19th Annual

APPLIED PHARMACOECONOMICS AND OUTCOMES RESEARCH FORUM

PE FORUM

Prior Authorization

8/25/2025

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Disclaimer

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Discussion

- Why Prior Authorization?
- Stakeholder Challenges
- Progress and Opportunities
- Manufacturer Efforts
- Situational Considerations
- Final Thought

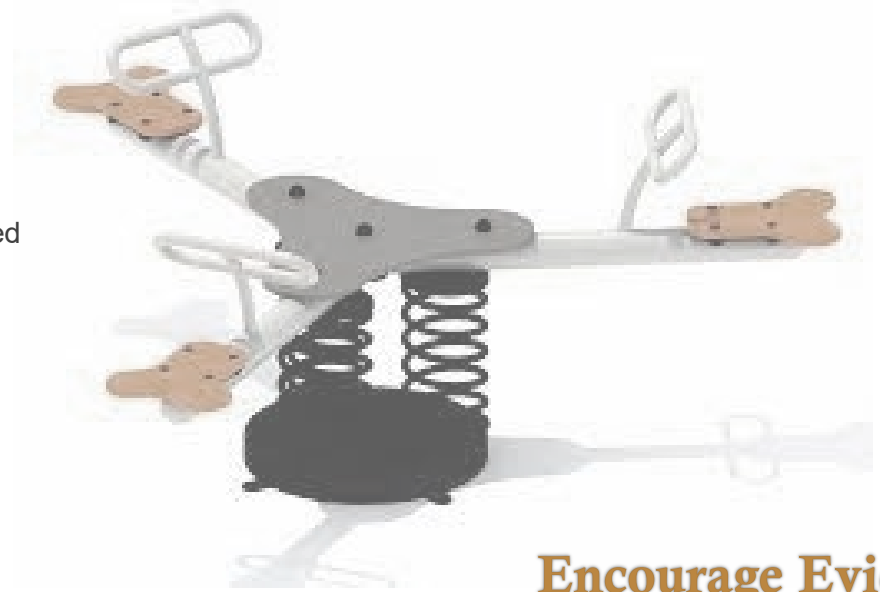
What Does Prior Authorization Solve For?

Cost Containment

Purpose: Contain healthcare spending by steering utilization toward lower cost, generic drugs, or lower-tier formulary alternatives.

Examples:

- Step therapy policies requiring lower-cost drugs to be tried first
- DME reuse and replacement thresholds to prevent redundant billing



Clinical Appropriateness

Purpose: Confirm that a treatment, test, or medication meets evidence-based clinical guidelines and is medically necessary for the patient's condition.

Examples:

- Avoiding use of high-risk therapies when safer alternatives exist
- Requiring diagnostics (e.g., genetic testing) before approving targeted therapies

Risk Management

Purpose: Reduce unnecessary, duplicative, or fraudulent care that could arise from misuse of high-cost therapies or services.

Examples:

- Flagging excessive refill requests or unqualified provider orders
- Verifying DME utilization thresholds or patient eligibility before approval

Encourage Evidence Generation and Real-World Validation

Purpose: Create a feedback loop—requiring outcomes reporting or RWE submission to continue coverage

Examples:

- Rare disease, novel therapies, or medical devices.
- Growing trend in value-based arrangements.

Stakeholder Challenges

Who are the key stakeholders and what are their challenges?

Stakeholders

CLINICAL

1. Physicians / Prescribers
- Initiate PA requests
- Provide documentation and clinical rationale
- Often experience the **greatest administrative burden**

2. Pharmacists (Retail and Specialty)
- Often the **first point of denial detection**
- Help initiate or follow up on PA requests
- Coordinate with prescribers to complete forms and corrections

3. Nurses / Case Managers / Medical Assistants
- Help gather clinical information
- Coordinate submission and follow-up
- Often handle appeals and second-level reviews

PAYER & INTERMEDIARY

4. Health Plans / Payers (Commercial, Medicare Advantage, Medicaid MCOs)
- Set PA policies and review criteria
- Review submissions and approve/deny coverage

5. Pharmacy Benefit Managers (PBMs)
- Administer PA for **pharmacy benefit** medications
- Manage formularies, step therapy, and alternative options

6. Utilization Management (UM) Vendors
- Third-party vendors contracted by payers to handle PA operations (e.g., Evicore, AIM, NIA)

7. Health Information Technology Vendors (e.g., ePA systems)
- Provide electronic prior auth (ePA) platforms (e.g., CoverMyMeds, Surescripts)
- Facilitate integration between EHRs and payer systems

Patients
- Directly impacted by PA delays, denials, or step therapy
- May need to initiate appeals or coordinate with providers

INDUSTRY

8. Pharmaceutical Manufacturers
- Work to reduce access barriers to medications
- Provide PA support tools, HUB services, and field reimbursement teams

9. Medical Device Manufacturers
- May face **unclear or variable PA criteria**
- Provide clinical documentation tools, appeals support, and payer engagement teams

10. HUB Services / Field Access Specialists
- Contracted or in-house support for providers to complete PA paperwork
- Educate on clinical criteria and payer-specific requirements

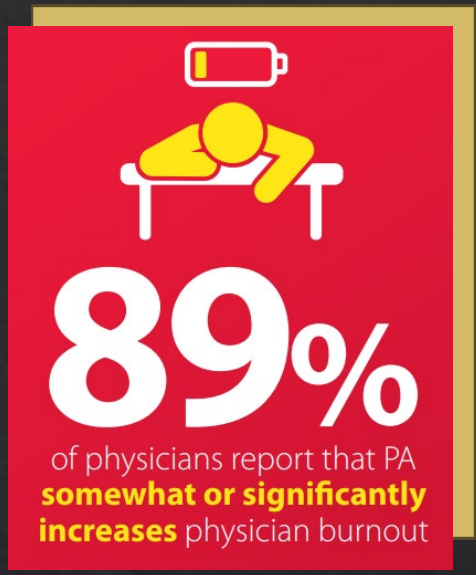
REGULATORY & ADVOCACY

11. Federal and State Regulators (e.g., CMS, state Medicaid agencies)
- Set rules for **timeliness, transparency, and fairness**
- May implement reform (e.g., CMS ePA mandates, transparency laws)

12. Professional Societies and Advocacy Groups
- E.g., AMA, ASHP, National MS Society, etc.
- Advocate for reform and publish studies on PA burden and patient impact

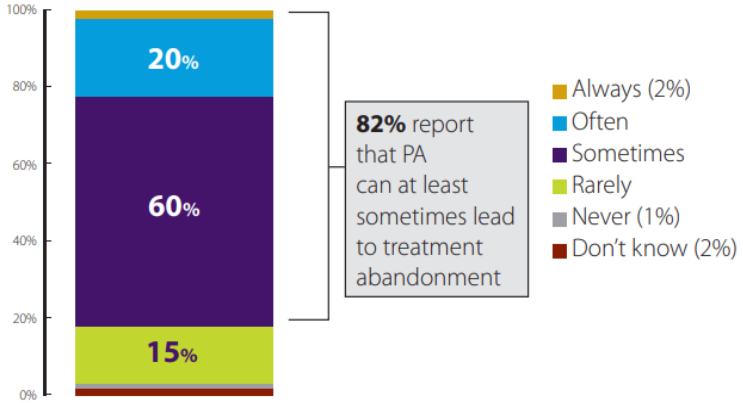
13. Legal Teams (Payer or Manufacturer)
- Involved in appeals, denials, or disputes over coverage criteria
- Address compliance with regulations (e.g., ADA, ACA)

Perspectives: Physicians and Patients



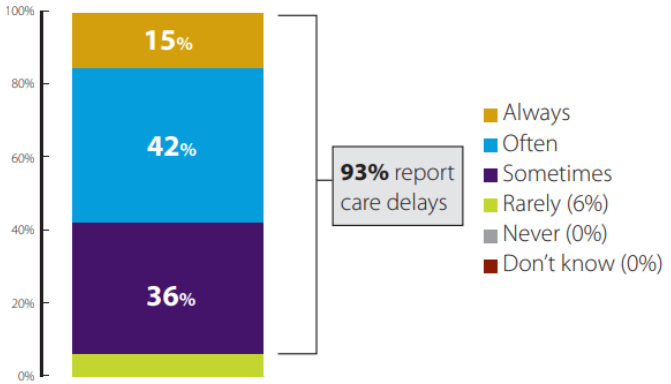
Treatment abandonment due to PA

Q: How often do issues related to the PA process lead to patients abandoning their recommended course of treatment?



Care delays associated with PA

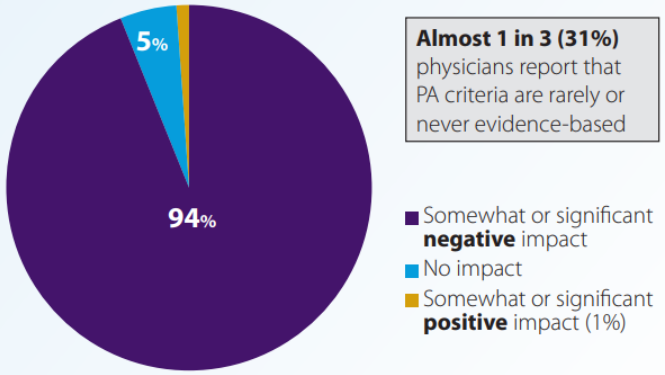
Q: For those patients whose treatment requires PA, how often does this process delay access to necessary care?



Percentages do not sum to 100% due to rounding.

Impact of PA on clinical outcomes

Q: For those patients whose treatment requires PA, what is your perception of the overall impact of this process on patient clinical outcomes?



61% of physicians report that they are **concerned** that augmented intelligence (AI) increases/will increase PA denial rates

https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

Perspectives: Manufacturer

Treatment Delays

FDA-approved treatments are stalled, potentially leading to worse outcomes

Administrative Overload

Navigating various PA criteria across payers is a burden

Financial

Discounts, HUB services, field reimbursement teams

Denied Access

Denial could lead to no treatment (i.e., primary non-adherence)

Policy Disconnects

Aligning inconsistent PA criteria across medical vs pharmacy benefit

Value Misalignment

Long-term value misaligned with short-term metrics.

PROGRESS & OPPORTUNITIES

What are we seeing in the market today?

Regulatory Environment: Communicating Value to Curb PA

FDA Modernization Act of 1997 (FDAMA 114)

- Congress 1st attempt in creating a **safe harbor for manufacturers to communicate health care economic information** (HCEI) not found in the label to formulary committees and "similar entities".
- Challenges arose with defining HCEI and defining the intended audience

21st Century Cures Act, Dec 2016 (amended FDAMA 114)

- **Comparative analyses were included** and added more clarity to the **intended audience → payers and decision makers** (i.e., entities with knowledge and expertise in economic analysis including formulary and reimbursement teams)
- HCEI needs to be ~~***directly***~~ related to an approved indication

FDA Guidance "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Q&As"

- Added **standards for use of RWD/RWE → "CARSE"** standards
- **Safe Harbor includes investigational products/potential new indications**

Competent **A**nd **R**eliable **S**cientific **E**vidence whereby data should be derived from good research practices including clearly presenting study design and methodology, generalizability, limitations, sensitivity analyses and information relevant to balance the presentation.

Pre-approval Information Exchange (PIE) Act of 2022

- **Formal permission for manufacturers to exchange certain information** with payers and other specified entities **BEFORE** a product receives FDA approval or clearance
- Led to updated **AMCP Dossier Format 4.1**

Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, § 114; 21st Century Cures Act, Pub. L. 114-255, § 3037; https://www.congress.gov/bill/117th-congress/house-bill/7008

Medical Devices

FDA's Payer Communication Task Force Aims To Improve Coverage Decisions and Patient Access

- **FDA's Center for Devices and Radiological Health (CDRH)**
  - Established the **Payor Communication Task Force** → Aims to:
    - **Facilitate communication between device manufacturers and insurers**
    - Potentially **shorten the time** between FDA marketing authorization and coverage decisions, **which may expedite patient access**.
- The **Payor Communication Task Force** activities related to medical device coverage include:
  - **Early Payor Feedback Program (EPFP)**
  - **Parallel Review** with the Centers for Medicare & Medicaid Services.
- CDRH provides a **voluntary opportunity for medical device manufacturers** to obtain payor input on clinical trial design or other plans for gathering clinical evidence needed to **support coverage decisions**.
  - Manufacturers can meet with CDRH directly or with various payor organizations.

https://www.fda.gov/about-fda/cdrh-innovation/medical-device-coverage-initiatives-connecting-payors-payor-communication-task-force; Content current as of 02/26/2025; Accessed 8/20/2025

List of Payors

FDA's Center for Devices and Radiological Health (CDRH) references the following payers in support of manufacturers planning for coverage decisions.

- Aetna, a CVS Health Company, including Aetna's Medicaid Plan: Aetna Better Health
- BlueCross BlueShield Association
- CareFirst BlueCross BlueShield (HealthWorx)
- Centers for Medicare & Medicaid Services (CMS) (Coverage and Analysis Group)
- Cigna/Evernorth
- Duke Evidence Synthesis Group, Duke Clinical Research Institute, Duke University
- ECRI Institute Headquarters
- EXCITE International Health Innovations External Link Disclaimer (Payor and clinical expert feedback)
- Health Services for Children with Special Needs, Inc. External Link Disclaimer, a Medicaid plan for Washington, DC, serving children and young adults
- Highmark Blue Shield, including Highmark Blue Shield's Medicaid Plans (Highmark Wholecare, Highmark Health Options Delaware, and Highmark Health Options West Virginia), and Hospital System/Provider Feedback
- Kaiser Permanente
- Molina Healthcare
- National Institute for Health and Care Excellence (NICE Advice)
- Premier, Inc. (includes Hospital System Feedback)
- Social Innovation Ventures
- United Healthcare
- Highmark Blue Shield has a Coverage with Evidence Development (CED) medical policy and process that may provide an opportunity to potentially accelerate patient access to innovative, high-quality medical devices.

https://www.fda.gov/about-fda/cdrh-innovation/medical-device-coverage-initiatives-connecting-payors-payor-communication-task-force; Content current as of 02/26/2025; Accessed 8/20/2025

Federal and Payer Momentum

HHS Pledge on Prior Authorization

Over 50 major insurers commit to simplifying PA across MA, Medicaid, and Commercial plans.

Jan 1, 2026

- **Reduce services requiring PA**
- **Honor PA across plan changes**
- **Simplify communication**

2027

- **ePA via FHIR APIs**
- **80% real-time decisions**

FOR IMMEDIATE RELEASE
June 23, 2025

Contact: HHS Press Office
202-690-6343
Submit a Request for Comment

HHS Secretary Kennedy, CMS Administrator Oz Secure Industry Pledge to Fix Broken Prior Authorization System

WASHINGTON, DC—JUNE 23, 2025—U.S. Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. and Centers for Medicare & Medicaid Services (CMS) Administrator Dr. Mehmet Oz today met with industry leaders to discuss their pledge to streamline and improve the prior authorization processes for Medicare Advantage, Medicaid Managed Care, Health Insurance Marketplace® and commercial plans covering nearly eight out of 10 Americans.

In a roundtable discussion hosted by HHS, health insurers pledged six key reforms aimed at cutting red tape, accelerating care decisions, and enhancing transparency for patients and providers. Their commitments reinforce the role of CMS in monitoring outcomes and promoting accountability. Companies represented at the roundtable included Aetna, Inc., AHIP, Blue Cross Blue Shield Association, CareFirst BlueCross BlueShield, Centene Corporation, The Cigna Group, Elevance Health, GuideWell, Highmark Health, Humana, Inc., Kaiser Permanente, and UnitedHealthcare.

Will this be implemented in time and with impact?

https://www.hhs.gov/press-room/kennedy-oz-cms-secure-healthcare-industry-pledge-to-fix-prior-authorization-system.html

Automating Prior Authorization: ePA vs AI Chart Review

Dimension	ePA (Electronic PA via EHR/Claims)	AI Chart Review (NLP on Clinical Notes, Labs, Etc.)
Efficiency	✓ Real-time approvals; reduces paperwork ✓ CMS-aligned (e.g., FHIR API mandates) ✓ Embedded into EHR workflows	✓ Supports complex clinical decisions ✓ Extracts context from progress notes, labs, imaging ✓ Fewer manual reviews for clinical nuance
Impact on Patient Access	✓ Faster starts for common approvals × May delay access for complex, rare, or off-label cases × Less effective in low-EHR-resource clinics	✓ Enables faster exception approvals for high-complexity cases × May contribute to opaque or automated denials without clinician oversight
Exception & Appeals Handling	× Rigid logic may limit appeal flexibility ✓ Can be configured for flagging urgent exceptions	✓ Identifies nuanced evidence for exception approval × Requires human audit trail and override mechanism
Challenges	× Requires payer-EHR integration × Limited nuance—structured data only × Variability across payers and systems	× Data quality and chart variation across sites × Risk of misinterpretation × Regulatory concerns over explainability and fairness
Equity Considerations	× Limited adoption in rural/underfunded clinics × May overlook SDOH-related barriers if not structured into claims/HER	× NLP bias risk: under-documentation in underserved populations × Dependent on clinical documentation quality, which varies with access to resources

Manufacturer Efforts

Where do manufacturers invest resources to achieve a better balance with prior authorization?

What Manufacturers Are Doing?

- Evidence Generation
  - Design and conduct comparative HEOR and RWE that provide economic models, real-world evidence / value data centered around PA.
  - Evaluate the impact of PA on population health and quality measures
- Payer and PBM Engagement
  - Prepare evidence-based dossiers to help justify coverage and reduce unnecessary PAs
- Field-based Patient Access Support
  - Educate provider offices on payer-specific PA requirements
  - Hub Services for patient access support (PA submission assistance, benefit verification, appeals)
  - Provider training guides and tools
- Technology & Automation
  - ePA integrations, partner with EHR vendors
- Patient Advocacy and Education
  - Patient education,
  - Copay assistance,
  - Policy influence
- Regulatory & Policy Shaping
  - Submit comments to CMS and state Medicaid programs
  - Trade group collaboration (AMCP, ADA, etc)
  - Influence legislation

What strategies are most effective?

Situational Considerations for Impact

PRODUCT TYPE

- Bio/Pharmaceutical vs Medical Device

BENEFIT DESIGN

- Medical vs Pharmacy

PERSPECTIVE

- Payer vs Medical Provider vs Manufacturer vs Patient
- Burden → Health System vs Patient vs Society

COMPLEXITY

- Product-specific, Therapeutic Class/category vs Condition

BENEFIT STRUCTURE

- Integrated vs Carved-out Pharmacy

VALUE DEFINITION

- Clinical Endpoints vs HCRU
- TCOC vs Cost-effectiveness vs Distributional CEA
- Quality Improvement vs Equity

HCRU: Health care resource utilization; TCOC: Total Cost of Care; CEA: cost-effectiveness analysis

Questions for the Room

- What signs of progress are you seeing on the January 1, 2026 commitments?
  - How can we measure progress?
- Are PA policies and processes blocking modern innovation?
  - Can we co-create smarter, evidence-based PA frameworks?
- Are we prioritizing the patient enough over other stakeholders?
  - Who defines 'value'—and who bears the cost of delay?
- What else can manufacturer do? Or where can manufacturers focus it efforts?

Final Thought

Time For Medicare Advantage Leaders—Including Me—To Eat Our Own Cooking

By Sachin H. Jain, Contributor. ⓘ I cover transformation and innovation across... Follow Author

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In every industry, the best leaders live the experience of the customer. Car executives drive their own vehicles. Airline leaders occasionally fly coach. Restauranteurs eat from their own kitchen.

But in healthcare—and specifically in Medicare Advantage (MA), which now serves more than 30 million Americans—the leaders designing these plans rarely, if ever, use them themselves. This disconnect breeds an empathy gap between decision-makers and the seniors whose lives and well-being depend on these products.

"As a current CEO of company that sells Medicare Advantage plans, I am proposing a standard that would apply to me and every other leader in this space: if you run a Medicare Advantage plan—or sit on its executive team that runs these plans—you should be required to enroll in that plan. No carve-outs. No executive-only exemptions. No platinum side-door coverage." – Dr. Sachin Jain

Do we need to embrace this mindset for Prior Authorization?