Pharmacy Prior Authorization
GMH/SU and Non-Title 19/21 SMI
Non-Formulary and Prior Authorization Guidelines

Scroll down to see PA Criteria by drug class, or Ctrl+F to each document by drug name

Guideline or Policy Title	Authorization Requirements/Criteria	Duration of Approval if Requirements Are Met
Brand Name Medication Requests	Mercy Care requires use of generic agents that are considered therapeutically equivalent by the FDA. For authorization of a brand name medicationplease submit a copy of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulationsmade by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf	**Initial Approval:** One year
Quantity Level Limits	Requests that exceed established Quantity Level Limits will require prior authorization Drugs subject to additional utilization management requirements (for example, non-formulary, clinical prior authorization, and step therapy) must meet clinical criteria and medical necessity for approval, in addition to any established Quantity Level Limit Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review **Authorization Criteria for Quantity Limit Exceptions:** • **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:** o Member is tolerating medication with no side effect, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence o Request meets one of the following: ▪ Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication ▪ Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request • **Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):** o Request meets one of the following:	**Initial Approval:** One year **Renewal Approval:** One year

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	▪ There was inadequate response or intolerable side effect to optimized dose ▪ There is a manufacturer shortage on higher strengths ▪ Member is unable to swallow tablet/capsule due to size, and cannot be crushed ▪ Effect of medication is wearing off between doses ▪ Member cannot tolerate entire dose in one administration • **Quantities for Medications that <u>do not</u> have Established Food and Drug Administration (FDA) Maximum Dose:** o Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence o Requested dose is considered medically necessary	
Non-Formulary Medication Guideline	**Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:** • Appropriate diagnosis/indication for requested medication • Appropriate dose of medication based on age and indication • Member meets one of the following: o Documented trial of all formulary medications in the same therapeutic class for adequate duration has not been effective or tolerated o All other formulary medications are contraindicated based on member diagnosis, other medical conditions or other medication therapy o There are no other medications available on the formulary to treat member condition • For combination drug product requests: o Documented reasoning that combination product is clinically necessary and not just for convenience Note: Patient medication trials and adherence are determined by review of pharmacy claims data over	**<u>Hospital Discharge</u>:** 14 Days **<u>Initial Approval:</u>** Six months or lesser of requested duration based on course of therapy **<u>Renewal Approval:</u>** One year or lesser of requested duration based on course of therapy ***Requires:*** • Documentation of

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	preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review. **Off-Label and Orphan Drugs can be approved when the following criteria is met:** • Prescribed by physician treating a chronic, disabling, or life-threatening disease • The drug has been approved by the Food and Drug Administration (FDA) • Documentation of trial and failure, intolerance or contraindication to Food and Drug Administration (FDA) approved medications (formulary and non-formulary) for same indication, if available • The drug is listed in any of the following standard drug reference compendium as accepted for off-label use o The United States Pharmacopoeia Drug Information o National Comprehensive Cancer Network o American Hospital Formulary Service Drug Information o Thomson Micromedex DrugDex o Clinical Pharmacology	positive response to therapy
Attention-deficit Hyperactivity Disorder (ADHD) medications for children under 6 years old[i] Stimulants (amphetamines,	**Food and Drug Administration (FDA) Approved Indication:** Treatment of Attention Deficit Hyperactivity Disorder (ADHD) **Guidelines for Approval:** • The requesting clinician has documented that the child has a diagnosis of Attention-deficit Hyperactivity Disorder (ADHD) • Psychosocial issues and non-medical interventions are being addressed by the clinical team. • Documentation of psychosocial evaluation occurring before request for Attention-deficit Hyperactivity Disorder (ADHD) medications. • Documentation of non-medication alternatives that have been attempted before request for	**Hospital Discharge:** 14 days **Initial Approval:** 6 months **Renewal Apprval:** 12 months

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methylphenidate) Strattera guanfacine ER Kapvay Clonidine ER	Attention-deficit Hyperactivity Disorder (ADHD) medications. **Coverage is <u>Not Authorized</u> for:** • Indications other than Attention-deficit Hyperactivity Disorder (ADHD) • Doses greater than Food and Drug Administration (FDA) recommended maximum daily dosage. Provider can submit a prior authorization with the clinical justification for doses exceeding the Food and Drug Administration (FDA) maximum.	
Antidepressant medications in children under 6 years old[ii]	**Guidelines for Approval:** Child has one of the following diagnosis per current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria: o Major Depressive disorder (MDD) o Obsessive Compulsive disorder (OCD) o Generalized Anxiety disorder (GAD) • Psychosocial issues and non-medical interventions are being addressed by the clinical team. o Documentation of interventions tried, date and duration of trial and why interventions were not successful • Documentation of psychosocial evaluation occurring before request for antidepressant medications. • Documentation of non-medication alternatives that have been attempted to address symptoms before request for antidepressant medications. • Documentation must include information on the expected outcomes and an evaluation of potential adverse events. • Member will continue with psychosocial treatment while on antidepressant mediation **Coverage is <u>Not Authorized</u> for:** • Use of medication without psychosocial treatment • Concomitant use of tricyclic antidepressants (TCAs) with other antidepressants	**<u>Hospital Discharge:</u>** 14 days **<u>Initial Approval:</u>** 6 months **<u>Renewal:</u>** 6 months ***Requires:*** Discontinuation trial after 6-9 months of medication with gradual downward taper OR clinical documentation/reasoning for continuation of therapy.

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	Dosing recommendation: Major Depressive disorder (**MDD):** • Fluoxetine for 4 to 5 years old • Max dose: 5mg/day Generalized Anxiety disorder (**GAD):** • Fluoxetine: 8-10 week trial if well tolerated starting at 1 to 2mg/day • Max dose: 5 to 10 mg/day • Sertraline can be considered if failure with fluoxetine **Obsessive Compulsive disorder (OCD)** • Fluoxetine: 10-12 weeks trial if well tolerated starting at 2.5 to 5mg/day • Max dose: 15-20mg/day	
Antipsychotic – Antimanic medications in children under 6 years old[iii]	**Food and Drug Administration (FDA) Approved Indication:** With the exception of risperidone, antipsychotics have not been approved for use in children less than 6 years old. There are few randomized controlled trials to demonstrate safety and efficacy in this population. **Guidelines for Approval:** • Child diagnosed, per current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria, with one of the following disorders: o Bipolar Spectrum Disorder o Schizophrenic Spectrum Disorder o Tourette's or other tic disorder o Autism Spectrum Disorder • Psychosocial issues and non-medical interventions are being addressed by the clinical team. • Documentation of psychosocial evaluation occurring before request for antipsychotic medications. • Documentation of non-medication alternatives that have been attempted to address symptoms before	**Hospital Discharge:** 14 days **Initial Approval:** 6 months **Renewal Approval:** 12 months

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	request for antipsychotic medications. • Documentation must include information on the expected outcomes and an evaluation of potential adverse events. **Coverage is <u>Not Authorized</u> for:** • Members with known hypersensitivity to requested agent. • Members not meeting above stated criteria.	
Buprenorphine	**Guidelines for Approval:** • Member is pregnant or breast feeding **Coverage Limitations:** Opioid dependence products are subject to quantity limitations determined by the maximum bioequivalent amount of buprenorphine allowed per day: • Buprenorphine 2mg – 12 tablets per day • Buprenorphine 8mg – 3 tablets per day	**<u>Hospital Discharge:</u>** 14 days **<u>Initial Approval:</u>** 1 year **<u>Renewal Approval:</u>** 1 year ***Requires:*** Coverage criteria continues to be met
Clozapine Under Age 18	**Guidelines for Approval:** • Patient has a clear diagnosis of Schizophrenia or Schizoaffective Disorder that was determined after a detailed psychiatric evaluation by a child and adolescent Behavioral Health Medical Provider (BHMP) to include full family, psychiatric and medical history, full medical and psychiatric review of systems and complete MSE. • Psychosis is not better accounted for by other diagnoses including severe PTSD, substance induced psychosis, bipolar disorder, neurologic condition or hypnogogic hallucinations and is persistent in the	**<u>Hospital Discharge:</u>** 14 days **<u>Initial Approval:</u>** 3 months **<u>Renewal Approval:</u>**

Guideline or Policy Title	Authorization Requirements/Criteria	Duration of Approval if Requirements Are Met
	absence of stressors. • Targeted treatment goal must be psychosis only. Requests for targeting other symptoms including aggression or conduct symptoms will not be authorized. The targeted treatment goal must be presented for approval and progress presented for continued authorization. • Patient has previously tried and had an inadequate response with at least 1 other formulary antipsychotic medications at maximum tolerated doses. o The BHMP has evaluated and determined that medication non-adherence is not the reason for the inadequate response to maximum tolerated doses o The BHMP has ruled out a non-response due to an unrecognized or under-treated co-morbid disorder. • Informed consent and youth assent must be obtained prior to initiation • If youth is inpatient; Acute or BHIF, consultation with outpatient BHMP and CFT must occur to ensure consensus and the ability to consistently follow required lab assessment protocol to ensure safety and continuity of care. • Baseline laboratory studies must be completed prior to initiation of medication • BHMP must be enrolled in REMS program	6 months ***Requires:*** • Improvement in psychosis • Continued follow-up of labs per protocol • Documentation of member adherence and tolerability
Concomitant Antidepressant Treatment[iv]	**Approved Indication:** Treatment Resistant Depression and Obsessive Compulsive Disorder (clomipramine with fluvoxamine). For other uses, please submit the required prior authorization and supporting documentation. These shall be processed in conjunction with the AHCCCS Medical Policy Manual Policy 310-V. **Special Considerations:** • Cross tapers may be approved for up to 60 days. Providers must submit a prior authorization request for continued utilization past 60 days for dual antidepressant therapy (excluding trazodone, mirtazapine, and bupropion) in the following combinations:	**Hospital Discharge:** 14 days **Initial Approval:** • 6 months for non-cross taper • 60 days for <18 years of age

Guideline or Policy Title	Authorization Requirements/Criteria	Duration of Approval if Requirements Are Met
	o Two SSRIs o An SSRI in combination with an SNRI o Two SNRIs o An SNRI in combination with atomoxetine o Two Tricyclics (TCAs) o A TCA with an SSRI/SNRI **Guidelines for Approval:** • Approval will be granted when a member who is 18 years of age or older is cross-tapering while transitioning from one medication to another over the course of 60 days. • Evidence of adequate trials of at least three (3) individual antidepressant agents listed on the AHCCCS Behavioral Health Drug List, from at least two (2) different therapeutic classes, for 4-6 weeks at maximum tolerated doses and failure is due to: o An inadequate response at maximum tolerated doses, o Adverse reaction(s), or o Break through symptoms. **Additional Requirements:** • Attestation if 2 different prescribers are prescribing that coordination of care has occurred • Provider must provide supporting documentation that: o Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials; AND o Appropriate clinical monitoring of target symptoms, adverse reactions including but not limited to signs and symptoms of serotonin syndrome, adherence to treatment, suicide risk, heart rate, blood pressure, and weight has been completed; AND o Appropriate clinical monitoring has been completed for TCAs, which includes but is not limited to,	**Renewal:** • 1 year • 60 days for <18 years of age

Guideline or Policy Title	Authorization Requirements/Criteria	Duration of Approval if Requirements Are Met
	TCA levels and/or an ECG at baseline and follow up. **Coverage is <u>Not Authorized</u> for:** • Members with known hypersensitivity to the requested agent(s) • Members not meeting the above stated criteria • Members currently taking an MAOI medication • Members with significant polypharmacy or concomitant psychiatric/medical co-morbidities that have a potential for adverse effects • Members on medication combinations, doses, or for identified indications that do not meet published practice guidelines or treatment protocols • Members on medication regiments that do not have adequate safeguards or monitoring to ensure safety and reasonable expectation of response to regimen	
Concomitant Antipsychotic Treatment[v]	**Approved Indications:** Treatment refractory Schizophrenia spectrum disorders or Bipolar disorder, with psychosis and/or severe symptoms **Special Considerations:** Cross tapers should be approved for 60 days when the member is 18 or older and for 30 days when the member is 17 or younger. Providers must submit a prior authorization request for continued concomitant use of any two antipsychotics beyond the 30 or 60 days allowed for cross tapering. **Guidelines for Approval for refractory schizophrenia spectrum disorder:** • Evidence of adequate trials of at least three (3) individual antipsychotics listed on the AHCCCS Behavioral Health Drug List for 4-6 weeks of maximum tolerated doses, and failure is due to: o Inadequate response to maximum tolerated dose o Adverse reaction(s), o Break through symptoms	**<u>Hospital Discharge:</u>** 14 days **<u>Initial Approval:</u>** • 6 months for non-cross taper • 60 days for less than18 years of age • Cross Taper: o Age less than 18: 30 days o Age greater than or equal to 18: 60

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	Guidelines for Approval for refractory bipolar disorder with psychosis and/or severe symptoms: • Evidence of adequate trials of at least four (4) evidence based treatment options dependent upon the episode type. Trials may include, but are not limited to, combination therapy of antipsychotics and mood stabilizers and/or anticonvulsants. Trials should be 4-6 weeks of maximum tolerated doses, with failure due to: o Inadequate response to maximum tolerated dose o Adverse reaction(s), o Break through symptoms **Additional Requirements:** Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials. Provider should provide attestation that care coordination has occurred if more than 1 prescriber. **Coverage is <u>Not Authorized</u> for:** • Members with known hypersensitivity to requested medication(s). • Prior Authorization Requests not meeting the above stated criteria.	days **<u>Renewal Approval:</u>** • 1 year • 60 days for less than 18 years of age
Long Acting Antipsychotic Injectables Under 18 years of age[vi] Fluphenazine Decanoate Haloperidol Decanoate	**Continuity of Care will be allowed for the following conditions:** o Members started on an antipsychotic during a recent hospitalization will receive a 60-day approval o Medication must be prescribed for a Food and Drug Administration (FDA) approved indication and dosing **May be authorized when all of the following criteria are met:** o Member is between the ages of 16 and 18 o Diagnosis of a Food and Drug Administration (FDA) approved indication: • Schizophrenia / Schizoaffective Disorder • Bipolar I (Risperdal Consta, Abilify Maintena)	**<u>Initial Approval:</u>** 1 year **<u>Renewal Approval:</u>** 1 year ***Requires*:** • Metabolic screening within the last 60 days

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Invega Sustenna Invega Trinza Abilify Maintena Aristada Risperdal Consta	• Documentation that member has received the recommended oral dosage (per Food and Drug Administration (FDA) approved labeling) to confirm tolerability and efficacy • Member had non-adherence to oral antipsychotic medications which places member at risk for poor outcomes • Will not receive concurrent oral antipsychotics after the initial overlap period (per Food and Drug Administration (FDA) approved labeling) • Provider agrees to support baseline and routine monitoring of all the following: • Weight, body mass index (BMI), or waist circumference • Blood pressure • Fasting glucose • Fasting lipid panel • Tardive dyskinesia ▪ Using the Abnormal Involuntary Movement Scale (AIMS) or ▪ Dyskinesia Identification System Condensed User Scale (DISCUS) o For Abilify Maintena and Invega Trinza only: Not taking a Cytochrome P450 3A4 (CYP3A4) inducer **<u>Additional Drug Specific Criteria</u>** **Invega Trinza**: • Trial of stable dose of Invega Sustenna for 4 months	
Lucemyra[vii] **(lofexidine)**	**May be authorized when the following criteria are met:** • Member is 18 years of age or older • Symptoms of opioid withdrawal are experienced due to abrupt opioid discontinuation • Opioids have been discontinued	**<u>Initial Approval</u>**: 14 days per episode of treatment (224 total tablets)

Guideline or Policy Title	Authorization Requirements/Criteria	Duration of Approval if Requirements Are Met
	• Member meets one of the following criteria: o Trial and failure, or contraindication to clonidine, or member has a clinically significant adverse effect o Medication was initiated in an inpatient setting • Member is on a behavioral modification plan for substance abuse counseling (psychosocial support) • Member is not currently taking benzodiazepines, alcohol, barbiturates, or other sedating agents	**Dosing**: Three 0.18 mg tablets taken orally four times daily for 7 days Approvable for a maximum of 224 tablets per 14-day supply for a 1-month period **Quantity Level Limit (QLL)**: Maximum dose 0.72 mg/dose (4 tablets) or 2.88 mg/day (16 tablets per day) or 224 tablets
Monoamine Depletors[viii] Ingrezza Austedo	**Medical Records required for all Indications** **Tardive Dyskinesia (Ingrezza, Austedo)** • Member is 18 years of age or older • Diagnosis of moderate to severe tardive dyskinesia • Prescribed by, or in consultation with a neurologist or psychiatrist • Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6 • Provider has attempted an alternative method to manage condition o For example, dose reduction, discontinuation of offending medication, or switching to alterative agent such as atypical antipsychotic	**Initial Approval:** 3 months **Renewal Approval:** 6 months **Tardive Dyskinesia** ***Requires:*** • Documentation of improvement in AIMS score (decrease from

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	▪ Documentation of atypical antipsychotic used ▪ Time frame of stability on the atypical antipsychotic **Additional Criteria for Austedo:** • Member does not have any of the following: o Hepatic dysfunction o Active suicidal thoughts or behaviors o Untreated or undertreated depression o Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval **Additional Criteria for Ingrezza:** • Member does not have any of the following: o Active Suicidal thoughts and behaviors o Untreated or undertreated depression o Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval	baseline by at least 2 points). • Provider is monitoring for all the following: o Emergent or worsening depression o Suicidal thoughts and behaviors o EKG, for members at risk for QT prolongation o Hepatic dysfunction (for Austedo only) **Quantity Level Limits:** • Ingrezza 30/30 • Austedo 120/30
Nuedexta[ix]	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Diagnosis of pseudobulbar affect (PBA) • Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA) o Cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example,	**Initial Approval:** 3 months **Renewal:** 1 year

Guideline or Policy Title	Authorization Requirements/Criteria	Duration of Approval if Requirements Are Met
	Center for Neurologic Study-Lability Scale (CNS-LS) ≥ 13, The Pathological Laughter and Crying Scale (PLACS) ≥ 13) • Member does not have any contraindication to therapy (for example, QT prolongation, Atrioventricular (AV) block or currently on monoamine oxidase inhibitor (MAOI) therapy)	***Requires***: Documentation to support the following: • Decreased pseudobulbar affect (PBA) episodes
Spravato (esketamine)	https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy	

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