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# Drug Use Evaluation: Melatonin Usage in Pediatric and Adult Members

**Research Questions:**

1. How have the number of prescriptions for sedative medications (e.g., benzodiazepines, melatonin receptor agonists, non-benzodiazepine hypnotics) changed since the addition of melatonin coverage to the Oregon Health Plan (OHP) fee-for-service (FFS) pharmacy benefit for pediatric members?
2. What proportion of pediatric members receiving prescriptions for melatonin have a diagnosis for insomnia or a comorbid diagnosis predisposing them to insomnia (e.g., depression, anxiety, attention deficit hyperactivity disorder, or autism spectrum disorder), indicating that treatment with melatonin is warranted?
3. Are the daily doses of melatonin for pediatric members appropriate, defined as 3 to 5 mg, as recommended by clinical practice guidelines (e.g., evidence-based dosing)?
4. If insomnia was added as a funded disease state, what proportion of adults have received a prescription for a sedative for longer than 30 days in the past year and could potentially benefit from the coverage of melatonin?
5. If funding of insomnia medications depended on trial of cognitive behavioral therapy (CBT), how many adults would be eligible for such coverage with the documentation of at least one claim for CBT?

**Conclusions:**

- The total percentage of prescriptions written for melatonin and other sedative medications has remained unchanged since the addition of melatonin to the pharmacy benefit for pediatric members. However, melatonin utilization has improved through a 43.5% increase in paid claims while benzodiazepines paid claims decreased by 41.8%.
- 57.5% of pediatric members have a comorbid diagnosis that predisposes them to insomnia. However, only 21.3% have a diagnosis of insomnia and 36.3% have no diagnosis that supports the use of melatonin.
- Among all age groups of pediatric members, the average daily dose of melatonin when initially prescribed was within the recommended 3-5 mg by clinical guidelines. Members between 13 and 18 years old did have an average daily dose of 4.9 mg, compared to members between 6 and 12 years old who had an average daily dose of 3.5 mg
- Among adults receiving sedative prescriptions, 43% received long-term sedatives (defined as a total of 30 or more days).
- Among adult members receiving a long-term sedative, 49.8% have a least one claim for CBT.

**Recommendations:**

- No policy changes recommended.

**Background:**

The consequences of sleep loss on daytime functions are more well documented in adults than in children.[1] However, one comparative study has examined the impact of sleep duration on emotional functioning and cognitive performance in children.[1] The results showed that modest differences, more than one hour

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over two weeks, can affect emotional functioning, short-term memory, working memory, attention, and math fluency.[1] Based on these findings, the authors recommend that children experiencing difficulties in any of these areas be screened for sleep problems as a potential cause.[1]

In children, behavioral sleep problems, or behavioral insomnia, are characterized by bedtime refusal or resistance, delayed sleep onset, and prolonged night awakenings requiring parental intervention.[2] This can negatively affect the quality of life for children and carries an increased risk of mood and behavioral problems, academic failure, and worsened health related conditions.[2]

Chronic behavioral insomnia is estimated to occur in 10 to 30 percent of children depending on the exact definition used and the specific age group being studied.[2] Some subgroups of children experience a higher prevalence of insomnia, including those with psychiatric comorbidities, neurodevelopmental disorders, genetic syndromes, and acquired conditions.[2] **Table 1** summaries subgroups of children more likely to experience insomnia.[2]

**Table 1.** Pediatric Subgroups Predisposed to Insomnia[2]

| Psychiatric | Neurodevelopmental | Genetic | Acquired |
|---|---|---|---|
| Depression<br>Anxiety<br>Stress | Attention deficit hyperactivity disorder<br>Autism spectrum disorder | Smith-Magenis Syndrome<br>Angelman Syndrome | Fetal alcohol syndrome |

Prior to the initiation of pharmacologic interventions, it may be appropriate to obtain a sleep history by using one of several tools.[2] The BEARS survey, which looks at Bedtime issues, Excessive daytime sleepiness, night Awakenings, Regularity and duration of sleep, and Snoring, or sleep diaries can help clinicians decide the primary problem.[2] Common causes of insomnia include bedtime resistance, difficulty initiating or maintaining sleep, and behavioral disorders.[2] Poor sleep hygiene, including light and screen time before bed, may also be a cause of sleep disruption in children.[3]

The decision to initiate pharmacotherapy for insomnia in children should be based on efficacy, side effects, safety, and ethical considerations.[4] Specific side effects to consider include increased risk of inability to sleep without use of medications and daytime sleepiness associated with prescription sedatives. For some children, despite the previously mentioned considerations, sedatives and hypnotics may deemed appropriate therapy for insomnia.[4] In particular, the use of melatonin has increased in the United States over the past decade as treatment for insomnia in children.[4] This trend may be due to the relative safety of melatonin compared to prescription sedatives. Adverse effects from melatonin include headache, dizziness, nightmares, and excessive daytime sleepiness.[5]

The American Academy of Sleep Medicine clinical practice guideline, based on moderate quality evidence from a singular study, weakly recommends treatment with strategically timed melatonin versus no treatment in children and adolescents with delayed sleep-wake phase disorder.[6] This trial found improved sleep latency with a mean difference ranging from 38.39 minutes to 44.24 minutes depending on the dosage of melatonin given.[6] The clinical guideline proposes the same weak recommendation, based on low quality evidence from two reviewed studies, for treatment in children and adolescents with delayed sleep-wake phase disorder and comorbid psychiatric conditions.[6] A separate systematic review evaluated the effectiveness of pharmacotherapy for sleep disturbances in children with cognitive disabilities.[7] Of the 13 trials included in the review, 12 evaluated the efficacy of oral melatonin.[7] The pooled mean difference for the trials showed a 29.6 minutes increase in sleep time with melatonin, which was statistically significant. However, almost all of the trials had high or unclear risk of bias.[7] Melatonin at dosages ranging from 3-5 mg may be effective in children and adolescents.[6]

In October 2021, the Oregon Health Authority (OHA) added melatonin coverage to the OHP FFS pharmacy benefit for members 18 years of age or younger. All other sleep drugs still require a prior authorization (PA), including benzodiazepines which are only approved for an initial 30 days. In addition, melatonin is not covered for adult members and insomnia remains an unfunded condition. This drug use evaluation examines utilization of melatonin in pediatric OHP members, including appropriate dosage and indication, as well as associated costs due to the addition of melatonin to the pharmacy benefit plan. Furthermore, this drug use evaluation will provide insight into overall melatonin utilization in adults OHP members.

**Methods:**

Melatonin Coverage in Children Policy Evaluation

To evaluate changes in utilization, members 18 years of age or younger with a paid or denied FFS claim for melatonin or other sedatives (**Appendix 1**) from 10/01/2020 to 12/31/2022 were included.

The index event (IE) was defined as the first paid or denied FFS claim for a new start melatonin or other sedative (members without a history of melatonin or other sedative use in the past three months) in the evaluation window. If members had a paid and denied claim on the same day, the claim was classified as paid. For each member, the baseline and follow-up periods were defined based on the IE:

- The baseline period was defined as 6 months prior to the IE (exclusion of the IE).

Members were categorized into the following groups based on the IE.

(1) First claim for melatonin or sedative medication from October 1, 2020 to September 30, 2021 (pre-policy change)
(2) First claim for melatonin or sedative medication from January 1, 2022 to December 31, 2022 (post-policy change)

Average daily dose was collected and categorized into dosing groups (< 3 mg, 3-5 mg, > 5 mg) based on the IE dosage.

Inclusion Criteria:

- Paid or denied FFS claim for melatonin or other sedatives (**Appendix 1**). Denied claims were included if they were associated with error codes of 3002 “NDC requires PA”, 4002 “No coverage for billed NDC”, 3022 “Non-Preferred Drug, PA Required”, 1017 “Non-rebatable eligible indicator”, or 1016 “Non-participating manufacturer” without any of the error codes listed in **Appendix 1.**

Exclusion criteria:

- 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<br>BMD<br>MED | Qualified Medicare Beneficiary + Oregon Health Plan with Limited Drug<br>Oregon Health Plan with Limited Drug<br>Qualified Medicare Beneficiary |
| Limited or no Medicaid drug benefit | MND<br>CWM | Transplant package<br>Citizenship Waived Emergency Medical<br>Special Low-Income Medicare Beneficiary Only |

| | | |
|---|---|---|
| | SMF<br>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 Coordinated Care Organization (CCO) enrollment on the IE date
- Patients identified in both pre- and post-policy groups will be excluded from the post-policy change group

Outcomes:

- Proportion of members prescribed melatonin or other sedative who have a diagnosis of insomnia, delayed sleep-wake phase disorder, depression, anxiety, attention deficit hyperactivity disorder, or autism spectrum disorder based on medical claims in the baseline period (**Appendix 1**).
- Proportion of members who have a paid or denied FFS claim for melatonin and the dosage prescribed.

<u>Sedative Coverage in Adults</u>

Inclusion Criteria:

- Members > 18 years old with a paid FFS claim for a sedative medication from 01/01/2022 to 12/31/2022 will be identified.

The IE was defined as the first paid FFS claim for sedative in the evaluation window. For each member, the baseline and follow-up periods were defined based on the IE:

- The baseline period was defined as 6 months prior to the IE (exclusion of the IE).
- The follow-up period was defined as the 45 days following the IE (inclusive of the IE).

Exclusion Criteria:

- 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<br>BMD<br>MED | Qualified Medicare Beneficiary + Oregon Health Plan with Limited Drug<br>Oregon Health Plan with Limited Drug<br>Qualified Medicare Beneficiary |
| Limited or no Medicaid drug benefit | MND<br>CWM<br>SMF<br>SMB | Transplant package<br>Citizenship Waived Emergency Medical<br>Special Low-Income Medicare Beneficiary Only<br>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 FFS enrollment in the follow-up period
- Patients with CCO coverage during the follow-up period

Outcomes:

- Proportion of adult members who have an FFS paid claim for long-term sedative medications (30 days based on day supply)
- Documentation of any visits for CBT during the baseline period. Documentation of CBT was identified using medical service codes (**Appendix 1**).

**Results:**

In OHP FFS, 1,669 pediatric members during the pre-policy time period and 1,610 in the post-policy time period were identified as having a paid or denied claim for melatonin or other sedative medication. After all the exclusion criteria were applied, 126 pediatric members from the pre-policy period and 80 from the post-policy period were included for analysis. For adults, 32,716 members were identified as having an FFS claim for melatonin or other sedative; however, only 762 were included for analysis after the exclusion criteria was applied. Details regarding the number of patients included from the analysis can be found below in **Tables 1A and 1B**.

**Table 1A: Population of included pediatric patients**

| | Pre-Policy | | Post-Policy | |
|---|---|---|---|---|
| **Number of included pediatric patients** | # | % | # | % |
| Pediatric paid or denied claim for melatonin or sedative medication | 1,669 | | 1,610 | |
| After exclusion of Medicare Part D, limited benefit plans, and TPL | 1,310 | 78.5% | 1,315 | 81.7% |
| After exclusion of non-continuous Medicaid enrollment in the baseline period | 1,242 | 74.4% | 1,245 | 77.3% |
| After exclusion of patients enrolled in a CCO on the index date | 126 | 7.5% | 93 | 5.8% |
| **After exclusion of members in Post group who were already in the Pre group** | **126** | **7.5%** | **80** | **5.0%** |

**Table 1B: Population of included adult patients**

| **Number of included adult patients** | # | % |
|---|---|---|
| Adult paid FFS claim for melatonin or sedative medication | 32,716 | |
| After exclusion of Medicare Part D, limited benefit plans, and TPL | 30,715 | 93.9% |
| After exclusion of non-continuous Medicaid enrollment in the baseline period | 28,535 | 87.2% |
| **After exclusion of non-continuous FFS enrollment in the follow-up period** | **762** | 2.3% |

**Table 3: New start sedative prescriptions in pediatric patients**

| | Before | | | | | | After | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Paid Claim | | Denied Claim | | Total | | Paid Claim | | Denied Claim | | Total | |
| | 59 | % | 67 | % | 126 | % | 69 | % | 11 | % | 80 | % |
| Benzodiazepines | 58 | 98.3% | 8 | 11.9% | 66 | 52.4% | 39 | 56.5% | 6 | 54.5% | 45 | 56.3% |
| Melatonin-receptor agonists | | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.0% |
| Non-benzodiazepine hypnotics | 1 | 1.7% | | 0.0% | 1 | 0.8% | | 0.0% | 1 | 9.1% | 1 | 1.3% |
| Melatonin | | 0.0% | 59 | 88.1% | 59 | 46.8% | 30 | 43.5% | 4 | 36.4% | 34 | 42.5% |
| Received benzodiazepine in 90 days after melatonin | | 0.0% | | 0.0% | | 0.0% | 1 | 1.4% | | 0.0% | 1 | 1.3% |

During the pre-policy time period all information on melatonin dosages came from denied claims. Among those denied claims, 13.6 percent were for a daily dose less than 3 mg, 45.8 percent was for 3 to 5 mg, and 40.7 was for a dose greater than 5 mg. The average daily dose of these claims was 3.2 mg for pediatric members 0 to 5 years old, 5 mg for 6 to 12 years old, and 5.2 mg for 13 to 18 years old.

Following the policy change, the statistics for melatonin prescriptions is based on both paid and denied claims. Among the claims for melatonin 8.8 percent were for a daily dose less than 3 mg, 61.8 percent were for 3 to 5 mg, and 29.4 percent were for a dose greater than 5 mg. The average daily dose of these claims was 3.0 for pediatric patients 0 to 5 years old, 3.5 mg for 6 to 12 years old, 4.9 for 13 to 18 years old. All of this information can be found below in **Table 4**.

**Table 4. Melatonin prescription statistics**

| | Before | | | | | | After | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Paid Claim | | Denied Claim | | Total | | Paid Claim | | Denied Claim | | Total | |
| | 0 | % | 59 | % | 59 | % | 30 | % | 4 | % | 34 | % |
| **Daily Dose of Melatonin at IE** | | | | | | | | | | | | |
| < 3 mg | 0.0% | | 8 | 13.6% | 8 | 13.6% | 3 | 10.0% | | 0.0% | 3 | 8.8% |
| 3-5 mg | 0.0% | | 27 | 45.8% | 27 | 45.8% | 20 | 66.7% | 1 | 25.0% | 21 | 61.8% |
| > 5 mg | 0.0% | | 24 | 40.7% | 24 | 40.7% | 7 | 23.3% | 3 | 75.0% | 10 | 29.4% |
| **Average Daily Dose of Melatonin at IE by Age** | | | | | | | | | | | | |
| 0-5 | | | 3.2 | | 3.2 | | 3.0 | | | | 3.0 | |
| 6-12 | | | 5.0 | | 5.0 | | 3.0 | | 5.0 | | 3.5 | |
| 13-18 | | | 5.2 | | 5.2 | | 4.3 | | 10.0 | | 4.9 | |

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During the pre-policy period, 22.2 percent of claims were for insomnia with no claims for delayed sleep-wake phase disorder. For comorbidities contributing to insomnia, 36.5 percent of pediatric members had a diagnosis of depression, 33.3 percent had anxiety, 27 percent had ADHD, and 4 percent had autism. Among all diagnoses, 57.1 percent of pediatric members had any comorbid diagnosis and 34.9 percent had no diagnosis (neither insomnia nor a comorbid diagnosis).

In the post-policy period, 1.3 percent of claims were for a sleep disorder and 20 percent were for insomnia. In terms of comorbidities related to insomnia, 30 percent of pediatric members had a diagnosis of depression, 37.5 percent had anxiety, 26.3 percent had ADHD, and 11.3 percent had autism. Of those diagnoses, 57.5 percent of pediatric members had any comorbid diagnosis and 36.6 percent had no diagnosis. Information on the proportions of paid and denied claims for the diagnoses can be found below in **Table 5**.

**Table 5: Pediatric patient diagnoses in the 6 months before the index event**

| | Before | | | | | | After | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Paid Claim | | Denied Claim | | Total | | Paid Claim | | Denied Claim | | Total | |
| | 59 | % | 67 | % | 126 | % | 69 | % | 11 | % | 80 | % |
| **Evidence-supported diagnoses** | | | | | | | | | | | | |
| Sleep disorder | | 0.0% | | 0.0% | | 0.0% | 1 | 1.4% | | 0.0% | 1 | 1.3% |
| Insomnia | 13 | 22.0% | 15 | 22.4% | 28 | 22.2% | 15 | 21.7% | 1 | 9.1% | 16 | 20.0% |
| Delayed sleep-wake phase disorder | | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.0% |
| **Comorbidities contributing to insomnia** | | | | | | | | | | | | |
| Depression | 12 | 20.3% | 34 | 50.7% | 46 | 36.5% | 20 | 29.0% | 4 | 36.4% | 24 | 30.0% |
| Anxiety | 17 | 28.8% | 25 | 37.3% | 42 | 33.3% | 27 | 39.1% | 3 | 27.3% | 30 | 37.5% |
| ADHD | 7 | 11.9% | 27 | 40.3% | 34 | 27.0% | 19 | 27.5% | 2 | 18.2% | 21 | 26.3% |
| Childhood Autism | 4 | 6.8% | 1 | 1.5% | 5 | 4.0% | 7 | 10.1% | 2 | 18.2% | 9 | 11.3% |
| Any comorbid Dx | 23 | 39.0% | 49 | 73.1% | 72 | 57.1% | 40 | 58.0% | 6 | 54.5% | 46 | 57.5% |
| **No diagnosis (neither evidence-supported or comorbid)** | 29 | 49.2% | 15 | 22.4% | 44 | 34.9% | 24 | 34.8% | 5 | 45.5% | 29 | 36.3% |

Among the adult members with a prescription for sedative medications, 328 met the defined criteria for having long-term sedative prescriptions. Of these members, 92.1 percent of long-term sedative medications prescribed were benzodiazepines. In addition, only 27.7 percent of patients with sedative prescriptions and 32.0 percent of those long-term sedative prescriptions have documentation of CBT. More information on sedative prescriptions in adult members can be found below in **Table 6**.

**Table 6: Adult patients with long-term sedative prescriptions**

| | All | | With History of CBT | |
|---|---|---|---|---|
| **Adult Patients with sedative prescriptions** | 762 | % | 211 | % |
| **Adult Patients with *long-term* sedative prescriptions** | 328 | 43.0% | 105 | 49.8% |
| Benzodiazepines | 302 | 39.6% | 97 | 46.0% |
| Melatonin-receptor agonists | 1 | 0.1% | | 0.0% |
| Non-benzodiazepine hypnotics | 25 | 3.3% | 8 | 3.8% |
| Melatonin | | 0.0% | | 0.0% |

**Discussion:**

The addition of melatonin to the OHP FFS pharmacy benefit increased utilization and access for pediatric members. However, there was no evidence of impact to benzodiazepines or other sedative prescriptions from opening access to melatonin. While the proportion of paid claims for benzodiazepines did decrease, there were no additional policy changes to explain why this may have occurred. A potential benefit to benzodiazepines usage may be seen in the fact that only one member received a prescription for benzodiazepines 90 days after starting melatonin. Further studies will be needed to determine if requiring trial of melatonin could prevent new starts of benzodiazepines.

Sixty-five percent of pediatric members had insomnia or comorbidity predisposing them to insomnia. While it represents a minority, the 21 percent of members without any diagnosis remains concerning. These patients may benefit from deprescribing if they are receiving a sedative without a corresponding indication.

Many claims for melatonin were for dosages consistent with clinical practice guidelines. Average higher daily doses were seen in older adolescents, which could coincide with weight-based dosing. Based on the average doses seen in pediatric members, there are no concerns for adding quantity limits to melatonin at this time.

In adults, 43 percent of sedative prescriptions were for long-term sedatives defined as a total of more than 30 days. Among adults on long-term sedative prescriptions, only 32 percent had documentation of CBT. It is difficult to determine if coverage of insomnia would benefit many adult members since only a minority of sedative prescriptions are for long-term use, and an unknown number of prescriptions are being used for insomnia. In addition, if documentation of CBT is required for payment of insomnia medications, even fewer adult members will benefit from the additional coverage.

**Limitations:**

- Medicaid includes a significant proportion of members who are only transiently enrolled in FFS. Often members are quickly enrolled into a CCO upon eligibility for Medicaid and remain in FFS for only a few months. In order to accurately capture data from this population in the analysis, a baseline period of 6 months was required. However, this limitation led to several assumptions when identifying pediatric members who were starting melatonin or a sedative. Members were assumed to not be receiving a new start if they met the following criteria: had prior claims for melatonin or other sedatives paid by Medicaid. However, there is a limitation to this definition, and it is possible that members were previously paying out of pocket for sedative medication or purchasing melatonin over-the-counter.

- A significant proportion of pediatric patients were excluded because they had partially incomplete claims data due to other primary insurance or were not eligible for Medicaid for the required 6-month baseline period. After all exclusion criteria, about 7.5% of pediatric members in the pre-policy group and 5% in the post policy group were included for analysis. This study assumes that included members would still be representative of most pediatric patients prescribed melatonin or other sedatives in Medicaid.
- In order to fairly assess if the policy change had any impact on melatonin and other sedative use in pediatric members, a 3-month gap period was left between the end of the pre-policy evaluation period and the beginning of the post-policy evaluation period. It was assumed that 3 months would be long enough for providers to adjust their prescribing patterns; however, it may not have allowed for enough for such changes to occur.
- This analysis relied on evidence-supported diagnoses and conditions that have been shown to predispose children to insomnia. However, any diagnoses that are commonly accepted in clinical practice without being documented in current literature would have been excluded.
- This analysis defined long-term sedative use in adults as 30 days, based on total days' supply. This definition assumes that prescriptions totaling less than 30 days' supply are not considered long-term, regardless of the quantity or how long the prescription may last. However, it is possible that members are not taking the medication as frequently as their prescriber has allowed. In this scenario, members could be sporadically using sedative medications for many months, but would not have been included in this analysis.
- In order to find claims data for CBT, this analysis relied on a list of medical service codes. The list was based on common service codes found during preliminary research. Since the research for services codes occurred through online resources, without the consultation of a clinician or subject matter expert, it is possible that some service codes were unintentionally omitted. As such, a higher proportion of adults on long-term sedative medications may be documentation of CBT than the number portrayed in this study.
- This analysis included benzodiazepines for treatment of insomnia and other sleep disorders. However, benzodiazepines are commonly prescribed for other indications not related to sleep, including medical and dental procedures.

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**Appendix 1. Data Coding**

**Table A1. Melatonin GSN codes**

| GSN | Form | Generic | Type |
|---|---|---|---|
| 026076 | Tablet | Melatonin | Extended-release |
| 071898 | Tablet | Melatonin | Extended-release |
| 076846 | Tablet | Melatonin | Extended-release |
| 077022 | Tablet | Melatonin | Extended-release |
| 024665 | Tablet | Melatonin | Immediate-release |
| 039195 | Tablet | Melatonin | Immediate-release |
| 041568 | Tablet | Melatonin | Immediate-release |
| 063960 | Tablet | Melatonin | Immediate-release |
| 069202 | Tablet | Melatonin | Immediate-release |
| 081048 | Tablet | Melatonin | Immediate-release |
| 068895 | Tablet Rapid | Melatonin | Immediate-release |
| 070353 | Tablet Rapid | Melatonin | Immediate-release |
| 071356 | Tablet Rapid | Melatonin | Immediate-release |
| 075697 | Tablet Rapid | Melatonin | Immediate-release |
| 080947 | Tablet Rapid | Melatonin | Immediate-release |
| 081652 | Tablet Rapid | Melatonin | Immediate-release |
| 070234 | Tablet Chew | Melatonin | Immediate-release |
| 073498 | Tablet Chew | Melatonin | Immediate-release |
| 079871 | Tablet Chew | Melatonin | Immediate-release |
| 082032 | Tablet Chew | Melatonin | Immediate-release |
| 048015 | Tablet Sublingual | Melatonin | Immediate-release |
| 070888 | Tablet Sublingual | Melatonin | Immediate-release |
| 073509 | Tablet Sublingual | Melatonin | Immediate-release |
| 080957 | Lozenge | Melatonin | Immediate-release |
| 053232 | Drops | Melatonin | Immediate-release |
| 083165 | Drops | Melatonin | Immediate-release |
| 061740 | Liquid | Melatonin | Immediate-release |
| 071047 | Liquid | Melatonin | Immediate-release |
| 032584 | Capsule | Melatonin | Immediate-release |
| 040954 | Capsule | Melatonin | Immediate-release |
| 061738 | Capsule | Melatonin | Immediate-release |

**Table A2. Diagnosis codes**

| Condition | ICD-10 Diagnosis Code |
|---|---|
| Sleep Disorders | |
| Behavioral insomnia of children | Z73.819 |
| Insomnia | G47X, F51X |
| Delayed Sleep-Wake Phase Disorder | G47.21X |
| Depression | |
| Depressive Episode | F32X |
| Recurrent Depressive Disorder | F33X |
| Persistent Mood Affective Disorders | F34X |
| Anxiety | |
| Other Anxiety Disorders | F41X |
| Attention Deficit Hyperactivity Disorder | F90X |
| Childhood Autism | F840 |

**Table A3. Medical service codes for CBT**

| Code | Description |
|---|---|
| 90785 | Psytx complex interactive |
| 90791 | Psytx diagnostic evaluation |
| 90792 | Psytx diagnostic evaluation with medication services |
| 90832 | Psytx with patient 30 minutes |
| 90833 | Psytx with patient with evaluation and management 30 minutes |
| 90834 | Psytx with patient 45 minutes |
| 90836 | Psytx with patient with evaluation and management 45 minutes |
| 90837 | Psytx with patient 60 minutes |
| 90838 | Psytx with patient with evaluation and management 60 minutes |
| 90839 | Psytx crisis initial 60 minutes |
| 90840 | Psytx crisis each additional 30 minutes |
| 90845 | Psychoanalysis |
| 90847 | Family psytx with patient 50 minutes |
| 90853 | Group psychotherapy |
| 90899 | Psychiatric service/therapy |
| 9615X | Health and behavior assessment |

**Table A4. 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 |
| 1001 | BILLING PROV HAS NO CONTRACTS FOR DOS |
| 2017 | RECIPIENT SERVICES COVERED BY HMO PLAN |
| 2809 | DOB IS INVALID |
| 2804 | CASE NUMBER NOT ON FILE |
| 4014 | NO PRICING SEGMENT ON FILE |

**Table A5. Drug definitions for other sedative drugs**

| Drug Category | Generic Drug Name | HSN |
|---|---|---|
| Benzodiazepines | Alprazolam | 001617 |
| | Chlordiazepoxide HCl | 001610 |
| | Clonazepam | 001894 |
| | Diazepam | 001615 |
| | Lorazepam | 004846 |
| | Midazolam | 001619 |
| | Oxazepam | 001616 |
| | Temazepam | 001592 |
| | Triazolam | 001594 |
| Melatonin Receptor Agonists | Ramelteon | 033126 |
| | Tamsimelteon | 072007 |
| Non-Benzodiazepine Hypnotics | Eszopiclone | 026791 |
| | Zaleplon | 020347 |
| | Zolpidem tartrate | 007842 |