California’s Drug Formulary: An Overview

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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?