one SSRI, two SNRI and one other antidepressant; Commercial: Added failure of amitriptyline or cyclobenzaprine if duloxetine cannot be used; references reviewed and updated. |
| CP.PMN.126 Toremifene (Fareston®) | Clinically Significant Change(s) | Commercial Medicaid | 2Q 2018 annual review: removed strength of tamoxifen to be used; removed requirement that member is a postmenopausal female as NCCN allows use in men and premenopausal women; added soft tissue sarcoma criteria per NCCN; added Commercial line of business; references reviewed and updated. |
| CP.PST.14 Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists | Clinically Significant Change(s) | Medicaid | Added new FDA-approved drug: Ozempic. |
| CP.PST.19 Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors | Clinically Significant Change(s) | Medicaid | Added new FDA-approved drugs: Steglatro, Segluromet, Steglujan. Added requirement for Steglujan to step-through a preferred SGLT2 or DPP-4 inhibitor. |
| **New Policies** | | | |
| CP.PHAR.373 Benralizumab (Fasenra™) | New | Commercial HIM Medicaid | Policy created. |
| CP.PHAR.374 Vestronidase alfa-vjbk (Mepsevii™) | New | Commercial HIM Medicaid | Policy created. |
| CP.PHAR.375 Brodalumab (Siliq™) | New | Medicaid | Policy created. |
| CP.PHAR.376 Apalutamide (Erleada™) | New | Commercial HIM Medicaid | Policy created. |
| CP.PMN.118 Netarsudil (Rhopressa®) | New | Commercial HIM Medicaid | Policy created. |
| CP.PMN.119 Ozenoxacin (Xepi) | New | Commercial HIM | Policy created. |

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| CP.PMN.137 Carbamazepine ER (Equetro®) | New | HIM<br>Medicaid | Policy created. |
| CP.PMN.138 Age Limit Override (Codeine, Tramadol, Hydrocodone) | New | Commercial<br>HIM<br>Medicaid | Policy created. |
| CP.PST.01 Step Therapy | New | Medicaid | Policy created. |
| **No Significant Clinical Changes** | | | |
| CP.PHAR.16 Palivizumab (Synagis®) | No Significant Clinical Change(s) | Commercial<br>Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Commercial and Medicaid; references reviewed and updated. |
| CP.PHAR.60 Capecitabine (Xeloda®) | No Significant Clinical Change(s) | HIM<br>Medicaid | 2Q 2018 annual review: added HIM line of business; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; removed central nervous cancers-brain metastases from off-label because it is addressed by the primary tumor (breast cancer criteria); removed mucinous carcinoma of the ovary as it is covered in ovarian cancer criteria; added continuity of care statement; references reviewed and updated. |
| CP.PHAR.68 Gefitinib (Iressa®) | No Significant Clinical Change(s) | Commercial<br>Medicaid | 2Q 2018 annual review: added age; added that disease must be recurrent or metastatic per FDA labeling and NCCN compendium; Medicaid line of business added to existing commercial policy; added COC statement for reauth and requirement for positive response to therapy; references reviewed and updated. |
| CP.PHAR.69 Sorafenib (Nexavar®) | No Significant Clinical Change(s) | HIM<br>Medicaid | 2Q 2018 annual review: Added HIM line of business; added age; added NCCN compendium use for solitary fibrous tumor/hemangiopericytoma; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated. |
| CP.PHAR.71 Lenalidomide (Revlimid®) | No Significant Clinical Change(s) | Commercial<br>HIM<br>Medicaid | 2Q 2018 annual review: added HIM line of business; policies combined for Commercial and Medicaid lines of business; MDS: removed criteria requirements for low-risk disease and deletion 5q cytogenetic abnormality; MCL: removed disease staging; removed off-label use for primary cutaneous B-cell lymphoma; references reviewed and updated. |
| CP.PHAR.73 Sunitinib (Sutent®) | No Significant | Commercial<br>HIM<br>Medicaid | 2Q 2018 annual review: no significant changes; added HIM and Commercial lines of business; references reviewed and updated. |

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| | Clinical Change(s) | | |
| CP.PHAR.76 Nilotinib (Tasigna®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Medicaid and Commercial; HIM line of business added; added age (not ALL) ; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated. |
| CP.PHAR.77 Temozolomide (Temodar®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: added HIM line of business; added age; added continuity of care language; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; updated NCCN Compendium supported uses; references reviewed and updated. |
| CP.PHAR.78 Thalidomide (Thalomid) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: added HIM line of business; added prescriber and age requirements; removed off label indication for systemic light chain amyloidosis that is no longer included in NCCN Compendium; added off-label use for Kaposi Sarcoma; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated. |
| CP.PHAR.92 Tetrabenazine (Xenazine®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: no significant changes; added HIM line of business; Removed DDI requirements from Section I (information added to Appendix C); added caution to prevent duplicate therapy with similar agents references reviewed and updated. |
| CP.PHAR.107 Regorafenib (Stivarga®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q2018 annual review: no significant changes; policies combined for commercial and Medicaid; added HIM line of business; age added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated. |
| CP.PHAR.108 Omacetaxine (Synribo®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes; added Commercial and HIM lines of business; added continuity of care statement; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated. |
| CP.PHAR.112 Ponatinib (Iclusig®) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Commercial and Medicaid; added age (CML), added COC statement; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated. |
| CP.PHAR.120 Sipuleucel-T (Provenge®) | No Significant | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Commercial and Medicaid; HIM line of business added; age and dose added; summarized NCCN and FDA approved uses for improved clarity; |

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| | Clinical Change(s) | | added specialist involvement in care; added continuity of care statement; references reviewed and updated |
| CP.PHAR.152 Laronidase (Aldurazyme®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial, HIM, and Medicaid lines of business; Commercial: simplified policy requirements to align with previously approved policy for Medicaid; removed requirement for severity of MPS I Scheie form as this is a non-specific, non-actionable requirement; references reviewed and updated. |
| CP.PHAR.153 Eliglustat (Cerdelga®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policies; policies combined for Medicaid, HIM and Commercial lines of business; added age limit where relevant; added requirement for documentation that the member is symptomatic; HIM: added requirement of Cerdelga monotherapy; Commercial: added specific examples of response to therapy for reauthorization; removed requirement for prior trial of intravenous therapeutic alternatives due to a lack of financial benefit; requirement of Cerdelga monotherapy; changed approval durations from length of benefit to 6 months initial/12 months reauthorization; references reviewed and updated. |
| CP.PHAR.154 Imiglucerase (Cerezyme®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Medicaid and Commercial lines of business; HIM added; Commercial: split from CP.CPA.241 Gaucher Disease Therapy policy; added age limit; removed maximum dose limit, as dosing is individualized per patient response to therapy; added the requirement that Cerezyme not be used concurrently with other enzyme replacement therapies; added specific examples of positive response to therapy, for reauthorization. Medicaid: added coverage for Type 3 Gaucher disease, as covered under the Commercial policy; references reviewed and updated. |
| CP.PHAR.155 Cysteamine oral bitartrate (Cystagon®, Procysbi®) | No Significant Clinical Change(s) | HIM Medicaid | Q2 2018 annual review: no significant changes; HIM added; age restriction removed; added requirement of a prior trial of Cystagon for all Procysbi requests; added specific parameters for documenting a positive response to therapy, for reauthorization; references reviewed and updated. |
| CP.PHAR.156 Idursulfase (Elaprase®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: no significant changes; HIM added; referenced reviewed and updated. |

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| CP.PHAR.157 Taliglucerase alfa (Elelyso®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Medicaid and Commercial lines of business; HIM added; Commercial: split from "CP.CPA.241 Gaucher Disease Therapy – Enzyme Replacement" into individual Elelyso commercial policy; added age limit; removed maximum dose limit, as dosing is individualized per patient response to therapy; added the requirement that Elelyso not be used concurrently with other enzyme replacement therapies; added specific examples of positive response to therapy, for reauthorization. Medicaid: added coverage for Type 3 Gaucher disease, as covered under the Commercial policy; references reviewed and updated. |
| CP.PHAR.158 Agalsidase beta (Fabrazyme®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Commercial and Medicaid lines of business; HIM added; Commercial: added diagnosis confirmation testing requirement; added age limit; added requirement for documentation of positive response to therapy for reauthorization; changed approval durations from length of benefit to 6/12 months; references reviewed and updated. |
| CP.PHAR.159 Sebelipase alfa (Kanuma®) | No Significant Clinical Change(s) | HIM-Medical Benefit Medicaid | 2Q 2018 annual review: no significant changes; added HIM; references reviewed and updated. |
| CP.PHAR.160 Alglucosidase alfa (Lumizyme®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Commercial and Medicaid lines of business; HIM added; Commercial: removed Myozyme from the policy as it is no longer available in the U.S.; added diagnosis confirmation testing requirement; added requirement for documentation of positive response to therapy for reauthorization; changed approval durations from length of benefit to 6/12 months; references reviewed and updated. |
| CP.PHAR.161 Galsulfase (Naglazyme®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Commercial and Medicaid lines of business; HIM added; Commercial: added diagnosis confirmation testing requirement; added age limit; added specific examples of positive response to therapy for reauthorization; changed approval durations from length of benefit to 6/12 months; references reviewed and updated. |
| CP.PHAR.162 Elosulfase alfa (Vimizim®) | No Significant | HIM-Medical Benefit | 2Q 2018 annual review: no significant changes; HIM added; references reviewed and updated. |

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| | Clinical Change(s) | Medicaid | |
| CP.PHAR.163 Velaglucerase alfa (VPRIV®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Medicaid and Commercial lines of business; HIM added; Commercial: split from "CP.CPA.241 Gaucher Disease Therapy – Enzyme Replacement" into individual Elelyso commercial policy; added age limit; removed maximum dose limit, as dosing is individualized per patient response to therapy; added the requirement that VPRIV is not be used concurrently with other enzyme replacement therapies; added specific examples of positive response to therapy, for reauthorization. Medicaid: added coverage for Type 3 Gaucher disease, as covered under the Commercial policy; references reviewed and updated. |
| CP.PHAR.164 Miglustat (Zavesca®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Medicaid and Commercial lines of business; added HIM; Commercial: added specific examples of response to therapy for reauthorization; added age limit, requirement of Zavesca monotherapy; changed approval durations from length of benefit to 6 months initial/12 months reauthorization; references reviewed and updated. |
| CP.PHAR.176 Paclitaxel, protein-bound (Abraxane®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: converted to new template; added HIM; added age; NCCN category 2B indication for cervical cancer removed; for all indications: removed requirements to check for contraindications per safety guidance, summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated. |
| CP.PHAR.228 Trastuzumab (Herceptin®), Trastuzumab-dkst (Ogivri®) | No Significant Clinical Change(s) | Medicaid HIM-Medical Benefit | 2Q 2018 annual review: no significant changes; HIM line of business added; references reviewed and updated. |
| CP.PHAR.230 AbobotulinumtoxinA (Dysport®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: removed specific diagnostic requirements for limb spasticity; combined Medicaid and Commercial lines of business; added HIM; Medicaid: removed requirement of at least 12 weeks have passed since last treatment; Commercial: approval durations changed from length of benefit to 6 months initial and 12 months continued approval; references reviewed and updated. |
| CP.PHAR.231 IncobotulinumtoxinA (Xeomin®) | No Significant | Commercial HIM | 2Q 2018 annual review: no significant changes from previously approved corporate policy; combined Medicaid and Commercial lines of business; |

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| | Clinical Change(s) | Medicaid | added HIM; intent of therapy language removed from upper limb spasticity indication; Medicaid: removed requirement of at least 12 weeks have passed since last treatment; Commercial: approval durations changed from length of benefit to 6 months initial and 12 months continued approval; references reviewed and updated. |
| CP.PHAR.232 OnabotulinumtoxinA (Botox) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: combined Medicaid and Commercial lines of business; added HIM line of business; expanded maximum dose for chronic migraine treatment to 200 units per treatment per 2012 NICE guidelines; Hirschsprung's Disease and Internal Anal Sphincter Achalasia: removed requirement for dietary and fluid control; Medicaid: removed requirement of at least 12 weeks have passed since last treatment; Commercial: approval durations changed from length of benefit to 6 months initial and 12 months continued approval; references reviewed and updated. |
| CP.PHAR.233 RimabotulinumtoxinB (Myobloc®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; combined Medicaid and Commercial lines of business; added HIM; Medicaid: removed requirement of at least 12 weeks have passed since last treatment; Commercial: approval durations changed from length of benefit to 6 months initial and 12 months continued approval; references reviewed and updated. |
| CP.PHAR.239 Dabrafenib (Tafinlar®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Medicaid, Commercial, and HIM ; added age; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care and continuity of care statement; references reviewed and updated. |
| CP.PHAR.240 Trametinib (Mekinist®) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Commercial and Medicaid; added age; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement and updated approval duration from 3/6 to 6/12 months for Medicaid; references reviewed and updated. |
| CP.PHAR.241 Abatacept (Orencia®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: added HIM; added rheumatologist specialist requirement for RA; removed TB testing from RA and PJIA; revised dosing in initial and continuation approval criteria for PJIA per package insert; references reviewed and updated. |
| CP.PHAR.242 Adalimumab (Humira®) | No Significant | HIM Medicaid | 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; Medicaid and HIM: removed TB testing requirement from all criteria, modified trial and failure for RA to at least one conventional |

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| | Clinical Change(s) | | DMARD, removed requirements for specific criteria relating to diagnosis for CD and PsO, modified gastroenterologist specialty requirement to gastrointestinal specialist for CD/UC, added aminosalicylate as an option for trial and failure for UC, removed trial and failure of phototherapy and topical therapy for PsO, modified trial and failure for PsO to require methotrexate (or another agent if methotrexate is not tolerated or contraindicated, generalized trial of failure of systemic antibiotics for HS, added rheumatologist as an option for specialist requirement for UV, modified trial and failure for UV to require both systemic corticosteroid and immunosuppressive therapy; references reviewed and updated. |
| CP.PHAR.243 Alemtuzumab (Lemtrada) | No Significant Clinical Change(s) | HIM-Medical Benefit Medicaid | 2Q 2018 annual review: no significant changes; removed HIV contraindication; added HIM; references reviewed and updated. |
| CP.PHAR.244 Anakinra (Kineret®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: added HIM; removed TB testing requirement from all indications; references reviewed and updated. |
| CP.PHAR.245 Apremilast (Otezla®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; HIM: removed azathioprine as an option for trial and failure for PsA, removed specific diagnosis requirements for PsO, removed trial and failure of phototherapy and topical therapy for PsO, added requirement for trial and failure of cyclosporine or acitretin if methotrexate use is not tolerated or contraindicated; Medicaid: removed requirement that Otezla will not be used concurrently with a biologic agent; references reviewed and updated. |
| CP.PHAR.246 Canakinumab (Ilaris®) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: policies combined for Medicaid and Commercial lines of business; Commercial: split from CP.CPA.234; condensed all periodic fever syndromes into one criteria set; duration of initial approval for periodic fever syndromes modified to 6 months; added dermatologist and gastrointestinal specialist requirement to SJIA; removed requirement for TB testing from all criteria; moved examples of positive response to therapy to Appendix C: General Information; references reviewed and updated. |
| CP.PHAR.247 Certolizumab (Cimzia) | No Significant | HIM Medicaid | 2Q 2018 annual review: added HIM; removed specific diagnosis requirements for CD; modified specialist requirement to any GI specialist |

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| | Clinical Change(s) | | for CD; removed TB testing for all indications; modified trial and failure for RA to at least one conventional DMARD; references reviewed and updated. |
| CP.PHAR.248 Dalfampridine (Ampyra) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant change from previously approved corporate policy; policies combined for Commercial, Medicaid and HIM; Medicaid: removed history of seizure; HIM: removed MRI requirement; added age restriction; Commercial: added requirement that member must have walking impairment; added age; references reviewed and updated. |
| CP.PHAR.249 Dimethyl fumarate (Tecfidera®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Medicaid, HIM and Commercial lines of business; age added; HIM: removed MRI requirement; Commercial: removed COC statement for reauth; added requirement for no concurrent use with other MS therapies; references reviewed and updated. |
| CP.PHAR.250 Etanercept (Enbrel) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; modified trial and failure for RA to at least one conventional DMARD; removed TB testing for all indications; modified max dose requirements to specify pediatric and adult-specific dosing for PJIA and PsO; removed specific diagnosis requirements for PsO; removed trial and failure of phototherapy and topical therapy for PsO; added off-label criteria for HS; references reviewed and updated. |
| CP.PHAR.251 Fingolimod (Gilenya®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Medicaid, HIM and Commercial lines of business; age added; Medicaid: removed the following contraindications per safety guidance endorsed by Centene Medical Affairs: recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure; history of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker; HIM: Removed MRI requirement; Commercial: removed COC statement for reauth; added requirement for no concurrent use with other MS therapies; references reviewed and updated. |
| CP.PHAR.252 Glatiramer (Copaxone®, Glatopa®) | No Significant Clinical Change(s) | Medicaid HIM | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Centene Medicaid and HIM lines of business; HIM: MRI requirement removed; age added; modified requirement for "failure" of Glatopa 20 to "contraindications or adverse effects to excipients" as it is the same active ingredient as Copaxone 20; references reviewed and updated. |

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| CP.PHAR.253 Golimumab (Simponi®, Simponi Aria®) | No Significant Clinical Change(s) | HIM-Medical Benefit Medicaid | 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; HIM: removed specific diagnosis requirements for RA, modified trial and failure for RA, AS, PsA to require both Humira and Enbrel, removed trial and failure of Enbrel from UC as Enbrel is not indicated; Medicaid: added requirement for concomitant use of MTX or another DMARD for RA; Medicaid and HIM: modified trial and failure for RA to at least one conventional DMARD, removed TB testing for all indications, added aminosalicylate as an option for trial and failure for UC, modified gastroenterologist specialty requirement to gastrointestinal specialist for UC; references reviewed and updated. |
| CP.PHAR.254 Infliximab (Remicade®, Inflectra®, Renflexis™) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: removed TB testing requirement from all criteria; removed requirements for specific criteria relating to diagnosis for CD and PsO; modified gastroenterologist specialty requirement to gastrointestinal specialist for CD/UC; modified preferencing for infliximab products for all indications, added aminosalicylate as an option for trial and failure for UC; modified trial and failure for RA to at least one conventional DMARD; added requirement for concomitant use of MTX or another DMARD for RA; removed trial and failure of phototherapy and topical therapy for PsO; modified trial and failure for PsO to require methotrexate (or another agent if methotrexate is not tolerated or contraindicated); added specific max dosing requirements for continued therapy approval; references reviewed and updated. |
| CP.PHAR.255 Interferon beta-1a (Avonex®, Rebif®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: added coverage for SPMS per AAN guidelines; added age restriction for Avonex per prescribing information; added redirection to 2 preferred INF agents; references reviewed and updated. |
| CP.PHAR.256 Interferon beta-1b (Betaseron®, Extavia®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: added coverage for SPMS per AAN guidelines; added redirection to 2 preferred INF agent; references reviewed and updated. |
| CP.PHAR.257 Ixekizumab (Taltz®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: criteria added for new FDA indication; psoriatic arthritis; removed specific diagnosis requirements for PsO; removed trial and failure of phototherapy and topical therapy for PsO, modified requirement for trial and failure of MTX (and if intolerance or contraindication to MTX, trial and failure of cyclosporine or acitretin) for |

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| | | | PsO; added trial and failure of Enbrel for PsO; removed TB testing for PsO; references reviewed and updated. |
| CP.PHAR.259 Natalizumab (Tysabri®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: for CD: removed requirements for specific criteria relating to diagnosis, altered specialist requirement to GI specialist, changed trial and failure duration to 3 consecutive months, added brand names of preferred agents for trial and failure; references reviewed and updated. |
| CP.PHAR.260 Rituximab (Rituxan®), Rituximab and hyaluronidase (Rituxan Hycela™) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: added HIM line of business; summarized NCCN and FDA approved uses for improved clarity for Non-Hodgkin's Lymphoma; added specialist involvement in care into one criteria set; removed diagnosis requirement for ACR criteria in RA; revised conventional DMARD requirement in RA to require at least one conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine); off-label criteria added for additional NCCN-recommended diagnoses; removed off-label criteria for autoimmune hemolytic anemia and immune thrombocytopenia, will instead defer to off-label policy; approval durations updated; references reviewed and updated. |
| CP.PHAR.261 Secukinumab (Cosentyx®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; HIM: modified trial and failure to require both Enbrel and Humira for PsA and AS, modified requirements for dose increase to 300 mg for PsA to require trial and failure of at least 3 consecutive months on 150 mg dose or evidence of coexistent PsO; Medicaid and HIM: removed specific diagnosis requirements for PsO, removed trial and failure of phototherapy and topical therapy for PsO, added trial and failure of Enbrel for PsO, removed TB testing for all indications; references reviewed and updated. |
| CP.PHAR.262 Teriflunomide (Aubagio®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: no significant changes; removed severe hepatic impairment as a contraindication per safety guidance endorsed by Centene Medical Affairs; references reviewed and updated. |
| CP.PHAR.263 Tocilizumab (Actemra®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; HIM: removed specific diagnosis requirements for RA, removed trial and failure of NSAIDs for SJIA as it is not first line; Medicaid and HIM: modified trial and failure for RA to at least one conventional DMARD, modified requirement of corticosteroid trial to be 3 consecutive months for GCS, removed TB testing for all indications, added dermatologist and GI specialist as prescriber specialists for SJIA; references reviewed and updated. |

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| CP.PHAR.264 Ustekinumab (Stelara®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; For HIM and Medicaid: removed specific diagnosis requirements for PsO and CD, added rheumatologist as prescriber specialty requirement for PsO, removed trial and failure of phototherapy and topical therapy for PsO, modified trial and failure to require use of methotrexate or alternative DMARD and Enbrel and Humira for PsO, modified max dosing requirements per package insert, removed TB testing for all indications; references reviewed and updated. |
| CP.PHAR.265 Vedolizumab (Entyvio®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: modified gastroenterologist specialty requirement to gastrointestinal specialist; modified trial and failure of all agents for all conditions to have duration of at least 3 consecutive months; added aminosalicylate as an option for trial and failure for UC; specified brand names for preferred trial and failure agents in all conditions; removed specific diagnosis requirements for CD; references reviewed and updated. |
| CP.PHAR.266 Rilonacept (Arcalyst®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: policies combined for Medicaid and Commercial lines of business; commercial: split from CP.CPA.234; added HIM; moved examples of positive response to therapy to Appendix C: General Information; references reviewed and updated. |
| CP.PHAR.267 Tofacitinib (Xeljanz®, Xeljanz® XR) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: criteria added for new FDA indication: psoriatic arthritis; added HIM; removed TB testing requirement for RA; references reviewed and updated. |
| CP.PHAR.269 Daclizumab (Zinbryta™) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: no significant changes; modified age restriction from ≥ 18 years to ≥ 17 years per prescribing information; references reviewed and updated. |
| CP.PHAR.270 Paricalcitol (Zemplar®) | No Significant Clinical Change(s) | HIM-Medical Benefit Medicaid | 2Q 2018 annual review: no significant changes; added HIM; references reviewed and updated. |
| CP.PHAR.271 Peginterferon beta-1a (Plegridy®) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Medicaid and Commercial lines of business; added coverage of clinically isolated syndrome and secondary progressive MS; added age; removed COC statement for reauth for commercial; added requirement for no concurrent use with other MS therapies; references reviewed and updated. |

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| CP.PHAR.273 Vismodegib (Erivedge®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: policies combined for Medicaid and HIM lines of business; added prescriber and age requirement; updated NCCN Compendium supported use in BCC with nodal or distant metastases; removed pregnancy as not an absolute CI per PI; added continuity of care language; references reviewed and updated. |
| CP.PHAR.335 Ocrelizumab (OcrevusTM) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: no significant changes; removed HBV screening requirement as a specialist is involved in care; references reviewed and updated. |
| CP.PHAR.337 Telotristat ethyl (Xermelo™) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Medicaid and Commercial lines of business; references reviewed and updated. |
| CP.PHAR.338 Cerliponase alfa (Brineura®) | No Significant Clinical Change(s) | HIM- Medical Benefit Medicaid | 2Q 2018 annual review: added HIM lines of business; age added; modified continued therapy criteria to allow provider to determine presence of positive response instead of requiring no decline or decline or one category of CLN2 Clinical Rating Scale score and added requirement that member has at least a score of at least 1 to ensure continued ambulation; references reviewed and updated. |
| CP.PHAR.339 Durvalumab (Imfinzi®) | No Significant Clinical Change(s) | HIM-Medical Benefit Medicaid | 2Q 2018 annual review: added new FDA indication for NSCLC; HIM added; references reviewed and updated. |
| CP.PHAR.340 Valbenazine (Ingrezza™) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Medicaid and Commercial lines of business; added caution to prevent duplicate therapy with similar agents; references reviewed and updated. |
| CP.PHAR.341 Deutetrabenazine (Austedo™) | No Significant Clinical Change(s) | Commerical Medicaid | 2Q 2018 annual review: no significant changes; modified continued approval duration for Medicaid for 6 to 12 months; references reviewed and updated. |
| CP.PHAR.342 Brigatinib (Alunbrig™) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; combined policies for Medicaid and Commercial lines of business; added age; approval duration for commercial changed to length of benefit; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated. |

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

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| CP.PHAR.343 Edaravone (Radicava™) | No Significant Clinical Change(s) | Commercial HIM-Medical Benefit Medicaid | 2Q 2018 annual review: removed Airlie House diagnostic criteria requirement; policies combined for Medicaid and commercial lines of business; HIM added; references reviewed and updated. |
| CP.PHAR.344 Midostaurin (Rydapt) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Commercial and Medicaid; references reviewed and updated. |
| CP.PHAR.346 Sarilumab (Kevzara®) | No Significant Clinical Change(s | Medicaid | 2Q 2018 annual review: removed TB testing requirement; references reviewed and updated. |
| CP.PHAR.349 Ceritinib (Zykadia®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes; policies combined for Commercial, HIM, Medicaid lines of business; specialist involvement in care added; dose lowered from 750 to 450 mg daily per PI; references reviewed and updated. |
| CP.PHAR.364 Guselkumab (Tremfya®) | No Significant Clinical Change(s | Medicaid | 2Q 2018 annual review: removed trial and failure of phototherapy and topical therapy; modified trial and failure to require use of cyclosporine or acitretin if methotrexate is not tolerated or contraindicated; added trial and failure of Enbrel; removed TB testing requirement; references reviewed and updated. |
| CP.PHAR.369 Alectinib (Alecensa®) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes; references reviewed and updated. |
| CP.PMN.11 Oral Antiemetics (5-HT3 Antagonists) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: added aprepitant as a step therapy requirement for Akynzeo; references reviewed and updated. |
| CP.PMN.13 Dose Optimization | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes; added HIM and Commercial; deleted Appendix D: Examples of Exceeding FDA Max Dose. |
| CP.PMN.27 Linezolid (Zyvox®) | No Significant | HIM Medicaid | 2Q 2018 annual review: no significant changes; safety updated per safety guidance endorsed by Centene Medical Affairs; references reviewed and updated. |

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| | Clinical Change(s) | | |
| CP.PMN.35 Armodafinil (Nuvigil®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial, HIM, and Medicaid lines of business; Commercial: split from CP.CPA.105 armodafinil (Nuvigil), modafinil (Provigil); Commercial: age added; Narcolepsy: added criterion related to stimulant trial; OSA: added documented evidence of residual sleepiness despite compliant CPAP use; MS-related fatigue: added requirement related to trial and failure of amantadine and methylphenidate HIM and Medicaid: removed timeframe of trial within the last 6 for months for stimulants for the relevant indications; Medicaid: removed requirement pertaining to hypersensitivity to armodafinil/modafinil; modified initial approval duration from 6 months to 12 months; references reviewed and updated. |
| CP.PMN.39 Modafinil (Provigil®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial, HIM, and Medicaid lines of business:<br>Commercial: split from CP.CPA.105 armodafinil (Nuvigil), modafinil (Provigil); commercial: added age; Narcolepsy: added criterion related to stimulant trial; OSA: added documented evidence of residual sleepiness despite compliant CPAP use; MS-related fatigue: added requirement related to trial and failure of amantadine and methylphenidate; HIM: added the preferred use of armodafinil because of market pricing; Medicaid: modified initial approval duration from 6 months to 12 months; Narcolepsy and MS-related fatigue: removed timeframe of trial within the last 6 months; references reviewed and updated. |
| CP.PMN.42 Sodium oxybate (Xyrem®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial, HIM, and Medicaid lines of business; added age requirement as safety and effectiveness in pediatric patients have not been established per PI; Commercial: Cataplexy: added requirement related to trial and failure of antidepressants; EDS: added requirements related to stimulant and armodafinil or modafinil trial; HIM and Medicaid: modified initial approval duration from 3 to 6 months; Medicaid: added quantity limit of 18 mL/day; references reviewed and updated. |

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| CP.PMN.48 Cyclosporine (Restasis®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: combined Medicaid, HIM, and commercial lines of business criteria; commercial: removed ophthalmologist or optometrist prescriber requirement; expanded requirement of any OTC wetting agent to artificial tears and anti-inflammatory agent; Medicaid: expanded approval duration from 6 months (initial) and 12 months (continued) to length of benefit |
| CP.PMN.49 Dabigatran (Pradaxa®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: listed out preferred agents Eliquis and Xarelto; changed optional trial of preferred Xa inhibitor or warfarin to trial of both; references reviewed and updated. |
| CP.PMN.53 No Coverage Criteria/Off-Label Use Policy | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: no significant changes; Section IA2a/b: added "approved within the last 12 months"; Section IB: Added the requirement that a P & T off-label use criteria must not be available as several criteria address off-label uses. |
| CP.PMN.54 Clobazam (Onfi®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: no significant HIM added; added age; added QL of 2 tablets/day, or 16 mL/day to max dose; increased initial approval duration from 6 to 12 months; references reviewed and updated. |
| CP.PMN.57 Febuxostat (Uloric®) | No Significant Clinical Change(s) | HIM Medicaid | Medicaid: changed approval duration to length of benefit |
| CP.PMN.58 Propranolol HCl oral solution (Hemangeol®) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: no significant changes - policies combined for HIM and Medicaid; references reviewed and updated. |
| CP.PMN.61 ACEI and ARB Duplicate Therapy | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: no significant changes; references reviewed and updated. |
| CP.PMN.64 Quetiapine ER (Seroquel XR®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | Medicaid: changed approval duration from 12 months to length of benefit |
| CP.PMN.67 Sacubitril/valsartan (Entresto®) | No Significant | Commercial HIM | Medicaid: changed approval duration from 12 months to length of benefit |

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| | Clinical Change(s) | Medicaid | |
| CP.PMN.70 Ivabradine (Corlanor®) | No Significant Clinical Change(s) | Medicaid | Changed approval duration to length of benefit. |
| CP.PMN.72 Metformin ER (Glumetza®) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy, policies combined for Centene Medicaid and Commercial lines of business; added that members requesting brand Glumetza must have contraindication or intolerance to generic Glumetza; Medicaid: removed age limit and contraindication since other formulations of metformin are available freely on PDL without such restrictions;increased initial approval duration from 3 months to 12 months; Commercial: modified "failure" to allow only contraindication or clinically significant adverse effects; added requirement for positive response to therapy for continued therapy requests; references reviewed and updated. |
| CP.PMN.79 Doxycycline Hyclate (Acticlate, Doryx), Doxycycline (Oracea) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial and Medicaid lines of business Commercial: split from CP.CPA.210 doxycycline hyclate (Acticlate, Doryx), doxycycline (Oracea), and minocycline (Solodyn); rosacea: modified criterion pertaining to failure of immediate-release doxycycline to require medical justification supporting inability to use immediate-release doxycycline; added failure of a ≥ 4 week trial of one additional preferred oral tetracycline antibiotic, unless clinically significant adverse effects are experienced; modified initial/continued approval duration from length of benefit to 16 weeks of treatment per limitations stated in PI; Doryx and Acticlate requests: modified criterion pertaining to failure of immediate-release doxycycline to require medical justification supporting inability to use immediate-release doxycycline; added a requirement for failure of one additional preferred tetracycline antibiotic for Doryx 100, 150 mg; separated acne vulgaris and prophylaxis of malaria from other FDA approved indications and created specific criteria set for each; modified initial/continued approval duration from length of benefit to specific approval duration per indication; Medicaid: Added Acticlate to the policy; Removed criteria related to hypersensitivity to tetracyclines per safety guidance; Rosacea: added age requirement; removed criteria related |

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| | | | to topical treatments; Acne vulgaris: removed criteria related to topical treatments; added max dose; Other FDA approved indications: added max dose. References reviewed and updated. |
| CP.PMN.80 Minocycline ER (Solodyn®) and Microspheres (Arestin®) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: policies combined for commercial and Medicaid lines of business; added Arestin and criteria for periodontitis Commercial: split from CP.CPA.210 doxycycline hyclate (Acticlate, Doryx), doxycycline (Oracea), and minocycline (Solodyn); acne vulgaris: modified "failure of both generic immediate release minocycline and doxycycline" requirement to the following: "Medical justification supports inability to use immediate-release minocycline (e.g., member experienced clinically significant adverse effects to immediate-release minocycline or has contraindication(s) to the excipients in immediate-release minocycline) and "Failure of a ≥ 4 week trial of one additional preferred oral tetracycline antibiotic (e.g., immediate-release doxycycline) unless clinically significant adverse effects are experienced"; modified initial/continued approval duration from length of benefit to 12 weeks/up to 12 weeks of total treatment/365 days, respectively as safety of Solodyn has not been established beyond 12 weeks of use; Medicaid: Acne vulgaris: added age; removed criteria related to topical treatments and hypersensitivity to tetracyclines; added max dose; specified request is for Solodyn. Re-auth: modified approval duration from "up to 12 weeks of total treatment" to "up to 12 weeks of total treatment/365 days"; references reviewed and updated. |
| CP.PMN.86 Brimonidine (Mirvaso®), Oxymetazoline (Rhofade™) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: added quantity limit of 30 gm (1 tube) per month; combined commercial and HIM lines of business with Medicaid line of business policy; references reviewed and updated. |
| CP.PMN.92 CNS Stimulants | No Significant Clinical Change(s) | Commercial Medicaid | Medicaid: Revised approval duration to length of benefit |
| CP.PMN.110 Crisaborole (Eucrisa) | No Significant Clinical Change(s) | Commercial Medicaid | 2Q 2018 annual review: added maximum quantity per month; policies combined for Medicaid and Commercial lines of business; references reviewed and updated. |
| CP.PMN.113 Safinamide (Xadago®) | No Significant | Commercial Medicaid | 2Q 2018 annual review: policies combined for Medicaid and Commercial lines of business; Medicaid: added the trial of preferred agent; Commercial: |

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| | Clinical Change(s) | | removed the mandated trial of Comtan and added requirement for trial of any of the following agent: entacapone, ropinirole/ropinirole ER; pramipexole/promipexole ER, ritigotine, in line with previously approved clinical guidance; references reviewed and updated. |
| CP.PMN.121 Lisdexamfetamine (Vyvanse®) | No Significant Clinical Change(s) | Medicaid | 2Q 2018 annual review: no significant changes; reference number changed from PPA to PMN; added age; references reviewed and updated |
| CP.PMN.127 Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for HIM Commercial lines of business; Medicaid added; Commercial: added requirement for 2 immediate-release formulary opioid agents; changed approval durations to 6 months/12 months from Length of Benefit. HIM: replaced the requirement for a long-acting opioid analgesic with a requirement for concurrent use of fentanyl transdermal patches and added the requirement of a treatment plan; Changed initial approval duration to 6 months from 12 months; references reviewed and updated. |
| CP.PMN.128 dutasteride (Avodart®) and dutasteride/tamsulosin (Jalyn®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial and HIM lines of business; split from HIM.PA.39; added Medicaid line of business; Commercial: increased trial from 1 to 2 drugs; references reviewed and updated. |
| CP.PMN.129 Pramlintide (Symlin®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | New policy created: no significant clinical changes from previously approved corporate policy; replaces Medicaid CP.PST.13 ; split from commercial policy CP.CPA.16 ; references reviewed and updated. |
| CP.PMN.130 Cysteamine ophthalmic (Cystaran™) | No Significant Clinical Change(s) | HIM Medicaid | 2Q 2018 annual review: no significant changes; Medicaid added; reference number changed from HIM.PA to CP.PMN; references reviewed and updated. |
| CP.PMN.132 Tadalafil (Cialis®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | New policy: no significant changes from previously approved corporate policy; split from HIM.PA.39 and CP.CPA.277; policies combined for HIM and commercial lines of business; added Medicaid; added age and removed requirement of male use only as this is implied; modified redirection to formulary phosphodiesterase-5 inhibitor to require that the agent being requested is a formulary agent as most formulary agent require PA; changed |

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| | | | approval duration from benefit renewal date to 12 months; references reviewed and updated. |
| CP.PMN.136 Mecamylamine (Vecamyl®) | No Significant Clinical Change(s) | Commercial HIM Medicaid | 2Q 2018 annual review: no significant changes; replaces HIM.PA.111; added Medicaid and commercial; added age; reviewed and updated. |
| **Policies to retire** | | | |
| CP.PPA.01 celecoxib (Celebrex®) | Retire | Medicaid | Replaced by CP.PMN.122 |
| CP.PPA.03 lisdexamfetamine (Vyvanse®) | Retire | Medicaid | Replaced by CP.PMN.121 |
| CP.PPA.07 itraconazole (Sporanox®) | Retire | Medicaid | Replaced by CP.PMN.124 |
| CP.PPA.10 toremifene (Fareston®) | Retire | Medicaid | Replaced by CP.PMN.126 |
| CP.PPA.11 colchicine (Colcrys®) | Retire | Medicaid | Replaced by CP.PMN.123 |
| CP.PPA.15 milnacipran (Savella®) | Retire | Medicaid | Replaced by CP.PMN.125 |
| CP.PST.13 pramlintide (Symlin®) | Retire | Medicaid | Replaced by CP.PMN.129 Pramlintide (Symlin®) |

Based on Q2 P&T 2018