

**Congress of the United States**  
**Washington, DC 20515**

January 12, 2018

Mr. Mark Merritt  
President & Chief Executive Officer  
Pharmaceutical Care Management Association  
325 7th Street, NW  
Washington, DC 20004

Dear Mr. Merritt,

As Co-Chairs of the Congressional Diabetes Caucus, we have been conducting an inquiry into insulin prices and cost burdens on patients over the past six months. Throughout our inquiry, we have heard that formulary and benefit design have a significant impact on how much insured consumers pay for insulin. In some cases, formularies are designed so that health plan enrollees have minimal or no out-of-pocket costs for insulin. In other cases, formulary exclusions or placement on higher tiers make certain insulins prohibitively expensive. We therefore write today to learn more about how your member companies determine formulary placement and utilization management programs for insulin products.

In the simplest terms, formularies are lists of prescription drugs that a health plan covers. Their design varies considerably from plan to plan. Most formularies use a tiered structure with three to five different levels of cost sharing. Patients are typically responsible for a larger share of a drug's cost on the higher tiers. On the lowest tier, patients may be able to fill a prescription for their medication without any cost-sharing. Formularies may also attach utilization and access protocols to drugs on a given tier, such as step therapy or prior authorization requirements. The goal of both cost-sharing and utilization strategies are to encourage use of certain preferred drugs and discourage use of non-preferred products.

Many factors can influence formulary placement. For example, Pharmacy and Therapeutic Committees that are responsible for developing formularies review scientific evidence and peer-reviewed literature about a drug's effectiveness before making a formulary placement decision. The availability of alternative treatments may factor into formulary placement. Lastly, we understand that the size of rebates paid by pharmaceutical companies to pharmacy benefit managers (PBMs) and payers may be contingent upon formulary placement and associated contract terms related to dispensing.

While we have concerns that exclusions and placement on higher cost-sharing tiers may restrict patient access to affordable insulins, we also appreciate that formulary design is complex and involves difficult tradeoffs. For example, while formulary and benefit design decisions can make insulin less affordable for people with diabetes, they are important tools for lowering premiums and keeping health care costs contained for all enrollees. Any restrictions on plans' ability to develop their formularies could reduce leverage that PBMs and health plans have in negotiating lower prices with pharmaceutical companies. Potential unintended consequences of any policy changes in this area must therefore be considered very carefully.

With those thoughts in mind, we ask you to survey your members and respond to the following questions so we can learn more about how formularies and benefit design affect access to insulin.<sup>1</sup>

---

<sup>1</sup> We understand that redactions may be necessary to provide complete responses to some of these questions, particularly where specific examples are requested.

1. Please provide information about where different insulin products are placed on plan formularies in your member companies' health plans. We understand that it will not be possible to provide exhaustive data in response to this question. But we would appreciate the opportunity to review examples of where the full range of insulin products fall on specific formularies and the terms of utilization management programs that apply to insulin.
2. Please provide examples of specific internal processes used by your member companies to determine formulary placement of and utilization management programs for insulin. For example, who is responsible for conducting reviews of a drug's clinical performance and overall cost-benefit profile?
3. What factors do PBMs and the health plans consider when determining formulary placement and utilization management programs for insulin products? How do unique attributes of the insulin market influence these decisions?
4. We understand that formulary placement often plays a key role in rebate negotiations with pharmaceutical manufacturers. Please provide examples of specific contract provisions and terms related to formulary placement of insulin between PBMs and pharmaceutical companies. We would like to see examples from actual contract terms versus hypotheticals.
5. Do most plans have at least one insulin option on the lowest cost-sharing tier? Why or why not?
6. Are insulin products ever completely excluded from plan formularies? Why or why not? Please describe in detail the circumstances that might lead a PBM or plan to exclude an insulin product from its formulary. Please provide examples of appeals processes or exceptions available to patients who need a particular type of insulin not covered by their health plan.
7. We understand that patients are sometimes burdened with unexpected cost-sharing when a formulary is changed during the course of a plan year. How many times per year are your formularies updated or changed? What causes PBMs and payers to change their formularies mid-year? How do you alert consumers and providers about these formulary changes? Please provide specific examples, if possible.
8. Some states have passed laws that limit out-of-pocket payments or dictate formulary placement for prescription drugs in private health plans. Have these laws resulted in health insurance premium and/or out-of-pocket cost increases for health plans in the relevant states? Please provide data to support your answers.

We ask that you respond to these questions in writing before March 5, 2018. You can reach out to Logan Hoover ([logan.hoover@mail.house.gov](mailto:logan.hoover@mail.house.gov)) with Congressman Reed and Polly Webster ([polly.webster@mail.house.gov](mailto:polly.webster@mail.house.gov)) with Congresswoman DeGette with any questions. We are grateful for your ongoing participation in this inquiry and look forward to your response.

Sincerely,



---

TOM REED  
Member of Congress



---

DIANA DEGETTE  
Member of Congress