



Formulary Management and Benefit Design

Formulary management is an integrated patient care process that enables physicians, pharmacists, and other health care professionals to work together to promote clinically sound, cost-effective medication therapy, and positive therapeutic outcomes. Equitable access to appropriate medication, pharmacoequity, is critical to equitable health care, with medication formularies representing a key determinant of medication access.¹

Benefit Designs are the rules that dictate which services will be covered, which providers are in-network, and cost-sharing amounts — such as deductibles, co-payments, or co-insurance — that patients must pay. Many factors contribute to health disparities, including differences in health or key determinants that adversely affect marginalized or excluded groups. Health disparities can exist among ages, genders, race/ethnicities, disabilities, economic status, and other personal and community-level characteristics. It will take comprehensive efforts from all parts of the health care ecosystem to improve health equity and close these gaps. One of the levers that could improve health equity is a health insurance benefit design, which reflects in part what services health plans cover and what consumers are required to pay for these services out of pocket.^{2,3}

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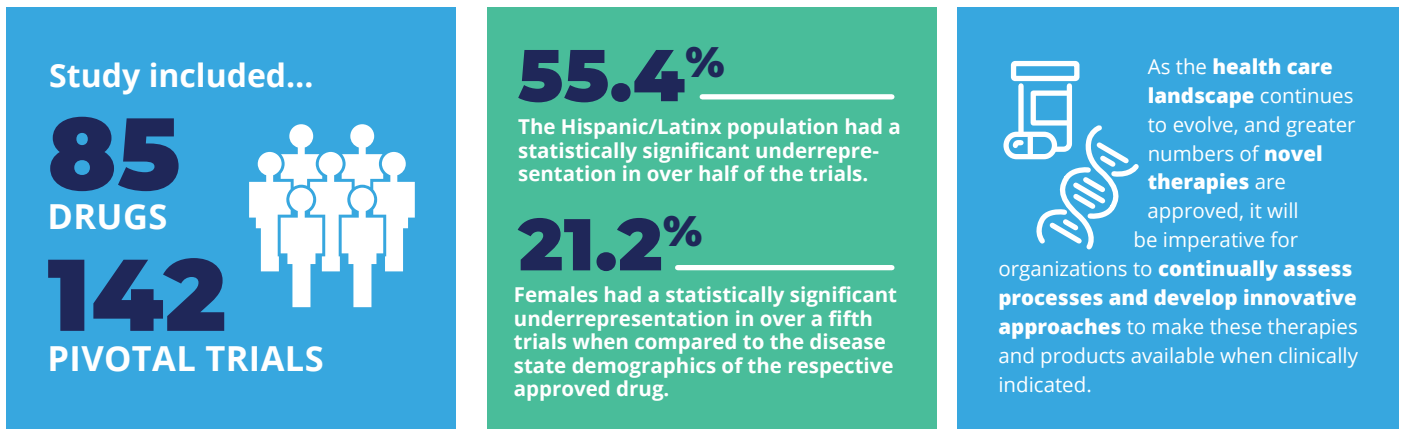


CALL TO ACTION

- ❑ Educate health care professionals on advocating and updating formularies annually about members and patients with diverse and inclusive language.
- ❑ Foster members' trust in plans by explaining why formularies on payers are becoming more diverse and inclusive to the patients that they serve.
- ❑ Understand the challenges individuals in underserved populations face with formulary management-related and benefit design disparities.
- ❑ Develop and implement inclusive and diverse strategies to address the specific needs of under-represented populations on medication formularies. Recognize and act upon organizational policies or procedures that may contribute to formulary management disparities.

WHY THIS MATTERS⁴

An article entitled, "New Drug Formulary Management and Utilization: Evidence in Sex, Race, and Ethnicity" was published in May of 2021 to review the demographic composition of pivotal trials and post-approval study requirements for recent FDA-approved drugs, analyzing the representation of minority groups and its generalization to the U.S. population or corresponding disease state. Drugs approved between July 2019 and June 2020 were identified, and demographic data, including race, ethnicity, and sex, was extracted from their pivotal trials.



- A total of 85 drugs and 142 pivotal trials were included in the study. Compared to the estimated U.S. population, the minority groups with a statistically significant underrepresentation across all pivotal trials were Black or African Americans and American Indian or Alaska Natives.
- The Hispanic/Latinx population had a statistically significant underrepresentation in 55.4% of trials. Females had a statistically significant underrepresentation in 21.2% of trials when compared to the disease state demographics of the respective approved drug.
- The study found that minority populations are underrepresented in generating safety and efficacy evidence for many new drugs.
- This discovery led to the idea that formulary management and drug utilization reviews (DUR) offer an integrated strategic opportunity for the clinical community to formally and carefully consider the data on sex, race, and ethnicity to address disparities in health care.
- As the health care landscape continues to evolve, and greater numbers of novel therapies are approved, it will be imperative for organizations to continually assess processes and develop innovative approaches to make these therapies and products available when clinically indicated.
- A periodic review of published literature is recommended to identify, adapt, and apply innovative formulary management strategies for high-cost agents. Biologics, biosimilars, and gene therapies are being FDA-approved in increasing numbers and require pharmacists to stay current on the formulary issues these novel agents create in managing patients.
- Pharmacists will be challenged with gene therapies and new modalities to treat some rare disease states. In addition to new therapy management challenges, pharmacists often are the health care providers who need to respond to drug shortages, which can create difficult situations. Guidance documents have been published that help pharmacy and therapeutics (P&T) committees effectively mitigate shortages and minimize the impact on patient care. Several federal agencies, private entities, and legislative efforts are trying to address the factors that lead to drug shortages to help mitigate future shortages.

Existing Standards

From a formulary perspective, Humana considers health equity in clinical reviews and formulary decision-making by evaluating the impact of health disparities within disease states and their effect on specific populations. Humana also maintains a running list of modeled pipeline drugs, where drugs that may present health equity issues are flagged. For example, Humana identified drugs that may be costly or difficult to access and drugs that have been studied in clinical trials that are not racially diverse. This information contributes to our clinical review and formulary placement discussions. Humana also understands the importance of literacy and that accessibility includes communication, so they have teams focused on driving down the readability of member notifications and content.

Innovative Methods of Formulary Management and Benefit Designs⁵⁻⁹

- Equitable access to medication is foundational to equitable health care. Disparities in access to and receipt of affordable medications and their subsequent impacts on health outcomes are well documented. Pharmaco-equity was recently proposed to highlight the need for “a health care system where all patients, regardless of race, class, or availability of resources, have access to the highest quality, evidence-based medical therapy indicated for their condition (John et al., 2023).”
- Medication formularies offer a potential path forward. Formularies reflect decisions traditionally made by payers and pharmacy benefit managers (PBMs) around the conditions under which medications are covered, how eligibility for covered medications is determined, and how covered medications can be obtained. Together, formulary policy tremendously impacts individuals’ appropriate and timely receipt of medication. Although formulary decisions have historically been based primarily on the perceived efficacy, safety, and cost of medications, less attention has been paid to formularies’ impact on equitable health outcomes.
- Employers and payers have the tools to make a difference and play a critical role in improving health equity. One of those tools is benefit design. They can effectively design benefits to increase healthcare access, address unmet needs, and personalize care for equity-lay patients. Benefit designs directly impact affordability and availability — the main barriers to access. To achieve this goal, employers and health plans must evolve their benefit designs from one-size-fits-all to a dynamic plan structure that removes barriers to care and addresses the unmet needs of their members affected by equity gaps.
- Dynamic value-based insurance design (VBID) models provide an innovative tool for payers to reduce plan costs and enhance the quality of care for members impacted by health disparities. These benefit designs are highly targeted with specific eligibility criteria, incurs lower direct costs, and has a measurable return on investment (ROI). Dynamic benefit designs include a bundle of interventions that address the “whole person social needs” of specific subpopulations and provide them equitable access to care and a better opportunity to avoid the progression of their chronic conditions to costly complications.
- Cost-sharing and other health plan design elements are built differently in dynamic benefit designs. This starts by identifying a target population segment with poor health outcomes due to health disparities. The second step is to find high-value services that benefit these members the most and then create a cost-sharing structure that encourages them to use the offered services. In addition to subsidizing cost-sharing for such ‘high-value’ services, dynamic benefits also enable health plans to provide supplemental benefits to address their unmet needs due to social drivers of health.
- By removing the financial barriers of needed care, the dynamic benefits model offers a unique opportunity to efficiently target underserved populations and promote health equity. Centers for Medicare and Medicaid Service (CMS) Innovation Center is already testing a version of benefits — “Value-Based Insurance Design (VBID)” in the Medicare Advantage program — allowing plans flexibility to provide supplemental benefits for beneficiaries based on health conditions and socioeconomic factors.

What can managed care do to address benefit design challenges?⁷

Target subpopulations.

- The first step is discovering the subpopulations that can benefit from the new plan designs. The direct costs of offering subsidized benefits to all members can be high, with smaller returns in cost avoidance. Under VBID, plans should target interventions to those who can most benefit. This means that plans should evaluate their population holistically and focus on sub-populations to identify health disparities.

Subsidize cost-sharing for primary care services.

- Primary care services are essential for all members, especially those with chronic conditions. Most benefit designs require deductibles to be met before applying cost-sharing for primary care services. Even minimal cost-sharing can cause individuals to delay or forego care. VBID enables better utilization of primary care services by keeping them outside of deductibles and subsidizing cost-sharing for targeted members.

Offer add-on supplemental benefits.

- There is a robust association between socioeconomic status and care quality for chronic conditions in U.S. primary care practices, showing that adult patients with diabetes who lived in more deprived and rural areas were significantly less likely to attain high-quality diabetes care than those in less disadvantaged and urban areas. Often, this is due to the high cost of medications and doctor visits, poor health literacy, lack of transportation, food insecurity, housing instability, and more. With a dynamic benefit design, supplemental benefits can be offered as add-ons to meet clinical and health-related social needs, such as transportation benefits (office visits or pharmacies) and healthy nutrition such as wholesome food cards, medically tailored meals, nutritional counseling, and education.

Employee/Member awareness and comprehension that understands the benefits.

- Incorporating benefits that aim to improve health equity and reduce health disparities is for naught if those benefits are not used. A communications strategy is needed to ensure workers and other plan participants know about the benefits. Additional educational materials are required so that workers understand the benefits and how it can be helpful to them. Employees may also need assistance navigating the health system to use the benefit. Each of these steps may need to be tailored for a particular population.
- Employers and carriers may also need to address factors beyond the benefit design to consider how the plan may affect access to care. For instance, what are the benefit eligibility requirements, and are they exacerbating disparities among populations (e.g., hourly vs. salaried, part-time vs. full-time workers)? In addition, it must be considered how employee premium contributions and out-of-pocket requirements will change with an updated benefit design strategy and whether the benefits remain affordable to the workers. Employers may wish to revise how they determine contribution requirements (subject to laws and regulations).

What Managed Care Pharmacy is Doing



Providence Health Plan

Mission: Providence recognizes that long-standing inequities and systemic injustices exist worldwide. This has led to health disparities among communities that have been marginalized because of their race, ethnicity, gender, sexual orientation, age, ability, religion, or socioeconomic status.

Developments: Providence Health Plan has made strides toward achieving health equity in its formulary management space. One of the most significant strides has been how Providence removed gender edits from their clinical criteria when deciding coverage for disease states like Hepatitis C or HIV. The efforts to remove gender edits have made it easier for their health plans to cover expensive Hepatitis C and HIV medications for populations that are underserved and need access.

Actions: Providence Health Plan also shared how the elimination of sex requirements for hormone therapies, contraception, and preventative cancer screenings would also allow access to communities that are underserved and can pose barriers to the transgender community. While certain utilization management tools like prior authorizations (PA) are needed to ensure that the proper medication is being used for the right patient safely, there are opportunities to reimagine how the PA is completed so that health plans can ease any barriers to care.

Communication: Providence Health Plan also improved communication between physicians and pharmacists with whom they collaborate. Communication barriers can cause damage in the formulary management process, affecting the patient's access to medications. Providence implemented a system called "CoverMyMeds," which is an integrated system. Implementing this system has led to improved communication between providers and pharmacists, which has benefited patients with their access to and proper coverage of medications.

Incentives: Providence also acknowledged that providers' compensation is not expected, but they have added quality incentives and report cards on their outcomes that boost incentives for providers. This process rewards providers for adequately navigating formulary processes, leading to patients becoming healthier and living longer lives due to coverage and access to their needed medications.

What Managed Care Pharmacy is Doing *(continued)*



ForHealth Consulting at UMass Chan Medical School in collaboration with Massachusetts Medicaid (MassHealth):

Mission:⁸ The MassHealth Pharmacy Drug Utilization Review (DUR) Program at ForHealth Consulting at UMass Chan Medical School recognizes and aligns with the MassHealth health equity mission to improve the health outcomes of its diverse members, their families, and communities by providing access to integrated healthcare services that sustainably promote health, well-being, independence, and quality of life. Addressing disparities, advocating for evidence-based policies for improved outcomes, and using data-driven practice to guide program development, system enhancements, and enhanced care aims to ensure that all Medicaid members can achieve their best health.

Developments:¹⁰⁻¹² MassHealth continues to build on past efforts with new incentives for health care provider organizations and plans tied to addressing structural racism and reducing health disparities. As an essential pillar of high-quality care in the Commonwealth, the aim is to continue to advance health equity. To make measurable progress toward closing identified disparities, MassHealth aims to gain further insights into the health disparities experienced by its members at the state, accountable care organization, and hospital levels. The goals of the MassHealth pharmacy team are to identify and address barriers to care, including data-driven utilization management obstacles, promote evidence-based practices, and recommend quality medication management for all.

Actions: The MassHealth Pharmacy DUR Program developed a Health Disparities Pharmacy Workgroup comprised of clinical and operational pharmacists to identify actionable, pharmacy-related interventions and address healthcare disparities impacting the Medicaid population. By engaging with internal and external stakeholders, assessing current practices, and identifying strategies necessary to better understand existing disparities and how to address them, the workgroup is an internal consultative group developing formulary management strategies. The workgroup has helped foster programmatic revisions to align with MassHealth's health equity initiatives and identify innovative approaches to optimize health care further.

Standardizing demographic data collection practices: The workgroup expanded demographic data collection efforts by updating all prior authorization (PA) fax forms for more detailed parameters related to sex assigned at birth (male, female, or intersex), current gender (male, female, transgender male, transgender female, or other), race, ethnicity, and preferred written and spoken languages. Race, ethnicity, and language categories are aligned with the most frequently reported information based on recent state census data and are adaptable moving forward. For enhanced reporting, the workgroup coordinated the implementation of this standardized data collection process across all state Medicaid-managed care organizations.

Language inclusivity: The workgroup evaluated more than 200 clinical criteria guidelines for gender-inclusive language and terminology, updating references to "male" and "female" gender in PA approval criteria in favor of the more neutral "patient" terminology approach. Where possible and necessary, the workgroup standardized language critical to coverage evaluations and outcome assessments (i.e., female or male sex assigned at birth). Gender edits were also eliminated at the point-of-sale processing to facilitate pharmacy adjudication for members.

What Managed Care Pharmacy is Doing *(continued)*

Information technology updates for data reporting: The workgroup updated internal PA documentation and tracking systems to align with the standardized demographic data collection categories for expanded reporting capabilities. Collaboration with information technology provided systematic data extraction abilities which allowed the opportunity to properly facilitate timely identification and reporting of member demographic data.

Formulary management template and presentation updates: The workgroup evaluated and updated proprietary drug monograph and quality assurance templates to incorporate background epidemiological disease state data and any pertinent consensus guideline disparity information. A direct comparison of epidemiological and clinical trial data and an overall summative assessment of currently known and unknown disparity information was incorporated into all formulary presentations to normalize the health disparities conversation and raise awareness of gaps in knowledge and care.

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2023 AMCP Health Disparities Advisory Group Members*

Lynn Deguzman, PharmD, BCGP, Clinical Pharmacy Services Director, Kaiser Permanente

Jennifer Dexter, Vice President, Policy, National Health Council

Christopher Diehl, PharmD, MBA, BCACP, Manager, Clinical Pharmacy Programs, Excellus BCBS

Matthew Dinh, PharmD, Senior Director, Pharmacy Quality Care & Experience, SCAN Health Plan

Rainelle Gaddy, PharmD, MBA, MS, Health Equity Strategy Lead, Humana

Karl Gregor, PharmD, MS, Vice President, Pharmacy Advisory Services, Optum

Troy Koch, PharmD, MBA, Director, Account Medical Lead, Takeda Pharmaceuticals

Tarul Kode, PharmD, Vice President, Senior Pharmacy Benefits Consultant, Segal

Hannah Lee-Brown, PharmD, RPH, CPHQ, Director, Pharmacy Benefits, Healthfirst

Arpana Mathur, MD, Executive Medical Director

Lilian Ndehi-Rice, PharmD, MBA, BCPS, Associate Vice President, Pharmacy Clinical and Specialty Strategies, Humana Inc.

Thomas C. Pomfret, PharmD, MPH, BCPS, Clinical Pharmacist Team Lead & Managed Care Pharmacy Residency Program Director, ForHealth Consulting at UMass Chan Medical School

Kellie Rademacher, PharmD, Director, Strategy, Inizio Evoke Access

Jenifer Smith, PharmD, BCPS, Clinical Pharmacy Manager, Providence Health Plan

Andrea Thoumi, MPP, MSc, Area Lead, Community Health and Equity, Duke-Margolis Institute for Health Policy, Faculty Director, Health Equity Education, Adjunct Assistant Professor and Core Faculty Member, Co-Director, Health Equity Policy and Primary Care Fellowship Consulting Associate, Department of Family Medicine and Community Health

AMCP Editorial Contributors

Mason Johnson, PharmD

Atlas Clarity Editorial Contributors

Lindsay Everett

Wendy Everett, ScD

Developed in partnership with the AMCP Health

Disparities Advisory Group, Atlas Clarity, and AMCP staff.

AMCP 2023 Health Disparities Advisory Group Members *

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