Policy Brief
September 2023

UPDATE FOR STATE MEDICAID OFFICIALS

Expanded Monitoring of Atypical Antipsychotics

In 2022, the Federal government announced several reforms aimed at improving the safety and quality of nursing home care. One particular focus has been to ensure appropriate mental health diagnoses and prescriptions for antipsychotics among older adults living in nursing homes. State Medicaid agencies are currently required to monitor and manage the appropriate use of antipsychotic medications by children under 18; if passed, the recently introduced federal legislation would require Medicaid programs to monitor antipsychotic medications given to *all* Medicaid beneficiaries, including people living in long-term care facilities (e.g., nursing homes) and people receiving home- and community-based services. This policy brief provides a relevant history of antipsychotic use among the Medicaid population, explains current federal efforts to expand monitoring, and discusses potential tracking and reporting practices state Medicaid agencies may consider if the federal legislation passes.

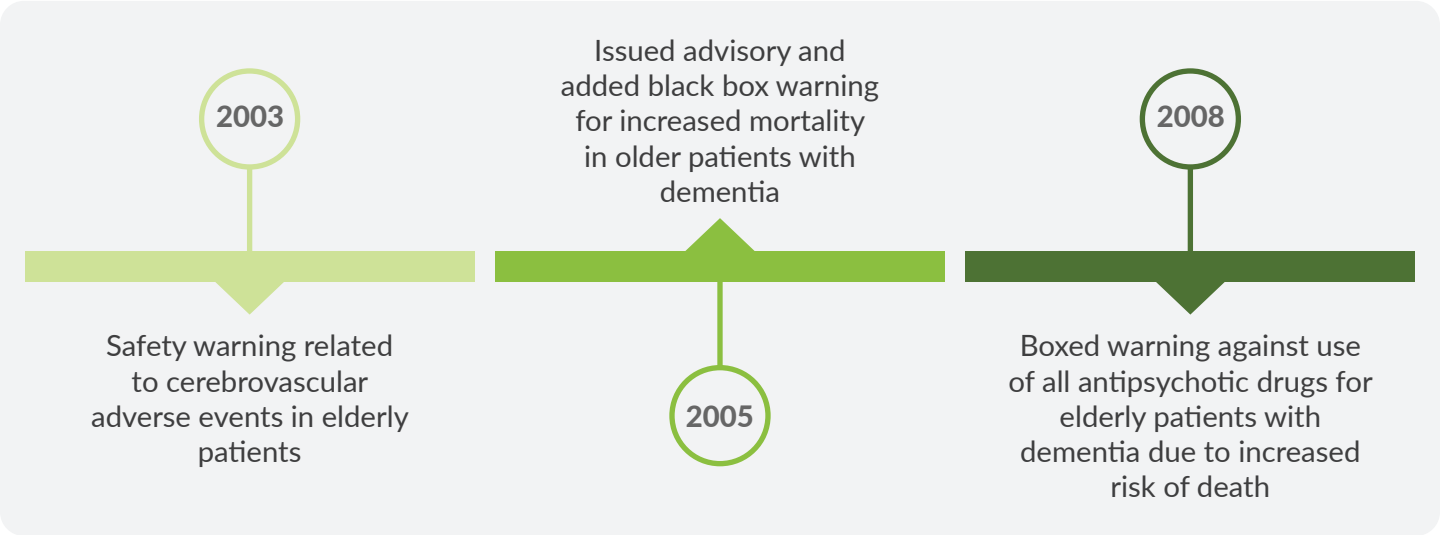
BACKGROUND

Atypical antipsychotics are second-generation antipsychotics that, until the early 1990s, were commonly reserved for adults with severe psychotic disorders.[1] As of 2023, there are 17 atypical antipsychotic drugs approved by the US Food and Drug Administration (FDA) and another 19 drug candidates in development.[2] There are no atypical antipsychotics with FDA approval for use in children under 5 years of age.[2] Six atypical antipsychotic agents have

FDA approval for children between the ages of 5 and 17: aripiprazole, asenapine, olanzapine, paliperidone, quetiapine, and risperidone.[5] Atypical antipsychotics have FDA approval for the following indications: schizophrenia, bipolar disorder, autism spectrum disorder, depression, Parkinson

FIGURE 1

US Food and Drug Administration (FDA) warnings for atypical antipsychotics[3,4]



disease, Tourette syndrome, and agitation associated with dementia due to Alzheimer disease.[3] In addition to use for approved indications, atypical antipsychotics are also prescribed off-label in response to behavioral symptoms and agitation caused by dementia.[3] Table 1 in the Appendix outlines FDA-approved atypical antipsychotics drugs and their indications, as well as new drugs in development with their intended indications.

Over the years, the FDA has issued several relevant boxed warnings and advisories related to atypical antipsychotics, displayed in Figure 1 above. In 2003, the FDA issued a safety alert related to the increased risk of cerebrovascular adverse events for older adult participants seen in risperidone trials. In 2005, the FDA issued an advisory of the increased risk of mortality in older adults and noted that atypical antipsychotics are not approved for the treatment of behavioral disorders in older adults with dementia.[4]

The FDA issued a boxed warning in 2008 on all antipsychotics among older adults with dementia due to increased risk of death.[6] In addition, aripiprazole, olanzapine-fluoxetine combination, and quetiapine fumarate carry an FDA boxed warning specific to children, regarding an increased chance of suicidal thinking and behavior for children and adolescents with major depressive disorder.[3]

Atypical Antipsychotics in Medicaid

Annual Medicaid spending on antipsychotics overall increased 154% between 1996 and 2002.[3] The dramatic increase was likely due to the widespread introduction of the atypical antipsychotic drug class in the late 1990s.[7] In 2015, 9% of all Medicaid spending was on psychotherapeutic agents.[8] In the early 2000s, Medicaid state agencies began implementing pharmacy preferred drug lists (PDLs) and clinical edits for atypical antipsychotics.[8] Program management for atypical antipsychotics grew quickly between 2001 and 2008.[8] Commonly used management strategies for these medications are prior authorization, step therapy, and quantity limits.[9]

By 2011, 14% of Medicaid enrollees were using a psychotropic medication, including almost half of children and adults who qualified for Medicaid on the basis of a disability.[9] Medicaid enrollees with a disability made up 10% of the total Medicaid population but in 2011 accounted for more than 50% of the psychotropic drug claims and 60% of the fee-for-service spending for this drug class.[9] Due to high use among enrollees and warnings from the FDA, around this time, states began additional

efforts, beyond formulary management strategies, to ensure appropriate use of psychotropic drugs in Medicaid programs.[10] Other factors also contributed to tighter restrictions on prescribing antipsychotic medication to children, including the passage of the Child and Family Services Improvement and Innovation Act in 2011.[3]

Beyond children, there are also concerns about the use of atypical antipsychotics in older adults. Atypical antipsychotics are commonly prescribed for the treatment of behavioral symptoms resulting from disturbances due to dementia.[3] As a consequence, these drugs are commonly prescribed to older adults in long-term care settings.[11] A 2002 study estimated that one quarter of Medicare beneficiaries in nursing homes were receiving atypical antipsychotics.[12] In 2011, a US Department of Health and Human Services report found that during a 6-month review period, 83% of atypical antipsychotic drug prescriptions for people in nursing homes were off-label, for indications not included in the FDA approval of the drug.[13] Outside the approval of brexpiprazole (Rexulti) for agitation associated with dementia due to Alzheimer disease in May 2023,[14] evidence does not show these drugs to be effective for off-label purposes such as dementia-related agitation and disturbances in older adults.[15]

Previous Federal Legislation Related to Atypical Antipsychotic Monitoring

The 2018 Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act directed state Medicaid agencies to monitor antipsychotic prescribing for children, among other things.[16] The SUPPORT Act requires state Medicaid agencies to report annually on the drug monitoring activities for individuals under the age of 18, and children in foster care specifically. By 2020, all states had a program in place for monitoring appropriate use of antipsychotic drugs in children.[17] The Centers for Medicare & Medicaid Services (CMS) has amended the annual drug utilization review (DUR) reporting form to include the following questions related to monitoring atypical antipsychotics in children[17]:

- Question #1: Does your state currently have restrictions in place to limit the quantity of antipsychotic drugs?
- Question #2: Does your state have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?

In response to Question #1, the federal fiscal year 2021 National Medicaid Fee-For-Service DUR Annual Report published by CMS listed 41 states as having restrictions in place to limit the quantity of antipsychotic drugs given to children.[17] For question #2, all 50 states responded yes to having documented programs to manage or monitor appropriate use of antipsychotic drugs in children.[17] The following states responded as not having program-wide quantity limits: California, Hawaii, Massachusetts, Michigan, New Mexico, Oregon, Rhode Island, West Virginia, and Wisconsin.[17] However, these states clarified that they do have quantity limitations in most cases for antipsychotic drugs used in particular populations and instances.[9]

KEY QUESTIONS

KQ1. Which states have the ability to manage atypical antipsychotics and which states are prohibited from doing so?

KQ2. What stakeholders (e.g., drug manufacturers, patient advocacy groups, federal and state oversight) and what activity is shaping public decision-making for atypical antipsychotic coverage decisions?

METHODS

We searched DuckDuckGo to identify relevant articles, studies, and commentaries concerning monitoring of atypical antipsychotics. We also

searched IPD Analytics for information regarding approved and in-development atypical antipsychotic drugs. We conducted key informant interviews with 2 industry experts and 1 Medicaid state agency.

To answer KQ1 and fill out Table 2, we reviewed publicly posted PDLs on state agency websites and looked for the following: preferred and nonpreferred atypical antipsychotic drugs, prior authorization requirements, other edits (e.g., quantity limits, clinical edits, step therapy), and notes about management strategies.

FINDINGS

Medicaid Agency Ability to Manage Atypical Antipsychotics

A 2015 study found that 31 states had implemented prior authorization policies for atypical antipsychotics for children.[18] In 2023, we found 45 states with prior authorization processes for atypical antipsychotics, including for adults and children, as listed in Table 2 in the Appendix. The 5 states that do not have atypical antipsychotics on their PDL are Alabama,[19] Kansas,[20] Missouri,[21] Nebraska,[22] and South Dakota.[23] States also use management strategies such as prior authorization, quantity limits, age limits, clinical edits, clinical reviews, and step therapy to manage atypical antipsychotic use[8]; more details can be found in Table 2 in the Appendix.

In most cases, drugs that are listed as preferred on a state's PDL do not require prior authorization. There are cases, however, where prior authorization is required for drugs listed as preferred. Column 3 in Table 2 reports cases where prior authorization is required for a preferred drug, or where there are general prior authorization requirements (e.g., children under 18) for both preferred and nonpreferred drugs. The information in Table 2 reflects information on each state's PDL at the time of writing this report, and is subject to change.

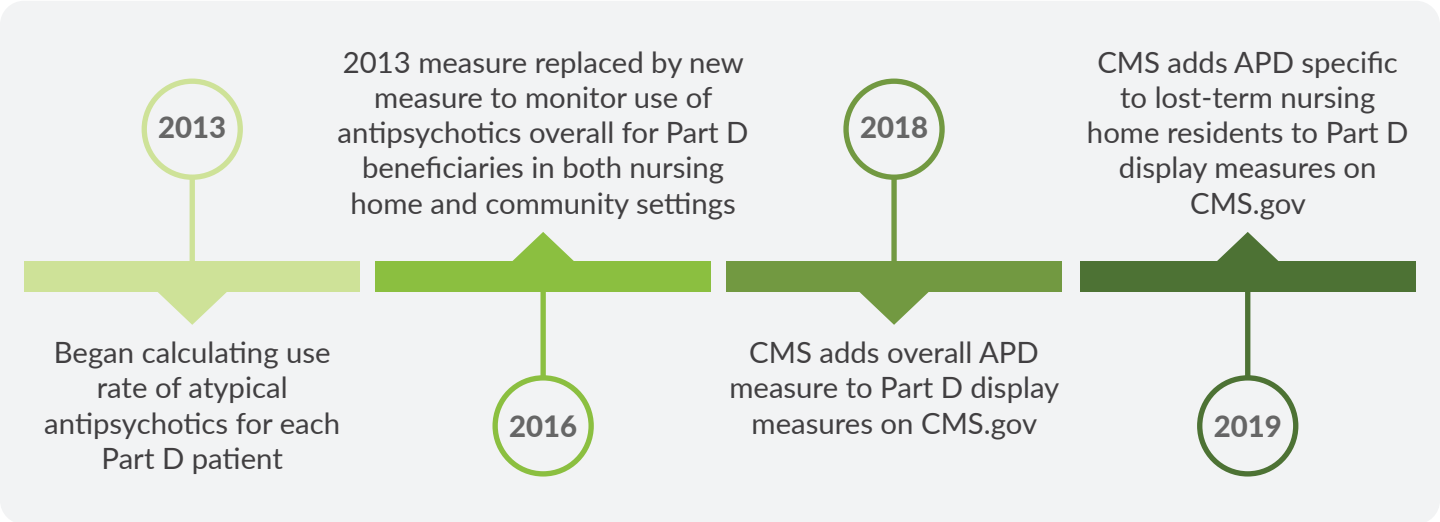
Federal Activity

Federal Reports

There have been a number of recently published federal reports examining atypical antipsychotic usage in nursing homes and other long-term care facilities.[24-27] CMS first started tracking use of atypical antipsychotics in nursing homes through Medicare quality measures in 2013.[26] Over the

FIGURE 2

CMS monitoring of atypical antipsychotics in nursing homes[26]



Abbreviations. APD: Antipsychotic Use in Person with Dementia measure; CMS: Centers for Medicare & Medicaid Services

past decade, CMS has taken additional steps to track and report on quality measures related to atypical antipsychotics and antipsychotic use in general, and among older adults in particular; Figure 2 outlines this process.

The initial quality measure was included for each Part D contract and named *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes*.[26] Then next iteration of the quality measure, established in 2016, was expanded to antipsychotics in general in both nursing home and community settings and named *Antipsychotic Use in Persons with Dementia (APD)*.[26] In addition to that measure, CMS began calculating *APD for Long-Term Nursing Home Residents*.[26] Starting in 2018, the APD quality measure is publicly reported on CMS.gov; in 2019 the APD measure specific to nursing homes was added to the website.[26]

A 2021 report by the US Department of Health and Human Services Office of the Inspector General (OIG) found the CMS methodology for counting the number of nursing home residents using antipsychotic drugs may not provide complete information.[26] CMS uses the Minimum Data Set (MDS) public reports to count the number of nursing home residents receiving antipsychotic drugs.[26] OIG analysts cross-referenced cases in the MDS with Medicare Part D submission data to validate the CMS reporting methodology.[26] This further analysis found that 5% of Medicare members in long-term care facilities over the age of 65 had a part D claim for an antipsychotic drug but were not reported as having received the drug in the MDS, indicating potentially problematic use of the antipsychotic.[26] The report suggested CMS should take additional steps to validate MDS data and bolster monitoring of antipsychotic use by incorporating additional data into the calculation methodology.[26]

After publication of the 2022 OIG report,[28] the Biden administration announced a new CMS effort to reduce the inappropriate use of antipsychotic medications by examining and targeting potentially inappropriate diagnoses perpetuating increased use of atypical antipsychotics for nursing home residents.[18] To achieve this goal, CMS focused efforts on improving the accuracy of quality measures calculated for its Nursing Home Care Compare rating system.[18]

The Nursing Home Care Compare rating system was established in 2008 to rate nursing homes on 3 domains: health inspections, staffing, and quality measures.[26] The ratings are publicly available and report information about quality of care at all Medicare- and Medicaid-certified nursing homes.[18] The rating incudes a quality measure for the number of long-stay residents receiving antipsychotics, as reported in the MDS[18]; this measure does exclude residents with a schizophrenia diagnosis, Huntington disease, or Tourette syndrome.[26]

The 2021 OIG report found that nearly one-third of residents who were reported as having a schizophrenia diagnosis in the MDS (which would exclude them from the quality measure rating calculation) did not have any Medicare service claims for that diagnosis.[26] Updates to the rating system echo findings from the 2021 OIG report and indicate underlying data integrity issues, as well as potentially problematic use of diagnostic coding, which threaten the validity of the quality measure used to publicly rate nursing homes.[18]

CMS conducted on-site surveys of nursing homes in 2021 and targeted the potentially "erroneous" schizophrenia diagnosis coding.[18] Those audits identified facilities with an established pattern of potentially inappropriate diagnoses.[26] In 2022, CMS conducted off-site surveys of MDS coding, with the same focus as the 2021 OIG report.[18] CMS audits found an absence of comprehensive psychiatric evaluations and behavior documentation for long-term residents receiving atypical antipsychotics.[18] Additionally, audit results showed that medical records reported sporadic behaviors often related to dementia rather than schizophrenia.[18] CMS has continued conducting audits of nursing homes, and this may result in adjusting the quality measure star ratings for

facilities whose audits reveal inaccurate MDS coding.[18] CMS has announced that it will publically post citations given to facilities related to the diagnosis coding audits.[4]

In February 2023, OIG announced an upcoming report titled *In-Depth Review of Nursing Home Citations Related to the Use of Antipsychotic Drugs*, scheduled to be published in 2024.[4] The report will be related to claims in the 2021 OIG report about "the potential falsification of schizophrenia diagnoses to make the use of antipsychotic drugs appear appropriate and avoid Federal attention."[4(p.1)] The report will examine the nature of nursing home citations resulting from use of antipsychotic drugs and identify vulnerabilities that contribute to the inappropriate use of these drugs.[29]

Federal Legislation

On June 14, 2023 US HB4096 was introduced to amend Title XIX of the Social Security Act, expanding the ability and practice of Medicaid state programs to monitor antipsychotics medications for all Medicaid beneficiaries.[29] The bill has been referred to the Subcommittee on Health within the House Committee on Energy and Commerce.[29] As of August 2023, the bill had not been up for any votes.[29]

HB4096 would add a new section into 42 USC 1396a(oo)(1)(B)[30] currently titled "Program to monitor antipsychotic medications by children."[30] The new section 1 (b) would be retitled "Expanding application of Medicaid state programs to monitor antipsychotic medications to all Medicaid beneficiaries" and would require that, beginning January 1, 2024, states have a program in place to monitor and manage the appropriate use of antipsychotic medications by individuals, regardless of age, enrolled under the State Plan (or under a waiver of the State Plan).[29] The bill would also require states to submit annual reports for individuals over the age of 65, individuals receiving home- and community-based services (as defined in §9817(a)(2) of Public Law 117–2), and individuals residing in institutional care settings, including nursing facilities and intermediate care facilities for individuals with intellectual disabilities.[30]

Current statute exempts residents of long-term care facilities from drug review and use reporting requirements, and the proposed legislation would eliminate this exemption.[29] In summary, the proposed legislation would add annual DUR reporting on the use of antipsychotics in the following populations: individuals over the age of 65, individuals receiving home and community-based services, and individuals over the age of 18 residing in institutional care settings including nursing facilities and intermediate care facilities for individuals with intellectual disabilities.[31]

Drug Manufacturer Activity

We did not find explicit evidence of direct involvement by drug manufacturers in response to CMS efforts to change monitoring of antipsychotic use in nursing homes. We did, however, find 1 organization funded by pharmaceutical companies that responded to CMS auditing nursing home quality measures, Project PAUSE.

Project Psychoactive Appropriate Use for Safety and Effectiveness (PAUSE) is an "ad hoc coalition of national patient and professional organizations collectively advocating on clinical regulatory and legislative issues in long-term care."[31(p1)] Project PAUSE members include:[32]

- Alliance for Aging Research
- Alzheimer's Foundation of America
- American Association for Geriatric Psychiatry
- American Association of Post-Acute Care Nursing
- American Health Care Association
- American Society of Consultant Pharmacists
- Caregiver Action Network
- The Gerontological Society of America
- National Community Pharmacists Association
- National Minority Quality Forum

- Pharmacy Quality Alliance
- The Society for Post-Acute and Long-Term Care Medicine

In 2023 Project PAUSE submitted a response to the news from OIG and CMS regarding additional audits to investigate the quality reporting of nursing home residents receiving antipsychotics.[32] The response outlines the coalition's belief that the nursing home rating quality measure should be improved to recognize clinically appropriate and inappropriate use, use of preadmission diagnoses, and further declared that efforts by CMS and OIG would not achieve this.[32] The advocacy group's response said the quality measure investigations were punitive and not focused on resident well-being.[33]

Patient Advocacy Activity

We also found responses from patient advocacy organizations regarding the recently announced efforts to examine use of antipsychotics and potentially edit quality measure ratings.

LeadingAge, an association of nonprofit aging service providers, published a statement in January 2023 responding to the newly announced federal efforts.[33] LeadingAge indicated the changes would mean increased transparency for nursing home, residents, families, and the general public, but stressed that without appropriate communication they could lead to confusion or negative unintended consequences.[33] The association encouraged service providers to communicate all CMS-announced changes with residents, families, and staff and explain any implications from the public reporting.[34]

The National Consumer Voice for Quality Long-Term Care also released a statement after CMS announced audit plans.[34] The organization had previously raised concerned about the accuracy of quality measures but supported the publicized actions.[34] The organization urged further action including additional enforcement, such as civil monetary penalties, against facilities found to have a pattern of inappropriately diagnosing residents as schizophrenic when receiving antipsychotics.[34] In addition to investigating potentially inappropriate schizophrenia diagnoses, the organization encouraged CMS to monitor increased use of other nonantipsychotic drugs to chemically restrain residents, and urged CMS to implement a minimum staffing standard.[17]

STATE CONSIDERATIONS

As states begin to consider the potential effects of legislation requiring expanded monitoring of atypical antipsychotics, they could look at recent efforts focused on monitoring of child use of these drugs. The monitoring requirements of the 2018 SUPPORT Act resulted in a new question to the national fee-for-service DUR report: *Does your state have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?*[35] By 2023, almost all states reported requiring prior authorization for children prescribed atypical antipsychotics, as outlined in Table 2 in the Appendix.

Due to the nature of recent federal reports focused primarily on nursing homes, state agencies may initially have concerns about their ability to fulfill reporting requirements of the newly introduced federal legislation. State staff may understandably believe the overlap between Medicare and Medicaid among the nursing home population of adults over 65 would complicate data analysis efforts.

If an individual is over 65 and has Medicare and Medicaid coverage, the drugs they receive in a nursing home would be covered by Medicare.[18] In contrast to the bill description and the subject of the recent federal reports, there are additional populations beyond older adults in nursing homes for which states would need to establish reporting. Specifically, the legislation in HB4096 would require states to report on antipsychotic use for the following populations, beyond older adults in nursing homes:

- Any individual receiving home and community-based services
- Individuals between ages 18 and 65 in any long-term care facility
- Individuals in intermediate care facilities for people with intellectual disabilities

States should have the ability to track atypical antipsychotics use for these populations as they are the payer of their pharmacy claims, unlike with adults over 65 covered by Medicare. To establish monitoring efforts, states may benefit from reviewing the auditing methodology CMS has announced it will use to conduct their audits. For older adults, CMS has been validating antipsychotic use and schizophrenia diagnoses by examining the facility's evidence for documenting, assessing, and coding a diagnosis of schizophrenia in the MDS.[18] Initial auditing efforts found comprehensive psychiatric evaluations and behavior documentations were missing in the MDS.[26] OIG validation efforts used Medicare claims to validate MDS data on antipsychotic use.[3]

For the non–nursing home populations listed in HB4096, states would have access to diagnosis codes and drug use claims, which could be used to execute a validation process similar to what CMS used in their inquiry into nursing home usage.

CONCLUSION

Medicaid payments for antipsychotic drugs dramatically increased in the early 2000s due to the introduction of the atypical antipsychotic drug class.[3] Concerns about use of atypical antipsychotics in the elderly population, especially those adults living with dementia, were reinforced with various FDA warnings between 2000 and 2010.[10] Initial monitoring efforts of atypical antipsychotics focused on children in foster care after the Child and Family Services Improvement and Innovation Act of 2011.[16] Required monitoring of children prescribed atypical antipsychotics was then expanded to all populations under 18 through the 2018 SUPPORT Act.[16] Today, all Medicaid agencies must monitor and report on atypical antipsychotic use by children.[29]

Recently introduced federal legislation proposes expanded monitoring requirements to now include adults in nursing homes, people receiving home- and community-based services, and members in long-term care facilities including intermediate care facilities for individuals with intellectual disabilities.[36] Although states may not be able to monitor and report use for adults over 65 in nursing homes since they are likely covered by Medicare, states may want to begin preparing for expanded monitoring for the other populations named in the bill.[29] States could follow the CMS strategy for monitoring, which involves confirming that people receiving atypical antipsychotics have the appropriate, and validated, behavioral health diagnoses that would indicate suitable use.

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APPENDIX

TABLE 1

Indications of Atypical Antipsychotics: Approved and Under Development

Generic name	Brand name(s)	Disease state or indications
FDA-approved drugs		
Aripiprazole	Abilify (2-mg tablet) Abilify (20-, 30-mg tablets) Abilify (5-, 10-, 15-mg tablets) Abilify (injection) Abilify (oral solution) Abilify Asimtufii Abilify DISCMELT Abilify Maintena Abilify MyCite Kit	• Autistic disorder (autism): irritability associated with autistic disorder • Bipolar disorder: acute agitation in bipolar patients • Bipolar disorder: acute treatment of bipolar I • Schizophrenia: acute agitation in schizophrenic patients • Schizophrenia: schizophrenia • Depression: major depressive disorder • Mental, behavioral and neurodevelopmental disorders (not otherwise classified): Tourette syndrome • Bipolar disorder: acute treatment of bipolar I • Bipolar disorder: maintenance of bipolar I
Aripiprazole Lauroxil	Aristada Aristada Initio Kit	• Schizophrenia: schizophrenia
Asenapine Maleate	Saphris	• Schizophrenia: schizophrenia • Bipolar disorder: acute treatment of bipolar I • Bipolar disorder: maintenance of bipolar I
Brexpiprazole	Rexulti	• Schizophrenia: schizophrenia • Depression: major depressive disorder • Neurodegenerative disorders: dementia-related agitation
Cariprazine Hydrochloride	Vraylar (capsule)	• Schizophrenia: schizophrenia • Bipolar disorder: acute treatment of bipolar I • Bipolar disorder: depressive episodes in bipolar I disorder • Depression: major depressive disorder
Clozapine	Fazaclo ODT (12.5 mg) Fazaclo ODT (150 mg) Fazaclo ODT (200 mg) Fazaclo ODT (25 mg, 100 mg)	• Schizophrenia: reduce suicidal behavior • Schizophrenia: treatment resistant schizophrenia • Schizoaffective disorder: reduce suicidal behavior
Iloperidone	Fanapt	• Schizophrenia: schizophrenia
Lumateperone Tosylate	Caplyta	• Schizophrenia: schizophrenia • Bipolar disorder: depressive episodes in bipolar I disorder • Bipolar disorder: depressive episodes in bipolar II disorder

Generic name	Brand name(s)	Disease state or indications
Lurasidone Hydrochloride	Latuda	• Schizophrenia: schizophrenia • Bipolar disorder: depressive episodes in bipolar I disorder
Paliperidone	Invega	• Schizophrenia: schizophrenia • Schizoaffective disorder: schizoaffective disorder
Paliperidone Palmitate	Invega Hafyera Invega Sustenna Invega Trinza	• Schizophrenia: schizophrenia • Schizoaffective disorder: schizoaffective disorder
Pimavanserin Tartrate	Nuplazid (capsule) Nuplazid (tablet)	• Parkinson disease: visual hallucinations
Quetiapine Fumarate	Seroquel Seroquel XR (150 mg) Seroquel XR (200 mg) Seroquel XR (300 mg) Seroquel XR (400 mg) Seroquel XR (50 mg)	• Schizophrenia: schizophrenia • Bipolar disorder: acute treatment of bipolar I • Bipolar disorder: maintenance of bipolar I • Bipolar disorder: depressive episodes in bipolar I disorder • Bipolar disorder: depressive episodes in bipolar II disorder • Depression: major depressive disorder
Risperidone	Perseris Kit Risperdal Consta Rykindo	• Schizophrenia: schizophrenia • Bipolar disorder: acute treatment of bipolar I
Risperidone	Uzedy	• Schizophrenia: schizophrenia
Ziprasidone Hydrochloride	Geodon (capsules) Geodon (oral suspension)	• Schizophrenia: acute agitation in schizophrenic patients • Schizophrenia: schizophrenia • Bipolar disorder: acute treatment of bipolar I • Bipolar disorder: maintenance of bipolar I
Ziprasidone Mesylate	Geodon (injection)	• Schizophrenia: acute agitation in schizophrenic patients • Schizophrenia: schizophrenia • Bipolar disorder: acute treatment of bipolar I • Bipolar disorder: maintenance of bipolar I
Drugs in development [a]		
AQS1301	Aripiprazole	• Bipolar disorder: maintenance of bipolar I (developing) • Autistic disorder (autism): autism spectrum disorder (developing) • Schizophrenia: schizophrenia (developing)
Caplyta	Lumateperone Tosylate	• Schizophrenia: schizophrenia (phase 3) • Schizoaffective disorder: schizoaffective disorder (phase 3) • Depression: major depressive disorder (phase 3)
Caplyta LAI	Lumateperone Tosylate	• Schizophrenia: schizophrenia (phase 1)

Generic name	Brand name(s)	Disease state or indications
Cyclurad	D-Cycloserine; Lurasidone	• Bipolar disorder: depressive episodes in bipolar II disorder (phase 3)
Fanapt	Iloperidone	• Bipolar disorder: acute treatment of bipolar I (phase 3)
ITI-1284	Deuterated Lumateperone	• Alzheimer disease: dementia associated with Alzheimer disease (developing) • Neurodegenerative disorders: dementia-related psychosis (developing) • Depression: depression (developing)
Lu AF35700	TBD	• Schizophrenia: treatment resistant schizophrenia (phase 3)
LY03010	Paliperidone Palmitate	• Schizophrenia: schizophrenia (developing) • Schizoaffective disorder: schizoaffective disorder (developing)
LYN-005	Risperidone	• Schizophrenia: schizophrenia (phase 3)
Nuplazid	Pimavanserin Tartrate	• Autistic disorder (autism): irritability associated with autistic disorder (phase 3) • Alzheimer disease: psychosis associated with Alzheimer disease (CRL) • Alzheimer disease: Alzheimer disease (phase 3) • Neurodegenerative disorders: Lewy body dementia (phase 3) • Neurodegenerative disorders: dementia-related psychosis (CRL) • Neurodegenerative disorders: vascular dementia (phase 3) • Neurodegenerative disorders: frontotemporal degeneration (phase 3) • Depression: major depressive disorder (phase 3) • Schizophrenia: schizophrenia (phase 3) • Parkinson disease: dementia (phase 3)
Relday	Risperidone	• Schizophrenia: schizophrenia (phase 1)
Rexulti	Brexpiprazole	• Alzheimer disease: inhibition of cognitive decline (phase 3) • Autistic disorder (autism): Irritability associated with autistic disorder (phase 3) • Bipolar disorder: acute treatment of bipolar I (phase 3) • Mood disorders (not otherwise classified): PTSD (phase 3)
Rexulti LAI	Brexpiprazole	• Schizophrenia: schizophrenia (phase 1)
Risperidone Implant	Risperidone	• Schizophrenia: schizophrenia (phase 3)
Risvan	Risperidone	• Schizophrenia: schizophrenia (CRL)

Generic name	Brand name(s)	Disease state or indications
Vraylar (capsule)	Cariprazine Hydrochloride	• Autistic disorder (autism): autism spectrum disorder (phase 3) • Bipolar disorder: acute treatment of bipolar I (phase 3) • Bipolar disorder: depressive episodes in bipolar I disorder (phase 3) • Depression: major depressive disorder (phase 3)
Vraylar (oral solution)	Cariprazine Hydrochloride	• Autistic disorder (autism): autism spectrum disorder (phase 3)
ZY102	Aripiprazole	• Schizophrenia: schizophrenia (developing)

Note. [a] Developing stage refers to drugs that are in the New Drug Application (NDA) stage of the drug review process.
Source. IPD Analytics. Atypical antipsychotic. 2023; https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Atypical-antipsychotic. Accessed June 29, 2023.
Abbreviations. CRL: complete response letter; FDA: US Food and Drug Administration; LAI: long-acting injectable; OTD: orally disintegrating tables; PTSD: post-traumatic stress disorder; XR: extended-release.

TABLE 2

Management of Antipsychotics by State as Noted on State Medicaid PDLs

State	Management restrictions?	PAs on preferred drugs?	Other edits	Notes
Alabama[19]	✓	✓	Quantity limit (with exemptions)	Antipsychotics note included in PDL
Alaska[36]	X	✓	N/A	PA required for children under 5 years old and when duplication occurs or quantity limit exceeded
Arizona[37]	X	✓	N/A	PA required for kids under 18 and under 6 years old depending on drug
Arkansas[38]	X	✓	Quantity limits and day supply	PA required for children
California[39]	X	(see Notes column)	Labeler restriction for some drugs in class	Requires Treatment Authorization Request for the use of any drugs, including antipsychotics for non–FDA-approved indications The use of antipsychotics for Medi-Cal beneficiaries residing in nursing facilities is restricted to FDA-approved indications
Colorado[40]	X	✓	Age limits; quantity limits	PA required for some drugs and required for all members younger than FDA-approved age
Connecticut[41]	X	✓ (for some)	N/A	PA required for nonpreferred
Delaware[42]	X	✓	Clinical PA for long-acting injectable	PA required for patients under 18 years old
Florida[43]	X	✓	Age limits (6, 10, and 18 years old, depending on drug); requires confirmation that FDA requirements were met	Auto PA for certain drugs in class
Georgia[44]	X	✓	Quantity limits	PA required for participants under 10 years old
Hawaii[45]	X	Administered by MCOs	N/A	MCOs administer pharmacy benefit and have their own PDLs
Idaho[46]	X	✓	N/A	PA required for some drugs
Illinois[47]	X	✓	N/A	PA required for participants under 8 years old and long-term care residents

State	Management restrictions?	PAs on preferred drugs?	Other edits	Notes
Indiana[48]	X	✓	Utilization edits	In accordance with Indiana law, all antianxiety, antidepressant, antipsychotic, and "cross indicated" drugs are considered as being preferred
Iowa[49]	X	✓	Step therapy required	PA required for some drugs
Kansas[20]	✓	X	N/A	State statute prohibits PAs or other restrictions on medications used to treat mental illness unless developed by Medicaid Drug Utilization Review Board
Kentucky[50]	X	✓	Clinical criteria and quantity limits	N/A
Louisiana[51]	X	✓	Additional clinical information required for some drugs; quantity limits for some drugs	PA required for certain agents and depending on age
Maine[52]	X	✓	Quantity limits for some drugs	PA required for all members under age and for use of 2 or more medications
Maryland[53]	X	✓	Clinical criteria	PA required for members under 17 years old
Massachusetts[54]	X	✓	N/A	PA required for children under 6 years old; depends on drug and quantity
Michigan[55]	X	X	N/A	No nonpreferred agents listed; PA not required on preferred agents
Minnesota[56]	X	✓	N/A	N/A
Mississippi[57]	X	✓	N/A	PA criteria: minimum age limits for certain drugs; concurrent therapy limits; clinical criteria for nonpreferred drugs
Missouri[21]	✓	N/A	N/A	Atypical antipsychotics not on PDL
Montana[58]	X	✓	Dose optimization edits; clinical criteria apply	PA required for alternative dosage and for children under 7 years old
Nebraska[22]	✓	N/A	N/A	Atypical antipsychotics not on PDL
Nevada[59]	X	✓	N/A	PA required for members under 18 years old
New Hampshire[60]	X	✓	Quantity limits	PA required for some drugs

State	Management restrictions?	PAs on preferred drugs?	Other edits	Notes
New Jersey[61]	X	N/A	Dose optimization; age limit restrictions; quantity limits	PDL only includes ziprasidone
New Mexico[62]	X	✓	Quantity limit; age limit	Pharmacy benefit under MCOs
New York[63]	X	✓	Dose optimization, clinical criteria, step therapy	PA required for patients under minimum age (drug specific); for patients under 21 with concurrent use; for quantities of certain drugs
North Carolina[64]	X	✓	N/A	N/A
North Dakota[65]	X	✓	Step therapy for cariprazine (Vraylar)	PA required for concurrent use of certain drugs in class
Ohio[66]	X	✓	Step therapy	PA required for certain drugs in class
Oklahoma[67]	X	✓	N/A	PA required for children under 5 years old
Oregon[68]	X	✓	Quantity limits; age restrictions	Some are preferred; some are voluntary nonpreferred; some have not been reviewed for PDL placement
Pennsylvania[69]	X	✓	Age restrictions, quantity limits	PA required for certain ages
Rhode Island[70]	X	✓	Quantity limits for certain drugs	PA required for certain drugs in class
South Carolina[71]	X	✓	N/A	Patients currently receiving nonpreferred agent will be able to continue without a PA; PA required for children under 6 years old
South Dakota[23]	✓	N/A	N/A	Atypical antipsychotics not listed on PDL
Tennessee[72]	X	✓	Quantity limit	PA required for certain drugs including those on preferred list
Texas[73]	X	N/A	Dosage limits	Recommended maximum doses listed by drug and age
Utah[74]	X	✓	Quantity limits; age restrictions	PA required for children under 6 years old
Vermont[75]	X	✓	Clinical criteria for children under 18; quantity limits	Separate PDLs for adults and children
Virginia[76]	X	✓	N/A	PA required for children younger than 18 years old

State	Management restrictions?	PAs on preferred drugs?	Other edits	Notes
Washington[77]	X	✓	All drugs in class subject to second opinion network limits when drug is prescribed outside guidelines by Children and Youth Behavioral Health Work Group	PA required for certain drugs in class
West Virginia[78]	X	✓	N/A	PA required for all children under 18 years old and for certain drugs in class
Wisconsin[79]	X	✓	N/A	PA required for children under 8 years old
Wyoming[80]	X	✓	Dosage limits for each drug and age group; clinical criteria for some drugs	PA required for children under 18 years old for some drugs and under 5 years old for other drugs; also for certain drugs and dosage combinations

Notes. ✓ denotes "yes"; X denotes "no." Information in table reflects state PDL lists as of August 2023 and are subject to change.
Abbreviations. FDA: US Food and Drug Administration; MCO: managed care organization; N/A: not applicable; PA: prior authorization; PDL: preferred drug list.

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