



2024

Annual Report

The Certainty of Evidence
in Uncertain Times

centerforevidencebasedpolicy.org

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Message From the Director

For more than 2 decades, the Center for Evidence-based Policy (Center) has helped states use evidence to ensure their policy decisions are rooted in objective information and proven research. Evidence allows policymakers to effectively address issues, make decisions that benefit their state, allocate resources efficiently, and ensure taxpayer money is spent on approaches with a proven record of success.

Evidence can also provide a measure of certainty during times of unpredictability and ambiguity by offering a reliable and verifiable touchstone for decision makers. State policymakers can use evidence to help provide:

- **Clarity.** Evidence offers a clear and solid foundation for decision making, reducing the number of unknowns and enabling more informed choices.
- **Stability.** Evidence offers a consistent framework in an otherwise turbulent environment. When circumstances change, reliable evidence can help calibrate or recalibrate decisions.

- **Certainty.** In uncertain times, ambiguity and confusion can arise. Evidence can cut through these challenges by providing a common ground to explore and resolve shared problems.
- **Trust.** Evidence is reliable and can help build trust, even among parties that disagree. Increased trust strengthens confidence in navigating uncertainty together.
- **Guidance.** Evidence enhances our understanding of complex situations, which in turn helps us adapt to changing circumstances.

This annual report reviews some of the challenges we face in this current time of accelerated change and uncertainty. It also highlights examples of how, in the last year, the Center has offered states objective, reliable information to reduce confusion, increase stability, and inform decisions during times of uncertainty. This grounding is an important tool in navigating uncharted and unpredictable environments with clarity and confidence.



Evidence Provides a Measure of Certainty

Making and implementing health decisions is just as difficult in the public sphere as it is for us as individuals. When unsure of what to do, we often seek guidance to make an informed decision. One of the most reliable tools for this is evidence, and the source of that evidence matters.

The best evidence is derived using reproducible scientific methods, which means that those methods can be scrutinized by both experts and the public. The methods used to produce evidence help to collect and interpret data in ways that enable us to distinguish between chance and true effects.

- Evidence grounds our choices in facts that are testable, verifiable, and corroborated. And in the face of ambiguity faced by states every day, evidence functions as a stabilizing force, offering a clearer view of reality.
- In an era of misinformation, where claims can be made with little to no

factual support, evidence can help distinguish between what is likely and what is uncertain. The rigorous vetting of information through peer-reviewed studies, statistical analyses, and systematic reviews allows for a more reliable understanding of complex issues.

- Evidence also provides a means to evaluate and learn from the past, allowing us to identify patterns and outcomes that can inform current decisions and increase the chances they are sound.
- Evidence supports accountability and transparency. By documenting decisions and grounding them in evidence, states can foster trust and build confidence, even when outcomes are uncertain. Transparency reassures that decisions are not being made arbitrarily or based on political agendas, but are instead rooted in a commitment to sound reasoning and pragmatic information.

In 2024,
the Center:

Produced **50**
evidence reports

Researched
40 topics

Screened over
30,000 titles and
abstracts

Reviewed in detail
more than **3,000**
research articles

Graded **600**
articles for quality

Evidence is not perfect, but the process of gathering and evaluating it helps to make decisions more consistent and transparent. A deliberative process can save time, resources, and lives by avoiding the consequences of ill-considered decisions.

Evidence helps us make more informed decisions, reduces the risk of error, and promotes trust and accountability. While no amount of evidence can fully eliminate uncertainty, it offers a pathway to ground us in what we know rather than what we fear or hope. In a world where unpredictability can reign, relying on evidence remains one of our most effective tools for navigating the unknown.

The Center focuses on providing the best evidence available to answer states' questions and help them address critical policy decisions. We use rigorous and transparent research methods to find, assess, and summarize information for our state partners. States can trust that our analyses are based on the evidence and not opinion.

Key Questions About Evidence

In other sections of this annual report, we provide a more detailed explanation of what goes into assessing the level of certainty that evidence provides and how that assessment involves understanding the benefits, harms, and burdens of the available options. Policymakers can begin by asking sensible questions about evidence such as:

1. **Who produced the evidence?** Are they a reliable source or are there conflicts of interest?
2. **What exactly is the intervention and could anything besides the intervention have produced or influenced the results?** This is especially important when there is no control or comparison group.
3. **What is the quality of the evidence?** It is important to look for the best-available information and consider the populations, study types, and outcomes that are relevant to your decision.
4. **Are there other reviews or studies?** Do they reach the same conclusions? And if not, what might be causing any differences?
5. **Are there other perspectives that need to be considered?** Would patients or caregivers, clinicians, other policymakers and payers, or citizens interpret this evidence in the same way?



I truly appreciate all the effort you put into providing us with the information we need to make tough decisions, ensuring those decisions are grounded in evidence-based criteria.”

Melinda Rowe, Assistant Medical Director, Alabama Medicaid

Not All Evidence Is Created Equal

Making evidence-based decisions in health care is challenging. Decision makers must clearly define the issue they want to address, determine what evidence is appropriate for the context, establish how to assess whether something is working or not, and evaluate their confidence in that evidence.

Recognizing the hierarchy of evidence (in other words, acknowledging that some forms of evidence are more robust than others) is a founding principle of evidence-based health care. When assessing whether an intervention works, systematic reviews of randomized controlled trials are generally accepted as the most reliable form of evidence, and can serve as a lens through which to evaluate and interpret the broader body of evidence included in those systematic reviews. However, within the systematic review, many judgments are made by both authors and readers, explicitly and implicitly, regarding the

quality of the evidence. These judgments influence our confidence in the findings and ultimately, the willingness of decision makers to act on those findings.

The Center helps states make informed judgments, prevent errors, and critically appraise and communicate evidence using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach, developed by an international working group in 2000, to assess and rate the certainty of evidence (CoE).

We apply the GRADE approach in our reports to provide an overall rating of CoE by outcome, along with an explanation of why we rated the CoE as *high*, *moderate*, *low*, or *very low*. This approach aims to give state decision makers sufficient information to understand which interventions are effective and how confident they can be in the evidence underpinning their decisions.

“The DERP Collaborative provides MO HealthNet with excellent, and timely, in-depth research to guide evidence based clinical policy. Along with insight into the pipeline, DERP helps ensure MO HealthNet makes policy that data supports.”

Josh Moore, Director of Pharmacy for MO HealthNet (Missouri)

The Revised Evidence Pyramid

Systematic reviews and meta-analyses are a lens through which evidence is viewed and applied to patient care.

Image from Murad MH, Asi N, Alsawas M, Alahdab F. New evidence pyramid. *BMJ Evidence-Based Medicine*. 2016;21(4):125-127.



Principles for Assessing Certainty of Evidence (CoE)

CoE reflects our certainty that the true effect, accuracy measure, or association lies beyond a particular threshold, or within a particular range in quantitative research; CoE is also known as quality of evidence or confidence

When assessing CoE, we consider:

- **Risk of bias.** Study limitations that may reduce our certainty in the findings.
- **Imprecision.** Uncertainty in the true effect estimate due to small sample sizes or few observed events.
- **Inconsistency.** When studies observe different effects.
- **Indirectness.** When studies do not examine interventions of interest in populations of interest, or report only on surrogate outcomes.
- **Other features.** Such as publication bias, large effects, dose-response gradients, and plausible opposing confounding.

We categorize each relevant outcome as having:

- **High CoE.** Further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate CoE.** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- **Low CoE.** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- **Very low CoE.** Any estimate of effect is very uncertain.

We use GRADE tables to present the results of evidence synthesis and an assessment of CoE.



Making Decisions Is Difficult When Information Is Limited

Decision making in health care involves evaluating an intervention, treatment, or therapy relative to its costs and potential harms. Individuals make these decisions about their own health care every day. State policymakers also do this when weighing coverage decisions for medical and pharmaceutical therapies—work that the Center has supported for more than 2 decades. In these decisions, state policymakers weigh the benefits of improved patient outcomes against the potential harms and financial costs of new and emerging therapies. This approach is most effective when there is robust evidence documenting potential benefits and harms, but it always requires careful consideration of tradeoffs.

Prescription drug therapies offer significant benefits, such as reducing disease burden, improving quality of life, and preventing costly complications. For instance, effective treatment for chronic conditions like diabetes or hypertension can avert hospitalizations and long-term disability. In oncology, new therapies aim to improve patient survival and reduce symptom burden, while emerging gene therapies seek to cure illnesses with previously limited treatment options. These benefits

are measurable in terms of health care cost savings, quality of life improvements, or gains in life-years, providing tangible value for policymakers and payers. By quantifying these outcomes, research and analyses help justify investments in high-cost therapies.

The potential harms associated with therapies must also be considered. Adverse drug reactions, ranging from mild side effects to life-threatening complications, can increase medical costs and undermine patient trust. For example, while a new cancer drug might significantly extend survival, its high toxicity levels could result in expensive supportive care and reduced quality of life for some patients. These unintended consequences can challenge the assumption that clinical benefits always outweigh financial and human costs. Another consideration is the variability in how drug therapy benefits and harms are distributed across populations. A medication that is highly effective for many people may have limited efficacy or increased risks for specific subgroups, such as older adults, children, those with preexisting conditions, or people with lower incomes, like those typically served by the state Medicaid programs supported

by the Center. States must account for these disparities to ensure equitable access to therapies and avoid exacerbating health inequalities.

The Center's Medicaid Evidence and Cost Review Initiative (MERCI) takes a detailed look at these tradeoffs (and others) that policymakers often consider when new prescription therapies enter the market. MERCI summarizes existing clinical evidence and evaluates the cost implications of select prescription medications approved through the US Food and Drug Administration (FDA) accelerated approval program. This accelerated process expedites the approval of drugs that treat serious or life-threatening conditions and address unmet needs for indications with no or limited therapeutic alternatives. The pathway allows drugs to enter the market more quickly, but approval is based on less rigorous evidence relative to traditional drug approval processes.

Accelerated approval drugs are often approved based on surrogate outcomes and clinical data from narrowly defined patient populations, which may not fully represent real-world usage, particularly among Medicaid members. Additionally, accelerated approval drugs tend to be very costly, sometimes millions of dollars per course of treatment, requiring state Medicaid programs to carefully account for these costs against the therapeutic benefit for their members.

Even when evidence is limited, as is the case for accelerated approval drug therapies, it is important for policymakers to have access to the best and most complete information available. The work we do in MERCI, and across our full research portfolio aims to do exactly that—provide the best and most comprehensive information possible to ensure health policymakers can make evidence-informed decisions.

MERCI: Medicaid Evidence and Cost Review Initiative

In 2024, the Center published its first briefs under the MERCI project, funded by Arnold Ventures. The MERCI project is analyzing 8 accelerated approval drugs and identifying opportunities to refine policymaking to protect patients and their access to drugs, while ensuring effective use of taxpayer dollars. Each of the 8 briefs provides an individual case study with detailed evidence, including:

- The estimated prevalence of the target diagnosis (the accelerated approval drug's indication[s]) within state Medicaid memberships
- The clinical trial population used to support FDA approval, and its similarity to Medicaid members overall
- The projected drug costs for state Medicaid programs, including a breakdown of state and federal funds using the Federal Medical Assistance Percentage

MERCI analyses include directly relevant national and state-level data wherever available. To date, selected drugs have indications for sickle cell disease, Duchenne muscular dystrophy, non-small cell lung cancer, cervical cancer, risk of preterm birth, and transfusional iron overload. Four briefs have been released publicly, with additional publications planned for early 2025. Find them all at centerforevidencebasedpolicy.org.



New York State Medicaid relies on the Center's consistent, high-quality expertise and reports... Their dedication to evidence-based science affords [us] the opportunity to advise and assist our program in providing access to the highest quality of care for millions of New Yorkers.”

Kate Bliss, New York Medicaid

The Fast Pace of Drug and Device Approvals Also Accelerates the Need for Evidence

The rapid pace of drug and device approvals by the FDA brings products to market faster than ever before, which in turn affects Medicaid programs. Despite limited evidence of clinical effectiveness, state Medicaid programs must still consider coverage requests for digital health technologies and develop clinical criteria for accelerated approval drugs. The FDA review process for digital health technologies requires only limited evidence. The accelerated approval pathway requires evidence from a phase 2 clinical trial with a reasonably likely surrogate endpoint, rather than a phase 3 trial with clinically relevant outcomes. As a result, state Medicaid programs face the challenging task of making coverage determinations and recommending clinical safety edits with limited supporting information.

This challenge is compounded by the growing development of devices and drugs. The market for digital health

technologies has developed rapidly in the last decade. As of 2021, over 25 digital therapeutic products have been granted market authorization worldwide, with more than 150 digital health technologies in earlier stages of development. The FDA's accelerated approval program, created in 1992, enables earlier approval for drugs that treat serious or life-threatening conditions and address unmet needs. Between 1992 and 2024, more than 320 approvals came via the FDA's accelerated approval pathway. With this growing pipeline of activity, the importance of the Center's work with states to help them assess the limited evidence used for approvals with evidence review as well as policy and data analysis, drawing on peer-reviewed journals and publicly available data sets, is clear.



Focus on Health Technology Assessment

Since 2007, the Center has been supporting states in their efforts to evaluate health technologies and inform policy with the goal of ensuring that new technologies are safe and effective. In 2024, the Center supported Health Technology Assessment (HTA) programs in 3 states.

New York

The New York State Department of Health (NYSDOH) relaunched its Medicaid Evidence Based Benefit Review Advisory Committee (EBBRAC) in 2024 after a hiatus of several years. Established by New York State law, EBBRAC makes recommendations to the NYSDOH on the coverage of health technologies and services to ensure that Medicaid program benefits are based on up-to-date evidence of efficacy, safety, improved outcomes, and cost-effectiveness. The Center provides in-depth evidence reviews to inform EBBRAC's deliberations. In 2024, the Center conducted an evidence review for collagen crosslinking for individuals with progressive keratoconus (an ophthalmologic condition), reviewed regulatory pathways for digital therapeutics, and presented evidence on 2 digital therapeutic products for EBBRAC's consideration: *Freespira for Panic Disorder and Posttraumatic Stress Disorder* and *Canvas Dx as a Diagnostic Aid for Autism in Young Children*. To provide context for EBBRAC's deliberations, the Center also prepared a policy analysis of *Digital Health Technologies: Definitions, Regulatory Framework, and Considerations*.

Oregon

The Oregon Health Evidence Review Commission (HERC) was created by legislative mandate in 2011 to review clinical evidence for medical procedures, devices, and tests covered by Medicaid to provide guidance to the Oregon Health Authority on benefit-related decisions for its health plans. All HERC meetings, including evidence deliberations, are held publicly and offer opportunities for public comment. The Center produces detailed evidence reports on the efficacy, effectiveness, safety, and cost-effectiveness of treatments and tests, which HERC uses to determine coverage policies. In 2024, we conducted and presented systematic evidence reviews to HERC on chronic disease self-management programs for adults with chronic pain, and hypoglossal nerve stimulation for adults with obstructive sleep apnea. We also provided rapid evidence support on a range of topics, including planned out-of-hospital birth (i.e., community birth) and the Impella device for people with cardiogenic shock.

“Our CEbP team is amazing with their coverage guidances and I’m so happy to work with them.”

Ariel Smits,
Oregon

Washington

The Washington HTA program has guided coverage decisions in the state since 2007. It is unique in the US as the only state HTA program whose decisions are binding across a broad array of public health care payers. Over its duration, the program’s prudent coverage decisions have helped reduce state spending on ineffective and harmful treatments and tests. The Center produces detailed evidence reports on the efficacy, effectiveness, safety, and cost-effectiveness of treatments and tests, which the independent Health Technology Clinical Committee uses to determine coverage policies within the state. In 2024, we published and presented an updated review on bariatric surgery in adults and adolescents with overweight or obesity, available on the Washington Health Care Authority’s website at hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/bariatric-surgery.

Gene Therapies Bring Uncertainty

In the last decade, the pharmacy landscape has evolved to include the development of cell and gene therapies that treat, restore lost function from, or even cure disease. However, patients, caregivers, and states face significant uncertainty and challenges related to accessing these new treatments, including high costs, safety concerns, durability of effects, and the complexities of administration and reimbursement. These advanced therapies tend to be single-dose, potentially long-lasting options for a variety of indications spanning oncology, chronic and rare diseases, and more. The up-front cost of these therapies contrasts with chronic care treatment, where costs are incurred more gradually over a patient's lifetime. While studies have shown that some gene therapies can be cost-effective even at very high prices, uncertainty about their long-term effectiveness and affordability remain critical concerns for patients, their families, and payers.

The FDA has developed 4 approaches designed to accelerate drug availability on the US market; these pathways are called *Priority Review*, *Breakthrough*

Therapy, *Accelerated Approval*, and *Fast Track*. While gene therapies are intended to produce permanent or long-lasting clinical benefits, whether these treatments will result in the desired effects long term remains uncertain, as faster FDA approval processes often rely on short-term or medium-term clinical evidence.

The lack of long-term safety and efficacy data for most approved gene therapies poses additional challenges for evaluating their cost-effectiveness, particularly from the payer's perspective.¹ Clinical trials for accelerated approval drugs are allowed to use less rigorous evidence standards for their study endpoints. This, combined with limited long-term data on safety and effect durability, complicates decision making for patients, clinicians, and payers who must weigh the risks and benefits of gene therapies. Cell and gene therapies approved through accelerated pathways demonstrate the tradeoffs of speeding up drug development while dealing with uncertainty about overall benefits and safety for patients with serious or life-threatening diseases.

The uncertainty surrounding the durability of clinical benefits from gene therapy is compounded by the financial shock of their high upfront costs. Prices for gene therapies are now surpassing \$3 million, challenging health care payers, including Medicaid, with figuring out how to afford access to potentially transformative treatment for members, while also allocating funds to support the health care needs of other individuals made vulnerable by poverty, disability, and serious illness.¹ Traditional approaches to balancing costs and access to drug therapies include utilization management and tiered program designs that aim to ensure only clinically appropriate patients receive treatment. However, the potentially curative benefits

of many gene therapies, combined with the limited evidence available from clinical trials, make it difficult for payers to design coverage policies narrower than the broadly defined criteria in FDA approval language.

Developing and implementing any value-based payment approaches requires time and effort over multiple years. Many states and other payers have been willing to explore these types of contracts but acknowledge that successfully executing these arrangements has proven very challenging due to the internal effort and expertise required. The demand for more value-based contracts varies across payer types, and the growing number of gene

Innovative Payment Approaches Address Uncertainty

Innovative value-based payment approaches recently pursued to address the dual challenges of uncertainty and cost include:

Milestone-based contracts. A performance-based contract where the pharmaceutical company agrees to refund the cost of therapy (partially or fully) to the payer if an agreed-upon outcome is not achieved.

Warranties. A patient-specific warranty policy purchased by the pharmaceutical company that reimburses payers for treatment-related costs associated with suboptimal drug performance over an agreed-upon period. The value is related to covered health care costs and is not a refund for the cost of the treatment.

Performance-based annuities. A performance-based contract in which payments for a cell or gene therapy are spread over multiple years and linked to therapy performance. If an agreed-upon therapeutic outcome is not met, no further payments are made.

Subscription model. A payment approach in which the pharmaceutical company provides treatment either for a set fee, regardless of the number of patients treated, or at a set price per patient.

Recent Gene Therapy Reports from the Center

Overview of Approved and Pending Gene Therapies, published October 2024

New and Emerging Gene Therapies for Sickle Cell Disease, published October 2024

Gene Therapies for Hemophilia A and B, published February 2023

Gene Therapies for Sickle Cell Disease and Beta Thalassemia, published November 2022

therapies expected over coming years is expected to burden payer resources and further complicate interest and contract execution.

The promise and transformative potential of gene therapies is an exciting development in the pharmacy and health care landscape. These treatments, often administered in just a single session, have revolutionized potential health outcomes for many patients living with serious or fatal conditions. Balancing the long-term health benefits against the high short-term costs is difficult for patients, clinicians, caregivers, and health care payers. Gene therapies enter the marketplace with limited data and unique levels of uncertainty regarding the safety and

durability of their beneficial effects. The growing number of these drugs poised for market entry also poses a challenge. These factors create ongoing financial, logistical, and delivery uncertainties for health systems globally.

These complex social, ethical, health, and economic issues require the input of all invested parties (patients, caregivers, clinicians, the public) to navigate the ongoing challenges of ensuring access to these important advances in complex disease treatment. The Center is uniquely positioned to help state policymakers navigate this evolving landscape with comprehensive reports, research tools, stakeholder engagement, and policy analysis.

STEM: Systematically Testing the Evidence on Marijuana

STEM is an independent, methodologically rigorous, and updated cannabis evidence resource for the health care sector that synthesizes existing research and identifies gaps in knowledge about the health effects of cannabis. The STEM project is a collaboration between the Center and the US Department of Veterans Affairs and is funded by the US Department of Veterans Affairs: Office of Rural Health. In 2024, we published 6 living systematic reviews on the health effects of cannabis. These reviews will continue to be updated regularly to reflect new evidence. Find these reviews and more on the STEM website at cannabisevidence.org.



... we value MED's dedication to evidence, the collaborative atmosphere, and the ability to share with other states."

Christopher Chen, Washington Health Care Authority



Focus on Data

In 2024, the Center's Data Team leveraged a range of data and analytic strategies to help states build a reliable and consistent foundation for decision making, identify patterns, trends, and potential risks, and make informed adjustments to mitigate uncertainty.

Health System Tracking

The Commonwealth Fund has a longstanding interest in tracking the performance of health care in the US and, since 2006, has published a series of health system scorecards to evaluate how well the nation and each state performs relative to achievable benchmarks for access, quality, efficiency, outcomes, and equity. Since 2023, the Center has supported this initiative by developing methodologies for several of the Commonwealth's internal research efforts, notably their [Health System Scorecards](#) and [State Health Data Center](#). These resources use the most recently available data to monitor and assess health system performance at national and state levels, highlighting gaps in health care performance and opportunities for improvement. The Center also supported 2 major Commonwealth reports in 2024: the second edition of their racial disparities report, [Advancing Racial Equity in US Health Care: The Commonwealth Fund 2024 State Health Disparities Report](#), released April 2024, and the first annual [State Scorecard on Women's Health and Reproductive Care](#), released July 2024. This new report provides a state-by-state analysis of disparities in access to reproductive health care services, the quality of care, and health outcomes for women and children. For more information, visit commonwealthfund.org/publications/scorecards.

OCID

The Oregon Child Integrated Dataset (OCID) is a nonpartisan, data-driven project based at the Center that supports policymakers as they work to improve outcomes for children and families in Oregon. Created in 2019, OCID contains linked, cross-agency, and cross-program information for children born in Oregon from 2001 onward, along with their birth parents. The OCID dataset shows the trajectories of children's lifespans, and tracks program and service participation to identify historical and current patterns that would otherwise remain isolated within the data of individual agencies, programs, or services. Over the last year, OCID analyzed school mobility for youth with foster care experience, as well as early childhood outcomes for young children with health and social needs, and is now completing an investigation into how cross-program data can inform policy to improve services for children with behavioral health needs. OCID information, including analyses and interactive data visualizations from past work, is publicly available on the OCID website, ocid-cebp.org.

“OCID is an exciting, one-of-a-kind resource for Oregon’s state policymakers. OCID’s rich integrated data allows decision makers to better understand the paths children and their families take through state services and how those paths connect, or don’t connect, to outcomes. Leveraging this amazing data resource will help us to better triage and target limited resources.”

Elizabeth Steiner,
Oregon State Treasurer

Data Equity

Center staff engaged in a 3-part internal training to examine the core issues facing the equitable and ethical use of data in research. Provided by WeAllCount, the trainings provided an in-depth look into the challenges that arise from turning complex human questions into numerical data and then transforming that data back into meaningful, objective information for decision makers.

2024 Evidence Reports

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Center Staff

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Mike Bonetto, Consultant

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Center for Evidence-based Policy

3030 S Moody Ave, Suite 250
Portland, OR 97201

centerforevidencebasedpolicy.org

