

October 27, 2017

The Honorable Tom Reed
US House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
US House of Representatives
Washington, DC 20515

Dear Representatives Reed and DeGette:

On behalf of the Endocrine Society, thank you for your attention to rising insulin costs and the consequent burden on patients and impact on care. Rising insulin costs and changing formularies have created a challenging environment for endocrinologists to provide optimal care and for patients to access therapies to appropriately manage their diabetes. As you have noted, average insulin prices have nearly tripled over the past 15 years and patients are becoming increasingly exposed to these costs due to high deductible plans and coinsurance. We appreciate your thoughtfulness in addressing these issues and look forward to working with you as Congress moves forward in identifying solutions to these serious problems.

The Endocrine Society is the oldest and largest global professional membership organization representing the field of endocrinology. We are dedicated to advancing hormone research and excellent care of patients with diabetes, obesity, osteoporosis, infertility, rare cancers, thyroid conditions and other endocrine disorders. Our more than 18,000 members include scientists, physicians, educators, nurses, and students, in 122 countries around the world. As diabetes experts, our members are greatly concerned about the impact of insulin costs and non-medical switching on their patients' ability to follow their treatment plan and effectively manage their disease.

In response to your request for the Society's assistance to gather more information about the cost of insulin, we conducted a series of focus groups and discussions with our members and convened a meeting with our Clinical Affairs Core Committee to address the questions posed in your September 20 letter. Participants in these discussions were endocrinologists who treat patients with diabetes in different practice settings (academic health centers, hospitals, community practices) across the United States. Below we have aggregated their responses and included a summary of recommendations our members generated that we hope you will consider as you move forward in addressing this issue.

- 1. Please describe what physicians typically take into consideration when making prescribing decisions for patients who need insulin. How do physicians choose which insulin products might work best for a particular patient?**

Our members all agreed that physician expertise and cost were the two largest drivers for making prescribing decisions for patients with diabetes. In general, endocrinologists evaluate the current medication the patient is



taking, potential or ongoing side effects, and estimate the cost of a new prescription that may be needed to address any health needs.

While endocrinologists have a variety of options from which to choose, they have found that patient adherence will decrease when prescribed a therapy that is too costly. Unfortunately, our members outlined many barriers that prevent physicians from addressing this issue at point of care. For example, physicians have no way of determining actual medication costs across the multiple insurance plans they encounter on a day-to-day basis. As a result, the therapy that is prescribed may not be an optimal choice because of cost or formulary restrictions, and this may not be known until the patient returns for their next appointment. During this time, the patient may have to choose between other life needs and paying for their medication out of pocket. Even when providers have all this information available at the point of care, patients may not feel comfortable engaging in a conversation about what they can afford.

Although there are multiple commercially-available prescribing options for managing diabetes, our members shared that choices are restricted, and care is often fragmented because of formulary changes. Our members indicated that they often are forced to change a patient's medication multiple times in a year, even when the current medication is effectively managing their disease. They described two reasons for this. First, formularies change – Medicare formularies can change twice a year and Medicaid formularies can change four times a year. Second, our members described a common scenario resulting from rising costs, which involves chasing down an affordable prescription throughout the year. For example, a patient with a high deductible plan sees the doctor in January and the physician prescribes a drug that is the least costly alternative. Three months later, the patient now gets prescribed a different drug because it is the lowest cost drug determined by the formulary. By autumn the patient has fallen into the "donut hole" and the physician provides samples or discount cards for yet another drug. This scenario is made even more challenging because physicians lack the information about the specific cost-burden of a medication for an individual patient.

The prescribing environment is exceedingly complex, with fluctuations in costs, formularies, and coinsurance often occurring in tandem. These issues create a burden on practices that are already dealing with a lack of resources and growing patient population. As a result, our members expressed significant frustration that these challenges make it difficult to provide the best care possible to their patients.

2. Is information about how an insulin product is covered by the patient's health insurance plan typically available to physicians at the time of prescribing? Do physicians usually have a general sense of how much a particular insulin product will cost a patient when they prescribe it?

While some physicians have access to limited insurance and formulary information in their electronic medical record, it is not always reliable or current and rarely includes specific information on drug prices. Some of our members are in practices that employ staff assigned to track information on health plans and pharmacies, but for other members this is not an option because of limited resources. Our members also



described an added complexity in determining patient costs: patients covered by the same insurance company or Medicare Advantage plan may have different benefits, and tracking individual benefit information is beyond the capabilities of most practices. When considering that these formularies may change multiple times throughout the year, this becomes even more challenging and burdensome.

While our members reported that they have a general sense of insulin costs, most agreed that they lack enough information to make appropriate, patient-centered decisions at point of care, as outlined above. This creates a cycle where the physician prescribes a therapy without knowing if the patient can afford it until the patient attempts to fill the prescription. If the patient cannot afford it, the patient either does not take the drug, returns to the physician office, or suffers a significant, unnecessary, unexpected cost burden. Our members would like to be able to discuss the cost of the medication at the time of prescribing to ensure that the patient obtains an affordable prescription option.

3. How familiar are your members with patient assistance programs or discount coupons/cards? Do your members often recommend these programs to patients as a way to reduce out-of-pocket costs? How accessible are these programs to patients?

Endocrinologists are familiar with patient assistance programs and discount coupons/cards. However, use varies.

Our members described several barriers that reduce patients' access to these programs, and limit their use. These include restrictive enrollment criteria, a complicated, time-intensive application process, and patients' need for assistance to complete the process. A major frustration is that these programs are often inaccessible or overly complicated for the patients who need them the most. For example, people with Medicare or any insurance coverage are often unable to enroll. In addition, our members noted that many of these programs communicate poorly with the patient or prescribing physician. A practice may complete the paperwork yet never hear whether the patient is accepted into the program. This is problematic because it affects prescribing decisions and requires the physician to spend additional time determining the status—time that could be used to care for their patient's chronic disease.

The use of discount coupons or cards also varies among the endocrinologists with whom we spoke. Our members noted that coupon programs benefit the patient less and the pharmaceutical company more as they often drive patients to more expensive products by masking the price.

Our members also were interested in learning more about new discount programs offered by some insulin manufacturers and PBMs, such as the Blink Health program, but expressed frustration that information about how they work and usage is not widely available.



4. What effect do marketing and other communications by pharmaceutical manufacturers have on physician prescribing decisions?

In discussing marketing and other communications by manufacturers, our members unanimously responded that there was very little or no impact on their prescribing decisions. Endocrinologists utilize their medical expertise, along with information on patient needs (including costs) and disease progression to determine their treatment approach.

5. What factors do physicians consider when deciding whether to switch a patient from one type of insulin to another? Is this a common occurrence? Are insulin cost burdens on the patient a common reason for switching insulin products?

There are several factors that contribute to an endocrinologist's decision to switch a patient from one type of insulin to another. Cost is a major driver along with blood glucose control, patient compliance, and the need to address complications or lifestyle factors. For example, a patient who has recently been diagnosed with rheumatoid arthritis or who has poor vision may benefit from using an insulin pen instead a syringe. However, most commonly, endocrinologists switch their patients from one insulin to another because of cost and formulary changes rather than medical factors.

As noted above, formularies change multiple times each year requiring physicians and practices to find the lowest cost option for their patients each time. Such changes create confusion among their patients and may require additional diabetes education depending on whether the insulin was changed to a comparable therapy or an alternative.

6. In your members' experience, what risks are associated with switching from one type of insulin to another? To what extent are studies and peer-reviewed literature available assessing these risks? Please identify any important studies we should be aware of.

In general, the risks associated with switching a patient from one brand of insulin to another comparable brand of the same type of insulin are minimal. However, it does create confusion and anxiety, increases administrative tracking, and requires subsequent education and discussion with the patient to ensure they are in compliance with their treatment. The most serious impact of switching, and our members noted this happens, is that the patient's diabetes becomes uncontrolled, which could lead to dangerous health consequences and hospitalizations.

Based on discussions with endocrinologists who treat patients with diabetes, the Society would like to offer the following recommendations to address insulin pricing and formulary switching:



1. The Centers for Medicare and Medicaid Services, along with private insurers, should work with electronic medical record vendors to provide up-to-date formulary and coverage information, including out-of-pocket costs and deductible information. Such changes would enable physicians to make appropriate prescribing decisions based on the needs of the patient.
2. Health plans should exempt insulin from coinsurance/co-pays in high-deductible plans due to its lifesaving nature and high cost.
3. Insurance companies and federal programs should maintain formularies for a minimum of one year to reduce non-medical switching; or patients who have well-controlled blood glucose levels on their current insulin should be able to stay on that insulin for at least one year.
4. Congress should consider policies that would reduce patient cost-sharing for insulin and ensure that patients benefit from rebates at point of sale.
5. Patient Assistance Programs for insulin should be less restrictive and more accessible. A first step in this accessibility could be developing a common application for all programs that can be saved for subsequent applications to the same or different programs. These programs should be expanded to include Medicare and Medicaid beneficiaries, and patients on any insurance plan.

Thank you for reaching out the Endocrine Society to discuss these important issues. We hope that there are subsequent opportunities to have our members meet with you in-person to share their experiences in more detail. Should you have any questions, please contact Mila Becker, Chief Policy Officer, at mbecker@endocrine.org or 202-971-3633.

Thank you,

Lynnette Nieman, M.D.
President, Endocrine Society