

Moving to a single PDL for a state's Medicaid program

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State Medicaid programs have recently been contemplating implementing a requirement that a single preferred drug list (PDL) be used across their fee-for-service and managed care programs.¹ States have considered a single PDL for multiple reasons, such as providing smooth continuity of care transitions for members who move between managed care plans, reducing confusion and potential administrative complexities for physicians who currently have Medicaid patients subject to different PDLs, and the potential to maximize federal and supplemental drug rebate dollars paid to the state. This paper discusses several decision points and considerations for states evaluating a single PDL requirement.

Constructing a single PDL

Constructing a single PDL involves designating which drugs are preferred and non-preferred in each drug therapeutic class. A drug classification system, such as those available from Medi-Span or First Databank, should be adopted first. The drug classification system groups medications into therapeutic classes based on mechanism of action. From there, various analyses and information can support drug designation decisions within each therapeutic class such as:

- Current PDL designations, for both fee-for-service and managed care populations
- Clinical information for each drug, such as efficacy and safety

- Current distribution of utilization by drug
- Cost of each drug, before federal and supplemental pharmacy rebates (gross cost) and after federal and supplemental pharmacy rebates (net cost)

Constructing a PDL is often an iterative process. The state might first review a therapeutic class with current PDL designations and clinical information in mind. Then the state may consider what drugs are currently being used by members who will be subject to the PDL, potential disruptions that may occur as members need to change medications for chronic conditions, and costs of each drug.

Decisions will also need to be made about which therapeutic classes, if any, to exclude from the PDL and allow managed care plans to control. The state may exclude therapeutic classes because of clinical complexity (e.g., oncology, treatments for certain rare diseases, etc.) or over-the-counter status (e.g., vitamins). Additionally, the state will need to decide the level at which medications will be designated as preferred or non-preferred. Medications may be designated at the National Drug Code (NDC) level or by generic product name, for example.

Policy and operational considerations

Along with constructing a single PDL, a state will need to make policy and operational decisions so that a single PDL is administered consistently across its fee-for-service and managed care programs. Policy considerations may include transitions, grandfathering, utilization management, and excluded therapeutic classes as described below.

- **Transitions.** Timelines, e.g., 90 days, and specific requirements for transitioning members from their current medications to preferred medications on the single PDL need to be determined.
- **Grandfathering.** The therapeutic classes where members will not be required to transition from their current medications to preferred products on the single PDL should be decided. Therapeutic classes that are typical candidates for grandfathering include those with narrow therapeutic range (e.g., anticonvulsant medications), that require trial and error to find the right treatment (e.g., antipsychotic medications), or that may result in worsening clinical outcomes or resistance (e.g., antiretrovirals) or have complex dosing and monitoring (e.g., Factor VIII or IX medications).

¹ Mandros A. (October 24, 2019). What is a uniform PDL & why does it matter? Openminds.com. Retrieved January 7, 2020, from <https://www.openminds.com/market-intelligence/executive-briefings/what-is-a-uniform-pdl-why-does-it-matter/>.

- **Utilization management.** A state will need to decide what utilization management criteria, such as prior authorization, quantity limits, and age limits, will apply to medications on the single PDL as well as what flexibility, if any, health plans have to set their own criteria.
- **Excluded therapeutic classes.** If a state elects to exclude certain therapeutic classes from its single PDL, health plans will need to clearly understand how the NDCs for excluded drugs can be identified and any guidelines or restrictions that apply to the excluded classes.

From an operational perspective a state will need to determine how it will communicate updates to the single PDL on an ongoing basis. Decisions will be needed regarding how frequently, when, and to whom PDL updates will be communicated, as well as the vehicle for communicating them. There will be several other operational items to address, such as:

- Identifying the necessary fields in the file used to communicate the PDL
- Deciding whether each file includes the full PDL or if periodic updates will only contain changes to the PDL
- Determining the timeline within which health plans are required to implement PDL changes
- Responsibilities for communicating the initial PDL as well as PDL updates to physicians and affected patients

A state will need to be concerned about compliance with the single PDL in order to maximize federal and supplemental rebates. It will need to develop methods to monitor member and health plan compliance, such as by reviewing PDLs published by the health plans and analyzing pharmacy encounters submitted by the health plans. A state will also need to determine, communicate, and enforce penalties for noncompliance.

Financial impact

Financial impact is always a consideration with any Medicaid program change, and a single PDL is no exception. States will need to estimate how much in federal and supplemental drug rebates it will receive under a single PDL relative to current conditions, as well as how managed care capitation rates paid to health plans will need to change due to the single PDL. For instance, capitation rates may need to increase, but may be offset by higher federal and supplemental drug rebates, resulting in net fiscal savings to the state.

Estimating the net fiscal impact requires a robust analysis. In order to estimate changes to rebates and capitation rates, states will need to consider how utilization is expected to shift from current medications to preferred medications on the single PDL and the associated impact to prescription drug spending. The analysis may also need to reflect items such as: transition timelines and requirements, grandfathered therapeutic classes, the potential need for additional office visits and nonemergency transportation if a new prescription is needed to move a patient to a preferred medication, how much (if any) supplemental rebates health plans will still receive, and the ability of health plans to achieve managed care efficiencies under a single PDL.

States should also be aware of cash flow timing and the financial risk of implementing a single PDL. The financial analysis may indicate that managed care capitation rates will need to increase due to utilization shifting to preferred medications on the single PDL. A state pays capitation rates each month to the health plans. Federal and supplemental rebates, however, are typically invoiced at the end of each quarter and received by the state six months after invoicing. Thus, actual receipt of rebates often occurs several months after the state has paid the higher capitation rates to health plans. If the utilization shift does not materialize, a state will not receive the expected increase in rebates, yet will have still paid the higher capitation rates.

Conclusion

Although there may be compelling reasons for a state to implement a single PDL across its fee-for-service and managed care programs, there will be many challenges to address in the course of its development, implementation, and maintenance. States should engage appropriate subject matter expertise throughout the process, such as pharmacists, pharmacy benefit managers, policy experts, and financial experts. If a state chooses to move forward with a single PDL, then receiving input from and collaborating with health plans, Medicaid enrollees, and other stakeholders along the way will help to ensure a successful rollout and sustainable program.

Case study

The authors' recent experience analyzing attention deficit hyperactivity disorder (ADHD) medications for a PDL highlights several of the considerations discussed in this paper. Prior to arriving at a final estimated mix of medications for new patients prescribed specified ADHD agents, a few different modeling scenarios were considered. This case study will highlight the first scenario, last scenario, and the decisions made during the process leading to the need for a different modeling approach.

To begin, we considered the therapeutic classes for ADHD medications. There are three Medi-Span Generic Product Identifier (GPI) 6 drug subclasses for the primary ADHD medications: Stimulants – Misc., Amphetamines, and Amphetamine Mixtures. We segmented each of the drug subclasses between short-acting and long-acting medications to reflect that the shifts within each class are likely to occur between medications with similar durations of action.

Focusing on the long-acting amphetamines, current PDLs applicable to the fee-for-service program and for each health plan were reviewed. We found that the brand drugs Adderall XR and Vyvanse were preferred in the fee-for-service program and available without prior authorization or step therapy. Amphetamine-dextroamphetamine extended release (adER), the generic equivalent to Adderall XR, was a preferred drug for the health plans. Some health plans also preferred dextroamphetamine sulfate (generic for Dexedrine) and all health plans preferred Vyvanse. However, all health plans had prior authorization or step therapy requirements for Vyvanse.

After the state completed a clinical review and considered the cost of each drug before and after federal and supplemental rebates, adER and Vyvanse were chosen as the preferred drugs for the amphetamine subclass. It was also determined that ADHD medications would be grandfathered for existing patients in order to minimize disruption for patients who currently have effective treatments. Utilization management criteria was retained to limit the drugs to patients 6 to 18 years old, which was consistent with both the fee-for-service program and health plan PDLs. With these decisions, estimating the portion of new patients prescribed adER and Vyvanse became essential as these agents will have a significant influence on the drug spend for ADHD treatment.

To estimate how much managed care capitation rates paid to the health plans would need to change, we initially modeled the Amphetamines and Amphetamine Mixtures drug subclasses separately to estimate the mix of drugs new patients would use, as illustrated in Figure 1. However, after input from stakeholders and clinical review, it was determined that modeling the Amphetamines and Amphetamine Mixtures drug subclasses separately did not adequately reflect prescribing for ADHD with respect to potential changes in Vyvanse utilization. We then modeled the Amphetamine and Amphetamine Mixtures drug subclasses together, as illustrated in Figure 2.

The change in modeling resulted in a difference between the estimated mix of drugs for new patients for both adER and Vyvanse. The initial modeling estimated 94% and 6% of new patients would be prescribed adER and Vyvanse, respectively. The final modeling scenario resulted in approximately 85% of new patients prescribed adER and 15% Vyvanse.

This process demonstrated the need to expand beyond GPI silos when modeling single PDLs for certain classes to reflect prescribing patterns and changes. In the end, we estimated that the gross cost (before rebates) of amphetamine medications would increase by approximately 20% for the upcoming year. However, after considering federal and supplemental rebates, the net cost of amphetamine medications was estimated to decrease by approximately 1%.

FIGURE 1: INITIAL MODELING SCENARIO OF TWO ADHD SUBCLASSES

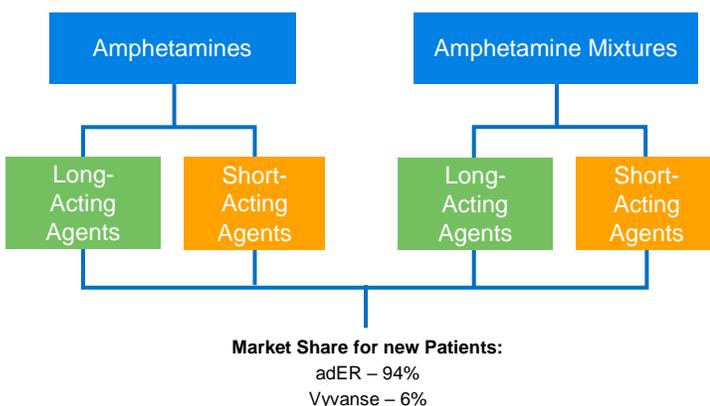
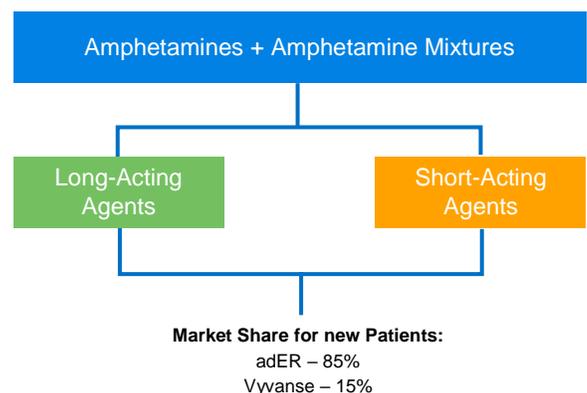


FIGURE 2: FINAL MODELING SCENARIO OF TWO ADHD SUBCLASSES





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