AMCP

PARTNERSHIP FORUM

No. 2 — 2019

Optimizing Prior Authorization for Appropriate Medication Selection

JUNE 25–26, 2019 | HILTON MARK CENTER | ALEXANDRIA, VA

Welcome

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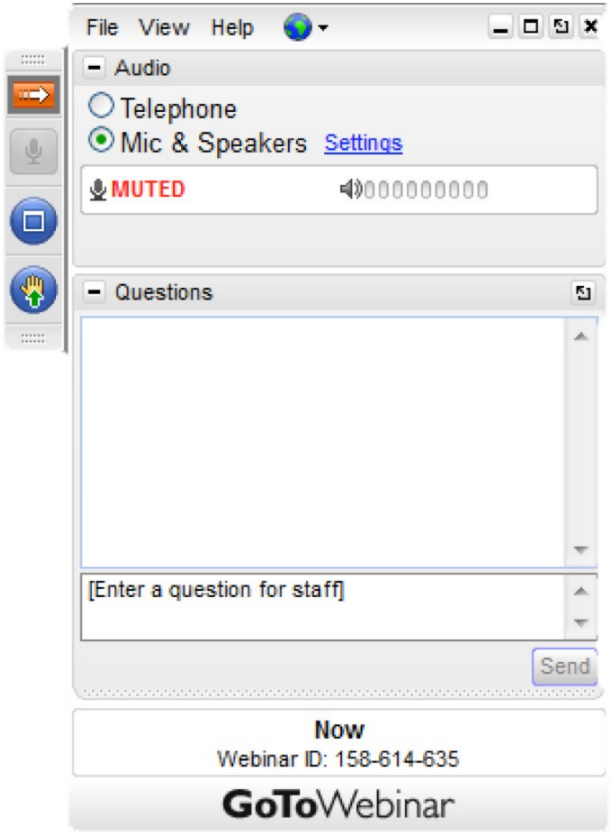
How to Ask Questions



AMCP Partnership Forums

Collaboration for Optimization

The live, hands-on AMCP Partnership Forums bring key decision makers in managed care, integrated care, the pharmaceutical industry, and other stakeholders together to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes in integrated care and managed care.

AMCP Partnership Forums

- Adopt a proactive, collaborative approach
- Provide a voice
- Gain consensus and remove barriers
- Allow stakeholders to work together on common goals and interests
- Garner high visibility
- Find common ground and actionable results

2019 AMCP Partnership Forums

- Pharmacy and Therapeutics (P&T) Practices: What's Next?
  March 28 | Marriott Marquis, San Diego, Calif.
- Optimizing Prior Authorization for Appropriate Medication Selection
  June 25–26 | Hilton Mark Center, Alexandria, Va.
- Digital Therapeutics: What Are They and Where Do They Fit in Pharmacy and Medical Benefits?
  Sept. 17–18 | Hilton Mark Center, Alexandria, Va.
- What's Next for Specialty Medication Benefit Design and Reimbursement
  Dec. 10–11 | Hilton Mark Center, Alexandria, Va.

2020 AMCP Partnership Forums

Live Forums in Alexandria, Va.

- Helping Patients Anticipate and Manage Drug Costs | March 12–13
- Preparing for and Managing Rare Diseases | Sept. 8–9
- Biosimilars: Policy, Practice, and Post Marketing Surveillance to Support Treatment and Coverage Decisions | Dec. 15–16

Workgroup

- Addressing Barriers to Value-based Payment Models in Integrated Delivery Networks

AMCP Partnership Forum Sponsors

Our Faculty

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Agenda

- Background
- Forum findings and recommendations
- Q&A
- Next steps and action items

Forum Objectives

- Improving efficiencies in the prior authorization (PA) and step therapy (ST) processes
- Addressing administrative burdens
- Increasing visibility of the clinical and economic value of these programs
- Collecting best practices around the PA process
- Improving communications among all stakeholders to minimize care delays while enhancing understanding of authorization requirements

Forum Deliverables

- Develop recommendations for approaches to reduce administrative burden for select utilization management (UM) programs
- Describe and provides examples of the value in PA programs, which include the clinical and economic value from the patient and societal perspectives
- Provide multi-stakeholder perspectives and recommendations on the elements of good practices for PA and UM programs

PA and ST

- Tools that are often applied to certain pharmacy and medical benefit services
  - Require advanced approval to qualify a product for coverage
- Support evidence-based coverage decisions, patient safety, and cost-effective medication use
- May create administrative burdens for health care providers and patients
- Stakeholders have called for review of these programs

Characteristics of Managed Medications

- Specific safety concerns, including certain drug interactions
- Availability of more affordable alternatives
- Potential for off-label use
- Potential for misuse or abuse
- Limited distribution or special handling requirements
- Multiple indications across benefits (e.g., medical and cosmetic)

Perspectives on UM Programs

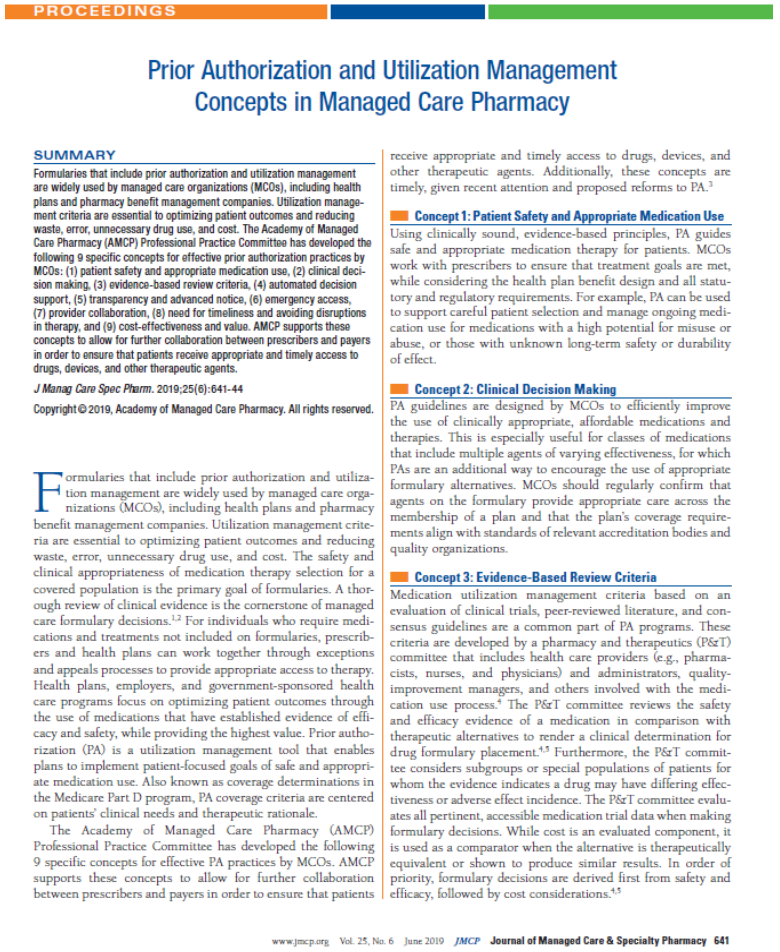
Aspect	Perspectives from Participants
Description of PA	• PA is a process for the provider to obtain approval for medications and/or services to qualify for coverage by the plan • It can be a collaborative process • It includes evidence-based criteria
Purpose of PA	• The purpose of PA is to ensure selection of safe, cost-effective, evidence-based treatment that maximizes therapeutic value • Processes should be reasonable, accessible, and timely
Appropriate use	• It's important for patients to receive access to cost-effective, evidence-based treatments. Incentives should be aligned in a manner that influences total cost of care. • Complying with appropriate PA and ST shouldn't be challenging to operationalize for providers
Disclosure and review of PA requirements	• Communications need to be relevant, available in multiple formats, and easily accessible to patients, prescribers, and pharmacists • There's a need to have some materials that are appropriate for patients, and health literacy and readability should be considered when designing these communications • Patient, prescriber, and pharmacist communication should be incorporated throughout the PA process

AMCP PA Concepts

AMCP Professional Practice Committee developed the nine specific concepts for effective PA practices by MCOs:

1. Patient safety and appropriate medication use
2. Clinical decision making
3. Evidence-based review criteria
4. Automated decision support
5. Transparency and advanced notice
6. Emergency access
7. Provider collaboration
8. Need for timeliness and avoiding disruptions in therapy
9. Cost-effectiveness and value

J Manag Care Spec Pharm, 2019 Jun;25(6):641-644.



PROCEEDINGS

Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy

SUMMARY

Formularies that include prior authorization and utilization management are widely used by managed care organizations (MCOs), including health plans and pharmacy benefit management companies. Utilization management criteria are essential to optimizing patient outcomes and reducing waste, error, unnecessary drug use, and cost. The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed the following 9 specific concepts for effective prior authorization practices by MCOs: (1) patient safety and appropriate medication use, (2) clinical decision making, (3) evidence-based review criteria, (4) automated decision support, (5) transparency and advanced notice, (6) emergency access, (7) provider collaboration, (8) need for timeliness and avoiding disruptions in therapy, and (9) cost-effectiveness and value. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices, and other therapeutic agents.

J Manag Care Spec Pharm. 2019;25(6):641-44

Formularies that include prior authorization and utilization management are widely used by managed care organizations (MCOs), including health plans and pharmacy benefit management companies. Utilization management criteria are essential to optimizing patient outcomes and reducing waste, error, unnecessary drug use, and cost. The safety and clinical appropriateness of medication therapy selection for a covered population is the primary goal of formularies. A thorough review of clinical evidence is the cornerstone of managed care formulary decisions.[1,2] For individuals who require medications and treatments not included on formularies, prescribers and health plans can work together through exceptions and appeals processes to provide appropriate access to therapy. Health plans, employers, and government-sponsored health care programs focus on optimizing patient outcomes through the use of medications that have established evidence of efficacy and safety, while providing the highest value. Prior authorization (PA) is a utilization management tool that enables plans to implement patient-focused goals of safe and appropriate medication use. Also known as coverage determinations in the Medicare Part D program, PA coverage criteria are centered on patients' clinical needs and therapeutic rationale.

The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed the following 9 specific concepts for effective PA practices by MCOs. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices, and other therapeutic agents. Additionally, these concepts are timely, given recent attention and proposed reforms to PA.[3]

Concept 1: Patient Safety and Appropriate Medication Use

Using clinically sound, evidence-based principles, PA guides safe and appropriate medication therapy for patients. MCOs work with prescribers to ensure that treatment goals are met, while considering the health plan benefit design and all statutory and regulatory requirements. For example, PA can be used to support careful patient selection and manage ongoing medication use for medications with a high potential for misuse or abuse, or those with unknown long-term safety or durability of effect.

Concept 2: Clinical Decision Making

PA guidelines are designed by MCOs to efficiently improve the use of clinically appropriate, affordable medications and therapies. This is especially useful for classes of medications that include multiple agents of varying effectiveness, for which PAs are an additional way to encourage the use of appropriate formulary alternatives. MCOs should regularly confirm that agents on the formulary provide appropriate care across the membership of a plan and that the plan's coverage requirements align with standards of relevant accreditation bodies and quality organizations.

Concept 3: Evidence-Based Review Criteria

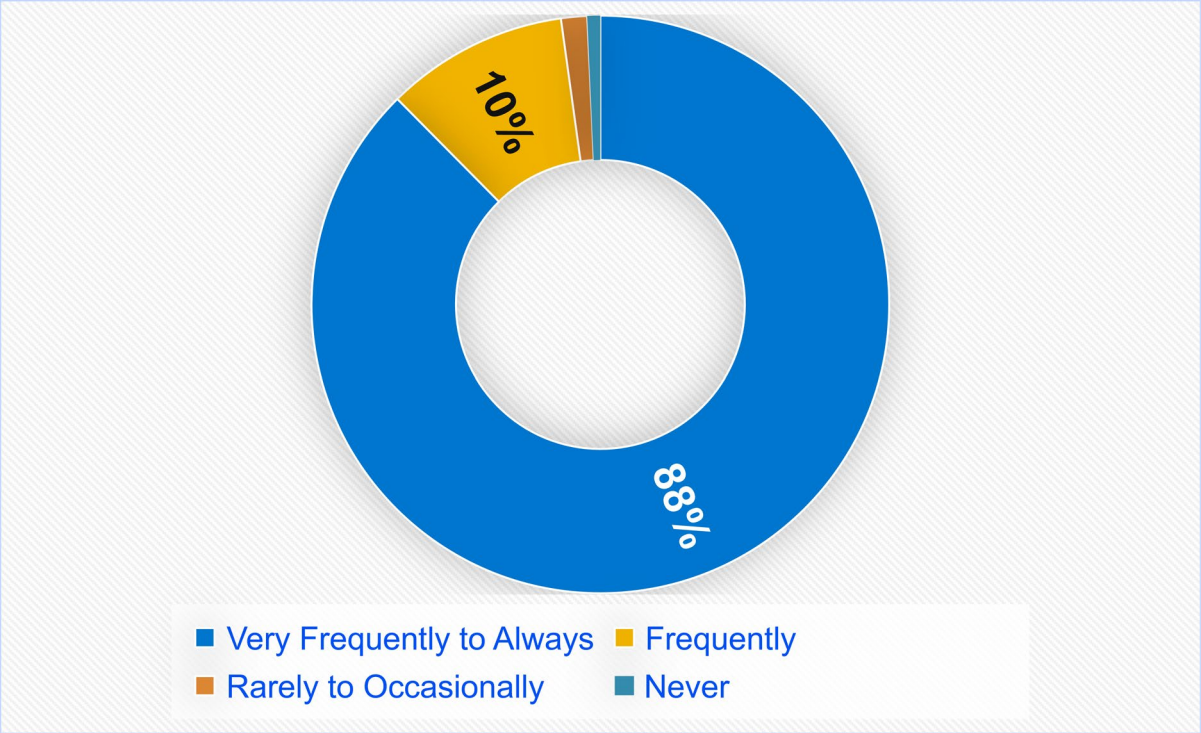
Medication utilization management criteria based on an evaluation of clinical trials, peer-reviewed literature, and consensus guidelines are a common part of PA programs. These criteria are developed by a pharmacy and therapeutics (P&T) committee that includes health care providers (e.g., pharmacists, nurses, and physicians) and administrators, quality-improvement managers, and others involved with the medication use process.[4] The P&T committee reviews the safety and efficacy evidence of a medication in comparison with therapeutic alternatives to render a clinical determination for drug formulary placement.[4,5] Furthermore, the P&T committee considers subgroups or special populations of patients for whom the evidence indicates a drug may have differing effectiveness or adverse effect incidence. The P&T committee evaluates all pertinent, accessible medication trial data when making formulary decisions. While cost is an evaluated component, it is used as a comparator when the alternative is therapeutically equivalent or shown to produce similar results. In order of priority, formulary decisions are derived first from safety and efficacy, followed by cost considerations.[4,5]

Patient Safety and Appropriate Medication Use

- A vast majority of organizations use clinically sound, evidence-based principles **in consultation with prescribers** to develop PA criteria

Concept 1

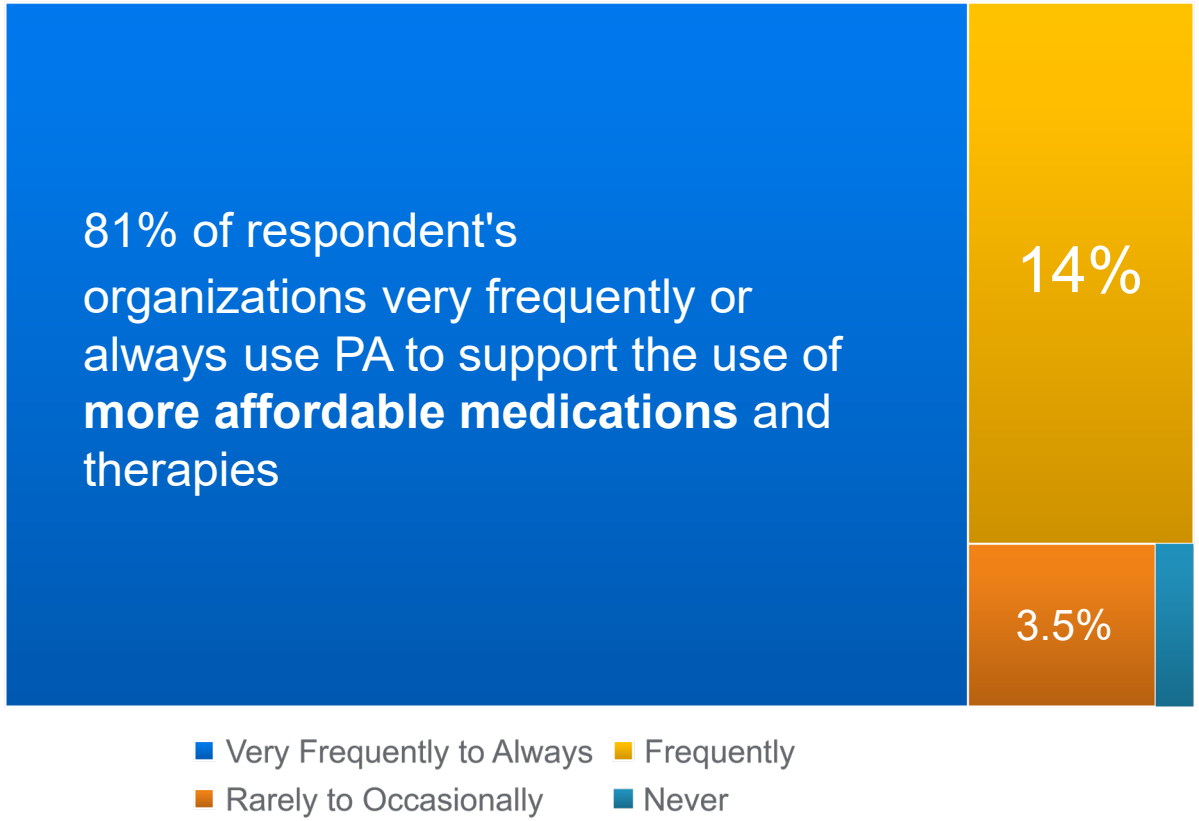
- Use clinically sound, evidence-based principles; PA guides safe and appropriate medication therapy for patients. Work with prescribers to ensure that treatment goals are met, while considering the health plan benefit design and all statutory and regulatory requirements.



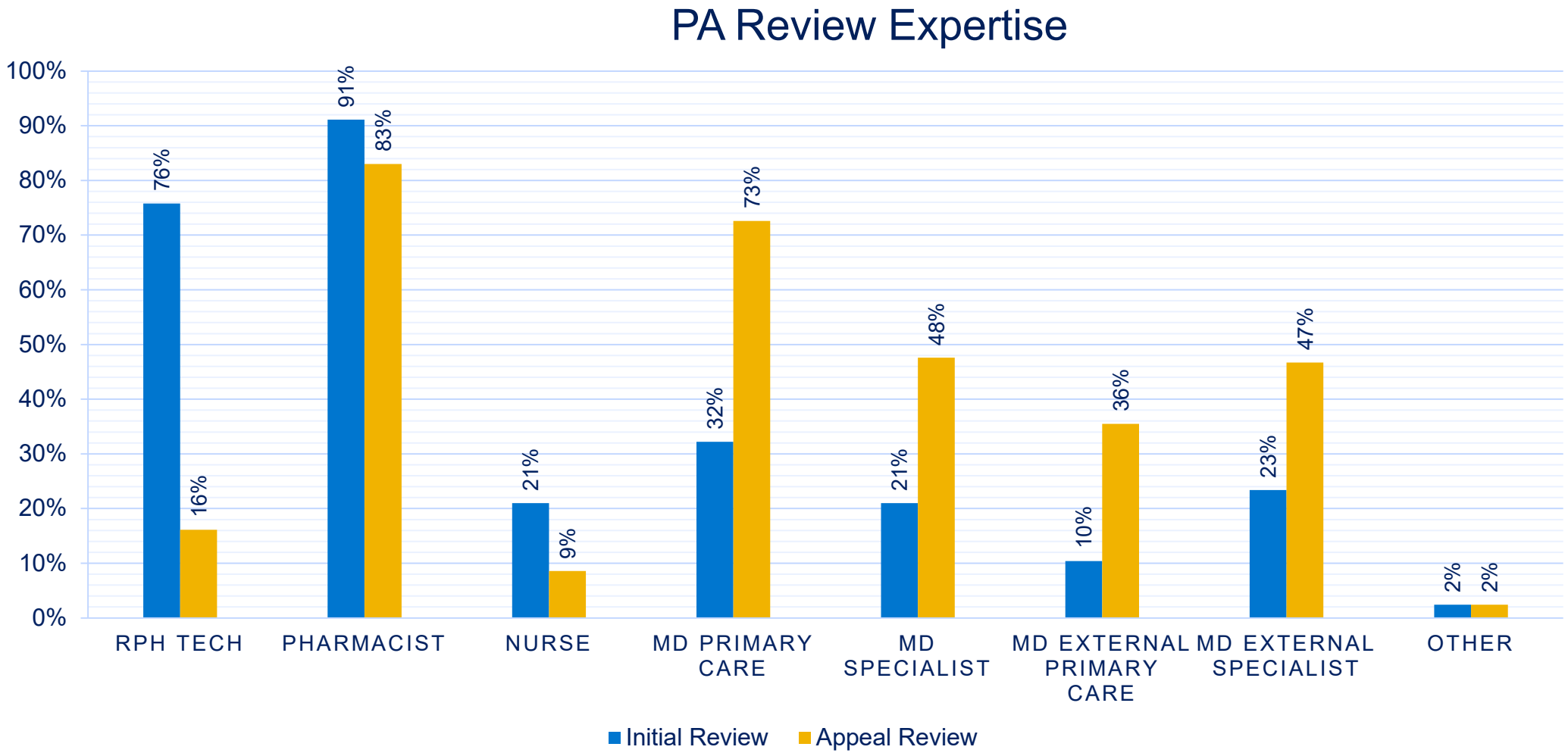
Clinical Decision Making

Concept 2

- PA guidelines are designed to efficiently improve the use of clinically appropriate, affordable medications and therapies. This is especially useful for classes of medications that include multiple agents of varying effectiveness, which PAs are an additional way to encourage the use of appropriate formulary alternatives. Regularly confirm that agents on the formulary provide appropriate care across the membership of a plan and that the plan's coverage requirements align with standards of relevant accreditation bodies and quality organizations.



Data Collection and Reporting



Q: What are the specialties of your organization's staff/clinicians engaged in PA reviews? (Choose all that apply)

Opportunities for Improvement

- Addressing burdens for patients, prescribers, and pharmacists
- Transparency for stakeholders
- Clarity regarding requirements
- Addressing variability among plan requirements
- Reducing complexity of criteria
- Expanding the use of electronic PA (ePA)

Guiding Principles for PA Reform

	Organization					
	AMA	ASCO	NPF	SAIM	NAF	AMCP
Clinical criteria for protocol development	✓	✓	✓	✓	✓	✓
Transparency of protocol	✓	✓	✓	✓	✓	✓
Continuity of care	✓	✓	✓	✓	✓	✓
Opportunity to appeal	✓	✓	✓	✓	✓	✓
Flexibility for provider input	✓	✓	✓	✓	✓	✓
Financial considerations	✓	–	–	–	–	✓
Evaluation of program impact	✓	✓	–	✓	–	–
Protocol updates	–	✓	–	✓	–	✓

✓= stakeholder discusses theme, – = stakeholder silent on theme. AMA = American Medical Association, ASCO=American Society of Clinical Oncologists, NPF=National Psoriasis Foundation, SAIM=State Access to Innovative Medicines Coalition, NAF=National Arthritis Foundation.

Adapted from: Karmarkar T. Legislative activities and reform principles in prior authorization: Where are we today? Presented at: AMCP Partnership Forum. Optimizing Prior Authorization for Appropriate medication Selection. Alexandria, VA, June 26, 2019

Themes for UM Reform

- Focus on the patient's experience while addressing other stakeholder needs
- Return autonomy to the point-of-care for prescribers who practice evidence-based medicine
  - Requires accountability for cost-effective care
- Decision-support resources that remain abreast of new evidence are important to support evidence-based decision making

Contributors to Burden

- The burden on prescribers, pharmacists, and patients is well described
- Complicated by a lack of consistency across formularies, requirements, and processes among plans, even for the same medication
- Inconsistency due to:
  - Different employer priorities
  - Variations among regulations by state and line of business
  - Variations in plan organizational priorities and business operations

Opportunities with ST and Clinical Pathways

- Develop criteria that allows prescribers to answer “yes” or “no”
- Rely on provider attestations to avoid submitting patient records (e.g., PDFs)
  - PDFs may not be readable/interoperable with some technology systems
- Define role of clinical practice guidelines
  - Readily available, current, and sufficiently specific for the disease being treated
  - Could support consistency of criteria among plans

Opportunities with Denial and Appeal Processes

- Establish timelines for processes to minimize care delays
- Define qualifications of individuals reviewing requests
- Provide clear patient-centric communications about reason(s) for denials

Pharmacist-initiated PA

- Shifts administrative burden from physicians
- Pharmacists can access information from the patient's prescription history to supply to the plan to process the PA
- Ideally, pharmacists will also have direct access to the patient's electronic health record (EHR)
- Greater accessibility of pharmacists to patients, particularly on evenings and weekends, is a benefit for patients

Evaluating and Changing PA Criteria

- Criteria and associated metrics should be reviewed regularly
- Can identify therapies that no longer warrant PA, as well as those that PA is appropriate
  - Ideally, information about rationales for denials and appeals will be available to assess the clinical relevance of the criteria
- Sunset and gold card programs remove criteria either entirely or for a subset of providers
  - Can reduce provider burden but also have undesirable changes in prescribing behavior

ePA Programs

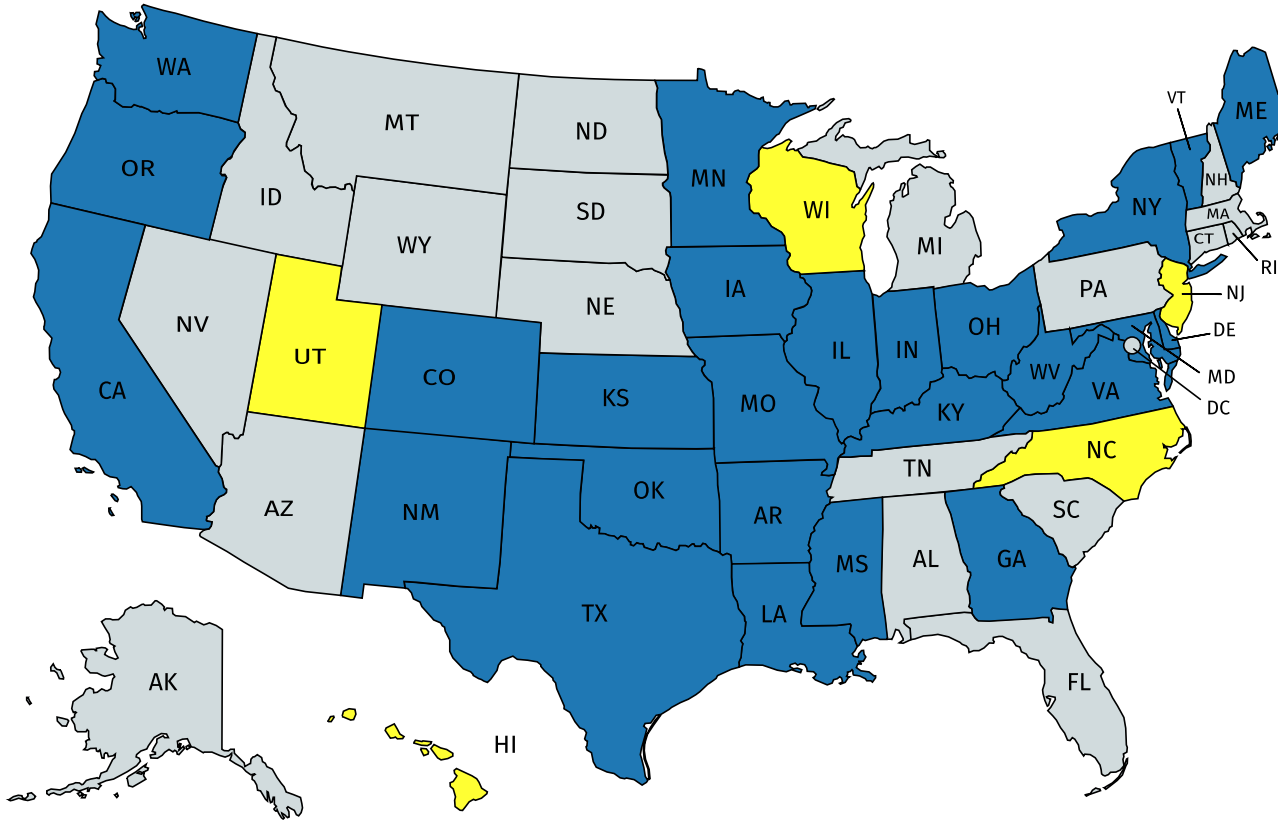
- Can automate many steps of PA process, reducing burdens
  - More seamless process and can reduce time for approval
  - Can function as a decision support tool, but access to such programs is limited
  - Use polar questions (e.g., yes/no responses)
- Ideally would connect in real time with EHR systems to gather required information
  - Faces interoperability challenges
- Standardized user interfaces and processes could improve consistency of ePA programs and improve consistency

State Legislative Concepts

- Generally aligned with stakeholder principles and statements
  - Clinical criteria must be evidence-based, current, consider provider input, and accommodate unique patient populations
  - ST protocols should be accessible, include electronic processes for communication, and have flexibility to accommodate individual needs
  - Patients should not be required to repeat treatment steps
  - Interruptions in care should be avoided
  - Appeals processes should be clear and readily accessible
  - Prescribers have the option to request overrides with appropriate justification

State Legislative Concepts as of June 2019

- Most existing state legislation has provisions for clear exceptions and appeals processes for PA and ST
- Common areas of focus include timelines and appeals processes
  - For example, state-required time limits for the review of appeals range from 24 to 72 hours
- A few states have specific provisions for patients with advanced metastatic cancer



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Federal Legislation

- Safe Step Act (H.R. 2279)
- Amends ERISA to require an exceptions process for ST programs
- Calls for clear processes for exceptions
- Lists requirements for granting exceptions
- Requires that exceptions be granted within 72 hours
  - 24 hours in urgent situations

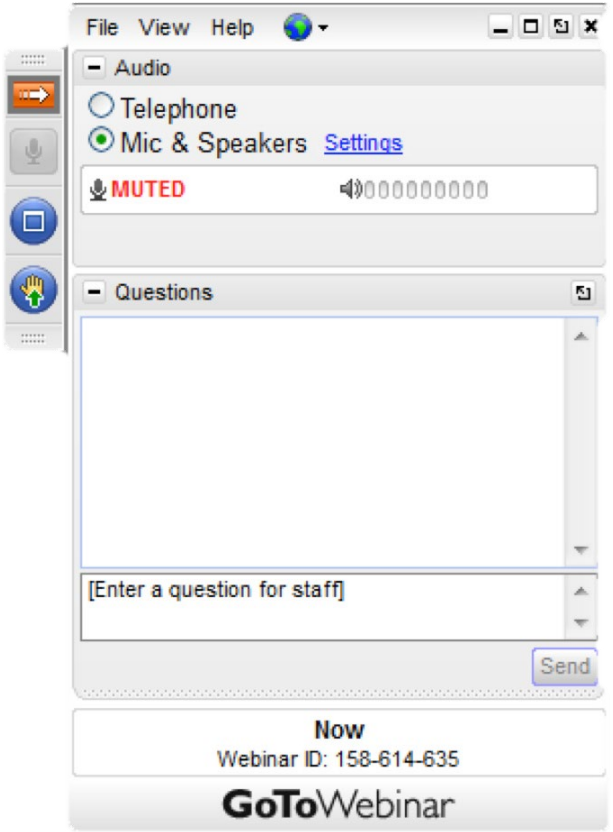
Strategies to Advance Reform

- Creation of model legislative language to address all stakeholder needs
- Beyond legislation, other options can include reporting requirements for certain plans (e.g., Medicare Part D) and work with accrediting bodies
- The role of health plans/PBMs in adopting process improvements

Summary

- Ongoing collaborations are needed to develop solutions that meet the needs of all involved parties
- Solutions may increase automation and transparency
- Maintaining prescriber autonomy, coupled with accountability, can support evidence-based, cost-effective treatments
- Legislative and regulatory approaches should consider needs of all stakeholders
- Focus on ensuring evidence-based cost-effective patient care

How to Ask Questions



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Next Steps

The proceedings of the Partnership Forum has been published in the January 2020 *Journal of Managed Care and Specialty Pharmacy*.

For a list of upcoming webinars, visit www.amcp.org/calendar

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Mission

To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.