

# The Myth of Average

Why Individual Patient Differences Matter

January 2022



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## ACKNOWLEDGEMENTS

This update builds on work published in 2013. The authors would like to acknowledge the following individuals and organizations for their support and important insights in the development of the original booklet and accompanying conference, *Myth of the Average: Why Individual Patient Differences Matter*: Jennifer Graff (formerly of NPC), Penn Quarter Partners, the National Health Council, WellPoint, the Alliance for Aging Research, the American Association of Colleges of Pharmacy, American Autoimmune Related Diseases Association, American Osteopathic Association, Biotechnology Industry Organization, Easter Seals, Friends of Cancer Research, Healthcare Leadership Council, HealthHIV, Men's Health Network, National Alliance for Hispanic Health, National Alliance on Mental Illness, National Alliance of State Pharmacy Associations, National Grange, National Minority Quality Forum, Partnership to Fight Chronic Disease, and Personalized Medicine Coalition. The authors would also like to acknowledge the important contributions of Emily Ortman and Andrea Hofelich of NPC, Berna Diehl of Brighton Communications and graphic designer Emily Speakman.

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## ABOUT THE NATIONAL PHARMACEUTICAL COUNCIL

The National Pharmaceutical Council (NPC) is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation. Founded in 1953 and supported by the nation's major research-based biopharmaceutical companies, NPC focuses on research development, information dissemination, and education on the critical issues of evidence, innovation and the value of medicines for patients. NPC affirms its commitment to foster an inclusive community and leverage diversity of thought, background, perspective, and experience. For more information, visit [www.npcnow.org](http://www.npcnow.org) and follow NPC on Twitter @npcnow.



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## EXECUTIVE SUMMARY

Over the years, health insurance has become more complicated, causing some patients to face significant barriers when trying to access the health care treatments and services they need. As an update to the first edition of “The Myth of Average,” published in 2013, this booklet explores how the health care landscape has changed over time and addresses important questions such as:

- If a patient is not “average,” how could that impact their access to treatment?
- Why do individuals have different responses to the same treatments?
- What tools and evidence do insurers rely on to make coverage decisions?
- What challenges do insurers face when trying to cover patients with different treatment responses?
- How can insurance benefit design change to improve patient access to high-quality health care treatments and services?

The goal of this booklet is to help patients, their caregivers and their representatives navigate the complexities of health insurance coverage and engage with the health system to improve patient access.



## KEY TAKEAWAYS FROM THIS REPORT

### #1. Patients differ.

When discussing health care data or treatment side effects, we commonly hear the phrases “on average” or “the average patient.” But as we learn more about treatments and optimal health care, it’s clear that most patients are not “average” at all. Our bodies can respond in different ways to the same treatment. One person will have bothersome side effects, while someone else will not. Another person’s condition will be successfully treated with one medicine, while the next person experiences no benefit from the same treatment. Patients are actually quite different, and today’s treatments are being developed to reflect those differences.

### #2. Health care decisions are often made at the population level, rather than the individual patient level.

Even though differences among patients are common, they are not always considered in treatment and coverage decisions. Most health insurance plans design their policies to meet needs of the majority of people. Therefore, people who require different treatment options due to factors related to age, genetics, chronic conditions, or sex, among other reasons, can have difficulty accessing those treatments. By using evidence about the “average” patient to make coverage decisions for individuals, insurers may unintentionally create barriers to the most effective, appropriate care for some patients.

#### **Opportunities to improve health care decision-making:**

- **Incorporate patient priorities when assessing the value of a treatment**

New tools for assessing the value of treatments are available to help health care decision-makers determine treatment and coverage decisions. However, because these tools may influence patient access to needed medications and services, it’s important that they incorporate elements that are most important to patients.

- **Ensure coverage decisions align with clinical evidence**

Currently, a patient’s coverage for a prescribed medication is likely to vary substantially depending on their insurer. Patients should have access to medications based on whether the underlying clinical evidence supports coverage, not based on their insurer or plan.



### #3. Health insurance coverage needs to be more patient-centered and fair.

In response to rising health care costs, insurance companies, employers and state governments have changed the types of health care benefits they offer. A growing portion of health costs are being shared with patients, translating into higher deductibles, higher copays, tiered access to medications, and new challenges when navigating the health care system.

#### **Opportunities to improve insurance benefit design and coverage:**

##### **• Align patient cost sharing with clinically appropriate care**

Sometimes patients with the same condition may need different treatments due to their genetic characteristics, comorbidities, disease severity, or other factors. In some cases, pursuing the treatment that may work best for them will require patients to face substantially higher copays, deductibles, or other cost sharing. To promote fairer, more patient-centered care, insurers and other health care payers should adopt policies that align patient cost sharing with clinically appropriate care.

There are multiple ways to do this, including:

- Providing flexibility in cost sharing for patients: In cases where a patient's biology or genetics prevent a treatment from working, they shouldn't be punished with higher cost sharing. Instead, to incentivize high-value care, the more clinically beneficial that a therapy is for a patient, the lower their cost sharing should be.
- Covering high-value treatments and services before patients meet their deductible: High-deductible health plans (HDHPs) have become increasingly common. Patients enrolled in HDHPs must pay significant out-of-pocket costs before their insurance coverage kicks in. For some patients with chronic diseases, these high upfront costs can prevent them from accessing medications and services that they need to manage their condition, resulting in poorer health and more intensive health care utilization down the line. To address this, health plans should provide pre-deductible coverage for high-value treatments, including medications that prevent exacerbations of chronic conditions.

##### **• Implement best practices for step therapy**

Patients often lack meaningful access to medicines, even if they have insurance. Most health care benefits include utilization management mechanisms like step therapy, which requires patients to try a first-line medication before a health plan will cover another treatment option. Step therapy can be resource-intensive and costly for everyone involved, making it an inefficient way to control costs. A patient's treatment plan should be based on what's clinically appropriate for them, not a health plan's unique requirements. Therefore, step therapy policies should adhere to common standards that account for patient needs and concerns, not just costs.

## HETEROGENEITY AND INDIVIDUAL TREATMENT EFFECTS

It's hard to be excited about being average. But when a patient is facing a health challenge, being average can make treatment decisions and management easier and more predictable. Being average means that their illness progresses like it does in most people, they respond to treatments like most people, and their journey to achieving better health resembles what other patients are experiencing.

In the real world, though, each person is unique, thanks to a multitude of factors such as their racial and ethnic backgrounds, age, genetics, chronic conditions, gender, sex, environment, socioeconomic circumstances, and even personal preferences when it comes to health treatments. These factors can affect how patients respond to treatments.

Within this booklet, we refer to differences in how individuals respond to treatments as **“heterogeneity”** and **“individual treatment effects.”** Individual differences can have an important impact on a patient's health, from finding the right treatment to making sure it is covered under the patient's health insurance plan.



### What does “heterogeneity” mean?

The dictionary says:

het-er-o-ge-ne-i-ty  
[he-tə-rō-jə-'nē-ə-tē] noun

1. The quality or state of consisting of dissimilar or diverse elements.<sup>1</sup>

Researchers say:

1. Used in a general sense to describe the variation in, or diversity of, participants, interventions, and measurement of outcomes across a set of studies, or the variation in internal validity of those studies.
2. Used specifically, as statistical heterogeneity, to describe the degree of variation in the effect estimates from a set of studies. Also used to indicate the presence of variability among studies beyond the amount expected, due solely to the play of chance.<sup>2</sup>

## Why Do Patients Have Different Responses to Treatment?



### Pharmacologic Differences

Sometimes the same treatment will have different effects on patients with the same condition. In some cases, patients with certain racial backgrounds or genetic ancestry may metabolize a medication differently. For example, some patients are poor metabolizers for specific enzymes, which might mean they require a different treatment or different dosing for common medications like antidepressants or high blood pressure treatments.<sup>3</sup>



### Genetic Risk

Some patients may require a different treatment based on their genetics. For example, some patients have a genetic predisposition to high cholesterol, which can't always be managed with traditional therapies like statins. Instead, these patients may need a treatment that takes into account their specific genetic makeup.



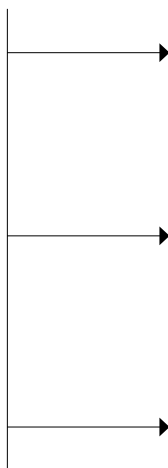
### Social Determinants of Health

Health outcomes may vary based on nonbiologic factors, often called social determinants of health. These factors include environment, income, employment and access to housing, food, health care, transportation and social support. Sometimes, a patient may require a different treatment based on these factors. For example, a patient in a rural community who must travel a significant distance to access health care services may require an alternative treatment compared with a patient who lives nearer to a hospital system.

**Because different patients can have different treatment responses, the treatment that's best for most patients may not be the one that's right for a specific individual.**

#### For example:

Aspirin is commonly used to treat headaches.



**For some people,** it works well and *without side effects*.



**For other people,** it cures the headache *but causes stomach upset*.



**And for certain people,** aspirin doesn't cause an upset stomach, but it *also doesn't stop the headache pain*.



## WHY INDIVIDUAL TREATMENT EFFECTS MATTER

What happens when a patient is not average? Because people are different in so many ways and have diverse characteristics, there may not be research on patients who are similar to them. When that happens, it can be harder to know what treatment is right for that patient, and it might be harder for them to access the most appropriate treatment.

Within the health care system there has always been a struggle — among researchers, medical professionals, health insurance companies, and others — to meet the needs of millions of people and still recognize the unique needs of each individual person.

Medical research is great at determining how the “average” patient in a study will respond to a treatment, but it may not always do a good job of determining how a specific individual will respond if they don’t fall into that average group. In addition, until about 30 years ago, most clinical trials only included Caucasian male participants, resulting in crucial gaps in the data about how other patients respond to the studied treatment.

**In other words, when research studies are designed assuming the world looks like this:**



**The findings of that research may not translate well to patients in the real world who look like this:**



Fortunately, researchers have been increasing their efforts to broaden diversity in clinical trials and real-world evidence studies, and to design trials to better detect possible heterogeneity in patient responses.

However, most health plans still design their policies to meet the needs of the majority of people. In many instances, insurance companies are using research findings about the “average” patient to make coverage decisions for individuals. When this happens, patients who need different treatment options due to factors such as age, genetics, chronic conditions, or sex, among other reasons, may have a difficult time accessing the treatment that’s most suited to their specific health needs.

## NEW URGENCY IN UNDERSTANDING INDIVIDUAL TREATMENT EFFECTS

To both improve health care quality and control rising health spending, health care stakeholders seek to better understand which treatments and interventions work “best” and which are the most cost-effective.

Comparative effectiveness research (CER) involves comparing one treatment to another treatment. The Affordable Care Act established the Patient-Centered Outcomes Research Institute (PCORI) to fund and oversee much of the CER conducted in the United States in collaboration with academic, public and private partners. Over the past decade, PCORI has built a wealth of CER resources for researchers, patients, insurers and the broader public that provide important data that promote the delivery of patient-centered health care.

Meanwhile, several academic institutions, research institutes, professional organizations and private payers have started to use value assessment frameworks to try to determine the relative “value” of a health care intervention based on both its benefit *and* its cost. Value assessment tools can be used in a variety of ways, from helping to facilitate shared decision-making between patients and their health care team, to providing a resource for insurers as they make health care coverage decisions.

Considering individual treatment effects and patient preferences when evaluating the effectiveness and value of health care interventions is essential to providing patient-centered health care.

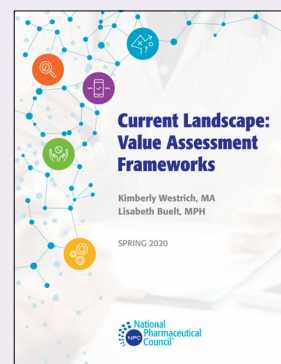
### Emerging Tools and Programs for Assessing the Value of Health Care Treatments and Services

Value assessments are a new and evolving area in the United States. In recent years, several organizations such as the Institute for Clinical and Economic Review (ICER), National Comprehensive Cancer Network (NCCN), American Society for Clinical Oncology (ASCO), and Innovation and Value Initiative (IVI) have developed frameworks to assess new treatments. However, unlike the CER conducted by PCORI, some value assessment tools incorporate cost-effectiveness analysis (CEA). CEA combines CER with an economic assessment and compares the cost of an intervention with its benefits (relative to other interventions).

Some patient groups have voiced concern that CEAs — particularly those that rely on the use of a controversial measure called a quality-adjusted life year (QALY) — assume that all patients are the same, both in how they will respond to a treatment and in their definition of treatment value.<sup>4</sup> In real-world care, treatments lead to varying degrees of benefits for patients. Therefore, it’s critical that coverage and treatment decisions are not made using a one-size-fits-all approach.

Public and private insurers are looking to CER and value assessments to provide direction about what treatments offer the most promise for the majority of people. Yet many patients and caregivers fear this approach could be used to deny access to treatments. People who have conditions like depression, where treatment responses can vary greatly, know firsthand that a one-size-fits-all approach to medical treatment can be very harmful to patients.

**To help patients, providers and insurers better understand value assessment, NPC analyzed the seven existing value assessment frameworks in the United States.**



The report, [“Current Landscape: Value Assessment Frameworks.”](#) compares the strengths and limitations of each framework.<sup>5</sup>

## How Can We Make Value Assessment More Patient-Centered?

Some insurers and health care decision-makers, including state governments, are using value assessment tools to inform their coverage decisions. Because patients differ vastly in their clinical makeup and their treatment preferences, it's important that value assessment tools consider the priorities and needs of individual patients to ensure that coverage decisions are appropriate and patient-centered.

**To achieve this goal, value assessment tools must do the following:**



### **Account for patient heterogeneity**

Although it may be more efficient to calculate a population-level assessment, such value determinations could undermine access to treatments and services for some patients. When assessing the value of a treatment, a framework must incorporate the elements that matter most to patients, not offer a one-size-fits-all solution. This includes incorporating elements that reflect those patients whose biology and genetics may prevent them from succeeding on a treatment that works well for the broader population. Furthermore, it's critical that value assessment tools take into account patient preferences regarding various aspects of their care or treatment, like whether it will extend their life, how the treatment is administered, or the impact on daily functioning or ability to work. Research has shown that patient preferences for these elements of value vary, even within a population with the same condition, such as breast cancer.<sup>6</sup>



### **Rely on rigorous methods**

Value assessment tools are relatively new, and some rely on innovative and emerging methodologies that are subject to critical limitations. If these frameworks are being used to make clinical treatment and coverage decisions, the underlying methods must be sound and validated.



### **Continue to develop and validate patient-centered assessment methods**

Researchers are currently testing new methods for capturing patients' concerns, experiences, and treatment preferences in a way that traditional value assessment models and methods do not. This includes a method known as multi-criteria decision analysis (MCDA), which offers a unique way to quantify what matters most to patients when they consider the value of a health service. MCDA models allow stakeholders to assign a personalized weight to different dimensions of value (e.g., caregiver burden, simplicity of taking the treatment, effect on productivity, etc.), qualitatively and/or quantitatively.<sup>7</sup>



### **Improve transparency**

What elements does the value assessment's model use to determine "value"? Does it incorporate comprehensive data and evidence on treatment attributes that matter most to patients? How are the various components weighted and do those weights align with patient values and preferences? As health care decision-makers — including insurers, employers, health care providers, and patients and their representatives — explore the use of value assessment tools, it's imperative that all end users know what methods and evidence went into the assessment model and if resultant value determinations are replicable.



### **Reflect a broad and dynamic evidence base**

High-quality evidence, including real-world data, should be incorporated into value assessment frameworks. For new treatments, there may be limited evidence available to inform an early value assessment. Moreover, the available evidence may only come from randomized clinical trials (RCTs) that often don't reflect the diversity and variability of a real-world patient population. In addition, value assessment reports reflect the evidence about a treatment's cost and benefit at a specific point in time. But as new evidence comes in, it is important that the organizations conducting these analyses update the assessments to incorporate new knowledge. This is particularly true for disease areas such as cancer, where evidence evolves quickly and frequent updates are needed.



### **Produce clear outputs**

Framework outputs must be clear to ensure end users (e.g., patients and their care team, insurers, etc.) do not misinterpret the assessment results. It's crucial that anyone using a value assessment tool to inform a health care decision has the context to interpret its results. Research has shown that some value assessments do not reflect the full range of plausible results, leaving decision-makers with incomplete information that could lead to harmful decisions for patient health.<sup>8</sup>



### **Use a systemwide health perspective**

Assessments should be conducted on a broad range of services across the health care system. Patient care involves many interrelated health care services, including physician visits, treatments such as drugs or surgeries, and hospital care. Moving to value-based health care requires a comprehensive focus on all health care services. Value assessments should consider all these interrelated services and should be conducted for a broad range of these services.



### **Engage with patients and their caregivers in a meaningful way**

Regardless of a value assessment's intended end user, patients are the recipient of health care, and they must be meaningfully involved in assessments of treatment value. Developers of value assessment tools should collaborate with patient organizations and formally integrate patient recommendations into their models, assessment reports, and processes. In addition, as value assessors and researchers explore new methodological approaches to value assessment like MCDA, it is vital that patients contribute to the identification and selection of criteria to ensure such methods deliver on the promise of patient-centricity.

Assessing the value of a health care intervention is a complex task because the benefit of a treatment can vary depending on a patient's genetics, preferences, and disease severity, as well as several other factors. Therefore, insurers should not rely on a single model or tool to assess a treatment's value and inform coverage decisions. Instead, value assessment tools can be one of many resources that insurers and care teams use to make health care decisions.



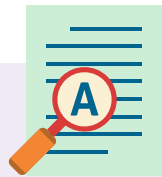
## DENIED FOR BEING DIFFERENT: PATIENT DIFFERENCES AND HEALTH BENEFITS

### Health Benefit Designs Can Create Access and Affordability Challenges for Patients

U.S. health care costs have been on the rise for decades, generating growing concern about health care spending sustainability and affordability. In response to increased spending, insurers and other health care payers have developed new strategies to contain costs. For example, health care payers are shifting a larger portion of health care costs to patients, asking them to pay more out of pocket through higher deductibles, copays, and coinsurance.

In addition, many insurance companies have implemented utilization management programs that influence which treatments and services a patient can receive based on the insurer's assessment of whether it is appropriate. Examples of utilization management include prior authorization, where the insurer must authorize that a prescribed treatment or service is medically necessary before the patient can receive it, or step edits (also referred to as step therapy), which require patients to prove that prior treatments were ineffective before the insurer will pay for another treatment option.

#### KEY TERMS



**Coinsurance** — A percentage of the cost of a service that an insured individual must pay.

**Copay** — A set amount that an insured individual must pay for covered services.

**Deductible** — The amount an insured individual must pay out of pocket before their insurer starts paying.

**Prior authorization** — A utilization management strategy in which a patient's health insurer or plan must authorize that a certain service or treatment is medically necessary before a patient can receive it.

**Step edit or step therapy** — A utilization management strategy that requires a patient to prove that prior treatments were ineffective before the health plan will cover another treatment.

**Utilization management** — Strategies implemented by health care payers to help manage costs by influencing patient care decision-making through case-by-base assessments of the appropriateness of care before it is provided.

The implementation of utilization management programs continues to expand, creating more hurdles for patients as they try to access needed medications. A recent study found that when it comes to specialty drugs, about a third of the coverage decisions made by the largest U.S. insurers are more restrictive than the Food and Drug Administration (FDA) label.<sup>9</sup> The most common restriction types are step edits (73%), limitations on the types of physicians who can prescribe the medication (31%), and restrictions to certain patient subgroups (16%).

Furthermore, a patient's coverage for a prescribed medication is likely to vary substantially based on their insurer. This is largely because insurers use different sources and evidence to inform their decision-making. A recent NPC study found considerable variation in the consistency, volume and types of evidence cited by major commercial payers in their coverage policies.<sup>10</sup> But the fact of the matter is patients should have access to medications if the underlying clinical and economic evidence supports coverage — not widely differing access depending upon the their insurer or health plan.

The challenge with utilization management strategies is that the decisions that health care providers make for individual

patients can collide with “one-size-fits-most” approaches designed for the “average” patient. In particular, step edits can lead to delays in care, which might hold minor consequences for some but significant consequences for others.

For many patients, delays in access to needed care can result in higher costs over time. Though health plans might see short-term drug cost savings with utilization management, those gains may be lost to long-term increases in hospitalizations or treatments for managing worsening conditions.

## How Can We Make Insurance Benefit Design More Patient-Centered?

There are several ways to improve insurance benefit design and utilization management programs to make them more evidence-based, equitable, and patient-friendly.

### Align Patient Cost Sharing with Clinically Appropriate Care

What happens when a health plan only covers one treatment for a condition and that treatment doesn’t work for a specific individual? Patients who don’t respond, respond poorly, or experience side effects to therapies can find themselves paying higher out-of-pocket prices for additional options.

Numerous studies have found that higher out-of-pocket costs can result in patients not filling or discontinuing the use of their prescribed medications. When lower-cost treatments provide equal or greater benefits to higher-cost treatments, it makes sense that insurers would institute higher cost sharing to encourage more cost-effective, appropriate treatments. But when higher-cost medications provide greater benefits than the less expensive alternative, incentivizing appropriate treatments through patient cost sharing is more complicated.

## CASE EXAMPLE

### Step Edits for Patients With Rheumatoid Arthritis (RA)

When an insurer requires a patient to try and fail on a therapy before accessing another treatment better suited to their needs, this delay in access can result in a broad spectrum of consequences depending on a patient’s genetic makeup and severity of disease.



Manageable inconvenience



Short-term pain and loss of some productivity



Irreversible joint deterioration,  
worsening health

On average, a delay in getting the ideal medication may not be problematic for some RA patients. But for those who don’t have a positive response to a medication that works for an “average” patient, their joints may deteriorate more rapidly, and such unnecessary steps could lead to irreversible damage.

**To promote fairer, patient-centered care, insurers and other payers should:**



**Offer more equitable benefit designs**

Most people who have insurance in the United States get it through an employer (including dependents and spouses). But most employers tend to offer few, one-size-fits-all benefit designs where premiums and patient cost sharing are the same, regardless of how much the employee is compensated. However, some employers are now focusing on diversity, equity, and inclusion practices to address inequitable benefit design, and a small minority are offering plans that allow lower-wage employees to pay less for health care.<sup>11</sup>

There are several ways employers can make the health care options they offer more equitable. For example, they can engage with their employees through focus groups or surveys to get a better understanding of employee needs and priorities, as well as of barriers employees face with existing options. Employers can also help make the benefits they offer more affordable for lower-income individuals by providing subsidies in the form of lower premiums, wage-based health savings account (HSA) contributions or other options.



**Offer variable or “dynamic” cost sharing**

Sometimes patients with the same or similar condition may need different treatments because of their genetic characteristics, comorbidities, or disease severity. Often, multiple medications treat the same condition, but each one has different out-of-pocket costs for patients depending on their insurer.<sup>12</sup>

The more clinically beneficial a therapy is for a patient, the lower their cost share should be. Conversely, treatments that are not proven to be effective for certain patients, or low-value care, may have higher out-of-pocket costs. This concept of value-based insurance design (VBID) has gained substantial traction over time and has been implemented through enactment of both state and federal government health care policies.

To better align patient cost sharing with appropriate care, NPC identified five guiding principles in which cost sharing obligations would be particularly problematic (see figure below).<sup>12</sup> By adhering to NPC’s principles, health plans can create more patient-centered benefit designs and advance the delivery of more affordable, high-value care.

**When Is Higher Cost-Sharing for Patients Less Acceptable?**

1.

If the initial lower-cost therapy is unsuccessful, patients should have access to higher-cost therapy and lower out-of-pocket costs.

2.

If there is high confidence the health benefits of a treatment are significant, then financial barriers should be lowered.

3.

If the treatment costs are balanced with better effectiveness and safety, then cost sharing should be lower.

4.

If patients need higher-cost treatments based on their biology or genetics, then cost sharing should be reduced.

5.

Cost sharing differences incentivize trying lower-cost treatments, but big jumps in costs for patients should be avoided.



### **Provide pre-deductible coverage for high-value medicines**

Another way health plans can align patient cost sharing with appropriate care is by removing cost sharing for high-value treatments. Over time, high-deductible health plans (HDHPs) have become more common. Patients enrolled in HDHPs must pay significant out-of-pocket costs before their insurance coverage kicks in. For some patients with chronic disease, high upfront costs can prevent them from accessing medications and services they need to manage their condition, which can result in poorer health and more intensive health care utilization down the line. To address this, health plans should provide pre-deductible coverage for high-value treatments, including medications that prevent exacerbation of chronic conditions.<sup>13</sup>

Health plans and employers have been implementing policies that waive cost sharing for high-value care incrementally. Due to a recent change in federal policy, HDHPs with HSAs can now cover an expanded list of preventive services and medications before patients meet their plan's annual out-of-pocket deductible. As a result, a growing number of employers are waiving some cost sharing for chronic disease medicines. While this is encouraging, there is still more work to be done. All patients who take high-value chronic care medications and are enrolled in HDHP-HSA eligible plans would benefit from more uniform uptake of this policy across health plans and employers.

### **Implement Best Practices for Step Therapy Requirements**

Step edits can lead to treatment discontinuation for patients and place significant administrative burden on health care providers (e.g., providers often spend time identifying other treatment options or interacting with payers and pharmacies on their patients' behalf). For these reasons, physician societies and patient advocacy organizations have created guiding practices for the use of step therapy, and over 30 states have legislated processes for the administration of step therapy. Yet, little consensus exists for when the use of step therapy is appropriate.

To better understand the optimal development and implementation of step therapy protocols, NPC convened a multistakeholder group of experts from the patient, provider, plan, pharmacy, policy, and ethics communities to build consensus on criteria for appropriate step therapy use.<sup>14</sup> Although roundtable stakeholders did not always agree on when step therapy is appropriate, they did agree on 21 criteria across five themes: clinical evidence as the foundation for protocol development, implementation of protocols, transparency and communication of processes, navigation of the appeals process, and evaluation of health and administrative impact. Stakeholders agreed 14 of these standards could be implemented and achieved immediately.

To make step therapy programs more patient-centered, insurers need to, at a minimum, create a codified process to review up-to-date evidence, communicate decisions and processes transparently, and support flexibility.







## QUESTIONS THAT PATIENTS LOOKING FOR A HEALTH PLAN SHOULD CONSIDER



### What Is the List of Drugs the Plan Will Cover?

This list is known as a formulary. If you take medications for a chronic illness such as high blood pressure, asthma or diabetes, be sure those medicines are on the formulary before you select that plan. If they aren't, you could be expected to switch to different medications or pay the cost yourself.

- How many treatments are covered for my health condition(s)?
- Does the health plan have to approve my medicine before they will pay for it (called "prior authorization")?
- Will I need to try several treatments before getting the one that works for me (called "step therapy")?
- Is the appeals process easy for patients to navigate?



### How Much Will My Medications Cost?

Most health plans will require a copay for each prescription. Many plans will have three or four levels, or "tiers," of copays that apply to different medicines. Find out what copay level applies to your medicines by calling the plan or looking at their materials. Many plans also require you to pay a deductible, a set amount that you pay out of pocket before your insurance kicks in. Depending on your health plan, you might have a separate deductible for prescription drugs.

- How much is the deductible? Is there a separate deductible for prescription drugs? If so, how much is it?
- Does the deductible have to be met before my plan will cover prescription drugs?
- Does the plan pay for any medications before I meet my deductible?

Sometimes you can get a coupon to help pay for your medicines. But some insurers track your use of coupons through copay accumulator adjustment programs, also known as "coupon adjusters" or "copay accumulators." These programs don't allow payments made using a coupon to count toward your deductible or out-of-pocket maximum. Similarly, an insurer may have a "copay maximizer" program in which the value of the coupon is applied evenly over the year. Insurers aren't required to include information about these programs in Summary of Benefits and Coverage or marketing materials, which may make it difficult to find out if your plan includes one.

- Does my plan allow me to use a coupon for my medicine(s)?
- Is there a coupon adjuster program that prevents coupons from counting toward my deductible or out-of-pocket maximum?

## NAVIGATING CARE: ACKNOWLEDGING PATIENT DIFFERENCES

This booklet describes numerous challenges that patients confront when navigating the health care system. Here we provide some important conversation starters to help patients and their health care team achieve the best possible health outcomes.

While much work remains to be done on understanding individual treatment effects and their role in health care, there are opportunities for patients to use the available knowledge to improve their health outcomes.

It is important for patients to discuss available treatment options with their health care providers and caregivers as they weigh medical decisions. Patients, caregivers and advocates can play a key role in bringing individual treatment effects to the forefront of the conversation. Patients should feel comfortable raising concerns about the possibility that they won't respond to a treatment, discussing potential side effects, and making clear what outcomes are most important to them. Having these conversations can make it easier to determine the best strategy for a patient whose treatment response is different from the "average" patient.

### Sample questions patients can bring to their next health care appointment:

- ☐ What are my treatment options, and what are the potential benefits and risks?
- ☐ Do any of my personal preferences (e.g., lifestyle, work capabilities, health outcomes) help inform which treatment option might be best for me?
- ☐ What side effects could I experience with each treatment option?
- ☐ Am I at high or low risk of developing the condition this treatment is designed to prevent? How does that affect your treatment recommendation?
- ☐ Given my personal characteristics (e.g., age, sex, race, etc.) and health history, do you think I could have an unexpected response to the treatment you are recommending? Has there been any research into responses for patients with my characteristics and condition? How different are patient responses to this treatment?
- ☐ If I don't respond to the therapy, what would be the next steps in treating my condition?
- ☐ If I don't respond to this treatment, will my health insurance plan cover other options?

## GLOSSARY

**Coinsurance** — A percentage of the cost of a service that an insured individual must pay. For example, a patient whose health plan requires 20% coinsurance will be responsible for \$20 of a \$100 procedure.

**Comorbidity** — More than one illness or disease occurring in one person at the same time.

**Copay** — A set amount that an insured individual must pay for covered services (e.g., \$10 per doctor's office visit).

**Copay accumulator or coupon adjuster** — A program used by an insurer that does not allow payments from prescription drug coupons to count toward a patient's deductible or out-of-pocket maximum.

**Copay maximizer** — A program (like a copay accumulator) employed by an insurer to prevent prescription drug coupons or copay cards from counting toward a patient's deductible or out-of-pocket maximum. However, a maximizer evenly applies the value of the coupon over the benefit year, rather than allowing the maximum value of the coupon to be used all at once.

**Deductible** — The amount an insured individual must pay out of pocket before their insurer starts paying. In other words, a patient is responsible for paying the full cost of covered services until they reach their deductible.

**Health equity** — The absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically, or geographically.

**Health savings account (HSA)** — A type of savings account, often coupled with a high-deductible health plan, that allows an individual to set aside money on a pre-tax basis to pay for qualified medical expenses.

**Heterogeneity** — The quality or state of consisting of dissimilar or diverse elements. Within the context of health care, heterogeneity is a term that is used to describe the variation in, or diversity of, participants, interventions, and measurement of outcomes across a set of studies or the variation in internal validity of those studies.

### **Multi-criteria decision analysis (MCDA) —**

A method that evaluates multiple conflicting criteria in decision-making. In the context of value assessment, MCDA models allow stakeholders to assign a personalized weight to different dimensions of value (e.g., caregiver burden, simplicity of taking the treatment, effect on productivity, etc.), qualitatively and/or quantitatively.

**Pre-deductible coverage** — When a health plan covers a medication or service before a patient has met their deductible.

**Prior authorization** — A utilization management strategy in which a patient's health insurer or plan must authorize that a certain service or treatment is medically necessary before a patient can receive it.

**Social determinants of health (SDOH)** — Conditions in the environments in which people are born, live, learn and work that affect a wide range of quality-of-life outcomes and risks. SDOH represent nonmedical factors such as housing, transportation and poverty that impact health and can cause hardship for patients.

**Step edit or step therapy** — A utilization management strategy that requires a patient to prove that prior treatments (e.g., one or more other drugs) were ineffective before the health plan will cover another treatment.

**Utilization management** — Strategies implemented by health care payers to help manage health care costs by influencing patient care decision-making through case-by-base assessments of the appropriateness of care before it is provided.

**Value assessment** — A way of measuring the value of a health care intervention based on its benefits and cost, typically using health economic models, methodological approaches and inputs to derive a numerical or categorical output or range of outputs.

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