EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP) Comments
25 September 2014

I. RECENTLY APPROVED U.S. FDA AGENTS REVIEW – Non-Insulin Diabetes Drug Class:

A. GLP1RA: Albiglutide (Tanzeum) – UF Recommendation:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** Tanzeum be designated formulary on the UF, based on clinical and cost effectiveness.

B. GLPR1RA: Albiglutide (Tanzeum) – Prior Authorization (PA) Criteria:

An existing automated PA (step therapy) criteria for the GLP1RAs requires a trial of metformin or a sulfonylurea first, based on positive long-term outcomes data with metformin and the sulfonylureas. The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** PA criteria for Tanzeum, requiring a trial of metformin or a sulfonylurea by all new and current users of Tanzeum, consistent with the PA requirements for the other GLP1RAs. Use of Tanzeum is approved only for patients with Type 2 diabetes mellitus; this is consistent with the FDA-approved indication.

The full PA criteria are as follows:

All new and current users of Tanzeum are required to try metformin or a sulfonylurea (SU) (examples of SUs include glyburide and glipizide) before receiving Tanzeum.

Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days, AND

Manual PA criteria: If automated criteria are not met, Tanzeum is approved (e.g., trial of metformin or SU is NOT required) if:

- The patient has confirmed diagnosis of Type 2 Diabetes Mellitus
- The patient has experienced any of the following issues on metformin:
  - impaired kidney function precluding treatment with metformin
  - history of lactic acidosis – which is a type of abnormality of metabolism of the body's waste products that can also cause impaired kidney function.
- The patient has experienced any of the following issues on a sulfonylurea:

- Hypoglycemia (low blood sugar) requiring medical treatment – which includes the patient being given orange juice or a sugar tablet, or sometimes in severe cases requiring hospitalization.

- The patient has had inadequate response to metformin or a SU or a (Di-peptidyl Peptidase 4) DPP-4 inhibitor (these are oral drugs for diabetes that have a different mechanism of action than the GLP1RAs). They include drugs such as Januvia and Janumet.
- The patient has a contraindication to metformin or a SU or DPP-4 inhibitor – in other words, the patient has some other medical condition that makes them not eligible to receive one of these three drug classes, because it would put them at a high risk of severe side effects.

C. **GLP1RA: Albiglutude (Tanzeum) – PA Implementation Plan:**

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** an effective date of the first Wednesday after a **30-day** implementation period in all points of service (POS).

Summary of Physician Perspective:

There was no controversy with the recommendation to have Tanzeum on the Uniform Formulary. The drug has the advantage of once weekly dosing, (like Bydureon), and Tanzeum was cost effective relative to the other drugs in the class.

The Committee recommended PA criteria for Tanzeum, which is similar to the other GLP-1RAs. All patients have to try metformin or a sulfonylurea first, because there is data showing that these two drug classes help reduce the long-term complications of diabetes, including death, and are more cost effective than the GLP-1RA drug class.

The class was last reviewed in November 2012 for Uniform Formulary status. There are several drugs in the pipeline, and one product, dulaglutide (Trulicity), which is administered once a week, was approved by the FDA this past Friday. The newer GLP-1RA drugs are noted to have longer administration times (once weekly), than the first products on the market - (Byetta) is administered twice a day, and Victoza, is administered once daily. However, none of the products have published data showing that a less frequent administration schedule leads to improvement in patient adherence.

Summary of Panel Questions/Comments:

There were no questions or comments from the Panel. Without further discussion, the Chair called for a vote on the UF Recommendation, PA Criteria and Implementation Plan for the GLP1RA: Albiglutide (Tanzeum).

A. GLP1RA: Albiglutide (Tanzeum) – UF Recommendation:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

B. GLP1RA: Albiglutide (Tanzeum) – PA Criteria:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

C. GLP1RA: Albiglutide (Tanzeum) – PA Implementation Plan:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

II. RECENTLY APPROVED U.S. FDA AGENTS REVIEW - Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Subclass:

A. Methylphenidate ER Oral Suspension (Quillivant XR)—UF Recommendation:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** Quillivant XR be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

B. Methylphenidate ER Oral Suspension (Quillivant XR)—UF Implementation Plan:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** 1) an effective date of the first Wednesday after a **90-day** implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

***Summary Physician Perspective*:**

There was no controversy here with the recommendation to have Quillivant XR as non-formulary.

There are several extended release products for ADHD on the Uniform Formulary which can be mixed with food, or are available in a capsule formulation that can be opened up and mixed with applesauce or sprinkled on food (examples include Adderall XR, Metadate CD, Ritalin LA, and Focalin XR).

Several behavioral specialists at the MTFs and civilian providers were surveyed for their opinions on this methylphenidate particular formulation. Overall, the survey responders felt that this product was a 2nd or 3rd line drug, which should be reserved for younger patients, or those who are unable or unwilling to swallow tablets, or those with a G-tube who can't take anything by mouth. Additionally, there was very little practical experience with the product, as 50% of the responders had either not heard of Quillivant XR or had not prescribed it. The survey also impacted the recommendation to have Quillivant XR as non-formulary.

***Summary Panel Questions/Comments*:**

There were no questions comments from the Panel members. Without further discussion, the Chair called for a vote on the UF Recommendation and Implementation Plan for the Osteoporosis Drugs.

A. Methylphenidate ER Oral Suspension (Quillivant XR)—UF Recommendation:

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

Director, DHA:

☒ These comments were taken under consideration prior to my final decision.

B. **Methylphenidate ER Oral Suspension (Quillivant XR)—Implementation Plan:**

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

Director, DHA:

☒ These comments were taken under consideration prior to my final decision.

III. UF CLASS REVIEWS—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBs):

A. TIBs – UF Recommendation:

The P&T Committee recommended (**16 for, 1 opposed, 0 abstained, 0 absent**) the following for the TIBs, based on clinical effectiveness, and cost effectiveness.

- UF and step-preferred ("in front of the step"): Humira
- UF and non-preferred ("behind the step"): Otezla, Simponi, Xeljanz, and Stelara
- NF and non-preferred: Orencia, Kineret, Cimzia, Enbrel, and Actemra
- This recommendation includes step therapy, which requires a trial of adalimumab Humira for all new users of a TIB.

B. TIBs – PA Criteria:

Existing manual PA criteria currently apply to all the TIBs. The P&T Committee recommended (**17 for, 0 opposed, 0 abstained, 0 absent**) that automated criteria (step therapy) for all new users of the non-preferred TIBs [which are Orencia, Kineret, Otezla, Cimzia, Enbrel, Simponi, Actemra, Xeljanz, and Stelara], requiring a trial of Humira before the non-step preferred drugs.

A trial of Humira is not required if:

- Contraindications exist to Humira
- The patient has had an inadequate response to Humira, and requires a different anti-TNF biologic or a non-TNF biologic
- The patient has experienced adverse reactions to Humira which are not expected to occur with the requested non-preferred TIB
    - There is no formulary alternative for the following: Enbrel: Patient is a child younger than four years of age or the patient has hepatitis C virus
    - Non-TNF TIB (Orencia, Actemra, Xeljanz, Kineret, Stelara, and Otezla): Patient has symptomatic chronic heart failure
    - Actemra, Orencia or Simponi: Patient has been stable on an intravenous formulation, with continuous use in the past three months, and needs to transition to the subcutaneous formulation These three products also have IV products, in addition to shots which the patient can administer to themselves at home.

The P&T Committee also recommended manual PA criteria for all users of Humira or a non-preferred TIB. Coverage for the TIBs is only allowed for the FDA-approved indications, and coverage is not approved for **concomitant** use of the TIB with other biologics.

Note that for all the products, manual PA criteria have previously been recommended by the P&T Committee and have been in place. The PA criteria below reflect the current PA manual criteria, along with the new step therapy criteria.

The full PA criteria are as follows:

1. **Adalimumab (Humira)**

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy (therapy with light or Ultraviolet radiation), and when other systemic therapies are medically less appropriate
- Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade (which is an IV TIB that is not part of the pharmacy benefit), or an inability to tolerate Remicade
- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants (drugs that suppress the immune system including prednisone)

Coverage approved for pediatric patients (age 4–17) with:

- Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric arthritis with more than one joint affected).

Coverage is NOT provided for concomitant use other TIBs including but not limited to Humira, Kineret, Cimzia, Enbrel, Simponi, Remicade, Orencia, Actemra

2. **Golimumab (Simponi)**

Automated PA criteria:
The patient has filled a prescription for Humira at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Simponi if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira is not expected with requested non-step preferred TIB
- Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to SC formulation

AND

Coverage approved for patients > 18 years with:

- Moderate to severe active rheumatoid arthritis in combination with methotrexate
- Active psoriatic arthritis or active ankylosing spondylitis
- Moderately to severely active ulcerative colitis with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy (oral prednisone or IV products that are similar to prednisone).

Rheumatoid arthritis patients require an active methotrexate script.

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

3. Certolizumab (Cimzia)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Cimzia if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderately to severely active Crohn's disease following an inadequate response to conventional therapy.

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

4. **Etanercept (Enbrel)**

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Enbrel if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative (Enbrel for children < 4years of age; Enbrel for hepatitis C virus infection)

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy

Coverage approved for pediatric patients (age 2–17) with:

- Moderate to severe active polyarticular Juvenile Idiopathic inflammatory Arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

5. **Anakinra (Kineret)**

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Kineret if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative (Kineret for pediatric patient with Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryoprin Associated Period Syndrome (CAPS) NOMID – these are rare conditions in children where there are metabolic abnormalities
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic Congestive Heart Failure

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, who have failed ≥ 1 disease modifying anti-rheumatic drugs (DMARDs)

Coverage approved for pediatric patients (all ages) with:

- Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryoprin Associated Period Syndrome (CAPS)

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

6. Abatacept (Orencia)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Orencia if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic Congestive Heart Failure
- Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to SC formulation (Orencia)

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis
- Subcutaneous Orencia is not approved for use in systemic or polyarticular Juvenile Idiopathic Arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

7. Tocilizumab (Actemra)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during

the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Actemra if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic Congestive Heart Failure
- Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to SC formulation (Actemra)

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs)
- Subcutaneous Actemra is not approved for use in systemic or polyarticular Juvenile Idiopathic Arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

8. Tofacitinib (Xeljanz)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Xeljanz if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative: patient requires a TNF TIB for symptomatic Congestive Heart Failure

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

9. Apremilast (Otezla)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 day.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Otezla if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB

AND

Coverage approved for patients ≥ 18 years with:

- Active psoriatic arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

10. Ustekinumab (Stelara)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Stelara if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB

AND

Coverage approved for patients ≥ 18 years with:

- Active psoriatic arthritis
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

***C.* TIBs—UF Implementation Plan:**

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** 1) an effective date of the first Wednesday after a **90-day** implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

***Summary of Physician Perspective*:**

This is a drug class that is very complex, due to the different products available and variety of FDA-approved indications. The TIBs account for over $200 million in yearly expenditures. Additionally, now there are oral products starting to come onto the market. Due to all these reasons, the TIBs were a good candidate to review for Uniform Formulary status.

The Uniform Formulary recommendation is for Humira to be the preferred TIB. Humira is the only TIB that is FDA-approved for all 7 indications, and has been on the market since 2002, so the safety profile is well known. These clinical reasons, plus the cost effectiveness evaluation, factored into the recommendation for Humira to be the preferred product.

Patients will be "grandfathered", meaning that only new patients will be required to try Humira first. The reasons for "grandfathering" are because the Committee did recognize the complexity of the disease states treated by the TIBs, and did not want to disrupt therapy for a patient stabilized on one of the non-preferred products.

Although Humira is step-preferred, the recommendation is to have several products on the Uniform Formulary. This allows for additional drugs to cover all the main indications rheumatology, dermatology and GI. Specifically, Simponi is an alternative to Humira for GI conditions; the recommendation includes an oral drug (Xeljanz) for rheumatoid arthritis; and includes two non-TNF drugs with alternative mechanisms of action for rheumatoid arthritis (Stelara and Xeljanz).

The PA criteria are complicated, but the criteria do reflect the FDA approved indications for the TIBs, and also take into account the unique aspects of the drugs – for example Enbrel is recognized for use in young children and for patients with hepatitis C; and the non-TNFs are allowed for patients with heart failure.

For the Uniform Formulary recommendation, the one opposing vote was because the member felt that having all the products on the Uniform Formulary would allow for patients to have more choices for treatment.

***Summary of Panel Questions/Comments*:**

The Panel members asked for clarification of the process/steps used to implement grandfathering of affected beneficiaries.

In response the presenters stated that the system will conduct a 180 day "look back" for non preferred agents in PDTS. Operationally, grandfathering is used behind-the-scenes by operational pharmacists as a standard procedure. For example, the step-therapy will look for Humira. The grandfathering will look for the current drug the patient has been taking.

Without further discussion, the Chair asked for a vote on the Targeted Immunomodulatory Biologics (TIBs).

A. Targeted Immunomodulatory Biologics (TIBs) – UF Recommendation:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

B. Targeted Immunomodulatory Biologics (TIBs) – PA Criteria:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

C. Targeted Immunomodulatory Biologics (TIBs) – UF Implementation Plan:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

III. UTILIZATION MANAGEMENT

For the utilization management section, this is where we present new prior authorization criteria for products that may not have been reviewed yet for formulary placement by the P&T Committee, or where there have been updated to the FDA-approved package inserts for products that the P&T Committee has already had PA criteria in place. You'll see a variety of different drugs and drug classes presented in the section.

A. Valeritas V-Go Insulin Delivery Device—PA Criteria:

The V-Go system is a disposable insulin delivery device approved for patients with Type 2 diabetes mellitus. Insulin can be given with an insulin pump, with a vial that requires filling a syringe, or with an insulin pen, which the patient then used to inject himself. Unlike an insulin pump, V-Go does not require any tubing or catheters. The device is filled daily with rapid acting insulin, which provides a constant release of insulin, which is

called "basal" insulin. Boluses can be given around a mealtime, which is called "meal time insulin". After 24 hours, the device is discarded and replaced with a new unit.

Advantages of the V-Go system include convenience to the patient desiring increased control over their blood glucose (sugar) levels and elimination of the need for multiple daily insulin injections. Additionally, V-Go may reduce prandial (meal time) glycemic (blood sugar level) excursions (fluctuations) compared to giving multiple insulin injections.

Potential disadvantages of V-Go include the risk of hypoglycemia (low blood sugar) and infection (because the device is attached to the body with a small needle that is in place for 24 hours and can act as a doorway for bacteria to enter the body), the requirement for daily manual filling of the device with insulin, non-adjustable preset basal rates (once the basal rate is set, it can't be readjusted), and the potential for wastage.

The P&T Committee considered PA criteria for V-Go, consistent with the product labeling, including the capacity and purpose of the system (there is a maximum allowable dose of insulin of 76 units per day), and the meal time bolus insulin dose capability (no less than 2 unit increments of insulin).

The P&T Committee recommended (**17 for, 0 opposed, 0 abstained, 0 absent**) manual PA criteria for all new users of V-Go. Coverage will be approved if the patient meets all of the following criteria:

1. Patient has Type 2 diabetes mellitus; AND
2. Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily; AND
3. Patient does not need less than 2 unit increments of bolus dosing; AND
4. Patient has been maintained on stable basal insulin for at least three months (at dosages of 20U, 30U, or 40U); what we mean here is that the patient has been maintained on stable doses of insulin that correspond to available strengths of the V-go system. We don't mean that if a patient is currently maintained on 24 units of insulin that they aren't eligible for the V-go system.

AND

5. Patient has been using prandial (meal time) insulin for at least three months.

B. **Valeritas V-Go Insulin Delivery Device—PA Implementation:**

The P&T Committee recommended (**17 for, 0 opposed, 0 abstained, 0 absent**) implementation of the PA upon signing of the minutes.

***Summary of Physician Perspective*:**

The V-Go system is a new technology that offers some conveniences to the patient, so they don't have the hassle of using multiple injections of insulin. However, there are some drawbacks to the product, as mentioned previously.

Not all patients are candidates for V-Go – it should be used in the most appropriate patient. The recommended PA criteria reflect this, and correlate with the FDA-approved uses for the device.

V-Go will be reviewed at the November P&T Committee meeting, to determine how it compares clinically and on cost with the insulin pens and vials. There are also several products under development, so you will be seeing more information on these devices.

Summary of Panel Questions/Comments:

The Panel members questioned the immediate implementation plan for the V-Go Insulin Delivery Device.

The presenters stated that the implementation plan is quicker than normal. They further clarified the process for approval of P&T committee recommendation and comments from the UF BAP Panel. They are forwarded to the Director, Defense Health Agency for review and approval. Additionally, the P&T committee wanted to get the PA Criteria in place as quickly as possible to ensure the most appropriate candidate received the device.

Without further discussion, the Chair asked for a vote on the Valeritas V-Go Insulin Delivery Device PA Criteria and PA Implementation Plan.

A. Valeritas V-Go Insulin Delivery Device—PA Criteria Recommendations:

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

~~**Director, DHA:**~~

☑ These comments were taken under consideration prior to my final decision.

B. Valeritas V-Go Insulin Delivery Device—PA Implementation Plan:

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

~~**Director, DHA:**~~

☑ These comments were taken under consideration prior to my final decision.

IV. UTILIZATION MANAGEMENT

A. Newer Sedative Hypnotics (SED-1s): Tasimelteon (Hetlioz)—PA Criteria

Hetlioz is a melatonin receptor agonist (a derivative of the supplement melatonin) that is approved for treating blind patients who have non-24 hour sleep-wake disorder and have no light perception (this is a very specific indication that is different than non-blind patients who have insomnia). Hetlioz will be reviewed as a new drug at an upcoming meeting. Automated PA (step therapy) currently applies to the SED-1s Drug Class, where a trial of generic zolpidem immediate release (IR) (generic Ambien) or zaleplon (generic Sonata) is required first. Other drugs in this class include Ambien CR and Lunsta).

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** PA criteria for all new users of Hetlioz who are blind and have non-24 hour sleep-wake disorder. PA criteria will require a trial of generic zolpidem IR or zaleplon before Hetlioz.

The full PA criteria for Tasimelteon (Hetlioz) are as follows:

PA criteria apply to all new users of Hetlioz. A trial of generic zolpidem IR or zaleplon is required before Hetlioz.

Automated PA:

The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA:

If automated criteria are not met, Hetlioz is approved (e.g., trial of zolpidem immediate release or zaleplon is NOT required) if the patient meets criterion #1, below, and one of the other criteria (#2, #3, or #4).

1. The patient is totally blind and has no light perception. AND
2. The patient has received a trial of zolpidem Immediate Release or zaleplon and had an inadequate response. OR
3. The patient received a trial of zolpidem Immediate Release or zaleplon but was unable to tolerate it due to adverse effects. OR
4. Treatment with zolpidem IR or zaleplon is contraindicated for this patient (e.g., due to hypersensitivity, aberrant behaviors (sleep-walking or sleep driving), or intolerable rebound insomnia (insomnia that occurs when a patient tries to discontinue Ambien or one of the other sedative hypnotics).

B. SED-1s: Tasimelteon (Hetlioz)—PA Implementation

The P&T Committee recommended (**17 for, 0 opposed, 0 abstained, 0 absent**) an effective date of no later than the first Wednesday after a **30-day** implementation period in all POS.

Summary or Physician Perspective:

For Hetlioz, the recommendation was to have it follow the same step therapy criteria as the other drugs in the class. However, the Committee did recognize the specific indication for Hetlioz for patients who are blind. The PA criteria are intended to ensure the most appropriate patients receive the drug – for example, Hetlioz would not be the best option in patients who are not blind who have short term insomnia for instance due to jet lag.

Summary of Panel Questions/Comments:

There were no questions or comments from the Panel. Without further discussion, the Chair asked for a vote on the Tasimelteon (Hetlioz) PA Criteria and Implementation Plan.

A. Newer Sedative Hypnotics (SED-1s): Tasimelteon (Hetlioz)—PA Criteria:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

B. Newer Sedative Hypnotics (SED-1s): Tasimelteon (Hetlioz)—PA Implementation Plan:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

V. UTILIZATION MANAGEMENT

A. Metastatic Melanoma Medications: Trametinib (Mekinist) and Dabrafenib (Tafinlar)—PA Criteria:

Mekinist and Tafinlar are oral drugs approved for a specific type of cancer called metastatic melanoma – this is skin cancer which has spread or metastasized to other parts of the body. It has a high mortality rate.

There are several of these oral products for cancer that are already on the market, and several more are in the pipeline. These products have very specific FDA-indications, and usually are approved for patients with a very specific genetic laboratory test – meaning that the patients' genetic code will dictate whether they will respond to the drug or not. The P&T committee does recommend PA criteria for these products, to ensure that they are being used in the appropriate patient. The PA criteria for these oral cancer drugs reflect what is in the FDA-approved package insert.

Mekinist and Tafinlar are oral kinase inhibitors (their mechanism of action) approved for treating patients with unresectable (skin cancer which cannot be surgically removed) or metastatic melanoma who have documented BRAF V600E or V600K mutations as detected by an FDA-approved test (this is the specific genetic test that the drug has been shown to work in; patient who don't have this specific genetic code won't respond to the drugs). PA criteria currently apply to other oral kinase inhibitors for this diagnosis.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** manual PA criteria should apply to all new users of Mekinist and Tafinlar, consistent with the FDA-approved product labeling. The PA will ensure that candidates likely to respond to Mekinist and Tafinlar are identified prior to initiating therapy.

The full PA criteria are as follows:

Manual PA criteria apply to all new users of Mekinist and Tafinlar.

Mekinist:

- Coverage approved for treatment of patients alone or in combination with Tafinlar in patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
- Coverage not approved as a single agent in patients who have received prior BRAF-inhibitor therapy

Tafinlar:

- Coverage approved as a single agent for treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.
- Combination use with Mekinist in the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
- Not approved for patients with wild-type BRAF melanoma

Summary of Physician Perspective:

There was no controversy here. The recommended PA criteria match the FDA-approved uses for these two drugs. Additionally, PA criteria were recommended to be consistent with the class - PA criteria were previously approved in February 2012 for a similar drug, Zelboraf® (vermurafenib), which is also approved for metastatic melanoma.

Summary of Panel Questions/Comments:

There were no questions or comments from the Panel. Without further discussion, the Chair asked for a vote on the Metastatic Melanoma Medications: Trametinib (Mekinist) and Dabrafenib (Tafinlar) PA Criteria.

A. Metastatic Melanoma Medications: Trametinib (Mekinist) and Dabrafenib (Tafinlar) — PA Criteria:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

VI. UTILIZATION MANAGEMENT

A. Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR)—PA Criteria:

Trokendi XR and Qudexy XR are branded Extended Release (or ER) formulations of topiramate that are dosed once daily. Generic formulations of topiramate Immediate Release (IR) have been marketed since 1996, and include both tablets and capsules. Generic topiramate IR is FDA-approved for treating patients with seizures (or epilepsy), down to the age of two years, and is also approved for treating patients with migraine headache. Topiramate is sometimes used off –label (meaning for an indication which has not been approved by the FDA) for weight loss.

Trokendi XR and Qudexy XR are indicated by the FDA for the treatment of seizures, but are only approved for patients down to the age of six or ten years, depending on the specific type of seizure disorder that they have.

The P&T Committee recommended **(16 for, 1 opposed, 0 abstained, 0 absent)** PA criteria for all new users of Trokendi XR and Qudexy XR that is consistent with the product's labeling for treatment of seizures, due to the potential for off-label use. Patients will be required to try generic topiramate IR first, unless there is a contraindication or adverse reaction with the generic product.

The full PA criteria are as follows:

Manual PA criteria apply to all new users of Trokendi XR and Qudexy XR:

- Coverage approved for
  - Partial onset seizure and 1° generalized tonic-clonic seizures in patients ≥ 10 years
  - Lennox-Gastaut seizures in patients ≥ 6 years
- Coverage not approved for
  - Non-FDA approved indications, including migraine headache and weight loss
- Patient is required to try generic topiramate IR first unless the following has occurred
  - Inadequate response not expected to occur with Trokendi XR or Qudexy XR
  - Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR

B. Seizure Medications: Topiramate ER capsules (Trokendi XR and Qudexy XR)—PA Implementation:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** an effective date no later than the first Wednesday after a **30-day** implementation period in all POS.

Summary of Physician Perspective:

PA criteria were recommended by the Committee due to the differences in the indications between the two branded products and the topiramate (Topamax) original formulation. Advantages of the generic Topamax formulation are that it is approved for treating young children with seizures, and additionally for patients with migraine headache.

The PA will be a paper (or hard copy) PA that requires a patient to try the generic first. The one opposing vote was because the member felt that PA criteria were not warranted, due to difficulty of treating seizure disorders.

Summary of Panel Questions/Comments:

The Panel members requested clarification of the "Non-FDA approved indication" listed under the "Covered not approved for" Bullet.

In response, the presenters stated that the difference between the original FDA approved indication for topimax topiramate IR verses the two particular new products are only indicated procedures.

Even though it contains the same active ingredients, the companies for the two new products only attain the indications for seizures. It's the same active ingredients, but they are extended release tablets that can't be cut in half. We wanted to follow the FDA labeling specifically.

There were no other questions or comments from the Panel. Without further discussions, the Chair asked for a vote on the Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR) PA Criteria

A. Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR)—PA Criteria:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

B. Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR)—PA Implementation Plan:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

VII. FISCAL YEAR 2008 NDAA, Section 703:

A. Fiscal Year 2008 NDAA, Section 703—Drugs Designated Non-Formulary:

The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not in compliance with the Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the Uniform Formulary and will require pre-authorization prior to use in the Retail POS and medical necessity in the MTFs. These NF drugs will remain available in the Mail Order Point of Service without preauthorization.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** that the following products be designated Non-Formulary on the Uniform Formulary:

Auxilium Pharma:	Robaxin 750, Robaxin, Levatol
Bluepoint Lab:	Nitrofurantoin Mono-M; Nitrofurantoin
Eli Lilly:	Livalo

Kowa:	Livalo
Major Pharma:	sulfasalazine, methotrexate
Orexo:	Zubsolv
Purdue:	Dilaudid, Intermezzo
VistaPharm:	sucralfate
Xenoport:	Horizant
Zylera:	Ulesfia

B. Fiscal Year 2008 NDAA, Section 703—Pre-Authorization Criteria for NF Drugs:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** the following pre-authorization criteria for the drugs recommended Non-Formulary above: 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any POS other than retail network pharmacies.

C. Fiscal Year 2008 NDAA, Section 703—Implementation Period for Pre-Authorization Criteria:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** 1) an effective date of the first Wednesday after a **90-day** implementation period in the Retail Network; and, 2) DHA send a letter to beneficiaries affected by these decisions.

D. Fiscal Year 2008 NDAA, Section 703—Drugs Designated Formulary:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** retaining the following drugs, due to their unique clinical niches: oxycodone 5 mg/mL solution (VistaPharm); nitrogen mustard topical gel for the treatment of mycosis fungoides-type cutaneous T-cell lymphoma (Valchlor; Actelion); and, typhoid vaccine live oral (Vivotif; Berne Products Crucell).

Allerman interjects this is a standing part of every meeting. These correspond with the requirements of the law so there are no comments from Dr. Kugler.

Summary of Physician Perspective:

No comments from Dr. Kugler.

Summary of *Panel Questions/Comments:*

The Panel members asked if the P&T Committee "niche", can the P&T Committee override the law.

The presenters stated that the P&T Committee can override the law if they believed the need was compelling despite the company being non-compliant with the law.

Without further discussion, the Chair asked for a vote on the Fiscal Year 2008 NDAA, Section 703 Drugs Designated Non-Formulary.

A. Fiscal Year 2008 NDAA, Section 703—Drugs Designated Non-Formulary:

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

Director, DHA:

☐ These comments were taken under consideration prior to my final decision.

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
September 25, 2014
Washington, D.C.

Present Panel Members

- Robert L. Lewis, the Chief Warrant and Warrant Officer's Association
- Theresa Buchanan, the National Military Family Association
- John Wagoner, HealthNet Federal Services
- Sandra S. Delgado, Humana
- Robert Duane Tackitt – Association of the Military Surgeon of the United States – Interim Chair
- Michael Anderson, United Healthcare
- Bryan Hammons, Express Scripts, Inc.
- Katherine O. Tracy, Military Officers Association of America

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. Colonel J. Michael Spilker called the proceedings to order at 9:00 A.M. The Panel convened to review and comment on the therapeutic drug class recommendation resulting from the November 13 & 14 Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee meeting held in San Antonio, TX.

Agenda

The agenda for the meeting of the Panel is as follows:

- Welcome and Opening Remarks
- Public Citizen Comments
- Review and Panel discussion of P&T Committee recommendations for the following therapeutic drug class.

  - Designated Newly-Approved Drugs
    - Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RA) – albiglutide injection (Tanzeum)
    - Attention Deficit Hyperactivity (ADHD) Drugs – methylphenidate extended release oral suspension (Quillivant XR)

  - Drug Class Reviews:
    - Targeted Immunomodulatory Biologics (TIBs)

  - Utilization Management Issues
    - Prior Authorization Criteria
      - Insulin Delivery Device: Valeritas System (V-Go)
      - Newer Sedative Hypnotics: Tasimelteon (Hetlioz)

- Metastatic Melanoma Drugs: Trametinib (Mekinist) and Dabrafenib (Tafinlar)
- Seizure Medications: Topiramate extended release capsules (Trokendi XR and Qudexy XR)

➢ Section 703 Review

➢ Panel Discussions

The Uniform Formulary Beneficiary Advisory Panel will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will discuss the recommendation and vote to accept or reject the recommendations. The Panel will provide comments on their vote as directed by the Panel Chairman.

Opening Remarks

Col J. Michael Spilker introduced himself as the Designated Federal Officer for the Uniform Formulary Advisory Panel. The panel has convened to comment on the recommendations of the DoD P&T Committee meeting, which occurred on August 13, 2014.

Col Spilker, DFO, indicated that Title 10, United States Code, (USC) section 1074g, subsection b requires the Secretary of Defense to establish a DoD Uniform Formulary (UF) of the pharmaceutical agent and establishes the P&T committee to review formulary on a periodic basis and 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 Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. Comments of the panel must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF.

The panels meetings are conducted in accordance of the Federal Advisory Committee Act (FACA).

The duties of the Beneficiary Advisory Panel include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and subsequently recommending changes. Comments of the Director of the DHA regarding recommended formulary status, pre-authorizations 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 panel may not hold meetings except at the call or with the advance approval of the DFO and his consultation with the chairperson of the Panel.

- To prepare minutes of the proceedings and prepared comments of the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website, and comments will be prepared by DHA.

As guidance to the Panel regarding this meeting, Colonel Spilker said the role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the department appreciates that the BAP maybe interested in the drug class the selected will review, drugs recommended for the basic core formula (BCF) or specific pricing data, these titles do not fall under the purview of the BAP.

The P&T Committee met for approximately 10 hours conducting this review of the drug class recommendation presented today. Since this meeting is considerably shorter, the panel will not receive the same extensive information as presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the panel are available on the TRICARE website.

Detailed minutes of this meeting are being prepared. The BAP minutes, the DoD P&T Committee minutes, and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO provided ground rules for conducting the meeting:

- All discussions take place in an open public forum. There is to be no committee discussion outside the room, during breaks, or at lunch.
- Audience participation is limited to private citizens who signed up to address the Panel.
- Members of the Pharmacoeconomic Branch and P&T Committee are available to answer questions related to the BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure the minutes accurately reflect relevant facts, regulations, or policy.

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

There were no public citizen comments submitted or any sign-ups prior to the meeting.

Chairman's Opening Remarks

Dr. Robert Duane Tackitt greets the BAP and audience good morning and gives the floor to Dr. Downs.

DRUG CLASS REVIEW PRESENTATION:

(PEC Script – CAPT Downs)

Good morning, I am CAPT Walter Downs, Chief, Pharmacy and Therapeutic (P & T) Operations Section, Formulary Management Branch of the Pharmacy Operations Division. Joining me is Doctor and retired Army Colonel John Kugler, the Chairman of the P & T Committee. He will provide the physician perspective and comment on the recommendations made by the P & T Committee. Also joining us from the Formulary Management Branch today is Dr. Angela Allerman, a clinical pharmacist.

The Department of Defense (DoD) Formulary Management Branch supports the DoD P & T Committee by conducting a relative (relative meaning in comparison to the other agents defined in the same class) clinical-effectiveness analyses and relative cost-effectiveness analyses of the drug classes under review and consideration by the DoD P & T Committee for the Uniform Formulary (UF).

We are here to present an overview of the analyses presented to the P & T Committee. 32 Code of Federal Regulations (CFR) establishes procedures for inclusion of pharmaceutical agents on the Uniform Formulary based upon both relative clinical effectiveness and relative cost effectiveness.

The goal of this presentation is not to provide you with the same in-depth analyses presented to the DoD P & T Committee but a summary of the processes and analyses presented to the DoD P & T Committee. These include:

1) A brief overview of the relative clinical-effectiveness analyses considered by the DoD P & T Committee. All reviews include but are not limited to the sources of information listed in 32 CFR 199.21 (e)(1).

2) A brief general overview of the relative cost-effectiveness analyses. This overview will be general in nature since we are unable to disclose the actual costs used in the economic models. This overview will include the factors used to evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes.

3) The DoD P & T Committee's Uniform Formulary recommendation is based upon its collective professional judgment when considering the analyses from both the relative clinical- and relative cost-effectiveness evaluations. The Committee reviewed one Uniform Formulary Drug Classes: Targeted Immunomodulatory Biologic (TIBs)

   Additionally, 2 newly approved drugs were reviewed – albiglutide injection (Tanzeum) from the non-insulin diabetes drug, glucagon-like peptide-1 receptor agonist drug subclass; and methylphenidate extended release oral suspension (Quillivant XR) from the attention deficit hyperactivity (ADHD) drug class.

   We will also discuss Prior Authorizations for a drug for a new insulin delivery device, Valeritas System (V-Go); a new sedative hypnotics, tasimelteon (Hetlioz); two metastatic

melanoma drugs, trametinib (Mekinist) and dabrafenib (Tafinlar); and finally, two seizure medications, topiramate extended release capsules (Trokendi XR and Qudexy XR).

4) The DoD P & T Committee's recommendation as to the effective date of the agents being changed from the Formulary tier to Non-formulary tier on the Uniform Formulary. Based on 32 CFR 199.21 such change will not be longer than 180 days from the final decision date but may be less.

We have given you a handout that includes the Uniform Formulary recommendations for all the drugs discussed today; these are found on pages 2 through 6. There is a reference Target Immunomodulatory Biologic figure on page 3 that gives the drugs in the class and their FDA indications. The IV formulation of the medications is NOT a pharmacy benefit but added for your reference. The table at the end of the handout (page 6), summarizes the formulary recommendations and the number of beneficiaries impacted. We will be using trade names as much as possible, so you can refer to your handout throughout the presentation.

I. REVIEW OF NEWLY APPROVED DRUGS

P&T Comments

(Dr. Allerman)

A. Non-Insulin Diabetes Drug Class and Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA) Subclass: Albiglutide (Tanzeum). This is the Relative Clinical Effectiveness and Conclusion.

Tanzeum is the fourth GLP1RA and the second product with once weekly dosing. Similar to the other GLP1RAs [(exenatide once weekly (Bydureon), liraglutide (Victoza), and exenatide twice daily (Byetta)], Tanzeum has beneficial effects on reducing hemoglobin A1c – which is a lab test that measure blood sugar values over several months, blood pressure, weight, and improving cholesterol. Tanzeum has a lower incidence of nausea and vomiting compared to Bydureon, Victoza, or Byetta. However, it has a slightly higher incidence of diarrhea.

All four GLP1RAs have the same warnings and contraindications for the risk of serious adverse effects, including medullary thyroid cancer – which is a rare tumor of the thyroid gland, multiple endocrine neoplasia syndrome type 2 – which are rare tumors that occur in more than one gland, and pancreatitis- inflammation of the pancreas. There are currently no long-term cardiovascular outcome studies published with any GLP1RA (which means that although these drugs have been shown to decrease blood sugar values, they have not yet been shown to have a beneficial effect in reducing some of the long term consequences of diabetes, including heart disease, and the need for kidney dialysis or a kidney transplant.

Military Health System (MHS) expenditures for the Non-insulin Diabetes Drug class was $276 million in the period from August 2013 to March 2014. The GLP1RA

subclass represents $71.5 million, or approximately 25% of the total expenditures. Across all the three points of service [Retail Network, Mail Order Pharmacy, and the Military Treatment Facilities (MTFs)] in the GLP1RA subclass, Victoza has the highest utilization (about 18,000 30-day equivalent prescriptions dispensed monthly), followed by Byetta and Bydureon, at about 6,000 and 5,000 30-day equivalent prescriptions dispensed monthly. There is very little use of Tanzeum since it was just recently approved over the summer.

Relative Clinical Effectiveness Conclusion—

The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** the main benefit of albiglutide (Tanzeum) is its once weekly dosing regimen and lower incidence of nausea compared to the other GLP1RA drugs. The GLP1RAs will be re-reviewed at an upcoming meeting for UF and potential Basic Core Formulary (BCF) placement.

B. GLP1RA: (Albiglutide (Tanzeum) – Relative Cost-Effectiveness Analysis and Conclusion

Cost minimization analysis (CMA) was performed to evaluate Tanzeum with the other GLP1RA agents. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** that Tanzeum is cost-effective compared with other GLP1RA agents on the UF.

C. GLP1RA: Albiglutide (Tanzeum) – UF Recommendation

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** Tanzeum be designated formulary on the UF, based on clinical and cost effectiveness.

D. GLPR1RA: Albiglutide (Tanzeum) – Prior Authorization (PA) Criteria

An existing automated PA (step therapy) criteria for the GLP1RAs requires a trial of metformin or a sulfonylurea first, based on positive long-term outcomes data with metformin and the sulfonylureas. The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** PA criteria for Tanzeum, requiring a trial of metformin or a sulfonylurea by all new and current users of Tanzeum, consistent with the PA requirements for the other GLP1RAs. Use of Tanzeum is approved only for patients with Type 2 diabetes mellitus; this is consistent with the FDA-approved indication.

The full PA criteria are as follows:

All new and current users of Tanzeum are required to try metformin or a sulfonylurea (SU) (examples of SUs include glyburide and glipizide) before receiving Tanzeum.

Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days, AND

Manual PA criteria: If automated criteria are not met, Tanzeum is approved (e.g., trial of metformin or SU is NOT required) if:

- The patient has confirmed diagnosis of Type 2 Diabetes Mellitus
- The patient has experienced any of the following issues on metformin:
  - impaired kidney function precluding treatment with metformin
  - history of lactic acidosis – which is a type of abnormality of metabolism of the body's waste products that can also cause impaired kidney function.
- The patient has experienced any of the following issues on a sulfonylurea:
  - Hypoglycemia (low blood sugar) requiring medical treatment – which includes the patient being given orange juice or a sugar tablet, or sometimes in severe cases requiring hospitalization.
- The patient has had inadequate response to metformin or a SU or a (Di-peptidyl Peptidase 4) DPP-4 inhibitor (these are oral drugs for diabetes that have a different mechanism of action than the GLP1RAs). They include drugs such as Januvia and Janumet.
- The patient has a contraindication to metformin or a SU or DPP-4 inhibitor – in other words, the patient has some other medical condition that makes them not eligible to receive one of these three drug classes, because it would put them at a high risk of severe side effects.

E. GLP1RA: Albiglutude (Tanzeum) – PA Implementation Plan

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** an effective date of the first Wednesday after a **30-day** implementation period in all points of service (POS).

Physician Perspective:

There was no controversy with the recommendation to have Tanzeum on the Uniform Formulary. The drug has the advantage of once weekly dosing, (like Bydureon), and Tanzeum was cost effective relative to the other drugs in the class.

The Committee recommended PA criteria for Tanzeum, which is similar to the other GLP-1RAs. All patients have to try metformin or a sulfonylurea first, because there is data showing that these two drug classes help reduce the long-term complications of diabetes, including death, and are more cost effective than the GLP-1RA drug class.

The class was last reviewed in November 2012 for Uniform Formulary status. There are several drugs in the pipeline, and one product, dulaglutide (Trulicity), which is administered once a week, was approved by the FDA this past Friday. The newer GLP-1RA drugs are noted to have longer administration times (once weekly), than the first products on the market - (Byetta) is administered twice a day, and Victoza, is administered once daily. However, none of the products have published data showing that a less frequent administration schedule leads to improvement in patient adherence.

Panel Questions and Comments:

There were no questions or comments from the Panel. Without further discussion, the Chair called for a vote on the UF Recommendation, PA Criteria and Implementation Plan for the GLP1RA: Albiglutide (Tanzeum).

A. GLP1RA: Albiglutide (Tanzeum) – UF Recommendation:

The BAP voted:

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

B. GLP1RA: Albiglutide (Tanzeum) – PA Criteria:

The BAP voted:

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

C. GLP1RA: Albiglutide (Tanzeum) – PA Implementation Plan:

The BAP voted:

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

II. REVIEW OF NEWLY APPROVED DRUGS

P&T Comments

(Dr. Allerman)

A. Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Subclass: Methylphenidate Extended Release (ER) Oral Suspension (Quillivant XR). This is the Relative Clinical Effectiveness and Conclusion

Quillivant XR is FDA-indicated for the treatment of ADHD in children six years of age or older. It is an oral powder formulation of methylphenidate Extended Release that is reconstituted as a suspension at the time of dispensing and is dosed once daily. With Quillivant XR, the medication is given as a suspension, instead of mixing beads or

powder from opened capsules in food, which is required with other long-acting stimulants (e.g., Metadate CD, Ritalin LA, Adderall XR). There are no head-to-head studies comparing Quillivant XR to other ADHD medications.

Current clinical practice guidelines suggest that all stimulant compounds indicated for ADHD have very few differences among them in their ability to improve symptoms, their tolerability profiles, or risk of adverse events.

MHS expenditures for ADHD Stimulant Subclass in the past year were $138 million. The overall utilization was 1.6 million 30-day equivalent prescriptions dispensed over the year. There have been only 994 30-day equivalent prescriptions dispensed for Quillivant XR over the last 3 months.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** that although Quillivant XR offers the convenience of an oral suspension of methylphenidate ER, it failed to demonstrate clinically compelling advantages over existing UF agents for ADHD. Other long-acting stimulant preparations with alternative dosing formulations (e.g., sprinkles) are available on the UF.

B. Methylphenidate ER Oral Suspension (Quillivant XR)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed to evaluate Quillivant XR with other long-acting methylphenidate agents on the UF. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** that Quillivant XR was not cost-effective compared with other long-acting methylphenidate agents on the UF.

C. Methylphenidate ER Oral Suspension (Quillivant XR)—UF Recommendation

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** Quillivant XR be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

D. Methylphenidate ER Oral Suspension (Quillivant XR)—UF Implementation Plan

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** 1) an effective date of the first Wednesday after a **90-day** implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

Physician Perspective:

There was no controversy here with the recommendation to have Quillivant XR as non-formulary.

There are several extended release products for ADHD on the Uniform Formulary which can be mixed with food, or are available in a capsule formulation that can be

opened up and mixed with applesauce or sprinkled on food (examples include Adderall XR, Metadate CD, Ritalin LA, and Focalin XR).

Several behavioral specialists at the MTFs and civilian providers were surveyed for their opinions on this methylphenidate particular formulation. Overall, the survey responders felt that this product was a 2nd or 3rd line drug, which should be reserved for younger patients, or those who are unable or unwilling to swallow tablets, or those with a G-tube who can't take anything by mouth. Additionally, there was very little practical experience with the product, as 50% of the responders had either not heard of Quillivant XR or had not prescribed it. The survey also impacted the recommendation to have Quillivant XR as non-formulary.

Panel Questions and Comments:

There were no questions comments from the Panel members. Without further discussion, the Chair called for a vote on the UF Recommendation and Implementation Plan for the Osteoporosis Drugs.

A. Methylphenidate ER Oral Suspension (Quillivant XR)—UF Recommendation:

The BAP voted:

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

B. **Methylphenidate ER Oral Suspension (Quillivant XR)—Implementation Plan:**

The BAP voted:

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

III. UF CLASS REVIEWS—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBs)

P&T Comments

(CAPT Downs)

A. **TIBs – Relative Clinical Effectiveness and Conclusion:**

Please turn to page 3 of the handout to see the drugs in the class and their FDA-approved indications. The P&T Committee evaluated the relative clinical effectiveness of the TIBs Drug Class, which is comprised of the following injectable and oral medications:

- **Anti-tumor necrosis factor (TNF) biologics:** adalimumab (Humira), certolizumab (Cimzia), etanercept (Enbrel), and golimumab (Simponi)

- **Non-TNF biologics:** abatacept (Orencia), anakinra (Kineret), apremilast (Otezla), tocilizumab (Actemra), tofacitinib (Xeljanz), and ustekinumab (Stelara)

The TIBs are FDA-approved for a variety of indications, including rheumatologic (which refers to several types of arthritic conditions), dermatologic (skin conditions including psoriasis), and gastrointestinal inflammatory conditions (conditions affecting the intestines and colon, such as Chrohn's disease and ulcerative colitis).

The TIBs were reviewed for UF placement in November 2007 and Humira was recommended as the only multi-indication TIB (having FDA-approval for several indications) on the Extended Core Formulary (ECF). Since the 2007 class review, several new TIBs have been marketed. Two oral therapies, Xeljanz and Otezla are now available.

Military Health System (MHS) expenditures for the class were $265.3 million in the period from June 2013 to May 2014. Across all the three points of service [Retail Network, Mail Order Pharmacy, and the Military Treatment Facilities (MTFs)], Humira has the highest utilization at about 11,000 30-day equivalent prescriptions dispensed monthly, followed by Enbrel, at about 5,000 30-day equivalent prescriptions dispensed monthly. There is very little use of the remaining products. Humira utilization is the bulk of the TIB market share at 55%, with $109 million in yearly expenditures.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** the following conclusions for the TIBs, based on FDA-approved indications:

1. All the TIBs (Humira, Enbrel, Cimzia, Simponi, Orenica, Kineret, Actemra, Xeljanz, Stelara and Otezla) are highly effective for their FDA indications versus placebo (non-active product or sugar pill), based on randomized controlled trials (RCTs).

2. There are few direct head-to-head trials between the TIBs; the majority of studies are non-inferiority trials (non-inferiority trials show that one product is "just as good as" another product, but not better). Comparative effectiveness is primarily determined though network meta-analysis (NMA) and indirect comparison; i.e., number needed to treat (NNT). NMA is a type study design that provides a conclusion about several placebo controlled trials from different drugs where we don't have head to head studies. NNT tells us how many patients need to be treated with one drug to have a beneficial effect. The strength of evidence (or quality of the evidence) is typically low.

3. For rheumatoid arthritis, the available evidence is insufficient to clearly show superiority of one TIB over another with regard to the American College of Rheumatology 50 (ACR50) endpoint for response to treatment. This endpoint is used for patients with arthritis to determine how effective the TIB is. It includes such things as how many joints are inflamed, and how severely they are inflamed.

   In three systematic reviews, there was a trend favoring Enbrel over the other TIBs in terms of efficacy. The same reviews found Kineret had a statistically significant

lower mean (average) response when compared to Enbrel and Humira, but the strength of evidence was low.

4. For juvenile inflammatory arthritis (children with arthritis) , there is insufficient evidence to suggest clinically relevant differences between Humira and Enbrel, the two TIBs approved in pediatric patients.

5. For psoriatic arthritis, due to the lack of head-to-head clinical trials and heterogeneous study populations (widely different patient characteristics, or dissimilar patients) , there is insufficient evidence to determine comparative efficacy between the four anti-TNFs (Humira, Cimzia, Enbrel, and Simponi), as well as Stelara, and Otezla. Indirect comparisons from randomized controlled trials (the "gold" standard for conducting a clinical trial) suggest similar NNTs for these drugs.

6. For psoriasis, three products are approved, Humira, Enbrel, and Stelara. In one head-to-head RCT, Stelara was superior to etanercept in achieving response, based on the Psoriasis Activity and Severity Index 75 (PASI 75) score – this is the typical scoring system used for patients with psoriasis to evaluate efficacy and determine how severe and how many skin plaques they have. NMA demonstrated similar efficacy for Humira and Stelara.

7. For Crohn's disease, a NMA demonstrated that Humira and Cimzia are both effective for the induction of response and maintenance of remission (symptoms of severe diarrhea and stomach cramps are no longer occurring) and maintenance of response. The same analysis showed Humira is superior to Cimzia for induction of remission.

8. For ulcerative colitis, Humira and Simponi are effective for inducing clinical response, clinical remission, and mucosal healing – healing of the lining of the intestines and colon. There is insufficient data for direct comparison of these agents.

9. With regard to safety, the overall rates of adverse events (AEs) are similar between the TIBs. In short-term trials, adalimumab and abatacept had a lower risk of serious AEs (serious infections, malignancies, lymphomas, (which are types of cancers) and withdrawals of therapy due to side effects) compared to other TIBs.

10. Evidence from indirect comparisons of two systematic reviews and one NMA shows the rate of serious infections is higher with Cimzia than the other TIBs. The TIBs help treat arthritis and the other conditions by suppressing the patient's immune system, but this puts them at risk for being susceptible to bacterial and viral infections. A subgroup analysis from one systematic review and a NMA showed the risk of serious infections was NOT increased with Enbrel, in contrast to the increased risk seen with the other anti-TNF drugs, as compared to controls.

11. The risk of tuberculosis (TB) is increased with the TIBs as a group. There is evidence (which is low strength) that suggests an increased risk of TB with Humira, compared with Enbrel.

12. The evidence (low strength) from indirect comparisons suggesting a safety benefit with Enbrel in terms of serious infections and TB compared to the other anti-TNFs, must be weighed against its lack of efficacy for gastrointestinal conditions such as Crohn's disease and ulcerative colitis. Enbrel is approved by the FDA only for treating rheumatologic and dermatologic conditions.

13. Although the strength of evidence is low, there does not appear to be an elevated risk of malignancy (or cancer) with the TIBs. However, the risk of non-melanoma skin cancer (skin cancer which does not typically spread within the body) is increased with Humira and Enbrel, as compared to controls.

14. Concurrent use of a TIB with another TIB (using two TIBs at the same time) results in increased AEs and is not recommended by current practice guidelines from professional organizations.

15. Unique safety concerns with the non-TNF biologics include the following:

    - Orencia: Increased risk of chronic obstructive pulmonary disease (COPD) exacerbation in adults with COPD (worsening of shortness of breath in patients with emphysema)
    - Actemra and Xeljanz: gastrointestinal perforation (where the GI tract bursts) and lab abnormalities, including elevated lipids (which measure blood cholesterol) and transaminases (which measure liver function)
    - Otezla: psychiatric adverse effects such as depression and suicidal ideations

16. Overall, Humira has the highest clinical utility within the Military Health System (MHS) given its seven FDA-approved indications and wide spectrum of clinical coverage.

17. Inclusion of a non-TNF option on the formulary is required for patients who do not respond to an anti-TNF biologic.

B. TIBs – Relative Cost-Effectiveness Analysis and Conclusion

CMA and budget impact analysis (BIA) were performed to evaluate the TIBs used to treat rheumatologic (stratified by rheumatoid arthritis and psoriatic arthritis), dermatologic, and gastrointestinal (stratified by Crohn's disease and ulcerative colitis) inflammatory conditions. The P&T Committee concluded (**17 for, 0 opposed, 0 abstained, 0 absent**) the following:

1. CMA results for the TIBs showed the following:

    - For rheumatoid arthritis, Humira was the most cost-effective TIB, followed by Cimzia, Kineret, Xeljanz, Simponi, Enbrel, Orencia, and Actemra.

- For psoriatic arthritis, Humira was the most cost-effective drug, followed by Otezla, Cimzia, Simponi, Enbrel, and Stelara.
- For dermatologic conditions, Humira was the most cost-effective TIB, followed by Enbrel, and Stelara.
- For Crohn's disease, Humira was the most cost-effective agent, followed by Cimzia. For ulcerative colitis, Humira was the most cost-effective agent, followed by Simponi.

2. A Budget Impact Analysis was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and UF or non-preferred and NF.'

   Robust BIA results showed the scenario with Humira designated as formulary and step preferred on the UF; Otezla, Simponi, Xeljanz, and Stelara designated as formulary and non-preferred; and, Orencia, Kineret, Cimzia, Enbrel, and Actemra designated as NF and non-step preferred, was the most cost-effective option for the MHS.

C. TIBs – UF Recommendation

The P&T Committee recommended **(16 for, 1 opposed, 0 abstained, 0 absent)** the following for the TIBs, based on clinical effectiveness, and cost effectiveness.

- UF and step-preferred ("in front of the step"): Humira
- UF and non-preferred ("behind the step"): Otezla, Simponi, Xeljanz, and Stelara
- NF and non-preferred: Orencia, Kineret, Cimzia, Enbrel, and Actemra
- This recommendation includes step therapy, which requires a trial of adalimumab Humira for all new users of a TIB.

D. TIBs – PA Criteria

Existing manual PA criteria currently apply to all the TIBs. The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** that automated criteria (step therapy) for all new users of the non-preferred TIBs [which are Orencia, Kineret, Otezla, Cimzia, Enbrel, Simponi, Actemra, Xeljanz, and Stelara], requiring a trial of Humira before the non-step preferred drugs.

A trial of Humira is not required if:

- Contraindications exist to Humira
- The patient has had an inadequate response to Humira, and requires a different anti-TNF biologic or a non-TNF biologic
- The patient has experienced adverse reactions to Humira which are not expected to occur with the requested non-preferred TIB
    - There is no formulary alternative for the following: Enbrel: Patient is a child younger than four years of age or the patient has hepatitis C virus
    - Non-TNF TIB (Orencia, Actemra, Xeljanz, Kineret, Stelara, and Otezla): Patient has symptomatic chronic heart failure
    - Actemra, Orencia or Simponi: Patient has been stable on an intravenous formulation, with continuous use in the past three months, and needs to transition to the subcutaneous formulation These three products also have IV products, in addition to shots which the patient can administer to themselves at home.

The P&T Committee also recommended manual PA criteria for all users of Humira or a non-preferred TIB. Coverage for the TIBs is only allowed for the FDA-approved indications, and coverage is not approved for **concomitant** use of the TIB with other biologics.

Note that for all the products, manual PA criteria have previously been recommended by the P&T Committee and have been in place. The PA criteria below reflect the current PA manual criteria, along with the new step therapy criteria.

The full PA criteria are as follows:

1. **Adalimumab (Humira)**

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy (therapy with light or Ultraviolet radiation), and when other systemic therapies are medically less appropriate
- Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade (which is an IV TIB that is not part of the pharmacy benefit), or an inability to tolerate Remicade
- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants (drugs that suppress the immune system including prednisone)

Coverage approved for pediatric patients (age 4–17) with:

- Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric arthritis with more than one joint affected).

Coverage is NOT provided for concomitant use other TIBs including but not limited to Humira, Kineret, Cimzia, Enbrel, Simponi, Remicade, Orencia, Actemra

2. **Golimumab (Simponi)**

Automated PA criteria:
The patient has filled a prescription for Humira at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Simponi if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira is not expected with requested non-step preferred TIB
- Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to SC formulation

AND

Coverage approved for patients > 18 years with:

- Moderate to severe active rheumatoid arthritis in combination with methotrexate
- Active psoriatic arthritis or active ankylosing spondylitis
- Moderately to severely active ulcerative colitis with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy (oral prednisone or IV products that are similar to prednisone).

Rheumatoid arthritis patients require an active methotrexate script.

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

3. **Certolizumab (Cimzia)**

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Cimzia if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderately to severely active Crohn's disease following an inadequate response to conventional therapy.

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

4. **Etanercept (Enbrel)**

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND.

Manual PA criteria:

If automated criteria are not met, coverage is approved for Enbrel if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative (Enbrel for children < 4years of age; Enbrel for hepatitis C virus infection)

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy

Coverage approved for pediatric patients (age 2–17) with:

- Moderate to severe active polyarticular Juvenile Idiopathic inflammatory Arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

5. **Anakinra (Kineret)**

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Kineret if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)

- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative (Kineret for pediatric patient with Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryoprin Associated Period Syndrome (CAPS) NOMID – these are rare conditions in children where there are metabolic abnormalities
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic Congestive Heart Failure

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, who have failed ≥ 1 disease modifying anti-rheumatic drugs (DMARDs)

Coverage approved for pediatric patients (all ages) with:

- Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryoprin Associated Period Syndrome (CAPS)

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

6. Abatacept (Orencia)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Orencia if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic Congestive Heart Failure

- Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to SC formulation (Orencia)

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis
- Subcutaneous Orencia is not approved for use in systemic or polyarticular Juvenile Idiopathic Arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

7. **Tocilizumab (Actemra)**

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Actemra if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic Congestive Heart Failure
- Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to SC formulation (Actemra)

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs)

- Subcutaneous Actemra is not approved for use in systemic or polyarticular Juvenile Idiopathic Arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

8. Tofacitinib (Xeljanz)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Xeljanz if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative: patient requires a TNF TIB for symptomatic Congestive Heart Failure

AND

Coverage approved for patients ≥ 18 years with:

- Moderate to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

9. Apremilast (Otezla)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during

the previous 180 day.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Otezla if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB

AND

Coverage approved for patients ≥ 18 years with:

- Active psoriatic arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

10. Ustekinumab (Stelara)

Automated PA criteria:

The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Stelara if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB

AND

Coverage approved for patients ≥ 18 years with:

- Active psoriatic arthritis

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

Coverage is NOT provided for concomitant use other TIBs including but not limited to the previously stated TIBs.

E. TIBs—UF Implementation Plan: The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** 1) an effective date of the first Wednesday after a **90-day** implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

Physician Perspective:

This is a drug class that is very complex, due to the different products available and variety of FDA-approved indications. The TIBs account for over $200 million in yearly expenditures. Additionally, now there are oral products starting to come onto the market. Due to all these reasons, the TIBs were a good candidate to review for Uniform Formulary status.

The Uniform Formulary recommendation is for Humira to be the preferred TIB. Humira is the only TIB that is FDA-approved for all 7 indications, and has been on the market since 2002, so the safety profile is well known. These clinical reasons, plus the cost effectiveness evaluation, factored into the recommendation for Humira to be the preferred product.

Patients will be "grandfathered", meaning that only new patients will be required to try Humira first. The reasons for "grandfathering" are because the Committee did recognize the complexity of the disease states treated by the TIBs, and did not want to disrupt therapy for a patient stabilized on one of the non-preferred products.

Although Humira is step-preferred, the recommendation is to have several products on the Uniform Formula. This allows for additional drugs to cover all the main indications – rheumatology, dermatology and GI. Specifically, Simponi is an alternative to Humira for GI conditions; the recommendation includes an oral drug (Xeljanz) for rheumatoid arthritis; and includes two non-TNF drugs with alternative mechanisms of action for rheumatoid arthritis (Stelara and Xeljanz).

The PA criteria are complicated, but the criteria do reflect the FDA approved indications for the TIBs, and also take into account the unique aspects of the drugs – for example Enbrel is recognized for use in young children and for patients with hepatitis C; and the non-TNFs are allowed for patients with heart failure.

For the Uniform Formulary recommendation, the one opposing vote was because the member felt that having all the products on the Uniform Formulary would allow for patients to have more choices for treatment.

Panel Questions and Comments:

The Panel members asked for clarification of the process/steps used to implement grandfathering of affected beneficiaries.

In response the presenters stated that the system will conduct a 180 day "look back" for non-preferred agents in PDTS. Operationally, grandfathering is used behind-the-scenes by operational pharmacists as a standard procedure. For example, the step-therapy will look for Humira. The grandfathering will look for the current drug the patient has been taking.

Without further discussion, the Chair asked for a vote on the Targeted Immunomodulatory Biologics (TIBs).

A. Targeted Immunomodulatory Biologics (TIBs) – UF Recommendation

The BAP voted :

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

B. Targeted Immunomodulatory Biologics (TIBs) – PA Criteria

The BAP voted :

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

C. Targeted Immunomodulatory Biologics (TIBs) – UF Implementation Plan

The BAP voted :

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

V. UTILIZATION MANAGEMENT

For the utilization management section, this is where we present new prior authorization criteria for products that may not have been reviewed yet for formulary placement by the P&T Committee, or where there have been updated to the FDA-approved package inserts for products that the P&T Committee has already had PA criteria in place. You'll see a variety of different drugs and drug classes presented in the section.

P&T Comments

(Dr. Allerman)

A. Valeritas V-Go Insulin Delivery Device—PA Criteria

The V-Go system is a disposable insulin delivery device approved for patients with Type 2 diabetes mellitus. Insulin can be given with an insulin pump, with a vial that requires filling a syringe, or with an insulin pen, which the patient then used to inject himself. Unlike an insulin pump, V-Go does not require any tubing or catheters. The device is filled daily with rapid acting insulin, which provides a constant release of insulin, which is called "basal" insulin. Boluses can be given around a mealtime, which is called "meal time insulin". After 24 hours, the device is discarded and replaced with a new unit.

Advantages of the V-Go system include convenience to the patient desiring increased control over their blood glucose (sugar) levels and elimination of the need for multiple daily insulin injections. Additionally, V-Go may reduce prandial (meal time) glycemic (blood sugar level) excursions (fluctuations) compared to giving multiple insulin injections.

Potential disadvantages of V-Go include the risk of hypoglycemia (low blood sugar) and infection (because the device is attached to the body with a small needle that is in place for 24 hours and can act as a doorway for bacteria to enter the body), the requirement for daily manual filling of the device with insulin, non-adjustable preset basal rates (once the basal rate is set, it can't be readjusted), and the potential for wastage.

The P&T Committee considered PA criteria for V-Go, consistent with the product labeling, including the capacity and purpose of the system (there is a maximum allowable dose of insulin of 76 units per day), and the meal time bolus insulin dose capability (no less than 2 unit increments of insulin).

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** manual PA criteria for all new users of V-Go. Coverage will be approved if the patient meets all of the following criteria:

1. Patient has Type 2 diabetes mellitus; AND

2. Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily; AND

3. Patient does not need less than 2 unit increments of bolus dosing; AND

4. Patient has been maintained on stable basal insulin for at least three months (at dosages of 20U, 30U, or 40U); what we mean here is that the patient has been maintained on stable doses of insulin that correspond to available strengths of the V-go system. We don't mean that if a patient is currently maintained on 24 units of insulin that they aren't eligible for the V-go system.

   AND

5. Patient has been using prandial (meal time) insulin for at least three months.

B. Valeritas V-Go Insulin Delivery Device—PA Implementation

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** implementation of the PA upon signing of the minutes.

***Physician Perspective*:**

The V-Go system is a new technology that offers some conveniences to the patient, so they don't have the hassle of using multiple injections of insulin. However, there are some drawbacks to the product, as mentioned previously.

Not all patients are candidates for V-Go – it should be used in the most appropriate patient. The recommended PA criteria reflect this, and correlate with the FDA-approved uses for the device.

V-Go will be reviewed at the November P&T Committee meeting, to determine how it compares clinically and on cost with the insulin pens and vials. There are also several products under development, so you will be seeing more information on these devices.

Panel Questions and Comments:

The Panel members questioned the immediate implementation plan for the V-Go Insulin Delivery Device.

The presenters stated that the implementation plan is quicker than normal. They further clarified the process for approval of P&T committee recommendation and comments from the UF BAP Panel. They are forwarded to the Director, Defense Health Agency for review and approval. Additionally, the P&T committee wanted to get the PA Criteria in place as quickly as possible to ensure the most appropriate candidate received the device.

Without further discussion, the Chair asked for a vote on the Valeritas V-Go Insulin Delivery Device PA Criteria and PA Implementation Plan.

A. Valeritas V-Go Insulin Delivery Device—PA Criteria Recommendations:

The BAP voted:

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

B. Valeritas V-Go Insulin Delivery Device—PA Implementation Plan:

The BAP voted:

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

VI. UTILIZATION MANAGEMENT

P&T Comments

(Dr. Allerman)

A. Newer Sedative Hypnotics (SED-1s): Tasimelteon (Hetlioz)—PA Criteria

Hetlioz is a melatonin receptor agonist (a derivative of the supplement melatonin) that is approved for treating blind patients who have non-24 hour sleep-wake disorder and have no light perception (this is a very specific indication that is different than non-blind patients who have insomnia). Hetlioz will be reviewed as a new drug at an upcoming meeting. Automated PA (step therapy) currently applies to the SED-1s Drug Class, where a trial of generic zolpidem immediate release (IR) (generic Ambien) or zaleplon (generic Sonata) is required first. Other drugs in this class include Ambien CR and Lunsta).

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** PA criteria for all new users of Hetlioz who are blind and have non-24 hour sleep-wake disorder. PA criteria will require a trial of generic zolpidem IR or zaleplon before Hetlioz.

The full PA criteria for Tasimelteon (Hetlioz) are as follows:

PA criteria apply to all new users of Hetlioz. A trial of generic zolpidem IR or zaleplon is required before Hetlioz.

Automated PA:

The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA:

If automated criteria are not met, Hetlioz is approved (e.g., trial of zolpidem immediate release or zaleplon is NOT required) if the patient meets criterion #1, below, and one of the other criteria (#2, #3, or #4).

1. The patient is totally blind and has no light perception. AND
2. The patient has received a trial of zolpidem Immediate Release or zaleplon and had an inadequate response. OR
3. The patient received a trial of zolpidem Immediate Release or zaleplon but was unable to tolerate it due to adverse effects. OR
4. Treatment with zolpidem IR or zaleplon is contraindicated for this patient (e.g., due to hypersensitivity, aberrant behaviors (sleep-walking or sleep driving), or intolerable rebound insomnia (insomnia that occurs when a patient tries to discontinue Ambien or one of the other sedative hypnotics).

B. SED-1s: Tasimelteon (Hetlioz)—PA Implementation

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** an effective date of no later than the first Wednesday after a **30-day** implementation period in all POS.

Physician Perspective:

For Hetlioz, the recommendation was to have it follow the same step therapy criteria as the other drugs in the class. However, the Committee did recognize the specific indication for Hetlioz for patients who are blind. The PA criteria are intended to ensure the most appropriate patients receive the drug – for example, Hetlioz would not be the best option in patients who are not blind who have short term insomnia for instance due to jet lag.

Panel Questions and Comments:

There were no questions or comments from the Panel. Without further discussion, the Chair asked for a vote on the Tasimelteon (Hetlioz) PA Criteria and Implementation Plan.

A. Newer Sedative Hypnotics (SED-1s): Tasimelteon (Hetlioz)—PA Criteria

The BAP voted:

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

B. Newer Sedative Hypnotics (SED-1s): Tasimelteon (Hetlioz)—PA Implementation Plan

The BAP voted:

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

VII. UTILIZATION MANAGEMENT

P&T Comments

(Dr. Allerman)

A. Metastatic Melanoma Medications: Trametinib (Mekinist) and Dabrafenib (Tafinlar)—PA Criteria

Mekinist and Tafinlar are oral drugs approved for a specific type of cancer called metastatic melanoma – this is skin cancer which has spread or metastasized to other parts of the body. It has a high mortality rate.

There are several of these oral products for cancer that are already on the market, and several more are in the pipeline. These products have very specific FDA-indications, and usually are

approved for patients with a very specific genetic laboratory test – meaning that the patients' genetic code will dictate whether they will respond to the drug or not. The P&T committee does recommend PA criteria for these products, to ensure that they are being used in the appropriate patient. The PA criteria for these oral cancer drugs reflect what is in the FDA-approved package insert.

Mekinist and Tafinlar are oral kinase inhibitors (their mechanism of action) approved for treating patients with unresectable (skin cancer which cannot be surgically removed) or metastatic melanoma who have documented BRAF V600E or V600K mutations as detected by an FDA-approved test (this is the specific genetic test that the drug has been shown to work in; patient who don't have this specific genetic code won't respond to the drugs). PA criteria currently apply to other oral kinase inhibitors for this diagnosis.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** manual PA criteria should apply to all new users of Mekinist and Tafinlar, consistent with the FDA-approved product labeling. The PA will ensure that candidates likely to respond to Mekinist and Tafinlar are identified prior to initiating therapy.

The full PA criteria are as follows:

Manual PA criteria apply to all new users of Mekinist and Tafinlar.

Mekinist:

- Coverage approved for treatment of patients alone or in combination with Tafinlar in patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
- Coverage not approved as a single agent in patients who have received prior BRAF-inhibitor therapy

Tafinlar:

- Coverage approved as a single agent for treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.
- Combination use with Mekinist in the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
- Not approved for patients with wild-type BRAF melanoma

Physician Perspective:

There was no controversy here. The recommended PA criteria match the FDA-approved uses for these two drugs. Additionally, PA criteria were recommended to be consistent with the class

PA criteria were previously approved in February 2012 for a similar drug, Zelboraf® (vermurafenib), which is also approved for metastatic melanoma.

Panel Questions and Comments:

There were no questions or comments from the Panel. Without further discussion, the Chair asked for a vote on the Metastatic Melanoma Medications: Trametinib (Mekinist) and Dabrafenib (Tafinlar) PA Criteria.

A. Metastatic Melanoma Medications: Trametinib (Mekinist) and Dabrafenib (Tafinlar) — PA Criteria:

The BAP voted:

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

VIII. UTILIZATION MANAGEMENT

P&T Comments

(Dr. Allerman)

A. Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR)—PA Criteria

Trokendi XR and Qudexy XR are branded Extended Release (or ER) formulations of topiramate that are dosed once daily. Generic formulations of topiramate Immediate Release (IR) have been marketed since 1996, and include both tablets and capsules. Generic topiramate IR is FDA-approved for treating patients with seizures (or epilepsy), down to the age of two years, and is also approved for treating patients with migraine headache. Topiramate is sometimes used off –label (meaning for an indication which has not been approved by the FDA) for weight loss.

Trokendi XR and Qudexy XR are indicated by the FDA for the treatment of seizures, but are only approved for patients down to the age of six or ten years, depending on the specific type of seizure disorder that they have.

The P&T Committee recommended **(16 for, 1 opposed, 0 abstained, 0 absent)** PA criteria for all new users of Trokendi XR and Qudexy XR that is consistent with the product's labeling for treatment of seizures, due to the potential for off-label use. Patients will be required to try generic topiramate IR first, unless there is a contraindication or adverse reaction with the generic product.

The full PA criteria are as follows:

Manual PA criteria apply to all new users of Trokendi XR and Qudexy XR:

- Coverage approved for
  - Partial onset seizure and 1° generalized tonic-clonic seizures in patients ≥ 10 years
  - Lennox-Gastaut seizures in patients ≥ 6 years
- Coverage not approved for
  - Non-FDA approved indications, including migraine headache and weight loss
- Patient is required to try generic topiramate IR first unless the following has occurred
  - Inadequate response not expected to occur with Trokendi XR or Qudexy XR
  - Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR

B. Seizure Medications: Topiramate ER capsules (Trokendi XR and Qudexy XR)—PA Implementation

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** an effective date no later than the first Wednesday after a **30-day** implementation period in all POS.

Physician Perspective:

PA criteria were recommended by the Committee due to the differences in the indications between the two branded products and the topiramate (Topamax) original formulation. Advantages of the generic Topamax formulation are that it is approved for treating young children with seizures, and additionally for patients with migraine headache.

The PA will be a paper (or hard copy) PA that requires a patient to try the generic first. The one opposing vote was because the member felt that PA criteria were not warranted, due to difficulty of treating seizure disorders.

Panel Questions and Comments:

The Panel members requested clarification of the "Non-FDA approved indication" listed under the "Covered not approved for" Bullet.

In response, the presenters stated that the difference between the original FDA approved indication for topimax topiramate IR verses the two particular new products are only indicated procedures.

Even though it contains the same active ingredients, the company for the two new products only attain the indications for seizures. It's the same active ingredients, but they are extended release tablets that can't be cut in half. We wanted to follow the FDA labeling specifically.

There were no other questions or comments from the Panel. Without further discussions, the Chair asked for a vote on the Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR) PA Criteria

A. Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR)—PA Criteria:

The BAP voted:

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

B. Seizure Medications: Topiramate Extended Release capsules (Trokendi XR and Qudexy XR)—PA Implementation Plan:

The BAP voted:

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

IX. FISCAL YEAR 2008 NDAA, Section 703

P&T Comments

(Dr. Allerman)

A. Fiscal Year 2008 NDAA, Section 703—Drugs Designated Non-Formulary

The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not in compliance with the Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the Uniform Formulary and will require pre-authorization prior to use in the Retail POS and medical necessity in the MTFs. These NF drugs will remain available in the Mail Order Point of Service without preauthorization.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** that the following products be designated Non-Formulary on the Uniform Formulary:

Auxilium Pharma:	Robaxin 750, Robaxin, Levatol
Bluepoint Lab:	Nitrofurantoin Mono-M; Nitrofurantoin
Eli Lilly:	Livalo
Kowa:	Livalo
Major Pharma:	sulfasalazine, methotrexate

Orexo:	Zubsolv
Purdue:	Dilaudid, Intermezzo
VistaPharm:	sucralfate
Xenoport:	Horizant
Zylera:	Ulesfia

B. Fiscal Year 2008 NDAA, Section 703—Pre-Authorization Criteria for NF Drugs

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** the following pre-authorization criteria for the drugs recommended Non-Formulary above: 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any POS other than retail network pharmacies.

C. Fiscal Year 2008 NDAA, Section 703—Implementation Period for Pre-Authorization Criteria

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** 1) an effective date of the first Wednesday after a **90-day** implementation period in the Retail Network; and, 2) DHA send a letter to beneficiaries affected by these decisions.

D. Fiscal Year 2008 NDAA, Section 703—Drugs Designated Formulary

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** retaining the following drugs, due to their unique clinical niches: oxycodone 5 mg/mL solution (VistaPharm); nitrogen mustard topical gel for the treatment of mycosis fungoides-type cutaneous T-cell lymphoma (Valchlor; Actelion); and, typhoid vaccine live oral (Vivotif; Berne Products Crucell).

Allerman interjects this is a standing part of every meeting. These correspond with the requirements of the law so there are no comments from Dr. Kugler.

Physician Perspective:

No comments from Dr. Kugler.

Panel Questions and Comments:

The Panel members asked if the P&T Committee "niche", can the P&T Committee override the law.

The presenters stated that the P&T Committee can override the law if they believed the need was compelling despite the company being non-compliant with the law.

Without further discussion, the Chair asked for a vote on the Fiscal Year 2008 NDAA, Section 703 Drugs Designated Non-Formulary

A. Fiscal Year 2008 NDAA, Section 703—Drugs Designated Non-Formulary

The BAP Votes:

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

Mr. Tackitt turns the floor over to Col Spilker. Col Spilker thanked the members of the UF BAP and adjourned the meeting.

Mr. Robert Duane Tackitt

Brief Listing of Acronyms Used in This Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in Panel discussions are listed below for easy reference. The term "Panel" in this summary refers to the "Uniform Formulary Beneficiary Panel," the group whose meeting is the subject of this report.

- AB – Bioequivalence
- ACR50 – American College of Rheumatology 50
- ADHD – Attention Deficit Hyperactivity Drugs
- AE – Adverse Effects
- BAP – Beneficiary Advisory Panel
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- BRAF – Proto-oncogene
- CAPS – Cryoprin Associated Period Syndrome
- CFR – Code of Federal Regulations
- CMA – Cost Minimization Analysis
- COPD – Chronic Obstructive Pulmonary Disease
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DMARDs – Disease Modifying Anti-Rheumatic Drugs
- DoD – Department of Defense
- DPP-4 – Dipeptidyl Peptidase 4
- ECF – Extended Core Formulary
- ER – Extended Release
- FACA – Federal Advisory Committee Act
- FDA – Federal Drug Administration
- GI – Gastro Intestinal
- GLP1RA – Glucagon-Like Peptide-1 Receptor Agonist
- IR – Immediate Release
- IV – Intravenous
- LA – Long Acting
- MHS – Military Health System
- MTF – Military Treatment Facility
- NDAA – National Defense Authorization Act
- NF – Non-Formulary
- NMA – Network Meta-Analysis
- NNT – Number Need to Treat
- NOMID – Neonatal-Onset Multisystem Inflammatory Disease
- P&T – DoD Pharmacy & Therapeutics Committee
- PA – Prior Authorization
- PASI 75 – Psoriasis Activity and Severity Index 75
- PEC – Pharmacoeconomic Branch

- POS – Point of Service
- RCT – Randomized Controlled Trial
- SC – Subcutaneous
- SED-1s – Sedative Hypnotics
- TB – Tuberclulosis
- TIBs – Targeted Immunomodulatory Biologics
- TNF – Tumor Necrosis Factor
- TRICARE – Military Health Care System
- U – Units
- UF – Uniform Formulary
- USC – United States Code
- V-Go – Valeritas System
- XR – Extended Release