Key Considerations for Manufacturers to Work within the DoD Program

by

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Nationwide Pharmaceutical LLC
Key Considerations for Manufacturers to Work within the DoD Program

- Discuss the impact of policy change proposals on the DoD pharmacy benefit
- Explore TRICARE pharmacy benefit utilization and cost trends
- Gain insight into DHA pharmacy goals and budget challenges
- Identify ongoing initiatives to improve quality, safety and cost effectiveness
Structure and Vision of the DHA

The DHA will enable the medical Services to provide a medically ready force and a ready medical force in both peace time and wartime.
Leadership

- DHA Pharmacy Operations Division Chief:
  - Dr. George Jones, george.e.jones@dha.mil

- Air Force Pharmacy Consultant:
  - Col. Scott Sprenger, scott.a.sprenger.mil@mail.mil

- Army Pharmacy Consultant:
  - COL John Spain, john.spain1@us.army.mil

- Navy Pharmacy Consultant:
  - CAPT Thinh Ha, thinh.ha@med.navy.mil
Current Contracting Points of Contact

☐ Industry Liaison
  - Lt Col Robert “Chris” Conrad: Robert.conrad@dha.mil

☐ Contracting Officer
  - Bruce Mitterer: bruce.mitterer@dha.mil
  - CO Assistant
    - Matthew Halbe: Matthew.Halbe.ctr@dha.mil
DHA Pharmacy Initiatives

- Operational Initiatives – to ensure optimal function
  1. *Transition* – to develop an operational unit under DHA
    - Unit Manning / Position descriptions being reviewed
  2. *Essential Processes*
    - Develop Central approach to managing Pharmacy Funds
    - Identify / Pursue clinical pharmacy support in care settings
Pharmacy Initiatives

- Program Initiatives – Integrated System; Savings
  - 1. Move Select Maintenance Medications to Mail / MTF
    - TRICARE For Life Pilot
    - Standard Prescription Transfer Process
    - Uniform staffing formula / augmentation process for MTFs
  - 2. Optimize MTF Capability and Capacity
    - Develop Requirements for Central Refill Support
    - Optimize MTF to TMOP process
    - Implement e-Prescribing to MTFs from community providers
Pharmacy Initiatives, continued

3. **Optimal MTF Use of Centralized Purchasing Rules**
   - Enhanced reporting driving to full automation
   - Improve communication of business rules / opportunities
   - Expand collaborative initiatives with Federal Partners

4. **Fully Leverage Formulary Management Capability**
   - Business Process Reengineering
   - Improve Communication
   - Fully Integrate Clinical Practice
     Guidelines into Formulary Process
     and Outcome assessment
5. **Reengineer New Drug Addition to Formulary Status**
   - Proposed regulation; Tracking / medical necessity process

6. **Centralize Pharmacy Automation Contracts**
   - Identify existing contracts
   - Articulate uniform automation requirements
   - Develop central acquisition strategy (Pending a relook)

7. **Evaluate Future Role for Satellite Pharmacy Locations**
   - Collaborate with Health Plan Initiatives
   - Define requirements for satellite facilities / contracts

8. **Implementation of DEA Rule**
E-Prescribing
How is formulary status determined?

- The electronic prescribing solution utilizes the "non-formulary" and "IP/OP" indicators associated with the pharmacy site's formulary group within the CHCS Formulary Management (FRM) option.
How are non-formulary medications handled by the eRx software?

- The eRx software is capable of receiving electronic prescriptions for non-formulary medications.
- If CHCS determines that an electronic prescription is for a non-formulary drug (which is determined by the formulary status in the CHCS Formulary Management (FRM) file) that prescription will be placed in the CHCS holding queue for pharmacy intervention.
Electronic Health Record

- FY 2015 3rd quarter
  - Contract Award
- FY 2016 4th quarter
  - 1st Deployment in Northwest
- 6 years to implement
Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee Overview

- Representatives of uniform services facilities and representatives of providers of the uniformed services
- Charter requires 14 uniformed voting members
- PEC-B Director is the Recorder
- Committee meets quarterly
- Develops the Uniform Formulary (UF), reviews the UF on a periodic basis, makes additional recommendations as necessary and appropriate
- Conduct a relative clinical and cost effective analysis on FDA approved ambulatory drugs for placement on the Uniform Formulary, BCF and ECF
Agents are presumed to be on Uniform Formulary

Agent excluded from formulary if DoD P&T Committee finds that agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome

New Drugs

- Initially on formulary until go through UF review process…for now
DoD P&T Committee Process Flow

PEC-B
Collects
Analyzes
Presents

DoD P&T
Makes
Recommendations

BAP
Comments

DHA Director
Makes Decisions

Minutes posted
Uniform Formulary Decision Cycle

Preliminary review (T-270)
- P&T Committee meets (T-180)
  - Defines class, BCF or ECF
Request for Pricing Info (T-100)
Price Quotes Received (T-30)
P&T Committee meets (T)
  - Final review, recommendations
BAP meets (T+45)
  - Comments to DHA
TMA Director reviews & signs minutes (T+60)
Implementation of decisions (no later than T+240)

90-Day Decision Cycle
Clinical Effectiveness Review
How do they compare?

- What are the medications used for?
- In what populations?
- STEPO – Safety, tolerability, efficacy, provider preference, other
- Clinical coverage
- Therapeutic interchangeability
- Prescribing & utilization patterns
  - Compliance with clinical practice guidelines
  - Typical regimens
  - Switching between drugs
  - Typical uptake of new meds – unmet clinical needs
  - Medication adherence (& tie to outcomes)
Cost Effectiveness

- Pharmacoeconomic analysis
  - Type depends on clinical conclusions
    - Usually CMA or CEA
  - Define measures, deal with data issues
  - May do multiple analyses & see if they agree
  - May do multiple analyses based on different indications, populations
  - Costs with/without manufacturer retail refund bids, based on scenario
    - e.g., put A & B in Tier 3 (no additional refund offered) & C in Tier 2 (manufacturer offers additional refund for better formulary placement)
Economic Appraisal

Decision Criteria

- Cost: Increase
- Effect: Decrease
- Rejection Threshold
- Acceptance Threshold
- Zone of Uncertainty
## DOD / TRICARE
### Co-Pay for Outpatient Prescriptions

<table>
<thead>
<tr>
<th>Type of Pharmacy</th>
<th>Formulary Drugs</th>
<th>Non-Formulary (Tier3)¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Generic (Tier 1)</td>
<td>Brand Name (Tier2)</td>
</tr>
<tr>
<td>MTF (up to 90-day supply)</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td></td>
<td>Not on electronic formulary</td>
<td></td>
</tr>
<tr>
<td>Home Delivery (up to 90-day supply)</td>
<td>$0</td>
<td>$13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$43</td>
</tr>
<tr>
<td>Retail Network Pharmacy (up to 30-day supply)</td>
<td>$5</td>
<td>$17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$44</td>
</tr>
<tr>
<td>Non-Network Pharmacy (up to 30-day supply)</td>
<td>TRICARE Prime options: 50% copayment applies after point-of-service (POS) deductible is met</td>
<td>TRICARE Prime options: 50% copayment applies after POS deductible is met</td>
</tr>
<tr>
<td></td>
<td>All other beneficiaries: $17 or 20% of the total cost, whichever is greater, after annual deductible is met</td>
<td>All other beneficiaries: $44 or 20% of the total cost, whichever is greater, after annual deductible is met</td>
</tr>
</tbody>
</table>

¹ Approval is required for active duty service members (ADSMs). Non-formulary drugs may be obtained free of charge by ADSMs only if medical necessity has been established. All other beneficiaries will pay the copayments listed above. Medical necessity information should be submitted along with the prescriptions. The Department of Defense Pharmacy and Therapeutics Committee may set quantity limits on some medications. For more information, visit www.tricare.mil/pharmacy.

² Non-formulary drugs are generally not available at MTFs.
DoD Formulary Tools

- Tier status
  - Copays at retail/mail; availability at MTFs
  - Tier 3 ($44) – modest impact on utilization retail/mail; can be profound at MTFs

- Quantity limits
  - Safety, costs, wastage

- Warning messages
  - Safety issues

- Prior authorization (PA)
  - Must meet criteria

- Step therapy / PA
  - Must try preferred agent 1st
  - Automated look-back
  - Often applies only to new users

- Age, gender “edits”
  - Clinical appropriateness
DoD Uniform Formulary Impact on Drug Pricing

- MTFs & Mail Order
  - Lower prices negotiated with manufacturers
    - Blanket Purchase Agreements (BPAs)
    - Represents additional saving off FSS/Big 4

- Retail
  - Additional refunds
    - Voluntary Agreements for Retail Rebate (VARR)
    - Administered and collected from manufacturers along with standard refunds (MARRs)
Managing Trend & Spend
MHS Drug Spend (FY 02-12)

Notes:
- Totals represent prescription expenditures incl. mail order dispensing fee, minus copays, OHI, & retail refunds/rebates collected.
- Not included: MTF Cost of Dispensing, other contract costs for retail and mail.
- Data sources: PDTS Data Warehouse; TMA POD (refunds/rebates) OHI - other health insurance.
Tier Based Cost-Share System

- Tier 1
- Tier 2
- Tier 3
- 703
- Pilot Programs
  - OTC: PPIs, etc.
Drug classes may be re-evaluated from time to time, prompted by the following circumstances:

- Approval of new agent by the US FDA
- Approval of a new indication for an existing agent
- Changes in the clinical use of existing agents
- New information concerning the safety, efficacy or clinical outcomes of existing agents
- Price changes
- Shifts in market share
- Scheduled review of a therapeutic class
- Requests from DoD P&T Committee members, MTFs or other MHS officials
- Protest
Patient Access to Pharmaceutical Agents

- Agents used exclusively in medical treatments that are expressly excluded from TRICARE benefits
  - Drugs prescribed for cosmetic purposes
  - Fluoride preparations
  - Food supplements
  - Homeopathic and herbal preparations
  - Multivitamins
  - Over-the-counter products (except insulin, diabetic supplies, and smoking-cessation products)
  - Weight reduction products
The DoD Uniform Formulary (UF)

- **Uniform Formulary** (TRICARE Pharmacy Benefit)
  - **Basic Core Formulary (BCF)**
  - **ECF**
  - **Formulary Drugs**
  - **Non-Formulary Drugs**
  - **Drugs not covered** (i.e., inpt meds, OTCs, weight loss meds, etc.)

(TRICARE Medical Benefit)
Concept for DoD to give manufacturers the ability to bid on more discrete variables instead of being tied to a story condition set.
Story:
Antilipidemics 1 Use: One to two branded agent(s) on the UF with Zero to one of the branded agent(s) of the same line on the BCF. Step therapy applies, one branded agent will be designated as a step-preferred agent and available prior to step therapy.
(1-2 branded UF, one step-preferred branded agent will be available prior to Step Therapy, 0-1 branded BCF)

Discrete Variables:
MTF:
- BCF no step/before step
- ECF no step/before step
- UF not BCF
Mail:
- T1 no step/T2 no step
- T1 before/T2 after step
- T2 before/T2 after step
Retail:
- T1 no step/T2 no step
- T1 before/T2 after step
- T2 before/T2 after step
<table>
<thead>
<tr>
<th>MTF and Mail</th>
<th>Mail and Retail</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Share the same contracting vehicle (Blanket Purchase Agreement)</td>
<td>□ Share the same rules (Voluntary Agreement for Retail Refunds)</td>
</tr>
</tbody>
</table>
Electronic Bidding

- In testing phase
- Better compliance
- Less non-responsive bids
- Pre-bid FSS check
<table>
<thead>
<tr>
<th>Condition Set #</th>
<th>Category</th>
<th>One of (X) Number of Suites</th>
<th>Military Treatment Facility and Mail Order Price per Strip</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 UF Suite (No grandfathering)</td>
<td>Military Treatment Facility 20151BGXX1BCBS1X Mail Order 20151BGXX1T2BS1X</td>
<td>Basic Core Formulary &amp; Tier 2 BEFORE Step Therapy</td>
<td>1</td>
</tr>
<tr>
<td>2 UF Suites (1 Suite with 1 BCF strip, 1 additional suite UF) (No grandfathering)</td>
<td>Military Treatment Facility 20151BGXX1BCBS1M Mail Order 20151BGXX1T2BS1M</td>
<td>Basic Core Formulary &amp; Tier 2 BEFORE Step Therapy</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Military Treatment Facility 20151BGXX1UFBS1M Mail Order 20151BGXX1T2BS1M</td>
<td>Uniform Formulary &amp; Tier 2 BEFORE Step Therapy</td>
<td>2</td>
</tr>
<tr>
<td>1 UF Suite (Grandfathering NF products)</td>
<td>Military Treatment Facility 20151BGXX1BCBS1XG Mail Order 20151BGXX1T2BS1XG</td>
<td>Basic Core Formulary &amp; Tier 2 BEFORE Step Therapy</td>
<td>1</td>
</tr>
<tr>
<td>2 UF Suite (1 Suite with 1 BCF strip, 1 additional suite UF) (Grandfathering NF products)</td>
<td>Military Treatment Facility 20151BGXX1BCBS1M Mail Order 20151BGXX1T2BS1M</td>
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</tr>
<tr>
<td></td>
<td>Military Treatment Facility 20151BGXX1UFBS1MG Mail Order 20151BGXX1T2BS1MG</td>
<td>Uniform Formulary &amp; Tier 2 BEFORE Step Therapy</td>
<td>2</td>
</tr>
<tr>
<td>Condition Set #</td>
<td>Category</td>
<td>One of (X) Number of Suites</td>
<td>Refund per NDC Percentage is Static WAC *(Y%)</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
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<td>---------------------------------------------</td>
</tr>
<tr>
<td>1 UF Suite (No Grandfathering)</td>
<td>Tier 2 BEFORE Step Therapy</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>20151BGXX1T2BS1X</td>
<td>Tier 2 BEFORE Step Therapy</td>
<td>2</td>
<td></td>
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<tr>
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<tr>
<td>20151BGXX1T2BS1MG</td>
<td>Tier 2 BEFORE Step Therapy</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
How does the VARR Process work?

- NFAMP-FCP = Standard Refund (required by law)
- NFAMP * Y% = Additional Refund (bid submission usually)
- For SMBGS it will be Refunded per NDC WAC *(Y%)
How much must DoD save over 6 years?

- MHS will meet $17 – 22 billion savings by FY19
- DHA shared services will meet $2.3 billion savings by FY19
- Pharmacy must deliver $1.3 billion of that savings
With the TRICARE for Life (TFL) pilot beginning soon, the DHA Pharmacy Operations Division (POD) will provide uniform guidance and central resource support to efficiently move prescriptions from retail to home delivery and MTFs.

### Initiative

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Business Process Reengineering</td>
</tr>
<tr>
<td>2</td>
<td>Centralized Pharmacy Checkbook</td>
</tr>
<tr>
<td>3</td>
<td>Staff Augmentation Contract to Meet Workload Requirements</td>
</tr>
</tbody>
</table>

### Benefit to Pharmacy Community

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<thead>
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<tbody>
<tr>
<td></td>
<td>Results will standardize select pharmacy processes across MTFs in order to improve operational efficiency and to enhance the pharmacy experience for beneficiaries</td>
</tr>
<tr>
<td></td>
<td>The DHA POD will centrally manage funds for outpatient pharmaceutical purchases and support requirements associated with workload growth</td>
</tr>
<tr>
<td></td>
<td>The DHA POD will guide contract staffing augmentation process to support increased workloads resulting from retail recapture</td>
</tr>
</tbody>
</table>
DHA Pharmacy Ops worked with MTF-level Service SMEs to develop policy and guidance designed to make the transfer process into the MTF easier and more efficient:

- HA policy with DHA procedural guidance to support prescriptions that are transferred into the MTF should a beneficiary request it
  - MTF pharmacies will transfer prescriptions that are on the DoD Uniform Formulary into their MTF should a beneficiary ask
- DHA standard tool to help facilitate transfers with less manual effort from MTF pharmacists
  - Interim tool will include a standard transfer authorization with common data fields necessary for transfer
  - Final tool will be an online transfer database to eliminate time spent trying to call other MTFs to validate and complete transfers
- DHA Pharmacy Ops expects the policy and operational guidance to be published in the near future
DHA Pharmacy Ops will control the Pharmacy “checkbook” for outpatient pharmaceutical purchases to ensure MTFs are able to make consistent and cost-effective enterprise based purchasing decisions:

- Consistent implementation of Uniform Formulary product selection
- Central funding will allow the DHA to provide flexible staffing and resources to support recapture
- DHA will be able to plus-up drug supply, augment staffing based on workload increases, centrally support automation contracts and services, and support expanded MTF formularies
DHA Pharmacy Ops is committed to supporting MTF pharmacies, should prescription workload increase, by supplying flexible staffing consistent with changing workloads:

• Provide MTF outpatient pharmacies with the opportunity to acquire pharmacy manpower through one or more DHA-established staff augmentation contracts

• The DHA Pharmacy Ops manpower standard will be used to assess changes in MTF workload and identify the need for additional staff
  – Manpower model is based on the validated AF staffing model
  – FY13 data is the baseline for prescription workloads
MTF and Mail Order

FY14 Forecast
$5.4B

Pharm PV
$3.696B

Med/Surg PV
$520M
Capital Equipment
$299M
Traditional Med/Surg
$169M
Traditional Pharm
$230M
ECAT $138M
Hospital $55M
Compounding Update

- GAO Report published in October 2014

Tobacco Use

First in the Service...

The favorite cigarette with men in the Army, the Navy, the Marines, and the Coast Guard is Camel.

(Based on actual sales records in Post Exchanges and Canteens.)
Obesity
TRICARE beneficiaries who are Medicare eligible (using TRICARE for Life) must refill their brand-name maintenance prescriptions using either Home Delivery or MTF Pharmacy

• Implementation started spring of 2014

• Communications:
  – Letters to affected beneficiaries
  – Explanation Of Benefit (EOB) messages
  – Express Scripts education and marketing
  – Civilian and MTF provider education
TFL Pilot Patient Activity Summary of Trends

- Feb – June 2014 utilization: Mail Order ↑11.8%; MTF ↑1%; Retail ↓5%

- Awareness of the TFL pilot has increased prompting many beneficiaries to send maintenance prescriptions directly to mail without filling at retail.
  - Over 35,000 prescriptions YTD have been filled this way.

- Beneficiaries are also moving their non-targeted drugs to mail
  - YTD over 470,000 prescriptions have moved to mail.
  - In July 2014, over 94,000 prescriptions for non-targeted drugs (from 45,000 TFL patients) moved

- The TFL pilot program continues to identify beneficiaries who had not previously reported having OHI. YTD, over 1,900 beneficiaries have subsequently reported OHI eligibility impacting almost 3,000 medications.

Source: ESI’s TFL Pilot Monthly Summary Contract Report
Home Delivery Growth

<table>
<thead>
<tr>
<th>Volume Growth From Prior Year</th>
<th>2011</th>
<th>2012</th>
<th>2013 YTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Delivery</td>
<td>9.9%</td>
<td>31.2%</td>
<td>10.0%</td>
</tr>
<tr>
<td>Retail</td>
<td>-0.2%</td>
<td>-10.0%</td>
<td>-6.8%</td>
</tr>
</tbody>
</table>

Source: Express Scripts Home Delivery Growth Dashboard

Retail Maintenance Volume:
- **Down 2.5%** in 2011;
- **Down 14.6%** in 2012;
- **Down 13.1%** in 2013 YTD
The most current DoD Suicide Event Report (DoDSER), 2011 indicated a large percentage of suicide attempts involved prescription medications.

The Drug Enforcement Administration (DEA) did not include language in their regulation to allow an ultimate user to return controlled substances to DEA registrants.

- Beneficiaries were not able to return their unwanted, unused, or expired controlled substances to pharmacies.

A medication take-back program can securely and easily reduce access to prescription medications by providing Service members and their families the opportunity to dispose of medications that could be used for suicide or suicide attempts.
On September 9, 2014, the DEA released their Final Rule, Disposal of Controlled Substances

- Effective on October 9, 2014
- Hospital/clinics with an on-site pharmacy can be “collectors”
  - MTF pharmacies registered with the DEA can be collectors
- Collectors can have mail-back programs and collection receptacles
  - Drug take back events must have Federal, State, tribal, or local law enforcement present

DoD Drug Take Back Efforts
- Develop Directive-type Memorandum, directing the Services to have drug-take back programs
- Develop Operational Guidance for implementation
November 2014 DoD P&T Committee

UF Class review
- Pulmonary Artery Hypertension
- Multiple Sclerosis
- V-Go
- Blood Glucose Test Strips

New Drugs
- COPD drugs: umeclidinium/ vilanterol (Anoro Ellipta)
- Ophthalmic NSAIDs: bromfenac (Prolensa)
- Glaucoma: brimonidine/ brinzolamide (Simbrinza)
UF Class review

- ORAL ONCOLOGICAL AGENTS/PROSTATE I & II
- TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL
- TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL

New Drugs

- ZONTIVITY
- HETLIOZ
- JARDIANE
- ESOMEPRAZOLE STRONTIUM
- STENDRA
- BELSOMRA - Solicitation Cancelled
Formulary Management Process

Through Aug 2014, the DoD P&T Committee has evaluated over 50 drug classes for the Uniform Formulary (over 100 total reviews)

- ~80% of total DoD spend
- ~$1.3B in cost avoidance/savings attributable to formulary management process in FY12

Future classes

- www.pec.ha.osd.mil under “TRICARE Program Information for manufacturers”
## Top 20 Specialty Drug Categories

All POS, by 2QFY14 Total Spend for Specialty Agents

<table>
<thead>
<tr>
<th>Categories</th>
<th>Cost 2QFY14 ($M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONCOLOGICAL</td>
<td>$97.4</td>
</tr>
<tr>
<td>TIBs</td>
<td>$65.3</td>
</tr>
<tr>
<td>MULTIPLE SCLEROSIS</td>
<td>$53.3</td>
</tr>
<tr>
<td>HEPATITIS C</td>
<td>$25.8</td>
</tr>
<tr>
<td>ANTIRETROVIRALS</td>
<td>$18.2</td>
</tr>
<tr>
<td>RESPIRATORY MISC (PAH)</td>
<td>$16.7</td>
</tr>
<tr>
<td>ANTIHEMOPHILIC FACTORS</td>
<td>$14.1</td>
</tr>
<tr>
<td>ENDOCRINE (corticotropin, cinacalcet)</td>
<td>$10.0</td>
</tr>
<tr>
<td>ANTICOAGULANTS (LMWH)</td>
<td>$9.2</td>
</tr>
<tr>
<td>GROWTH STIMULATING</td>
<td>$6.8</td>
</tr>
<tr>
<td>IMMUNOLOGICAL –MISC (infusion/injectables)</td>
<td>$6.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Categories</th>
<th>Cost 2QFY14 ($M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEUROLOGICAL –MISC (mostly botulinum)</td>
<td>$6.7</td>
</tr>
<tr>
<td>OSTEOPOROSIS (mostly teriparatide)</td>
<td>$6.2</td>
</tr>
<tr>
<td>WBC STIMULANTS</td>
<td>$5.1</td>
</tr>
<tr>
<td>ANTISERA (e.g., Hizentra)</td>
<td>$4.8</td>
</tr>
<tr>
<td>ADHD –WAKEFULNESS – sodium oxybate [Xyrem]</td>
<td>$4.6</td>
</tr>
<tr>
<td>IMMUNOSUPPRESSIVES</td>
<td>$4.4</td>
</tr>
<tr>
<td>FSH-LH FERTILITY</td>
<td>$3.9</td>
</tr>
<tr>
<td>RBC STIMULANTS</td>
<td>$3.8</td>
</tr>
</tbody>
</table>

55% of total spend

**Top 20 = 93% of total**

Refund-adjusted (at NDC level); omits paper claims, compounds, COB claims, OTC; based on 2QFY14 Specialty Agent Reporting List.
Specialty Medications

Background

- No industry standard definition of specialty
- US specialty drug spending projected to quadruple by 2020 to $402B per year
- Top 3 specialty therapy classes FY13: oral oncology agents; inflammatory conditions (targeted immunomodulatory biologics); multiple sclerosis
- MHS spent $1.2B in FY13 (19% of total spend)
A product can be classified as a DOD Specialty Agent if it meets at least two of the following:

- Costs $500 or more per dose or $6,000 or more per year;
- Difficult or unusual process of delivery;
- Requires patient management beyond traditional dispensing practices;
- As defined by DOD

Standard definition for reporting and monitoring

Begin analysis on optimizing this new drug “class” across all points of service
Increases in Overall Spend
3QFY14 vs. 1QFY12

Refund-adjusted (estimated); omits paper claims, compounds, COB claims, OTC; based on 2QFY14 Specialty Agent Reporting List
# Specialty vs. Non-Specialty Spend

By Beneficiary Category

<table>
<thead>
<tr>
<th>Row Labels</th>
<th>4Q FY13</th>
<th>1Q FY14</th>
<th>2Q FY14</th>
<th>3Q FY14</th>
<th>Grand Total (SM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty</td>
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<tr>
<td>Non-specialty</td>
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<td>$1,270</td>
<td>$1,256</td>
<td>$1,297</td>
<td>$5,139</td>
</tr>
<tr>
<td>Grand Total</td>
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<td>$1,596</td>
<td>$1,624</td>
<td>$1,701</td>
<td>$6,563</td>
</tr>
</tbody>
</table>

Refund-adjusted (estimated); omits paper claims, compounds, COB claims, OTC; based on 2QFY14 Specialty Agent Reporting List

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### 30-day Rxs

- **Specialty**: 173.6M
- **Non-specialty**: 1.2M

### Spend

- **Specialty Spend**: $1.4B
- **Non-specialty Spend**: $5.1B

### Spend by Beneficiary Category

- **AD**: 5%
- **ADFM**: 9%
- **Retiree**: 38%
- **RetireeFM**: 48%
- **Non-specialty**: 30dEqRx
- **Spend**: Billions

- **Specialty**: $5.1B
- **Non-specialty**: $1.4B
Specialty vs. Non-Specialty Spend
By POS

<table>
<thead>
<tr>
<th>Row Labels</th>
<th>4Q FY13</th>
<th>1Q FY14</th>
<th>2Q FY14</th>
<th>3Q FY14</th>
<th>Grand Total ($M)</th>
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<tbody>
<tr>
<td>Specialty</td>
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<tr>
<td>Non-specialty</td>
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</tr>
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</table>

**Beneficiary Category by POS**

- **Specialty Spend**
  - MTF: 18%
  - Mail Order: 18%
  - Retail: 64%

- **Non-Specialty Spend**
  - MTF: 23%
  - Mail Order: 35%
  - Retail: 42%
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Jeremy@nwp-mail.com