Defense Health Agency

Compound Pharmacy Forum - Formulary Action Update

Hosted By

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Agenda

- Welcome and Opening Remarks – MG Thomas
- DoD Uniform Formulary Process – Dr. George Jones
- Formulary Consideration – Compound Medications
- Formulary Action – 1 May Implementation
  - Safety Focus
  - Strategic Communication / Beneficiary Outreach
  - Enhanced Screening Process
  - Prior Authorization
  - Cost Considerations
- Questions

Opening Remarks – MG Thomas

- GOAL – Ensure Sustainable Access for TRICARE Beneficiaries to Compound Medications
- Our Overall Approach
- Good Stewardship leads to Sustainment

DoD Uniform Formulary Process

- National Defense Authorization Act (NDAA) Fiscal Year (FY) 2000 Section 701: Pharmacy Benefits Program
  - Title 10 USC, Section 1074g
    - Creation of a 3 tiered Uniform Formulary
    - DoD Pharmacy and Therapeutics (P&T) Committee
    - Uniform Formulary Beneficiary Advisory Panel (BAP)
    - Established Central Data Repository
- P&T Committee considers safety, efficacy, and cost effectiveness of pharmaceutical agents and makes recommendations on their placement on the Uniform Formulary
  - Thorough literature evaluation / Pharmacoeconomic Modeling
  - Drives toward Optimal Therapy / Cost of Care Outcomes

DoD Uniform Formulary Process - BAP

- DoD Uniform Formulary Beneficiary Advisory Panel
  - An advisory committee operated under the Federal Advisory Committee Act
  - Provides public forum for consideration of Formulary Actions recommended by the P&T committee
- Ensures consideration of the views and interests of TRICARE beneficiaries on the development of the Uniform Formulary actions
  - Comments must be reviewed and considered by Director, DHA before taking action on a P&T committee recommendation
- The BAP is an advisory body

Formulary Consideration – Compound Medications

- Military Health System's top priority is quality and patient safety
- A system upgrade for pharmacy claim submissions, by Express Scripts, the TRICARE pharmacy contractor, increased visibility of ingredients contained in a compounded prescription and allowed identification of specific bulk powder and chemical ingredients that are not approved by the U.S. Food and Drug Administration (FDA) for commercial marketing
- Many compound drugs contain ingredients lacking clinical or medical evidence of their safety and effectiveness
- Based on enhanced screening of compounds, TRICARE determined it could not reimburse for non-FDA approved bulk powder and chemical ingredients in compound medications starting July 2013

Formulary Consideration – Compound Medications

- TRICARE delayed compound change to February 2014 in order to monitor developments in private and public environments concerning compounds (i.e. FDA actions; Commercial Best Practices, etc.)
- DHA postponed February 2014 implementation until April 2014 pending assessment of impact of FDA actions under Public Law 113-54 - The Drug Quality and Security Act
- DHA has closely monitored FDA actions on compound drugs. FDA has not published lists of approved bulk drug substances and list of substances that present demonstrable difficulties. FDA focus is sterile compounding.
- Government Accountability Office in October 2014 recommended that DOD align TRICARE's payment practices for compounded drugs with applicable regulations governing the TRICARE program

Formulary Consideration – Compound Medications

- Many Commercial Plans adopted a coverage denial for bulk chemical ingredients – essentially not covering about 97% of compounds
  - Growth rate of compound prescription cost to TRICARE greatly increases
- In November 2014, Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee unanimously recommended a Prior Authorization for compound drugs
- In January 2015, Beneficiary Advisory Panel (BAP) reviewed the P&T recommendation and advised that it did not concur with the P&T compound recommendation
- In February 2015, Director, DHA disapproved the P&T Committee's recommendation pending additional consideration of the BAP comments
- Section 704 of the Fiscal Year (FY) 2015 National Defense Authorization Act authorizes flexibility to consider coverage even if it does not meet the normal test of proven safety and effectiveness

Formulary Consideration – Compound Medications

- DHA Pharmacy Operations, working collaboratively with the Services, reviewed Beneficiary Advisory Panel comments/recommendations, commercial best practices and input from the compounding industry
- Following a deliberative approach and careful consideration of stakeholder viewpoints, In March 2015, Director, DHA approved and signed modified determination of P&T Committee recommendation for Formulary Action
  - Is it lawfully marketed in the US
  - Is it considered safe and effective
  - Is it appropriate for the patient based on clinical need and cost effectiveness
- A comprehensive Communications Plan was developed to ensure effective communication to all stakeholders
- Implementation of the modified Formulary Action will occur 1 May, 2015

Basis of Formulary Action – Safety and Efficacy

- DoD's highest priority is providing safe and effective care to our beneficiaries
- Some compound drugs contain ingredients whose use is not supported by a widely recognized body of peer-reviewed clinical evidence
- Providers can submit evidence to ESI to demonstrate that a non-covered ingredient is safe and effective
- Compound drugs have recently raised safety concerns in the U.S.
  - Many compound drugs contain a combination of multiple potent active drug ingredients
  - Exposure to high concentrations of these ingredients can cause serious reactions
  - For some compound ingredients, there is a not a body of widely recognized clinical research evaluating potential harmful reactions or drug interactions, nor is there a process in place to systemically review these drugs for safety

Enhanced Screening

- **Management Strategy –** Clinical (safety) and Cost Focused
  - ❑ Enhanced claims screening process for compound claims
    - DoD Pharmacy and Therapeutics Committee (P&T) Committee Recommendation – Prior Authorization (PA)
      - ▻ Modified to combine electronic screen and PA option
    - Express Scripts – Network Agreement Addendum
      - ▻ Establish pricing standard for compound ingredients
  - ❑ HA guidance for Service/eMSM compliance
    - Memorandum to Services
    - Pharmacy Shared Services Initiative / World-Wide Webinar brief

Screening Criteria and Process – ESI Process

- When a TRICARE retail network pharmacy files a claim for a compound drug, each ingredient will be screened based on these criteria:
  - ❑ Is it lawfully marketed in the US
  - ❑ Is it considered safe and effective
  - ❑ Is it appropriate for the patient based on clinical need and cost effectiveness
- This is similar to the process currently used by TRICARE to ensure that other prescriptions meet TRICARE's coverage standards

Enhanced Screening Process – ESI Process

- When an electronic compound claim is submitted, ESI's system will review each of the individual components of the compound for coverage
  - If all components are covered, the claim will process
  - If ANY of the components are not covered, the claim will reject 70: Product/Service not covered with secondary messages indicating that there are not covered components (indicated by an "N") and that SCC = 8 can override the non covered ingredients
- At this point the pharmacist has the option to:
  - Change the compound formulation to eliminate non-covered products
  - Contact the physician to change the prescription and/or ingredient(s)
  - Accept $0 reimbursement for the cost of the non-covered ingredient(s) by entering a SCC = 8 to override

Prior Authorization (PA) – Consistent With Standard PA Process

- The prescribing provider can request prior authorization for the compound drug if they can't substitute an ingredient or prescribe a different drug
- Prior authorization is a standard process used by TRICARE and other health plans to evaluate individual patient needs and manually review additional evidence not considered in the initial screening
- More than 80 other prescription drugs require prior authorization for TRICARE coverage
- If the prior authorization is denied, beneficiaries also have the option of using the standard TRICARE appeals process

Prior Authorization Criteria

- What is the diagnosis?
- Has the patient tried commercially-available products for the diagnosis provided?
- Is there a current national drug shortage of an otherwise commercially available product?
- What is the proposed duration of therapy?
- Has the prescriber submitted evidence supporting the therapy for this patient and that an FDA-approved, commercially-available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight, ineffectiveness of such products for the patient) and/or an FDA-approved product cannot be taken due to allergies or contraindication?

Prior Authorization Criteria (cont'd)

- Is the prescription cost-effective either because it meets the pricing standard as established between ESI and its network pharmacies or because the cost is reasonable in the context of the clinical indication?
- Other information the requestor believes supportive of the request.
- Like all other DoD Uniform Formulary PAs:
  - PA Form is available on DoD website
  - Prescriber submits required information to ESI
  - Request is reviewed and notification occurs (normally with in 5 days of receiving all required information)
- Standard appeal process is available if the submission is denied

Basis for Coverage Criteria

- Lawfully marketed in the United States and is (are) considered safe and effective - each ingredient(s) submitted for payment is a chemical entity of a FDA-approved drug for marketing in the United States AND the drug(s) have not been withdrawn for safety reasons from the U.S. market. Ingredients may meet these criteria by complying with (1)a. or b., below.
  - ❑ The ingredients submitted for payment are approved by the FDA for commercial marketing; OR
  - ❑ (1) Pharmacies performing compounding or acting as outsourcing facilities under the provisions of Sections 503A and 503B, respectively, of the Drug Quality and Security Act will conform with the requirements specified in those provisions; AND

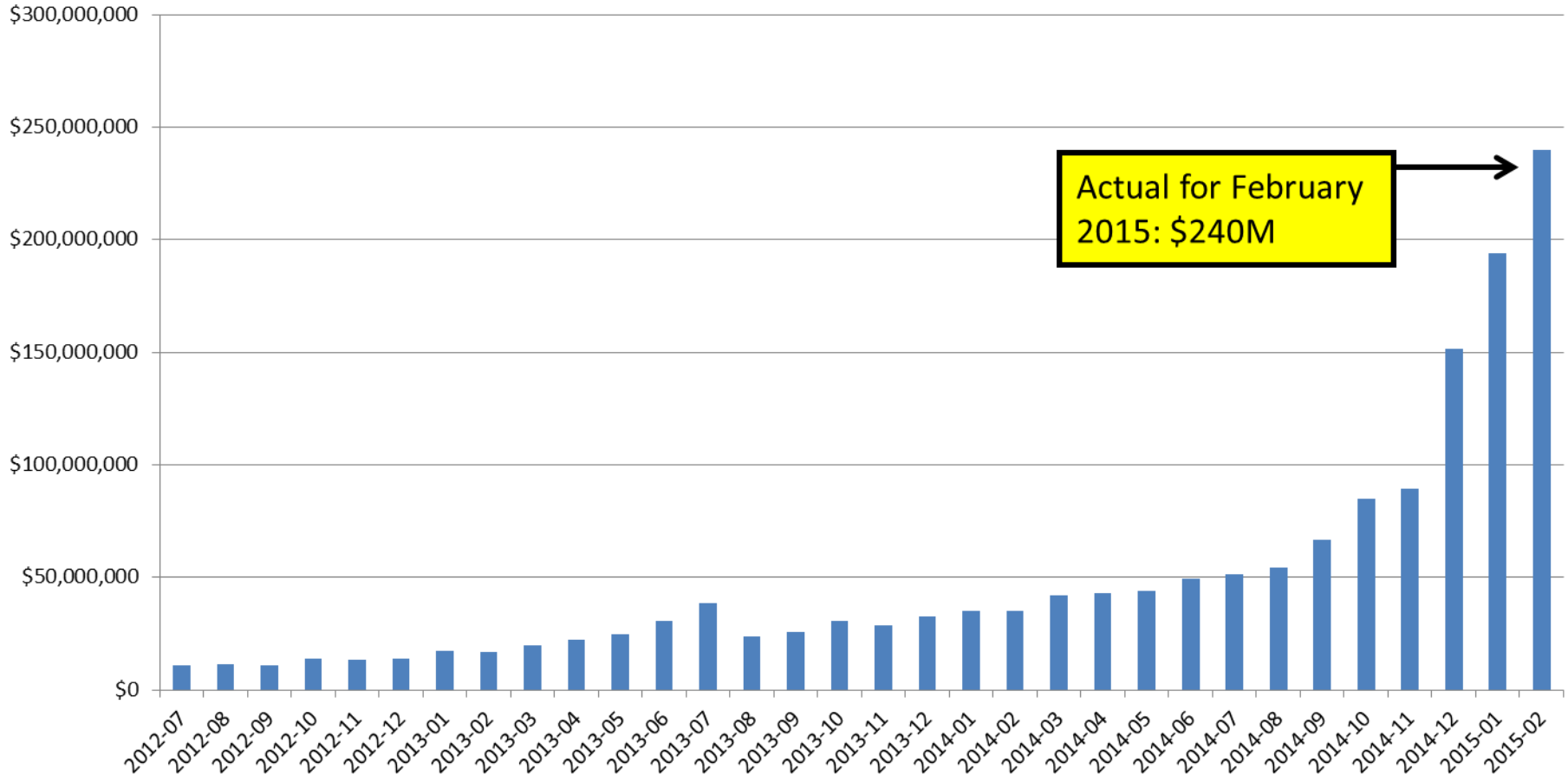
Basis for Coverage Criteria

- (2) The ingredients of the compounds will meet the requirements for being widely recognized in the United States as being safe and effective. The provider and/or pharmacy requesting payment for such a compound will provide evidence that the compound is widely recognized as being safe and effective.
  - Evidence that may be considered for this purpose will be consistent with examples provided in 10 U.S.C. § 1079c to include: clinical trials published in refereed medical literature; formal technology assessments; positions of national medical policy organizations, professional associations, and/or expert opinion organizations. Other sources may be submitted by the provider and/or pharmacy and can be considered as validated evidence as the Secretary considers appropriate.

Cost Considerations

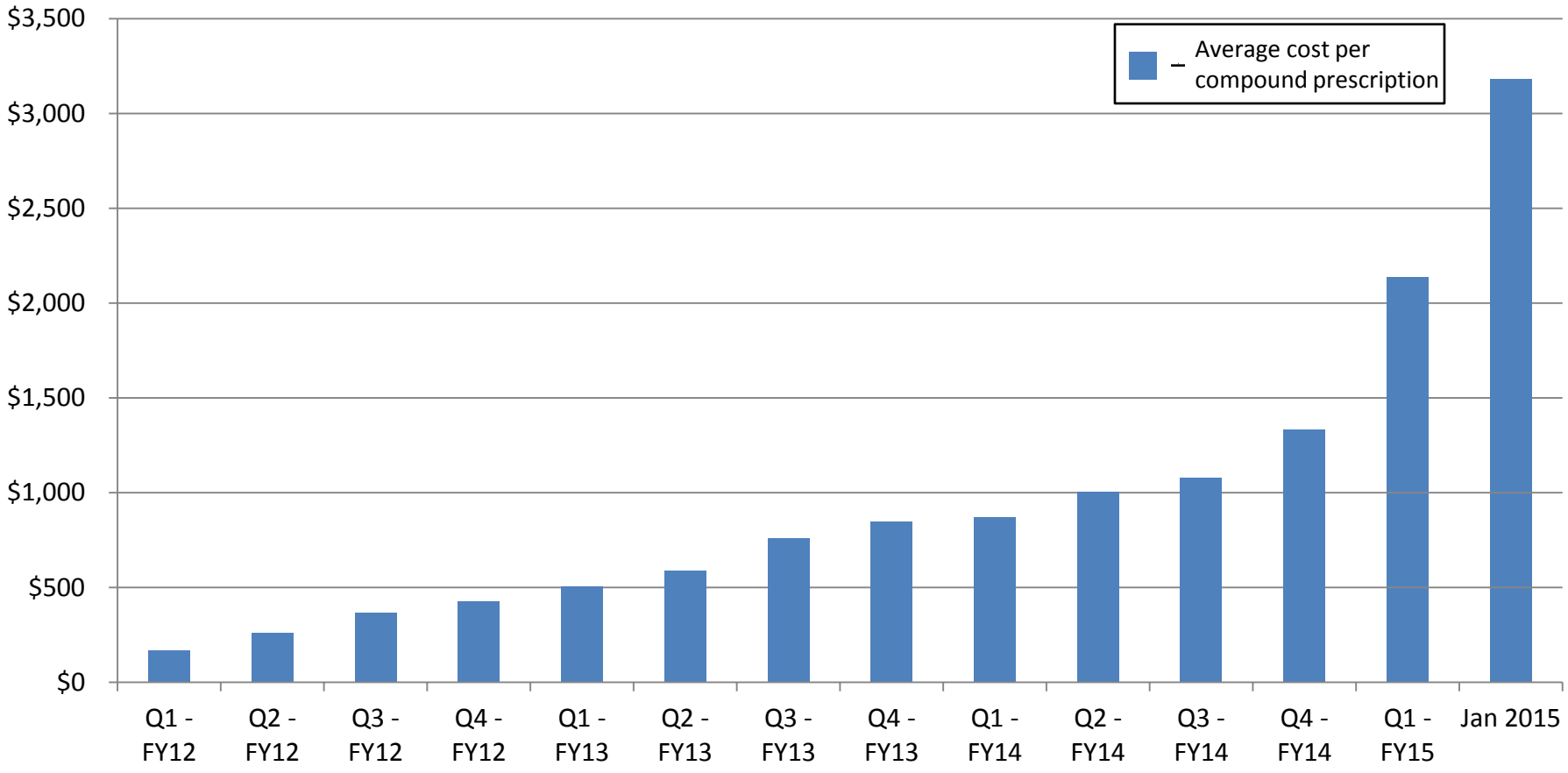
- GOAL – Sustained Access
- DoD must be good stewards of taxpayer dollars
- Application of Cost Management Strategy

Compound Pharmacy Expenses



Source: PDTS

DoD Compound Drug Cost Per Prescription Over Time



Source: PDTS

Cost Consideration

- The DoD has a responsibility to be effective stewards of taxpayer dollars, and provide value for the care we cover
- Without systemic evidence showing the effectiveness of compound drugs, there is no way determine if the DoD is getting value for our dollars
- Costs for compound drugs have skyrocketed in recent years
  - October 2012 - $12 million
  - October 2013 - $31 million
  - October 2014 - $81 million
  - January 2015 - $194 million
- The average DoD cost for compounds has risen from $170 per prescription in Q1 FY12 to $2,135 per prescription in Q1 FY15

Cost Considerations

- ESI is preparing a contract addendum including a pricing schedule for commonly used compound ingredients
- Network pharmacies will be required to sign and adhere to the pricing when submitting compound claims
- ESI will monitor claim processing for adherence
- DHA Pharmacy Operations will monitor program cost and the effect of Formulary Actions

Key Messages

- DoD's highest priority is to ensure we are providing safe and effective care to our beneficiaries
- TRICARE must be a responsible steward of taxpayer dollars, and provide value for the care we cover.
- Many compound medications will still be covered because they include ingredients proven to be safe.
- Reviewing prescription drugs to ensure they are covered is standard operating procedure for TRICARE and other government and civilian health care plans.

Defense Health Agency

- Information Resources

  Uniform Formulary Website
  (Determination of the Director, DHA Compound Formulary Action – posted)
  http://pec.ha.osd.mil/PT_min_charter.php?submenuheader=5

  Patient Focused: www.TRICARE.mil/compounddrugs

  Provider focused: www.health.mil/compounddrugs

  Information: www.express-scripts.com/TRICARE/

  DoD.customer.relations@Express-Scripts.com

  Express Scripts at 1-877-363-1303.

- DHA will consider the merits of another Forum after some experience following implementation

Questions?

Thank You
Have a Great Day