CENTENE PHARMACY THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 MARKETPLACE/AMBETTER SUMMARY TABLE

Coverage Guideline/Policy & Procedure	Status	Revision Summary Description
HIM.PA.49 lacosamide (Vimpat)	Revised	Converted to new template. Added max dose. Updated references.
HIM.PA.50 isotretinoin (Claravis, Sotret, Amensteem, Myorisan)		Converted to new template. Added specific brand agents based on the Ambetter 2017 formulary. Added specific topical preparations needed for trials and examples of oral antibiotics that can be used per AAD.
HIM.PA.51 oral bisphosphonates	Revised	Converted to new template. Osteoporosis: removed requirement for alendronate plus vitamin D, member must be unable to take alendronate and vitamin D as 2 separate tablets. If this is the medication prescribed, the member should be able to receive it if all other criteria are met. Paget's disease continued therapy: added that member has had a medication-free period of 60 days per Actonel PI. Added member has evidence of relapse or failure to normalize serum alkaline phosphate per PI. Paget's disease changed approval duration to 2 months per Actonel PI.
HIM.PA.53 glucagon-like peptide-1 agonoists (GLP01 Agonists)	Revised	Removed age restriction. Modified A1c requirement from > 7% to > 6.5% and specified time frame for lab. Added specific dose and duration for metformin trial. Clarified criterion for failure of other anti-diabetic agents to specifically require a sulfonylurea and pioglitazone be used concurrently with metformin for 3 consecutive months. Removed criterion regarding concurrent insulin use as it is not an absolute contraindication. Modified initial approval duration from 12 months to 6 months to allow for earlier assessment of therapeutic response. Added criteria surrounding required therapeutic response for re-auth.
HIM.PA.54 celecoxib (Celebrex)	Revised	Converted to new template. Added max dose information. Added abbreviations in appendix A. Updated references
HIM.PA.55 aspirin dipyridamole	Revised	Removed requirement for diagnosis of stroke to have been made by a neurology specialist or in consult with a neurologist or vascular specialist as other specialties can diagnose stroke (plus, documentation to support diagnosis is now required per new template). Modified stroke diagnosis criteria to exclude the word "recent" as 1) there is no defined time frame for recent and 2) antiplatelet therapy is indicated for secondary prevention in all stroke patients regardless of when the stroke occurred. Added age limit since aspirin is unsafe to use in pediatric patients due to risk of Reye's syndrome.
HIM.PA.56 topical immunomodulators	Revised	Converted to new template and updated the name of the policy to reflect the only drug referenced in the policy.
HIM.PA.57 modafinil (Provigil)	Revised	Converted to new template. OSA, narcolepsy, and MS-related fatigue: added requirements for diagnosis and age per PI-serious skin rashes, including erythema multiforme major (EMM) and Stevens-Johnson Syndrome (SJS) have been associated

		with modafinil use in pediatric patients; added max dose; narcolepsy: modified duration of trial for stimulant(s) from 2 months to 1 month; added criteria for shift work disorder; MS –fatigue: added doses for amantadine and methylphenidate trials and specified that one of the trials must be within the last 6 months; Updated references.
HIM.PA.58 dipeptidyl peptidase-4 (DDP-4) inhibitors	Revised	Added criteria for diagnosis of type 2 diabetes mellitus. Removed age restriction. Removed criteria regarding suboptimal glycemic control as failure of metformin would include suboptimal glycemic control. Added specific dose and duration for metformin trial. Added requirement for failure of a formulary DPP-4. Added max dosing criteria.
HIM.PA.59 atypical antipsychotics	Revised	Removed requirement of medication being prescribed by a mental health provider. Added aripiprazole as a formulary atypical antipsychotics that can be trialed for schizophrenia. Changed trial from failure of 3 atypical antipsychotics to 2 for schizophrenia. Removed age from bipolar disorder, as age is not an absolute contraindication. Add max dose and updated references
HIM.PA.60 ezogabine (Potiga)	Revised	Converted to new template. Removed age restriction since it is not an absolute contraindication or contained in the black box warning per PI. Removed safety requirement related to vision assessment. Added max dose. Updated continuation criteria to allow for continuity of care. Updated references.
HIM.PA.61 desmopressin acetate (DDAVP)	Revised	Converted to new template. Updated references. Removed age limits as age is not an absolute contraindication.
HIM.PA.62 aprepitant (Emend)	Revised	Converted to new template. Added max doses.
HIM.PA.63 famciclovir (Famvir)	Revised	Converted to new template. Removed age restriction as it is not an absolute contraindication per FDA labeling. Added max dosing criteria. Added references.
HIM.PA.64 pregabalin (Lyrica)	Revised	Converted to new template. Diabetic peripheral neuropathy: removed anticonvulsants and tramadol from list of acceptable trials as they are not highly recommended first line agents Postherpetic neuralgia: removed opioids (e.g., morphine, methadone), tramadol, and capsaicin cream from list of acceptable trials to enforce the use of the most recommended first line agents and to avoid promoting opioid use. Partial onset seizures: removed 3 month duration from gabapentin trial as anticonvulsant regimens are individualized based on patient response and patient concomitant therapy. Fibromyalgia: removed fluoxetine as an accepted trial due to lack of sufficient evidence that it works. Replaced requirement for trial of Savella (tier 2 like Lyrica and

		requires PA) with duloxetine (tier 1) as duloxetine is generic, can be obtained without a PA, and is an SNRI that is FDA approved for fibromyalgia, similar to Savella Spinal cord nerve pain: removed tramadol and opioids from list of acceptable trials as these are second line agents and to avoid promoting opioid use. For all indications except partial onset seizures: added 30-day trial durations of all agents at up to maximally indicated doses. Trial duration and maximum indicated dosing is not required for partial onset seizures as anticonvulsant dosing is individualized based on patient response and patient concomitant therapy. Removed age restriction for all indications as they are not absolute contraindications per FDA labeling. Partial seizures: added other formulary anticonvulsants indicated for partial seizures to list of acceptable trials for partial. Added COC. Added max doses for all indications. Updated references.
HIM.PA.66 atomoxetine (Strattera)	Revised	Converted to new template. Modified criterion related to failure of 2 formulary stimulants to specifically require one from each class (amphetamine and methylphenidate). Added max dose to initial and re-auth. Removed requirement that atomoxetine will be used as mono-therapy. Updated references.
HIM.PA.67 febuxostat (Uloric)	Revised	Converted to new template. Removed age requirement as it is not an absolute contraindication per FDA labeling. Removed requirement for demonstrated adherence and added requirement for documentation of positive response upon re-auth.
HIM.PA.68 rifaximin (Xifaxan)	Revised	Removed age requirement as age is not an absolute contraindication for all diagnoses. For travelers' diarrhea: added levofloxacin as a trial option and removed BID dosing for azithromycin per IDSA. For traveler's diarrhea: removed Patient does not exhibit symptoms of severe or systemic bacterial infection, including fever and bloody stools (i.e. invasive infection); For hepatic encephalopathy: Removed "Documented adherent use of lactulose at dosing of 30-45 ml 3 to 4 times daily. Dosage should be titrated to produce 2 to 3 soft formed stools daily, unless contraindicated or not tolerated." Replaced with general statement of use at the max indicated dose. For hepatic encephalopathy: Removed "Concurrent use of lactulose at adequate dosing in the past 90 days (as evidenced by claims history)" replaced with use of lactose in the past 30 days per IDSA. Updated approval duration to 6 months. For IBS: Patient must meet Rome III diagnostic criteria for IBS.
HIM.PA.69 sodium oxybate (Xyrem)	Revised	Converted to new template. Narcolepsy with cataplexy: removed requirements related to trial and failure of stimulants and armodafinil/modafinil since these agents used to treat excessive sleepiness have little effect on cataplexy per American Academy of Sleep Medicine report; modified criteria to require trial and failure of 2

		antidepressants, instead of 1 for cataplexy. Narcolepsy with EDS: modified criteria to require failure of one CNS stimulant at up to maximally indicated doses instead of 2 stimulants, one from each class (amphetamine and methylphenidate) since modafinil and Xyrem are recommended as standard therapy per guideline. Updated references.
HIM.PA.71 topical acne treatments	Revised	Converted to new template.
HIM.PA.73 inhaled corticosteroids	Revised	Converted to new template. Added max dosages for Alvesco and Pulmicort Respules. Removed Pulmicort Flexhaler from policy as it no longer requires PA.
HIM.PA.74 Long-acting beta agonists and combination products	Revised	Removed trial duration per GOLD guideline 2017 update which recommends follow-up within 1-4 weeks (vs 4-6 weeks in the 2016 guidelines).
HIM.PA.75 levalbuterol (Xopenex)	Revised	Converted to new template. Updated clinical policy title to reflect only levalbuterol HFA inhaler since PA was removed off of levalbuterol inhalation solution per formulary; removed diagnosis; added requirement related to hypersensitivity to albuterol/levalbuterol; re-auth: added a requirement that albuterol HFA has not been used within the past 3 months; added QL per formulary; updated references.
HIM.PA.78 emtricitabine; tenofovir (Truvada)	Revised	Converted to new template. Added max doses to initial approval criteria. The CDC recommends those with a high number of sex partners should receive pre-exposure prophylaxis therefore added Not in a monogamous partnership to criteria. Updated references.
HIM.PA.79 lubiprostone (Amitiza)	Revised	Converted to new template. Added FDA Approved Indications. Added Limitation of Use. Removed requirement of female gender for Irritable Bowel Syndrome with Constipation (IBS-C) as it is not an absolute contraindication. Per PI insufficient to determine whether men with IBS-C respond differently to Amitiza from women. Added requirement of a trial of one bulk forming laxative for IBS-C per ACG recommendation that fiber provides overall symptom relief in IBS. Opioid-Induced Constipation: Changed requirement of concurrent use of docusate and bisacodyl as well as use of docusate and lactulose to a trial of a simulant laxative, osmotic laxative, or stool softener. Per Pergolizzi stimulant laxatives can be used as monotherapy.
HIM.PA.81 Risperidone ODT, Risperidone M tab, Risperidone Solution	Revised	Converted to new template. Initial: added requirement for diagnosis; modified "documented inefficacy of, contraindication or intolerability to regular release tablets" to inability to use regular risperidone tablets; added generalized max dose statement per relevant indication; re-auth: modified to allow continuity of care; added max dose. Updated references.
HIM.PA.85 dolasetron (Anzemet)	Revised	Converted to new template Added FDA approved indication

		Changed requirement of a trial of both ondansetron and granisetron to a trial of one or the other. The American Society of Clinical Oncology clinical practice guideline states that there is equivalency between ondansetron and granisetron.
HIM.PA.86 tapentadol (Nucynta)	Revised	Converted to new template.
HIM.PA.87 topical testosterone	Revised	Converted to new template. Added testosterone enanthate injection as a trial option.
HIM.PA.89 rasagiline (Azilect)	Revised	Converted to new template. Initial: added requirements for diagnosis and max dose/QL; re-auth: added max dose. Updated references.
HIM.PA.90 rufinamide (Banzel)	Revised	Converted to new template. Added prescriber specialty; removed continuity of care from initial approval section and incorporated it in the continuation criteria; added max dose. Updated references.
HIM.PA.93 nasal steroids	Revised	Converted to new template. Updated policy name from "Nasal Steroids" to mometasone (Nasonex) since generic budesonide (Rhinocort Aqua) no longer requires a PA per formulary; added max dose. Updated references.
HIM.PA.94 armodafinil (Nuvigil)	Revised	Converted to new template; modified age requirement from greater than 17 years to ≥ 17 years (pediatric patients defined as age < 17 years) per PI; changed initial approval duration from 6 to 12 months (to be consistent with Provigil criteria); modified duration of stimulant trial for narcolepsy to 1 month; MS-fatigue: added doses for amantadine and methylphenidate trials and specified that one of the trials must be within the last 6 months; updated references.
HIM.PA.95 telbivudine (Tyzeka)	Revised	Converted to new template.
HIM.PA.97 long-acting opioids	Revised	Converted to new template.
HIM.PA.98 guanfacine ER (Intuniv)	Revised	Converted to new template. Removed requirement that diagnosis of ADHD must be made by a pediatrician, family physician, or mental health provided; modified age restriction from 6-17 years to ≥ 6 years; modified stimulant trials by removing 1) extended release requirement and 2) trial duration of ≥ 2 weeks (with a titration to maximum dose, member would have trialed the medication for a sufficient timeframe); updated requirement related to immediate-release guanfacine trial to include "unless clinically significant adverse effects are experienced"; added once daily dosing requirement and max dose based on age per PI. Updated references.
HIM.PA.99 long acting injectable atypical antipsychotics	Revised	Converted to new template. Initial: added requirement for diagnosis; removed age restriction since not an absolute contraindication or carried within boxed warning per PI; added requirement that member does not have history of dementia-related

		psychosis per boxed warning; added max dose. Re-auth: modified to allow continuity of care; added max dose. Updated reference.
HIM.PA.103 Brand Name Override and Non-formulary medication policy	Revised	Converted to new template, added maximum dose criteria.
HIM.PA.107 cysteamine (Cystaran)	New	Policy created.
HIM.PA.108 isavuconazonium (Cresemba)	New	Policy created.
HIM.PA.109 Step Therapy	New	Policy created.
HIM.PA.SP1 sofosbuvir velpatasvir (Epclusa)	Revised	Removed age, as age is not an absolute contraindication.
HIM.PA.SP2 sofosbuvir (Sovaldi)	Revised	Added pediatric chronic hepatitis C infection criteria; Removed HCV RNA is not present or, if present, has not increased by >10 fold (>1 $\log_{10}$ IU/mL) per specialist feedback.
HIM.PA.SP3 ledipasvir sofosbuvir (Harvoni)	Revised	Added pediatric (≥12 years or ≥35 kg) indication expansion for genotype 1,4,5,6. Updated contraindications. Allowed full therapy regimen at initial approval duration.
HIM.PA.SP5 Lynparza	New	Policy created.
HIM.PA.52 Aromatase Inhibitors	Retire	Policy no longer needed.
HIM.PA.70 zileuton (Zyflo)	Retire	Policy no longer needed.
HIM.PA.76 lovastatin; niacin (Advicor) and simvastatin;niacin (Simcor)	Retire	Policy no longer needed.