Evaluating the Impact of Dedicated Clinicians on Prior Authorization Outcomes and Access to Therapy in Rare Diseases

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Background

Prior authorization (PA) is a utilization management strategy used by health insurers to promote appropriate medication use and assess value. While designed to support clinical and economic decision making, PA requirements often result in significant administrative burden and treatment delays that disproportionately affect patients. Providers frequently bear the responsibility of navigating PA processes, which are often time-consuming, lack standardization, may interfere with clinical decision making and reduce patient care time.[1] Additionally, implementing burdensome PA processes can strain the relationship between providers, patients, and payers.[2]

For patients, PA-related delays frequently impede timely therapy initiation and contribute to disease progression, preventable clinical harm, emotional distress, and erosion of trust in the healthcare system.[3] These challenges are more pronounced for individuals with rare diseases, which are conditions affecting fewer than 200,000 people in the United States. Rare diseases often have devastating manifestations that require specialized, high-cost therapies with limited alternatives, making timely access critical to prevent disease progression, maintain quality of life, or improve therapeutic outcomes. Compared to the general insured U.S. population (where approximately one-third of adults report experiencing coverage delays or denials) patients with rare diseases reported higher rates (over 60%) of treatment delays or denials due to pre-approval requirements.[4, 5]

Objective

To assess the impact of dedicated rare pharmacy clinician involvement on authorization outcomes and timely access to therapy for patients with rare diseases.

Methods

This retrospective cohort study leveraged data from a national rare disease pharmacy database to explore patterns in PA and appeal outcomes in relation to dedicated clinician support. The analysis included insured individuals newly prescribed rare disease therapies across seven unique therapy programs from January 1 through December 31, 2025.

PA and appeal cases were classified into two distinct analytic groups: dedicated clinician involvement from the pharmacy or healthcare provider (HCP)–owned cases within the prescribing office. Descriptive and comparative analyses assessed differences in key outcomes such as PA/appeal success rates, PA/appeal turnaround time steps, time to first fill (TTFF), and the number of free goods shipments prior to first commercial fill. Statistical analyses were conducted using a chi-square test with Cramer's V effect size to assess differences in overall approval rates (approval at any PA or appeal level), and a one-sided Mann–Whitney U test to compare time to first fill (TTFF) between analytic groups.

Results

Approval Rates and Denial Reasons

Figure 1: PA and Appeal Approval Rates

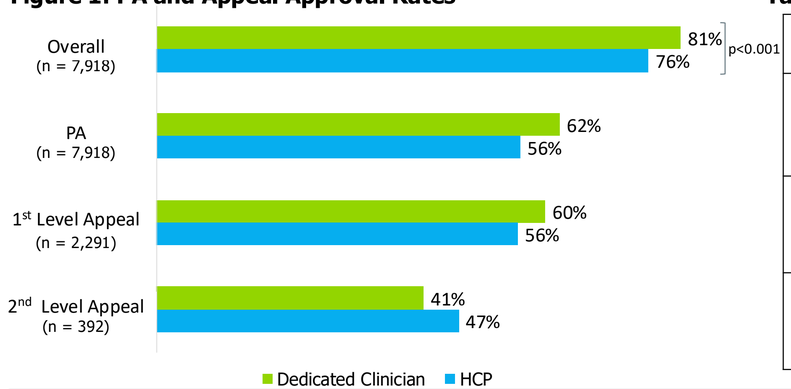


Table 1: Top 3 Known PA Denial Reasons

Category	Dedicated Clinician	HCP
Medical Necessity/ Clinical Criteria Not Met	33%	38%
Coverage Policy/Benefit Design	29%	28%
Step Therapy Trial & Failure	17%	12%

Approval Timelines

Figure 2: PA Approved Timeline

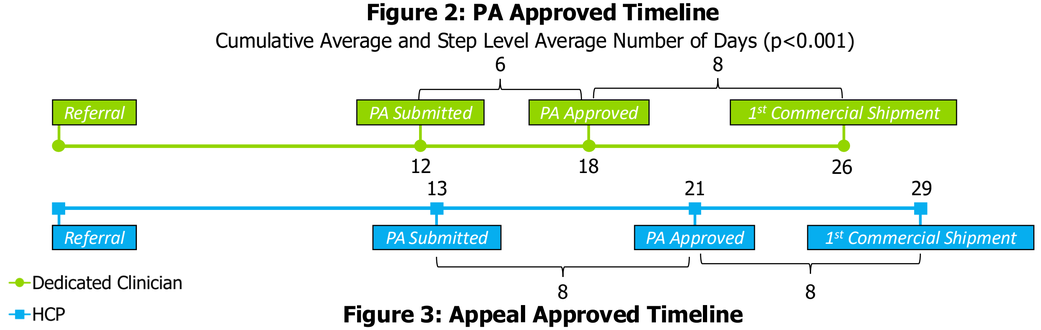
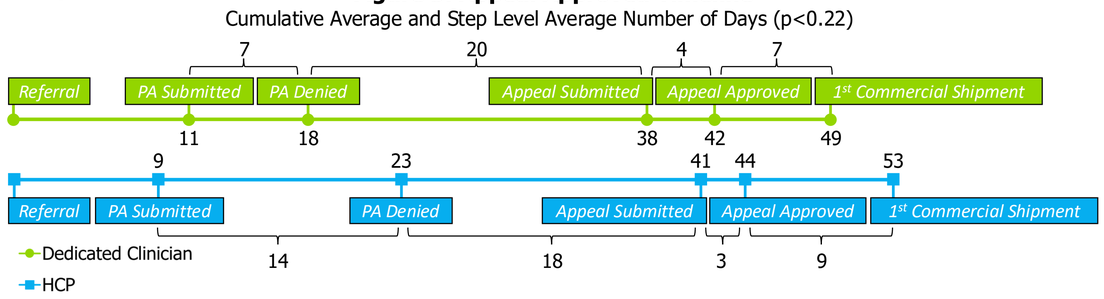


Figure 3: Appeal Approved Timeline



Interim Access Analysis

Table 2: Average Number of Free Goods Shipments Prior to First Commercial Fill

PA/Appeal Prepared by	Average Number of Free Goods Shipments	Average Cumulative Therapeutic Days
Dedicated Clinician	1.56	31
HCP	1.46	28

Discussion

Dedicated clinician involvement was associated with higher overall approval rate (81% vs 76%; Figure 1); this difference was statistically significant ($p<0.001$) but small in magnitude (Cramer's V=0.055), suggesting other factors also contributed to approval outcomes. Differences between dedicated clinician and HCP case approval rates were most evident earlier in the process (PA 62% vs. 56%, and 1st-level appeal 60% vs. 56% respectively), suggesting dedicated clinician support may improve submission completeness and payer alignment, thereby preventing escalation to later appeal stages. The top three PA denial reason categories were similar across groups and accounted for >75% of PA denial reasons, while four other categories accounted for 21% of dedicated clinicians cases and 22% of HCP cases (Table 1).

Approval timeline analysis suggested greater PA and appeal efficiency with dedicated clinician support. Average TTFF was 3 days shorter for PA approvals (dedicated clinician: 26 days, n=3,651; HCP: 29 days, n=891; Figure 2) and 4 days shorter for PA denials later approved on appeal (dedicated clinician: 49 days, n=1,092; HCP: 53 days, n=113; Figure 3). The TTFF difference for approved PA cases was statistically significant ($p < 0.001$), whereas the difference for approved appeal cases was not ($p = 0.22$), consistent with the very small observed effect size (Cohen's $d = 0.06$) and limited statistical power to detect effects of this magnitude in the available sample. Step-level differences elucidate where dedicated clinician support most substantially shortened the TTFF and can guide dedicated clinician workflows in the future.

The average number of free goods shipments and interim therapeutic days prior to first commercial fill were comparable between groups (dedicated clinician: 1.56 shipments, 31 days; HCP: 1.46 shipments, 28 days; Table 2). While dedicated clinician support led to higher approval rates and faster TTFF, interim access utilization remained similar through first commercial fill.

This retrospective cohort study used routinely collected operational data and documentation from a national rare disease pharmacy database not designed for research. Variability in real-world documentation practices, along with heterogeneity in therapy program requirements, contributed to analytic group classification complexity and may have affected recorded milestone timelines. As no workflow changes or interventions were introduced, findings may be influenced by unmeasured confounders (e.g., payer mix, program complexity, clinical severity).

Conclusion

Timely access to therapy is especially important for individuals living with rare diseases, where delays can carry adverse consequences. In this analysis, cases supported by dedicated clinicians were associated with higher overall approval rates and shorter TTFF compared with HCP-owned cases. These findings suggest dedicated clinician support may help ease authorization-related burden by streamlining documentation and reducing administrative barriers to treatment initiation.

References

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