



June 17, 2024

Hilary Marston M.D., M.P.H.,  
Chief Medical Officer  
Food and Drug Administration

Dear Dr. Marston,

As President of the Pediatric Endocrine Society, I am writing on behalf of over 1500 pediatric endocrinologists in the United States. I would like to make you aware of a critical situation and suggest a solution.

**Situation:** In the past 2 years, there has been a shortage of daily growth hormone injections triggered by production issues in NovoNordisk. The effect of the shortages have been medically challenging to our patients, and an administration nightmare for our clinical practices and the specialty pharmacies. While the shortages seem to be alleviating, we want to proactively address concerns so that in the future, we have a mechanism for a needed improvement in the system.

**Background:** Because GH products all need pre-authorization by the insurance companies all pediatric endocrine practices have had to essentially devote at least a full-time position solely for the job of processing forms to authorize/reauthorize growth hormone products or devices for their patients. Some of the larger hospital clinics, with up to 2000 patients on GH, may have 2-3 Growth hormone nurses and 2-3 insurance specialists to diagnose GH deficiency and ensure patients get the GH that has been approved by the FDA. When the GH shortage was discovered and then subsequently announced, a majority of our membership contacted us to complain about the process. The problem we faced was first obtaining GH for those with fragile medical conditions, such as pan-hypopituitarism when the absence of GH could result in profound hypoglycemia, and trying to decide if we should triage the available GH for those with acute life-threatening consequences of GH deficiency over those in whom it is needed primarily for growth. The second problem relates specifically to the insurance companies who initially denied GH for all non-preferred brands (even knowing there was a shortage) and also required a new prior authorization for every new GH brand or even pen size within the same brand. This undue process was despite the fact they had approved GH for a year in an individual patient. The result of this was pure havoc with families calling clinics multiple times a day trying to get the GH for their child. Because >50% of the GH treated population were unable to obtain supplies of their brand of GH, immense pressure was put on the other brands to pick up the slack. The normal process for preauthorization which can take up to 6 weeks was frequently

pushed out to months and had to be repeated up to four times within the year due to shortages and need to change medications/devices. Interestingly, by requiring multiple preauthorizations the insurance companies were able to save the cost of providing of the full year's supply of GH therapy per patient and hence may have had a perverse incentive to make the process very difficult.

Assessment: Due to unfortunate circumstances, drug shortages may occur. When they occur in drugs that typically require preauthorization, substitution with an alternative equivalent drug and/or device becomes difficult due to the need to get additional and repeat preauthorizations. Children and their families suffer medically from lack of access to medication and but also financially and emotionally from worry and time spent contacting their providers, insurance companies, and specialty pharmacies.

Recommendation: We request that the FDA implement "guidance" to insurance companies that would include waiver of all preauthorizations for replacement drugs until the annual preauthorization is due and that the companies honor the initial decision to provide GH to their customers for the approved year. The process should start with prompt approval of securing GH of the same approved manufacturer of any size pen delivery device. If the shortage includes all device sizes, then substitution with an alternative GH product should be automatic and not require preauthorization.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mark Palmert".

Mark Palmert, MD  
PES President