

The Sovaldi® Squeeze: High Costs Force Tough State Decisions



Coverage Decisions and Restrictions in State Medicaid Programs

**Viohl & Associates
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Overview and Survey Design:

The goal of this research project was to identify and to examine how state Medicaid programs are grappling with the blockbuster drug Sovaldi® and its high treatment costs. We analyzed state Medicaid program websites, pharmacy policies, preferred drug lists (PDLs) and other publicly available sources and spoke with State Medicaid pharmacy officials about their coverage policies and any actions taken regarding Sovaldi®. First we examined which states utilize managed care organizations (MCOs) to provide Medicaid services to beneficiaries and which states carve in or carve out pharmacy benefits in their MCO contracts. We then determined, by state, the degree to which MCO PDLs are required to align with a state's Medicaid fee-for-service (FFS) PDL. Finally, we analyzed if Sovaldi® is considered a preferred or a non-preferred drug on a state's FFS PDL and what restrictions, if any, a state has imposed on access to the drug.

We note that our findings are preliminary and are subject to change primarily because states continue to update their Medicaid FFS PDLs and determine which restrictions, if any, to place on the dispensing of Sovaldi®. Several states originally listed Sovaldi® as a preferred drug only to list it later this year as a non-preferred drug while also adding additional restrictions.

This research also did not include any survey of state corrections departments to determine whether policies for the administration of Sovaldi® to incarcerated individuals align with Medicaid policies.

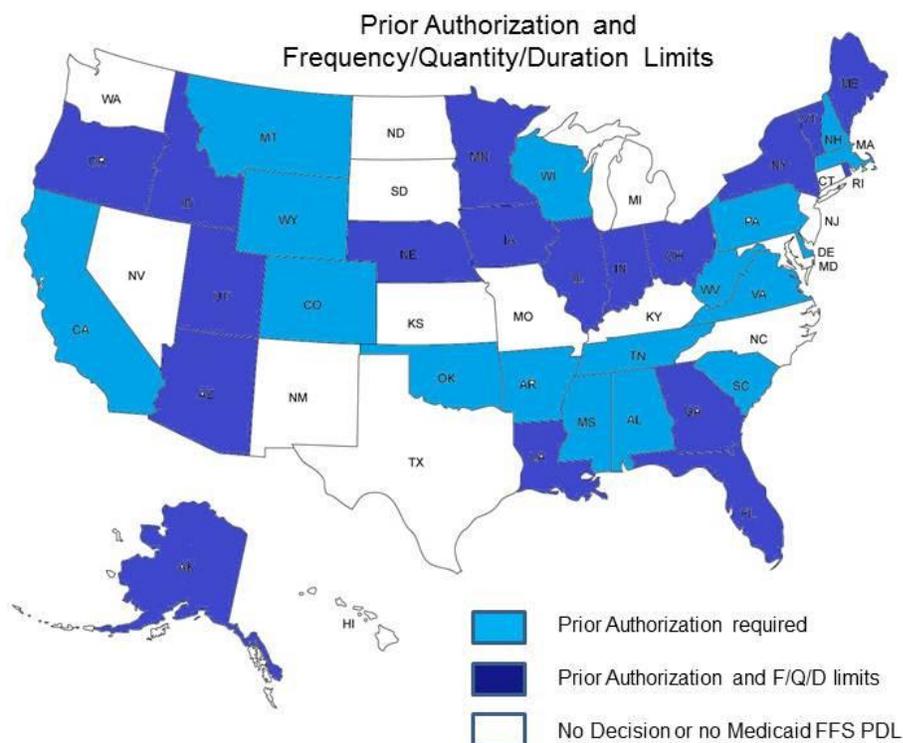
Background:

A breakthrough therapy, Sovaldi® (sofosbuvir) is a drug developed by Gilead Sciences that is used to treat a hepatitis C infection, "a viral (disease) that eventually leads to liver failure, cancer, or other life-threatening conditions."¹ More than three million individuals – many of whom are poor, in prison, or elderly – in the United States are infected with hepatitis C, which is most often transmitted through intravenous drug use and blood-to-blood contact.² The cost of treatment for Sovaldi® can range from \$84,000 to \$160,000 depending on HCV genotype and length of treatment, and the label indicates a predicted cure rate of between 68-92 percent with manageable side effects. Many states are particularly concerned about the drug's financial impact on their Medicaid programs and have implemented policies – for example, prior authorization and quantity prescribing restrictions – to limit use.

Findings:

Managed Care and MCO Pharmacy Benefits:

- Thirty-seven (37) states, in varying degrees, utilize MCOs to provide services to Medicaid beneficiaries. Thirteen (13) states do not use MCOs in their Medicaid program.
- Of those thirty-seven (37) states with MCOs, twenty-eight (28) states include pharmacy benefits in their contracts with MCOs while nine (9) states carve out the pharmacy benefit.



Medicaid FFS PDLs and MCO Requirements:

- Most states (22) do not require their MCOs to align their individual plans' PDLs with the State-approved Medicaid FFS PDL.
- At least four (4) states – Colorado, Florida, New Hampshire, and Texas – require their MCOs to align their individual plans' PDL with the State-approved Medicaid FFS PDL.
- Two (2) states – Hawaii and New Mexico – do not have a Medicaid FFS PDL.
- Nine (9) states allow their MCOs to tailor their individual plans' PDL, but may require their MCOs to partially align some sections of their PDLs with the state-approved Medicaid FFS PDL.

Overview of Prior Authorizations and Additional Requirements:

Thirty-five (35) states require prior authorization for Sovaldi®. Several states additionally require treatment candidates to meet a set of clinical or clinical-related criteria for prior authorization. Most, if not all, States with prior authorization requirements for Sovaldi® require candidates to undergo a liver biopsy to determine the severity of their disease before they are allowed to receive treatment with Sovaldi®. Some states with additional clinical or clinical-related criteria include the following:

- Alaska, as part of its prior authorization criteria, requires the Sovaldi® candidate to have abstained from the use of illicit drugs and alcohol for a minimum of three (3) months to be verified by a urine test.
- Illinois requires prospective patients to meet twenty-five (25) different criteria and receive prior authorization for Sovaldi®.
- In West Virginia, only a board certified gastroenterologist, hepatologist, or infectious disease physician may prescribe Sovaldi®.

Of the seventeen (17) States that list Sovaldi® as preferred, fourteen (14) States require prior authorization for the drug, and of those fourteen (14), seven (7) also place frequency, quantity and duration (F/Q/D) limits on the dispensing of the drug. F/Q/D limits signify any fixed limits in the amount and/or frequency in the dispensing of a certain drug.

- In Illinois, Sovaldi® will only be dispensed for two (2) weeks at a time with refills being available every two (2) weeks for a total of 12 weeks.
- In Florida, depending on the patient's genotype and co-infection status, generally, the State mandates two (2) prior authorization periods, the first lasting four (4) weeks and the second lasting eight (8) weeks, thereby making treatment continuation dependent upon compliance.
- In Louisiana, patients may only receive 28 units of Sovaldi® once every 28 days.
- Some states have implemented the so-called "once in a lifetime" rule, which allows Medicaid patients only one chance at treatment with Sovaldi®. Arizona is one example of a state with such a requirement. Some states, like Alaska, do not allow retreatment within a certain period, for example, two years.
- Some states have decided to not authorize or pay for any lost or stolen medication replacement requests. States with such restrictions include, but are not limited to Alaska, Florida, Iowa, and West Virginia.

Conclusion:

States continue to modify their Sovaldi® coverage policies related to their Medicaid programs and are very sensitive to the costs of treating HCV with Sovaldi®. With a few exceptions, and wide variations, states have placed restrictions and limitations – prior authorization, clinical and clinical-related criteria, and F/Q/D limits – on access to Sovaldi®.

Spending on specialty medications is expected to increase rapidly over the next several years. One industry report projects that specialty pharmacy costs may account for 40% of total drug spending by 2020.³ Following the release of Sovaldi® and its associated treatment costs, some industry experts noted that future specialty medications may be even more expensive on a per patient, per treatment basis. In state Medicaid programs, the growth of specialty pharmacy drugs will increase the pressure on states to effectively manage the drugs' treatment costs. States will continue to employ a variety of strategies and impose restrictions, including prior authorization and quantity prescribing limitations, to curtail the impact of such medications on their Medicaid programs.

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About Viohl & Associates

Viohl & Associates is a Washington, DC-based government relations consulting firm established in 1998 that offers state and federal policy consulting and government affairs services. Areas of special focus include healthcare, energy, and education policy. The firm specializes in analyzing and advising on federal programs administered by state governments, including the Medicaid program.

References:

¹ Chris Kardish, “The Risky Business of Limiting Medicaid Access to Sovaldi,” *Governing*, August 19, 2014. <http://www.governing.com/topics/health-human-services/gov-hepatitis-coverage-solvaldi-lawsuits.html>

² The Centers for Disease Control and Prevention, “Hepatitis C FAQs for the Public,” accessed Sept. 29, 2014. <http://www.cdc.gov/hepatitis/c/cfaq.htm>

³ MEDCO 2011 Drug Trend Report, <http://digital.drugtrendreport.com/issue/31288/39>.