Patients bear increased financial burden for growth hormone treatment despite FDA approval

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Despite an FDA approval of growth hormone treatment for children with idiopathic short stature (ISS), the mean cost burden to patients and their families has increased over time, according to findings from researchers at Children's Hospital of Philadelphia (CHOP) and the Leonard Davis Institute of Health Economics (LDI) of the University of Pennsylvania. The findings were presented during ENDO 2019 in New Orleans, LA.

Study findings indicate that increased patient cost-sharing and coverage restrictions are responsible for a greater cost burden that is placed on families and not necessarily insurance companies, which have seen decreased growth hormone costs per patient over the same period of time.

Growth hormone was approved by the U.S. Food and Drug Administration (FDA) for the treatment of ISS in 2003. This increased the potential availability of growth hormone from one in 3,500 children with growth hormone decificienty to the shortest 1.2 percent of the US population. However, over the last decade, insurance companies have instituted progressive restrictions on coverage of growth hormone, including adopting formulary preference strategies and more strict plan-specific critera for coverage, as well as denying any covering of growth hormone for ISS treatment.

"Because growth hormone is a very expensive medication that requires years of daily injections, cost-containment efforts by insurance providers have increasingly encroached upon and eroded patient-physician decision making autonomy and clinical care," said Adda Grimberg, MD, a pediatric endocrinologist and Scientific Director of the Growth Center at CHOP, Professor of Pediatrics at the Perelman School of Medicine, University of Pennsylvania and lead author of the study. "It was important for us to understand the extent of how these restrictions by insurance companies were impacting families and growth hormone use overall."

Using administrative claims data between 2001 and 2016, the study showed that the number of prescriptions for growth hormone rose from 5.1 patients per 10,000 beneficiaries in 2001 to 14.6 per 10,000 in 2016, although no dramatic change was observed in 2003 when growth hormone received FDA approval for ISS. While total growth hormone expenditures per patient decreased as did the estimated insurance-paid amount, the mean copayments, deductibles and total financial burden to patient families increased by 234 percent in nominal and 161 percent in real dollars. The insurance data also showed an increase in the frequency of switching between growth hormone brands.

"Because the different growth hormone brands use different injection delivery devices, brand switching poses additional patient family burdens: stress and anxiety about the switch and potential for interruptions in treatment, required retraining on the new device or devices, and potential for dosing errors," Grimberg said. "While progressive coverage restrictions and formularies have lowered the total cost and insurer burden of growth hormone treatment, those savings were not passed on to patients."

Provided by Children's Hospital of Philadelphia