Market Access Brief

The *ADHD Competitive Landscape* RISE module provided an overview of the ADHD market. This brief provides an overview of market access. Market access is the process of ensuring that patients can obtain clinically appropriate medications quickly, conveniently, and at prices that payers perceive as affordable.

MARKET ACCESS OVERVIEW

Market access has become increasingly important to pharmaceutical manufacturers as payers try to balance the increasing costs of medication with budget constraints.

- A payer is an organization that sets rates for provider services (including pharmacy benefits), collects money through premium payments (commercial health insurance payers) or tax dollars (government payers such as Medicaid), and processes and pays provider claims

- Health care provider (HCP), patient, and payer factors all influence market access for a medication

HCP (prescriber) factors

- Clinical benefit
- Patient's insurance coverage
- Patient's out-of-pocket costs

Payer factors

- Pharmacy benefit design
- Utilization restrictions (eg, prior authorization, step therapy, quantity limits)
- Provider networks (ie, patients may be directed to specific pharmacies)

Patient factors

- Insurance coverage
- Perception of cost and affordability

- This brief will focus mainly on payer factors that influence market access for a medication

TYPES OF PAYERS WHO PROVIDE PHARMACY BENEFIT COVERAGE TO PATIENTS

Private Insurance

Employers who provide health insurance to employees

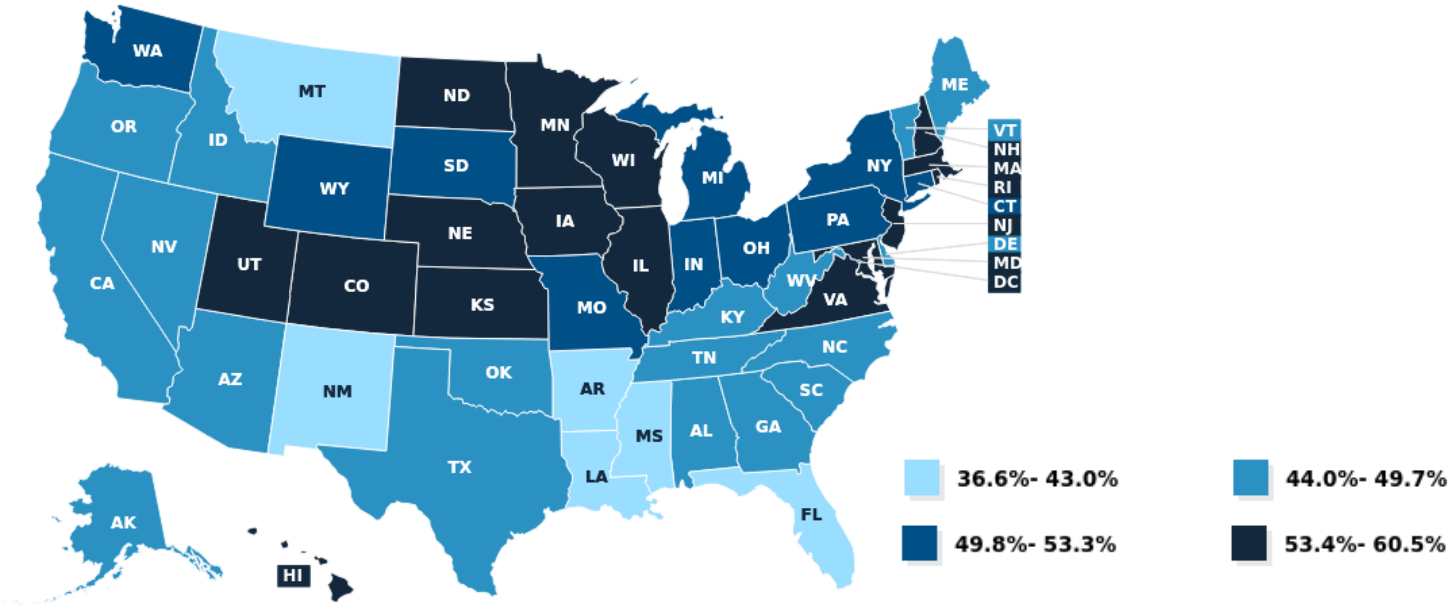
- Self-insured employers
- Employers who purchase insurance through commercial entities

Individuals who purchase their own health insurance directly

- Commercial insurance companies
- Health insurance exchange (Health Insurance Marketplace®)

- Overall, ~50% of total US population is covered by their employer
  - Another 6% of the US population is covered by private/commercial insurance, but they purchase their policy directly from an insurance company
- Percentage of US population covered by employer varies by state

Employer Health Insurance Coverage in the United States (2019)



Source: Kaiser Family Foundation's State Health Facts.

ADHD market is highly commercial along with Medicaid

Public Insurance

Medicaid

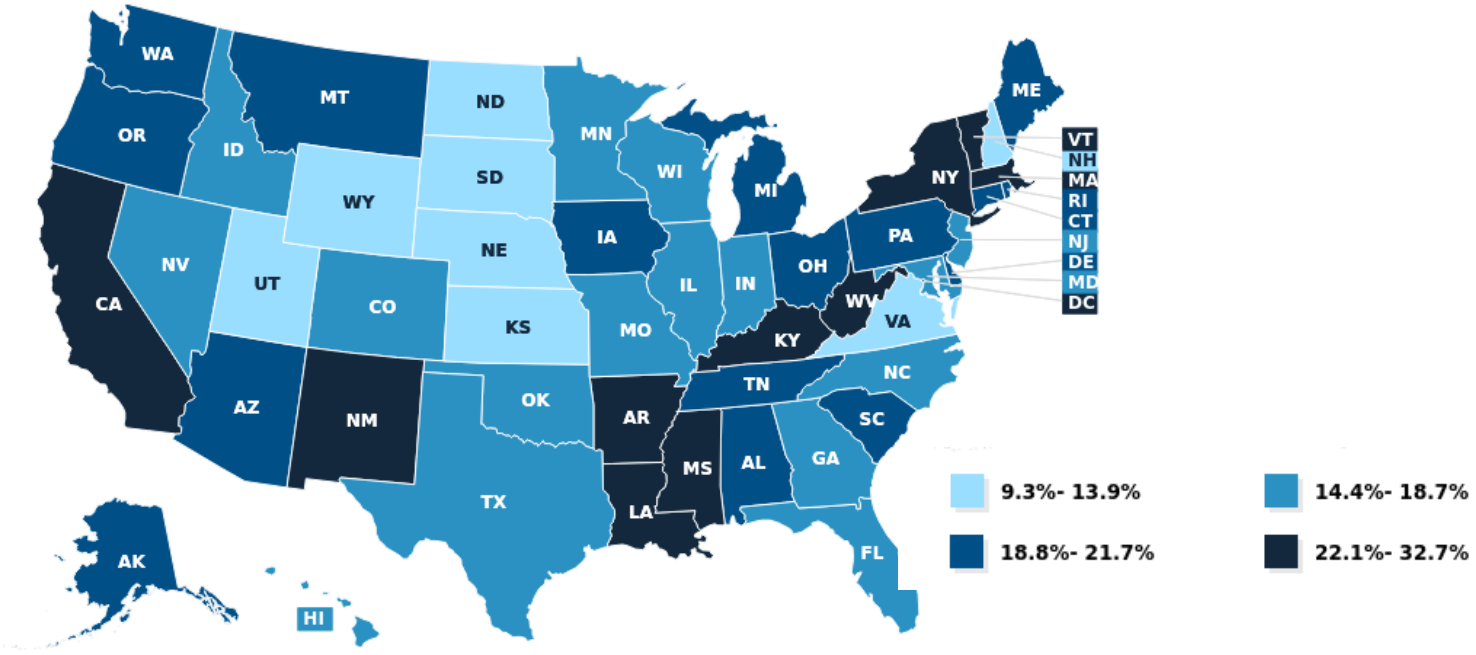
- Provides health insurance to low-income individuals
- Federal program managed by individual states
- Eligibility criteria and costs vary from state to state

Medicare

- Covers persons ≥65 years
- Covers those <65 years with a qualifying disability
- People with end-stage renal disease

- Overall, ~20% of US population is covered by Medicaid
- Percentage of US population covered by Medicaid varies by state

Medicaid Health Insurance Coverage in the United States (2019)



Source: Kaiser Family Foundation's State Health Facts.

US Centers for Medicare & Medicaid Services (CMS) is the federal government administrator for both Medicare and Medicaid.

PHARMACY BENEFITS PROVIDED BY PAYERS

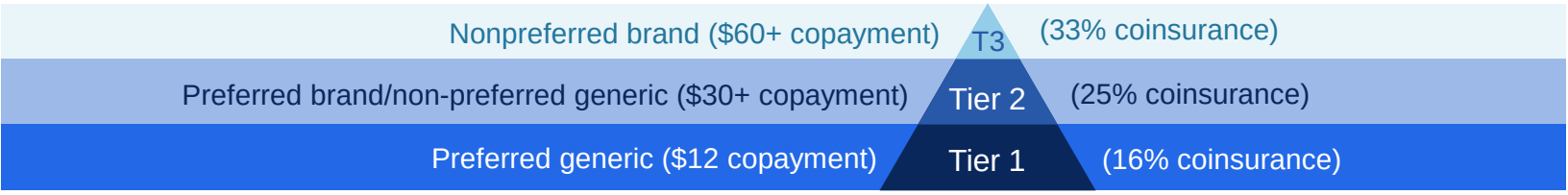
Overview of Pharmacy Benefit Managers (PBMs)

- PBMs are organizations that manage pharmacy benefits for different clients, such as
  - Commercial health insurers
  - Self-insured employers
  - Managed care organizations (MCOs)
  - Government purchasers
- PBMs function as brokers between payers (representing patients), pharmaceutical manufacturers, and pharmacies
  - Influence which medications are used most frequently
  - Determine what pharmacies are paid for prescription medications
  - Negotiate volume discounts from pharmaceutical manufacturers
- PBMs may do some or all of the following for their clients:
  - Pharmacy benefit plan design
  - Creation/administration of retail pharmacy and mail-order pharmacy networks
  - Pharmacy claims processing
  - Prescription medication formulary management
- PBMs are involved in the administration of pharmacy benefits for >266 million Americans
  - Large PBMs may have thousands of clients
  - A single PBM does not necessarily use the same prescription formulary for each client
- The 3 largest PBMs, accounting for >70% of prescription claims volume, are
  - CVS
  - Express Scripts
  - UnitedHealth's Optum

Private/Commercial Pharmacy Benefit Plans

Private/commercial insurance plans and public insurance plans may provide both medical and pharmacy benefits to patients, however, some patients may receive medical and pharmacy benefits from 2 different companies.

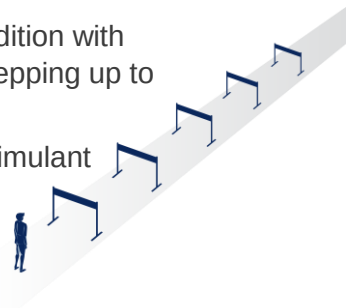
- Private/commercial insurance plans and PBMs use formularies, which are complex utilization management tools
  - A formulary is a continually updated list of medications that is supported by current evidence-based medicine and encourages the use of safe, effective, and affordable medications
  - Formularies are not structured equally across plans and PBMs, and may change due to market events
  - Formulary tiers correspond to different levels of beneficiary cost sharing that reward patients for using generic and preferred medications[a]
    - Formularies may have 3 tiers or ≥5 tiers, such as preferred generic, nonpreferred generic, preferred brand, nonpreferred brand, and specialty tiers



[a]Formulary tiers and actual copayments or coinsurance percentages vary by pharmacy benefit plan and may vary by client needs and affordability.

  - Formularies are managed and influenced by various committees and processes, such as
    - Therapeutic Assessment Committees
    - Pharmacy and Therapeutics (P&T) committees
    - Value Assessment Committees

- Pharmacy benefit design features may include utilization restrictions in addition to formularies that further influence cost and access to medications; utilization restrictions are common and can be expected in ADHD
  - **Prior authorization (PA):** HCPs must obtain preapproval from the PBM to qualify certain medications for coverage and reimbursement under a patient's insurance plan
    - For patients with ADHD, PAs are commonly required for a 12-month period
    - Examples of PAs for ADHD included proof of a diagnosis of ADHD, and/or the patient must be ≥6 years of age (ie, match the indication on product prescribing information)
  - **Step therapy:** The practice of initiating medication therapy for a medical condition with the most cost-effective and safest medication (ie, first-line therapy), before stepping up to an alternative medication (ie, second-line therapy)
    - For ADHD, payers often require proof of failure of 2 first-line generic stimulant medications



Note: The list of utilization restrictions continues on the next page.

- **Medication quantity limit:** A limit on the maximum dispensed amount (could be total quantity or days' supply)
- **Mandatory mail-order pharmacy:** Use of a mail-order pharmacy instead of a retail pharmacy is required
- **Verifications:** Verification of a diagnosis may be required before some medications are covered
- **New-to-market blocks (NTMBs):** At launch, a new medication is blocked from formulary coverage and reimbursement by the PBM or health plan
  - NTMBs are a significant utilization restriction
    - Majority of patients covered by commercial insurance will have a NTMB for *any* new medication
    - NTMBs are not limited to ADHD medications or new stimulant formulations
- **Appeals process:** Pharmacy benefit plans have established mechanisms through which an HCP or patient can initiate an appeal; for example, to obtain a medical exception to prescribe a certain medication for a patient and obtain reimbursement

Medicaid Pharmacy Benefit Structures

In addition to medical insurance, every state Medicaid program includes an outpatient prescription drug benefit (also called a pharmacy benefit).

- >70% of Medicaid enrollees are covered by MCOs, and the remainder are covered on a fee-for-service (FFS) basis
  - PBMs are typically used to manage the pharmacy benefit whether the state administers the pharmacy benefit through an MCO or by FFS
  - Utilization restrictions, such as formularies and PAs for nonpreferred medications, are used to manage medication costs for Medicaid enrollees
    - Majority of states have a mandatory single-payer preferred drug list (PDL) that determines product accessibility and reimbursement
      - PDL concept is similar to a PBM formulary
    - PDLs identify medically appropriate, cost-effective medications that are covered by a state Medicaid program
    - Most state Medicaid programs require generic substitution unless an HCP specifies that a brand is medically necessary
    - Generics account for the majority of medications covered by Medicaid

RELATIONSHIP BETWEEN HCPs, PHARMACIES, PATIENTS, AND PAYERS

HCPs

HCPs may write prescriptions for ADHD medications using a paper prescription pad or transmit prescriptions directly to a pharmacy via e-prescribing methods.

Pharmacies

Patients with ADHD will typically have their prescription filled by one of the following types of pharmacies:

Retail pharmacy chains

Mail-order pharmacies

Independent pharmacies

Depending on who administers their pharmacy benefit, patients may be able to choose whether they use a local retail pharmacy or a mail-order pharmacy.

- Payers may be directed to use specific pharmacy providers, such as a certain mail-order pharmacy, depending on their insurance coverage
- Pharmacies participate in various payer networks that are determined by a patient's commercial plan coverage

As you learned in the *Story of AZSTARYS* RISE module, factors related to prescribing and dispensing Schedule II medications (eg, all stimulants for ADHD) may vary from state to state.

Payers

- Communication between pharmacies and payers to process prescription medicine claims
    - Claim adjudication is the use of computerized resources to verify and apply the patient's pharmacy benefits
    - A pharmacy fills the prescription and is told what to charge the patient based on an individual patient's pharmacy benefits; a patient may pay
        - Full cost of prescription
        - Percentage of cost (coinsurance; ie, 16%, 25%, or 33%)
        - Flat fee (copayment [ie, a fixed amount for each prescription, $12, $30+, or $60+])
    - Payer or PBM reimburses pharmacy for agreed-upon cost minus the patient's copayment or coinsurance; the reimbursement amount is determined by
        - Patient's pharmacy benefits
        - Contractual pricing agreements between payer and pharmacy

ADHD MARKET ACCESS CHALLENGES

ADHD Is a Highly Genericized Market

- >70% of stimulant medications prescribed are generics
- Step therapy is common for ADHD; payers may mandate therapy initiation with generics
- Majority of ADHD medications will have a prior authorization by indication in the prescribing information

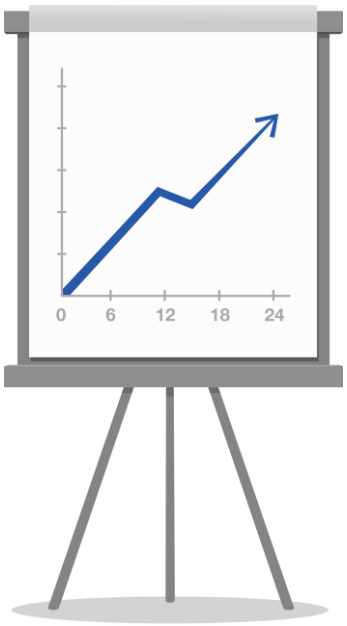
ADHD Is a Crowded Market

- As of 2021, there are >25 existing ADHD stimulant medications in the US market
  - >10 long-acting or extended-release methylphenidate formulations
  - >5 long-acting or extended-release amphetamine formulations
  - CONCERTA and VYVANSE are key AZSTARYS competitors, and a generic version of CONCERTA is available
- HCPs may not view novel, long-acting MPH formulations as sufficiently innovative to offset higher cost of a branded medication
- Refer to the *ADHD Competitive Landscape* RISE module for more information about the ADHD market

AZSTARYS Will Face Market Access Challenges

- AZSTARYS will have limited market access at launch, consistent with other ADHD medications
- Market access trajectory for AZSTARYS will grow and evolve over time; uptake at launch will be different than uptake 6, 12, 18, and 24 months postlaunch[a]

[a]Key performance indicators will be the percentage of coverage at 0–6 months, 6–12 months, 12+ months, 24+ months.



Specific strategies for initiating and growing AZSTARYS market access will be discussed during live training with the market access team

Cori's Dad receives a message from the pharmacy stating that Cori's prescription has not been filled because the insurance company requires a prior authorization

CORIUM CARES PATIENT SERVICES

- In general, patient services (sometimes called a "hub") allow a pharmaceutical manufacturer to connect with a patient during all phases of the prescription delivery process
  - Provides a single point of contact for patients and caregivers
  - Prevents barriers between a patient and their medication therapy, such as copay management, formulary coverage, prior authorizations, and step therapy policies

- Specifically, patients who are prescribed AZSTARYS will have access to patient services provided through CORIUM CARES
  - Financial services, such as
    - Benefits investigation and benefits verification (BI/BV) (ie, copays, formulary coverage, step-therapy policies)
    - Navigating the prior authorization process
  - Single point of contact for general inquiries by patients/caregivers or by HCPs on behalf of their patients, such as
    - FAQs about Corium medications
    - Requests for medical information
    - Adverse event reporting/ pharmacovigilance
    - Product inquiries and complaints