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# EXAMINING PRIOR AUTHORIZATION FOR SICKLE CELL DISEASE THERAPIES IN STATE MEDICAID PROGRAMS

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## Summary

**This issue brief explores current prior authorization policies for sickle cell disease therapies under state fee-for-service Medicaid programs to highlight variations across states and identify opportunities to build consistency and transparency in establishing policies for prior authorization.**


## Background

**Prior authorization (PA)** is a process that requires a healthcare provider to obtain health plan approval before certain therapies and medications can be covered by a patient's insurance. While prior authorizations function as a cost-saving mechanism and a patient safety tool, there are concerns that current prior authorization requirements and processes may create barriers and delays to receiving necessary care. The process for obtaining prior authorization varies by insurer, and the plans themselves often develop guidelines such as approval criteria. Most commonly, higher-cost therapies may require prior authorization.

Medicaid coverage in the United States is either managed by the state through a fee-for-service (FFS) model or by a managed care organization (MCO). Over 75% of Medicaid beneficiaries across the country have pharmacy benefits (i.e., prescription drugs administered at home) managed exclusively by FFS, regardless of whether medical care is managed by MCO or FFS.[1] Roughly 50-60% of the estimated 100,000 individuals living with sickle cell disease (SCD) in the U.S. are covered by Medicaid.[2]

## Methodology

To assess coverage and access restrictions in state Medicaid programs for therapies prescribed to individuals with SCD, Sick Cells contracted Artia Solutions to conduct an analysis of coverage policies in the 50 states and the District of Columbia. Sick Cells identified five pharmacy benefit products (Droxia®, Endari™, Oxbryta®, Siklos®, and generic hydroxyurea) and one medical benefit product (Adakveo®) indicated to treat complications of SCD to include in the analysis. Using comprehensive formulary and medical policy data provided by Artia Solutions, augmented by Sick Cells research, we analyzed coverage policies as of February 2023 for state (FFS) programs for SCD therapies. This issue brief discusses prior authorization use for SCD therapies across state Medicaid FFS programs; MCO in states was excluded.

## Findings

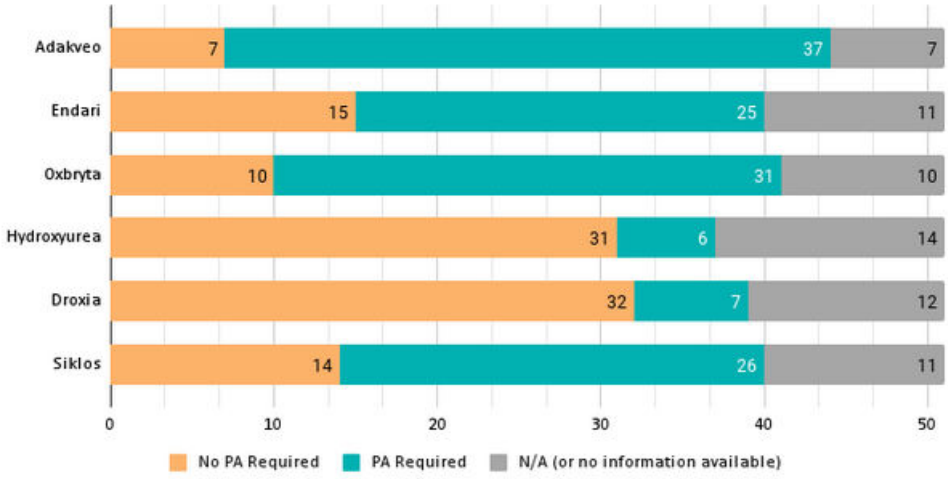
We find that in 2023:

- The **use of prior authorization for SCD therapies varies widely** across states and therapies
- There are **no set standards for prior authorization** requirements for SCD therapies
- Several states have **inadequate reporting of prior authorization** criteria and guidelines.

## Finding 1: Uses of Prior Authorization Vary Considerably by State and Therapy

States frequently use prior authorization for SCD therapies; however, there is significant variation in policies across states (**Figure 1**). Only **four states do not require prior authorization** for any of the six SCD therapies (AL, DE, NH, NC). **18 states have new drug policies** that automatically place prior authorizations on therapies for a minimum duration after Food & Drug Administration (FDA) approval. In contrast, others may have no prior authorization expected at launch.

Figure 1: Prevalence of Prior Authorization for SCD Therapies Across State Medicaid Programs




1. Stancil, John (Artia Solutions). "Coverage for Sickle Cell Disease Summit Presented by Sick Cells." 2022 Coverage for Sickle Cell Disease Summit (Virtual). August 2022. https://youtu.be/PzQf82CGH7E?t=9666
2. Bazell et al. "A claims-based analysis of sickle cell disease: Prevalence, disease, complications and costs, Considerations for commercial and managed Medicaid payers." October 2019. https://www.milliman.com/-/media/milliman/pdfs/articles/a_claims_based_analysis_of_sickle_cell_disease_prevalence_disease_complications_and_costs.ashx?la=en&hash=E8361366C9BFED00A66001CCC646B42F

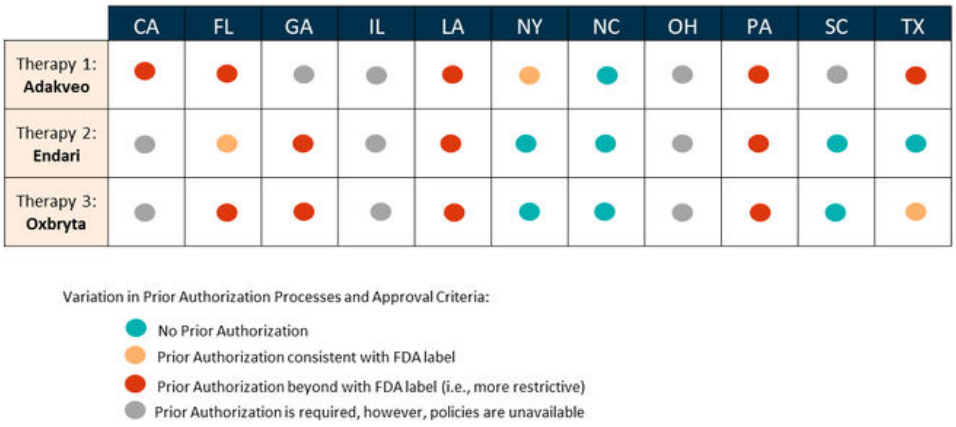
## Finding 1: Uses of Prior Authorization Vary Considerably by State and Therapy (Continued)

Findings also show variability within states for which SCD therapies require prior authorization. The majority of states require prior authorization for disease-modifying therapies that are more newly approved, such as:

- Adakveo® (crizanlizumab, approved 2019) **requires prior authorization in 37 states**
- Endari™ (L-glutamine, approved 2017) **requires prior authorization in 25 states**
- Oxbryta® (voxelotor, approved 2019) **requires prior authorization in 31 states**

However, older therapies, such as hydroxyurea and Droxia®, present the fewest barriers to access, with only **six and seven state policies with prior authorization**, respectively. Siklos **requires prior authorization in 26 states** despite also being a hydroxyurea-based therapy.

Figure 2: State Medicaid FFS Prior Authorization Policies and Approval Criteria for 3 SCD Therapies in 11 Selected States




## Finding 2: Prior Authorization Requirements for SCD Therapies Lack Standardization

States have adopted various approaches in their SCD coverage policies to manage prior authorization approval criteria. To gather actionable insights, Sick Cells identified 11 states (NY, FL, GA, TX, CA, LA, NC, IL, OH, SC, PA) with the highest populations of Medicaid and CHIP beneficiaries with SCD using the 2021 Medicaid and CHIP Sickle Cell Disease Report. Our findings illustrate the lack of adopted standards and coordination of requirements across SCD therapies (Figure 2).

Within the 11 selected states, Sick Cells found that **six states implement approval criteria more restrictive** than the Food & Drug Administration (FDA) label for at least one SCD product. For instance:

- **Four states** require **authorization from a hematologist** or sickle cell specialist (FL, GA, LA, PA)
- **Three states** require **step** (or "fail first") through hydroxyurea or other preferred therapy (GA, LA, PA)
- **Five states** require a minimum number of **medically-treated vaso-occlusive crises** (VOCs) within 12 months (CA, FL, GA, LA, TX)
- **One state** requires **older age criteria** than the FDA label (i.e., ≥ 12 years old instead of the label criteria of ≥ 3 years old) (FL)
- **Three states** require **"positive clinical response"** or "documentation of continued clinical benefits" to be reauthorized to continue receiving therapy (CA, FL, TX)

## Finding 3: Several State Policies and Criteria are Nontransparent

Without published information on prior authorization guidelines and approval criteria, it may be challenging for patients and providers to access therapies. Our findings demonstrate discrepancies in the transparency and availability of prior authorization criteria documents across FFS programs.

- **20 states** have published criteria for Adakveo® **out of 37 states** with prior authorization
- **19 states** have published criteria for Endari™ **out of 25 states** with prior authorization
- **23 states** have published criteria for Oxbryta® **out of 31 states** with prior authorization
- **One state** has published criteria for hydroxyurea **out of 6 states** with prior authorization
- **Two states** have published criteria for Droxia® **out of 7 states** with prior authorization
- **14 states** have published criteria for Siklos® **out of 26 states** with prior authorization

## Discussion

Our landscape analysis of sickle cell disease therapy coverage under state Medicaid programs highlights three main challenges related to prior authorization policies. These discrepancies offer opportunities to streamline processes, increase transparency, and improve access. State Medicaid programs should consider ways to align their policies with FDA labeling, reduce provider burden on prior authorization paperwork, and ensure patients do not experience gaps in coverage.

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