DoD Ambulatory Pharmacy Benefit Design Tools Review
January 2020

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

• Standardize access to medications
  • Military treatment facility (MTF) formulary alignment, portability across the enterprise

• Provides the tools to manage the OUTPATIENT pharmacy benefit
  • Prior Authorization (PA), Step Therapy (ST), and Quantity Limits (QL)
  • Medical Necessity (MN)
  • Tiered copayment structure

• Influence beneficiary and provider choice
  • Encourage use of preferred points of service (POS)

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

• The Services, Markets, MTF Directors/Commanders, and MTF Pharmacies are responsible for ensuring compliance with TRICARE Uniform Formulary policy and formulary management determinations

• For additional information:
  – Dec 2004 Health Affairs Policy 04-032, TRICARE Pharmacy Benefit Program Formulary Management
  – Defense Health Agency Procedural Instruction (DHAPI) 6025.31, Military Medical Treatment Facility Pharmacy Operations
TRICARE Uniform Formulary: Four-Tiered Structure

Basic Core Formulary (BCF) and Extended Core Formulary (ECF)
Considered the minimum scope of health care service offered at the local MTFs.
- BCF: Must be carried by all full service MTF pharmacies
- ECF: Must be carried if the service is offered

Tier 1 (UF) Generics
Tier 2 (UF) Brands
Tier 3 (NF) Brands & Generics
(PA) Tier 4 Not Covered

Tier 4 Medications that are not covered by TRICARE after the review process has determined that they provide very little or no clinical effectiveness relative to similar agents

PA = coverage for appropriate use
MN = provides copayment reduction at purchased care POS and access at MTF

*a Some UF branded products may be considered Tier 1 agents.
*b Products in all 3 tiers may require PA.
*c All Products require MN; some products will also require PA.

*The TRICARE Pharmacy Program provides outpatient prescription drugs using this four-tiered structure
Formulary Management Tools

- Tools in the DoD P&T Committee’s “tool box”:
  - Prior Authorization (UF and NF):
    - Specific criteria (generally clinically focused) must be met before certain medications are covered
    - Criteria used at all three POS
  - Grandfather vs. No Grandfather (Applies to PA at all POS):
    - Grandfathering: New/updated PA applies to new users only
    - No Grandfathering: New/updated PA applies to new and current users
  - Medical Necessity (applies to DoD NF medications):
    - Criteria must be met for access at MTF pharmacies
    - Criteria used at Mail and Retail POS in order to reduce copayment from Tier 3 (NF) to Tier 1 or 2 (UF) copayment
Formulary Management Tools (Continued)

- Automated Profile Review (Step Therapy)
  - Requires use of a *preferred* agent before use of a *non-preferred* agent is allowed
  - Express Scripts (ESI)* performs an automatic look back (usually 180 days)
  - If claim failed “Automated Profile Review”:
    - Message sent to pharmacy stating – “must try first line agent(s). If not appropriate for this patient, prescriber must call ESI”
    - Provider has the option to either change to preferred agent OR submit a PA to ESI for review

- QLs
  - Safety, cost avoidance due to wastage

- Age, gender restriction
  - Clinical appropriateness

- Tier 1 Brand Agents
  - When a brand pharmaceutical agent is the most cost effective agent for purchase by the Government compared to available alternatives in the class, the P&T Committee may designate the brand agent as Tier 1 with a generic copayment.

*Express Scripts is the TPHARM Contractor for the DOD*
Formulary Management Tools (Continued)

- **Tier 4/Non-Covered Drugs**
  - Drugs considered for complete exclusion because they provide very little to no clinical effectiveness relative to similar agents (i.e., others in class). (e.g. a me-too option with no clear clinical niche/role or safety concerns)

<table>
<thead>
<tr>
<th>MEASURES USED FOR TRICARE Tier 4/Non-Covered Drugs</th>
</tr>
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<tbody>
<tr>
<td>1</td>
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<td>4</td>
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<td>5</td>
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<tr>
<td>6</td>
</tr>
</tbody>
</table>
What Tier 4 is NOT

- **Tier 4 is not automatic**: Must be recommended by P&T Committee, reviewed by the BAP for comment, and approved by the DHA Director.

- **Tier 4 is not based on cost alone**: P&T Committee considers clinical effectiveness, safety, and available alternatives in making this decision.

- **Tier 4 is not another version of non-formulary**: No MN criteria to allow coverage.

- **Tier 4 is not necessarily permanent**: Medication could be moved back to another Tier if availability of similar agents changes and/or changes occur in clinical or cost evaluations.
Prior Authorization: Criteria Governance

- To obtain copies of current and past DoD P&T minutes visit: health.mil/PandT
C. COMMITTEE ACTION: PA CRITERIA—The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):

- Applying manual PA criteria to new users of Ruzurgi, Ezallor Sprinkle, Piqray, Balversa, Vyndaqel, and Evekeo ODT.

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>ADHD-Wakefulness Promoting Agents: Stimulants</td>
<td>Manual PA is required for all new users of Evekeo ODT.</td>
</tr>
<tr>
<td>amphetamine sulfate orally disintegrating IR tablets (Evekeo ODT)</td>
<td>Manual PA Criteria: Evekeo ODT is approved if ALL criteria are met:</td>
</tr>
<tr>
<td></td>
<td>• Patient is 6-17 years of age with a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record</td>
</tr>
<tr>
<td></td>
<td>• Patient has tried for at least two months and failed or has difficulty swallowing Adderall tabs (generic)</td>
</tr>
<tr>
<td></td>
<td>• Patient has tried for at least two months and failed or the patient has a contraindication to IR methylphenidate tablets or solution</td>
</tr>
<tr>
<td></td>
<td>Non-FDA-approved uses are not approved. PA does not expire.</td>
</tr>
</tbody>
</table>
Establishes appropriate clinical use of certain medications as identified and approved through the DoD P&T process.

Applies to:
1) All beneficiaries
2) MTF, Mail, and Retail POS
Prior Authorization Form

To obtain a prior authorization form that may be associated with a medication, visit the TRICARE formulary Search Tool:
Express-scripts.com/TRICAREformulary

After 2 fl(oids 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 877-882-3335 to convert this medication to Home Delivery or a Military Pharmacy to avoid paying the full cost of this medication.

Victoza
Brand
0.6 Mg/0.1 Pen Injector (ml)

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Is this drug covered?</th>
<th>You Pay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Active duty</td>
</tr>
<tr>
<td>Military Pharmacy (MTF)</td>
<td></td>
<td>Non-Formulary</td>
</tr>
<tr>
<td>Military Treatment Facilities are not allowed to carry this product on their formulary, but it may be available for enrolled beneficiaries to the MTF under certain circumstances. Use of a different product may be required.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home Delivery Pharmacy</td>
<td>▲ YES with limitations</td>
<td>Non-Formulary</td>
</tr>
<tr>
<td>Up to 90 days supply</td>
<td>Coverage notes</td>
<td></td>
</tr>
<tr>
<td>Retail Network Pharmacy</td>
<td>▲ YES with limitations</td>
<td>Non-Formulary</td>
</tr>
<tr>
<td>Up to 30 days supply</td>
<td>Coverage notes</td>
<td></td>
</tr>
</tbody>
</table>

Are there forms my doctor may need to fill out? YES

Priavor Authorization Form

Medical Necessary Form
To obtain a consolidated list of medications that require PA visit: [health.mil/formulary]
Prior Authorization: Establish Clinical Appropriateness

• Options for requesting PA:
  • ESI* performs review**:
    • **Paper Form**: Prescriber can download, complete, and fax (866-684-4477) 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 (e.g., SureScripts) 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

**Network prescriber and MHS GENESIS MTFs

*Express Scripts is the TPHARM Contractor for the DOD
Step Therapy
(Automated Profile Review)

ST is an automated lookback to see if there is history within the pharmacy profile of a preferred medication prior to obtaining a non-preferred medication.

- **Meet the Step** – If the Beneficiary has history (180 to 720 days) of the preferred agent in their system wide pharmacy profile, the claim for the non-preferred agent will not reject for a PA.

- **Prior Authorization** – If there is no history in the profile, the claim for the non-preferred medication will require a PA.

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

IV. UF DRUG CLASS REVIEWS

A. Proton Pump Inhibitors – Capsules and Tablets and Alternative Dosage Form Subclasses

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- The May 2007 drug class review concluded that PPIs have similar efficacy in treating a wide range of acid-related disorders and are highly therapeutically interchangeable. The P&T Committee did not find new clinical efficacy data that would change the original conclusion.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the PPIs. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

Tablets and Capsules Subclass

- CMA results for the Tablets and Capsules subclass showed that esomeprazole strontium, dexlansoprazole, and omeprazole/bicarbonate were substantially less cost-effective than the remainder of the class.

- BIA was performed for the Tablets and Capsules subclass to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating omeprazole (Prilosec, generics) and pantoprazole (Protonix, generics) as formulary and step-preferred, esomeprazole (Nexium, generics) and rabeprazole (Aciphex, generics) as UF and non-step-preferred, lansoprazole (Prevacid, generics) and omeprazole/sodium bicarbonate (Zegerid, generics) as NF and non-step-preferred, and dexlansoprazole (Dexilant) and esomeprazole strontium as Tier 4 demonstrated significant cost avoidance for the Military Health System (MHS).
Step Therapy: Criteria Governance

1. **COMMITTEE ACTION: TABLETS AND CAPSULES AND ALTERNATIVE DOSAGE FORMS UF/TIER 4/NOT COVERED RECOMMENDATION**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following formulary recommendations for the Proton Pump Inhibitors as outlined below, based on clinical and cost-effectiveness.

   *Capsules and Tablets Subclass*

   - **UF and step-preferred**
     - omeprazole 20 mg and 40 mg capsules (Prilosec, generics)
     - pantoprazole tablets (Protonix, generics)
   - **UF and non-step-preferred**
     - rabeprazole tablets (Aciphex, generics)
     - esomeprazole capsules (Nexium, generics)
   - **NF and non-step-preferred**
     - lansoprazole capsules (Prevacid, generics)
     - omeprazole/sodium bicarbonate capsules (Zegerid, generics)
   - This recommendation includes step therapy in new users, which requires a trial of omeprazole or pantoprazole before esomeprazole or rabeprazole, and a trial of all the UF step-preferred and non-step preferred products (omeprazole, pantoprazole, rabeprazole and esomeprazole) before lansoprazole or omeprazole/sodium bicarbonate. See PA section below.
   - **Tier 4/Not Covered**
     - dexlansoprazole (Dexilant)—The P&T Committee concluded that dexlansoprazole provides very little to no additional clinical effectiveness relative to the other PPIs; that the risk of use may outweigh any potential benefit including a higher discontinuation rate; and that the FDA reviewer expressed concerns regarding the benefit to risk profile. Overall the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the other PPIs.
     - esomeprazole strontium—The P&T Committee concluded that the esomeprazole strontium has little clinical data to support its use; has very little or no additional clinical effectiveness relative to the other PPIs and that the needs of TRICARE beneficiaries can be met by the other PPIs.
# Step Therapy: Criteria Governance

## 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></td>
<td>Note that Prior Authorization is not required for omeprazole capsules or pantoprazole tablets.</td>
</tr>
<tr>
<td></td>
<td>Manual and Automated PA criteria apply to all new users of esomeprazole (Nexium, generics) and rabeprazole (Aciphex, generics).</td>
</tr>
<tr>
<td>esomeprazole capsules (Nexium, generics)</td>
<td><strong>Automated PA Criteria:</strong> The patient has filled an Rx for generic omeprazole <strong>OR</strong> generic pantoprazole product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 365 days.</td>
</tr>
</tbody>
</table>
| rabeprazole tablets (Aciphex, generics) | **Manual PA Criteria:** Coverage is approved if all criteria are met:  
- Provider acknowledges that omeprazole and pantoprazole are the DoD’s preferred agents  
- Provider acknowledges that omeprazole and pantoprazole are Uniform Formulary and do not require prior authorization  
- The patient has a contraindication to omeprazole and pantoprazole **OR**  
- The patient has had an inadequate response or had an adverse reaction to omeprazole **OR**  
- The patient has had an inadequate response or had an adverse reaction to pantoprazole |

Non-FDA-approved uses are not approved. PA does not expire.
**Example: Step Therapy Criteria**

**Proton Pump Inhibitors: Nexium, Aciphex**

- Automated Profile Review:
  - Review looks for preferred Proton Pump Inhibitors (i.e., omeprazole (Prilosec)) prescriptions dispensed during the previous 365 days at a MTF, Mail, or Retail POS under the Tricare pharmacy benefit
  - If none found, stops claims for all *esomeprazole* (Nexium) and *rabeprazole* (Aciphex) new patients
  - Applies to new users of non-preferred proton pump inhibitors (i.e., grandfathering)
  - The automated “look back” period is medication specific and defined by the DoD P&T Committee (max is 720 days)

Goal: Promote use of preferred medications prior to use of a non-preferred medication
Establishes NF medication clinical need over use of a formulary medication

Applies to:
1) DoD NF Medications
2) All Active Duty (AD)
3) MTF, Mail, and Retail POS

*Can be used to justify a reduction in copayment at Retail and Mail for non-AD beneficiaries, but is not required to obtain the medication at the higher Tier 3 (non-formulary) copayment

*Also required for all beneficiaries to access the medication at MTF pharmacies and for AD beneficiaries to access the medication at Retail and Mail pharmacies
To obtain a medical necessity form that may be associated with a medication, visit the TRICARE Formulary Search Tool: Express-scripts.com/TRICAREformulary

**Medical Necessity Form**

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Is this drug covered?</th>
<th>You Pay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Military Pharmacy (MTF)</td>
<td></td>
<td>Non-Formulary</td>
</tr>
<tr>
<td>Home Delivery Pharmacy</td>
<td>✅ YES</td>
<td>Non-Formulary</td>
</tr>
<tr>
<td>Retail Network Pharmacy</td>
<td>✅ YES</td>
<td>Non-Formulary</td>
</tr>
</tbody>
</table>

Military Treatment Facilities are not allowed to carry this product on their formulary, but it may be available for enrolled beneficiaries to the MTF under certain circumstances. Use of a different product may be required.

*Are there forms my doctor may need to fill out? YES*

[Medical Necessity Form] - Applies if you can't take a formulary alternative.
Medical Necessity

To obtain a consolidated list of medications that require MN visit: (https://health.mil/formulary)
Quantity Limits

• Goal: Apply a maximum allowed quantity of a drug at all POS within a specified time period
• Results in a claims adjudication rejection (hard stop) at an MHS GENESIS pharmacy  
  – Quantity must be adjusted or the provider must call ESI to request an override
• Refills are allowed when 75% of the last fill has been used (e.g., 68 days for a 90-day fill)
Quantity Limits

• 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
    • Pharmacy 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

<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

- To see any QLs that may be in place, check the TRICARE formulary Search Tool: Express-scripts.com/TRICAREformulary

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 in the MTF section since most MTFs are still utilizing CHCS where the benefit rules are manually enforced.
# Coverage Notes

**Freestyle Lite Strips**  
*Over the counter*  
Strip

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Is this drug covered?</th>
<th>Coverage Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Military Pharmacy (MTF)</td>
<td>✅ YES</td>
<td>SELECT TEST STRIPS are covered for 100 units for a 30 day supply at Retail and 300 units for a 90 day supply at Mail. Please note that the coverage terms of this prescription benefit are subject to change.</td>
</tr>
<tr>
<td>Home Delivery Pharmacy</td>
<td>✅ YES</td>
<td></td>
</tr>
<tr>
<td>Up to 90 days supply</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retail Network Pharmacy</td>
<td>✅ YES</td>
<td></td>
</tr>
<tr>
<td>Up to 30 days supply</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Are there forms my doctor may need to fill out? NO*

No forms available for this medication.

You Pay

<table>
<thead>
<tr>
<th>Non-active duty</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>This is a Basic Core Formulary (BCF) designated drug should be available at your pharmacy.</td>
<td>$24.00</td>
</tr>
<tr>
<td></td>
<td>$28.00</td>
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</tbody>
</table>
Quantity Limits

- Example 2: sumatriptan oral tablets
- A patient fills a prescription for sumatriptan 50mg, quantity of 36 tablets at an MTF pharmacy
  - Seven weeks later, when the patient tries to fill the same medication/dosage form/strength, for a quantity of 36 tablets at an MHS GENESIS or Mail Order pharmacy:
    - The pharmacy will receive a Reject 76, “Plan limit exceeded” as the max fill at the MTF/Mail Order during a 90-day period is 54 tablets. The patient cannot fill both prescriptions for a total of 72 tablets within 90 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 a 60 days supply per the quantity limit of that strength (e.g., 100mg = 18 tabs)

<table>
<thead>
<tr>
<th>DRUG</th>
<th>QUANTITY LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sumatriptan Succinate (Imitrex) 50mg tablets</td>
<td>• Retail: 18 tablets/30 days</td>
</tr>
<tr>
<td>Migraine Agents Triptans UF Subclass</td>
<td>• MTF and Mail: 54 tablets/90 days</td>
</tr>
</tbody>
</table>
Coverage Notes

Sumatriptan Succinate 50 Mg Tablet

Is this drug covered?

Military Pharmacy (MTF)  
✅ YES

Basic Core Formulary (BCF) designated drugs should be available at your military pharmacy.

Home Delivery Pharmacy
Up to 90 days supply  
✅ YES

Retail Network Pharmacy
Up to 30 days supply  
✅ YES

Are there forms my doctor may need to fill out?  
NO

No forms available for this medication.

Coverage Notes

For Sumatriptan Succinate 50 Mg Tablet when using your Home delivery pharmacy benefit:

- IMITREX 25MG or IMITREX 50MG is covered for a maximum quantity totaling 18 tablets per 30 days at retail and 54 tablets per 90 days at mail.

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

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

• Example 4: **Collective Limit (PDE-5 Inhibitors)**
  - A patient fills a prescription for sildenafil, #30 tabs at the MTF
  - Then the patient presents a prescription for tadalafil, #30 tabs to be filled at a Retail pharmacy within 2 weeks from last fill at the MTF due to failing sildenafil
    - 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: 30 tablets/90 days</td>
</tr>
</tbody>
</table>
### 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>
</table>
| Tier Placement (Tier 3, NF)               | • Increases copayment Retail/Mail  
• Encourages use of MTFs and TRICARE Mail Order Pharmacy over Retail network and non-network pharmacies  
• Generally not available at MTFs, but it may be available for MTF-enrolled beneficiaries who meet MN criteria |
| Claims Processing Rules                   | • Age, gender restriction  
  • Clinical appropriateness  
  • Rejects  
  • High level safety issues, early refills  
  • Requires ESI to override  
  • Warning messages  
  • Low level safety issues  
  • May be overridden by the pharmacy |
| POS Restrictions (e.g. Exclusive Mandatory Mail) | • Select Maintenance drugs only available at MTF and Mail POS  
• Some NF medications not available at Retail POS |
Why have this review of the Uniform Formulary tools?

• MHS Genesis includes new commercial capabilities not traditionally utilized at the MTF
  – MTF claims adjudication will be similar to Retail and Mail order adjudication

• Outpatient prescriptions processed in MHS Genesis will go through automated formulary and benefit management reviews (as recommended by DoD P&T) via ESI*
  • 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 PAs and other situations.

*Express Scripts is the TPHARM Contractor for the DOD
Why have this review of the Uniform Formulary tools?

- MHS Genesis implements aspects of formulary and benefit management enhancing benefit consistency across all POS and impacting how a MTF pharmacy adjudicates an outpatient prescription in accordance with approved benefit design
- Effort to manage the MHS as a more cohesive system may result in more patients moving between the MTF, Retail, and Mail POS
- MTFs should consider moving away from site-specific formularies and moving towards adoption of the DoD P&T Committee UF decisions
  - MTFs are not expected to stock all formulary items, but may procure in a reasonable time upon receipt of a prescription
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

Pharmacy Data Transaction Service (PDTS) Review Against the full patient history, benefit, and safety check. Order becomes a “claim”

Take appropriate action to resolve reject
- Obtain PA
- Enter Override
- Correct Data
- Adjust quantity

Resubmit Claim

Accepted Claim: Medication Dispensed

Claim is Accepted or Rejected

Rejected Claim

Formulary Rules Applied

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

[link to health.mil/formulary]
How can a MTF P&T Committee provide change requests to DoD P&T Committee?
How can a MTF P&T Committee provide change requests to DoD P&T Committee?

- Requests are not accepted from individuals
  - 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
DoD P&T Formulary Management Documents health.mil/pandt
DoD P&T Formulary Management Documents

DoD P&T Committee Resources

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

Formulary Management Documents

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<td>Formulary Management Table for Oral Contraceptives</td>
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DoD P&T Formulary Management Documents

MTF Formulary Management for Basal Insulin Analogs
Defense Health Agency Pharmacy Operations Division

Uniform Formulary Decision: The Director, DHA, approved the recommendations from the August 2017 DoD P&T Committee meeting on October 30, 2017. Implementation will occur on November 22, 2017.

BCF drugs MTFs must have on formulary
Non Step-Preferred
• detemir pen (Levemir)
• degludec (Toujeo)
• glargine 100 U/mL (Basaglar)

Clinical Summary
- Basal insulin analogs are dosed subcutaneously once daily and have similar initial dosing:
  - Lantus was first marketed in 2000 and was designed as BCF in 2010.
  - Insulin detemir may be dosed once or twice daily.
  - Levemir has a long duration of action of up to 42 hours versus 24 hours for the other products. It also has flexibility with regard to time of administration and is available in two concentrations (100 U/mL, 200 U/mL).
  - Basaglar is another insulin glargine identical to Lantus in terms of amino acid sequence and pH.
  - Toujeo is a more concentrated version of Lantus containing 300 U/mL, and has an onset of action developing over 6 hours compared to Lantus at 3-4 hours.

- While basal insulins differ in pharmacokinetic profiles, this variance does not translate into improved glycemic control or improvements in A1C when comparing one product to another.
- Head-to-head trials did not show clinically relevant differences between the basal insulin analogs and their effect on glycemic control. Lantus was the active comparator in the majority of the inferiority trials.
- Common adverse effects are similar among the basal insulin analogs. Cardiovascular outcomes trials with glargine (ORIGIN) and degludec (DEVOTE) showed no increased risk for cardiovascular events. To date, the FDA has not concluded that any insulin increases the risk of cancer.
- Hypoglycemia: Overall, it is difficult to conclude definitively that one basal insulin is less likely to cause clinically relevant severe or nocturnal hypoglycemia events due to the differences in the definitions of hypoglycemia used in the individual clinical trials and different primary endpoints.
- The basal insulin analogs are rated pregnancy category C with the exception of Levemir, which is rated as pregnancy category B.
- Lantus, Levemir, and Tresiba are approved for use in pediatrics.
- DoD clinicians were asked to provide their opinion on the basal insulins. The majority of providers (90%) preferred Lantus in their clinical setting and for inclusion on the BCF due to their familiarity with the product. Additionally, most clinicians voiced preference for allowing two basal insulins on the formulary.
- After Lantus, most providers stated a preference for Levemir, followed by Tresiba as a second available agent.
- The majority of DoD patients can be treated with Lantus, based on the lack of compelling advantages of the newer basal insulins, existing MHS utilization, and MHS provider opinions.

Step Therapy and Prior Authorization (PA)
- All new users of the non-step-preferred products (Levemir pen and vial, Tresiba, Toujeo, and Basaglar) must try Lantus first. If a patient has not already received one of the non step-preferred products, manual PA must be filled out to receive Levemir, Tresiba, Toujeo, and Basaglar.
- For the full manual PA criteria, refer to the August 2017 DoD P&T Committee meeting minutes (link provided below).
- Acceptable clinical reasons for a patient to receive a non step-preferred basal insulin after a trial of Lantus include the following examples:
  - therapeutic failure or intolerable adverse effects to Lantus (all the products)
  - patient is as young as one year old (Tresiba)
  - patient is pregnant and cannot use Lantus (Levemir)
  - patient is using a minimum of 100 units of Lantus daily and is experiencing clinically significant, severe hypoglycemic episodes despite splitting the Lantus dose (Toujeo)
- Medical Necessity (MN) criteria is also required for the nonformulary drugs (Levemir pen, Tresiba, and Basaglar). Medical necessity requirements pertain to all MTF patients receiving a nonformulary drug. However, at the TRICARE Mail Order Pharmacy and the Retail Network, MN is only required for non active duty beneficiaries. Non active duty beneficiaries meeting MN criteria may submit a completed form for a reduced cost share at the TRICARE Mail Order Pharmacy or Retail Network pharmacies.

References
- DoD P&T Committee minutes:
  http://health.mil/PandF
- Current/future drug classes under review by the DoD P&T Committee:
- TRICARE Formulary Search Tool:
  http://www.health.mil/formulary
- Prior Authorization/Medical Necessity forms:
  See Formulary Search Tool above.
- Formulary Management Documents (including this one) available at:
  http://www.health.mil/DoDPT/Resources
- Point of contact for additional information:
  dha.abea.pharmacy.ist.poduf@mail.mil

Basal Insulin Analogs
Price Comparison at MTF

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<th>MTF Cost/Month (Aug 2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Core Formulary Step-Preferred</td>
<td></td>
</tr>
<tr>
<td>detemir pen and vial (Levemir)</td>
<td>$5</td>
</tr>
<tr>
<td>degludec (Toujeo)</td>
<td>$3</td>
</tr>
</tbody>
</table>

Uniform Formulary Non Step-Preferred

| detemir pen (Levemir) | $5 | Least Cost-Effective |
| degludec (Toujeo) | $3 | Less Cost-Effective |
| glargine 100 U/mL (Basaglar) | $1 | Least Cost-Effective |

Legend:
- “Most Cost-Effective” represents Rx with the lowest cost and best clinical efficacy
- “Less Cost-Effective” represents Rx with similar clinical efficacy
# DoD P&T Formulary Management

## Medication Class/Disease State Executive Summaries

### Executive Summaries

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### Table 1: Ophthalmic-1s: Antihistamine and Dual Acting Antihistamine/Mast Cell Stabilizers

<table>
<thead>
<tr>
<th>Subclass</th>
<th>Generic Name</th>
<th>Brand</th>
<th>Manufacturer</th>
<th>Generic as of April 2017</th>
<th>Strength</th>
<th>FDA Approval</th>
<th>Patent Expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihistamine</td>
<td><strong>Lidocaine</strong></td>
<td><strong>Lidane</strong></td>
<td><strong>Nuron</strong></td>
<td>No</td>
<td>0.00%</td>
<td>1067</td>
<td>2013</td>
</tr>
<tr>
<td></td>
<td><strong>Albuterol</strong></td>
<td><strong>Lansinor</strong></td>
<td><strong>Avergen</strong></td>
<td>No</td>
<td>0.00%</td>
<td>2015</td>
<td>2016</td>
</tr>
<tr>
<td></td>
<td><strong>Prabuxin</strong></td>
<td><strong>Optilast</strong></td>
<td><strong>Yes</strong></td>
<td>Yes</td>
<td>0.00%</td>
<td>2000</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Tropicamide</strong></td>
<td><strong>Imecode</strong></td>
<td><strong>Yes</strong></td>
<td>Yes</td>
<td>0.00%</td>
<td>2000</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Lotepidol</strong></td>
<td><strong>Zaditor</strong></td>
<td><strong>Atarax</strong></td>
<td>Yes (OTC)</td>
<td>0.00%</td>
<td>1996</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Gliclazide</strong></td>
<td><strong>Patent</strong></td>
<td><strong>Novo</strong></td>
<td>No</td>
<td>0.1%</td>
<td>2016</td>
<td>2017</td>
</tr>
<tr>
<td></td>
<td><strong>Febbyan</strong></td>
<td><strong>Patent</strong></td>
<td><strong>Novo</strong></td>
<td>No</td>
<td>0.2%</td>
<td>2017</td>
<td>2018</td>
</tr>
<tr>
<td></td>
<td><strong>Plamono</strong></td>
<td><strong>Novo</strong></td>
<td><strong>Novo</strong></td>
<td>No</td>
<td>0.7%</td>
<td>2016</td>
<td>2017</td>
</tr>
</tbody>
</table>

*Note: Plamono is OTC and not part of the TRICARE Pharmacy benefit. The formulary recommendation does not apply.*

- The full Ophthalmic-1 Drug Class was reviewed in August 2015 by the DoD P&T Committee. The basic Corticosteroid (CSC) choice is dexamethasone 0.1% (Pentose, Genentech). Ketorolac (Zontain) is not available over the counter (OTC) but is part of the formulary recommendation. See Table 2 for the formulary status of the ophthalmic drug acting as AEMCS agents recommended at the May 2017 DoD P&T Committee meeting.
- Several generic formulations of dexamethasone 0.1% (Pentose) are commercially available. Generic formulations of dexamethasone 0.2% (Pentose) are expected to be released early in 2017. However, only one company has a generic tentative approval by the FDA.
- Current Medical Therapy System (CMTS) prescription data show that Pentose, genentech, and Pentose account for over 90% of the utilization in the class.