RWD120

Evaluating the Impact of Human Growth Hormone (HGH) Drug Shortages on Patient Treatment-Switching Patterns Using Real-World Data

Symphony Health
An ICON plc Company

Angela Lawrence,[1] Sean Fahy,[1] Annette Urbanski,[1] Mike Byzon[1]

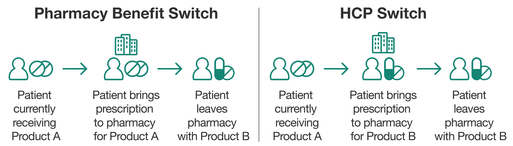
[1]Symphony Health, an ICON plc company, Blue Bell, PA, USA

Background

- Since the first approval of recombinant human growth hormone (HGH) in 1987, HGH has been the mainstay of treatment for patients diagnosed with growth hormone deficiency (GHD), Prader-Willi syndrome, Turner syndrome, and others.[1]
- Following proper adherence to treatment protocols, daily administration of HGH has demonstrated a positive impact on the unfavorable symptomology associated with GHD.[2] Increases in motivation, energy, and social function, along with improved body composition, muscle mass, and physical function, have been reported in numerous independent studies.[2]
- Citing supply chain issues, shortages of one HGH product approved for the treatment of GHD were first reported in December 2022. Following this initial report, additional drug shortages have been reported across the HGH market.[3]

Methods

- In order to track and evaluate pharmacy benefit and healthcare provider (HCP)-driven switching volumes and patterns among patients treated with HGH before and after US Food and Drug Administration (FDA) reported drug shortage periods, pharmacy claims data from the ICON Symphony Health Integrated Dataverse (IDV®) were leveraged.
- The foundation of the data used in the current analysis is the IDV. The IDV is an open, multisource dataset representative of all 50 US states, as well as US territories. These claims data are captured through thousands of sources, including pharmacy direct feeds and lifecycle (network intelligence bureau) feeds. IDV encompasses medical, hospital, and prescription claims across all payment types (commercial, Medicare, Medicaid, managed Medicaid, cash, and assistance programs). The dataset represents 17+ years of historical data for more than 307 million active deidentified patients, 1.9 million HCPs, and 18,000+ unique health plans.
- Patients having an approved pharmacy prescription claim from January 2022 through September 2023 for an HGH market product were identified in IDV.
- Pharmacy benefit products used for this analysis were Genotropin® (somatropin), Humatrope® (somatropin), Norditropin® (somatropin), Nutropin® (somatropin), Omnitrope® (somatropin), Skytrofa® (lonapegsomatropin-tcgd), and Zomacton® (somatropin).
- **Baseline:** January 2022 to November 2022
- **Shortage:** December 2022 to September 2023
- Switches were determined by creating claim clusters, using an 18-day look-forward period from any claim with an initial submission for any HGH product. Two classifications were created based on the claim-transaction activity patterns for these patients:



- Once a switch was identified during the study period, observations were developed at both the patient level (ie, prior treatment(s), demographics, total number of treatment changes) and market level (ie, total switch volume).

Results

- Total population:
  - During the study period from January 2022 through September 2023, 15,423 patients were observed switching HGH treatment.
- Demographics:
  - The total population switching therapies during the study period is a reflective sample of the total population with GHD. The qualifying study population was predominantly under the age of 18 (80%, **Figure 1**) and male (67%, **Figure 2**).[3]

Figure 1: Age Distribution

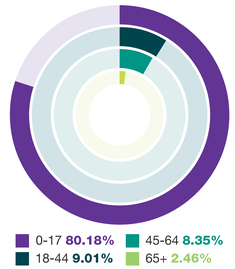
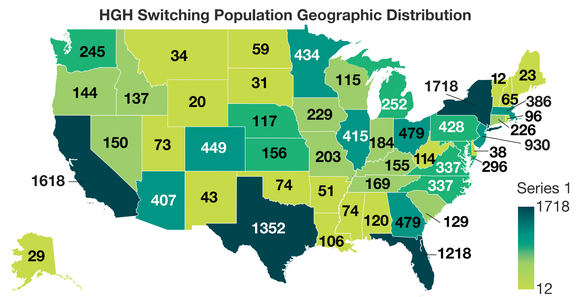


Figure 2: Gender Distribution

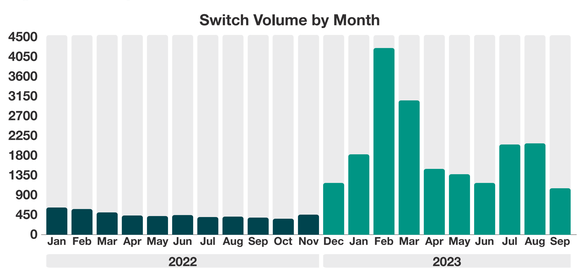
- Geographical distribution:
  - Geographical distribution of the switch population generally followed population density and was concentrated near major metropolitan areas.
  - The southern region had the highest proportion of patients, 34% of the total population, further demonstrating representation of the total population with GHD[2] (**Figure 3**).

Figure 3: Geographical Distribution



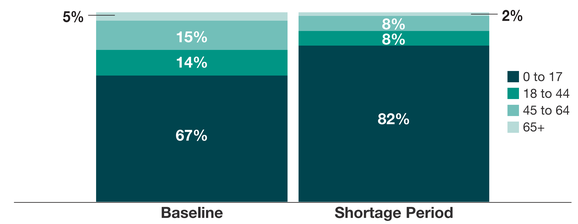
- Monthly switch volume:
  - Total switch volumes remained consistent from January through November 2022, averaging 235 patients switching per month. Corresponding to the public announcement of a shortage of Norditropin, the volume of patients switching increased by 315% in December 2022, eventually peaking at 4255 in March 2023, a 968% increase year-over-year (**Figure 4**).

Figure 4: Monthly Switch Volume



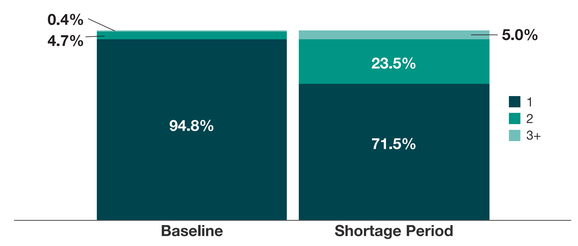
- Shortage impact on switching by age:
  - When benchmarked against baseline volumes, a higher proportion of patients who switched were concentrated within the pediatric population: 67% in the baseline period versus 87% in the shortage period (**Figure 5**).
  - Pediatric populations were disproportionately impacted by the drug shortages.

Figure 5: Proportion of Switches by Age Group



- Total switch counts in baseline and shortage periods:
  - After the shortage period, 28% of patients switching therapies experienced 2 or more changes in therapy. This is an increase of more than 23% (**Figure 6**).
  - These changes in therapy represent a large disruption in continuity of care for these patients and will likely impact overall outcomes, as treatment persistency is critical to achieving optimal outcomes.

Figure 6: Baseline vs Shortage Period, Total Number of Switches



Conclusions

- Drug shortages in all markets present significant barriers to patients regarding continuity of access, treatment persistency, and compliance, as well as achieving optimal outcomes.
- While the pediatric population represents the largest proportion of patients prescribed HGH, these patients were disproportionately impacted by ongoing drug shortages. We expected to see a similar proportion of pediatric patients switching products during the baseline period and shortage period; however, pediatric patients represented a higher overall proportion within the shortage period.
- Ongoing drug shortages were observed to increase the total number of treatment switches at the patient level. This further demonstrates the continued impact of drug shortages on the continuum of care for patients with GHD.
- Most switches were initiated by HCPs, indicating that prescribers were informed on current outages; however, continued coordination of care among HCPs, payers, and drug manufacturers remains paramount for optimal patient outcomes.

Study Limitations

- Some of the products in this study were blocked by specific pharmacies in open claims.
- Data collected through network intelligence bureaus may be limited in showcasing the impact of pharmacy switches.
- This analysis was claims based and did not account for any changes in days' supply.

References

1. Grimberg A, Stewart E, Wajnrajch MP. Gender of pediatric recombinant human growth hormone recipients in the United States and globally. *J Clin Endocrin Metab*. 2008;93(6):2050-2056. doi: 10.1210/jc.2007-2617
2. Höybye C. Comparing treatment with daily and long-acting growth hormone formulations in adults with growth hormone deficiency: challenging issues, benefits, and risks. *Best Pract Res Clin Endocrinol Metab*. 2023;37(6):101788. doi: 10.1016/j.beem.2023.101788
3. US Food and Drug Administration. FDA drug shortages. Accessed April 16, 2024. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Somatropin%20Injection&st=c

Disclosure and Acknowledgments

Research sponsored by Symphony Health, an ICON plc company.

For more information, please contact: **Angela Lawrence**
Symphony Health, an ICON plc company
Angela.Lawrence@iconplc.com

Scan this QR code with your electronic device to receive a PDF file of the poster or visit https://icon.widen.net/s/rmmnwl7r77/symphony_ispor-2024-hgh-poster.

Presented at ISPOR. May 5-8, 2024, Atlanta, GA, USA