DoD Ambulatory Pharmacy Benefit Design Tools Review

November 2017

Note: There is an accompanying audio file available for request. If interested, please email us at: dha.jbsa.pharmacy.list.poduf@mail.mil.

Defense Health Agency
Pharmacy Operations Division

“Medically Ready Force . . . . Ready Medical Force”
Agenda

• Role of Uniform Formulary

• DoD Formulary Management Tools

• MHS Genesis Outpatient Prescription Claims
Uniform Formulary Role

• DoD Pharmacy and Therapeutics Committee (P&T) has authority to manage the TRICARE Uniform Formulary (UF)
  – Holds quarterly meetings to recommend changes
  – Recommends medications for inclusion on the UF based on clinical and cost effectiveness of the agents in each therapeutic class

• Provides the tools to manage the OUTPATIENT pharmacy benefit
  – Prior Authorization (PA), Step Therapy, and Quantity Limits (QL)
  – Medical Necessity (MN)
  – Formulary Status

• Influence beneficiary and prescriber choice
  – Points of service; preferred agents

• Standardize access to medications
  – MTF formulary alignment; portability of benefit
Administration of the Uniform Formulary

• The Services and MTF Commanders are responsible for ensuring compliance with TRICARE Uniform Formulary policy and formulary management determinations

• For additional information see Dec 2004 Health Affairs Policy 04-032, TRICARE Pharmacy Benefit Program Formulary Management
TRICARE Uniform Formulary: Three-Tiered Structure

**Unclassified**

- Non-preferred Brand & Generic medications
- Must not be added to the local MTF formulary
- Mail Copay: $49 for up to 90 day supply
- Retail Copay: $150 for 90 day supply or $50 per 30 day supply
- Active Duty: MN applies
- Non Active Duty: MN may be utilized at mail or retail to reduce copay to UF amount**

**Tier 1 or Tier 2 depending if NF medication is a brand or generic medication**

**Tier 3 - Non-Formulary**

**Tier 2 – Formulary Brand**

Copay:
- Mail: $20 for up to 90 day supply
- Retail: $24 per 30 day or $72 per 90 day supply

**Tier 1 – Formulary Generics**

Copay:
- Mail: $0 for up to 90 day supply
- Retail: $10 per 30 day or $30 per 90 day supply

- Mandatory use of generics required
- *Some brand medications have a Tier 1 copay as determined by DoD P&T.*
- *Within all tiers: PA or QLs may apply*
## DoD Formulary Tools

Promote safe and cost-effective use of preferred medications

<table>
<thead>
<tr>
<th>Tool</th>
<th>Description &amp; Impact</th>
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</table>
| Prior Authorization (PA)    | • Establishes coverage criteria for certain pharmaceutical agents to assure clinically appropriate use as determined by the DoD P&T Committee  
• May apply to brand over generic requests, age limits, and quantity limits  
• To be completed at MTF, Mail Order, and Retail                                                                                                                                                                                                                                   |
| Step Therapy (Automated)    | • Automated process in which adjudication system reviews patient’s TRICARE pharmacy profile and allows for processing of a non preferred medication if patient has had therapy with a preferred medication                                                                                                                                                  |
| Quantity Limits (QL)        | • QL establishes a maximum medication quantity per 30 and 90-day period, or drug-specific dosing regimen (e.g., 30 and 90 days) at all POS based on safety and waste considerations, as determined by the DoD P&T Committee                                                                                                                                 |
| Medical Necessity (MN)      | • Applies to Non-Formulary (NF) medications only  
• Establishes clinical need over use of formulary medication (for Active Duty and MTF dispensing) and reduces copayment from Non-Formulary to appropriate* formulary tier at retail and mail  
*Tier 1 or Tier 2 depending if NF medication is a brand or generic medication                                                                                                                                                                                                                          |
Prior Authorization: Criteria Governance

- To obtain copies of current and past DoD P&T minutes visit: https://health.mil/PandT

DoD Pharmacy & Therapeutics Committee

The Department of Defense Pharmacy & Therapeutics (DoD P&T) Committee’s mission is to uniformly, consistently, and equitably provide appropriate drug therapy to meet the clinical needs of DoD beneficiaries in an effective, efficient, and fiscally responsible manner.

To learn more, please see the Doc 2004 Health Affairs Policy 04-032, TRICARE Pharmacy Benefit Formulary Management (clarified 22 Mar 2005).

DoD P&T Committee Meeting Schedule

View DoD P&T Meeting Minutes  See Archived Meeting Pages

November 15-16, 2017

Uniform Formulary Request for Quote Information
- UF BPA & UF ADP RFQ Documents Posted: August 21, 2017
- Pre-Proposal Teleconference: September 7, 2017 @ 1200 Central
- Clinical/Cost Presentation Meeting Window: August - September, 2017
- UF BPA & UF ADP Quotes Due: October 13, 2017
- P&T Committee Meeting: November 15-16, 2017
Prior Authorization: Criteria Governance

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Alzheimer’s Disease Agents: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric)

3. COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA—Manual PA criteria were recommended at the August 2015 DoD P&T Committee meeting, with an implementation date of February 3, 2016. The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) maintaining the previously approved PA criteria for Namenda XR and Namzaric. See Appendix C for the full criteria.

Appendix C—Table of Prior Authorization (PA) Criteria

<table>
<thead>
<tr>
<th>Drug / Drug Class</th>
<th>Prior Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Memantine ER (Namenda XR)</td>
<td>Manual PA criteria apply to all new users of Namenda XR.</td>
</tr>
<tr>
<td>Alzheimer’s Disease Agents</td>
<td>Manual Prior Authorization criteria originally approved August 2015 with an implementation date of February 3, 2016. No changes recommended to PA criteria November 2015. Manual PA criteria apply to all new users of Namenda XR.</td>
</tr>
<tr>
<td></td>
<td>Manual PA criteria—Namenda XR is approved if:</td>
</tr>
<tr>
<td></td>
<td>• The patient is being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia), AND</td>
</tr>
<tr>
<td></td>
<td>• Taking Namenda IR (memantine) twice daily causes undue burden to the patient or care provider, AND</td>
</tr>
<tr>
<td></td>
<td>• The patient’s functional status has not declined while receiving Namenda IR</td>
</tr>
<tr>
<td></td>
<td>Prior Authorization does not expire.</td>
</tr>
</tbody>
</table>
Prior Authorization Form: Establish Clinical Appropriateness

Establishes appropriate clinical use of certain medications as determined by the DoD P&T process.

Independent of a medication’s formulary or tier status

Applies to all TRICARE beneficiaries* and all points of service (MTF, Mail, & Retail)

* Beneficiaries in which TRICARE is the primary form of health care coverage
Prior Authorization Form

- To obtain a prior authorization form that may be associated with a medication visit the TRICARE formulary Search Tool; (www.Tricare.mil/pharmacyformulary)
To obtain a consolidated list of medications that require prior authorization visit: (https://health.mil/formulary)
Prior Authorization: Establish Clinical Appropriateness

• Options for requesting PA:
  – Express Scripts* performs review:
    • Paper Form: Prescriber can download, complete, and fax (866-203-2451) back to ESI for review (48 hours) and determination
    • Phone: Prescriber can call ESI coverage review department (866-684-4488) and perform a real time review over the phone
    • Electronic PA (ePA): Prescriber can log into ePA Portal (CoverMyMeds) and complete online form
      • All 3 options use the same criteria
  – MTF-approved PA:
    • MTF can contact ESI (855-315-1921) to have them document a MTF-completed PA on the patient profile
      • Entered in real time

*Express Scripts is the TPHARM Contractor for the DOD
Step Therapy is a specific type of automated PA where there are two different paths to obtaining a non-preferred medication

• **Meet the Step** — Beneficiaries must first try the *preferred agent* to treat their medical condition before they are covered for a *non-preferred agent* for that condition
  - ESI performs an automatic look back (up to 720 days*); Claim will only be paid if patient has preferred agent on their profile and will be transparent to pharmacy and patient; otherwise, Rx will reject for Prior Authorization

• **Obtain Prior Authorization** — Providers contact ESI and provide clinical justification for the patient requiring the non-preferred agent

*Medication Specific; determined by DoD P&T*
Step Therapy: Criteria Governance

V. UF DRUG CLASS REVIEWS

A. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Overall Relative Clinical Effectiveness Conclusion: Other than their potential for weight loss, the SGLT2 inhibitors offer no additional clinical advantages over the other non-insulin diabetes drugs on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analyses (BIA) were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- BIA was performed to evaluate the potential impact of designating selected agents as formulary (and step-preferred) or NF (and non step-preferred) on the UF. BIA results showed that designating empagliflozin (Jardiance) and empagliflozin/linagliptin (Glyxambi) as formulary and step-preferred resulted in the greatest cost avoidance for the MHS.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following:

- UF and step-preferred:
  - Empagliflozin (Jardiance)
  - Empagliflozin/linagliptin (Glyxambi)

- NF and non step-preferred:
  - Canagliflozin (Invokana)
  - Dapagliflozin (Farxiga)
This recommendation includes step therapy (automated PA), which requires a trial of empagliflozin or empagliflozin/metformin prior to use of the NF, non step-preferred SGLT2 inhibitors in all new and current users. PA criteria currently apply to the SGLT2 inhibitors subclass.

COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) AND MANUAL PA CRITERIA—Existing automated PA (step therapy) requires a trial of metformin, a sulfonylurea, or a DPP-4 inhibitor prior to use of a SGLT2 inhibitor.

Additionally, empagliflozin-containing products (Jardiance or Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users must try a preferred empagliflozin product before trying canagliflozin- or dapagliflozin-containing products.

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) modifying the existing PA criteria to require a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses prior to use of an SGLT2 inhibitor in new users. The P&T Committee also recommended step therapy criteria for Invokana, Invokamet, Farxiga, and Xigduo XR. See Appendix C for the full criteria.
Appendix C—Table of Prior Authorization (PA) Criteria

<table>
<thead>
<tr>
<th>Drug / Drug Class</th>
<th>Prior Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>All new users of an SGLT2 inhibitor are required to try metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin or a sulfonylurea (SU) and a DPP-4 inhibitor first. Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first.</td>
<td></td>
</tr>
<tr>
<td><strong>Automated PA criteria</strong></td>
<td></td>
</tr>
<tr>
<td>• The patient has filled a prescription for metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</td>
<td></td>
</tr>
<tr>
<td>• The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</td>
<td></td>
</tr>
<tr>
<td><strong>AND</strong></td>
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<tr>
<td><strong>Manual PA criteria</strong>—if automated PA criteria are not met, Jardiance or Glyxambi is approved (e.g., a trial of metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes are NOT required) if:</td>
<td></td>
</tr>
<tr>
<td>• The patient has had an inadequate response to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or</td>
<td></td>
</tr>
<tr>
<td>• The patient has experienced a significant adverse effect from metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or</td>
<td></td>
</tr>
<tr>
<td>• The patient has a contraindication to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes.</td>
<td></td>
</tr>
<tr>
<td><strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>In addition to the above criteria regarding metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes, the following PA criteria would apply specifically to all new and current users of canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/metformin ER (Xigduo XR):</td>
<td></td>
</tr>
<tr>
<td>• The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance or Glyxambi) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.</td>
<td></td>
</tr>
</tbody>
</table>
Example: Step Therapy Criteria
SGLT2 Inhibitors: Invokana, Farxiga

• Automated Profile Review
  – Review looks for preferred SGLT2 Inhibitor (e.g. empagliflozin (Jardiance), empagliflozin/linagliptin (Glyxambi)) prescriptions dispensed during the previous 180 days at a Military Treatment Facility (MTF), a retail network pharmacy, or the mail order pharmacy under the Tricare pharmacy benefit
  – If none found, stops claims for all Invokana (canagliflozin) and Farxiga (dapagliflozin) current and new patients
  – Applies to current and new users of non-preferred SGLT2 inhibitors (e.g., no grandfathering)
  – The automated “look back” period is medication specific and defined by the DoD P&T committee (most are 180 days).

Goal: Promote use of preferred medications (e.g., empagliflozin or empagliflozin/linagliptin) prior to use of a non-preferred medications
Quantity Limits (QL)

- Example 1: Precision Xtra Test Strips
  - A patient fills prescription for 100 Precision Xtra test strips at a retail pharmacy
    - One month later, the patient tries to fill a second prescription for 300 test strips at the MTF
      - Receives a Reject 76, “Plan limit exceeded”
      - Limits are cumulative: Both fills were within the limit of 300 but together exceed the 300 strips per 90 day limit
      - Potential Resolution: Adjust QTY to 200 to meet plan limit, and re-submit claim

Goal: Apply a maximum allowed quantity of a drug at all points of service within a specified time period

<table>
<thead>
<tr>
<th>DRUG</th>
<th>QUANTITY LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Precision Xtra Test Strips (Self Monitoring Blood Glucose Systems)</td>
<td>• 100 strips per 30 days</td>
</tr>
<tr>
<td></td>
<td>• 300 strips per 90 days</td>
</tr>
</tbody>
</table>
Quantity Limits (QL):
SMBG Test Strips – Nov. 2014

5. COMMITTEE ACTION: QLs—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) QLs for the SMBGS test strips, limiting use to 100 strips per 30-day supply in the Retail Network and 300 strips per 90-day supply in the Mail Order and MTF points of service. See Appendix F for the full criteria.

Quantity Limits for the SMBGS test strips may be exceeded in the following situations: patient is receiving insulin; using an insulin pump; has gestational diabetes; requires more frequent testing due to endocrine disorders (e.g., insulinoma, endogenous hyperinsulinism, non-islet cell tumor); or, has a history of poorly controlled blood glucose levels with adverse outcomes (e.g., ketoacidosis or hypoglycemic episode), requiring medical intervention.
Quantity Limits (QL)

- To see any quantity limits that may be in place, check the TRICARE formulary Search Tool.

Coverage notes will indicate any additional benefit rules that apply to the medication.

*MTFs using MHS Genesis should check the Retail coverage notes. At this time the coverage rules do not appear under the MTF portion of, since most MTFs are still utilizing CHCS where the benefit rules are manually enforced.
Coverage Notes

Coverage notes

For Freestyle Lite Strips Strip when using your Retail pharmacy benefit:

- Your plan provides coverage for this medication with certain quantity limits. SELECT TEST STRIPS are covered for a maximum quantity totaling 100 units per 30 day period and 300 units per 90 day period by mail. If your doctor determines that there are circumstances that may qualify you to receive additional quantities of this medication, your doctor may request a coverage review (prior auth).

- This medication is covered for the member/cardholder only.

- Please note that the coverage terms of this prescription benefit are subject to change.
### Quantity Limits (QL)

- **Example 2: Xeljanz XR**
- A patient fills a prescription for Xeljanz XR, quantity of 30 tablets at a retail network pharmacy
  - One week later, when the patient tries to fill the same medication/dosage form/strength, but a quantity of 60 tablets at the MTF
    - The pharmacy will receive a Reject 76, “Plan limit exceeded” as the max fill at the MTF during a 60-day period is 60 tablets, but the patient already picked up 30 tablets at retail within the last 60 days
    - However, if the patient had attempted to fill the same drug, but a **different** dosage form or strength, then the patient would have been allowed to fill 60 days supply at the MTF

<table>
<thead>
<tr>
<th>DRUG</th>
<th>QUANTITY LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tofacitinib (Xeljanz XR) Targeted Immunomodulatory Biologics (TIBs)</td>
<td>• Retail Network: 30 tablets/30 days • MTF and Mail Order: 60 tablets/60 days</td>
</tr>
</tbody>
</table>
Quantity Limits (QL)
Xeljans XR (tofacitinib) – May 2016

<table>
<thead>
<tr>
<th>Drug / Drug Class</th>
<th>Quantity Limits</th>
</tr>
</thead>
</table>
| **Fluticasone/Salmeterol (Advair HFA)** | • Current: Retail Network: 1 inhaler (60 actuations/30 days)  
• MTF and Mail Order Pharmacy: 3 inhalers (180 actuations/60 days)  
• Additional Recommendation: The automated setup will check for HiCL + Dosage Form + Strength to allow for different strengths of the same inhalers, without exceeding recommended salmeterol doses  
| 5.1g inhaler = 60 inhalations; 8.9g inhaler = 120 inhalations  
• Retail Network: 5.1g-#2 inhalers/30 days; 8.9g-#1 inhaler/30 days  
• MTF and Mail Order Pharmacy: 5.1g-#6 inhalers/60 days; 8.9g-#3 inhalers/60 days |
| **Flunisolide (Aerospan)** |  |
| **Pulmonary Is – Inhaled Corticosteroids / Long Acting Beta Agonists** |  |
| **Tofacitinib (Xelanz XR)** | • Retail Network: 30 tabs/30 days  
• MTF and Mail Order Pharmacy: 60 tabs/60 days |
| **Targeted Immunomodulatory Biologics (TIBs)** |  |
| **Ivakizumab (Taltz)** | • Retail Network: 28 days supply  
• MTF and Mail Order Pharmacy: 56 days supply |
| **Targeted Immunomodulatory Biologics (TIBs)** |  |
| **Secukinumab (Cosentyx)** |  |
| **Targeted Immunomodulatory Biologics (TIBs)** |  |
Coverage Notes

Coverage notes

For Xeljanz Xr 11 Mg Tablet, Extended Release 24 Hr when using your Retail pharmacy benefit:

After 2 fill(s) at a retail network pharmacy, you will pay a higher cost for this and certain other drugs you take on a long-term basis. Please call 877-862-3335 to convert this medication to Home Delivery or a Military Pharmacy to avoid paying the full cost of this medication.

Your plan provides coverage for this medication in certain situations. You must try Humira first. Prescribers may call Lni for override if not appropriate. Your plan provides coverage for this medication with certain quantity limits. XELJANZ XR is covered for a maximum quantity of 30 tablets per 30 day period at retail and 60 tablets per 60 day period at mail. If your doctor determines that there are circumstances that may qualify you to receive additional quantities of this medication, your doctor may request a coverage review (prior authorization).

This medication is covered. This medication is covered for the member/cardholder only.

Please note that the coverage terms of this prescription benefit are subject to change.
Quantity Limits (QL)

- Example 3: sofosbuvir/velpatasvir (Epclusa)
- A patient fills a prescription for Epclusa, 28 tabs at the MTF
  - Then the patient transfers the prescription to a retail pharmacy and wants to fill the drug within 2 weeks from last fill at the MTF
    - Even though this is a transferred prescription with a ‘new’ prescription number, the pharmacy will still get a Reject 76, “Plan limit exceeded”, since the max fill quantity is 28 tabs in 28 days for any point of service pharmacy
    - The QL is not based on whether the prescription is new or not. As long as it’s the same drug, same dosage form, and same strength, QLs will apply

<table>
<thead>
<tr>
<th>DRUG</th>
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</tr>
</thead>
<tbody>
<tr>
<td>sofosbuvir/velpatasvir (Epclusa)</td>
<td>Retail, MTF and Mail Order: 28 tablets/28 days</td>
</tr>
<tr>
<td>Hepatitis C Virus (HCV) Direct-Acting Antiviral Agents (DAAs) Subclass</td>
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</table>
Quantity Limits (QL)

- Example 4: **Collective Limit (PDE-5 Inhibitors)**
  - A patient fills a prescription for Viagra, #18 tabs at the MTF
  - Then the patient presents a prescription for Cialis, #18 tabs to be filled at a retail pharmacy within 2 weeks from last fill at the MTF due to failing Viagra.
    - Even though this is a new prescription for a different medication within the PDE-5 class, the pharmacy will still get Reject 76, “Plan limit exceeded”, since the PDE-5 class has a **Collective Limit** applied.
    - For a collective limit, the QL is based on total amount dispensed within the therapeutic **class** of medication

<table>
<thead>
<tr>
<th>DRUG</th>
<th>QUANTITY LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDE-5 Inhibitors (e.g. sildenafil (Viagra), tadalafil (Cialis))</td>
<td>Retail, MTF and Mail Order: 18 tablets/90 days</td>
</tr>
</tbody>
</table>
7. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—The P&T Committee considered QLs for the treatment of ED as well as QLs for other indications. Based on the results of the clinical and economic evaluations presented, the P&T Committee recommended (11 for, 0 opposed, 0 abstained, 0 absent) the following QLs:

**Treatment of ED:**

- **Mail Order:** Collective QL of 18 tablets per 90 days
- **Retail:** Collective QL of 6 tablets per 30 days
Medical Necessity: Criteria Governance

An MTF formulary cannot include a pharmaceutical agent that is classified as non-formulary in regard to the UF. Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries through MTF pharmacies for prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary pharmaceutical agent in lieu of a pharmaceutical agent that is on the MTF formulary.


III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly-approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5) (previously known as “innovator drugs”), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.
XIV. ADJOURNMENT

The meeting adjourned at 1230 hours on May 11, 2017. The next meeting will be in August 2017.

Appendix A—Attendance: May 2017 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Formulary Recommendations for Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as Innovator Drugs)

Appendix F—Mail Order Status of Medications Designated Nonformulary During the May 2017 DoD P&T Committee Meeting

Appendix G—Pharmacy and Therapeutics Committee Processes and Recommendations/Approval Authorities

Appendix H—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary

Appendix I—Table of Abbreviations
Medical Necessity: Criteria Governance – May 2017

Example: Rhofade (oxymetazoline)

B. COMMITTEE ACTION: MN CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for crisaborole (Euceris), plecanatide (Trulance), insulin degludec/liraglutide (Xultophy), morphine sulfate ER (Arymo ER), and oxymetazoline (Rhofade). See Appendix B for the full criteria.
Establishes NF medication clinical need over use of a formulary medication

Applies to:
1) DoD Non-Formulary Medications
2) All active Duty
3) MTF, Mail Order, Retail

*Can be used to justify a reduction in copy cost share at retail and mail order for non-Active duty beneficiaries, but is not required to obtain the medication at the higher Tier 3 (non-formulary) cost share
Medical Necessity Form

• To obtain a medical necessity form that may be associated with a medication visit the TRICARE formulary Search Tool; (www.Tricare.mil/pharmacyformulary)
Medical Necessity

To obtain a consolidated list of medications that require medical necessity visit: [https://health.mil/formulary](https://health.mil/formulary)
## Additional DoD Formulary Tools

Promote safe and cost-effective use of preferred medications

<table>
<thead>
<tr>
<th>Tool</th>
<th>Description &amp; Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier Placement (Tier 3, Non-Formulary)</td>
<td>• Increases copays retail/mail&lt;br&gt;• Encourages use of MTFs and TRICARE Mail Order Pharmacy over Retail network and non-network pharmacies&lt;br&gt;• Generally not readily available at MTFs</td>
</tr>
<tr>
<td>Claims Processing Rules</td>
<td>• Age, gender criteria&lt;br&gt;• Clinical appropriateness&lt;br&gt;• Rejects&lt;br&gt;• High level safety issues, early refills&lt;br&gt;• Warning messages&lt;br&gt;• Low level safety issues</td>
</tr>
<tr>
<td>Point of Service Restrictions (e.g. Exclusive Mandatory Mail)</td>
<td>• Select Maintenance drugs only available at MTF and Mail Order&lt;br&gt;• Some non-formulary medications not available at Retail</td>
</tr>
</tbody>
</table>
Why have this review of the Uniform Formulary tools?

- MHS Genesis includes new commercial capabilities not traditionally utilized at the MTF

- Outpatient prescriptions processed in MHS Genesis will go through an automated formulary and benefit management review (as recommended by DoD P&T) via Express Scripts

- MTF outpatient pharmacies utilizing MHS Genesis will receive prescription rejections when DoD formulary benefit design criteria are found to not be met based on this automated review
  - Outreach to prescribers to address prior authorizations and other situations
Why have this review of the Uniform Formulary tools?

• MHS Genesis allows technical implementation of formulary and benefit management tools enhancing benefit consistency across all points of service

• Effort to manage the MHS as a more cohesive system may result in more patients moving between the MTF, Retail and Mail

• MTFs may want to consider moving away from site-specific formularies and moving towards adoption of the UF
Why does the Uniform Formulary matter to me?
MHS Genesis Outpatient Prescription Workflow

New Prescription Order → Review and Clear MHS Genesis Alerts; Send to Pharmacy → Pharmacy Reviews the Order → Review Against the full patient history, benefit, and safety check
Order becomes a “claim”

Claim is Accepted or Rejected → Accepted Claim: Medication Dispensed

Rejected Claim
Reject Code: 75 Prior Authorization Required
Reject Code: 76 Plan Limits Exceeded
Resolution: Contact ESI MTF Help Desk

Formulary Rules Applied
Take appropriate action to resolve reject
- Obtain PA
- Enter Override
- Correct Data
- Adjust quantity
Resubmit Claim
Other Tools

https://health.mil/formulary

TRICARE Formulary

The TRICARE Uniform Formulary (UF) is a list of brand name and generic drugs and supplies that TRICARE covers. The formulary is:

- Developed by the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee.
- Updated quarterly. [View Recent Formulary Changes](#)

You can search the TRICARE Formulary to:

- Look up costs, quantity limits and therapeutic alternatives
- Download medical necessity or prior authorization forms
- See if your prescription is on the Basic Core Formulary or Extended Core Formulary.

Search the TRICARE Formulary

A non-formulary drug can be provided at the formulary cost share if your [provider supplies](#) information showing that there is a medical necessity to use the non-formulary drug instead of a therapeutic alternative.
How can a MTF P&T committee provide change requests to DoD P&T committee?

DoD Pharmacy & Therapeutics Committee

The Department of Defense Pharmacy & Therapeutics (DoD P&T) Committee's mission is to uniformly, consistently, and equitably provide appropriate drug therapy to meet the clinical needs of DoD beneficiaries in an effective, efficient, and fiscally responsible manner.

To learn more, please see the Dec 2004 Health Affairs Policy 04-032, TRICARE Pharmacy Benefit Formulary Management (clarified 22 Mar 2005).

DoD P&T Committee Meeting Schedule

- View DoD P&T Meeting Minutes
- See Archived Meeting Pages

November 15-16, 2017
Uniform Formulary Request for Quote Information

- UF BPA & UF ADP RFQ Documents Posted: August 21, 2017
- Pre-Proposal Teleconference: September 7, 2017 @ 1200 Central
- Clinical/Cost Presentation Meeting Window: August - September, 2017
- UF BPA & UF ADP Quotes Due: October 13, 2017
- P&T Committee Meeting: November 15-16, 2017

<table>
<thead>
<tr>
<th>Class Review</th>
<th>Designated Newly Approved Drugs</th>
<th>FDA Innovator Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Loss Agents: Belviq, Belviq XR, Contrave, Qsymia, Saxenda, Xenical</td>
<td>ArmonAir RespiClick, Baxdela, Benlysta, Benvaza, Cotempia XR ODT, Duzallo, Endari, Fiasm, Floloid</td>
<td>To be determined</td>
</tr>
<tr>
<td>Oncological Agents - Multiple Myeloma: Alkeran, Farydak, Melphalan, NINlaro, Pomalyset, Revlimid, Thalomid</td>
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</tbody>
</table>

Contact Us

Clinical Presentation POC
- Call 1-210-536-6116

RFQ POC
- Call 1-303-676-3529
- Send an Email Message

Industry Technical Liaison
- Call 1-210-536-6121
- Send an Email Message

DoD Retail Refund Pricing Agreement POC
- Call 1-703-681-0494
- Send an Email Message

Related Links

- Beneficiary Advisory Panel
- DoD Formulary Management of FDA Innovator Drugs
- DoD P&T Committee Charter
- Guidance for DoD P&T Committee Member's Interaction with Industry
- Information for Pharmaceutical Manufacturers
- MTF Drug Request Review Form
How can a MTF P&T Committee provide change requests to DoD P&T Committee?

Must be submitted via MTF P&T Committee

Must contain:

1) Issue to be addressed
2) Documentation and/or clinical evidence to support change request
3) Other information that should be considered by the DoD P&T Committee
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DoD P&T Committee Resources

View and download Formulary Management Documents and/or Executive Summaries from below.

<table>
<thead>
<tr>
<th>Formulary Management Documents</th>
<th>File</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Formulary Management for Antihistamine Mast Cell Stabilizers</td>
<td>8/18/2017</td>
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<tr>
<td></td>
<td>Formulary Management for Idiopathic Pulmonary Fibrosis</td>
<td>8/18/2017</td>
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<td>Formulary Management for Diabetes Drugs</td>
<td>3/20/2017</td>
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<td></td>
<td>Formulary Management for Oral Anticoagulants</td>
<td>2/21/2017</td>
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<td>Formulary Management for PCSK9 Inhibitors</td>
<td>2/21/2017</td>
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<td>Formulary Management for Anticonvulsants and Anti Mania Agents</td>
<td>8/2/2016</td>
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<td>Formulary Management for Atypical Antipsychotic Agents</td>
<td>8/2/2016</td>
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<td>Formulary Management for Emergency Contraceptive Agents</td>
<td>8/2/2016</td>
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<td>Formulary Management for Ophthalmic Immunomodulatory Agents: Cyclosporine 0.05% Ophthalmic Emulsion</td>
<td>5/19/2015</td>
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<td></td>
<td>Formulary Management for Oral Contraceptives and Miscellaneous Contraceptives</td>
<td>5/19/2015</td>
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<td>Formulary Management for OTC Doxylamine</td>
<td>5/19/2015</td>
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<td>Formulary Management for Topical Antifungals for Onychomycosis Subclass</td>
<td>5/19/2015</td>
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<td></td>
<td>Formulary Management Table for Oral Contraceptives</td>
<td>5/19/2015</td>
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</tbody>
</table>
MTF Formulary Management

Ophthalmic- Antihistamines and Dual Acting Antihistamine/Mast Cell Stabilizers (AHMCS) Subclass

Defense Health Agency Pharmacy Operations Division

**Bottom Line**
- Generic olopatadine 0.1% (Patanol generic) remains on the Basic Core Formulary (BCF).
- Olopatadine 0.1% (Patanol) is new Uniform Formulary (UF), along with azelastine (Ostionix generic) and epinastine (Bleustar generic).
- Olopatadine 0.2% (Patanol) moves from UF to Nonformulary (NF) status. Cost-effective generic Olopatadine formulations are not yet commercially available.
- Prior Authorization (PA) applies to the class – see below.
- The 19,000 Military Treatment Facility (MTF) patients with prior/current prescriptions for Olopatadine will need to be converted to one of the UF products, conversion to generic olopatadine will result in considerable cost avoidance.
- There is a high degree of therapeutic interchangeability with the AHMCS drugs.

**UF Decision:** The Director, DHA, approved the recommendations from the May 2017 DoD P&T Committee meeting on July 27, 2017. Implementation will occur by November 1, 2017.

<table>
<thead>
<tr>
<th>Uniform Formulary (UF) Agents</th>
<th>MTFs must have on formulary</th>
<th>MTFs may have on formulary</th>
<th>MTFs must not have on formulary</th>
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</thead>
<tbody>
<tr>
<td>BCF drugs</td>
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<tr>
<td>Olopatadine 0.1% (Patanol generic)</td>
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<tr>
<th>Nonformulary (NF) Agents</th>
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<tr>
<td>Azelastine (Ostionix generic)</td>
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<td>Epinastine (Bleustar generic)</td>
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<tr>
<td>Olopatadine 0.1% (Patanol)</td>
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<tr>
<td>Azelastine 0.25% (Lastozol)</td>
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<tr>
<td>Bepotastine 1.2% (Bripeva)</td>
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<tr>
<td>Bromelastine 0.02% (Brodeine)</td>
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<tr>
<td>Olopatadine 0.2% (Patanol)</td>
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</table>

**Formulary Management Issues and Prior Authorization**
- Allergic conjunctivitis is a highly seasonal condition, and Military Health System (MHS) utilization for the class reflects this variability. Peak usage of the AHMCS occurs in the month of March.
- Currently, Patanol accounts for 30% of MTF utilization, with olopatadine 0.1% comprising 35% of the market share. Patanol will move to NF status, and patients currently receiving Patanol will need to change to one of the formulary AHMCS drugs.
- Manual Prior Authorization (PA) applies to the nonformulary drugs in the class (Lastozol, Bripeva, Emastine, and Patanol). All new and current users of a nonformulary product require manual PA in order to stay on the nonformulary drug. PA criteria requirements include the following:
  - The patient must have tried and failed two formulary drugs (Olopatadine 0.1%, Patanol, azelastine or epinastine) in the past 60 days, or
  - The patient has experienced intolerable adverse effects from two formulary products (Olopatadine, azelastine or epinastine), or
  - The patient is pregnant (Lastozol and Emastine are pregnancy category B).
- The price of generic olopatadine 0.1% continues to fall, making this drug a cost-effective AHMCS.
- The over-the-counter (OTC) product ketotifen (Zaditor; generics) is not part of the TRICARE pharmacy benefit, and the formulary recommendation does not apply to OTC formulations.

**Clinical Summary**
- The AHMCS have both antihistamine properties that provide relief of ocular itching and hyperemia along with mast cell stabilizing properties that prevent early phase release of inflammatory mediators. Onset of action occurs within minutes of administration.
- The AHMCS are the standard of care for treating the signs and symptoms of allergic conjunctivitis.
Executive Summaries

<table>
<thead>
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<tbody>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Antihistamine and Dual Acting Antihistamine Mast Cell Stabilizers</td>
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</tr>
<tr>
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</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Direct-Acting Anticoagulants</td>
<td>5/11/2017</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: PCSK9 Inhibitor Subclass</td>
<td>2/21/2017</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Macrogol Agents - Triptans</td>
<td>11/28/2016</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Alcohol Detoxifiers - Narcotic Antagonists</td>
<td>11/28/2016</td>
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<tr>
<td>DoD P&amp;T Committee Executive Summary: Topical Acne and Rosacea Agents</td>
<td>11/28/2016</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Anticonvulsants and Anti Mania Agents</td>
<td>8/1/2016</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Allergic Anticholinergic Agents</td>
<td>8/1/2016</td>
</tr>
<tr>
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<td>8/1/2016</td>
</tr>
<tr>
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</tr>
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<td>5/19/2016</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Topical Antifungal Drugs for Candidiasis</td>
<td>5/19/2016</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Chronic Medicosensory Leukemia</td>
<td>12/14/2015</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Extended Release Opioids</td>
<td>12/14/2015</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Glucose-Like-Peridine-1 Receptors Agonist (GLP1RA)</td>
<td>12/14/2015</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Sodium-Glucose Co-Transporter 2 Inhibitors (SGLT2)</td>
<td>12/14/2015</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Hepatitis C Virus Direct Acting Agents</td>
<td>12/14/2015</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Pulmonary Arterial Hypertension Drugs</td>
<td>2/1/2015</td>
</tr>
<tr>
<td>DoD P&amp;T Committee Executive Summary: Prostate Cancer Subclass I/II Drugs Oral Oncology</td>
<td>2/1/2015</td>
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<tr>
<td>DoD P&amp;T Committee Executive Summary: Transdermal Immediate Release Febrile Products</td>
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Definitions

• **Uniform Formulary (UF)** – medications that encompass the Military Health System pharmacy benefit; includes medications designated as Uniform Formulary, Basic Core Formulary (BCF), and extended Core Formulary (ECF).

• **Non-Formulary (NF)** – designated medications excluded from the pharmacy benefit and excluded from being placed on local MTF formularies. Medications with a NF designation may be only be made available via the NF process which validates the medical necessity of the NF agent in lieu of a medication that is on the MTF formulary.

• **Basic Core Formulary (BCF)** – designated medications that are a subset of UF medications which each MTF must have on its formulary to support the primary care scope of practice.

• **Extended Core Formulary (ECF)** – designated medications within therapeutic classes that are used to support more specialized scopes (beyond primary care) of practice at a MTF than those agents on the BCF.

• **Medical Necessity (MN)** – A DoD P&T recommended medication specific process utilized to demonstrate the clinical need of a NF medication over use of a formulary medication.

See Dec 2004 Health Affairs Policy 04-032, TRICARE Pharmacy Benefit Program Formulary Management