DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA), on formulary status, pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. RECENTLY APPROVED U.S. FDA AGENTS—NON-INSULIN DIABETES DRUGS

P&T Comments

A. Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA): Albiglutide (Tanzeum)—Relative Clinical Effectiveness and Conclusion

Albiglutide (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)], albiglutide has beneficial effects on reducing hemoglobin A1c, blood pressure, weight, and improving lipid lab profiles. Albiglutide 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, multiple endocrine neoplasia syndrome type 2, and pancreatitis. There are currently no long-term cardiovascular outcome studies published with any GLP1RA.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the main benefit of albiglutide 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 (CMA) was performed to evaluate albiglutide (Tanzeum) with the other GLP1RA agents. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that albiglutide (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) albiglutide (Tanzeum) be designated formulary on the UF, based on clinical and cost effectiveness.

D. GLP1RA: Albiglutide (Tanzeum)—Prior Authorization (PA) Criteria

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 albiglutide, requiring a trial of metformin or a sulfonylurea in all new and current users of albiglutide (Tanzeum), consistent with the PA requirements for the other GLP1RAs. Use of albiglutide is approved only for patients with Type 2 diabetes mellitus, consistent with the FDA-approved indication.

The full PA criteria are as follows:

> All new and current users of albiglutide (Tanzeum) are required to try metformin or a sulfonylurea (SU) before receiving Tanzeum.
>
> Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy point 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, albiglutide (Tanzeum) is approved (e.g., trial of metformin or SU is NOT required) if:
>
> - The patient has a confirmed diagnosis of Type 2 Diabetes Mellitus
> - The patient has experienced any of the following issues on metformin:
>   - impaired renal function precluding treatment with metformin
>   - history of lactic acidosis
> - The patient has experienced any of the following issues on a sulfonylurea:
>   - hypoglycemia requiring medical treatment
> - The patient has had inadequate response to metformin or a SU or a DPP-4 inhibitor
> - The patient has a contraindication to metformin or a SU or DPP-4 inhibitor

E. GLP1RA: Albiglutide (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).

III. RECENTLY APPROVED U.S. FDA AGENTS—NON-INSULIN DIABETES DRUGS

BAP Comments

A. GLP1RA: Albiglutide (Tanzeum)—UF Recommendation, PA Criteria, and PA Implementation Plan

The P&T Committee's recommendations for albiglutide (Tanzeum) are listed above.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

IV. RECENTLY APPROVED U.S. FDA AGENTS—ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) STIMULANTS SUBCLASS

P&T Comments

A. Methylphenidate Extended Release (ER) Oral Suspension (Quillivant XR)—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 dosed once daily. Quillivant XR delivers medication directly via 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.

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 methylphenidate ER suspension (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) methylphenidate ER oral solution (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.

V. RECENTLY APPROVED U.S. FDA AGENTS—ADHD STIMULANTS SUBCLASS

BAP Comments

A. Methylphenidate ER Oral Suspension (Quillivant XR)—UF Recommendation and Implementation Plan

The P&T Committee's recommendations for methylphenidate ER oral suspension (Quillivant XR) are listed above.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

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

P&T Comments

A. TIBs—Relative Clinical Effectiveness and Conclusion

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

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 (adalimumab, etanercept, certolizumab, golimumab, abatacept, tocilizumab, tofacitinib, anakinra, ustekinumab and apremilast) are highly effective for their FDA indications versus placebo, 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. Comparative effectiveness is primarily determined though network meta-analysis (NMA) and indirect comparison; i.e., number needed to treat (NNT). The strength of 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.

   In three systematic reviews, there was a trend favoring etanercept over the other TIBs in terms of efficacy. The same reviews found anakinra had a statistically significant lower mean response when compared to etanercept and adalimumab, but the strength of evidence was low.

4. For juvenile inflammatory arthritis, there is insufficient evidence to suggest clinically relevant differences between adalimumab and etanercept, 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, there is insufficient evidence to determine comparative efficacy between the four anti-TNFs (adalimumab, certolizumab, etanercept, and golimumab) and two non-TNFs (ustekinumab and Apremilast). Indirect comparisons from RCTs suggest similar NNTs for these drugs.

6. For psoriasis, three products are approved, adalimumab, etanercept, and ustekinumab. In one head-to-head RCT, ustekinumab was superior to etanercept in achieving response, based on the Psoriasis Activity and Severity Index 75 (PASI 75) score. NMA demonstrated similar efficacy for adalimumab and ustekinumab.

7. For Crohn's disease, a NMA demonstrated that adalimumab and certolizumab are both effective for the induction of response, and maintenance of remission and

maintenance of response. The same analysis showed adalimumab is superior to certolizumab for induction of remission.

8. For ulcerative colitis, adalimumab and golimumab are effective for inducing clinical response, clinical remission, and mucosal healing. 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, withdrawals and other AEs) 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 certolizumab than the other TIBs. A subgroup analysis from one systematic review and a NMA showed the risk of serious infections was not increased with etanercept, in contrast to the increased risk seen with the other anti-TNF drugs, compared to controls.

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

12. The evidence (low strength) from indirect comparisons suggesting a safety benefit with etanercept in terms of serious infections and TB compared to the other anti-TNFs, must be weighed against its lack of efficacy for gastrointestinal conditions (Crohn's disease and ulcerative colitis).

13. Although the strength of evidence is low, there does not appear to be an elevated risk of malignancy with the TIBs. However, the risk of nonmelanoma skin cancer is increased with adalimumab and etanercept, compared to controls.

14. Concurrent use of a TIB with another TIB results in increased AEs and is not recommended by current practice guidelines.

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

    - abatacept: Increased risk of chronic obstructive pulmonary disease (COPD) exacerbation in adults with COPD
    - tocilizumab and tofacitinib: gastrointestinal perforation and lab abnormalities, including elevated lipids and transaminases
    - apremilast: psychiatric adverse effects such as depression and suicidal ideations

16. Overall, adalimumab 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, adalimumab (Humira) was the most cost-effective TIB, followed by certolizumab (Cimzia), anakinra (Kineret), tofacitinib (Xeljanz), golimumab (Simponi), etanercept (Enbrel), abatacept (Orencia), and tocilizumab (Actemra).
    - For psoriatic arthritis, adalimumab was the most cost-effective drug, followed by apremilast (Otezla), certolizumab, golimumab, etanercept, and ustekinumab (Stelara).
    - For dermatologic conditions, adalimumab was the most cost-effective TIB, followed by etanercept, and ustekinumab.
    - For gastrointestinal conditions (Crohn's disease), adalimumab was the most cost-effective agent, followed by certolizumab. For ulcerative colitis, adalimumab was the most cost-effective agent, followed by golimumab.
2. A BIA 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 adalimumab designated as formulary and step preferred on the UF; apremilast, golimumab, tofacitinib, and ustekinumab designated as formulary and non-preferred; and, abatacept, anakinra, certolizumab, etanercept, and tocilizumab 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"): adalimumab (Humira)
- UF and non-preferred ("behind the step"): apremilast (Otezla), golimumab (Simponi), tofacitinib (Xeljanz), and ustekinumab (Stelara)

- NF and non-preferred: abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), and tocilizumab (Actemra)
- This recommendation includes step therapy, which requires a trial of adalimumab 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) automated (step therapy) criteria for all new users of the non-preferred TIBs [abatacept (Orencia), anakinra (Kineret), apremilast (Otezla), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), tocilizumab (Actemra), tofacitinib (Xeljanz), and ustekinumab (Stelara)], requiring a trial of adalimumab (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

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 a TIB with other biologics.

The full PA criteria are as follows:

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, 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, or an inability to tolerate Remicade
- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

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

- Moderate to severe active polyarticular juvenile idiopathic arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

Golimumab (Simponi)

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 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 IV Simponi with continuous use in last 3 months and needs to transition to the SC formulation of Simponi

AND

Coverage approved for patients $\geq$ 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

Rheumatoid arthritis patients require an active methotrexate script.

Coverage is NOT provided for concomitant use other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel),

golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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 is prescribed for children < 4years of age; Enbrel is prescribed for patients with hepatitis C virus)

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 Arthritis

Coverage is NOT provided for concomitant use other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF

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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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 CHF
- Patient has been stable on IV Orencia with continuous use in last 3 months and needs to transition to the SC formulation of Orencia

AND

Coverage approved for patients $\geq$ 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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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 CHF
- Patient has been stable on IV Actemra with continuous use in last 3 months and needs to transition to the SC formulation of 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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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 non-TNF TIB for symptomatic CHF

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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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 days.

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)
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF
- 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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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)
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF

- 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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

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.

VII. UF CLASS REVIEWS—TIBs

BAP Comments

A. TIBs—UF Recommendation, PA Criteria, and Implementation Plan

The P&T Committee's recommendations for the TIBs Drug Class are listed above, including the full PA criteria for all TIBs in the class.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VIII. UTILIZATION MANAGEMENT

P&T Comments

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

V-Go is a disposable insulin delivery device approved for patients with Type 2 diabetes mellitus. Unlike an insulin pump, V-Go does not require any tubing or catheters. The device is filled daily with rapid acting insulin, allowing for continuous administration of basal insulin. After 24 hours, the device is discarded and replaced with a new unit. Advantages of V-Go

include convenience to the patient desiring increased control over their blood glucose levels and elimination of the need for multiple daily insulin injections. Additionally, V-Go may reduce prandial glycemic excursions compared to multiple insulin injections. Potential disadvantages of V-Go include the risk of hypoglycemia and infection, the requirement for daily manual filling of the device with insulin, non-adjustable preset basal rates, 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 (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); AND
5. Patient has been using prandial 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.

IX. UTILIZATION MANAGEMENT

BAP Comments

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

The P&T Committee's recommendations for the Valeritas V-Go insulin delivery device are listed above.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

X. UTILIZATION MANAGEMENT

P&T Comments

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

Tasimelteon is a melatonin receptor agonist that is approved for treating blind patients who have non-24 hours sleep-wake disorder and have no light perception. It 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) or zaleplon is required first.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) PA criteria for all new users of tasimelteon (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 are as follows:

Tasimelteon (Hetlioz)

PA criteria apply to all new users of tasimelteon (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, tasimelteon (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 IR or zaleplon and had an inadequate response. OR
3. The patient received a trial of zolpidem IR 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, or intolerable rebound insomnia).

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.

XI. UTILIZATION MANAGEMENT

BAP Comments

A. SED-1s: Tasimelteon (Hetlioz)—PA Criteria and PA Implementation

The P&T Committee's recommendations for tasimelteon (Hetlioz) are listed above.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XII. UTILIZATION MANAGEMENT

P&T Comments

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

Mekinist and Tafinlar are oral kinase inhibitors approved for treating patients with unresectable or metastatic melanoma who have documented BRAF V600E or V600K mutations as detected by an FDA-approved test. 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:

Trametinib (Mekinist) and Dabrafenib (Tafinlar)

Manual PA criteria apply to all new users of trametinib (Mekinist) and dabrafenib (Tafinlar).

Mekinist:

- Coverage approved for treatment of patients alone or in combination with dabrafenib (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

XIII. UTILIZATION MANAGEMENT

BAP Comments

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

The P&T Committee's recommendations for trametinib (Mekinist) and dabrafenib (Tafinlar) are listed above.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XIV. UTILIZATION MANAGEMENT

P&T Comments

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

Trokendi XR and Qudexy XR are branded ER formulations of topiramate that are dosed once daily. Generic formulations of topiramate IR (Topamax) have been marketed since 1996, and include both tablets and capsules. Generic topiramate IR is FDA-approved for treating patients

with seizures, down to the age of two years, and migraine headache. Topiramate is sometimes used off –label for weight loss.

Trokendi XR and Qudexy XR are indicated for the treatment of seizures, but are only approved for patients down to the age of six or ten years, depending on the diagnosis.

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 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:

Topiramate ER (Trokendi XR and Qudexy XR)

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 $\geq$ 10 years
  - Lennox-Gastaut seizures in patients $\geq$ 6 years
- Coverage not approved for
  - Non-FDA approved indications, including migraine headache and weight loss
- Patient required to try topiramate first
  - 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.

XV. UTILIZATION MANAGEMENT

BAP Comments

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

The P&T Committee's recommendations for topiramate ER capsules (Trokendi XR and Qudexy XR) are listed above.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

XVI. FISCAL YEAR 2008 NDAA, Section 703

P&T Comments

A. Fiscal Year 2008 NDAA, Section 703—Drugs Designated NF

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 UF 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 POS without preauthorization.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) that the following products be designated NF on the UF:

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 NF 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).

XVII. FISCAL YEAR 2008 NDAA, Section 703

BAP Comments

A. Fiscal Year 2008 NDAA, Section 703—Drugs Designated NF, Pre-Authorization Criteria for NF Drugs, Implementation Plan for Pre-Authorization Criteria, Drugs Designated Formulary

The P&T Committee's recommendations for drugs that are not in compliance with the Fiscal Year 2008 NDAA, Section 703, are listed above.

This section is reserved for BAP discussion and comments.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention