

The Role of the Diabetes Care & Education Specialist in Diabetes Formulary and Medical Device Decisions

It is the position of the Association of Diabetes Care & Education Specialists that diabetes care & education specialists should be included as expert consultants, at minimum, for decisions regarding diabetes medication formularies and medical devices. The objectives of this position statement are to differentiate between the types of formularies, discuss the implications of formularies and the potential barriers caused by formulary changes for people with diabetes (PWD). In addition, this paper will outline the overarching goal for establishing a role for diabetes care & education specialists within diabetes formulary and medical device selection and implementation processes.

Introduction

A formulary is an official list of medicines that may be prescribed. For the purpose of this paper, medical devices (such as syringes, insulin pens, insulin pumps, insulin patches, blood glucose meters, test strips, lancets and continuous glucose sensors) selected for coverage by a health insurance plan or a health system will also be included as part of formulary discussions. The purpose of a formulary is to optimize appropriate and efficient utilization of medications, with consideration for cost, efficacy and safety.¹ An increase in the aging population with a greater number of individuals with diabetes, the development of new biologic agents, higher costs associated with developing specialty medications and a rise in the innovative devices such as “smart” pumps and glucose sensors, have all lead to rising costs of medications and medical devices.²

In addition to the increased costs of medication and medical devices, the recent surge in the number of diabetes medications and medical devices, presents a unique challenge to formulary selection and management. The challenge exists for medical providers, healthcare systems and health insurance companies who are focused on the balance of optimal diabetes management for the patient, with the constant pressure of cost containment and optimal safety. Technologies such as insulin delivery devices (insulin pens and pumps) and continuous

glucose monitoring systems are changing rapidly, creating a challenging environment for PWD and providers to determine the best diabetes management systems available that best meets the individual needs of the PWD. Effective navigation of available diabetes medications and medical devices requires a thorough understanding of each product and extensive assessment and discussion with PWD.^{3, 4}

Types of Formularies

Health insurance formularies have grown over time from simple medication lists to complex medication and medical device formularies with specialty “tiers” and shared cost burden.⁵ Formulary composition and variations are also health system or company specific, creating greater complexity. In tiered formularies, medications are placed into categories, or “tiers,” based on lower-cost preferred drugs, higher-cost non-preferred drugs, quantity restrictions, and co-pay amounts. Medicare prescription drug plans are examples of tiered drug formularies.⁶ Costs for medications and medical devices will vary for PWD depending on their health insurance coverage and associated out-of-pocket costs, including deductibles, coinsurance, copayments and non-covered items.

Health systems, such as institutional and ambulatory care settings, are incentivized to use formularies due

to reimbursement eligibility requirements from Medicare as well as accreditation requirements from the Joint Commission.⁷ The highest cost “non-preferred” medications may require a *prior authorization* in order for the insurance company to pay any of the cost of that drug. Prior authorization procedures differ between insurers and can be extremely time consuming, often requiring proof that the PWD has failed on the formulary medication(s) or the formulary medication is not appropriate.⁸

Development of Formularies

Experts suggest it is most beneficial if a multi-faceted “value-based” approach is used to determine which medications and devices will and will not be provided on a formulary.⁹ Factors such as the quality of clinical data (efficacy, clinical performance, magnitude of effect), cost-effectiveness, likelihood of severe adverse effects, and overall budget impact should all be taken into account.^{9, 10} Device accuracy, ease of use, downloading capability (if applicable), ease of data interpretation, ability to customize, patient perception of device accuracy and other factors based on the specific device, should be considered. Usability barriers of both monitoring and delivery devices, due to physical or cognitive limitations must also be factored into decision-making.

Within a health system, a Pharmacy and Therapeutics (P&T) committee can be comprised of physicians, pharmacists, nurses, administrators and other staff involved in the medication and or device use process. In addition to creating and maintaining the formulary, the P&T committee conducts medication use evaluations, adverse-drug event monitoring and reporting, medication-error prevention, and development of local clinical guidelines.⁷ Formulary decision-making is guided by current clinical practice guidelines, unbiased review of the biomedical literature, and a focus on providing the most effective and safest patient care. Other considerations include rebate amounts proposed by the drug or device manufacturer, clinician knowledge of medications and devices and the processes for change-outs when medications or devices are changed within health systems if excessive choice is available. While economic factors also play an important role to reduce costs for the health system, it is not recommended that they solely guide drug and device selection.¹¹

Most health systems have policies in place that allow for generic or non-branded substitution or therapeutic interchange, such as switching a prescribed non-formulary medication to a formulary medication within the same therapeutic class, providing significant cost savings. Health systems should have processes in place for additions and deletions to the formulary, as well as a process to obtain non-formulary medications when the formulary medication is not the most effective choice for a PWD due to adverse effects, allergies, lack of therapeutic response, or other individualized reasons.⁷

Implications of Tiered Formularies

There is limited evidence that medication / device formularies and other cost-saving measures implemented by health insurance companies actually reduce spending and in fact, they may actually worsen clinical outcomes. A systematic review assessing the impact of medication formularies identified unintentional negative outcomes, including reduced medication adherence and poorer clinical outcomes.¹ One review showed that spending by insurance companies did decrease by 5-20% with the implementation of a tiered copayment system,¹² however this came at the expense of increased cost (by up to 148%) and non-adherence for PWD. Data regarding utilization of other healthcare resources and other clinical outcomes is indeterminate.^{8, 12}

With an increase in the availability of more costly drug classes including incretin-based therapies, inhaled insulin, insulin analogs and SGLT2 inhibitors, PWD are among those who may be negatively affected by tiered formularies. Moreover, different adverse event profiles and drug-drug and/or drug-disease interactions exist with varying diabetes drug classes and between drugs within a class, and thus, PWD may be vulnerable to formulary restrictions.¹³ Advances in insulin delivery devices, continuous glucose monitors and integrated systems may greatly benefit PWD but may be restricted based on a tiered system.

While formularies most often guide medication and device selection by prescribers, other outside factors may impact prescribing patterns. For example, despite the existence of a national formulary used among 139 facilities of the Department of Veterans Affairs (VA), a study of diabetes prescribing patterns within the VA found great variation in the use of a medication not on the national formulary.¹⁴

Regardless if the formulary is created by health systems or health insurance companies, it is important that any decision to restrict a medication or device from the formulary does not prevent access to medically necessary therapeutic options. Any diabetes medication or device formulary should include at least one medication or device from each class approved by the Food & Drug Administration (FDA).

The Role of the Diabetes Educator

The diabetes educator, at minimum, should be included as an expert consultant for P&T committees of health insurance companies and healthcare institutions that determine and manage diabetes formularies. It may also be appropriate for a diabetes educator to be a more permanent P&T committee member. The diabetes educator assisting with P&T decisions should be actively practicing in the area of diabetes and experienced with medications and devices used by PWD. If selected to serve as an expert consultant or member of the P&T committee, the diabetes educator should disclose any financial conflicts and abstain from the decision-making process regarding medications and devices that may pose a conflict of interest.

Diabetes care & education specialist should seek opportunities to establish relationships with the key players making formulary and coverage decisions in their area. This may take proactive research and collaboration on the part of the educator, as P&T committees may not automatically pursue the educator's expertise.

Uninformed decisions can lead to poor blood glucose results, increase short- and long-term complications and compromise safety, yielding high costs financially to the individual's health and / or health plan or health system.¹⁵ Due to the amount of time spent one-on-one with PWD and their comprehensive assessment of self-management skills, diabetes care & education specialist are in a prime position to inform P&T committees of the impact a change in drug or device coverage will have on a PWD's ability to effectively manage their diabetes. The diabetes educator's knowledge of diabetes-related self-care behaviors, including issues related to taking diabetes medications and self-monitoring blood glucose (SMBG), plays an important role in promoting appropriate medication-taking and device use behavior. Formulary changes may have a negative impact on PWD by altering the

daily diabetes self-care routine, especially in relation to medication and monitoring practices.^{16,17} Insulin delivery methods and self-blood glucose monitors have different features and functionalities. It is important for the selection of these items to be made with informed input from the PWD, the diabetes educator and the healthcare provider. PWD require coverage for medications, medication delivery devices and monitoring supplies that allow them to optimize safety and achieve desired glucose control.^{16,17} Diabetes care & education specialist can illustrate the implications of the loss of such coverage. Formulary changes also impact health systems, often requiring system-wide clinician training for effective and safe transition. The diabetes educator is an excellent resource to PWD, clinicians, and staff who are charged with implementing a formulary change in their system.

Challenges in the Present Diabetes Environment

At the time of this publication, there are twelve classes of medications that are FDA-approved and recommended by the American Diabetes Association (ADA) and/or American Association of Clinical Endocrinologists (AACE) to treat type 2 diabetes. Most PWD will require at least two of these medications to achieve their glycemic targets.^{18,19} In addition there are new insulin preparations with varying concentrations and combination insulin-GLP agents, usually requiring specialized training by diabetes care & education specialist for optimal glucose and safety outcomes. Diabetes devices which include glucose and ketone meters, insulin pumps, insulin pens, insulin patches and continuous glucose monitors differ in portability, levels of pain and accuracy and ease of use. Due to the high cost of many diabetes medications, healthcare systems and insurance companies implement cost-savings measures that include medication formularies. As previously outlined, while formularies likely can lead to decreased drug and/or device cost for the third-party payer, there is a risk that PWD must either absorb additional medication costs or accept medications that may be less effective or less convenient and impact safety.

Conclusion:

Diabetes care & education specialist are uniquely qualified to contribute to diabetes formulary and medical device coverage decisions. Diabetes care & education specialist should serve at minimum, as



expert consultants on P&T committees with formulary decisions related to diabetes medications and medical devices. Additionally, when a formulary change necessitates a change in medication regimen or device, diabetes care & education specialist play a critical role in providing necessary information and training to PWD, health care professionals and the health system as a whole, about the integration of new medications or devices for safe and effective transition.

The Association of Diabetes Care & Education Specialists supports the role of diabetes care & education specialist in diabetes formulary and medical device decisions and changes through:

1. Content expert representation (at minimum) on P & T committees with diabetes medication and device related decisions
2. Advocating for PWD's affected by formulary changes (including changes in insulin delivery devices, glucose meters and sensors)
3. Information dissemination and training on medications and medical devices to PWD, health care professionals and other relevant health system personnel
4. Active research participation in areas including formulary decisions and the clinical and economic impact of diabetes care & education specialist serving in these roles.

Resources

Pharmacy Benefits Management Services Department of Veterans Affairs: www.pbm.va.gov

Centers for Medicare and Medicaid Services - www.cms.gov

Formulary Lookup Resource - <https://lookup.decisionresourcesgroup.com/>

Prior Authorizations - <https://www.covermy meds.com/main/>

MMIT: Formulary guidance and transparency from P&T to point of care: <https://www.mmitnetwork.com/>

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