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"The Impact of Prior Authorization in Allergy/Immunology: A Position Statement of the American Academy of Allergy, Asthma & Immunology."

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Background

Prior authorizations (PA) are used by insurers to control healthcare costs by requiring providers to obtain approval before specific pharmaceuticals and/or medical services can be utilized. This process is often used for expensive therapies and limits plan members' access with the goal to reduce health expenditures. While initially used to promote lower-cost, but equally effective alternatives, it has become overutilized to the point where it is now a burdensome and time-consuming task, which diverts resources away from direct patient care to administrative duties.

The American Medical Association (AMA) Prior Authorization Physician Survey (here forward referred to as "AMA Survey" or "Survey") has revealed for decades that this activity disrupts patient care and adds administrative burden to physician practices.¹ In the most recent iteration of 1,004 physicians, **the 2021 Survey showed that 93% of physicians report a delay in care due to the PA process** with 56% stating that this occurs often or always. This unfortunately translates to 82% of Survey participants reporting that PA can sometimes, often, or always lead to treatment abandonment. This highlights the unnecessary burden placed on physician practices to acquire therapies that are deemed medically necessary by the practicing provider. Furthermore, while 98% of health plans have reported that a peer-reviewed, evidence-based process was used during the design of their PA program, **up to 30% of physicians that completed the survey answered that PA criteria are rarely or never evidence-based**.¹

AI (Allergy/Immunology) specialists are more commonly prescribing biologic agents, which have revolutionized the long-term management of asthma, chronic urticaria, and atopic dermatitis; however, PA continue to delay time to administration of these life-altering therapies. Of the 25 million individuals that have asthma in the US, 5-10% of them have severe asthma and may benefit from biologic therapy. Studies have shown that despite appropriate indications for therapy, the PA process delayed insurance approval to over 20 days on average for patients receiving this therapy, leading to 47% of patients with severe asthma requiring additional prednisone therapy during that waiting period which increases the risk of long-term complications.²

In addition to delays in care, the PA process often leads to significant impacts on patient clinical outcomes. The AMA Survey revealed that 91% of physicians report a negative impact on outcome measures when treatments require a PA.¹ Thirty-four percent (34%) of physicians reported that the PA process led to a serious adverse event for their patients. This included 24% of Survey participants stating that the PA process led to a patient's hospitalization, 18% noted this led to a life-threatening event or required intervention to prevent permanent impairment or damage, and 8% noted this led to a patient's disability/ permanent bodily damage, congenital anomaly/birth defect or death.

The burden of PA on medical practices has been well documented and has increased over the past decade. On average, medical practices complete 41 PA per physician per week, which equates to

physicians and their staff spending an average of nearly 2 business days per week exclusively on PA. **Eighty-eight percent (88%) of physicians report this being a high or very high burden** to their clinical practice and 40% of physicians have had to hire staff who exclusively work on PA.¹ For each patient on a therapy requiring a PA, the AI professional must go through this process at least once per year. Several insurance companies have shortened this period to as little as 3-6 months which may entail PA renewals up to 4 times per year. Additional office resources are needed when patients need to switch biologic therapies due to side effects or incomplete response as multiple PA must be completed in this situation. The administrative burden on practicing AI professionals has led to a loss in clinical time for direct patient care, adding to the deficiency in medical access for many patients in the U.S. Increasing physician burnout has also been tied to the increase in PA requests.³

While the intent of PA was to reduce healthcare costs, the AMA Survey highlighted that more than half (51%) of the participants reported that PA has interfered with a patient's ability to perform his or her job responsibilities, which does affect productivity and work performance.

In summary, the PA process has led to barriers limiting patient access to appropriate, evidence-based therapies and often leads to suboptimal clinical care. It interferes with the clinical decision making of practicing AI professionals by causing delays in therapies and often leads to an abandonment of the best treatment option available for the patient. In addition, they add an unnecessary burden to medical practices and furthers the deficiency in access for patients across the U.S. Despite this, healthcare plans are increasing their use of PA as a cost-control measure. The PA process must be updated to meet the needs of our patients as well as for clinicians to ensure optimal clinical outcomes.

The AAAAI supports the following positions to facilitate PA reform by healthcare plans for both pharmacy and medical benefits:

- Reduce the number of Allergy/Immunology (AI) specialists subject to PA requirements
 - Selective application of PAs can reduce the burden of AI specialists who utilize evidencebased care. Prescribing specialists with historically high PA approval rates and/or those that have patterns of prescribing according to evidence-based guidelines should have reduced PA requirements.
- Guideline-based criteria should be used to improve access of approved biologics
 - Biologics in allergic diseases have demonstrated improvement in quality and patientcentered outcomes. Utilization of guideline-based algorithms should be used to develop criteria for PA approval.
- Improve transparency
 - Healthcare plans need to restructure the prior authorization process to prevent harm to patients as both denials and delays in care can further result in negative outcomes. To minimize patient care delays, effective communication is essential between health care plans, AI specialists and their patients. Efforts to open more direct lines of communication between patients and providers with healthcare plans should be established. Notification of PA determination between AI specialists and their patients should be timely. Healthcare plans should provide clear PA criteria, rationale for denials, and ensure that reviewers are qualified in the specialty which they serve. Further, when a peer-to-peer is required, the reviewer should have relevant expertise regarding the therapy being prescribed.

- Ensure continuity of care
 - Patients with chronic or genetic conditions often require long-term treatments that are medically necessary to help prevent morbidity and potentially increased mortality. The frequency of PA renewals should be reduced to at most, annually or even less frequently for patients with known genetic conditions in need of lifelong therapies. Further, flexibility for member coverage to avoid gaps should be extended during member health plan changes and formulary changes.
- Institute national electronic standards for PAs
 - An established national electronic standard would help clarify criteria for PA approval in a systematic and timely way for all parties involved including patients, providers and healthcare plans.
- PAs should not delay access to emergency care medications
 - Lack of expedient access to acute emergency care medications could have drastic consequences for patients. Patients should have ready access to a limited supply of prescribed emergency care medications (e.g. icatibant, budesonide-formoterol) per clinical guidelines while waiting for full approval through the prior authorization process.

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