Mended Hearts

power of the patient voice
PATIENT ADVOCACY NETWORK

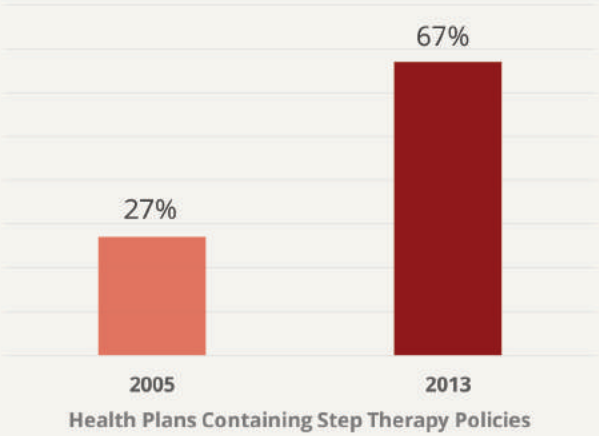
Eliminating Barriers to Innovative Cardiovascular Treatments and Devices

There are many factors that may limit a cardiovascular patient's ability to access the newest, innovative prescription medications, devices and treatments. Accessing affordable treatments is vital for all Americans, especially for those with chronic, potentially life-threatening conditions, such as cardiovascular disease. Mended Hearts believes and would advocate to ensure that all cardiovascular patients have access to the best treatments and care available.

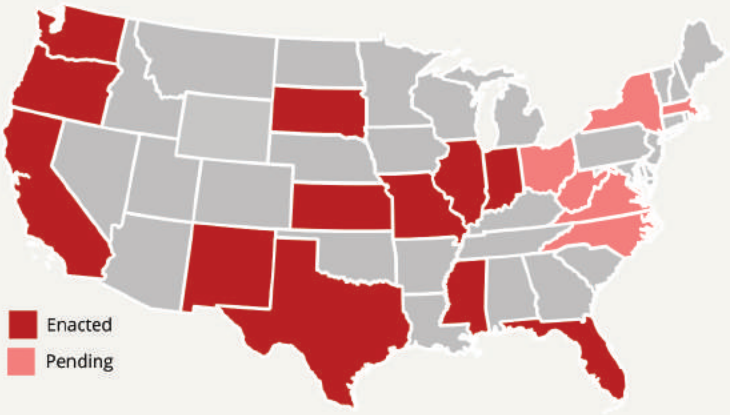
Step Therapy

Over the last several years, insurers have increasingly used step therapy policies, also known as "fail first", to contain prescription costs[1]. These policies require a person to try another medication – often lower priced– before they will approve the use of another medication for that condition. Step therapy removes physicians from the treatment decision and requires everyone to follow a one-size-fits-all treatment approach. Many patients fight these roadblocks while facing serious chronic diseases.

Step Therapy is on the Rise



Studies have shown that delaying effective treatment results in disease progression, worse patient outcomes[2], higher hospital costs[3], and some patients deciding to forgo treatment all together after encountering these obstacles[4]. The number of insurers using step therapy policies has grown rapidly. In 2005, just 27 percent of insurance plans had these policies; by 2013 more than 67 percent of insurance plans contained such policies[5].



Several states have enacted legislation to provide patients with a clear path to be granted a step therapy exception. They also require these step therapy protocols to be based on clinical evidence, not just cost. This legislation has reduced the time it takes to be granted an exception from over month to just three days; and in the case of emergencies just 24 hours. Mended Hearts will actively support legislation that is introduced in the States that provide step therapy protections for cardiovascular patients.

1 Chung, Adrienne, Joanna MacEwan, and Dana Goldman. "Does A 'One-Size-Fits-All' Formulary Policy Make Sense?" Health Affairs Blog. Health Affairs, 2 June 2016. Web. 14 Aug. 2016.1

2 Lard, Leroy R., Henk Visser, Irene Speyer, Irene E Vander Horst-Bruinsma, Aeilko H. Zwinderman, Ferdinand C. Breedveld, and Johanna M.w Hazes. "Early versus Delayed Treatment in Patients with Recent-onset Rheumatoid Arthritis: Comparison of Two Cohorts Who Received Different Treatment Strategies." The American Journal of Medicine 111.6 (2001): 446-51. Web.

3 Law, Michael R., Christine Y. Lu, Stephen B. Soumerai, Amy Johnson Graves, Robert F. Lecates, Fang Zhang, Dennis Ross-Degnan, and Alyce S. Adams. "Impact of Two Medicaid Prior-authorization Policies on Antihypertensive Use and Costs among Michigan and Indiana Residents Dually Enrolled in Medicaid and Medicare: Results of a Longitudinal, Population-based Study." Clinical Therapeutics 32.4 (2010): 729-41. Web.

4 Yokoyama, Krista, Winnie Yang, Ronald Preblick, and Feride Frech-Tamas. "Effects of a Step-Therapy Program for Angiotensin Receptor Blockers on Antihypertensive Medication Utilization Patterns and Cost of Drug Therapy." JMCP Journal of Managed Care Pharmacy 13.3 (2007): 235-44. Web.

5 "Step Therapy Comeback Continues." Managed Care Magazine Online. N.p., 30 Sept. 2012. Web. 14 Aug. 2016.

Prior Authorization

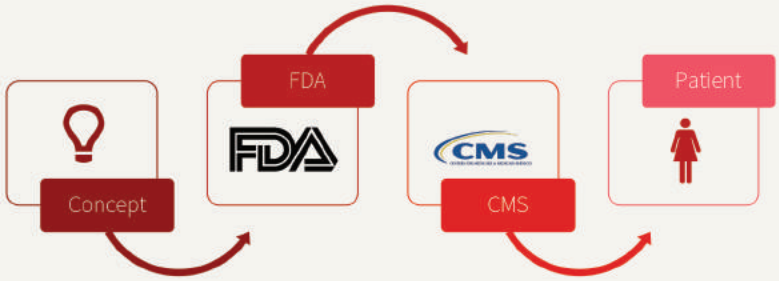
Prior authorization is when an insurance company will cover a medication only if particular criteria for coverage has been met. These measures are put in place to standardize care and contain costs, however, they present an access issue for many patients. Each payer has its own system of forms, protocols, and procedures, which cause delays and restrict access to a patient's care. The prior authorization process is also labor intensive and expensive for providers.

Research estimates that prior authorization requests consumed about 20 hours a week per medical practice: one hour of the doctor's time, nearly six hours of clerical time, plus 13 hours of nurses' time[6]. This translates to a significant financial burden on physicians. These complex procedures and policies also lead to patients never filling their prescriptions. Nearly 40 percent of prior authorization requests are abandoned due to complex procedures and policies and nearly 70 percent of patients encountering paper-based prior authorization requests do not receive the original prescription[7].

Mended Hearts actively supports legislation that would standardize prior authorization protocols and streamline patient access to innovative medications and treatments. These measures would establish a single standardized form for providers to submit for prior authorization. They would also require payers to make a prior authorization decision within 48 hours of submission or grant automatic approval.

Ensuring Patient Access to Critical Breakthrough Products Act

The Food and Drug Administration (FDA) has established an expedited review process and provides priority review for products that provide an effective treatment for a life-threatening condition for which there are no alternative treatments. On average, only three technologies a year qualify as a breakthrough. However, if a new technology meets the rigorous criteria to be labeled as a breakthrough product it can still take significant time to secure reimbursement from Centers for Medicare and Medicaid (CMS). This process can take up to three years.



In April 2016, Representatives Cárdenas and Boustany and Senator Coats introduced the Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 5009/S. 2298). This legislation develops a streamlined Medicare coverage and payment approach for medical devices approved through the FDA Expedited Review Process. If a product qualifies for the FDA expedited review process, it would be automatically eligibility for CMS reimbursement for three years.

Mended Hearts supports H.R. 5009/S. 2298, which bridges existing gaps in the medical technology innovation. It ensures that an efficient regulatory processes at FDA is matched with a timely payment determination at CMS. This measure encourages continued pharmaceutical and medical device research and development and protects patients access to these life-saving and life-sustaining treatments.

6 Casalino, L. P., S. Nicholson, D. N. Gans, T. Hammons, D. Morra, T. Karrison, and W. Levinson. "What Does It Cost Physician Practices To Interact With Health Insurance Plans?" Health Affairs 28.4 (2009): n. pag. Web.

7 "The Impact of the Prior Authorization Process on Branded Medications: Physician Preference, Pharmacist Efficiency and Brand Market Share." (n.d.): n. pag. Frost & Sullivan. Web.