

A Physician-Friendly Alternative to Prior Authorization for Prescription Drugs

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Prior authorization (PA) is a widely adopted method of drug utilization management that requires submission of qualifying clinical or drug utilization criteria for review by a third party before acceptance of a prescription drug claim.¹ Prior authorization programs have successfully contained drug costs over the past few decades, yet reports of unintended consequences have called into question their overall value.²⁻⁴ As implemented, PA often requires multiple telephone calls and facsimiles between pharmacy, practice, and a third-party administrator to gain resolution. In addition to causing clinician dissatisfaction,^{5,6} the process often results in patient attrition from therapy,⁷ delays in access to therapy,⁸ and, in some instances, negative patient outcomes.⁸⁻¹¹

In North Carolina, Medicaid has a long history of considering cost-containment policies that are palatable to clinicians and patients. Community Care of North Carolina (CCNC), an organization with more than 1000 primary care practice members focusing on medical home development and cost-effective care delivery, often works collaboratively with Medicaid administrators and policymakers to develop and implement statewide programs.¹² In the case of a new coverage policy for proton pump inhibitors (PPIs) implemented in June 2007, North Carolina Medicaid consulted with CCNC and the North Carolina Physician Advisory Group to develop a modified PA program that allowed for an optional instant approval (IA) process. The IA process was available to all prescribers and could be used in lieu of the traditional third-party submission process. This alternative process allowed prescribers to document PA criteria directly on the prescription so the pharmacist could fill the prescription without delay ([Appendix A](#)).

The North Carolina Medicaid PPI PA program (hereafter, the program) was developed using the best available clinical evidence for determining which PPI medications would require prior approval¹³⁻¹⁸ and included the following 3 prescribing options: (1) use of a “preferred” PPI, including omeprazole and Prilosec OTC (manufactured by AstraZeneca, Wilmington DE and distributed by Proctor and Gamble, Cincinnati, OH), without any coverage restrictions; (2) use of a “nonpreferred” PPI and the traditional PA process of submitting criteria to a third party; or (3) use of a nonpreferred PPI with approval criteria written on the prescription, bypassing the PA process. Written approval criteria included the following:

Objectives: To determine if the instant approval (IA) process differs from the traditional prior authorization (PA) process in preferred drug channeling, resultant gaps in therapy, and provider dissatisfaction.

Study Design: An interrupted time series analysis using pharmacy claims and a retrospective cohort study.

Methods: The study assessed changes in preferred drug use and subsequent cost reductions. A retrospective cohort study determined if the IA process produced fewer gaps in therapy than the PA process. Provider acceptance of the IA process was assessed using a brief survey of 240 randomly selected primary care practices.

Results: Market share for preferred proton pump inhibitors quadrupled from a range of 17.6% to 19.3% at baseline to 76% in the first month after implementation of the new IA policy. Most practices (81.1%) reported reduced administrative burden with the IA process. The median gaps between medication fills for patients using IA were approximately one-half those of patients using PA ($P < .001$) and were one-fourth in a subset of highly adherent, regularly filling patients ($P < .001$).

Conclusions: Instant approval may be more patient friendly and prescriber friendly than PA as assessed by a proxy measure for access (gap in therapy) and physician-reported acceptance. Despite its ease of use, IA does not seem to reduce switching to preferred drugs.

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Take-Away Points

Instant approval may be a more patient-friendly and prescriber-friendly process than traditional prior authorization as assessed by a proxy measure for access (gap in therapy) and physician-reported acceptance. Despite its ease of use, instant approval does not seem to reduce switching to preferred drugs.

- Administrative burden is not needed to encourage preferred drug use.
- Prescribers prefer the path of least resistance.
- Patient gaps in therapy are substantially reduced by preempting hard edits at the pharmacy.

the time series analysis regardless of age. For the cohort analysis of gaps in therapy, an additional exclusion criterion was added requiring continuous enrollment over the entire evaluation period to remove any potential bias imparted by loss of Medicaid eligibility.

For the survey, a stratified random sample of 240 practices was selected from approximately 1000 CCNC prac-

tices, representing more than 85% of primary care delivery in North Carolina. The following 3 strata, comprising 80 practices each, were created based on practice-level PPI prescribing volume during the calendar year (2006) before the study period: (1) 1 to 9 prescriptions (80 of 386 practices), (2) 10 to 49 prescriptions (80 of 506 practices), and (3) 50 or more prescriptions (80 of 153 practices).

(1) “failed omeprazole (40 mg) for 30 days,” (2) “esophagitis grade C” or “esophagitis grade D,” and (3) “cannot swallow tablets” or “cannot swallow capsules.”

Community Care of North Carolina was charged with educating prescribers and pharmacies about the new process. Facsimile, e-mail, and face-to-face meetings were used before and after initiation of the policy.

Ultimately, the program was constructed with the following 2 equally important objectives: (1) to generate drug cost savings and (2) to avoid some of the unintended consequences of traditional PA programs such as increased gaps in therapy and clinician dissatisfaction. In this study, we attempt to determine if both program objectives were met.

Data Analysis

Measuring Market Share and Drug Costs. Two interrupted time series were created using administrative pharmacy claims to assess the effectiveness of IA in reducing PPI costs and channeling patients to preferred medications. For the first time series, the market share of preferred PPIs as a percentage of total PPI use was computed and plotted for 12 sequential months (calendar year 2007). This period included 5 months immediately before and 7 months after program implementation. For the second time series, PPI cost totals for each of the 12 months were calculated. North Carolina Medicaid does not have a mandatory formulary and is the single provider of pharmacy benefits for all of its enrollees with no mail service option.

Measuring Timely Access to Medication. Gaps in therapy were calculated for 5 patient cohorts distinct in their program experience (described herein). A gap in therapy is calculated by subtracting the total number of days of medication provided from the total number of days between consecutive fills. It represents the number of days a patient is likely without medication. To determine if the method of approval produced differing gap lengths, we selected all patients with consecutive PPI fills that surrounded the program implementation date. The preprogram PPI fill must have occurred in the 5 months before the start of the program, and the postprogram PPI fill must have occurred in the 5 months after the start of the program (**Appendix B**). For enrollees refilling their first postprogram prescription early, the gap was left censored to zero to avoid reporting nonsensical “negative gaps.”

Because PPIs are customarily used chronically and on an as-needed basis, gap lengths were calculated for the entire

METHODS

Study Design

Before implementation of the program on June 1, 2007, there were no coverage restrictions on PPI medications for Medicaid enrollees in North Carolina. This offered a unique natural experiment because the optional alternative IA process was initiated simultaneously with the PA start date.

Three separate analyses were performed to evaluate program success. First, an interrupted time series analysis was used to evaluate drug cost savings and channeling to preferred PPIs. Second, gaps in therapy were determined as a proxy for patient access to PPIs by the type of override. Third, a survey was administered to primary care practices across North Carolina to assess provider satisfaction with the program. The study was approved by the institutional review board of the University of North Carolina School of Medicine at Chapel Hill.

Study Participants

For the interrupted time series analysis, all North Carolina Medicaid recipients with paid PPI claims during 2007 were included. Per the PPI PA policy, enrollees younger than 6 years or enrollees having an aid category indicating pregnancy were excluded from the analysis. Dually eligible enrollees having Medicare Part D coverage were also excluded from

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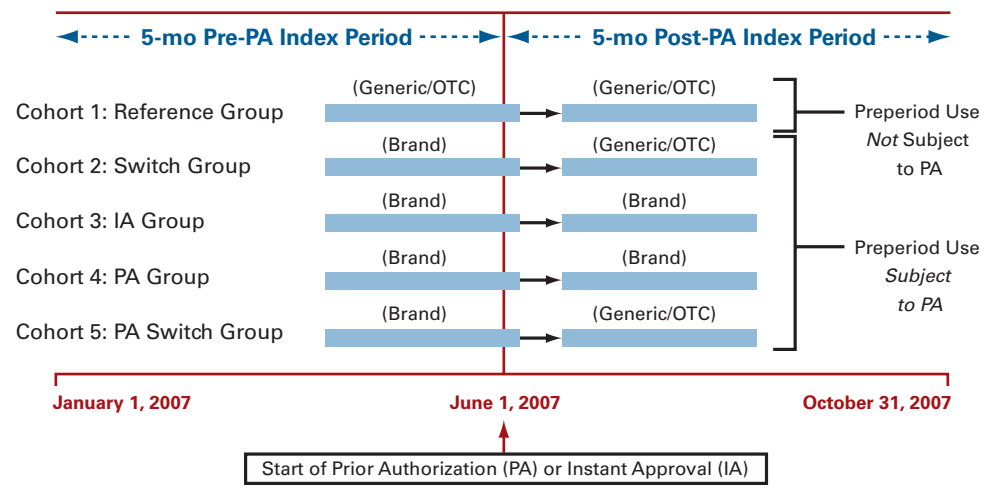
Medicaid population and for a subset of highly adherent, regularly filling PPI users. Regular PPI users were defined as patients having at least 5 PPI fills with a total number of medication days exceeding 150 in the 5 months before program implementation.

Five mutually exclusive cohorts, each representing a different patient-level result, were assembled for the analysis of gaps in therapy (Figure 1). An electronic record of pharmacy edits and overrides for IA and PA was used along with pharmacy claims to construct the cohorts. Cohort 1 (reference group) included patients filling preferred PPIs before and after program implementation. Approval was not required for this group at any time during the study period. Cohorts 2 through 5 represent patients using nonpreferred products immediately before the PA start date. Cohort 2 (switch group) included patients who ultimately switched from nonpreferred PPIs to preferred PPIs in their first fill after program implementation. Cohort 3 (IA group) included patients who continued filling nonpreferred PPIs on program implementation through the use of the IA process. Cohort 4 (PA group) included patients who continued filling nonpreferred PPIs on program implementation through the use of the traditional PA process. Cohort 5 (PA switch group) included patients who filled nonpreferred PPIs before program implementation, initiated the traditional PA process, but ultimately filled a preferred drug as their first PPI fill after program implementation. This group represents a cohort of patients who predominantly fall into 1 of the following 2 categories: (1) PA request was rejected by a third-party vendor or (2) PA request caused a delay sufficient to motivate the patient or prescriber to switch to a preferred product.

After creating boxplots of gap lengths for each cohort, we performed Wilcoxon rank sum exact test (SAS, version 9.2; SAS Institute Inc, Cary, NC) to determine if gap days differed by cohort. For the nested group of regular PPI users, we also determined the number and percentage of patients having more than 10- and 30-day gaps as a proxy measure for quality. The latter is considered a significant gap in therapy as a consensus quality-of-care standard for many classes of chronic drugs.¹⁹

Measuring Clinician Satisfaction. We also developed a survey to assess the adoption and satisfaction of the IA pro-

■ **Figure 1.** Creation of Reference and Comparator Groups of Proton Pump Inhibitor Users



OTC indicates over the counter.

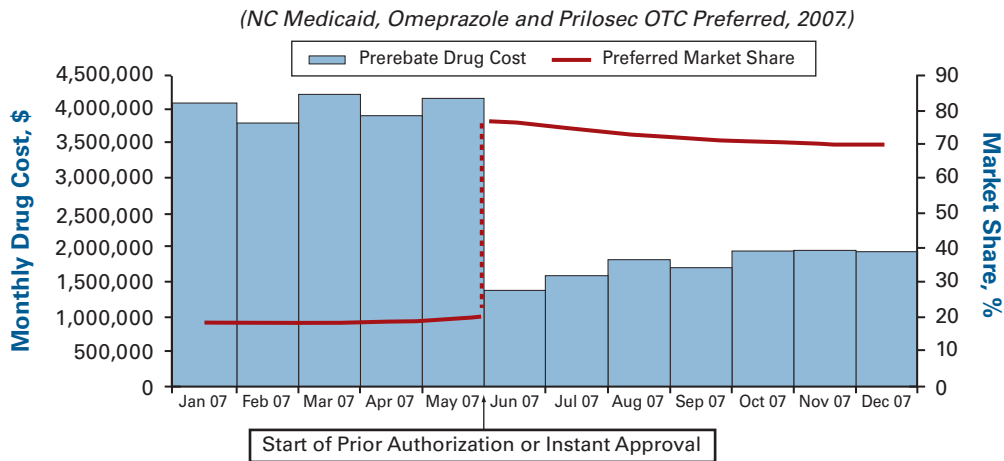
cess among prescribers. The survey inquired about a practice's use of IA, including provider and patient burden, as well as experience with and perceptions of IA and PA processes. A focus group of 2 physicians and a pharmacist was used to construct survey content (TKT, BDS). The draft survey was then pilot tested with physicians from 4 unaffiliated practices and was revised based on their responses by a panel familiar with the policy that included a biostatistician, an epidemiologist, a pharmacist, and a physician (TKT, BDS).

The finalized survey was sent from the North Carolina Physician Advisory Group and included a cover letter, the survey, and a postage-paid addressed return envelope. Community Care of North Carolina staff delivered in person a second copy of the survey to nonresponding practices approximately 6 weeks after the initial distribution. Respondents were instructed to answer on behalf of their practice and were selected based on convenience (any prescriber in the practice could respond). Receipt of completed surveys and responses were entered into a spreadsheet (EXCEL, version 2003; Microsoft, Redmond, WA).

Responses to the survey were summarized as frequencies (number and percentage) for each stratum and in aggregate with weighted and unweighted results. For each prescribing volume stratum, weighting was based on initial sampling proportions for each group. χ^2 Goodness-of-fit test was used to determine if responses differed between practices with varying volumes of PPI prescribing. χ^2 Contingency table test was applied to the Likert-type scale survey item.

Tying Survey Results to Administrative Claims. Responses to the practice survey were then combined with pharmacy claims using a coded practice identifier maintained

■ **Figure 2.** Market Share of Preferred Proton Pump Inhibitors by Month



for CCNC. In North Carolina, almost three-quarters of all Medicaid enrollees are linked with a CCNC practice to participate in primary care medical home care management. This practice linkage allowed us to track PPI use and trends over time for practices that responded to the survey. Another interrupted time series model was then created to examine if practices claiming any use of IA produced fewer switches to preferred PPIs than practices not claiming any use of IA using traditional PA exclusively for PPI PA overrides.

RESULTS

Market Share and Drug Costs

Market share for preferred PPIs remained stable at 17.6% to 19.3% in the preprogram period and increased to 76.3% in the first month of the program. Degradation of preferred market share was minimal (7.1%) in the 7 months after the start of the program (Figure 2). Subsequently, drug costs dropped from a pre-PA monthly mean of approximately \$4 million to a post-PA monthly mean of approximately \$1.5 million. Market share changes in the subset of CCNC-linked patients were similar for practices using IA and practices using PA (Figure 3).

Timely Access to Medications

All gap length comparisons between the reference cohort and all other cohorts, as well as between the IA cohort and the PA and PA switch cohorts, were statistically significant ($P < .001$, Wilcoxon 2-sample rank sum exact test). The median gap in therapy for patients using PA (26 days) was roughly twice the median gap in therapy for patients using IA (12 days) ($P < .001$) (Figure 4). For the subset of regular users, PA produced a gap (12 days) that was 4 times the gap (3 days) produced by IA ($P < .001$). The percentage of regular users with more than

a 30-day gap in therapy was significantly less for the users of the IA process (8.7%) compared with the users of the PA process (21.9%) ($P < .001$). The ordered rank of fewest to most gap days by group was the same for all users group and regular users group: (Fewest Gap Days) → Reference Group → IA Group → Switch Group → PA Group → PA Switch Group → (Most Gap Days).

Clinician Satisfaction

Of 240 selected practices, 169 (70.4%) completed and returned IA practice surveys. Almost half (49.7%) of respondents reported using IA, with greater percentages of medium-volume (57.4%) and high-volume (67.9%) prescribers opting to use this method ($P < .001$). Of those practices using IA, 81.1% believed that it reduced the administrative burden to the practice (Table). Approximately three-fourths (73.4%) of respondents indicated that IA was better or much better than traditional PA, with only 7.0% reporting that traditional PA was better or much better. No differences were found between practices with high, medium, or low volumes of PPI prescribing with respect to IA or PA preference or reduced burden of IA use. The use of IA was pronounced, comprising 68.2% (4959 IA and 2308 PA) of all PA overrides in the first PPI fill after policy implementation.

DISCUSSION

Despite the ease of use of IA, switching to preferred PPIs was similar to or exceeded that of PPI PA programs in other states and countries.^{6,20} Instant approval was a popular alternative to traditional PA, with survey responses indicating that almost half of all primary care practices in North Carolina used the optional IA process and that those practices preferred IA over PA more than 10 to 1 (73.4% believed that IA was better or much better, and 7.0% believed that PA was better or much better). Most importantly, offering an alternative IA did not seem to diminish the ability of PA to produce substantial cost savings.

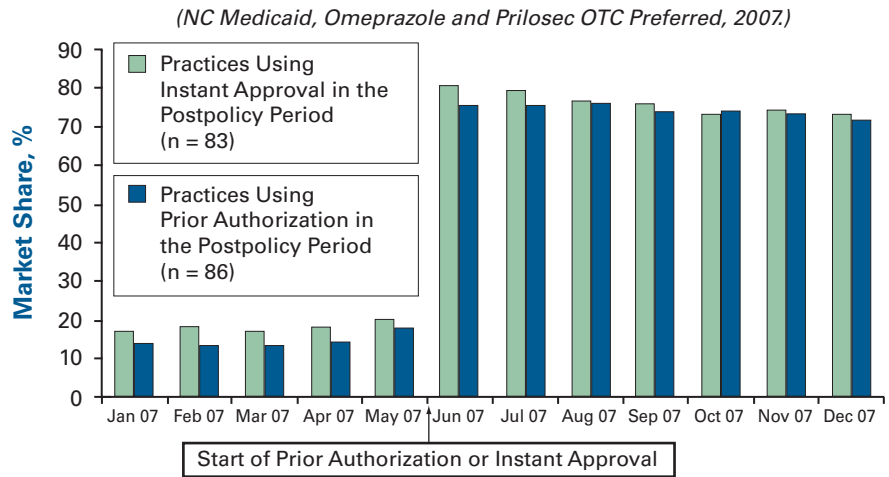
Many states are testing various modalities for drug utilization management that attempt to be more patient friendly and prescriber friendly. One emerging method is SmartPA, a sys-

tem that reviews a patient's claims history to determine eligibility for an instant override at the pharmacy.²¹ Another evolving method deployed alongside e-prescribing would allow the prescriber to affirm or submit PA criteria with real-time links to formulary and eligibility. Nonelectronic methods include collaborative practice agreements such as the Therapeutic Interchange Program used in Washington state.²²

The IA method used for North Carolina Medicaid was unique in its simplicity of administration. The prescriber was given the authority to override the PA on his or her own form (the prescription pad) at the ideal time (the point of prescribing). Subsequently, practices reported a median time savings of 15 minutes per patient using IA. As such, IA may reduce or totally eliminate the indirect PA submission cost to the practice (estimated as high as \$17.77).²³ Similarly, IA may reduce implementation costs to the payer (estimated at \$20-\$25 per enrollee per submission).^{6,23}

This study is limited by its quasi-experimental design, although an experimental design would have been impractical because PA programs are universally applied to enrolled populations. It is possible that factors may have been present that influenced patient selection into the type of override process used by the prescriber. However, the likelihood that observed differences in therapy gaps were due to drug or patient characteristics is low because the net result (extended gap length) is intrinsic to the override process itself, and prescriber choice of IA versus PA was not likely influenced by drug or patient.

Figure 3. Market Share of Preferred Proton Pump Inhibitors by Month and Type of Approval



Therefore, in the absence of large differences in baseline adherence between patients of prescribers using PA versus IA, a causal link may be inferred between override type and gap length.

We did not attempt to make a pre-post comparison of gaps in therapy but rather choose to create a cross-sectional view of gaps using the first post-PA fill as a patient-specific index date. This is the most relevant date because it represents the day when rejection occurs at the pharmacy in the absence of an override. Although gap measurements are a convenient proxy measure for access,⁸ the approach lacks specificity and precision because of baseline "noise" caused by well-known and widespread nonadherence among all drug classes. Fortunately, the inclusion of a reference group of PPI users not subject to the effects of the PA policy was available for comparison to mitigate this limitation. In addition, we analyzed a nested cohort of highly adherent users for gaps

Figure 4. Gaps in Therapy by Group (All Proton Pump Inhibitor [PPI] Users and Regular PPI Users)

		No. (%) in Group	No. (%) With No Gap	Median	Gap (in Days) ^a (25th and 75th Percentiles) (Boxplot)		No. (%) With >10-d Gap	No. (%) With >30-d Gap
All PPI Users (Enrollees with ≥1 preperiod and ≥1 postperiod PPI fill)	Cohort 1: Reference Group	5646 (19.5)	1545 (27.4)	7 (0, 37)				
	Cohort 2: Switch Group	15,433 (53.4)	2191 (14.2)	16 (4, 51)				
	Cohort 3: IA Group	4959 (17.2)	969 (19.5)	12 (2, 41)				
	Cohort 4: PA Group	2308 (8.0)	95 (4.1)	26 (10, 61)				
	Cohort 5: PA Switch Group	564 (2.0)	19 (3.4)	30 (13, 63)				
Regular PPI Users (Enrollees with ≥5 preperiod fills and a total days supply of ≥150)	Cohort 1: Reference Group	1299 (15.9)	620 (47.7)	1 (0, 4)		154 (12.0)	52 (4.0)	
	Cohort 2: Switch Group	4503 (55.3)	1078 (23.9)	5 (1, 14)		1460 (32.0)	548 (12.0)	
	Cohort 3: IA Group	1492 (18.3)	472 (31.6)	3 (0, 11)		387 (26.0)	130 (9.0)	
	Cohort 4: PA Group	671 (8.2)	48 (7.2)	12 (6, 27)		381 (57.0)	147 (22.0)	
	Cohort 5: PA Switch Group	181 (2.2)	9 (5.0)	17 (7, 32)		118 (65.0)	50 (28.0)	

IA indicates instant approval; PA, prior authorization.

^aWilcoxon 2-sample rank sum exact test revealed $P < .001$ for all reference group versus study group comparisons, as well as for the instant approval (IA) group versus the prior authorization (PA) group and for the IA group versus the PA switch group.

■ **Table.** Practice Survey Results

Survey Item	Response	Practice-Level PPI Drug Fill Volume ^a			All Practices	
		Low, 1-9 Fills	Medium, 10-49 Fills	High, ≥50 Fills	Unweighted	Weighted
Response rate, No./Total No. (%)	—	57/80 (71.3)	54/80 (67.5)	56/80 (70.0)	167/240 (69.6)	723.7/1045 (69.3)
Has this practice used the new instant approval override process for prior authorizations for PPIs? (implemented June 1st of this year for Medicaid recipients), No./Total No. (%)	Yes ^b	14/57 (24.6)	31/54 (57.4)	38/56 (67.9)	83/167 (49.7)	336.3/723.7 (46.5)
Do you believe that the instant approval process causes less burden on your practice than the traditional prior authorization process? (if yes to the above), No./Total No. (%)	Yes	12/14 (85.7)	24/31 (77.4)	33/38 (86.8)	69/83 (83.1)	272.8/336.3 (81.1)
Taking all things into consideration, give an overall comparison of the traditional prior authorization and instant approval programs for Medicaid patients who receive PPIs in your practice, No./Total No. (%)	Traditional PA much better	1/14 (7.1)	1/31 (3.2)	1/36 (2.8)	3/81 (3.7)	13.1/332.5 (3.9)
	Traditional PA better	0/14	1/31 (3.2)	2/36 (5.6)	3/81 (3.7)	10.2/332.5 (3.1)
	No difference	1/14 (7.1)	8/31 (25.8)	5/36 (13.9)	14/81 (17.3)	64.9/332.5 (19.5)
	IA better	7/14 (50.0)	14/31 (45.2)	14/36 (38.9)	35/81 (43.2)	149.1/332.5 (44.8)
	IA much better	5/14 (35.7)	7/31 (22.6)	14/36 (38.9)	26/81 (32.1)	95.2/332.5 (28.6)
Please estimate the total minutes of work saved by your practice per Medicaid patient receiving PPIs using the instant approval versus the traditional prior authorization process, median No. (25th, 75th percentiles), min	—	17.5 (10, 30)	15.0 (10, 30)	15.0 (8, 30)	15.0 (10, 30)	—

IA indicates instant approval; PA, prior authorization; PPIs, proton pump inhibitors.

^aVolume of PPI prescription fills for Community Care of North Carolina enrollees linked with the practice in 2006.

^bStatistically significant differences between groups (low, medium, and high) using χ^2 goodness-of-fit test ($P < .001$).

after PA implementation to “zero out” poor baseline adherence. We found identical ordering of cohorts, differing only in gap magnitude, but with similar relative gap lengths in this highly adherent group.

The generalizability of results may be limited by the drug class (PPIs) and the payer (Medicaid). It is unclear whether the results of this study would be replicated if IA was used for other drug classes that maintain stronger indications for chronic use or more serious or immediate consequences from delayed access. With respect to the survey, the available unit of analysis was the practice; therefore, a single prescriber was asked to respond on behalf of each practice, imparting the possibility of response bias based on self-selection. Furthermore, the sampling frame was limited to primary care practices within the CCNC membership. Although CCNC represents more than 85% of all primary care practices in North Carolina, fu-

ture work should make every attempt to include specialists, subspecialists, and institutionally based prescribers.

No formal time series hypothesis testing was performed. The magnitude and timing of the market share changes immediately after the policy implementation were so strong that it removed the need for inferential or other statistical analyses in time series. We did not attempt to measure attrition from therapy because a comparative population of nonpreferred PPI users subject to a PA policy without the IA process would have been required. We also made no attempt to perform a time-in-motion analysis or other continuous quality improvement exercise that should be considered if IA processes proliferate. Our emphasis herein was to determine the perceived palatability of the IA method from the prescriber perspective and its effect on medication access from the patient perspective.

CONCLUSIONS

Instant approval processes may be more patient friendly and prescriber friendly than traditional PA methods as assessed by a proxy measure for access (gap in therapy) and physician-reported acceptance. Despite the ease with which prescribers could use IA to override the PA requirement at the time of prescribing, patient switching to preferred PPIs was widespread, and subsequent drug cost savings were substantial. Collaborative efforts with providers and policymakers working side by side may lead to policies that better address the needs of prescribers, patients, and payers simultaneously.

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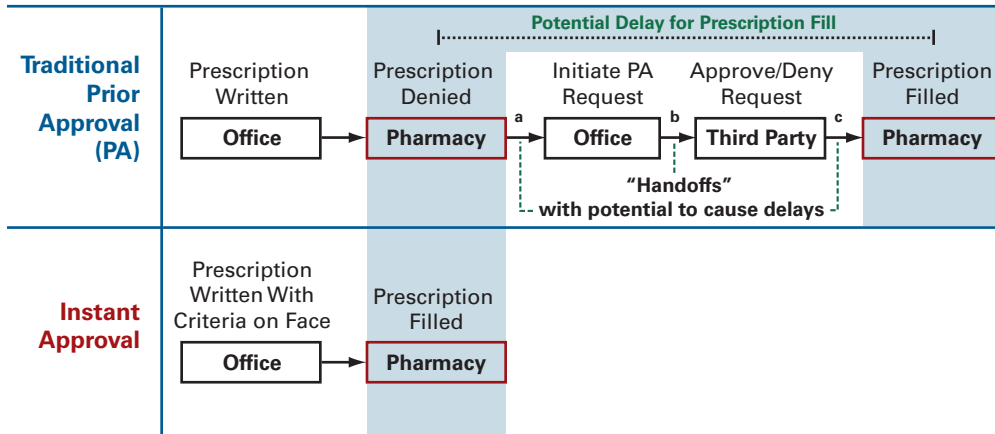
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■ **Appendix A.** Comparison of Traditional Prior Authorization and Instant Approval



■ **Appendix B.** Calculation of Gap in Therapy

