EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel Meeting

December 18, 2024

For the November 2024 DoD Pharmacy and Therapeutics Committee Meeting

The Uniform Formulary Beneficiary Advisory Panel (UF BAP) convened at 10:00 A.M. EDT on December 18, 2024 via teleconference. The current meeting took place approximately 2 ½ hours. The information presented included the recommendations from the November 2024 DoD Pharmacy and Therapeutics (P&T) Committee meeting.

The detailed meeting information is found starting on page 8.

I. UNIFORM FORMULARY (UF) CLASS REVIEW—TARGETED IMMUNOMODULATORY BIOLOGICS: INTERLEUKIN-17 AND INTERLEUKIN-23 INHIBITORS SUBCLASSES

A. Targeted Immunomodulatory Biologics (TIBs): IL-17s and IL-23s Subclasses—UF Recommendation

IL-17s

- UF and step-preferred
  - ixekizumab (Taltz) *moves from NF non-step-preferred*
- UF and non-step-preferred
  - secukinumab (Cosentyx)
- NF and non-step-preferred
  - brodalumab (Siliq)
  - bimekizumab (Bimzelx)
- Completely Excluded – None
- Note, as part of this recommendation the requirement for a trial of Humira will be removed for the plaque psoriasis indication for the step-preferred agent but the Humira trial will remain for the other agents and indications.

IL-23s

- UF and step-preferred
  - No agent selected, leaving option open for a future JNC IL-23 originator/biosimilar (anticipated 2025)
- UF and non-step-preferred
  - ustekinumab (Stelara)
  - guselkumab (Tremfya) *moves from NF non-step-preferred*
  - risankizumab (Skyrizi) *moves from NF non-step-preferred*
  - tildrakizumab (Ilumya) *moves from NF non-step-preferred*
- NF and non-step-preferred

    - mirikizumab (Omvoh) *moves from UF non-step-preferred*
- Completely Excluded – None
- Note a trial of Humira is still preferred for some indications

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

B. TIBs: IL-17s and IL-23s Subclasses —Manual PA Criteria

UF BAP Comments

Dr. Peloquin asked under the general changes for the IL-23 PA criteria, for Stelara and removing the trial for infliximab first and a patient is stable on infliximab, he didn't see that in the actual criteria for Stelara later in the section. Dr. Johnson responded that previously there was an additional option in the Stelara PA criteria that if the patient was stable on IV infliximab, the patient would not have to try Humira first in order to initiate Stelara. Since all the IL-23 products will now be UF and non-step-preferred we did not feel that leaving that option on only one drug was appropriate at this time. Additionally, with the JNC product going forward that will be step-preferred we will streamline the criteria.

Dr. Schweitzer asked if it mattered what type of provider is prescribing? Dr. Johnson replied that for the automated bypass, the criteria will look at that prescriber's NPI number to allow that bypass to occur. However other providers can prescribe the medication if they fill out the manual PA. It does not always have to go back to the specialist at this time.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

C. TIBs: IL-17s and IL-23s Subclasses —UF, PA, and Implementation Period

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

II. UF CLASS REVIEW—MIGRAINE AGENTS: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS ORAL

AGENTS

A. Migraine Agents CGRP Antagonists Oral Agents Subclass—UF Recommendation

- UF step-preferred
  - Qulipta
  - Ubrelvy
- NF non-step-preferred
  - Nurtec ODT

UF BAP Comments

Summary of Panel Questions and Comments

Dr. Peloquin commented on Qulipta being preferred over Nurtec for prevention, and stated he had a question on safety and adherence – were there more adverse effects with Qulipta? There's no head-to-head with these, but there was a higher odds of treatment-emergent adverse effects with Qulipta compared to placebo, while Nurtec did not differ from placebo, and there were no differences in discontinuation rates. Did the P&T Committee look at that? Major Escano relayed that the safety analysis is a major component of the analysis, and safety endpoints were discussed in detail at the P&T Committee meeting.

Dr. Peloquin then asked if there were any concerns of adherence for Nurtec with the every-other-day dosing versus Qulipta with the daily dosing and if there were any discussions on that? Major Escano affirmed that the issues of adherence was discussed in detail at the meeting.

Dr. Peloquin then questioned if there were significant differences in adverse events or adherence, was there any concern? Major Escano answered that there was no significant overlap or discrepancy between the safety and adherence between the products.

Dr. Peloquin then commented that for the P&T Committee in general when you make these significant changes, although he doesn't know the number of Nurtec users, he did give credit to the Committee for building it where you will make sure the PA itself doesn't impact patients who are currently on Nurtec - that is a good news story when you are moving and shifting beneficiaries to a different product within the same class. Having that logic would be very helpful to ensure continuity. He also expressed that there is still a little concern anytime you have these shifts that a patient will have to switch the medication and there is a process for that, but at least the PA part of it

is something that he liked to see to prevent beneficiary abrasion.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

B. Migraine Agents CGRP Antagonists Oral Agents Subclass —Manual PA Criteria

UF BAP Comments

Dr. Schweitzer stated that she appreciated building in the automated lookback, and felt that this is very helpful for beneficiaries.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

C. Migraine Agents CGRP Antagonists Oral Agents Subclass—UF, PA, and Implementation Period

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

III. UF DRUG CLASS REVIEW—INSULINS: RAPID-ACTING INSULIN ANALOGS SUBCLASS AND SHORT-ACTING, INTERMEDIATE-ACTING AND COMBINATION INSULIN SUBCLASS

A. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—UF Recommendation

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 1

B. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—PA Criteria

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 1

C. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—UF and PA Implementation Period

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 1

IV. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

A. Newly Approved Drugs Per 32 CFR 199.21(g)(5)—UF Recommendation

- UF
  - Libervant
  - Iqirvo
  - Xolremdi
  - Myhibbin suspension
  - Rextovy nasal spray
  - Rezdiffra
  - Winrevair
  - Tyenne
  - Ojemda
- NF
  - Simlandi
  - Voydeya
  - Duvyzat
  - Opsynvi
  - Zituvimet authorized generic
  - Spevigo
- Completely Excluded
  - Humira Cordavis

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

B. Newly Approved Drugs Per 32 CFR 199.21(g)(5)—PA Criteria

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

C. Newly Approved Drugs Per 32 CFR 199.21(g)(5)—UF and PA Implementation Period

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

V. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)—ONCOLOGICAL AGENTS FOR RENAL CELL CARCINOMA—EVEROLIMUS (TORPENZ), SKELETAL MUSCLE RELAXANTS—METHOCARBAMOL 1,000 MG AND ANTIEMETIC/ANTIVERTIGO AGENTS—ONDANSETRON 16 MG ORALLY DISINTEGRATING TABLETS AND IMPLEMENTATION PLAN

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

VI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEW FDA-APPROVED INDICATIONS

UF BAP Comments

Dr. Schweitzer commented on behalf of the beneficiaries that she appreciates that there is a process in place to continually scan and keep these PAs updated and to keep them current for the changes that are happening, and also for streamlining the PA process.

Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

VII. UTILIZATION MANAGEMENT UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR REASONS OTHER THAN NEW INDICATIONS

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

VIII. UTILIZATION MANAGEMENT UPDATED PA CRITERIA FOR ANTILIPIDEMIC-1s: NEXLETOL, NEXLIZET AND REPATHA AND IMPLEMENTATION PLAN

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

IX. RE-EVALUATION OF NF GENERICS ACNE AGENTS: TOPICAL ACNE AGENTS AND ROSACEA: FORMULARY STATUS AND IMPLEMENTATION PLAN

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 9 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:

[redacted] comments outlined above were taken under consideration cision.

Uniform Formulary Beneficiary Advisory
Panel Virtual Meeting Summary Minutes
December 18, 2024

Panel Members Present

- Dr. Pamela Schweitzer, Commissioned Offices Association of the US Public Health Service, Chair
- Mr. Jon Ostrowski, Non-Commissioned Officer Association
- Ms. Holly Daily, the Association of the United States Army
- Dr. Karen Dager, PharmD, Health Net Federal Services
- Mr. John DuTeil, US Army Warrant Officers Association
- Dr. Joseph McKeon, MD, Humana Military
- Ms. Amanda Meyers, Military Officers Association of America (MOAA)
- Dr. Jay Peloquin, PharmD, Express Scripts, Inc.
- Dr. Jennifer Soucy, PharmD, U.S. Family Health Plan, Martins Point Services

Designated Federal Officer (Non-Voting): CAPT Phung Nguyen, USN

DHA HCO and Pharmacy Operations Division Participants (Non-Voting)

- Dr. John Kugler, MD, Chief, Clinical Support Division: DoD P&T Committee Chair
- Edward VonBerg, PharmD, BCPS, Chief, Pharmacy Operations Division, Formulary Management (POD FMB)
- CAPT Scott Raisor, Deputy Chief, POD, FMB
- Lt Col Pansy Uberoi, POD FMB
- CDR Elizabeth Hall, POD FMB
- CDR Giao Phung, POD FMB
- Maj Angelina Escano, POD FMB
- Maj Kehinde Adesina, POD FMB
- Angela Allerman, PharmD, BCPS, POD FMB
- Heather Johnson, PharmD, BCPS, POD FMB
- Ms. Megan Gemunder, Office of General Counsel
- CAPT P. Thien Nguyen, DFO Alternate

Agenda is found starting on page 16.

Panel Discussion

The Uniform Formulary Beneficiary Advisory Panel (UF BAP) members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the UF BAP members will concur or non-concur on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. The UF BAP will provide comments on their vote as directed by the Panel Chair. Comments to

the Director, DHA, or their designee will be considered before making a final UF decision.

Opening Remarks

CAPT Nguyen introduced herself as the Designated Federal Officer (DFO) alternate for the Uniform Formulary (UF) Beneficiary Advisory Panel (UF BAP). The UF BAP has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on November 4-5, 2024.

CAPT Nguyen then indicated Title 10, United States Code, (U.S.C.) § section 1074g, subsection b requires the Secretary of Defense to establish a DoD Uniform Formulary (UF) of pharmaceutical agents and establishes the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

In addition, 10 U.S.C. § Section 1074g, subsection c, also requires the Secretary to establish a UF BAP to review and comment on the development of the Uniform Formulary. The UF BAP includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. The UF BAP's comments must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF. The UF BAP's meetings are conducted in accordance with the Federal Advisory Committee Act (FACA).

CAPT Nguyen then outlined the duties of the UF BAP which include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and to subsequently recommend changes. Comments to the Director, DHA, regarding recommended formulary status, preauthhorizations, and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.
- To hold quarterly meetings in an open forum. The UF BAP may not hold meetings except at the call of or with the advance approval of the DFO in consultation with the Chairperson of the UF BAP.
- To prepare minutes of the proceeding and prepare comments for the Secretary or his designee regarding the UF or changes to the formulary. The minutes will be available on the website and comments will be prepared for the Director, DHA.

The DFO provided guidance regarding this meeting.

- The role of the UF BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the Department of Defense appreciates that the UF BAP may be interested in the drug classes selected for review or specific pricing data, these topics do not fall under the purview of the UF BAP.

- The P&T Committee met for approximately 16 hours conducting its reviews of the drug class recommendations that will be presented today. Since this meeting is considerably shorter, the UF BAP will not receive the same extensive information that is presented to the P&T Committee members. However, the UF BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the UF BAP are available on the TRICARE website.
- Detailed minutes of this meeting are being prepared. The UF BAP meeting minutes, the DoD P&T Committee meeting minutes, and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO provided some ground rules for conducting the virtual meeting:

- The meeting will be conducted in a remote access format.
- All discussions take place in open public forum.
- There is to be no committee discussion outside the virtual forum or during breaks.
- Audience participation is limited to private citizen comments received in writing prior to the meeting.
- Participants will be joined in a listen only mode.
- To ensure that there are not disruptions to discussion and as a precaution, please mute your phones.

Panel and Presenter Guidance

- When asking or responding to questions:
  - Panel members are asked to state their name prior to asking your questions.
  - Presenters or anyone responding to a question are asked to state their name prior to responding.
  - The meeting is being recorded. Please speak clearly.
- Members of the Formulary Management Branch and the P&T Committee are available to answer questions related to the UF BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure the minutes accurately reflect relevant facts, regulations, or policy.

CAPT Nguyen introduced the individual Panel members (see list above) and noted house- keeping considerations.

Private Citizen Comments: No private citizen comments were received.

The meeting was handed over to the Panel Chair Dr. Pamela Schweitzer for her opening remarks.

Chair's Opening Remarks

Dr. Schweitzer welcomed the BAP panel members to the meeting. On behalf of the panel she would like to thank the P&T Committee and FMB for all the work put to allow us to comment on the recommendations and that she is very grateful for the panel members who have taken the time to review the materials. Then she turned the meeting over to the FMB.

Dr. VonBerg's Opening Remarks

The meeting then proceeded with comments from Dr. Ed VonBerg, Chief of the Formulary Management Branch, who introduced the team speaking (see list above).

Uniform Formulary Review Process: In accordance with 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA) or their designee, on formulary or complete exclusion status, prior authorization (PA), pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) or complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

The DoD Formulary Management Branch supports the P&T Committee by conducting the relative clinical effectiveness analyses and relative cost effectiveness analyses of the drugs and drug classes under review and consideration by the P&T Committee for the Uniform Formulary.

The goal of this presentation is not to provide you with the same in-depth analyses presented to the P&T Committee, but a summary of the processes and analyses presented to the P&T Committee. The cost-effective analyses will be general in nature since we are unable to disclose the actual costs used in the economic models.

The full presentations then started. Following some of the sections the DoD P&T Committee physician perspective was provided by Dr. John Kugler and is included starting on page 13. The information starting on page 19 includes the full meeting information.

Closing Remarks

Dr. VonBerg then thanked the UF BAP Panel members stated that he appreciated everyone's comments and participation in the process. He also relayed he was looking forward to working with the UF BAP Panel in the new year.

Dr. Schweitzer thanked the panel, the P&T Committee and the FMB for their presentations. She also echoed what Dr. VonBerg said and wished everybody a good holiday and would see everyone you next year. She also thanked everyone for hanging in there for the whole meeting.

CAPT Nguyen closed the meeting by thanking Dr. Schweitzer and expresses her warmest thanks for the Panel's devotion to the health and wellbeing of our nation's military and to providing our service members, veterans and families with the best possible pharmacy benefit

CAPT Nguyen then declared the meeting closed.

The meeting adjourned at 11:30 AM EDT.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

[redacted]

Pamela Schweitzer, PharmD
Chairperson, UFBAP

DoD P&T Committee Physician Perspective

Dr. John Kugler's comments on the formulary recommendations followed selected individual sections and are outlined below:

Drug Class Reviews

TIBs – IL-17s and IL-23 inhibitors

- The TIBs are a very complicated drug class, with multiple new drugs approved since the last review in 2014. The IL-17s and IL-23s were discussed in this meeting and we will be reviewing the remainder of the TIBs subclasses going forward. The IL-17s and IL-23s also included a new approach that will allow the DoD to participate more easily in Joint National Contracts with the VA, especially with the launch of biosimilars.
- The formulary recommendations will expand the options available for providers and patients.
- For the IL-17s, Taltz will now be UF and step-preferred. For plaque psoriasis, a trial of Humira will not be required for Taltz.
- For the IL-23s, Stelara will remain UF, and three products, Tremfya, Skyrizi and Ilumya were moved to UF status.
- A step-preferred IL-23 will not be selected, leaving room within the condition set for a biosimilar to Ustekinumab. The preferred biosimilar will be chosen through the JNC process. Clinical review of FDA-approved biosimilars by the DoD P&T Committee is complete. After the JNC announcement, the step-preferred product will be presented at the BAP meeting, and PA updates for the step therapy will be made at that time.
- The IL-23 Omvoh is the only product moving to NF status and currently has very low utilization, with only 13 patients. We will send letters notifying them of the copay change.
- Extensive changes were made to the TIBs PAs. These changes were due to formulary updates, new indications, professional guidelines, and a broader effect to streamline the forms. Automation for specialist bypass was added for several products, streamlining care for patients that see these specialist providers. The PA changes will apply to new patients, so patients currently on a non-preferred product can continue therapy.
- New Ulcerative Colitis guidelines were published in late November after the meeting was held. The P&T Committee is aware of this new guidance and will incorporate into future reviews.

Migraine Agents – Oral CGRPs

- We have reviewed this subclass previously, and the new clinical data and updated guidelines all suggest that these products are highly interchangeable.

- For formulary status, Ubrelvy will now be the preferred product for acute treatment, and Qulipta will be the preferred oral CGRP for preventive treatment. Nurtec will move to nonformulary and non-preferred status.
- For the PAs, we did take into consideration the guideline-recommended treatments that should be tried first, and there was no change to this part of the PA. However, all patients currently receiving Nurtec will be affected by the new step therapy and will need to try Qulipta or Ubrelvy, depending on the indication. We will mail letters to the patients receiving Nurtec. If a provider does not want to switch their stable Nurtec patients they can resubmit a PA and the patient can continue Nurtec for prevention.
- There were two opposing votes for these recommendations. The reason centered on the change in formulary status for Nurtec and how it would impact active-duty service members. The Committee is aware of the potential impact and is working on improving waivers and reconsideration processes for PA denials in active-duty service members for readiness and retention purposes.
- Additionally, automation was added for the PAs. For acute use for Ubrelvy, an automated lookback for Nurtec has been added, and the renewal criteria has been removed, so once a PA is approved, Ubrelvy will be approved indefinitely.

Rapid-Acting Insulins and Short-Acting, Intermediate-Acting and Combination Insulins

- The main reason for reviewing this class is due to market entrants of biosimilars, the termination of current pricing agreements, and the opportunity to participate in a Joint National Contract.
- The approach here is like what was just discussed with the TIBs. This review serves as the clinical effectiveness conclusion, and the JNC award will serve as the cost effectiveness conclusion. There are no changes to the formulary status or PAs for the insulins.
- When the JNC is awarded, the formulary status and PAs will be updated to reflect the new step-preferred product and then the recommendation will be brought back to the BAP for consideration.

New Drugs

- For the new drugs, there were 19 total drugs reviewed, with 10 recommended for UF status, and 7 as NF.
- Two drugs were selected to be completely excluded from the formulary. The first is an ophthalmic suspension, for which several alternatives are available. The second is the vial formulation of the weight loss drug Zepbound, which has a pen formulation that is on the formulary.
- For the drugs that were recommended for NF status, there are several formulary alternatives available, and some of them have the active ingredients available as generic products.

- Two of the drugs have new mechanisms of action – the antihypertensive drug (Tryvio) and the COPD drug (Ohtuvayre). Both drugs were recommended for NF status with PAs, since they are not mentioned in the guidelines. The antihypertensive drug has not yet been studied to show whether it reduces adverse cardiovascular outcomes like heart attacks or stroke, and the COPD drug has not yet been shown to reduce exacerbations.

AGENDA

Uniform Formulary Beneficiary Advisory Panel (UF BAP)
For the November 2024 Department of Defense Pharmacy and Therapeutics Committee Meeting
December 18, 2024 at 10:00 AM Eastern Daylight Time

Virtual Meeting

- **General session starts at 10:00 AM Eastern Daylight Time**
- **Roll Call**
- **Therapeutic Class Reviews**

  Members of the Defense Health Agency (DHA) Pharmacy Operations Division (POD) Formulary Management Branch (FMB) will present relative clinical and cost-effective analyses along with the Department of Defense (DoD) Pharmacy & Therapeutics Committee (P&T) recommendations for the Uniform Formulary (UF) and any recommended complete exclusion candidates.

  The DoD P&T Committee made recommendations for the following drugs/drug classes during the November *2024 meeting.*

- **Drug Class Reviews**
  - *Targeted Immunomodulatory Biologics (TIB) Class*
    - *Interleukin (IL)-17 Inhibitor Subclass*
    - *IL-23 Inhibitor Subclass*
  - *Migraine Agents Class - Oral Calcitonin Gene-Related Peptide (CGRP) Subclass*
  - *Insulins Class Clinical Effectiveness Review*
    - *Rapid-Acting Insulin Analogs Subclass*
    - *Short-Acting, Intermediate-Acting, and Combination Insulin Analogs Subclass*

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *aprocitentan (Tryvio)—Anti-Hypertensive Agents: Endothelin Receptor Agonists*
  - *carbidopa/levodopa extended release (XR) capsules (Crexont)—Parkinson's Agents*
  - *clobetasol 0.05% ophthalmic suspension (no brand name)—Ophthalmic Agents*
  - *clonidine XR 0.1 mg/mL oral suspension (Onyda XR)—Attention Deficit Hyperactivity Disorder Agents: Non-stimulants*
  - *ensifentrine nebulizer inhalation solution (Ohtuvayre)—Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease*

- *epinephrine nasal spray (Neffy)—Respiratory Agents*
- *lazertinib (Lazcluze)—Oncological Agents: Epidermal Growth Factor (EGFR) plus Non-Small Cell Lung Cancer (NSCLC)*
- *lebrikizumab-lbkz (Ebglyss)—Atopy Agents*
- *levacetylleucine (Aqneursa)—Neurological Agents*
- *nemolizumab-ilto (Nemluvio)—TIBs: Miscellaneous Interleukins*
- *norethindrone acetate/ethinyl estradiol orally dissolving tablets (ODT) (Femlyv)—Contraceptive Agents: Monophasics with 20 mcg estrogen*
- *palopegteriparatide (Yorvipath)—Osteoporosis Agents*
- *seladelpar (Livdelzi)—Gastrointestinal-2 Agents*
- *sofpironium 12.45% topical gel pump (Sofdra)—Antiperspirants*
- *tirzepatide vial (Zepbound vials)—Weight Loss Agents*
- *vadadustat (Vafseo)—Hematological Agents: Red Blood Cell (RBC) Stimulants Erythropoietin Agents*
- *vigabatrin 100 mg/mL oral solution (Vigafyde) —Anticonvulsant and Antimania Agents*
- *vorasidenib (Voranigo)—Oncological Agents*
- *xanomeline/trospium (Cobenfy) —Antipsychotic Agents: Atypicals*

➢ **Utilization Management Issues**

- **PA Criteria —Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**
  - *Oncological Agents—Renal Cell Carcinoma: everolimus tablets (Torpenz)*
  - *Skeletal Muscle Relaxants and Combinations: methocarbamol 1,000 mg tablets (generic, Tanlor)*
  - *Antiemetic-Antivertigo Agents: ondansetron 16 mg ODT*

- **PA Criteria—Updated PA Criteria for New FDA-Approved Indications**
  - *Oncological Agents—repotrectinib (Augtyro)*
  - *Oncological Agents: Lung Cancer—adagrasib (Krazati)*
  - *Oncological Agents: Lung Cancer—selpercatinib (Retevmo)*
  - *Oncological Agents: Ovarian Cancer—olaparib (Lynparza)*
  - *Psoriasis Agents—roflumilast 0.15% cream (Zoryve)*
  - *Atopy Agents—dupilumab (Dupixent)*
  - *Atopy Agents—benralizumab (Fasenra Pen)*

- *TIBs: Non-Tumor Necrosis Factor Inhibitors (TNFs)—apremilast (Otezla)*
- *TIBs—certolizumab (Cimzia)*
- *Anticonvulsant Antimania Agents Miscellaneous—lacosamide ER (Motpoly XR)*
- *Immunological Miscellaneous Agents—peanut (Arachis hypogaea) allergen powder-dnfp (Palforzia)*

- **PA Criteria—Updated PA Criteria for Reasons Other Than New Indications**
  - *Antipsychotic Agents: Atypical— pimavanserin (Nuplazid)*
  - *Antifungals—oteseconazole (Vivjoa)*
  - *Hematological Agents—iptacopan (Fabhalta)*
  - *Osteoporosis Agents: Parathyroid Hormone (PTH) Analogs—teriparatide (Forteo, Bonsity)*
  - *Gynecological Agents Miscellaneous—fezolinetant (Veozah)*
  - *Pancreatic Enzyme Replacement Therapy (PERT)—pancrelipase (Zenpep)*

- **PA Updates for the Antilipidemic-1s Class**
  - *Non-Statins and Combinations Subclass—bempedoic acid (Nexletol), bempedoic acid/ezetimibe (Nexlizet)*
  - *Proprotein Convertase Subtilisin/Kexin Type-9 (PSCK-9) Inhibitors Subclass—evolocumab (Repatha)*

➢ **Re-Evaluation of Non-Formulary Generics—Acne Agents: Topical Acne and Rosacea**

- *adapalene/benzoyl peroxide 0.1/2.5% gel pump (Epiduo generics)*
- *adapalene/benzoyl peroxide 0.3/2.5% gel pump (Epiduo Forte generics)*
- *clindamycin/BP 1.2/2.5% gel (Acanya generics)*

➢ **Panel Discussions**

The UF BAP members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will concur or non-concur on the recommendations of the DoD P&T Committee concerning the establishment of the UF and subsequent recommended changes. The Panel will provide comments on their vote as directed by the Panel Chairman. Comments to the Director, DHA, or their designee will be considered before making a final UF decision.