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

Defense Health Agency

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- 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

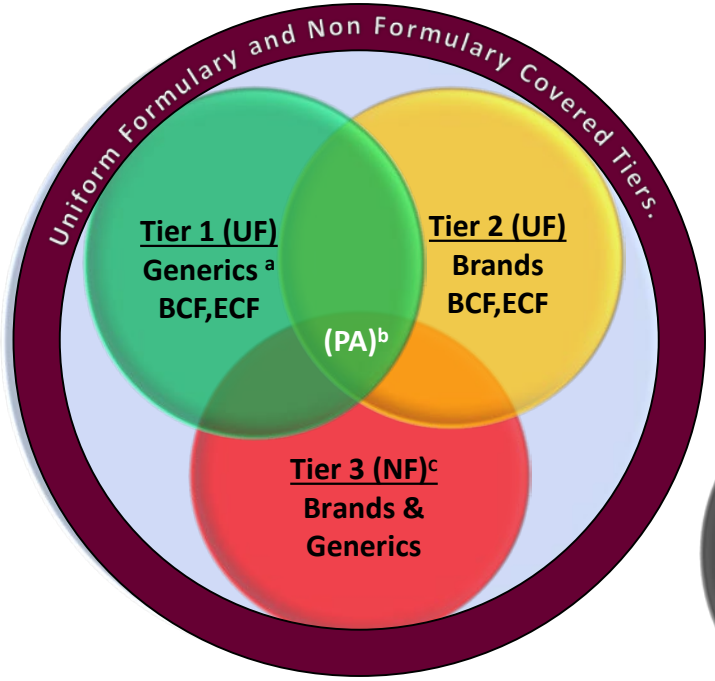
Unclassified

- 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
    - https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/DoD-Pharmacy-and-Therapeutics-Committee
  - Defense Health Agency Procedural Instruction (DHAPI) 6025.31, Military Medical Treatment Facility Pharmacy Operations

TRICARE Uniform Formulary: Four-Tiered Structure

Defense Health Agency

Unclassified



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 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)

MEASURES USED FOR TRICARE Tier 4/Non-Covered Drugs	
1	The drug has **very little to no additional clinical effectiveness** relative to similar agents in the class.
2	Significant **safety risk** for the agent, relative to other drugs in the class. (e.g., risk of use may outweigh any potential benefit based on post-marketing concerns)
3	The needs of TRICARE beneficiaries are met by available **alternative agents.**
4	This agent contains **at least one** ingredient that is **not covered** under the TRICARE benefit (e.g., dietary supplement, medical foods, cosmetic agent, OTC drug combo product).
5	**Negative concerns**, relative to other drugs in the class, have been **identified by** FDA Advisory Committees, **other regulatory** authorities, or nationally recognized **expert organizations.**
6	Or **other factors** that may arise.

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

Unclassified

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

Prior Authorization: Criteria Governance

Defense Health Agency

Unclassified

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

Drug / Drug Class	Prior Authorization Criteria
• amphetamine sulfate orally disintegrating IR tablets (Evekeo ODT) **ADHD-Wakefulness Promoting Agents: Stimulants**	Manual PA is required for all new users of Evekeo ODT. Manual PA Criteria: Evekeo ODT is approved if ALL criteria are met: • 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 • Patient has tried for at least two months and failed or has difficulty swallowing Adderall tabs (generic) • Patient has tried for at least two months and failed or the patient has a contraindication to IR methylphenidate tablets or solution Non-FDA-approved uses are not approved. PA does not expire.

Prior Authorization Form: Establish Clinical Appropriateness

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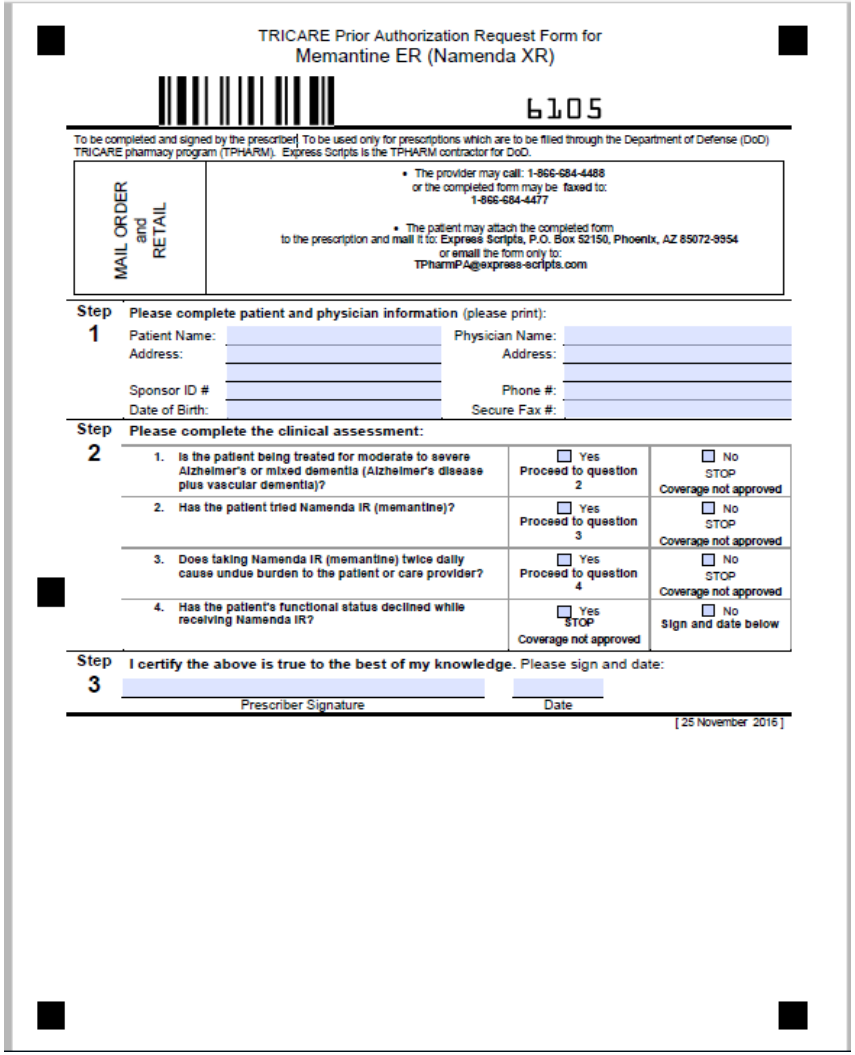
Establishes appropriate clinical use of certain medications as identified and approved through the DoD P&T process.

Applies to:

1) All beneficiaries
2) MTF, Mail, and Retail POS



TRICARE Prior Authorization Request Form for
Memantine ER (Namenda XR)

6105

To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) TRICARE pharmacy program (TPHARM). Express Scripts is the TPHARM contractor for DoD.

MAIL ORDER and RETAIL

- The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477
- The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TPharmPA@express-scripts.com

Step 1 Please complete patient and physician information (please print):

Patient Name: Address: Sponsor ID # Date of Birth:

Physician Name: Address: Phone #: Secure Fax #:

Step 2 Please complete the clinical assessment:

1. Is the patient being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia)?	☐ Yes Proceed to question 2	☐ No STOP Coverage not approved
2. Has the patient tried Namenda IR (memantine)?	☐ Yes Proceed to question 3	☐ No STOP Coverage not approved
3. Does taking Namenda IR (memantine) twice daily cause undue burden to the patient or care provider?	☐ Yes Proceed to question 4	☐ No STOP Coverage not approved
4. Has the patient's functional status declined while receiving Namenda IR?	☐ Yes STOP Coverage not approved	☐ No Sign and date below

Step 3 I certify the above is true to the best of my knowledge. Please sign and date:

Prescriber Signature Date

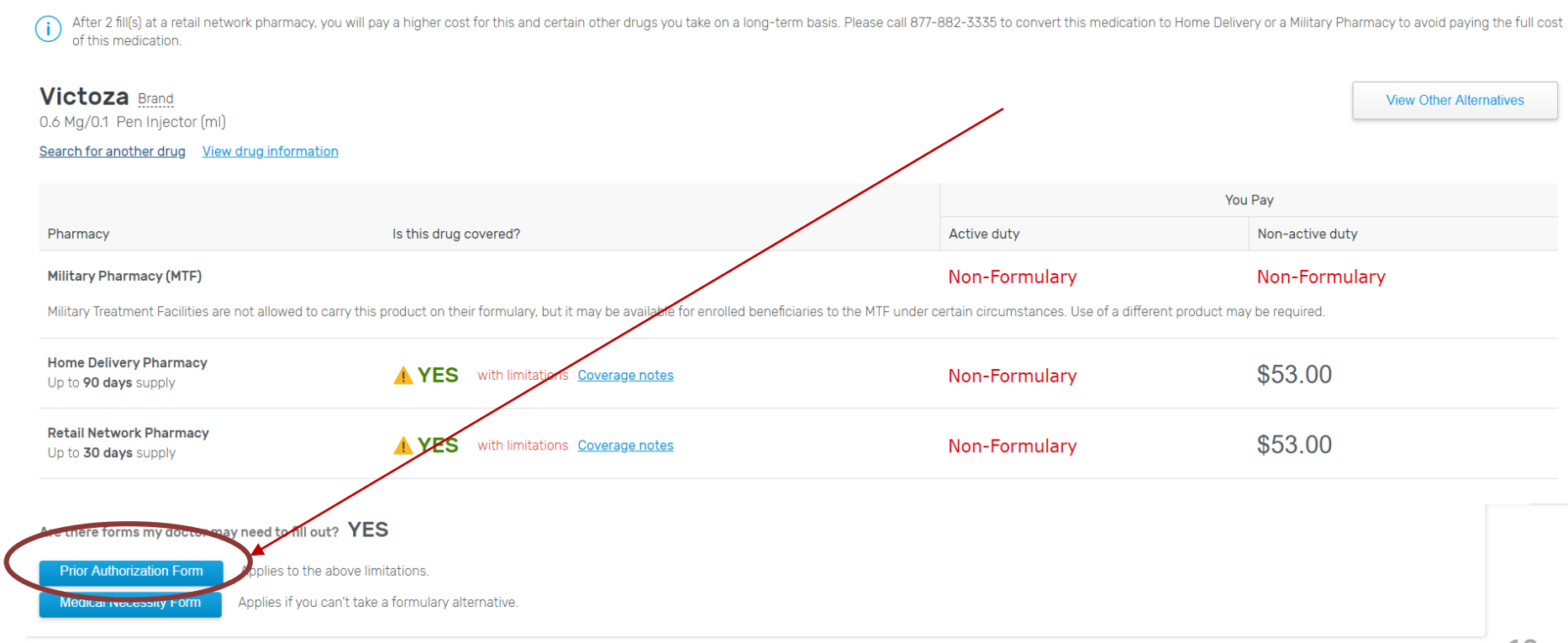
[25 November 2016]

Prior Authorization Form

Defense Health Agency

Unclassified

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

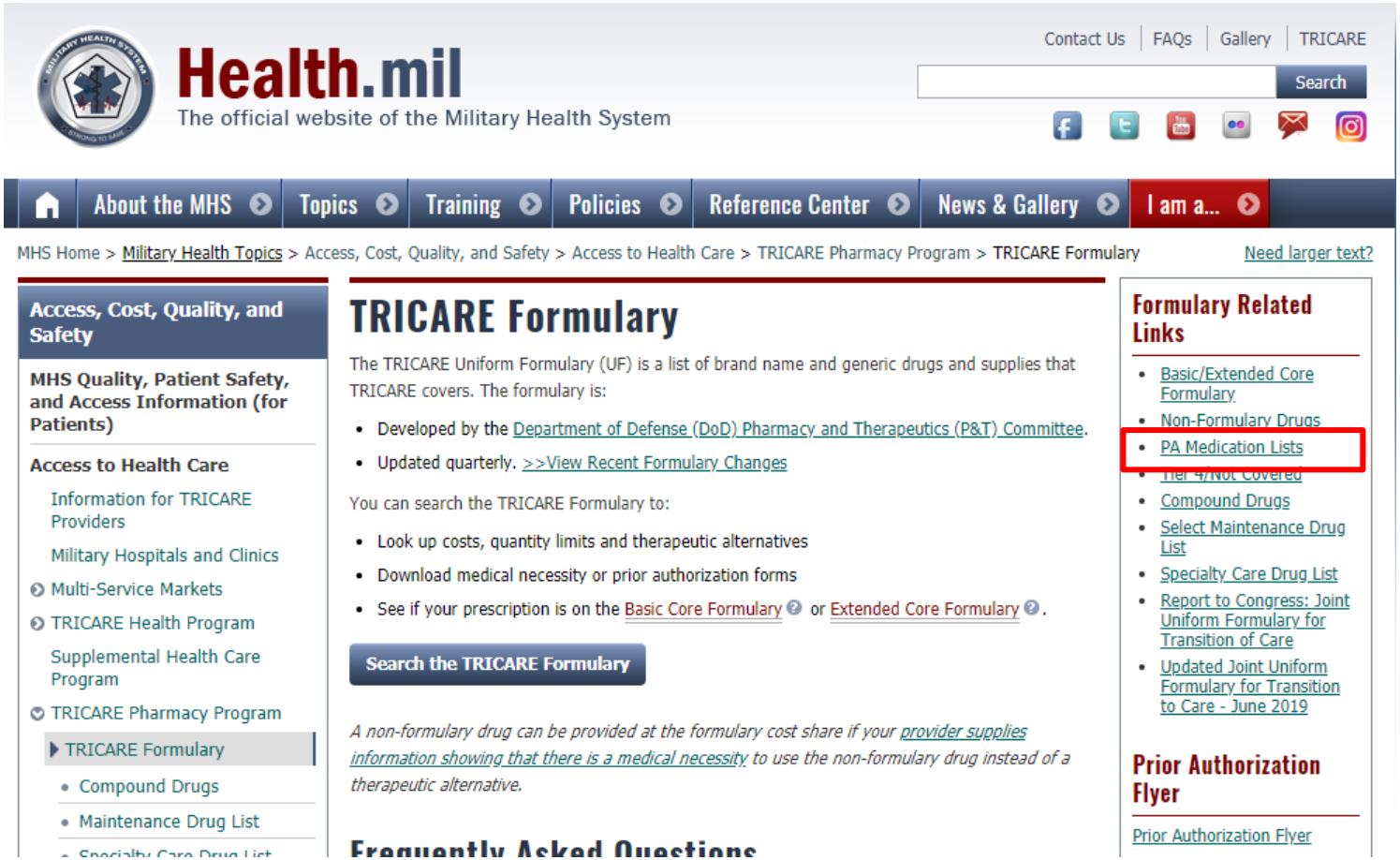


Prior Authorization Form

Defense Health Agency

Unclassified

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

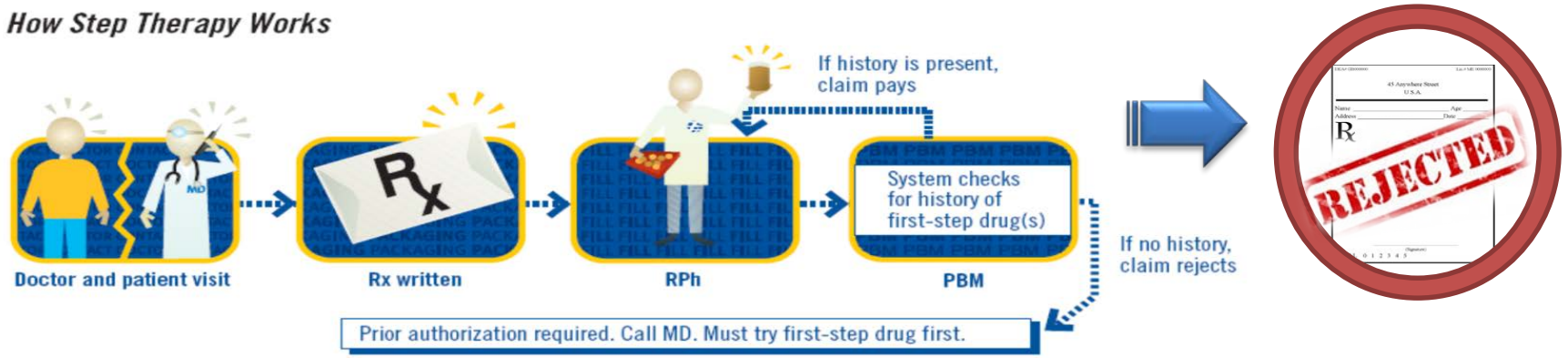
*Express Scripts is the TPHARM Contractor for the DOD

Step Therapy (Automated Profile Review)

Unclassified

ST is an <u>automated</u> 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 mediation will require a PA.



*Medication Specific; determined by DoD P&T

Step Therapy: Criteria Governance

Defense Health Agency

Unclassified

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

Defense Health Agency

Unclassified

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

Defense Health Agency

Unclassified

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• esomeprazole capsules (Nexium, generics) • rabeprazole tablets (Aciphex, generics) **Proton Pump Inhibitors: Capsules and Tablets**	Note that Prior Authorization is not required for omeprazole capsules or pantoprazole tablets. Manual and Automated PA criteria apply to all new users of esomeprazole (Nexium, generics) and rabeprazole (Aciphex, generics). Automated PA Criteria: The patient has filled an Rx for generic omeprazole **OR** generic pantoprazole product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 365 days. 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

Medical Necessity Form

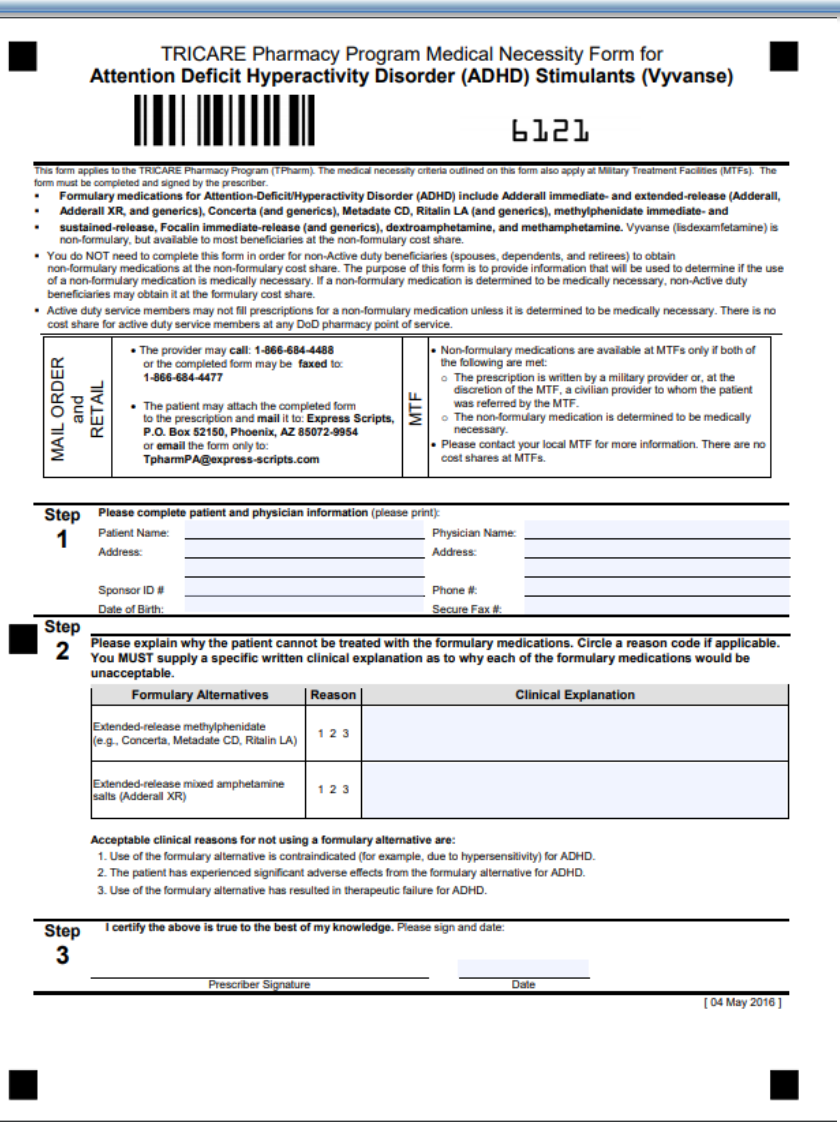
Unclassified

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**



TRICARE Pharmacy Program Medical Necessity Form for
Attention Deficit Hyperactivity Disorder (ADHD) Stimulants (Vyvanse)

6121

This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- **Formulary medications for Attention-Deficit/Hyperactivity Disorder (ADHD) include Adderall immediate- and extended-release (Adderall, Adderall XR, and generics), Concerta (and generics), Metadate CD, Ritalin LA (and generics), methylphenidate immediate- and sustained-release, Focalin immediate-release (and generics), dextroamphetamine, and methamphetamine.** Vyvanse (lisdexamfetamine) is non-formulary, but available to most beneficiaries at the non-formulary cost share.
- You do NOT need to complete this form in order for non-Active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-Active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

MAIL ORDER and RETAIL	MTF
• The provider may **call**: **1-866-684-4488** or the completed form may be **faxed** to: **1-866-684-4477** • The patient may attach the completed form to the prescription and **mail** it to: **Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954** or **email** the form only to: **TpharmPA@express-scripts.com**	• Non-formulary medications are available at MTFs only if both of the following are met: ○ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF. ○ The non-formulary medication is determined to be medically necessary. • Please contact your local MTF for more information. There are no cost shares at MTFs.

Step 1 **Please complete patient and physician information** (please print):

Patient Name: _____ Physician Name: _____
Address: _____ Address: _____
Sponsor ID # _____ Phone #: _____
Date of Birth: _____ Secure Fax #: _____

Step 2 **Please explain why the patient cannot be treated with the formulary medications. Circle a reason code if applicable. You MUST supply a specific written clinical explanation as to why each of the formulary medications would be unacceptable.**

Formulary Alternatives	Reason	Clinical Explanation
Extended-release methylphenidate (e.g., Concerta, Metadate CD, Ritalin LA)	1 2 3	
Extended-release mixed amphetamine salts (Adderall XR)	1 2 3	

Acceptable clinical reasons for not using a formulary alternative are:
1. Use of the formulary alternative is contraindicated (for example, due to hypersensitivity) for ADHD.
2. The patient has experienced significant adverse effects from the formulary alternative for ADHD.
3. Use of the formulary alternative has resulted in therapeutic failure for ADHD.

Step 3 **I certify the above is true to the best of my knowledge.** Please sign and date:

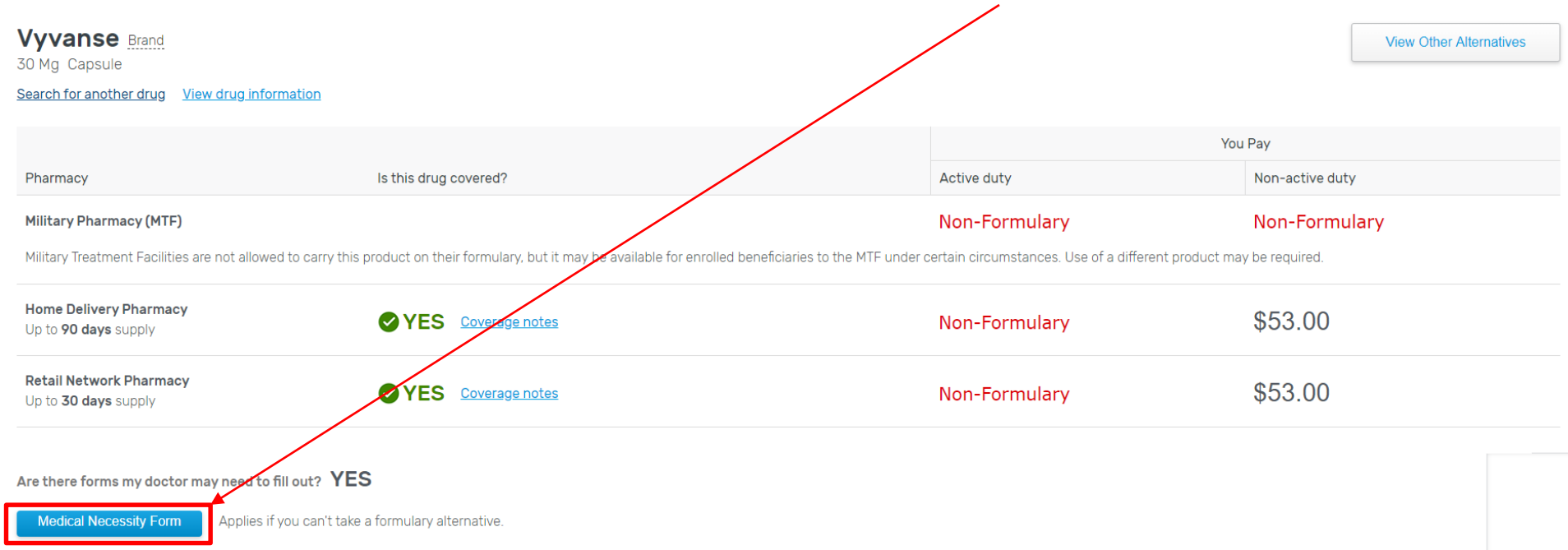
_____ _____
Prescriber Signature Date

[04 May 2016]

Medical Necessity Form

Unclassified

- 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

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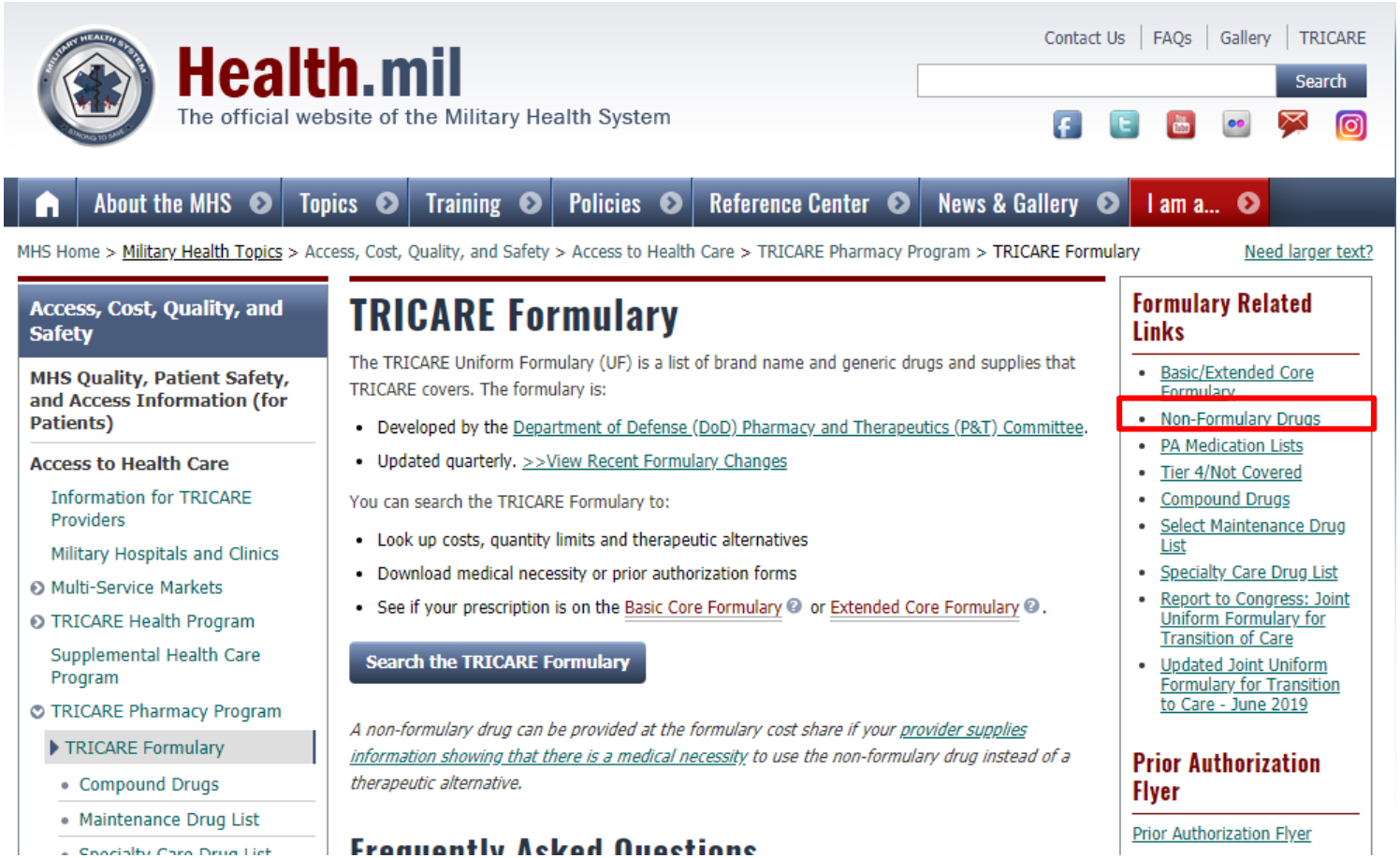
To obtain a consolidated list of medications that require MN visit: (https://health.mil/formulary)



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

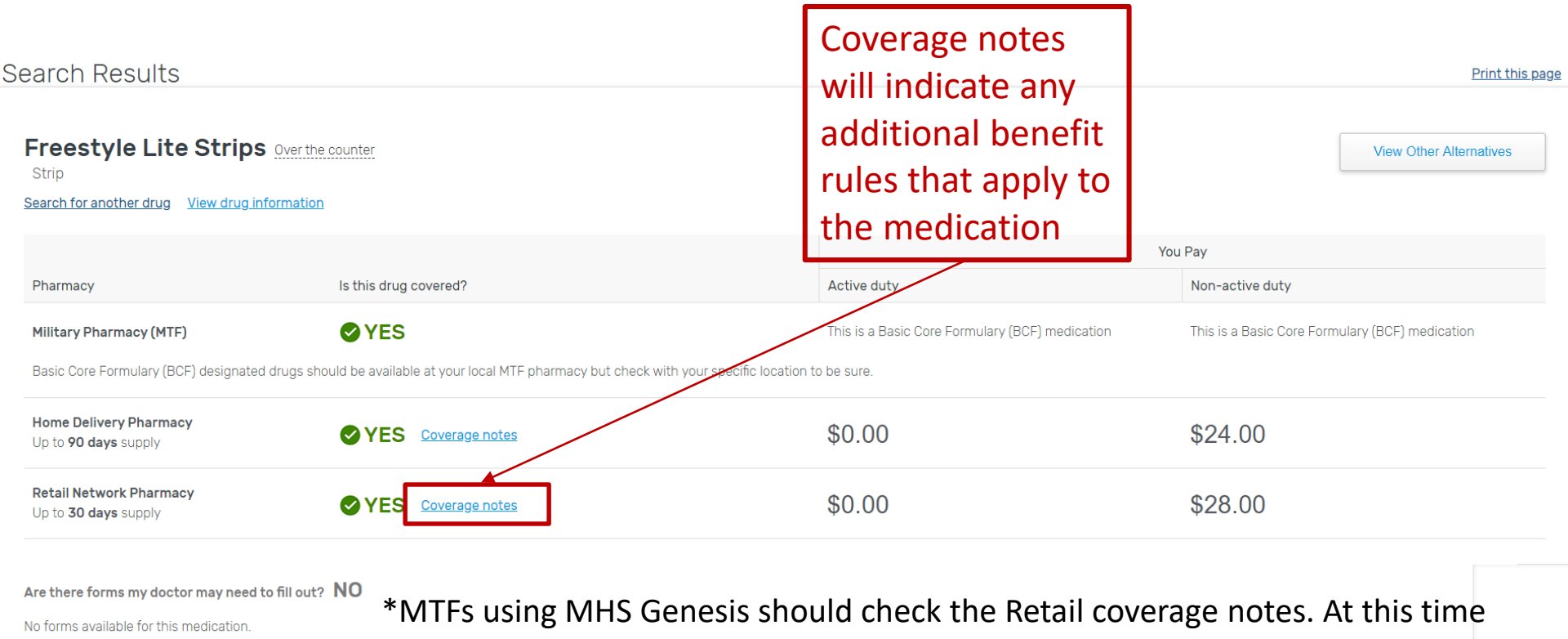
- Example 1: Precision Xtra Test Strips
  - A patient fills prescription for 100 Precision Xtra test strips at a retail pharmacy
  - One month later, the patient tries to fill a second prescription for 300 test strips at the MTF
    - Pharmacy receives a Reject 76, “Plan limit exceeded”
      - Limits 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

DRUG	QUANTITY LIMITS
• Precision Xtra Test Strips **(Self Monitoring Blood Glucose Systems)**	• 100 strips per 30 days • 300 strips per 90 days

Quantity Limits

Unclassified

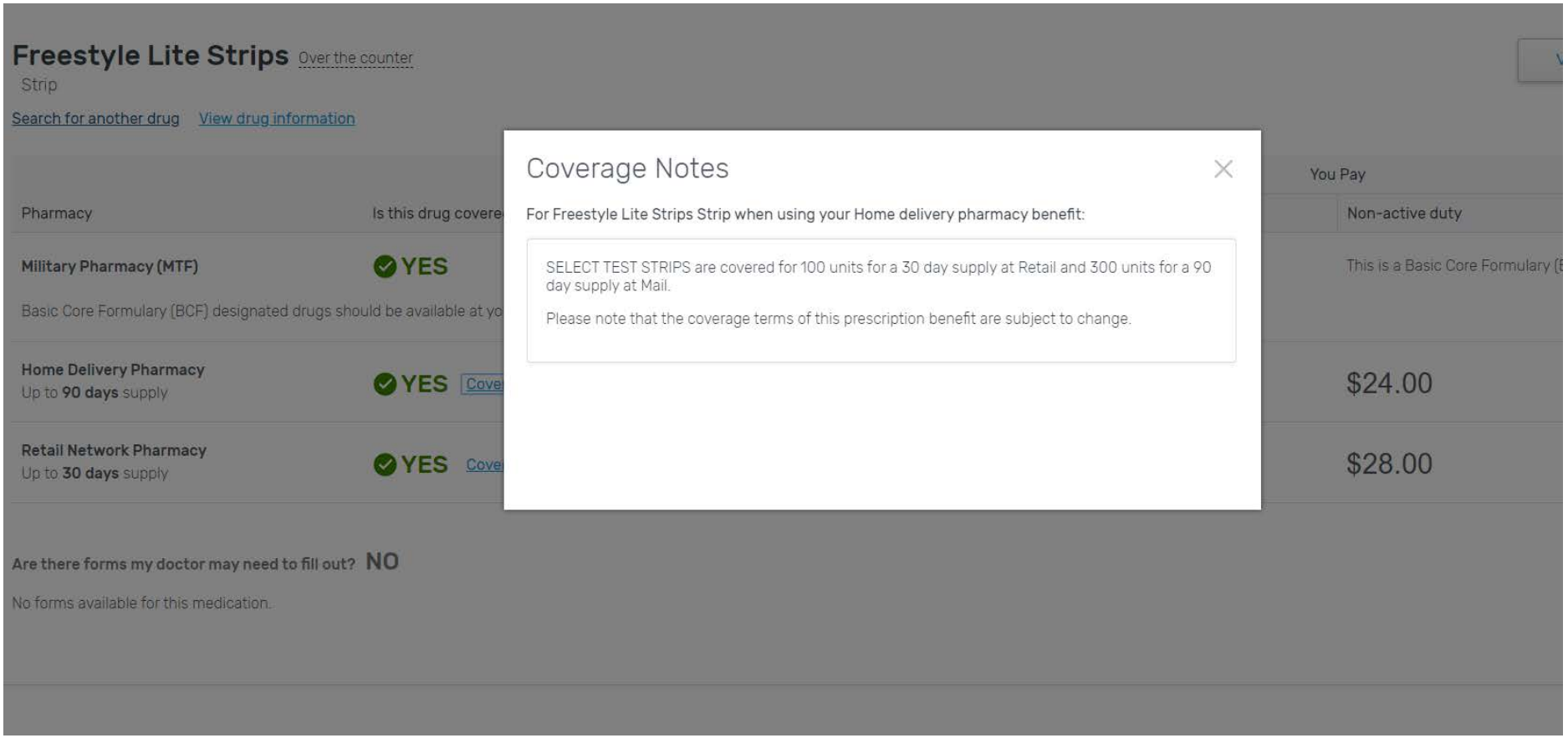
- To see any QLs that may be in place, check the TRICARE formulary Search Tool: Express-scripts.com/TRICAREformulary



*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

Unclassified



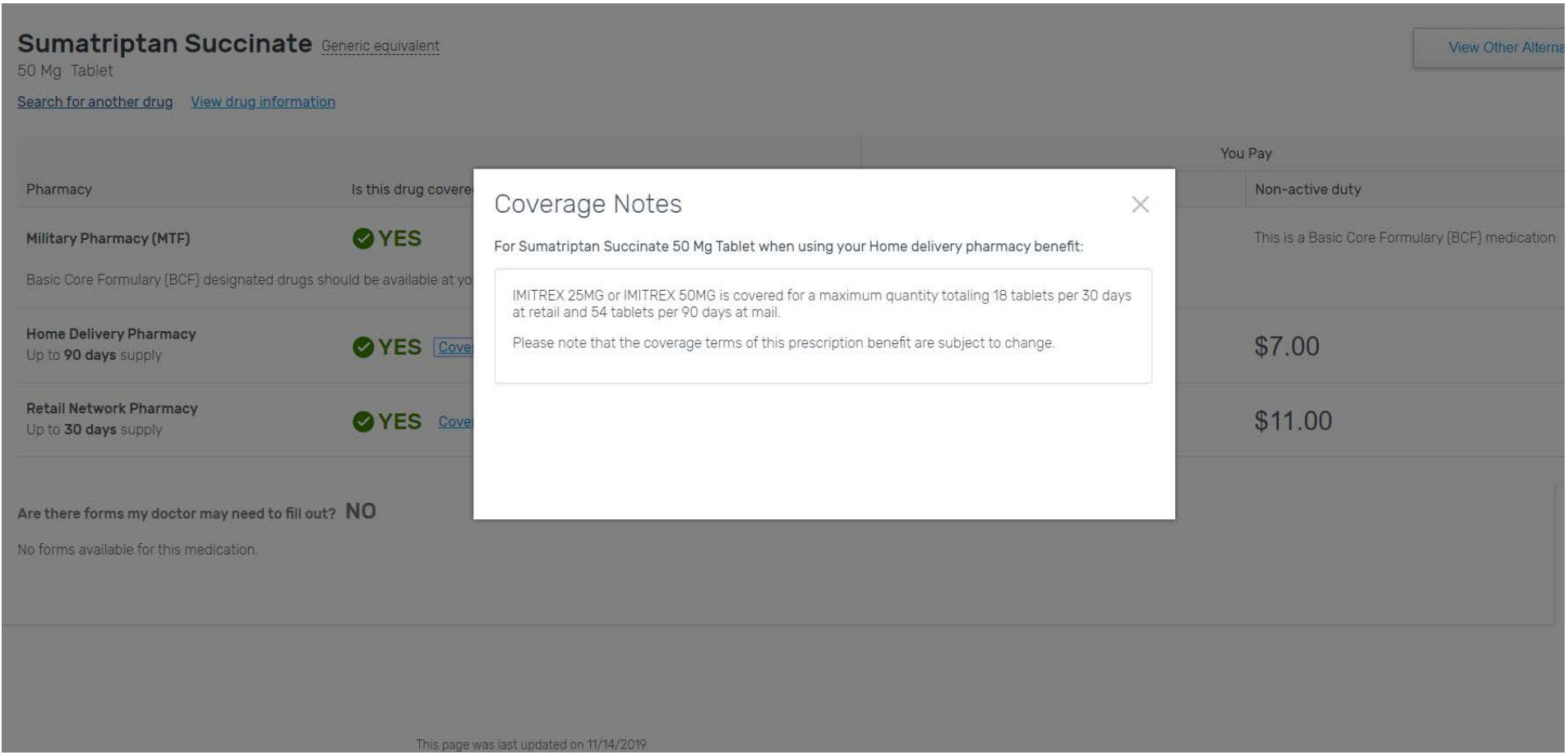
Quantity Limits

- 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 <u>different</u> 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)

DRUG	QUANTITY LIMITS
• Sumatriptan Succinate (Imitrex) 50mg tablets **Migraine Agents Triptans UF Subclass**	• Retail: 18 tablets/30 days • MTF and Mail: 54 tablets/90 days

Coverage Notes

Unclassified



Quantity Limits

Unclassified

- 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

DRUG	QUANTITY LIMITS
• sofosbuvir/velpatasvir (Epclusa) **Hepatitis C Virus (HCV) Direct-Acting Antiviral Agents (DAAs) Subclass**	• Retail, MTF, and Mail: 28 tablets/28 days

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

DRUG	QUANTITY LIMITS
• PDE-5 Inhibitors [e.g. sildenafil (Viagra), tadalafil (Cialis)]	• Retail, MTF, and Mail: 30 tablets/90 days

Additional DoD Formulary Tools

Promote safe and cost-effective use of preferred medications

Defense Health Agency

Unclassified

Tool	Description & Impact
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?

Defense Health Agency

Unclassified

- 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?

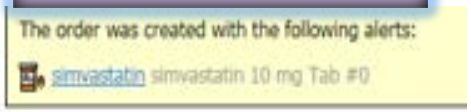
MHS Genesis Outpatient Prescription Workflow

Defense Health Agency

Unclassified

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"

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

health.mil/formulary

Defense Health Agency

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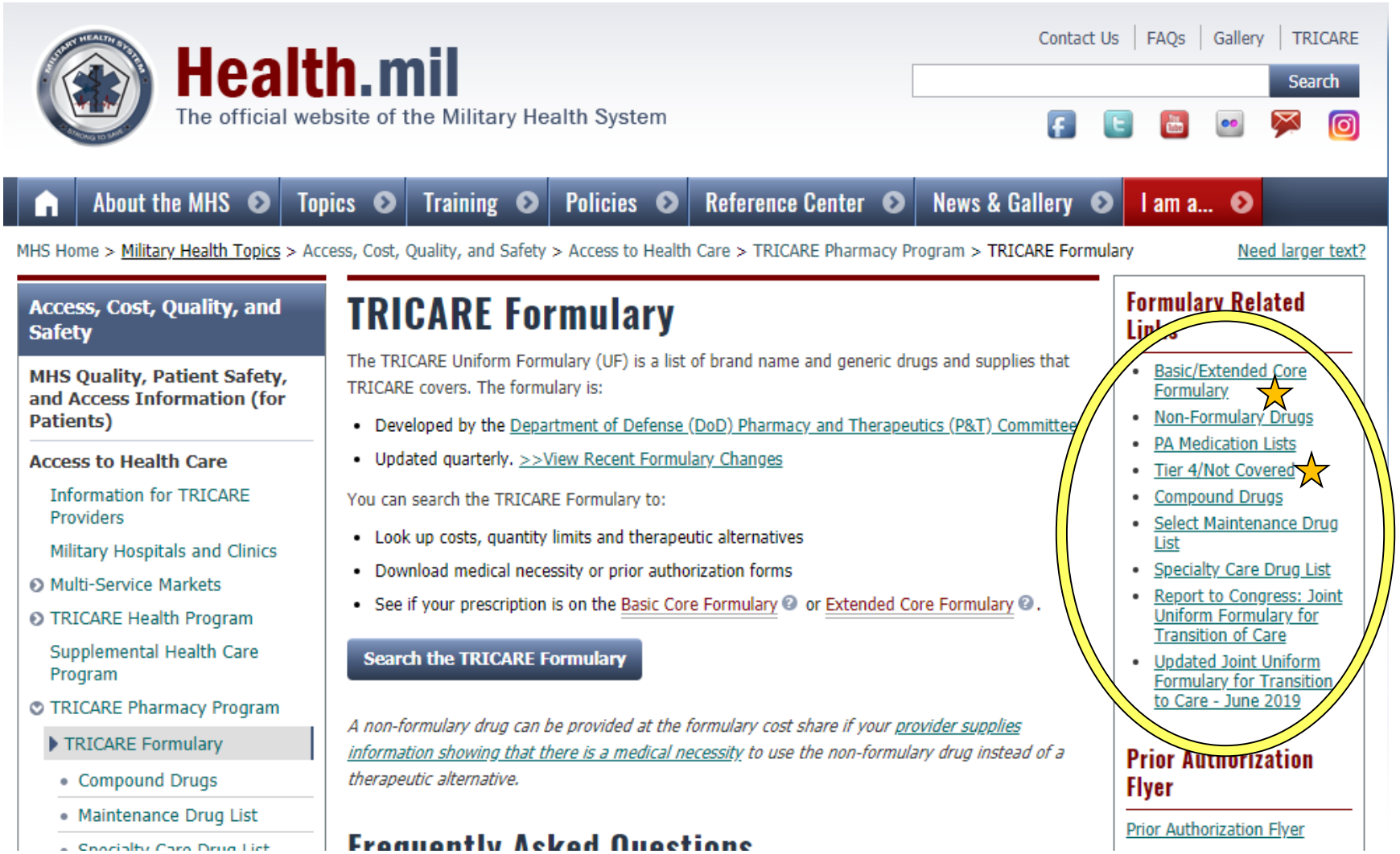
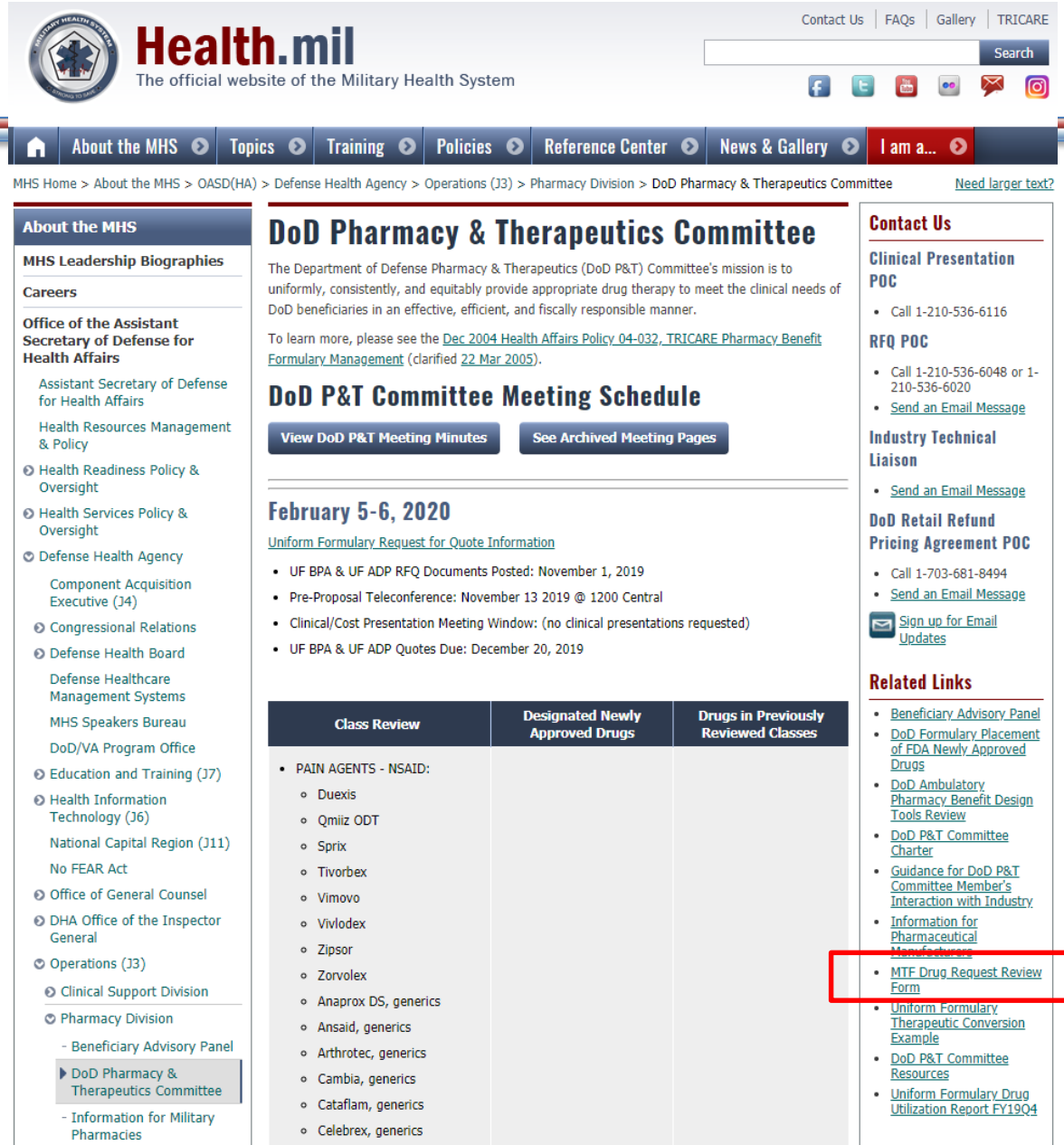


How can a MTF P&T Committee provide change requests to DoD P&T Committee?

Defense Health Agency

Unclassified



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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

February 5-6, 2020

Uniform Formulary Request for Quote Information

- UF BPA & UF ADP RFQ Documents Posted: November 1, 2019
- Pre-Proposal Teleconference: November 13 2019 @ 1200 Central
- Clinical/Cost Presentation Meeting Window: (no clinical presentations requested)
- UF BPA & UF ADP Quotes Due: December 20, 2019

Class Review	Designated Newly Approved Drugs	Drugs in Previously Reviewed Classes
• PAIN AGENTS - NSAID: ○ Duexis ○ Qmiiz ODT ○ Sprix ○ Tivorbex ○ Vimovo ○ Vivlodex ○ Zipsor ○ Zorvolex ○ Anaprox DS, generics ○ Ansaid, generics ○ Arthrotec, generics ○ Cambia, generics ○ Cataflam, generics ○ Celebrex, generics		

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

RFQ POC
- Call 1-210-536-6048 or 1-210-536-6020
- Send an Email Message

Industry Technical Liaison
- Send an Email Message

DoD Retail Refund Pricing Agreement POC
- Call 1-703-681-8494
- Send an Email Message

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- 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
- Uniform Formulary Therapeutic Conversion Example
- DoD P&T Committee Resources
- Uniform Formulary Drug Utilization Report FY19Q4

health.mil/pandt

How can a MTF P&T Committee provide change requests to DoD P&T Committee?

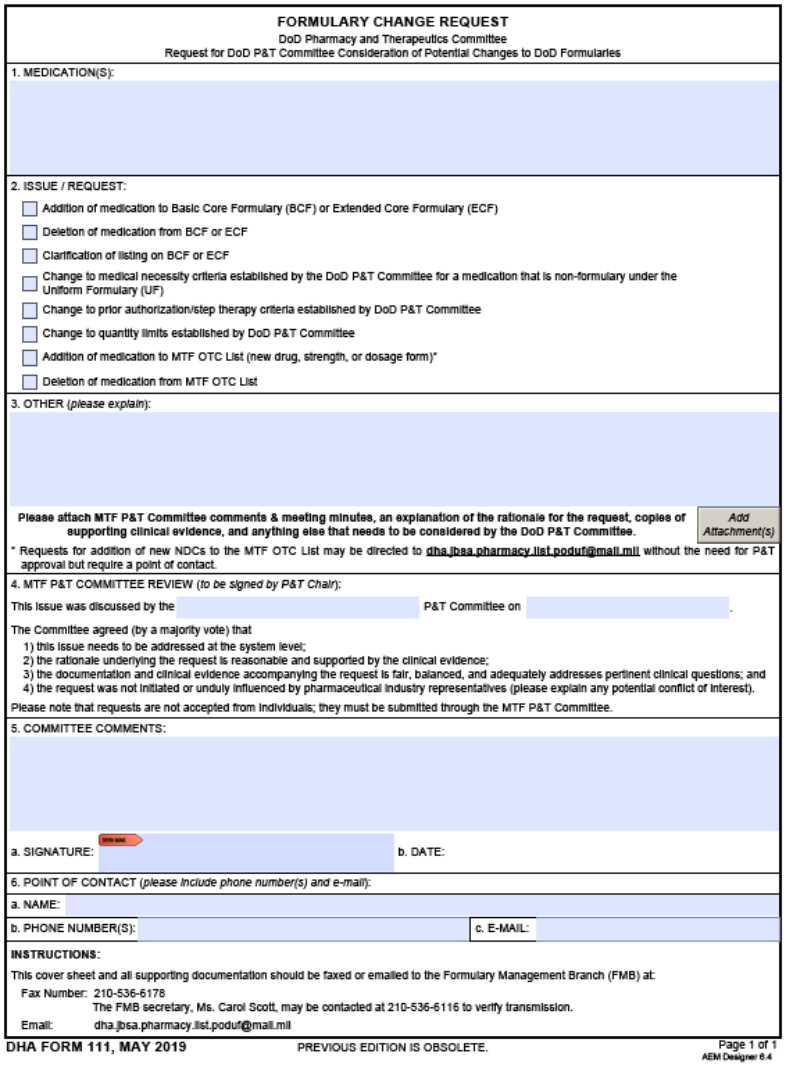
Defense Health Agency

Unclassified

- 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



FORMULARY CHANGE REQUEST

DoD Pharmacy and Therapeutics Committee
Request for DoD P&T Committee Consideration of Potential Changes to DoD Formularies

1. MEDICATION(S):

2. ISSUE / REQUEST:

- ☐ Addition of medication to Basic Core Formulary (BCF) or Extended Core Formulary (ECF)
- ☐ Deletion of medication from BCF or ECF
- ☐ Clarification of listing on BCF or ECF
- ☐ Change to medical necessity criteria established by the DoD P&T Committee for a medication that is non-formulary under the Uniform Formulary (UF)
- ☐ Change to prior authorization/step therapy criteria established by DoD P&T Committee
- ☐ Change to quantity limits established by DoD P&T Committee
- ☐ Addition of medication to MTF OTC List (new drug, strength, or dosage form)*
- ☐ Deletion of medication from MTF OTC List

3. OTHER (*please explain*):

Please attach MTF P&T Committee comments & meeting minutes, an explanation of the rationale for the request, copies of supporting clinical evidence, and anything else that needs to be considered by the DoD P&T Committee. *Add Attachment(s)*

* Requests for addition of new NDCs to the MTF OTC List may be directed to dha.jbsa.pharmacy.list.poduf@mail.mil without the need for P&T approval but require a point of contact.

4. MTF P&T COMMITTEE REVIEW (*to be signed by P&T Chair*):

This issue was discussed by the _____ P&T Committee on _____.

The Committee agreed (by a majority vote) that
1) this issue needs to be addressed at the system level;
2) the rationale underlying the request is reasonable and supported by the clinical evidence;
3) the documentation and clinical evidence accompanying the request is fair, balanced, and adequately addresses pertinent clinical questions; and
4) the request was not initiated or unduly influenced by pharmaceutical industry representatives (please explain any potential conflict of interest).

Please note that requests are not accepted from individuals; they must be submitted through the MTF P&T Committee.

5. COMMITTEE COMMENTS:

a. SIGNATURE: b. DATE:

6. POINT OF CONTACT (*please include phone number(s) and e-mail*):

a. NAME:

b. PHONE NUMBER(S): c. E-MAIL:

INSTRUCTIONS:

This cover sheet and all supporting documentation should be faxed or emailed to the Formulary Management Branch (FMB) at:

Fax Number: 210-536-6178
The FMB secretary, Ms. Carol Scott, may be contacted at 210-536-6116 to verify transmission.
Email: dha.jbsa.pharmacy.list.poduf@mail.mil

DHA FORM 111, MAY 2019 PREVIOUS EDITION IS OBSOLETE. Page 1 of 1
AEM Designer 6.4

DoD P&T Formulary Management Documents health.mil/pandt

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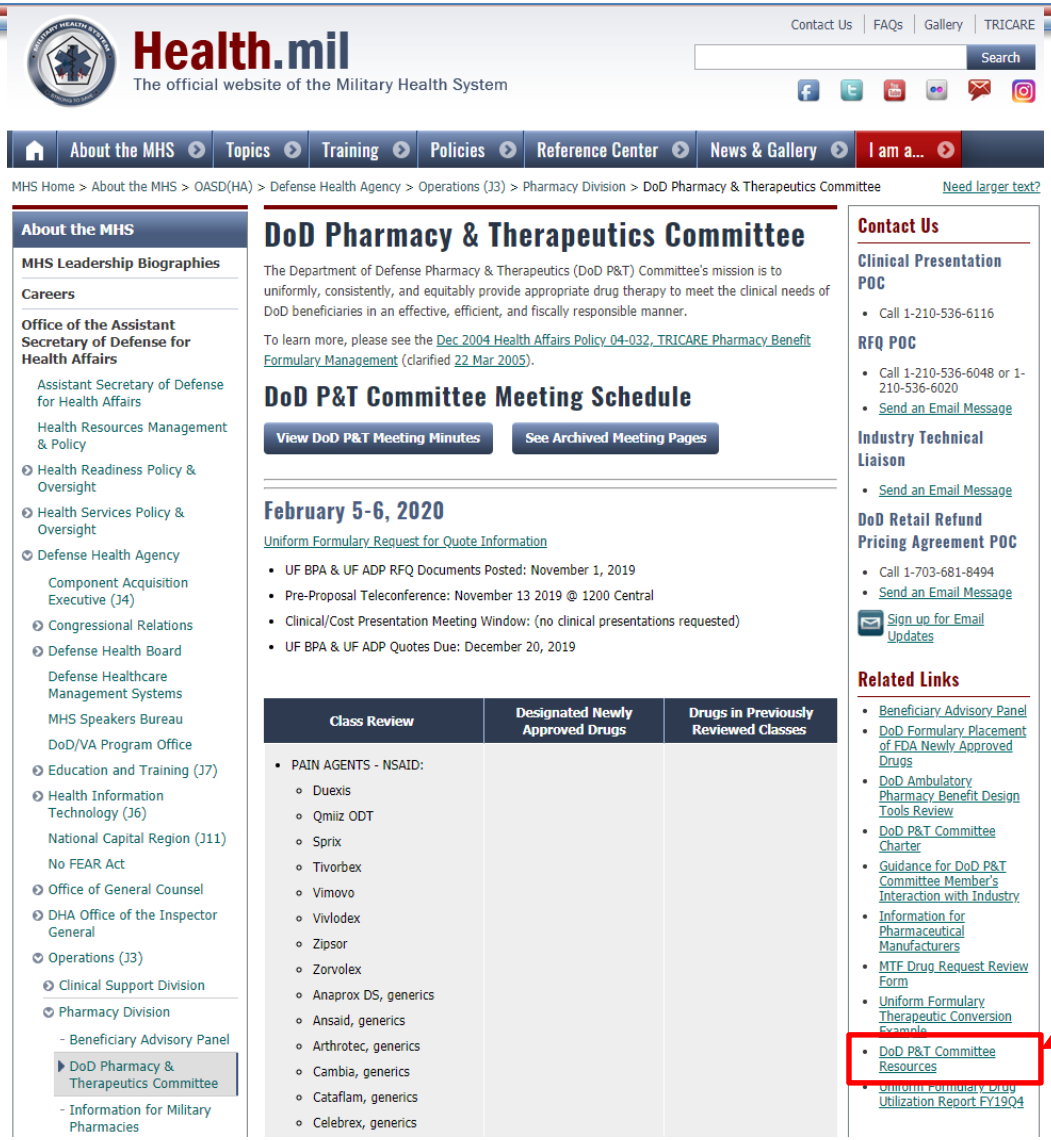

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DoD P&T Formulary Management Documents

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  - Operations (J3)
    - Clinical Support Division
    - Pharmacy Division

DoD P&T Committee Resources

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

Formulary Management Documents

File	Date
Formulary Management for Growth Stimulating Agents (GSAs)	10/15/2018
Formulary Management for Opioid Induced Constipation	10/15/2018
Formulary Management for Pancreatic Enzyme Replacement Therapy	10/15/2018
Formulary Management for the Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)	5/21/2018
Formulary Management of Weight Loss Agents	5/21/2018
Formulary Management for Basal Insulin Analogs	11/2/2017
Formulary Management for Ophthalmic-1s: Antihistamine and Dual Acting Antihistamine/Mast Cell Stabilizers	8/18/2017
Formulary Management for Idiopathic Pulmonary Fibrosis	8/18/2017
Formulary Management for Diabetes Drugs	3/20/2017
Formulary Management for Oral Anticoagulants	2/21/2017
Formulary Management for PCSK9 Inhibitors	2/21/2017
Formulary Management for Narcotic Antagonists August 2016	11/28/2016
Formulary Management for Topical Acne and Rosacea Agents August 2016	11/28/2016
Formulary Management for Triptans August 2016	11/28/2016
Formulary Management for Anticonvulsants and Anti Mania Agents	8/2/2016
Formulary Management for Atypical Antipsychotic Agents	8/2/2016
Formulary Management for Emergency Contraceptive Agents	8/2/2016
Formulary Management for Opthalmic Immunomodulatory Agents: Cyclosporine 0.05% Opthalmic Emulsion	5/19/2016
Formulary Management for Oral Contraceptives and Miscellaneous Contraceptives	5/19/2016
Formulary Management for OTC Doxylamine	5/19/2016
Formulary Management for Topical Antifungals for Onychomycosis Subclass	5/19/2016
Formulary Management Table for Oral Contraceptives	5/19/2016

DoD P&T Formulary Management Documents

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MTF Formulary Management for Basal Insulin Analogs

Defense Health Agency Pharmacy Operations Division

Bottom Line

- **Lantus pens and vials remain the Basic Core Formulary (BCF) basal insulin.**
- **Step therapy now exists in the class; all new users must first try Lantus (the step-preferred insulin) prior to use of the other basal insulin analogs. See below.**
- **New users of any of the non step-preferred products (Levemir, Tresiba, Toujeo, and Basaglar) will require manual prior authorization. See below.**
- **There are no clinically significant differences in glycemic control among the basal insulins.**

Uniform Formulary Decision: The Director, DHA, approved the recommendations from the August 2017 DoD P&T Committee meeting on October 20, 2017. Implementation will occur on November 22, 2017.

BCF drugs MTFs must have on formulary	Uniform Formulary MTFs may have on formulary	Nonformulary MTFs must not have on formulary
Step-Preferred • glargine pen and vial (Lantus)	**Non Step-Preferred** • detemir vial (Levemir) • glargine 300 U/mL (Toujeo)	**Non Step-Preferred** • detemir pen (Levemir) • degludec (Tresiba) • 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 designated as BCF in 2010.
  - Insulin detemir may be dosed once or twice daily.
  - Tresiba 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 non-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 emphatically 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 hypoglycemia 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/PandT
- Current/future drug classes under review by the DoD P&T Committee: http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-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/DoDPTResources
- Point of contact for additional information: dha.jbsa.pharmacy.list.poduf@mail.mil

Basal Insulin Analogs Price Comparison at MTF	
Drug	**MTF Cost/Month (Aug 2017)**
Basic Core Formulary Step-Preferred	
• glargine pen and vial (Lantus)	$ **Most Cost Effective**
Uniform Formulary Non Step Preferred	
• detemir vial (Levemir) • glargine 300 U/mL (Toujeo)	$$$ **Less Cost-Effective**
Non-Formulary Non Step-Preferred	
• detemir pen (Levemir) • degludec (Tresiba) • glargine 100 U/mL (Basaglar)	$$$$ **Least Cost-Effective**

Legend:

- $ = "Most Cost-Effective" represents Rxs with the lowest cost and best clinical efficacy
- $$ = "Less Cost-Effective" represents higher cost Rxs with similar clinical efficacy
- $$$ = "Less Cost-Effective" represents next higher cost Rxs with similar clinical efficacy
- $$$$ = "Least Cost-Effective" represents Rxs with the highest cost with similar clinical efficacy

DoD P&T Formulary Management

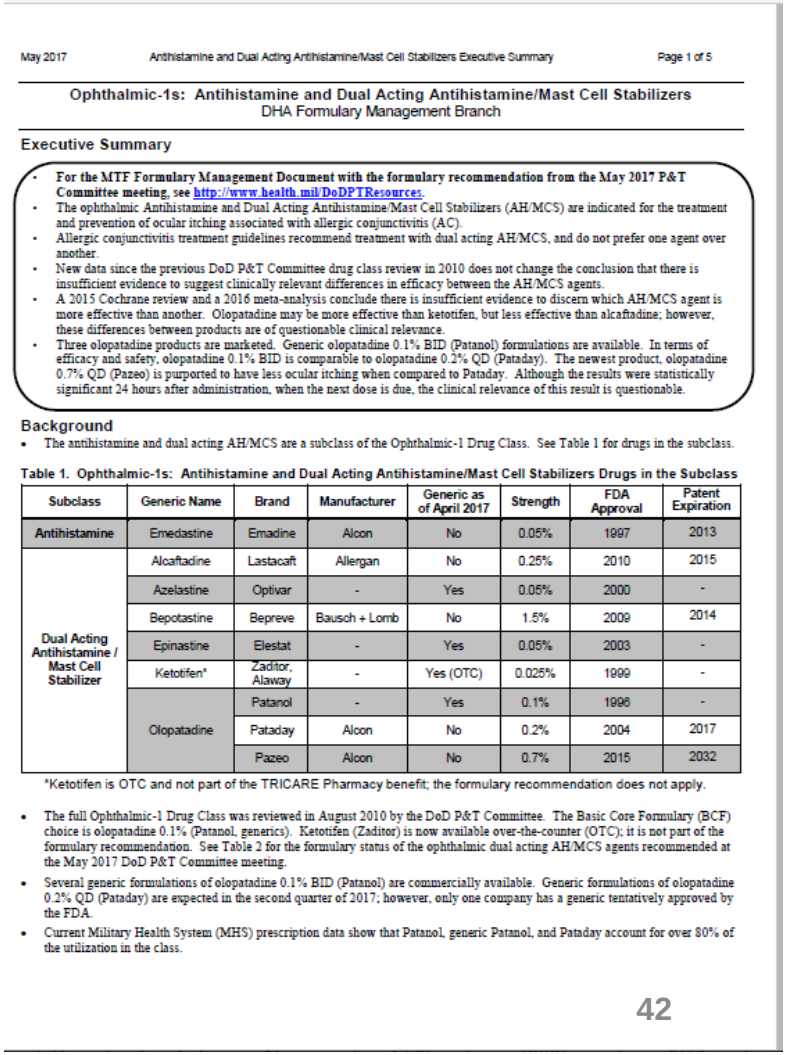
Medication Class/Disease State Executive Summaries

Defense Health Agency

Unclassified

Executive Summaries

File	Date
DoD P&T Committee Executive Summary: Ophthalmic-1s: Antihistamine and Dual Acting Antihistamine/Mast Cell Stabilizers	8/22/2017
DoD P&T Committee Executive Summary: Idiopathic Pulmonary Fibrosis	8/22/2017
DoD P&T Committee Executive Summary: Direct-Acting Anticoagulants	5/11/2017
DoD P&T Committee Executive Summary: PCSK9 Inhibitor Subclass	2/21/2017
DoD P&T Committee Executive Summary: Migraine Agents - Triptans	11/28/2016
DoD P&T Committee Executive Summary: Alcohol Deterrents - Narcotic Antagonist	11/28/2016
DoD P&T Committee Executive Summary: Topical Acne and Rosacea Agents	11/28/2016
DoD P&T Committee Executive Summary: Anticonvulsants and Anti Mania Agents	8/1/2016
DoD P&T Committee Executive Summary: Atypical Antipsychotic Agents	8/1/2016
DoD P&T Committee Executive Summary: Emergency Contraceptive Agents	8/1/2016
DoD P&T Committee Executive Summary: Contraceptive Agents	5/19/2016
DoD P&T Committee Executive Summary: Ophthalmic Immunomodulatory Agents Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)	5/19/2016
DoD P&T Committee Executive Summary: Topical Antifungal Drugs for Onychomycosis	5/19/2016
DoD P&T Committee Executive Summary: Chronic Myelogenous Leukemia	12/14/2015
DoD P&T Committee Executive Summary: Extended Release Opioids	12/14/2015
DoD P&T Committee Executive Summary: Glucagon-Like Peptide-1 Receptors Agonist (GLP1RA)	12/14/2015
DoD P&T Committee Executive Summary: Sodium-Glucose Co-Transporter 2 Inhibitors (SGLT2)	12/14/2015
DoD P&T Committee Executive Summary: Hepatitis C Virus Direct Acting Agents	5/1/2015
DoD P&T Committee Executive Summary: Pulmonary Arterial Hypertension Drugs	2/1/2015
DoD P&T Committee Executive Summary: Prostate Cancer Subclass I/II Drugs Oral Oncology	2/1/2015
DoD P&T Committee Executive Summary: Transmucosal Immediate Release Fentanyl Products	2/1/2015



May 2017 Antihistamine and Dual Acting Antihistamine/Mast Cell Stabilizers Executive Summary Page 1 of 5

Ophthalmic-1s: Antihistamine and Dual Acting Antihistamine/Mast Cell Stabilizers
DHA Formulary Management Branch

Executive Summary

- **For the MTF Formulary Management Document with the formulary recommendation from the May 2017 P&T Committee meeting, see http://www.health.mil/DoDPTResources.**
- The ophthalmic Antihistamine and Dual Acting Antihistamine/Mast Cell Stabilizers (AH/MCS) are indicated for the treatment and prevention of ocular itching associated with allergic conjunctivitis (AC).
- Allergic conjunctivitis treatment guidelines recommend treatment with dual acting AH/MCS, and do not prefer one agent over another.
- New data since the previous DoD P&T Committee drug class review in 2010 does not change the conclusion that there is insufficient evidence to suggest clinically relevant differences in efficacy between the AH/MCS agents.
- A 2015 Cochrane review and a 2016 meta-analysis conclude there is insufficient evidence to discern which AH/MCS agent is more effective than another. Olopatadine may be more effective than ketotifen, but less effective than alcaftadine; however, these differences between products are of questionable clinical relevance.
- Three olopatadine products are marketed. Generic olopatadine 0.1% BID (Patanol) formulations are available. In terms of efficacy and safety, olopatadine 0.1% BID is comparable to olopatadine 0.2% QD (Pataday). The newest product, olopatadine 0.7% QD (Pazeo) is purported to have less ocular itching when compared to Pataday. Although the results were statistically significant 24 hours after administration, when the next dose is due, the clinical relevance of this result is questionable.

Background

- The antihistamine and dual acting AH/MCS are a subclass of the Ophthalmic-1 Drug Class. See Table 1 for drugs in the subclass.

Table 1. Ophthalmic-1s: Antihistamine and Dual Acting Antihistamine/Mast Cell Stabilizers Drugs in the Subclass

Subclass	Generic Name	Brand	Manufacturer	Generic as of April 2017	Strength	FDA Approval	Patent Expiration
Antihistamine	Emedastine	Emadine	Alcon	No	0.05%	1997	2013
Dual Acting Antihistamine / Mast Cell Stabilizer	Alcaftadine	Lastacaft	Allergan	No	0.25%	2010	2015
	Azelastine	Optivar	-	Yes	0.05%	2000	-
	Bepotastine	Bepreve	Bausch + Lomb	No	1.5%	2009	2014
	Epinastine	Elestat	-	Yes	0.05%	2003	-
	Ketotifen*	Zaditor, Alaway	-	Yes (OTC)	0.025%	1999	-
	Olopatadine	Patanol	-	Yes	0.1%	1996	-
		Pataday	Alcon	No	0.2%	2004	2017
		Pazeo	Alcon	No	0.7%	2015	2032

*Ketotifen 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 2010 by the DoD P&T Committee. The Basic Core Formulary (BCF) choice is olopatadine 0.1% (Patanol, generics). Ketotifen (Zaditor) is now available over-the-counter (OTC); it is not part of the formulary recommendation. See Table 2 for the formulary status of the ophthalmic dual acting AH/MCS agents recommended at the May 2017 DoD P&T Committee meeting.
- Several generic formulations of olopatadine 0.1% BID (Patanol) are commercially available. Generic formulations of olopatadine 0.2% QD (Pataday) are expected in the second quarter of 2017; however, only one company has a generic tentatively approved by the FDA.
- Current Military Health System (MHS) prescription data show that Patanol, generic Patanol, and Pataday account for over 80% of the utilization in the class.