



Drug Use Evaluation: Low Dose Quetiapine

Plain Language Summary:

- Quetiapine is a medicine prescribed for many different mental health conditions.
 - Quetiapine can help improve mood and quality of life in people with bipolar disorder or schizophrenia.
 - Quetiapine tablets that provide medicine coverage for an entire day (called extended-release tablets) may also improve anxiety or depression.
 - Some providers also prescribe low doses of quetiapine to improve sleep.
- Quetiapine can have serious long-term side effects, and the risks of treatment may not be worth it in most people.
- The Oregon Health Plan (OHP) currently requires prescribers to provide information to the Oregon Health Authority (OHA) on why a low dose of quetiapine is needed. This process is called prior authorization.
- OHP commonly approves pharmacy claims for low dose quetiapine without delay for:
 - o people who have been prescribed other antipsychotic medicines
 - people who have a diagnosis of schizophrenia or bipolar disorder
 - people with prescriptions from a mental health provider
- Under the current policy, there are delays in pharmacy claims approval for:
 - people with depression or anxiety
 - o people who have been prescribed antidepressant medicines
- We recommend automatically approving extended-release quetiapine for people who are also prescribed an antidepressant for depression or anxiety.

Research Questions:

- What proportion of patients with claims for low dose quetiapine (<50 mg daily) have compendia-supported diagnoses?
- What proportion of patients with claims for low dose quetiapine are also prescribed other mental health medications?
- What proportion of patients are prescribed low dose quetiapine from a mental health specialist?

Conclusions:

Diagnoses in medical claims

- About 69% of people with claims for low dose quetiapine had an evidence-supported diagnosis in the 6 months before the first claim in the reporting period. The most common diagnoses included major depressive disorder (45%), generalized anxiety disorder (26%), bipolar disorder (26%), and schizophrenia (3%).
- About 5.5% of patients had a diagnosis indicating sleep disorders in the absence of another evidence-supported indication.

• Compared to people with diagnoses of bipolar disorder and schizophrenia, denied claims were more common for members with major depressive disorder and generalized anxiety disorder. Of members with denied claims, most had diagnoses for major depressive disorder (24%), generalized anxiety disorder (20%), or no evidence-supported diagnosis (58%).

Use of other mental health medications

- Members with claims for low dose quetiapine were commonly prescribed antipsychotics (76%), selective serotonin-reuptake inhibitors (SSRI) or serotonin norepinephrine-reuptake inhibitors (SNRI) (52%), other antidepressants (35%) and benzodiazepines (22%) in the 6 months prior to the first claim for low dose quetiapine in the reporting period.
- Nearly all patients (more than 99%) with an initial paid for low dose quetiapine had other paid claims for antipsychotics in the previous 6 months.
- Denied claims were more common for members with recent claims for an SSRI/SNRI or with no other prior claims for mental health drugs.
 - About 40% of members with denied claims had a recent claim for an SSRI or SNRI.
 - About 38% of members with denied claims had no prior claims for antidepressants, antipsychotics, benzodiazepines, or other bipolar medications.

Access to mental health prescribers

• Only 36% of members had low dose quetiapine prescribed by a mental health provider.

Recommendations:

- Update PA criteria for low dose quetiapine to incorporate GAD (Appendix 2).
- Automatically approve PA requests for extended-release quetiapine in members with recent claims for an SSRI or SNRI.
- Remove automatic approval for prescriptions for extended-release quetiapine when written by a mental health specialist. (Recommendation under further consideration until staff can evaluate potential impacts to access and barriers to care.)
- Make extended-release quetiapine tablets preferred.

Background:

Quetiapine is a second generation antipsychotic which is been approved by the Food and Drug Administration (FDA) for bipolar disorder, schizophrenia and as adjunct treatment for depression.^{1,2} Initial doses for someone starting therapy are as low as 50 mg daily and recommended doses range from 150 to 800 mg daily depending on the indication.¹ When starting treatment, dose adjustments can be made daily, and titration to the minimum recommended maintenance dose can be achieved within 2 to 5 days.¹ Low dose quetiapine (<150 mg) may be used off-label for a variety of conditions including insomnia, anxiety, obsessive compulsive disorder and dementia.² Because of significant safety concerns associated with long-term use and lack of evidence supporting efficacy, quetiapine is not recommended by current guidelines for treatment of insomnia. Quetiapine has also been associated with significant safety concerns including increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors in children and adolescents.^{1,2} Adverse effects documented with quetiapine also include:^{1,2}

- metabolic changes such as hyperglycemia, dyslipidemia, and weight gain;
- changes in thyroid hormones and prolactin levels;
- changes in blood pressure and increased risk of falls;
- extrapyramidal symptoms and tardive dyskinesia;
- anticholinergic effects such as urinary retention, sedation, and constipation; and
- development of cataracts with long-term use.

However, recent algorithms from the Mental Health Clinical Advisory Group document note that quetiapine extended-release tablets may have benefit when used as adjunctive to an SSRI or SNRI for adults with generalized anxiety disorder who have failed to have benefit with multiple trials of SSRI or SNRI monotherapy. Consultation with a mental health provider is recommended when considering adjunct use of quetiapine for generalized anxiety disorder. Previous drug use evaluations documented that most Medicaid members without an FDA-approved diagnosis present in medical claims were prescribed quetiapine at a dose of less than or equal to 50 mg daily. Currently, prescriptions for low dose quetiapine (≤50 mg daily) require prior authorization (PA) to discourage off-label use for sleep conditions for which risks outweigh benefits. Patients with diagnoses of schizophrenia, bipolar disorder, history of use for a second-generation antipsychotic, or prescriptions written by a mental health specialist can be automatically approved. This drug use evaluation examines utilization patterns with the current low dose quetiapine safety edit and explores how criteria could be modified to minimize administrative barriers for appropriate populations.

Methods:

Patients were identified for inclusion based on paid or denied FFS claims for quetiapine (First Databank HICL sequence number [HSN] 014015). The evaluation window for quetiapine claims was from 7/1/2021 to 06/30/2022. The index event (IE) was defined as the first paid or denied claim for quetiapine in the evaluation window. For each patient, the baseline and follow-up periods were defined based on the IE.

- The baseline period was defined as the 6 months prior to the IE (exclusive of the IE).
- The follow-up period was defined as the 3 months after the IE (inclusive of the IE)

Patients were categorized into the following groups based on the IE and claims for quetiapine in the follow-up period:

- (1) patients with a claim that was initially paid or paid within one day of the IE (i.e., the day after the IE).
- (2) patients with denied claims where there was a subsequent claim paid within 2-90 days following the IE or where there was no subsequent paid claim in the following 90 days.

Inclusion criteria:

- At least one paid or denied FFS claims for quetiapine during the evaluation window. Denied claims were included if they were associated with error codes of 3002 "NDC requires PA" or 3000 "units exceed authorized units on PA master file" without any of the error codes listed in **Appendix 1**.

Exclusion criteria:

- Patients with daily dose greater than 50 mg on the IE. Any claims for the dose pack (First Databank generic sequence number [GSN] 074076), which includes tablets of multiple strengths and is commonly used for titration, were classified according to the highest dose tablet (300 mg per tablet).
- Patients with Medicare part D coverage or limited or no Medicaid drug benefit in the baseline period

Category	Benefit Package	Description
Medicare Part D coverage	BMM	Qualified Medicare Beneficiary + Oregon Health Plan with Limited Drug
	BMD	Oregon Health Plan with Limited Drug
	MED	Qualified Medicare Beneficiary
Limited or no Medicaid drug benefit	MND	Transplant package
	CWM	Citizenship Waived Emergency Medical
	SMF	Special Low-Income Medicare Beneficiary Only
	SMB	Special Low-Income Medicare Beneficiary Only

- Patients with primary insurance coverage (i.e., third party liability [TPL]) in the baseline period
- Patients with non-continuous Medicaid enrollment in the baseline period
- Patients with non-continuous Medicaid enrollment in the follow-up period

Outcomes:

- Proportion of patients have an evidence-supported diagnosis for schizophrenia, bipolar disorders, major depressive disorder, or generalized anxiety disorder based on medical claims in the baseline period (**Appendix 1**).
- Proportion of patients who have paid claims (CCO or FFS) for other mental health drugs in the baseline period.
- Proportion of patients who have paid claims (CCO or FFS) for long-term therapy with mental health drugs (>90 covered days) in the baseline period
- Proportion of patients who have the IE prescribed by a mental health provider (identified by primary taxonomy listed in Appendix 1).

Results:

Table 1. Included patients

Number of included patients	#	%
Paid or denied FFS claim for quetiapine from 7/1/2021 to 06/30/2022	13,043	
After exclusion of IE with > 50 mg daily	5,053	38.7%
After exclusion of Medicare part D, limited benefit plans, and TPL	4,810	36.9%
After exclusion of non-continuous Medicaid enrollment in the baseline period	4,291	32.9%
After exclusion of non-continuous Medicaid enrollment in the follow-up period	4,226	32.4%

Table 2 includes demographics and basic drug information for people with paid or denied claims for low dose quetiapine. A total of 4226 people were included in this analysis and accounted for about 32% of people with claims for quetiapine. Of these patients, about 76% of members had an initial paid claim or claim paid within one day of an initial denial and 24% of members had a denied claim. About 63% of members were female, and almost 86% were adults 18 to 59 years of age. Five percent of claims were for children or adolescents less than 18 years of age. Immediate-release formulations of quetiapine accounted for 96% of initial claims. The dose per day for the first claim in the evaluation window was 26 to 50 mg per day for about 63% of members. Denied claims were slightly more common for members with doses lower than 25 mg daily. About 58% of members identified as white, 26% did not identify race to Medicaid, 7% identified as American Indian/Alaskan Native, and 9% included other racial groups.

Table 2. Demographics at the time of the IE

		Paid Claim (OR _paid within 1 day)		Initial Denied Claim Total		al
	3,216	76.1%	1,010	23.9%	4,226	%
Female	2,082	64.7%	590	58.4%	2,672	63.2%
Age – mean (range)	38	(5-94)	38	(7-91)	38	(5-94)

0-9	13	0.4%	7	0.7%	20	0.5%
10-17	179	5.6%	34	3.4%	213	5.0%
18-59	2,758	85.8%	873	86.4%	3,631	85.9%
>=60	266	8.3%	96	9.5%	362	8.6%
Dose						
<=25 mg/day	1,077	33.5%	479	47.4%	1,556	36.8%
26-50 mg/day	2,139	66.5%	531	52.6%	2,670	63.2%
Race						
White	1,879	58.4%	568	56.2%	2,447	57.9%
American Indian/Alaskan Native	220	6.8%	82	8.1%	302	7.1%
Other	269	8.4%	97	9.6%	482	8.7%
Unknown	848	26.4%	263	26.0%	995	26.3%
Formulation						
Immediate-release	3,091	96.1%	978	96.8%	4,069	96.3%
Extended-release	125	3.9%	32	3.2%	157	3.7%

About 69% of people with claims for low dose quetiapine had an evidence-supported diagnosis in the 6 months before the claim (**Table 3**). Diagnoses included 45% of members with major depressive disorder, 26% with generalized anxiety disorder, 26% with bipolar disorder, and 3% with schizophrenia. About 31% of members did not have a diagnosis supported by the evidence in the 6 months before the IE for low dose quetiapine. For people with and evidence-supported diagnosis in medical claims, almost 78% of members had an initial claim paid or paid within one day for low dose quetiapine. Initial paid claims were more common for people with diagnoses of schizophrenia and bipolar disorder (which are included in the auto-PA criteria), and denials were more common for members with diagnoses of major depressive disorder or generalized anxiety disorder. Of members with denied claims, most had diagnoses for major depressive disorder (24%), generalized anxiety disorder (20%) or no evidence-supported diagnosis (58%). Many patients had more than one diagnosis in medical claims making it difficult to determine the primary reason for the quetiapine prescription. Of the 1,010 members who had a denial, 328 (32%) had a subsequent paid claim in the 2-90 days after then initial denial (data not shown).

Diagnoses for insomnia and sleep disorders were present for only about 5% of people without an evidence-supported diagnosis. Denied claims were more common in this population, and of the 1,310 members without an evidence-supported diagnosis, and only 55% of members (n=720) had an initial paid claim.

	Paid clain paid within		Denied aim	Total		
	3,216	%	1,010	%	4,226	%
	_	_	-	-	-	
Evidence-supported diagnoses	2,496	77.6%	420	41.6%	2,916	69.0%
Major Depressive Disorder	1,671	52.0%	240	23.8%	1,911	45.2%

Table 3. Diagnoses in the 6 months before the IE

Generalized Anxiety Disorder * Bipolar Disorder * Schizophrenia	903 996 121	28.1% 31.0% 3.8%	199 97 6	19.7% 9.6% 0.6%	1,102 1,093 127	26.1% 25.9% 3.0%
None of the above (no evidence-supported diagnosis)	720	22.4%	590	58.4%	1,310	31.0%
Insomnia/circadian rhythm sleep disorders	90	2.8%	141	14.0%	231	5.5%
Dementia/delirium/Alzheimer's	25	0.8%	35	3.5%	60	1.4%
Parkinson's Disease	2	0.1%	3	0.3%	5	0.1%
Obsessive Compulsive Disorder	14	0.4%	7	0.7%	21	0.5%

*Incorporated in the auto-PA

Nearly all patients (>99%) with an initial paid claim for low dose quetiapine had paid claims for antipsychotics in the 6 months before the first claim for low dose quetiapine in the evaluation window (**Table 4**). This corresponds with the current PA policy to auto-approve requests if the member has prior history of antipsychotic use. All patients without an evidence-supported diagnosis in medical claims that had an initial paid claim for low dose quetiapine had claims for an antipsychotic in the previous 6 months. Although not included in the auto-PA, patients with history of lithium or divalproex also commonly had initial paid claims for low dose quetiapine regardless of diagnosis history. Just over half of members with claims for low dose quetiapine had claims for an SSRI/SNRI (52%). Denied claims were common in members with recent claims for an SSRI/SNRI; about 40% of members with denied claims had a recent claim for an SSRI or SNRI. A small proportion of patients (9.4%) had no recent claims for antipsychotics, antidepressants (including other antidepressants, SSRIs, or SNRIs), benzodiazepines or other bipolar disorder drugs. This group of members was likely to have denied claims and accounted for about 38% of members with denials.

To evaluate longer-term use of co-prescribed mental health medications, we examined utilization of medications dispensed for more than 90 days in the 6 months before the IE (**Table 4**). Compared to patients with any claim for other mental health drugs, a substantially smaller proportion of members had more than 90 covered days for antipsychotics (76% vs. 38%), SSRIs or SNRIs (52% vs. 37%), other antidepressants (35% vs. 22%), and benzodiazepines (22% vs. 5%). Utilization of other mental health medications is broken out by presence or absence of an evidence-supported diagnosis in **Table 5**. Utilization patterns for mental health medications were generally consistent, regardless of presence or absence of diagnoses in medical claims. Members with claims for low dose quetiapine were commonly prescribed antipsychotics or antidepressants in the previous 6 months for both populations.

Table 4. Patients with mental health medications prescribed in the 6 months before the IE

	Paid claim (OR paid within 1 day)		Initial Denied Claims		Total	
	3,216	76.1%	1,010	23.9%	4,226	%
Any paid claim	3,206	99.7%	622	61.6%	3,828	90.6%
* Antipsychotics (1 st gen, 2 nd gen, parenteral)	3,200	99.5%	11	1.1%	3,211	76.0%
Selective serotonin-reuptake inhibitors (SSRI) or serotonin norepinephrine-reuptake inhibitors (SNRI)	1,810	56.3%	400	39.6%	2,210	52.3%

Author: Servid

Other antidepressant	1,198	37.3%	301	29.8%	1,499	35.5%
Benzodiazepine	754	23.4%	183	18.1%	937	22.2%
Bipolar Disorder drug (lithium/divalproex)	297	9.2%	21	2.1%	318	7.5%
None of the above drug classes	10	0.3%	388	38.4%	398	9.4%
Paid claims for >90 covered days	2,385	74.2%	334	33.1%	2,719	64.3%
* Antipsychotics (1st gen, 2nd gen, parenteral)	1,597	49.7%	4	0.4%	1,601	37.9%
Selective serotonin-reuptake inhibitors (SSRI) or	1,330	41.4%	230	22.8%	1,560	36.9%
serotonin norepinephrine-reuptake inhibitors (SNRI)						
Other antidepressant	773	24.0%	139	13.8%	912	21.6%
Benzodiazepine	208	6.5%	9	0.9%	217	5.1%
Bipolar Disorder drug (lithium/divalproex)	172	5.3%	21	2.1%	193	4.6%

*Incorporated in the auto-PA

Table 5. Patients with other therapy mental health drugs prescribed in the 6 months before the IE (any paid claim)

.,	Paid claim (OR paid within 1 day)		Initial Denied Claims		, Total	al	
	3,216	76.1%	1,010	23.9%	4,226	%	
Evidence-supported diagnoses	2,489	77.4%	287	28.4%	2,776	65.7%	
* Antipsychotics (1st gen, 2nd gen, parenteral)	2,483	77.2%	7	0.7%	2,490	58.9%	
Selective serotonin-reuptake inhibitors (SSRI) or serotonin norepinephrine-reuptake inhibitors (SNRI)	1,467	45.6%	202	20.0%	1,669	39.5%	
Other antidepressant	990	30.8%	143	14.2%	1,133	26.8%	
Benzodiazepine	636	19.8%	84	8.3%	720	17.0%	
Bipolar Disorder Drug (lithium/divalproex)	249	7.7%	5	0.5%	254	6.0%	
None of the above drug classes	7	0.2%	133	13.2%	140	3.3%	
None of the above (no evidence-supported diagnosis)	717	22.3%	335	33.2%	1,052	24.9%	
* Antipsychotics (1st gen, 2nd gen, parenteral)	717	22.3%	4	0.4%	721	17.1%	
Selective serotonin-reuptake inhibitors (SSRI) or serotonin norepinephrine-reuptake inhibitors (SNRI)	343	10.7%	198	19.6%	541	12.8%	
Other antidepressant	208	6.5%	158	15.6%	366	8.7%	
Benzodiazepine	118	3.7%	99	9.8%	217	5.1%	
Bipolar Disorder drug (lithium/divalproex)	48	1.5%	16	1.6%	64	1.5%	
None of the above drug classes	3	0.1%	255	25.2%	258	6.1%	

*Incorporated in the auto-PA

Only 36% of members had prescriptions written by a mental health specialist. However, members with a prescription written by a mental health specialist more commonly had an initial paid claim compared to members with prescriptions from other prescriber types.

	Paid claim (OR paid within 1 day)		Initial Denied Claims		Total	
	3,216	%	1,010	%	4,226	%
Evidence-supported diagnoses						
Mental health provider	1,180	36.7%	20	2.0%	1,200	28.4%
Other	1,316	40.9%	400	39.6%	1,716	40.6%
None of the above (no evidence-supported diagnosis)						
Mental health provider	302	9.4%	25	2.5%	327	7.7%
Other	418	13.0%	565	55.9%	983	23.3%

Table 6. Provider taxonomy on the index event

Limitations and Discussion

Claims-based analyses have several inherent limitations including:

- Diagnostic data based on claims history may be incomplete or not accurately reflect true patient diagnoses. Social stigma associated with mental health conditions (from patients or providers) may result in incomplete or missing diagnoses billed on medical claims. Diagnostic data was evaluated only over a 6-month period, and diagnoses for patients on stable maintenance therapy may be missed if they had infrequent provider visits. Additionally, many members included in this analysis had more than one diagnosis in medical claims which makes it difficult to attribute prescription of quetiapine to a specific diagnosis. While the current policy for quetiapine does not explicitly allow coverage of quetiapine for generalized anxiety disorder, some members with this diagnosis did have paid claims for quetiapine. This could be due to multiple factors including:
 - Prescription of quetiapine by a mental health specialist
 - Comorbid diagnosis for a covered condition (such as schizophrenia or bipolar disorder)
 - Paid claims for an antipsychotic in the previous 6 months
- Provider type may be inaccurate or incomplete. Providers with a mental health specialty were identified based on primary prescriber taxonomy which may not accurately reflect their actual practice setting. For example, physician assistants working under the supervision of a mental health specialist may be categorized as a general practitioner. Additionally, it is unknown what proportion of general practitioners have consulted a mental health provider before prescribing low dose quetiapine.
- Utilization data of other mental health drugs, which are based on pharmacy claims, may not actually reflect true utilization or may be incomplete. This analysis uses paid pharmacy claims as a surrogate marker for utilization, but this may not reflect how the member actually takes the drug. Many mental

health medications are available as generics and are relatively inexpensive. Some patients who encounter barriers to coverage may elect to pay cash for their prescriptions. The extent of patients who pay cash for prescriptions is unknown, and these prescriptions would not be captured in this analysis.

- Of note, almost all members with an initial paid claim for low dose quetiapine had utilization for an antipsychotic in the prior 6 months. Several factors may contribute to this:
 - Pharmacy claims are adjudicated in real-time whereas medical claims take longer to adjudicate before they are available in the claims processing system. Therefore, pharmacy data may be a more consistent trigger for the autoPA (compared to diagnostic data from medical claims).
 - This analysis was limited to members who were continuously enrolled with Medicaid for a 9 month period (6 months before the IE and 3 months after the IE). Over 800 people (about 15%) were eliminated from the analysis because of these eligibility requirements. This methodology may select for members with more severe mental health conditions and comorbidities who are more likely to have received prior prescriptions for an antipsychotic.

References:

- 1. Seroquel XR (quetiapine) extended-release tablets [package labeling]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2022.
- 2. Quetiapine In: Merative Micromedex[®] Alternative Medicine (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: April 30, 2023).

Appendix 1. Drug Coding

Table A1. Quetiapine GSN codes

GSN 034187 034188 034189 043198 047198 060292 060293 062748 062749 062750 063240	Form TABLET TABLET TABLET TABLET TABLET TABLET TABLET TAB ER 24H TAB ER 24H TAB ER 24H	Generic quetiapine fumarate quetiapine fumarate	Type Immediate-release Immediate-release Immediate-release Immediate-release Immediate-release Immediate-release Extended-release Extended-release Extended-release Extended-release
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Table A2. Diagnosis codes

Condition	ICD-10 Diagnosis Code
Schizophrenia	F20x
Bipolar Disorders	F31x
MDD	F322-F323, F329; F33x
GAD	F411x

Dementia/delirium/Alzheimer's Disease	F01x-F05x, G30x
Parkinson's Disease	G20x
Obsessive Compulsive Disorder (OCD)	F42x
Insomnia or circadian rhythm sleep disorders	G470x, G472x

Table A3. Error Codes associated with denied claims that are excluded from the analysis

- Error Code Description 4999 THIS DRUG IS COVERED BY MEDICARE PART D 2508 RECIPIENT COVERED BY PRIVATE INSURANCE (PHARMACY) 2002 RECIPIENT NOT ELIGIBLE FOR HEADER DATE OF SERVICE 2507 RECIPIENT HAS MORE THAN ONE INSURANCE CARRIER 513 RECIPIENT NAME AND NUMBER DISAGREE 503 DATE DISPENSED AFTER BILLING DATE 628 Other Coverage Reject Code Required for OCC 3 205 PRESCRIBING PROVIDER ID MISSING 502 DATE DISPENSED EARLIER THAN DATE PRESCRIBED 214 DATE PRESCRIBED IS INVALID 268 BILLED AMOUNT MISSING 271 HEADER TOTAL BILLED AMOUNT INVALID 269 DETAIL BILLED AMOUNT INVALID 500 DATE PRESCRIBED AFTER BILLING DATE
 - 222 DAYS SUPPLY INVALID
 - 221 DAYS SUPPLY MISSING
 - 238 RECIPIENT NAME IS MISSING
 - 1040 PRESCRIBING PHYSICIAN NOT ENROLLED
 - 1026 PRESCRIBING PHYSICIAN ID NOT ON FILE

Table A4. Taxonomy codes associated with mental health providers

Taxonomy	Taxonomy Description
163WP0807X	REGISTERED NURSE - PSYCHIATRIC/MENTAL HEALTH
163WP0808X	REGISTERED NURSE - PSYCHIATRIC/MENTAL HEALTH
163WP0809X	REGISTERED NURSE - PSYCHIATRIC/MENTAL HEALTH
167G00000X	NURSING SERVICE - LICENSED PSYCHIATRIC TECHNICIAN
2080P0008X	PHYSICIAN-PEDIATRICS-NEURODEVELOPMENTAL DISABILITIES
2084A0401X	PSYCHIATRY & NEUROLOGY, ADDICTION MEDICINE
2084B0002X	PHYSICIAN-PSYCHIATRY&NEUROLOGY-BARIATRIC MEDICINE
2084B0040X	BEHAVIORAL NEUROLOGY & NEUROPSYCHIATRY
2084D0003X	PHYSICIAN-PSYCHIATRY&NEUROLOGY-DIAGNOSTIC NEUROIMAGING
2084F0202X	PHYSICIAN-PSYCHIATRY&NEUROLOGY-FORENSIC PSYCHIATRY

2084H0002X PHYSICIAN-PSYCHIATRY&NEUROLOGY-HOSPICE AND PALLIATIVE MEDICINE 2084N0008X PHYSICIAN-PSYCHIATRY&NEUROLOGY-NEUROMUSCULAR MEDICINE 2084N0400X PHYSICIAN-PSYCHIATRY&NEUROLOGY-NEUROLOGY 2084N0402X PHYSICIAN-PSYCHIATRY&NEUROLOGY-NEUROLOGY WITH SPECIAL QUAL IN CHILD NEUROLO 2084N0600X PHYSICIAN-PSYCHIATRY&NEUROLOGY-CLINICAL NEUROPHYSIOLOGY 2084P0005X PHYSICIAN-PSYCHIATRY&NERUOLOGY-NEURODEVELOPMENTAL DISABILITIES 2084P0015X PHYSICIAN-PSYCHIATRY&NEUROLOGY-PSYCHOSOMATIC MEDICINE 2084P0800X PHYSICIAN-PSYCHIATRY&NEUROLOGY-PSYCHIATRY 2084P0802X PHYSICIAN-PSYCHIATRY&NEUROLOGY-ADDICTION PSYCHIATRY 2084P0804X PHYSICIAN-PSYCHIATRY&NEUROLGY-CHILD&ADOLESCENT PSYCHIATRY 2084P0805X PHYSICIAN-PSYCHIATRY&NEUROLGY-GERIATRIC PSYCHIATRY 2084P2900X PHYSICIAN-PSYCHIATRY&NEUROLOGY-PAIN MEDICINE 2084S0010X PHYSICIAN-PSYCHIATRY&NEUROLOGY-SPORTS MEDICINE 2084S0012X PHYSICIAN-PSYCHIATRY&NEUROLOGY-SLEEP MEDICINE 2084V0102X PHYSICIAN-PSYCHIATRY&NEUROLOGY-VASCULAR NEUROLOGY 261QM0850X CLINIC/CENTER - ADULT MENTAL HEALTH 273R00000X **PSYCHIATRIC UNIT** 283Q00000X HOSPITALS: PSYCHIATRIC HOSPITAL 3104A0625X NURSING&CUSTODIAL CARE: ASSISTED LIVING - MENTAL ILLNESS 3104A0630X NURSING&CUSTODIAL CARE: ASSISTED LIVING - BEHAVIORAL DISTURBANCES 31050000X NURSING&CUSTODIAL CARE: ASSISTED LIVING - MENTAL ILLNESS 311500000X NURSING&CUSTODIAL CARE: ALZHEIMER CENTER (DEMENTIA CENTER) 323P00000X PSYCHIATRIC RESIDENTIAL TREATMENT FACILITY 363LP0808X NURSE PRACTITIONER - PSYCHIATRIC/MENTAL HEALTH 364SP0807X CLINICAL NURSE SPECIALIST - PSYCHIATRIC/MENTAL HEALTH 364SP0808X CLINICAL NURSE SPECIALIST - PSYCHIATRIC/MENTAL HEALTH 364SP0809X CLINICAL NURSE SPECIALIST - PSYCHIATRIC/MENTAL HEALTH 364SP0810X CLINICAL NURSE SPECIALIST - PSYCHIATRIC/MENTAL HEALTH 364SP0811X CLINICAL NURSE SPECIALIST - PSYCHIATRIC/MENTAL HEALTH 364SP0812X CLINICAL NURSE SPECIALIST - PSYCHIATRIC/MENTAL HEALTH 364SP0813X CLINICAL NURSE SPECIALIST - PSYCHIATRIC/MENTAL HEALTH

Table A. Drug definitions for other mental health drugs

Drug Category	PDL Class or generic drug name	HSN
Antipsychotics (by PDL class)	Antipsychotics, 2 nd gen	N/A
	Antipsychotics, 1 st gen	

	Antipsychotics, parenteral	
Benzodiazepines (by PDL class)	Benzodiazepines	N/A
Bipolar Drugs (by HSN)	Lithium carbonate	001669
· · · · · · · · · · · · · · · · · · ·	Valproic acid as sodium salt	001882
	Valproic acid	001883
	Divalproex sodium	001884
SSRI/SNRIs (by HSN)	desvenlafaxine	040202
	desvenlafaxine succinate	035420
	duloxetine HCl	026521
	levomilnacipran HCl	040632
	venlafaxine besylate	048091
	venlafaxine HCl	008847
	citalopram hydrobromide	010321
	escitalopram oxalate	024022
	fluoxetine HCl	001655
	fluvoxamine maleate	006338
	paroxetine HCl	007344
	paroxetine mesylate	025796
	sertraline HCl	006324
	olanzapine/fluoxetine HCl	025800
	vilazodone HCl	037597
	vortioxetine hydrobromide	040637
Other antidepressants (by HSN)	brexanolone	045692
	selegiline	033510
	amitriptyline HCl	001643
	amoxapine	001648
	clomipramine HCl	004744
	desipramine HCl	001645
	doxepin HCl	001650
	imipramine HCl	001641
	imipramine pamoate	001642
	maprotiline HCl	001651
	nortriptyline HCl	001644
	protriptyline HCl	001646
	trimipramine maleate	001649
	mirtazapine	011505
	bupropion HBr	036156

bupropion HCl	001653
nefazodone HCl	009612
trazodone HCl	001652
isocarboxazid	001638
phenelzine sulfate	001639
tranylcypromine sulfate	001640
esketamine HCl	041003

Appendix 2. Proposed Safety Edit

Low Dose Quetiapine

<u>Goal(s):</u>

- To promote and ensure use of quetiapine that is supported by the medical literature.
- To discourage off-label use for insomnia.
- Promote the use of non-pharmacologic alternatives for chronic insomnia.

Initiative:

• Low dose quetiapine, immediate- and extended-release

Length of Authorization:

• Up to 12 months (criteria-specific)

Requires PA:

- Quetiapine (HSN = 14015) doses ≤50 mg/day
- Auto-PA approvals for:
 - Patients with a claim for a second-generation antipsychotic in the last 6 months
 - Patients with prior claims evidence of schizophrenia or bipolar disorder
 - Prescriptions identified as being written by a mental health provider
 - Extended-release formulations in patients with claims for a selective serotonin reuptake inhibitor or serotonin norepinephrine reuptake inhibitor in the last 90 days

Covered Alternatives:

Preferred alternatives listed at <u>www.orpdl.org/drugs/</u>

Table 1. Adults (age ≥18 years) with FDA-approved or Compendia-supported Indications

Bipolar Disorder	

Major Depressive Disorder (MDD)	Adjunctive therapy with antidepressants for MDD
Schizophrenia	
Bipolar Mania	
Bipolar Depression	
Generalized Anxiety Disorder (GAD)	Adjunctive therapy with SSRI/SNRI

Table 2. Pediatric FDA-approved indications

S	Schizophrenia	Adolescents (13-17 years)	
E	Bipolar Mania	Children and Adolescents	Monotherapy
		(10 to 17 years)	

Note: For any requests in children ≤5 years of age, see criteria for Antipsychotics in Children

Approval Criteria			
 Is the request for an evidence-supported diagnosis (Table 1 or Table 2)? 	Yes: Go to #2	No: Pass to RPh. Deny; medical appropriateness.	
 Is the prescription for quetiapine less than or equal to 50 mg/day? (verify days' supply is accurate) 	Yes: Go to #3	No: Trouble-shoot claim processing with the pharmacy.	
 Is planned duration of therapy (at ≤50 mg) longer than 90 days? 	Yes: Go to #4	No: Approve for titration up to maintenance dose (60 days).	
 4. Is reason for dose ≤50 mg/day due to any of the following: low dose needed due to debilitation from a medical condition or age; unable to tolerate higher doses; stable on current dose; or impaired drug clearance? 	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness. Note: may approve up to 6 months to allow taper.	

 P&T/DUR Review:
 6/23 (SS); 4/21 (SF); 8/20; 3/19; 9/18; 11/17; 9/15; 9/10; 5/10

 Implementation:
 7/1/23; 1/1/18; 10/15; 1/1/11