



March 7, 2019

Honorable Members  
Joint Committee on Health Coverage, Insurance and Financial Services  
Maine State Capitol  
Augusta ME 04333-0100

**RE: LD 1009 (Step Therapy): Oppose**

Dear Members of the Committee:

On behalf of the Pharmaceutical Care Management Association (PCMA), I am writing you to provide our comments regarding LD 1009 (step therapy). PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for millions of Americans with health coverage provided through large and small employers, health plans, labor unions, state and federal employee-benefit plans, and government programs.

PCMA appreciates the opportunity to provide comment on LD 1009. Our industry is concerned about the bill because we believe it will restrict our ability to provide a high quality benefit that ensures that patients get the right drug, at the right time. It also will interfere with an important tool that payers use to put downward pressure on the rising cost of prescription drugs.

Health plans and PBMs implement a variety of guidelines and programs that are designed to ensure that patients receive clinically appropriate and cost effective drug therapies. Step therapy is one of these tools. It requires an enrollee to try a medically appropriate first-line drug, typically a generic alternative to a branded product, when a new therapy is initiated. Many drugs have harmful side effects or interact adversely with other medications; step therapy encourages trying safer, alternative therapies first.

Every plan has an established exceptions process that will permit the coverage of a drug that is not on a formulary, or reduces out-of-pocket cost if a physician provides information about side effects the patient has experienced from a lower-tiered drug, or offers another documented medical reason. These processes serve as a safeguard against the use of step therapy being too restrictive.<sup>1</sup> Additionally, plans and PBMs use Pharmacy & Therapeutic Committees that are comprised of independent experts including physicians and pharmacists to develop evidence-based guidelines used in drug management programs, such as step therapy, and assure cost controls do not impair the quality of clinical care. Finally, according to the Federal Trade Commission (FTC), "large PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance."<sup>2</sup>

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<sup>1</sup> "Making Medicines Affordable: A National Imperative," National Academies of Sciences, Engineering, and Medicine, Nov. 2017.

<sup>2</sup> Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," Federal Trade Commission, Aug. 2005.



Research firm Visante issued an analysis of the estimated cost of interfering with the tools that health plans and PBMs use, including step therapy. Although its analysis combines the cost of eliminating prior authorization in addition to step therapy, we thought it would be helpful to include the information on the potential costs of eliminating these programs, which would be an to employers and commercial health plans of increased \$247 million over the next ten years.<sup>3</sup>

It is essential that any legislation enacted does not erode programs that ensure a cost effective pharmacy benefit. PCMA believes that LD 1009 will unnecessarily restrict existing programs and therefore must respectfully oppose this legislation. We appreciate your consideration of our comments. Please contact me at 202-756-5743 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "April C. Alexander". The signature is fluid and cursive, with a long horizontal stroke at the end.

April C. Alexander  
Assistant Vice President, State Affairs

Enclosure: Cost of Limiting Prior Authorization and Step Therapy in Maine Summary

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<sup>3</sup> "Increased Costs Associated with Proposed State Legislation Impacting PBM Tools," Visante, Prepared for PCMA, January 2019, available at: <https://www.pcmanet.org/wp-content/uploads/2019/01/Visante-Study-on-the-Increased-Costs-Associated-With-State-Legislation-Impacting-PBM-Tools-Jan-2019-FINAL.pdf>.

## Cost of Limiting Prior Authorization and Step Therapy in Maine

Maine policymakers should carefully weigh the potential unintended cost impact of proposals to limit or prohibit the ability of health plans and their pharmacy benefit managers (PBMs) to implement prior authorization (PA) and step therapy (ST) protocols. Estimates from Visante specifically quantify these potential costs for Maine.

### Maine Impact:

- **If Maine implements prohibitions on PA and ST, projected drug costs for fully insured employers and commercial health plans would increase by \$247 million in the state over the next ten years.<sup>1</sup>**
- **Limiting or prohibiting PA and ST would impact employers and health plans that now cover some 394,000 beneficiaries in Maine.<sup>2</sup>**
- **As limits on PA and ST increased costs, the ability of Maine employers to offer health insurance—and jobs—would be diminished.**

**Use of PA and ST Guided by Independent Experts and Plan Sponsors:** Pharmacy & Therapeutics Committees, comprised of experts that include physicians, pharmacists, and other medical professionals, develop evidence-based guidelines used in drug management programs, including PA and ST. PBM clients then decide if and how PA and ST will be applied to its health benefit plan.

**PA and ST Used to Help Ensure Prescriptions Are Safe and Appropriate:** PA is often required for drugs with a high risk of abuse or overuse, significant side effects, or off-label uses not approved by the FDA. ST ensures that prescribers consider the medically appropriate available therapeutic alternatives before settling on a course of therapy for a specific patient.

**Every Plan Has an Appeals Process:** According to the National Academies of Sciences, Engineering, and Medicine (NASEM), “Every plan, whether Part D or an employer-sponsored pharmacy benefit, has an exception process that permits coverage of a drug not on formulary or reduces out-of-pocket cost if a physician provides information about side effects the patient has experienced from a lower-tiered drug or offers another medical reason for switching.”<sup>136</sup> This process safeguards against the use of PA and ST being too restrictive.

**Studies Show PA and ST Help Reduce Costs:** PA and ST are widely used by PBM clients to help ensure appropriate and cost-effective use of high-cost and/or high-risk drugs. PA can generate savings of up to 50% for targeted drugs or drug categories.<sup>137</sup> ST has demonstrated savings of more than 10% in targeted categories.<sup>138</sup>

**FTC Finds PA and ST Used to Lower Costs:** According to the Federal Trade Commission (FTC), “large PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance.”<sup>139</sup>

**NASEM Suggests Formulary Controls Keep Premiums Low:** Without formulary controls, “insurance premiums would rise,” according to NASEM.<sup>140</sup> PA and ST are among the most effective formulary controls, thus any state legislation to limit or prohibit their use would likely raise premiums.

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<sup>1</sup> “Increased Costs Associated With Proposed State Legislation Impacting PBM Tools,” Visante, January 2019.

<sup>2</sup> Ibid.

<sup>136</sup> “Making Medicines Affordable: A National Imperative,” National Academies of Sciences, Engineering, and Medicine (NASEM), Nov. 2017.

<sup>137</sup> “Specialty Utilization Management Proves Effective: Ampyra Prior Authorization Improves Safety and Saves Money,” Prime Therapeutics, 2011.

<sup>138</sup> Yokoyama, et al., “Effects of a step therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy,” *J Manag Care Pharm.* 2007;13(3):235-244.

<sup>139</sup> “Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,” Federal Trade Commission (FTC), Aug. 2005.

<sup>140</sup> “Making Medicines Affordable: A National Imperative,” National Academies of Sciences, Engineering, and Medicine (NASEM), Nov. 2017.