PES PEDIATRIC ENDOCRINE SOCIETY
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February 17, 2023

Dear Medical/Pharmacy Directors,

As President of the Pediatric Endocrine Society, I represent practicing pediatric endocrinologists from the United States, as well as North America. As you are no doubt aware, there has been a significant shortage of recombinant human growth hormone (GH), initially all formulations produced by Novo Nordisk (Norditropin®), but now including other manufacturers such as Eli Lilly (Humatrope®) and Pfizer (Genotropin®). These shortages are adversely affecting patients by resulting in prolonged delays in receipt of, or even loss of, their prescribed GH treatment. Some of these children require GH for other indications besides growth, such as to prevent severe hypoglycemia that can lead to seizures.

Current procedure dictates that change in product, and even change in strength of the same brand, require prior authorization paperwork, and if successful, then statement of medical necessity (SMN) forms. These steps require **hours of work** for **each patient** and represent substantial redundancy. For each of these patients, there has already been a medical review from previously submitted, and approved, medical records and prior authorization forms. Those approvals, based on typical insurance protocols, are for a specific insurance chosen brand of GH and often a specific pen size of that specific product.

We are respectfully requesting a temporary change in your approval process and procedures effective immediately through August 31, 2023, when supply issues are expected to resolve, as follows:

a) Approval or denial of growth hormone for new starts according to your current treatment guidelines
b) Requesting to start, the preferred brand, but without requiring any specific size pen/device/cartridge/vial size
c) If the preferred product is not available, then an alternate GH product be approved without requiring additional prior authorization or SMN forms. If desired, the insurance company can list their products in order of preference if their preferred product(s) is not available
d) Consider allowing the long-acting GH, Skytrofa®.

This remedy has to be a joint effort by the medical team, the insurance companies, the pharmacies, and hopefully with understanding by the families. Many families are getting quite frustrated and upset with the current processes and rigidity by the insurance companies, and several are in discussion with national news stations to launch reports. Additionally, the time involved by the medical providers and staff is interfering with their ability to provide medical care.

The Pediatric Endocrine Society is happy to facilitate more discussions, but this fix needs to be worked out as soon as possible.

Sincerely,

Craig A. Alter, M.D.
PES President