Formulary Management Practices in the Federal Sector

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CPE Information

• Target Audience: Pharmacists & Technicians
• ACPE#: 0202-0000-16-162-L04-P/T
• Activity Type: Knowledge-based

Learning Objectives

• Compare and contrast the review process within the IHS, VA, and DoD system that results in formulary decisions.
• Describe the tools used by IHS, VA, and DoD to help implement formulary decisions.
• Outline contracting mechanisms used by IHS, VA, and DoD to improve the cost-effectiveness of formulary decisions.
• Examine the budget impact of formulary management strategies within IHS, VA, and DoD systems.

Self-Assessment Questions

• Which of the following mechanisms are not used by VA to help implement formulary decisions?
  – A. Criteria for use
  – B. Drug standardization list
  – C. Tiered copays
  – D. National contracts

• IHS utilizes which of the following
  – A. Open Formulary
  – B. Basic Formulary
  – C. Closed Formulary
  – D. Core Formulary
Self-Assessment Questions

- True or false: DoD beneficiaries have access to three pharmacy points of service

AI/AN 2010 Population Census

<table>
<thead>
<tr>
<th>2010 U.S. RACE BREAKDOWN</th>
<th>POPULATION</th>
<th>PERCENTAGE</th>
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<td>White alone</td>
<td>229,397,472</td>
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<td>Two races excluding Some other race, and Three at most races</td>
<td>9,898,520</td>
<td>3.19%</td>
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United States Total: 309,349,689

Source: U.S. Census Bureau, 2010 American Community Survey

Indian Health Service

- Patients: 2.2M AI/AN Served
- Facilities
  - 662 facilities, 270 use PPV
- Budget: $4.8B in 2016
- Rx utilization: Unable to provide
- Rx Expenditures: $403M in 2016

Formulary Review Process

- IHS utilizes a National Core Formulary (NCF)
- The IHS National Pharmacy & Therapeutics Committee (NPTC) oversees and updates NCF

The Indian Health Care System

IHS

FEDERAL TRIBAL URBAN
**NPTC & NCF History:**

- 2001: Executive Leadership Group tasked the National Formulary Work Group (NFG) to make recommendations for a National Core Drug Formulary to:
  - Reduce disparities between facilities
  - Improve quality of care
  - Assist in managing pharmaceutical costs

- Prior attempts to influence prescribing through national disease management guidelines failed

**NPTC & NCF History (cont’d):**

- NFG convened, met with VA and DoD, and made several presentations to IHS leadership:
  - Final report delivered November 2002
  - Included recommendations for National Core Formulary, National P&T Committee, and a funding mechanism
  - Authorization of NCF and NPTC in February 2004
  - 1st meeting December 2004

**NPTC purpose & organization:**

- Permanent Committee chartered with the responsibility of:
  - maintaining the National Core Formulary (NCF)
  - providing ongoing therapeutic and cost management support for I/T/U facilities

- Comprised of:
  1. Field membership
     - 12 members, one pharmacist/physician from each Area, active in clinical practice
     - Physicians must maintain majority for field credibility/acceptance of NPTC decisions
  2. Executive officers / Leadership
     - Physician Chairperson: CAPT Stephen "Miles" Rudd, MD, FAAFP
     - Pharmacist Vice-Chair: CAPT Ryan Schupbach, PharmD, BCPS, CACP, NCPS

**So…what the heck is the NCF and why would the IHS want one?**

- NCF purpose defined...
  - "The principle purpose of a core formulary is to ensure the availability of drugs needed to provide basic standards of care for health conditions that cause the greatest morbidity and mortality in the service population" - Hays H. IHS Prim Care Prov. 2005. 30;(4):83‐91.
  - "Another purpose, however, is to promote practices that produce the greatest efficiencies in pharmacy cost management without sacrificing quality of care."

**How is the NCF different from others (VA, DoD) and why are there so few medications on it?**

- Core vs. Comprehensive Formulary
- Basic chronic disease management (2004)
  - DM, HTN, CVD, Asthma, Chronic Lung Disease, Stomach Ulcers, Arthritis, Depression & anxiety
- Local formulary and the NCF

**NCF Core Criteria: Inherent to all formulary additions**

Affirmative answers to questions lead to inclusion on NCF:

1. Is this drug expected to be used by a substantial proportion of IHS patients?
2. Is this drug a core component of the current standards of care?
   Conversely: Can an IHS provider deliver appropriate medical care to a significant majority of patients without using this medication?
3. Will the availability of this medication at all I/T/U facilities substantially enhance the portability of the pharmacy care benefit?
NPTC decisional considerations

Overall goal:
- develop a list of the safest, most effective medications that produce the desired goals of therapy at the most reasonable cost to the healthcare system

Safety: *Primum non nocere* (Latin: “First, do no harm”)
- ADRs, common dosing errors, recalls, look-alike/sound-alike, FDA Drug Safety Communications

Efficacy:
- Relative Risk Reduction, Absolute Risk Reduction, NNT/NNH, Odds ratio, Hazard ratio, Net benefit, composite outcomes/endpoints

National Pharmacy & Therapeutics Committee and the IHS National Supply Service Center

Pharmacoeconomic Review
- Agency procurement (purchasing) and utilization trends
- National Data Warehouse and implications
- When ≥2 medications produce similar effectiveness and safety, then business elements like cost, ease of delivery or other unique properties considered

Tools For Implementation

- www.ihs.gov/nptc/

www.ihs.gov/nptc/formulary/

IHS National Core Formulary: Pharmacologically Sorted
ANNUAL NPTC PERFORMANCE REVIEW: -2015-

NSSC/NPTC Contract Cost Avoidance: CY15

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<tr>
<td>Total</td>
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Actual IHS FY Expenditures vs Expenditure Based Trend: -Prior to NPTC established in 2004-

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<th>Actual Expenditure</th>
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<td>2009</td>
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www.ihs.gov/nptc/ or just google “IHS NPTC”

www.ihs.gov/nptc/clinicalguidance/
In 2015, the NPTC produced and/or provided the following:

**Action(s):**
- Disease Management Reviews: 8
- Medication Class Reviews: 8
- NCF Additions: 5
- NCF removal/replacements: 3
- Enhancements:
  - Webpage conversion & re-design
  - NCF reformatted
  - NCF database project, submitted
  - CME provided for meeting lectures

**Education:**
- Formulary Briefs: 14
- PIPI Manuscript: and Primary Care Provider
- FDA Drug Safety Communications: 30
- Interagency collaboration: ↑ 100%
  - Federal Bureau of Prisons
  - U.S. Coast Guard
- Joint Federal Partnerships
  - Peace Corps
  - CDC Federal Trade Center Health Program
  - CDC Antibiotic Stewardship Program

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**Contracting Strategies – National Contracts**

- Same as the VA
- Clinical review may lead to a national contract
  - Review will determine type of contract
- Two main types of national contracts
  - Therapeutic Interchange contract
    - Therapeutic equivalence - evaluated by price
  - Standardization contract
    - Generic contract - evaluated by price alone

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**VA Statistics (FY 2015)**

- Facilities
  - 167 VAMCs
  - 753 CBOCs
- Veterans
  - 22.0 million total (9% women)
  - 9.0 million enrollees
  - 6.3 million patients treated
  - 5.0 million pharmacy users

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**VA Statistics FY 2015**

- 273 million outpatient RXs (30-day Eqv)
  - 85% via mail order
  - 15% via local facility pharmacies
- $4.8 billion outpatient drug expenditures
  - Cost per 30-day Eqv RX nearly flat for 17 years
  - Cost low for population (elderly, male, comorbidities)

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**Key Objectives**

- Promote formulary decisions that are evidenced-based, not preference-based
- Promote appropriate drug therapy and discourage inappropriate drug therapy
- Reduce the geographic variability in utilization of pharmaceuticals across the VA system
- Promote portability and uniformity of the drug benefit
Key Objectives

• Initiate patient safety improvements
• Design and implement relevant outcomes assessment projects
• Improve the distribution of pharmaceuticals
• Reduce inventory carrying costs, drug acquisition costs and the overall cost of care

VA National “P&T” Committee

• Medical Advisory Panel (MAP)
  – 15 physicians
  – 12 PBM Clinical Pharmacists
  – 1 VPE member
• VISN Pharmacist Executives Committee (VPE)
  – 18 pharmacists
  – 1 MAP member
• Meetings
  – Monthly conference calls
  – Face-to-Face quarterly meetings (combined)
  – MAP vote prevails when consensus cannot be reached

NME Review Process

• NME approved by FDA
• Literature search and draft review completed
• Presented to VPE/MAP committees and changes incorporated
• Disseminated widely to clinical staff in field for comment
• Feedback presented to VPE/MAP committees and changes incorporated when appropriate
• VA National Formulary decision
• National criteria for use developed when indicated

Tools for Implementing Formulary Decisions

• Clinical Guidance Documents*
  – Clinical recommendations
  – Criteria for use
• Drug Standardization List*
• Contracting Strategies

* Available at pbm.va.gov

Contracting Strategies – National Contracts

• Clinical review may lead to a national contract
  – Review will determine type of contract

• Two main types of national contracts
  – Therapeutic Interchange contract
    • Therapeutic equivalence - evaluated by price
  – Standardization contract
    • Generic contract - evaluated by price alone

Example of Therapeutic Interchange Contract – DPP4 Inhibitors
Example of Standardization Contract - Fluticasone Nasal

VA Tiered Copay

- **Not** a means to control formulary utilization within VA
  - Copay is a function of Office of Management and Budget
- Current copay structure
  - $8 per 30 day supply (priority groups 2-6)
  - $9/30 day supply (priority groups 7-8)
- Effective February 2017
  - Tier 1: $5 (selected generics)
  - Tier 2: $8 (all other generics)
  - Tier 3: $11 (branded drugs)
  - Copay tier is irrespective of formulary status

Budget Impact of VA Formulary Management Practices

- Although RX volume continues to grow and the cost of drugs is trending upwards in general, VA has been successful in minimizing the increase in outpatient drug costs and cost/unique patient

VA Cost per Day30RX – FY15

VA Cost/Unique Patient FY15

DoD
DoD Statistics (FY 2015)

- **Patients**
  - Active duty, active duty dependents, retirees and retiree dependents, other
  - 9.44M eligible / 7.90M users
- **Structure**
  - Purchased care
    - Retail pharmacy
    - Mail order pharmacy
  - Direct care
    - Military treatment facilities

DoD Statistics FY 2015

- **Various health plan options (Tricare)**
- **Facilities**
  - 55 medical centers and inpatients facilities
  - 373 ambulatory clinics
  - 264 dental clinics
  - 59,670 civilian contracted pharmacies
- **Personnel**
  - 84,564 military personnel
  - 67,221 civilian personnel

DoD Statistics (FY 2015)

- **209.2 million outpatient RXs (30-day Eqv)**
  - 45% via mail order
  - 40% via MTF (direct)
  - 14% via retail
- **$11.6 billion outpatient drug expenditures**
  - $9.2B net cost to DoD

Formulary Review Process

- **DoD P&T Committee**
  - Military physicians (range of specialties) from each Service
  - Pharmacy consultants from each Service
  - Representatives/attendees from VA, Coast Guard, US Public Health Service, Defense Logistics Agency, Patient Safety, legal counsel, etc.
- **Comparative analysis**
  - Clinical effectiveness and safety
  - Economic analysis
- **Meets quarterly**

Formulary Review Process

- **Beneficiary Advisory Panel**
  - Beneficiary and stakeholder input
- **Clinical**
  - Provider input
- **Drug class targeting for cost savings opportunities**

Tools for Implementation

- **Tier status**
- **Quantity limits**
  - Safety, costs, waste
- **Age and gender limits**
- **Warning messages**
  - Safety
  - Utilization management
- **Prior authorization**
- **Step therapy**
MajRoska1 Need to verify this value
Roska, Ellen A., Maj, USAF, 10/6/2016
Contracting Mechanisms

**MTF and Mail Order**
- National contracts
- Blanket purchase agreements (BPA)
- Distribution and pricing agreement (DAPA) – DLA

**Retail**
- Retail refund program
  - Standard/mandatory
  - Additional/voluntary

DoD Pharmacy Savings Index FY16

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DoD VA Continuity of Care Drug List

- National Defense Authorization Act required to have a joint “formulary” for treatment of pain, sleep disorders, and psychiatric conditions (including PTSD)
- Reps from VA and DoD worked together to look at both formularies side by side and compare differences
- The vast majority of drugs in these classes were on both formularies
  - Roughly 50 drugs added to the VA National Formulary

Collaborative Activities

- P&T Committee Meetings
- VA/DoD Clinical Practice Guidelines
- FDA Drug Safety Oversight Board
- Joint National Contracts
- DoD/VA Continuity of Care Drug List

National Contract Collaboration

- Federal Pharmacy Executive Steering Committee – Contracting Subcommittee
  - Representatives from Bureau of Prisons (BOP), Department of Defense (DoD), Indian Health Service (IHS), and Department of Veterans Affairs (VA)
  - Meet monthly to discuss contracting issues and identify procurement targets

- As of 9/22/16
  - 177 jointly awarded national contracts
Summary

Key Points

• While IHS, VA, and DoD all have different missions and healthcare delivery systems, and formularies, their formulary management and implementation processes are very similar.
  – Formulary
  – Formulary Committees
  – Quarterly meetings
  – Formulary Review
  – Contracting & Cost Avoidance Opportunities
  – Formulary Implementation

IHS, VA, and DoD work closely together
  – Participate in each others P&T meetings
  – Federal Pharmacy Executive Steering Committee on Contracting
  – Meet monthly to share information and identify opportunities to combine market power and contract together.
  – FDA Drug Safety Oversight Board
  – Other collaborations

Answer to Self-Assessment Question 1

• Which of the following mechanisms are not used by VA to help implement formulary decisions?
  – A. Criteria for use
  – B. Drug standardization list
  – C. Tiered copays
  – D. National contracts

Answer to Self-Assessment Question 2

• IHS utilizes which of the following
  – A. Open Formulary
  – B. Basic Formulary
  – C. Closed Formulary
  – D. Core Formulary

Answer to Self-Assessment Question 3

• True or false: DoD beneficiaries have access to three pharmacy points of service
  – True
Closing Remarks

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