

## Formulary Management: Ensuring Patient Access to Safe, Cost-effective Drugs

### What is a formulary?

A drug formulary is a continually updated list of drugs that a health plan or pharmacy benefit manager will cover under a plan sponsor's pharmacy benefit, representing the current clinical judgment of healthcare providers who are experts in the diagnosis and treatment of a wide range of conditions. There are different types of formularies—open, closed, or tiered—and each type can be customized to meet a specific payer's objectives. **The primary purpose of the formulary is to optimize patient care by ensuring access to clinically appropriate, safe, and cost-effective drugs.**

### How are formularies developed and kept current?

Formularies are developed by a payer's Pharmacy and Therapeutics (P&T) Committee, made up of primary care and specialty physicians, pharmacists, and other health care professionals. P&T Committee members must disclose and appropriately handle any conflicts of interest, and their identity is usually kept confidential to avoid undue outside influence. P&T Committees evaluate available clinical evidence to select the best drugs for various conditions. This review focuses **only** on clinical considerations, including medical literature, FDA-approved prescribing information and safety data, and current therapeutic use guidelines—**not** economic or cost considerations.

P&T Committees meet on a regular basis, typically quarterly, to review recent developments, such as new drugs on the market and new safety or efficacy information for existing drugs. This regular P&T Committee review process helps prescribers and patients by recommending up-to-date prescribing guidelines and promoting clinical information for high-quality, affordable care. For example, P&T Committees would review the 46 new drugs and biologics and 80 first-to-market generic drugs as those approvals cleared the U.S. Food and Drug Administration in 2017.<sup>1</sup>

### What are the benefits of formularies?

- Only safe and effective products are covered by payers and used by patients.
- Ineffective and/or high-cost drugs with less expensive alternatives will generally not be included.
- Use of the most effective drugs leads to fewer physician office or ER visits, improved outcomes for patients, and lower overall costs for patients and payers.
- Patients experience lower out-of-pocket costs and convenient availability of drugs.

### Why does formulary management matter?

- The National Academies of Sciences, Engineering, and Medicine recommends **“expand[ing] flexibility in formulary design” as a strategy to improve the affordability of prescription drugs.**<sup>2</sup>
- Milliman examined legislative efforts to restrict payers' ability to make mid-year formulary changes that would limit coverage of or increase out-of-pocket costs for a specific drug, estimating that such legislation would increase drug costs in the fully-insured commercial market by approximately **\$4.84 billion nationwide from 2017 through 2021.**<sup>3</sup>

<sup>1</sup> U.S. Food and Drug Administration. “Novel Drug Approvals for 2017,” available at: <https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm537040.htm>.

<sup>2</sup> National Academies of Sciences, Engineering, and Medicine. (2017). *Making Medicines Affordable: A National Imperative*. Available at: <http://nationalacademies.org/hmd/Reports/2017/making-medicines-affordable-a-national-imperative.aspx>.

<sup>3</sup> Milliman, Inc. (2017). Estimated Cost of Potential “Frozen Formulary” Legislation: Fully-Insured Commercial Payer Impact, 2017-2021. Available upon request.