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# Do all US payer archetypes consider the same sources of evidence to inform their drug policies?

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## Introduction

- Drug policies are often developed by US payers to assist in the administration of health benefits.
- Drug policies typically express whether a healthcare service (eg, drug, medical device, procedure) has been shown to be effective based on the available clinical evidence, also noting whether the service is medically necessary, not medically necessary, experimental, investigational, or unproven, and whether the service will be covered by the health benefit.
- The clinical policy or clinical utilization management guidelines for a drug take into account the evidence published in peer-reviewed medical literature, as well as data collected from clinical trials, epidemiological studies, and observational studies, and, in the case of rare diseases, disease registries due to a lack of trial data.[1] Despite this, there is a lack of consistency in the data sources used by various US payer health plans.

## Objectives

- To determine what sources of clinical evidence are used by payer organizations to inform drug policies.
- To determine whether the same sources are used or different sources across different US payer archetypes to inform the coverage decisions.

## Methods

- Secondary research was performed to identify drug policy guidelines (or equivalent publications) from three payer archetypes (managed care organizations [MCOs], integrated delivery networks [IDNs], and Medicaid), covering multiple US payer organizations (United Healthcare, Anthem Blue Cross Blue Shield, Aetna, Geisinger, Kaiser Permanente) as well as Medicaid fee-for-service [FFS], and Managed Medicaid (Table 1).
- Secondary research search terms included "coverage determination guidelines," "coverage determination policies," "formulary guidelines," "clinical policies," "medical policies," "clinical utilization management policies," "State Medicaid clinical policies," "evidence-based referential drug database," "Truven health analytics," and "Institute for Clinical and Economic Review."
- The coverage reports of products including Besremi®, Emflaza®, and Spinraza® were evaluated in order to gather the information that payer organizations often take into account when determining coverage.

## Results

- All payer organizations evaluated refer to the label approved by the Food and Drug Administration (FDA) in their formulary guidelines (Table 1).
- All the three MCOs (United Healthcare, Anthem Blue Cross Blue Shield, and Aetna) detail the use of data from pivotal trials and peer-reviewed published literature as sources for drug policies.
- Several different sources were used by the MCOs to gather population health statistics. For example, United Healthcare used the United States Census Bureau and World Population statistics, while Aetna used the National Center for Health Statistics.
- Some of the clinical sources that were used for drug policies were clinical database and National Comprehensive Cancer Network (NCCN) clinical practice guidelines.
- To obtain comprehensive information on drugs, Anthem, in particular, used Truven Health analytics or DrugPoint Systems for majority of the medications covered by the health plan.
- For certain treatments that are covered under medical benefits, such as Spinraza®, the UnitedHealthcare community plan (Medicaid) has a drug policy that excludes certain states (Florida, Kansas, Kentucky, and Louisiana) and the policy is not applicable in those states; these states are required to refer to state-specific policy (Medicaid clinical policy).[7]
- The UnitedHealthcare community plan (Medicaid) used the same data sources as the UnitedHealthcare commercial plan for drug policy.
- MCOs such as Anthem and Aetna used drug referral platforms such as Lexi-Comp ONLINE with the American Hospital Formulary Service (AHFS) database to gather evidence-based referential drug data.
- IDNs and State Medicaid did not cite the data sources that were used to inform drug policies.

**Table 1:** Payer archetypes and data sources used to inform coverage determinations

| | Insurer | FDA-approved indication | Pivotal trials | Published literature | Additional/detailed sources of information considered in coverage decisions[a] |
|---|---|---|---|---|---|
| MCO (examples) | UHC[2] | ☑ | ☑ | ☑ | • NCCN Drugs and Biologics Compendium[b]<br>• Product information and AMCP dossier<br>• Clinical guidelines<br>• United States Census Bureau<br>• World Population statistics<br>• ClinicalTrials.gov |
| | Anthem[3] | ☑ | ☑ | ☑ | • NCCN Clinical Practice Guidelines[b]<br>• Clinical Pharmacology (online database)[b]<br>• Lexi-Comp ONLINE with AHFS[b]<br>• DailyMed (US National Library of Medicine) for package inserts<br>• DrugPoints System |
| | Aetna[4] | ☑ | ☑ | ☑ | • Clinical Pharmacology (online database)[b]<br>• Lexi-Comp ONLINE with AHFS[b]<br>• National Center for Health Statistics<br>• Muscular Dystrophy Association |
| IDNs (examples) | Geisinger[5] | ☑ | Not cited in formulary | | Not detailed |
| | Kaiser[6] | ☑ | | | Not detailed |
| CMS | Medicaid FFS | ☑ | | | Prescriber information |
| | Managed Medicaid | ☑ | | | Not detailed |

[a]Data retrieved from coverage reports of products (Emflaza®, Besremi®, and Spinraza®); [b]Source is also seen in another payer archetype

## Conclusions

- The data sources used by payers to inform drug policies are heterogeneous, which illustrates the need for more research to better understand the value drivers of drug policies across different US payer archetypes.
- While MCOs provide some detail about which data sources are consulted to inform coverage decisions, this is not the case for IDNs and Medicaid.
- IDNs and Medicaid are likely to rely on sources of data not listed in table 1 or internal protocols. As a result, drug coverage evaluation processes are not standardized, which warrants further research.
- Given that additional sources of information beyond the FDA-approved label and peer-reviewed literature are often considered by drug policy makers, pharmaceutical companies may need to align with these needs.
- The findings of this research can be used to identify disease areas where drug policymakers might lack strong sources of information to inform coverage decisions. This presents an opportunity for pharmaceutical companies to conduct targeted research in those areas and fill the knowledge gaps that may influence payer coverage decisions.
- Additionally, pharmaceutical companies can access sources that have been identified and considered by different payer organizations to gain deeper insights, and ascertain how these sources can be a valuable source of information for their products.
- Despite the growth of Institute for Clinical and Economic Review (ICER) in the US, a key organization in evaluating the cost-effectiveness of healthcare services, health plans' use of ICER to inform drug coverage policies is limited to certain drugs,[8] and none of the seven payer organizations mentioned ICER as a source of data in the drug policies for Emflaza®, or Spinraza®.
- This research was limited to seven US payer organizations; further research is needed to determine which data sources are most heavily relied upon by larger health plans.
- Further studies are needed to characterize payer decision-making patterns over time and to identify how policymakers' evidence requirements are evolving.

## References


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