California's Drug Formulary: An Overview

Barbara Wynn

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AB 1124 Requires an Evidence-based Prescription Drug Formulary

- Establish the formulary by July 1, 2017 as part of the medical treatment utilization schedule with maximum transparency possible
  - Applies to all prescribers and dispensers serving injured workers.
  - Does not apply to care provided in an emergency department or inpatient setting .
  - Phased implementation for workers injured prior to July 1, 2017.
- Guidance on its use should facilitate providing appropriate medications expeditiously while minimizing administrative burden and cost.
- Guidance should address:
  - Access to appropriate pain management therapies and off-label usage
  - Use of generic drugs unless use of a medically necessary brand-name is cost-effective and evidence-based

AB 1124 Provisions (con't)

- Networks must provide access to all formulary drugs. Standards for networks should:
  - Seek to reduce drug costs
  - Require access to a pharmacy within reasonable distance from worker's home.
- The formulary should be updated at least quarterly
  - The AD will consult with an independent 6-member Pharmacy and Therapeutics Committee (P&T)
  - Updates may be implemented through orders posted on the DWC website

Working Assumptions Guiding RAND's Analyses

- The formulary should be designed to maximize quality of care and health and work-related outcomes
  - Drug policies should:
    - Be consistent with MTUS and integrated with the medical necessity dispute resolution process (UR/IMR)
    - Provide an appeal process for obtaining medically necessary evidence-based drugs
  - Process for determining formulary drugs should be transparent and evidence-based
- Controlling spending is important but secondary objective. The tools for doing this are primarily:
  - Evidence-based use of generic drugs and therapeutic alternatives
  - *Prior authorization* of high cost or high risk drugs
  - OMFS for pharmaceuticals

Note: in this context, prior authorization means the drug must be pre-authorized before dispensed

Draft Criteria for Evaluating Alternative Formularies

- Reliance on evidence-based criteria in determining the drugs and recommendations for the formulary
- Established process for regular updates to the formulary drugs and recommendations
- Transparency in the decision process used to establish and maintain the formulary drug list and recommendations
- Compatibility with the medical treatment utilization guidelines
- Accessibility and ease of use by treating physicians, payers, and injured workers
- Focus on drugs needed for injured worker conditions

Should additional criteria be considered? Which are most important?

Issue: Compatibility with MTUS

- The existing evidence-based formularies that RAND is assessing are maintained by:
  - ACOEM
  - ODG
  - Washington State
  - MediCal (without manufacturer restrictions)
- Each formulary maintainer bases its formulary on its own treatment guidelines and has different policies for classifying drugs
- The MTUS draws on different sources for its guidelines:
  - ACOEM (body parts, e.g., neck and upper back, shoulder, low back, etc.)
  - ODG (chronic pain with modifications; mental health and stress–proposed)
  - DWC (opioid in rulemaking)
- It will be challenging to adopt an existing formulary that uses different guidelines than the MTUS

What approach should be taken to integrating the formulary and MTUS?

Issue: Integration with the UR/IMR process

- *Prior authorization* (PA) is a key tool used in WC formulary design
  - Creates an incentive to prescribe medically appropriate therapeutic alternatives that do not require prior authorization
  - Protects against prescribing a high risk or high cost drug unless it is medically necessary and there is no evidence-based treatment alternative

- For example, Tennessee will require PA for the "N" need prior authorization) drugs on the ODG formulary, compound drugs and topical ointments, and experimental drugs.

- When prior authorization is not required, an underlying assumption is that care is consistent with the treatment guidelines.

- Issue: what happens when care is inconsistent with the MTUS?

What safeguards should be employed at point-of-sale?
When should retrospective review occur?
Who is liable if retrospective review determines the treatment is inconsistent with the guidelines?

Other Important Topics

- What types of drugs should be included in the formulary?
- When should prior authorization be required?
- What policies should apply to the use of generic versus brand names? Off-label usage? Compound drugs? Investigational or experimental drugs?
- How do formulary policies integrate with medical treatment guidelines and UR/IMR?
- How are formulary policies enforced at point of sale?
- What special policies are needed, if any, for claims with dates of injury occurring before July 1, 2017 or for injured workers receiving drugs that are affected by a formulary update?

Issue: Criteria for Evaluating Formulary Alternatives

- Should other criteria be considered?
- Which criteria are most important?
- How important is a single integrated formulary?

Issue: What types of drugs should be included in the formulary?

- Should all FDA-approved prescription drugs be included?
  - Over-the-counter drugs?
  - Intrathecal drugs?
  - Any non-drug items?
- Should only outpatient drugs dispensed for home use be included? Should any drugs used during patient encounters in a hospital outpatient clinic, ambulatory surgery facility or physician office be included?

Issue: When should prior authorization be required?

- What criteria should be used to classify drugs as requiring prior authorization? Should the classification apply across-the-board to the drug or differentiate by condition?
- Should there be a “first fill” policy for new injuries?
- Should different policies apply to physician-dispensed versus pharmacy-dispensed drugs?

Issue: What policies should apply to specific types of drugs?

- Generic versus brand names?
- Off-label usage?
- Compound drugs?
- Investigational or experimental drugs?
- Other?

Issue: Integration with MTUS and UR/IMR process

Formulary design

What approaches should be considered to integrate the formulary drug list and policies with the MTUS?

Integration with UR/IMR

- **If prior authorization is not required,**
  - What safeguards should be employed at point-of-sale?
  - When should retrospective review occur?
  - Who is liable if retrospective review determines the treatment is inconsistent with the guidelines?
- Should IMR or a separate appeals process be used if treatment is denied or modified?

Issue: Enforcement of formulary policies at point-of-sale

- What are the processes/policies that could be used to enforce the formulary at point-of-sale?
- How might they differ for:
  - Network versus non-network pharmacies?
  - Pharmacy-dispensed versus physician-dispensed drugs?
- What policies need to be included in the formulary rules versus payer-determined?

Issue: Updating process

- How frequently should the formulary be updated?
- What update process should be used?
- What is the role of the Pharmacy and Therapeutics Committee?
- How should public input be obtained?

Issue: Implementation Policies

- What special policies are needed, if any, for:
  - Claims with dates of injury occurring before July 1, 2017
  - For injured workers receiving drugs that are affected by a formulary update?
- How much time is needed between adoption of the final rules and implementation for billing processing (and PBM) systems changes?
- Are there other key issues that need to be considered in the formulary design and implementation?