

Barriers to Growth Hormone Access in Patients at an Academic Medical Center

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PURPOSE

The purpose of this study was to assess factors that affect time to human growth hormone (hGH) approval, utilizing an integrated specialty pharmacy model.

METHODS

Setting and Design	Setting: Vanderbilt Specialty Pharmacy (VSP), Vanderbilt Health Systems with integrated specialty pharmacists Design: Retrospective cohort analysis
Outcome Measures	Time to approval of growth hormone (measured as the number of days between treatment decision and insurance approval)
Sample	Inclusion: Pediatric patients prescribed growth hormone therapy for an FDA indication by a pediatric endocrinology clinic from January 2018-December 2019 Exclusion: The decision to treat was rescinded prior to insurance approval, the hGH authorization was being pursued because of insurance change (rather than treatment initiation), or patients chose to initially pay out of pocket without insurance approval Analysis: Descriptive statistics, Cox proportional hazard analysis

Table 1. Patient Demographics, Diagnosis, and Medications

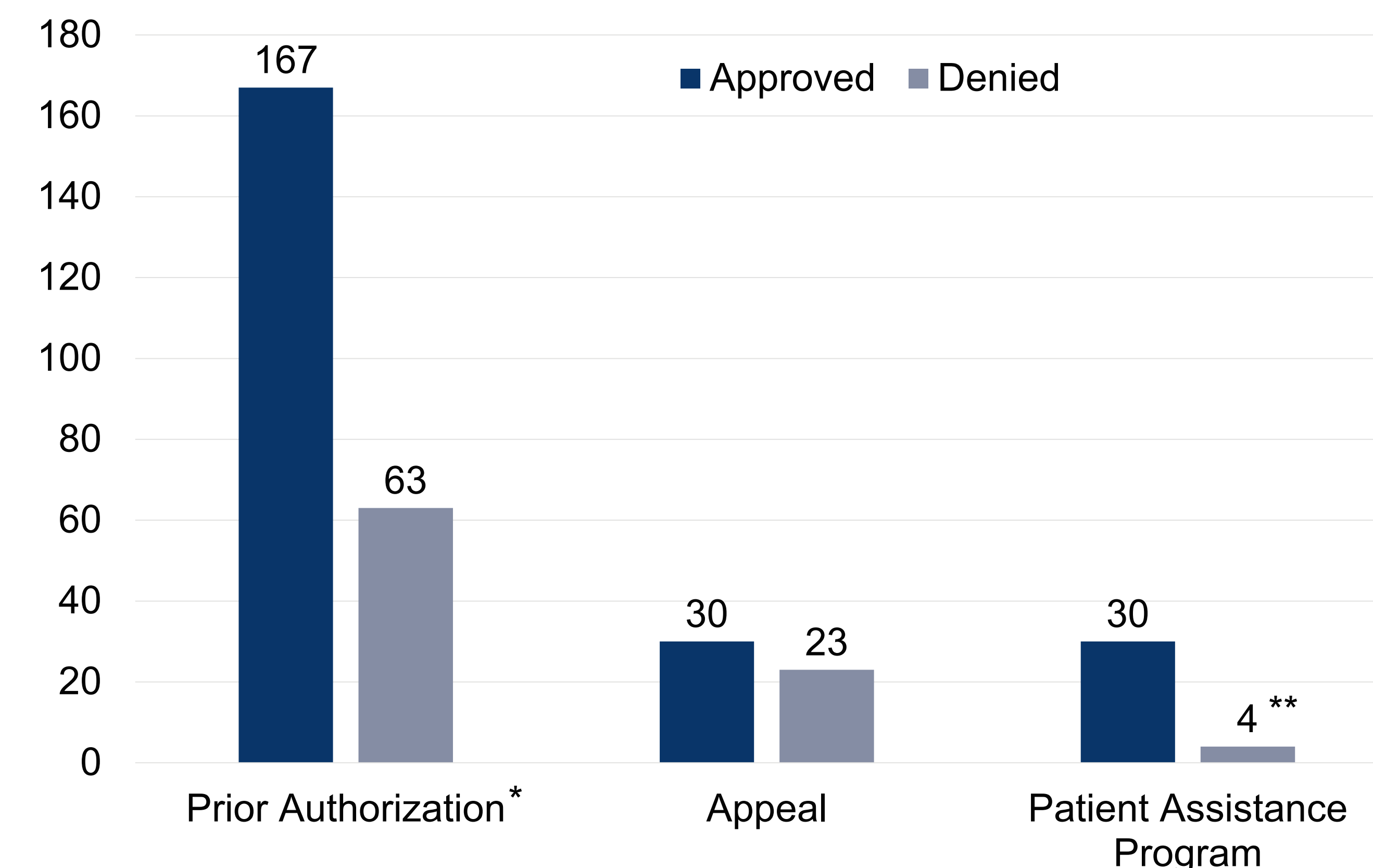
Characteristic	n=234 n (%)	Characteristic	n=234 n (%)
Age, median (IQR)	11 (8-13)	Diagnosis	
Gender, female	76 (33)	Growth Hormone Deficiency	106 (45)
Race		Small for Gestational age	72 (31)
White	185 (79)	Turner's syndrome	8 (3)
Black or African American	15 (7)	Panhypopituitarism	7 (3)
Other	34 (14)	Prader-Willi syndrome	26 (11)
Ethnicity		Idiopathic Short Stature	15 (6)
Not Hispanic, Latino/a, or Spanish origin	158 (68)	Medication	
Other Hispanic, Latino/a, or Spanish origin	19 (8)	Norditropin	62 (26)
Unknown	57 (24)	Nutropin	18 (8)
Insurance		Genotropin	76 (32)
Commercial	146 (62)	Humatrope	54 (23)
Tricare	8 (3)	Omnitrope	19 (8)
Medicaid	80 (34)	Zomacton	5 (2)

CONCLUSION

- Despite many challenges to accessing growth hormone, health-system specialty pharmacies helped all patients initiate treatment in a median time of 8 days.
- Patients with Idiopathic Short Stature and those for whom insurance requires additional testing are likely to have longer access times.

RESULTS

Figure 1. Patient Access Journey



*229 patients required a prior authorization, 5 patients did not
**Cash pay was decided after going through every step without approval

Table 2. Time to Insurance Approval Model

Variable	HR (95% CI)	P-Value
Idiopathic Short Stature – Reference		
Growth Hormone Deficiency	1.9 (1.3 – 2.8)	<0.001
Panhypopituitarism	2.6 (1.1 - 5.7)	0.02
Prader-Willi syndrome	2.1 (0.9 – 4.7)	0.06
Small for Gestational age	1.7 (1.0 – 2.7)	0.04
Turner's syndrome	1.6 (0.9 – 2.9)	0.09
Testing Not Required – Reference		
Testing Required	0.3 (0.2 – 0.5)	<0.0001
Commercial Insurance – Reference		
Medicaid	1.3 (0.9 – 1.7)	0.13
Tricare	1.1 (0.9 – 0.5)	0.79
Non-VSP Patient – Reference		
VSP Patient	1.4 (1.06 – 1.9)	0.02

- ✗ **52%** of PAs were denied due to diagnosis not being covered
- ✗ **43%** of PAs were denied due to not meeting criteria or the required formulary alternative
- 🔄 **40%** of patients required a second or third level of appeal (out of 53 patients that required an appeal)
- 📄 **9%** of patients were required to get additional testing done before approval

Figure 2. Time to Insurance Approval

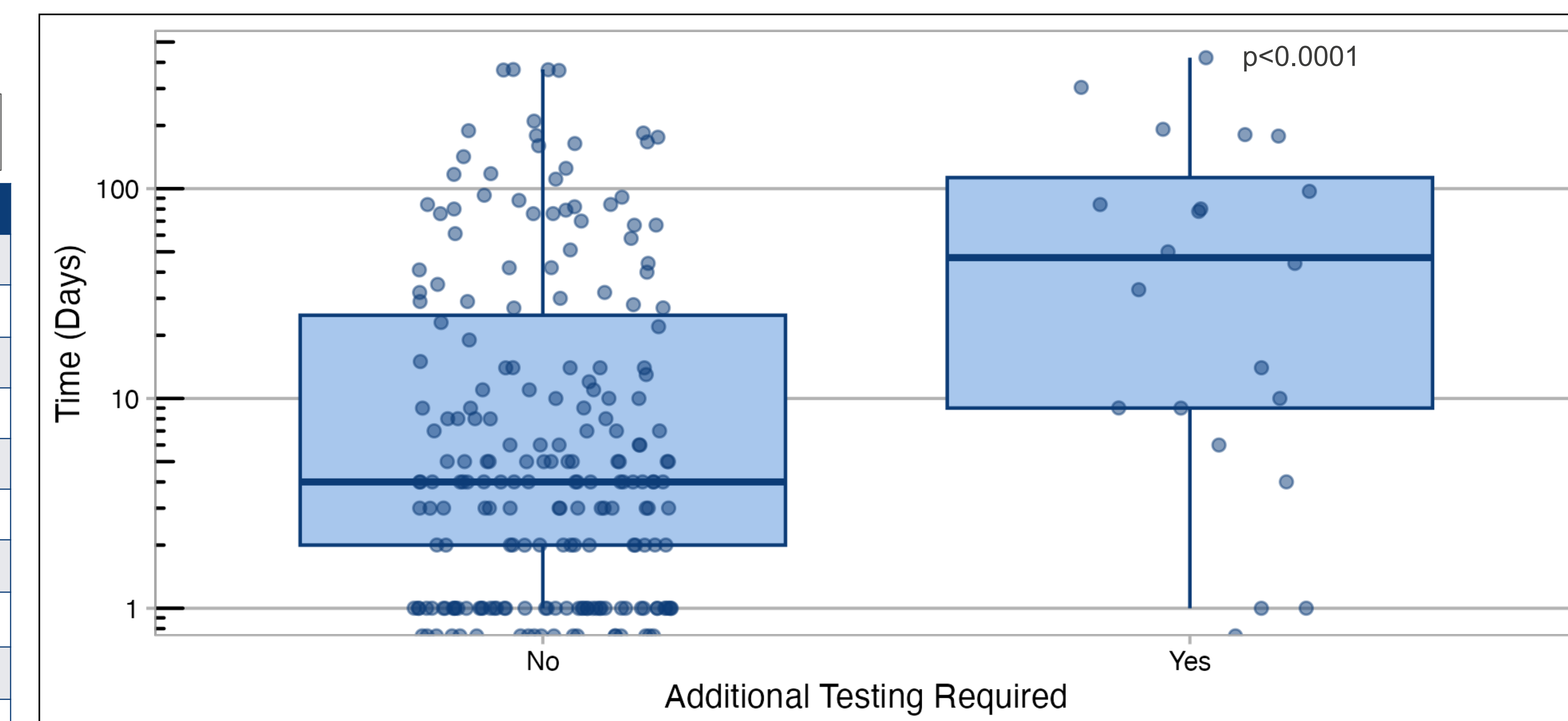
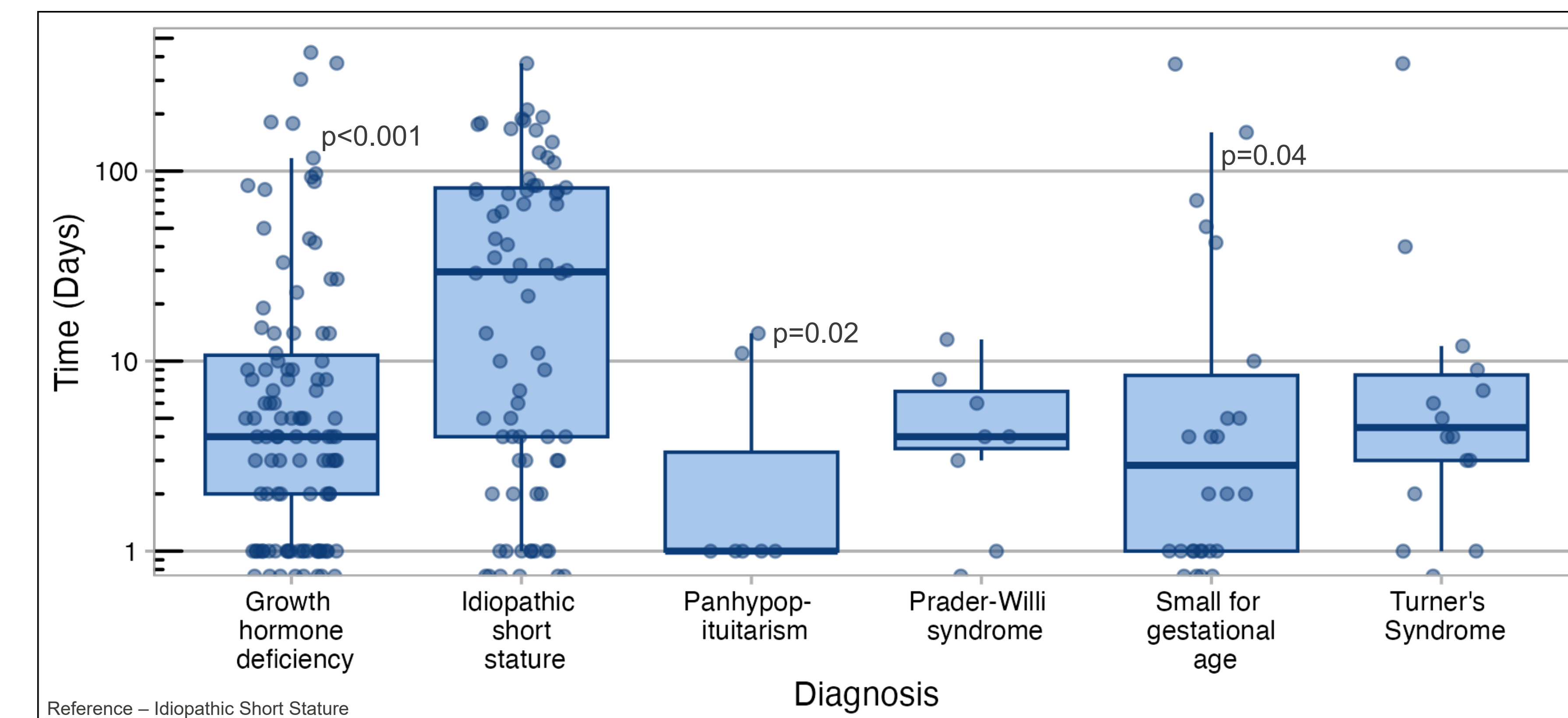


Figure 3. Median Time to Insurance Approval

