

# Position on non-medical switching for diabetes patients

## Editorial

The NDVLC is dedicated to the health and well-being of people with diabetes and their families. As such, we are strongly against the practice of changing diabetes patients' medications, treatment and supplies for non-medical reasons. This practice, called Non-Medical Switching, occurs when insurers force patients to switch from their current medication to a different drug for reasons other than the patient's health and safety. It can occur in two ways—insurers remove the current insulin from their formulary or they increase the patient's out-of-pocket costs so that the insulin becomes unaffordable.

In the case of generic medications, there is little risk to patients because they are manufactured from known chemicals and are characterized by their chemical equivalence making them virtually identical to the original branded medication. However, Non-Medical Switching has now been extended to biologic medications, such as insulin. The manufacturing processes for insulin use different cell lines, protein sources, as well as extraction and purification techniques. These are proprietary and often patented processes. The insulins may have similar abilities to lower blood glucose but they are not identical replacements.

When switching from one branded insulin to another, or between branded and biosimilar insulin, the main concern is the difference in pharmacodynamic properties. For example, although clinical trials have shown similar glycemic outcomes, higher doses and twice-daily injections are often required for detemir compared with glargine, which requires only once-daily injections.<sup>1,2</sup> Therefore, switching a patient from glargine to detemir would necessitate additional physician visits to reiterate the dosage and initiate a new injection regimen. Unfortunately, this often does not occur because the physician has not been notified of the switch and the patient does not know that a dosage change is needed.

Similar issues result when Non-Medical Switching occurs with other injectable diabetes drugs. Patients stable on GLP1 RAs frequently find they are forced to change their medication, which also results in a change of devices to deliver the medication. This requires education on the new device, a new titration and exposure to resultant GI side effects as well as an extra trip to the provider's office. Provider scheduling challenges for this forced extra visit, exacerbated by potential geographic distances for rural patients, often results in a period of time a patient is off their medication completely.

Another factor to consider is the added emotional burden that can result from Non-Medical Switching, which can exacerbate suboptimal adherence to insulin therapy. It is well-recognized that suboptimal medication adherence is a key contributor to poor glycemic control, which is associated with long-term complications, more frequent hospitalizations, higher healthcare costs and elevated mortality rates.<sup>3-6</sup> Although we are unaware of any specific studies that have assessed the impact of NMS on medication adherence, recent meta-analysis found that Non-Medical Switching was more often associated with mostly negative effects on economic outcomes (defined as medical or treatment costs) and medication-taking behaviors, particularly among

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patients with stable/well-controlled diabetes.<sup>7</sup>

In summary, Non-Medical Switching of biologic drugs, such as insulin, poses significant clinical and financial risks to patients and the healthcare system:

- i. Patients are at risk for adverse events due to poor glycemic control and potential immunological responses.
- ii. Patients and clinicians must bear the financial burden of additional physician visits and follow-ups to adjust insulin dosages.
- iii. NMS negatively impacts patient adherence to therapy, which can lead to poor glycemic control and costly long-term complications.

It is the position of NDVLC that any patient whose diabetes is stable or well-controlled should be allowed to continue with the medication, treatment and self-management devices that is allowing them to succeed without the potential disrupting burden of a non-medical switch. Further, we believe that burdening patients with "fail-first" or complex appeal processes is not in their best interest. Treatment and medications should be designed, recommended and prescribed by patients' medical teams and not by an insurance company or pharmacy benefit manager for economic reasons alone.

We call on Health Plans, Employers, Pharmacy Benefit Managers and Pharmacies to end this damaging practice on diabetes patients and their lives and to provide full transparency on the motivation behind the forced switch.

The National Volunteer Diabetes Leadership Council is a non-profit patient advocacy organization. Its membership consists of past lay volunteer leadership and officers of national volunteer health organizations such as the American Diabetes Association. We seek to improve the burden of diabetes on all people with diabetes and their families through encouraging public policy and improved outcomes around diabetes.

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## Conflict of interest

Author declares that there is no conflict of interest.

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