Improving Your Formulary and Denials Management

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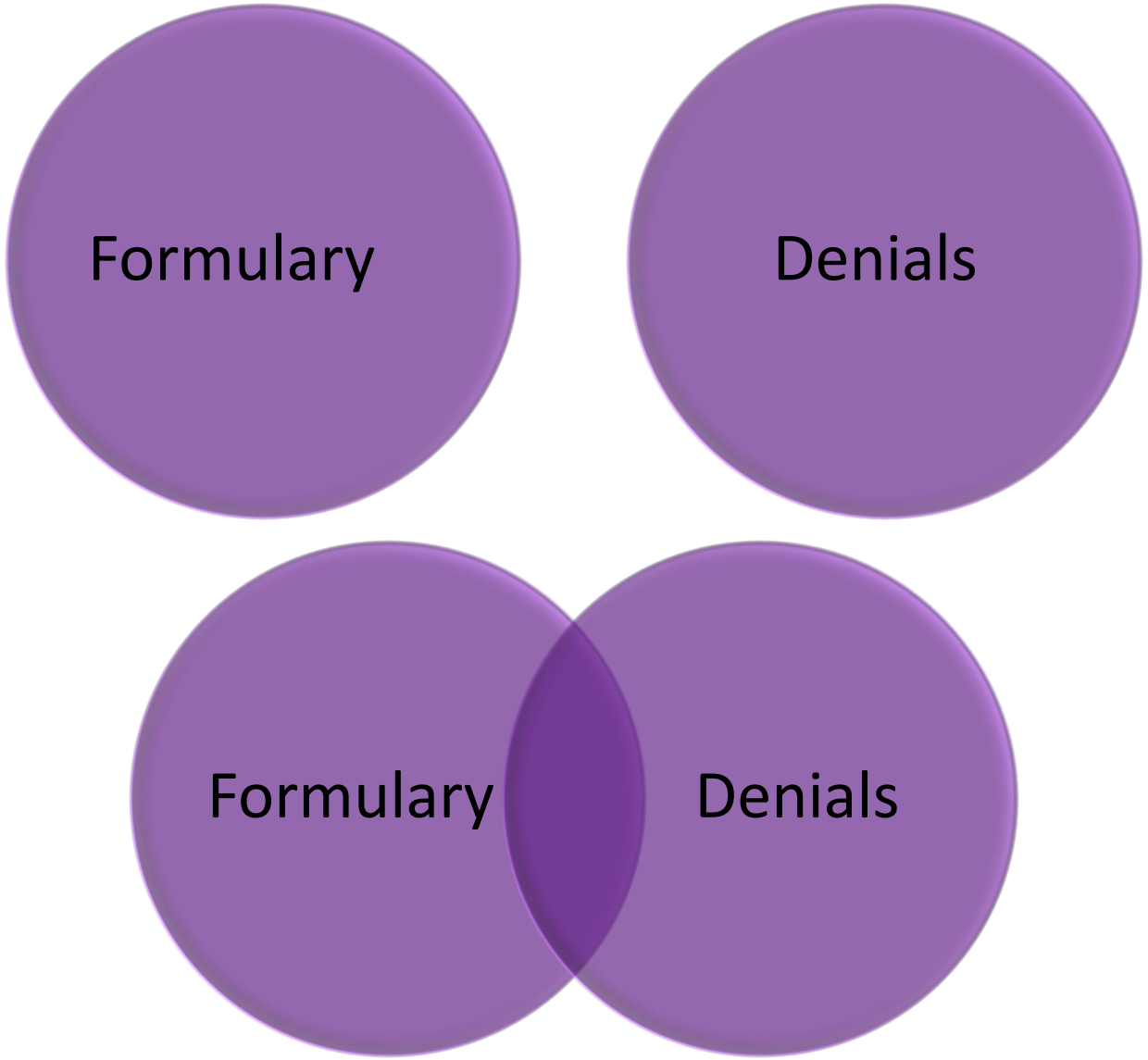
Interplay Between Formulary and Denials



Formulary Principles

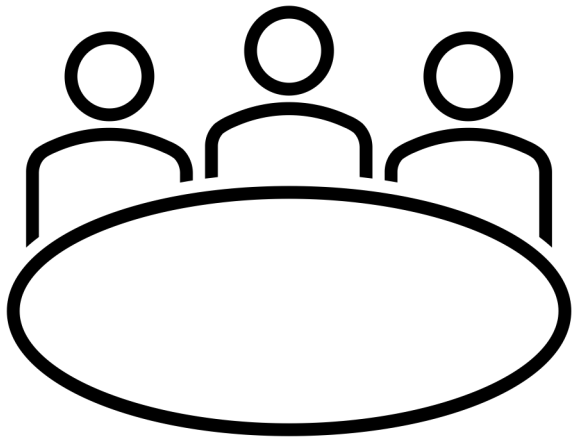
- Purpose of formulary
  - Guides providers to utilize effective, affordable, and safe medications
- Requires multidisciplinary input and discussion
- **Constantly** evolves based on up-to-date primary literature
  - Additions
  - Removals
  - Restrictions

Formulary Principles

Factors influencing formulary decision-making

- Clinical effectiveness (or lack thereof)
- Payor policies
- Cost
- Reimbursement (or lack thereof)
- Anticipated frequency of use
- Operational considerations
- U.S. Food and Drug Administration (FDA) approval limits (i.e., accelerated approval)

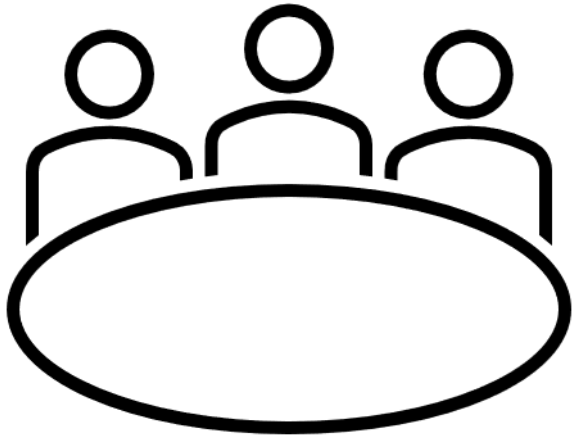
Establishing a Formulary Review Group



- Anti-cancer therapies **need** a dedicated forum to have meaningful discussions
  - *Imperative that the group meets regularly*
- Establish priorities and goals

Establishing a Formulary Review Group

- Membership must be multidisciplinary and should be content experts
  - *Absolute must to have is support for data needs*
- The group must have authority to establish policies and procedures that have system-wide implications



Tools to Develop and Assess Formulary

- Medication use evaluations
  - Process to systematically review and summarize trends in medication prescribing habits
  - Identify shifts in prescribing habits or gaps in formulary (i.e., indication creep)

Tools to Develop and Assess Formulary

- Medication monographs
  - Summarize key safety and efficacy data points
  - Monograph should make concise recommendation “where” this medication could/will be used
- Share costs and reimbursement openly

Factors Influencing Formulary Status

- FDA approvals/ indications
  - *Accelerated approvals should always be reassessed when data matures*
- FDA safety alerts
- Updates to practice guidelines (National Comprehensive Cancer Network [NCCN], American Society of Clinical Oncology [ASCO], etc.)

Factors Influencing Formulary Status

- Competitive pricing
  - Newly approved generics or biosimilar products
- Major cost, reimbursement, or payer policy changes/shifts

Factors Influencing Formulary Status

- Anticipated frequency of use
- Anticipated reimbursement (or lack thereof):
  - Unclassified Healthcare Common Procedure Coding System (HCPCS) code
  - Centers for Medicare & Medicaid Services (CMS) status indicator (K,G,N)

Factors Influencing Formulary Status

- Operational considerations:
  - Limited distribution or Risk Evaluation and Mitigation Strategy (REMS)-restricted medications
  - Storage requirements/limitations

Formulary Restrictions

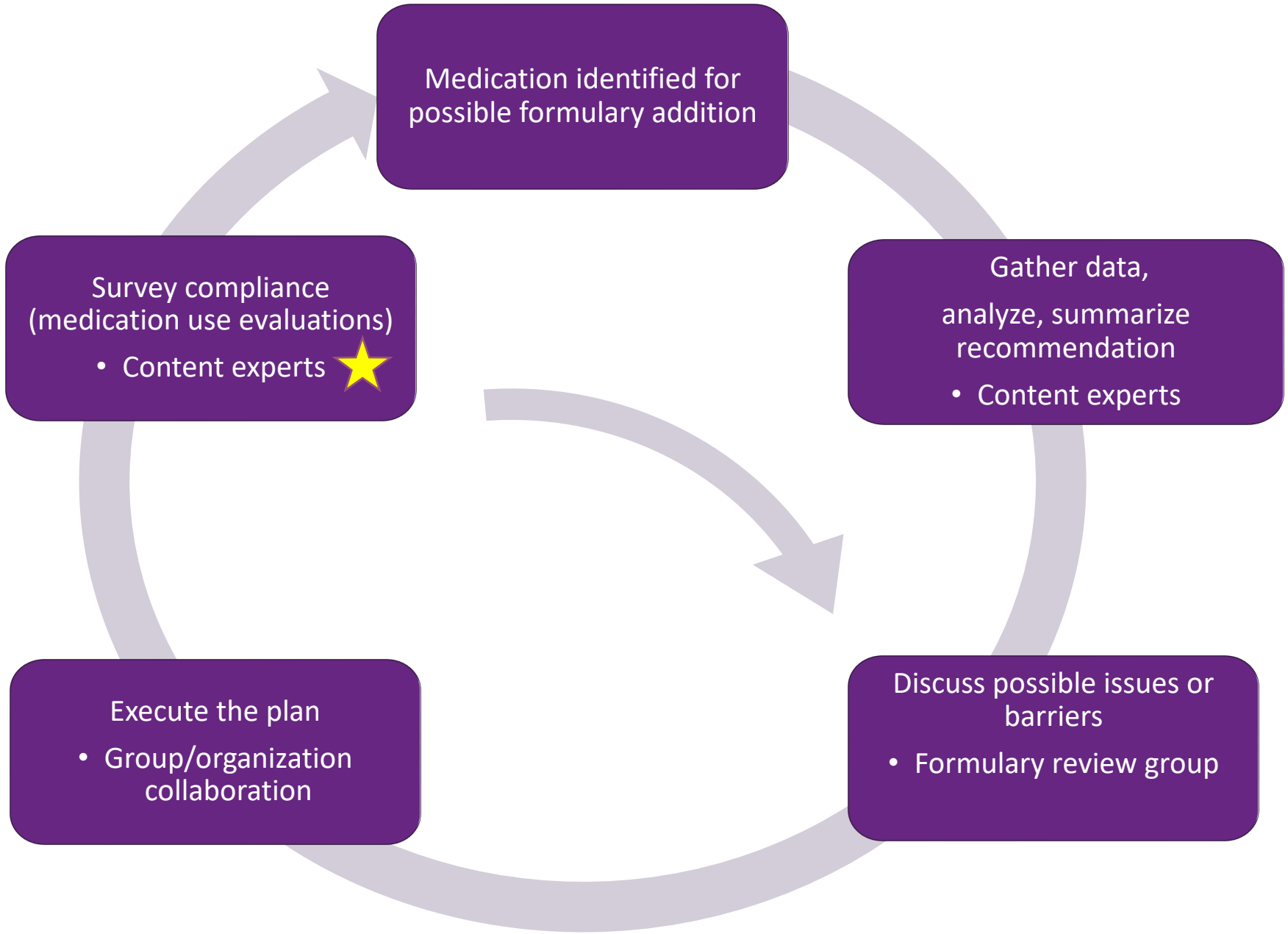
- Implemented for medications that merit formulary addition in very specific scenarios
- Requires policing/oversight to assure medication use doesn't "creep" to non-approved scenarios
- Restrictions can be based upon numerous criteria:
  - Specific patient populations or indications
  - Site of service (i.e., inpatient vs. outpatient)
  - Prescriber scope or sub-specialty

Factors Influencing Removal from Formulary

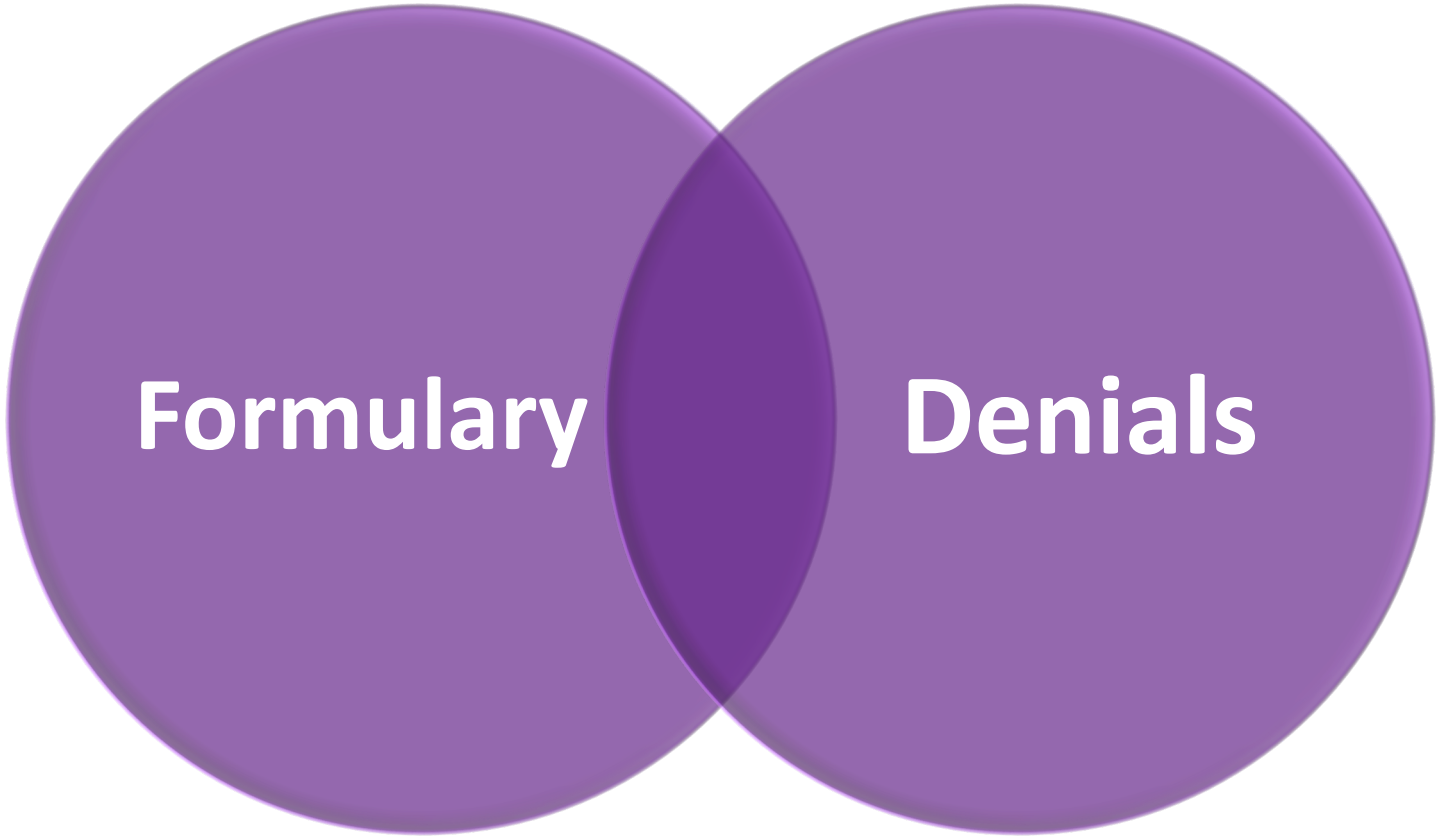
- Low or no utilization of an agent in a period of time
- FDA labeling updates:
  - Accelerated approval pitfalls
    - Olaratumumab
    - Approved via accelerated approval 2016
    - FDA approval withdrawn 2020
- Alternative agent with equal efficacy with lower cost or better (or both) is available
- Withdrawn from market

Formulary in Summary

- Formulary should reflect evidence-based, cost-effective medications that are needed to treat the majority of patients day-to-day
- Requires frequent assessment in the form of medication use evaluations
  - Verifies restrictions are being followed/enforced
    - *If they aren't….why aren't they being followed/enforced?*
  - Necessitates review of the current literature to confirm formulary offerings are in alignment with guidelines


Medication identified for possible formulary addition
Gather data, analyze, summarize recommendation
• Content experts
Discuss possible issues or barriers
• Formulary review group
Execute the plan
• Group/organization collaboration
Survey compliance (medication use evaluations)
• Content experts

Interplay Between Formulary and Denials



Helpful Resources for Denials Investigation

- HCPCS codes lookup
  - CMS Addendum B report1 (make sure it's the most recent quarterly report)
- Medically unlikely edits (MUEs)2 caps
  - CMS website
- FDA Purple Book3
  - Compendia that lists reference products and their corresponding biosimilar products or interchangeable biosimilar products

All are free!!

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Managing Denials

- Denials can be avoided in the majority of instances
- Denials are a symptom of a larger issue:
  - ✓ Workflow issues
  - ✓ “Broken” or deficient electronic health record (EHR) logic
  - ✓ Inappropriate medication selection (i.e., prescriber trends)
    - Ties back into formulary review process
  - ✓ Changing payor policies
- Prior authorization team members are imperative to ensure minimal denials

Common Reasons for Denials

- Site of care policies
  - Policies restricting the use of agents to a specific location
    - Carving out hospital-based encounters
- Mismatched indication with medication
  - No or inappropriate ICD-10 code submitted with claim

Common Reasons for Denials

- Wrong HCPCS code authorized
  - Commonly happens with biosimilar medications
- Medical vs. pharmacy benefit coverage
  - Rapidly growing trend where payers are carving out medication coverage and forcing the use of white bagging

Biosimilar Medications[4]

- A **biosimilar** is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product
- Reference product
  - The single biological product, already approved by FDA, against which a proposed biosimilar product is compared

Biosimilar Medications

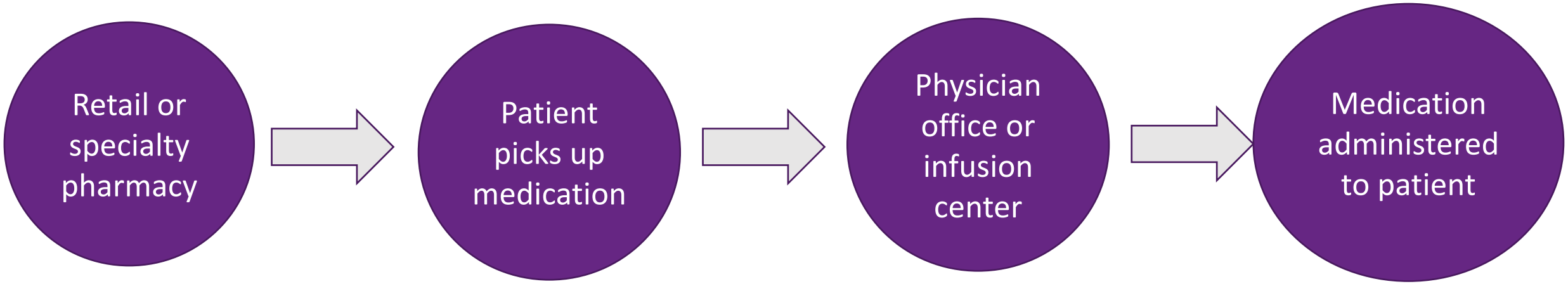
- Examples
  - Bevacizumab (Avastin®) — Reference product
  - Bevacizumab-awwb (Mvasi®)
  - Bevacizumab-bvzr (Zirabev®)
  - Bevacizumab-maly (Alymsys®)

  } Biosimilar products

Biosimilar Medications

- All biologics (reference product or biosimilar) have a unique HCPCS code:[5]
  - Bevacizumab—J9035
  - Bevacizumab-awwb—Q5107
  - Bevacizumab-bvzr—Q5118
  - Bevacizumab-maly—C9142
- Important tip:
  - When searching CMS Addendum B spreadsheets1 for biosimilars, you must use the proprietary (brand) name

Medication Bagging—Brown Bagging



Medication Bagging—White Bagging

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Unique Denial Reasons

- Exceeding the CMS established MUEs
  - MUE is a CMS managed list of a “maximum” doses
- Medications dosed on body weight or body surface area particularly at risk
- Important tip:
  - FDA labeling changes prior to MUEs list updating
    - Happened when nivolumab received FDA approval for 480mg every 4 weeks
    - Took 3 months for MUEs to match FDA labeling

Managing Denials “The Post-Mortem”

- Establish a process to escalate denials and set a cadence for review
- Reimbursement should be “followed” by accounts receivable
- Discrepancies need escalated back through to prior authorization group
  - Appeal and resubmit if needed
  - Pharmacy team needs to know about trends
- Weekly review of denials is ideal

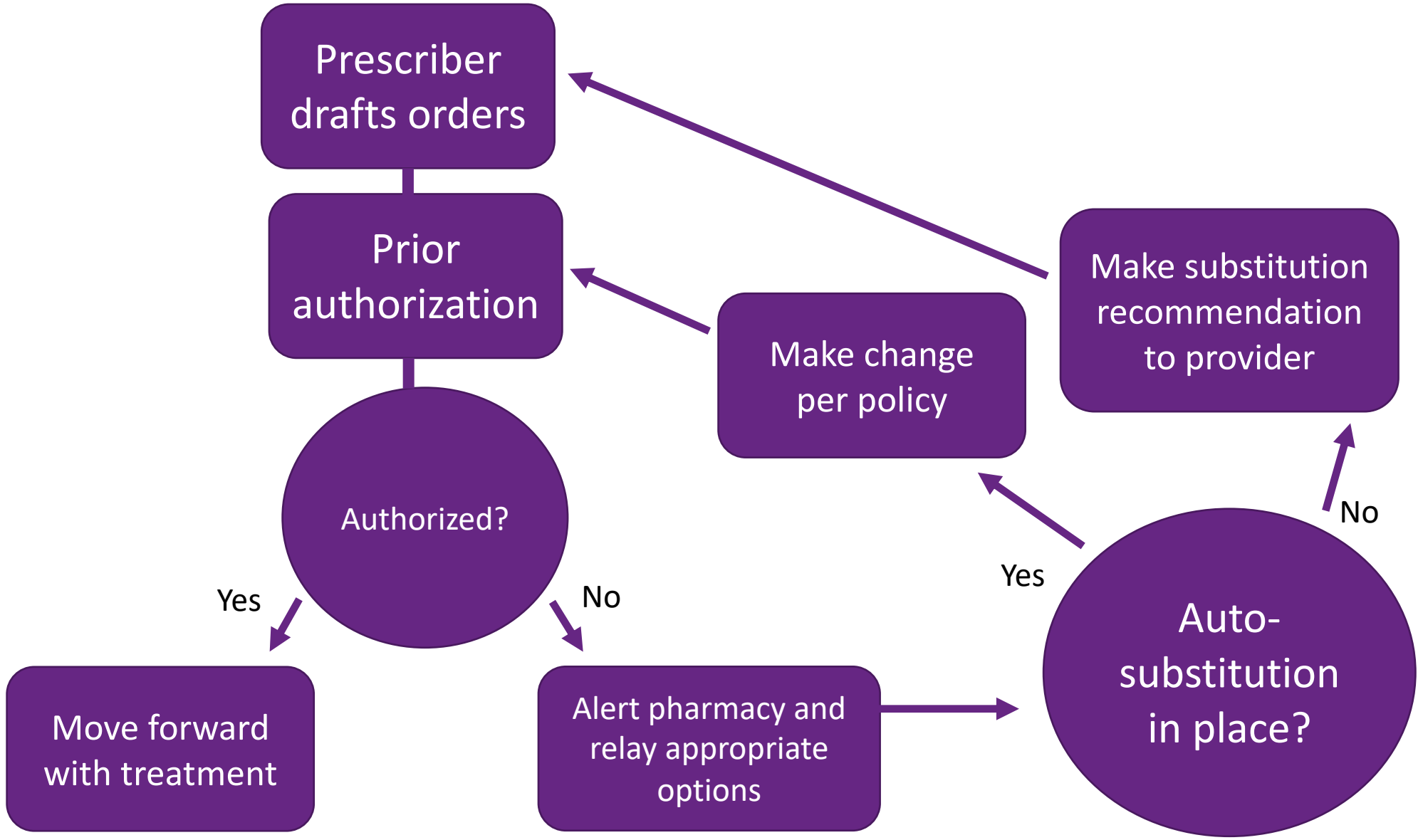
Managing Denials “The Post-Mortem”

- Determine the root cause of denial and communicate that information to the group(s) who have involvement in that task
- Assess workflow to determine if a task or process needs updated to prevent from happening in future
- Implement the change
- Assess effectiveness or ineffectiveness

Preventing Denials

- “Hard-wire” orders to default to the formulary-preferred medication
- Set up standard operating procedures when the formulary preferred doesn’t match a payer’s policy
  - Auto-substitution policies are your friend
  - Keep prescribers out of the process (unless their input is a must)
    - Consumes time

Prior Authorization Process Map



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Summary

- Formulary and denials influence one another
- Establish a formulary review group that's multidisciplinary
- Assess formulary compliance (or lack thereof)
  - *Ask, "What's getting denied and why?"*
- Use all the references you have (most of which are free!)
- Review denials weekly and communicate trends to formulary group
- Keep prescribers out of the process if possible

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