EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP)
January 4, 2018

I. UNIFORM FORMULARY DRUG CLASS REVIEWS

A. WEIGHT LOSS AGENTS

1. Weight Loss Agents—UF Recommendation

The P&T Committee recommended (15 for, 2 opposed, 0 abstained, 0 absent) the following:

a. UF
- benzphetamine (Didrex, generics)
- diethylpropion (Tenuate, Tandil, generics)
- phendimetrazine IR and SR (Bontril, Bontril SR, generics)
- phentermine (Adipex-P, generics)

b. NF
- liraglutide 3 mg injection (Saxenda)
- lorcaserin (Belviq, Belviq XR)
- naltrexone SR/bupropion SR (Contrave)
- orlistat (Xenical)
- phentermine 8 mg tablets (Lomaira)
- phentermine/topiramate ER (Qsymia)

2. Weight Loss Agents—Manual Prior Authorization (PA) Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for all the weight loss drugs, including the generic products, in all new and current users. In general, all the PAs have the following requirements: the patient is ≥ 18 years old; not pregnant; has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea); if the patient has impaired glucose tolerance or diabetes, they must have tried metformin first, or are concurrently taking metformin, have engaged in a trial of behavioral modification and dietary restriction for at least 6 months and have failed to achieve the desired weight loss; and will remain engaged throughout course of therapy to include after PA renewal. For Active Duty Service Members, the individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. Additionally, a trial of phentermine is required prior to use of the branded agents, unless the patient has significant

cardiovascular disease or other contraindications to a stimulant. Off label uses are not approved.

In general, renewal PA criteria are required after 12 weeks for the generic products, and after four months for the products approved for long-term use (Belviq, Belviq XR, Contrave, Qsymia, Saxenda, and Xenical). The patient must have lost ≥ 5% of baseline body weight since starting medication for renewal. The PA will be renewed for an additional 12 months.

PA Criteria:

a. benzphetamine, diethylpropion, phendimetrazine IR and SR, phentermine

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* phentermine, phendimetrazine, benzphetamine, and diethylpropion.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents
- *Patient has a BMI ≥ 30 or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If the patient has impaired glucose tolerance or diabetes, the patient must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

PA expires after 3 months

Renewal PA Criteria: PA will be renewed for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

b. phentermine 8 mg tablets (Lomaira)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* phentermine 8 mg tablets (Lomaira).

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*

a) The patient requires a dose of phentermine less than 15 mg due to elevated baseline heart rate
b) Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents
c) Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)
d) Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy
e) For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy
f) Patient is not pregnant
g) If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin

Off-label uses are not approved

PA expires after 3 months

Renewal PA Criteria: Lomaira will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

c. phentermine/topiramate ER (Qsymia)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Qsymia.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Qsymia will be approved for an additional 12 months if the criteria discussed previously and the following are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- For patients initially receiving Qsymia 7.5mg/46mg: discontinue Qsymia, or escalate to 15mg/92mg if 3% baseline body weight is not achieved at after 12 weeks
- For patients receiving Qsymia 15mg/92mg: discontinue if 5% baseline body weight is not achieved at 12 weeks
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

d. naltrexone SR/bupropion SR (Contrave)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Contrave.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient has tried and failed to achieve a 5% reduction in baseline weight after a 12 week course of phentermine unless there is a history of cardiovascular disease (e.g. arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or significant contraindication to phentermine)
- Patient is not on concurrent opioid therapy and does not have a seizure disorder or uncontrolled hypertension
- Patient is not currently on an monoamine oxidase inhibitor (e.g., Emsam, Marplan, Nardil), or another formulation of bupropion or naltrexone
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Contrave will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

e. lorcaserin (Belviq, Belviq XR)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Belviq or Belviq XR.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient has tried and failed to achieve a 5% reduction in baseline weight after a 12 week course of phentermine unless there is a history of cardiovascular disease (e.g. arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or significant contraindication to phentermine)
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Belviq or Belviq XR will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

f. orlistat (Xenical)—Adults ≥ 18 Years of Age

Manual PA criteria (specific to-read only non-italicized) apply to all new and current users of Xenical.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- The patient has tried and failed or has a contraindication to ALL of the following: Qsymia, Contrave, and Belviq/Belviq XR
- The patient does not have chronic malabsorption syndrome or cholestasis
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved, including nonalcoholic steatohepatitis (NASH)

Prior Authorization expires after 4 months

Renewal PA Criteria: Xenical will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*

Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy

g. orlistat (Xenical)—Pediatric Patients 12 to 17 Years of Age

Manual PA criteria apply to all new and current users of Xenical.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- Patient is between the ages of 12 and 17 years old
- The patient currently has a BMI of ≥ 95th percentile for age and sex, OR if in ≥ 85th percentile but < 95th percentile for age and sex and has at least one severe co-morbidity (type 2 diabetes mellitus, premature cardiovascular disease) or has a strong family history of diabetes or premature cardiovascular disease (CVD)
- Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy
- *Patient is not pregnant*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Xenical will be approved for an additional 12 months if the following are met:

- The patient is currently engaged in behavioral modification and on a reduced calorie diet
- The patient's current BMI percentile has decreased for age and weight (considering the patient is increasing in height and will have a different normative BMI from when Xenical was started) OR
- The patient currently has a BMI >85th percentile
- *The patient is not pregnant*

h. liraglutide 3 mg injection (Saxenda)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Saxenda.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient has tried and failed or has a contraindication to all of the following agents: Qsymia, Xenical, Contrave, and Belviq or Belviq XR
- If the patient is diabetic, must have tried and failed metformin and the preferred GLP1-RA (Bydureon)
- Concomitant use of Saxenda with another GLP1RA is not allowed (e.g., Bydureon, Byetta, Adlyxin, Victoza, Soliqua, Xultophy)
- The patient does not have a history of or family history of medullary thyroid cancer, or multiple endocrine neoplasia syndrome type 2
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*

Off-label uses are not approved, including Diabetes Mellitus

Prior Authorization expires after 4 months

Renewal PA Criteria: Saxenda will be approved for an additional 12 months if the criteria discussed previously and the following are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- Saxenda will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

3. Weight Loss Agents—UF and 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 90-day implementation in all points of service.

Summary of Physician's Perspective:

Unlike other drugs classes that have not yet been reviewed for formulary status, we don't know what the annual spend will be, since the weight loss agents have not previously been a covered TRICARE benefit.

There were two opposing votes for the formulary recommendation, as there was discussion as to whether any weight loss drug should be on the formulary, and also concern as to whether the individual service policies would be updated to reflect the new TRICARE Policy.

The justification to only have the generic products on the formulary was due to all the unknown variables that could affect utilization and cost, and the lack of long term efficacy data for the newer agents. The Committee felt that having only the generic products on the formulary will meet the clinical needs of DoD patients.

The Committee was unanimous in that all the weight loss drugs should require a PA, to reduce the risk of inappropriate use. Additionally the Committee strongly agreed that the PA criteria should require concurrent lifestyle intervention and include requirements for target BMIs, which is consistent with professional guidelines. The unique safety profiles of the individual drugs are also included in the PA criteria. For Saxenda, multiple products must be tried first, based on cost effectiveness.

The PA will apply to new and current users, since there are about 400 users of an obesity drug currently at the MTFs, primarily phentermine, followed by Saxenda.

This is an untested market, and the actual number of DoD patients who will fill a prescription for a weight loss drug is unknown at this time. We will watch the utilization for a year, and reassess if we need to re-review the class or update the PA criteria. Also several providers voiced that they had reservations about this drug class being included on the formulary; some of the reasons included that many providers lacked experience in prescribing these medications, and the fact that there is no magic bullet when it comes to weight loss.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria and UF and PA Implementation Plan for the Weight Loss Agents.

- **Weight Loss Agents – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  _____These comments were taken under consideration prior to my final decision

- **Weight Loss Agents – Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  _____These comments were taken under consideration prior to my final decision

- **Weight Loss Agents – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  _____These comments were taken under consideration prior to my final decision

B. ONCOLOGIC AGENTS: MULTIPLE MYELOMA SUBCLASS

1. **Oncologic Agents: Multiple Myeloma Subclass—UF Recommendation**
   The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the following, based on clinical and cost effectiveness:

   a. **UF:**
      - ixazomib (Ninlaro)
      - lenalidomide (Revlimid)

- panobinostat (Farydak)
- pomalidomide (Pomalyst)
- thalidomide (Thalomid)

b. NF: None

2. Oncologic Agents: Multiple Myeloma Subclass—Manual PA Criteria
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new users of Ninlaro, Revlimid, Farydak and Pomalyst.

Full PA Criteria

a. ixazomib (Ninlaro)

Manual PA criteria apply to all new users of Ninlaro.

Manual PA criteria—Ninlaro is approved if all of the following apply:

- Patient is > 18 years old
- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient is diagnosed with multiple myeloma
- Patient must not have had disease progression with a bortezomib (Velcade) or carfilzomib (Kyprolis)–containing regimen
- One or more of the following must apply:
- Patient must have failed or not be candidate for Velcade AND Kyprolis
- Patient has failed or is not a candidate for Kyprolis and has high risk cytogenetics
- Patient will be starting Ninlaro as third (or higher) line of therapy
- Must be used in combination with lenalidomide (Revlimid), pomalildomide (Pomalyst), OR thalidomide (Thalomid)
- Must be used in combination with dexamethasone
- Must not be used concurrently with Velcade or Kyprolis

Off-label uses are not approved

Prior Authorization does not expire

b. lenalidomide (Revlimid)

Manual PA criteria apply to all new users of Revlimid.

- Manual PA criteria—Revlimid is approved if all of the following apply:
- Patient is > 18 years old

- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient has one of the following diagnoses:
  - Multiple myeloma
  - Mantle Cell Lymphoma refractory to at least 2 prior treatment regimens, one of which contains bortezomib (Velcade) OR at least 1 prior treatment regimen and has failed or has a contraindication to bortezomib
  - Myelodysplastic syndrome w/5q deletion with one or more of the following: symptomatic anemia, transfusion-dependent anemia, or anemia not controlled with an erythroid stimulating agent
- Patient is not on concurrent pomalidomide (Pomalyst) or thalidomide (Thalomid)
- PA will be approved for the following non-FDA approved indications:
- Relapsed/refractory multi-centric Castleman Disease not responding to non-lenalidomide management
  - Diffuse large B-cell lymphoma (Non-Hodgkin Lymphoma) as second-line (or subsequent) therapy relapsed/refractory to non-lenalidomide management
  - Follicular lymphoma (Non-Hodgkin Lymphoma)
  - Relapsed/refractory classical Hodgkin's lymphoma
  - Myelofibrosis refractory to or with contraindications to alternative therapies
  - Systemic light chain amyloidosis with organ involvement

Off-label uses other than those listed above are not approved

Prior Authorization does not expire

c. panobinostat (Farydak)

Manual PA criteria apply to all new users of Farydak.

Manual PA criteria—Farydak is approved if all of the following apply:

- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient is > 18 years old
- Patient is diagnosed with multiple myeloma that is relapsed or refractory
- Patient's disease is NOT refractory to all of the following drugs: bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)
- Patient will be starting Farydak as the third (or higher) line of therapy
- Patient's previous regimens include at least one regimen with bortezomib, carfilzomib OR ixazomib, AND at least one regimen with lenalidomide, pomalidomide, OR thalidomide

- Must be used in conjunction with dexamethasone
- Must be used in conjunction with a bortezomib, carfilzomib, OR Ninlaro-containing regimen
- Must meet ALL of the following requirements:
    - Platelet count > $100x10^9/L$
    - QTc < 450 msec
    - Patient has no evidence of acute or chronic ischemic disease on EKG and no history of MI or unstable angina within the last 6 months
- Patient must have access to anti-diarrheal therapy

Off-label uses are not approved

Prior Authorization expires after 12 months

Renewal PA Criteria: PA will be re-approved for an additional 6 months, if the patient has not yet completed 16 cycles of treatment

d. pomalidomide (Pomalyst)

Manual PA criteria apply to all new users of Pomalyst.

Manual PA criteria—Pomalyst is approved if all of the following apply:
- Patient is > 18 years old
- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient is diagnosed with relapsed/refractory multiple myeloma that is refractory to lenalidomide AND all of the following must apply:
    - Patient has previously had a trial of a bortezomib, carfilzomib, OR Ninlaro-containing regimen
    - Patient will be starting Pomalyst as third (or higher) line of therapy
    - Must be used in combination with dexamethasone
- Patient is not using concurrent lenalidomide or thalidomide
- PA will be approved for the following non-FDA approved indications:
    - Myelofibrosis refractory to or with contraindications to alternative therapies (including lenalidomide) and erythropoietin levels > 500 mU/ml
    - Systemic light chain amyloidosis with organ involvement refractory to or with contraindications to alternative therapies including lenalidomide

Off-label uses other than those listed above are not approved

Prior Authorization does not expire

3. **Oncologic Agents: Multiple Myeloma Subclass—UF and PA 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 60-day implementation period in all points of service.

Summary of Physician's Perspective:

This is an extremely complicated disease to treat. As part of the clinical effectiveness review and PA criteria development, the Committee evaluated guidelines from the National Cancer Comprehensive Network (NCCN) and Mayo Clinic, individual clinical trial data, and several meta-analyses and systematic reviews, including one from the Institute for Clinical and Economic Reviews group.

Due to the risk of fetal malformations, there are strict requirements for Revlimid, thalidomide and Pomalyst. Dispensing is limited to one specialty pharmacy or about 6 MTF pharmacies who have satisfied the Risk Evaluation and Mitigation Strategy (REMS) REMS requirements.

All of the drugs were selected for formulary addition, as patients require access to multiple agents, due to the inevitable progression of the disease.

We have not previously had PA criteria for this drug class. PAs were recommended to highlight safety concerns and to ensure that the drugs are used for the FDA-approved indications. We did reach out to the oncology prescribers when developing the PA criteria. The PA criteria will only apply to new patients, so as not to disrupt patients who are currently undergoing therapy. Additionally, our data for DoD shows that patients are on these drugs for only 2 years.

Summary of Panel Questions and Comments:

Mr. Hostettler asked for clarification on the 39% increase in the last 5 years by the product Revlimid. According to presentation, it exceeds more than $100 million per year in expenditures. Can you differentiate from mantle disease for multiple myeloma?

Lt Col Khoury responds the information is dependent on accurate coding. The majority were either FDA approved indications or off-label indications with the majority being on-label indications. I can get you exact numbers, but it's dependent on the ICD-9 codes. We wanted to ensure they were either on or off label. In the analysis, approximately 60 of the 1000, that we analyzed, did not have any of the on or off label indications. That could mean that they

were on or off label not correctly on the agent or they were not correctly coded. Most were on and off label indications.

Mr. Hostettler asked if most of the patients were appropriately being treated. Lt Col Khoury replied that 60 of them potentially were not. This is not a large class. While impact appears minimal, there are only 1000 patients in this class.

Mr. Hostettler asked if the recommendation is consistent with all of the guidelines that were reviewed.

Lt Col Khoury stated that they were.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Oncologic Agents: Multiple Myeloma Subclass.

- **Oncologic Agents: Multiple Myeloma Subclass – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

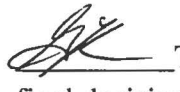
  Director, DHA:

   These comments were taken under consideration prior to my final decision

- **Oncologic Agents: Multiple Myeloma Subclass – Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

- **Oncologic Agents: Multiple Myeloma Subclass – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

C. VITAMINS: PRENATAL VITAMINS SUBCLASS

1. Vitamins: Prenatal Vitamins Subclass—UF Recommendation

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) placing the following legend products on the UF, with all other legend prenatal vitamins designated NF:

a. **UF**:
   - Prenatal Vitamins Plus Low I
   - Prenatal Vitamin + Low Iron
   - Prenatal Plus
   - Preplus

b. **NF**: All other legend prenatal vitamins.

c. Note that the products recommended for UF placement, listed above, include approximately 90% of the 30-day equivalent prescriptions dispensed for prenatal vitamins.

d. The products recommended for UF placement is different from, and thus supersedes, the list of agents identified as highest value in the August 2017 DoD P&T Committee minutes (available at https://health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes).

e. Selecting these agents facilitates the standardization of available agents in the Prenatal Vitamin subclass across DoD points of service.

2. Vitamins: Prenatal Vitamins Subclass—Prior Authorization Age and Gender Edit

Prenatal vitamins are not currently covered for male patients, and female patients older than 45 years of age, consistent with TRICARE coverage of legend prenatal vitamins for pregnancy-related use only. The P&T

Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current age and gender requirements for prenatal vitamins. The P&T Committee noted expert opinion stating that pregnancy was very rare past the age of 45, but agreed that the requirement should be overridden in such cases.

3. Vitamins: Prenatal Vitamins Subclass—UF and PA 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 points of service and, 2) DHA send letters to beneficiaries who are affected by the UF decision.

Summary of Physician's Perspective

Even though there is a question as to whether the prescription prenatal vitamins will remain legend products or change to OTC status, the Committee decided to go ahead and review the class, since they still remain part of the TRICARE benefit. The Committee also wanted to determine the UF status of the prescription products.

We have not previously reviewed the prenatal vitamins, since they include a mix of both prescription and OTC products. The vast majority (over 91%) of all prenatal vitamin prescriptions were dispensed at the MTFs, where there is about a 50-50 mix of OTC vs. prescription products dispensed. The Mail Order and Retail Network only dispense the legend products.

There were over 150 brand name and OTC products from 44 different manufacturers dispensed in the MHS. About 50% of the products have generic equivalents.

Although only four prescription products were recommended for addition to the formulary, the beneficiary impact of the products recommended for non-formulary placement will only affect about 12% of the patients taking a prenatal vitamin.

Summary of Panel Questions and Comments

Mr. Hostettler asks for clarification on pending litigation. Will this recommendation become a permanent decision regardless of outcome of the litigation for the OTCs.

CAPT VonBerg asked for clarification.

Mr. Hostettler replied they are under consideration for OTC status. Will this decision change that they are being considered for OTC status or will we always have prenatal vitamins available for that age group?

CAPT VonBerg replied that the committee in the previous decision and the committee in this decision were consistent in saying that prenatal vitamins should be available. This applies to the prenatal vitamins in legend status. If they are in OTC status, the committee has been consistent in recommending that prenatal vitamins should be available either way. The P&T committee has the authority to select OTC agents.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation and UF and PA Implementation Plan for the Prenatal Vitamins Subclass.

- **Vitamins: Prenatal Vitamins Subclass – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

- **Vitamins: Prenatal Vitamins Subclass – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

II. NEWLY-APPROVED DRUGS

A. NEWLY-APPROVED DRUGS PER CFR 199.21 (g)(5)

1. Newly-Approved Drugs per CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

a. **UF**:
   - abemaciclib (Verzenio) – Oral Oncology Agents for Breast Cancer
   - belimumab (Benlysta) – Immunosuppressive Agents – Systemic Lupus Erythematosus
   - plasma-derived human C1 esterase inhibitor SQ injection (Haegarda)– Hereditary Angioedema (HAE)
   - enasidenib (Idhifa) – Oral Oncology Agents for Acute Myelogenous Leukemia
   - fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta) – Pulmonary II Combination Agents – Chronic Obstructive Pulmonary Disease (COPD)
   - glecaprevir/pibrentasvir (Mavyret) – Hepatitis C Virus Direct Acting Antivirals (HCV DAAs)
   - L-glutamine (Endari) – Dietary Supplements
   - naldemedine (Symproic) – Gastrointestinal-2 Agents – Opioid Induced Constipation (OIC) Drugs
   - neratinib (Nerlynx) – Oral Oncology Agents for Breast Cancer
   - nitisinone (Nityr) – Metabolic Replacement Agents
   - perampanel (Fycompa oral solution) – Anticonvulsants/Anti-Mania Agents
   - sofosbuvir/velpatasvir/voxilaprevir (Vosevi) – HCV DAAs

b. **NF:**
   - amantadine ER (Gocovri) – Parkinson's Disease Drugs
   - betrixaban (Bevyxxa) – Oral Anticoagulants
   - delafloxacin (Baxdela) – Antibiotics – Quinolones
   - fluticasone propionate (ArmonAir RespiClick) – Pulmonary I Agents – Inhaled Corticosteroids
   - guselkumab (Tremfya) injection – Targeted Immunomodulatory Biologics (TIBs)
   - insulin aspart (Fiasp) – Insulins – Short-Acting Agents
   - lesinurad/allopurinol (Duzallo) – Antigout Agents – Chronic
   - methylphenidate ER orally dissolving tablet (Cotempla XR ODT) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
   - simvastatin oral suspension (FloLipid) – Antilipidemic-1s

2. Newly-Approved Drugs per CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Applying the same manual PA criteria for Tremfya in new users, as is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for Tremfya, a trial of both

secukinumab (Cosentyx) and ustekinumab (Stelara) is required if the patient cannot be treated with Humira.

- Applying the same manual PA criteria to new users of Vosevi and Mavyret as is currently in place for the other non-step-preferred DAAs for chronic hepatitis C infection. Harvoni is the preferred agent.

- Revising the manual PA criteria for Haegarda in new users to not allow concomitant use with another C1 esterase inhibitor product. *The full PA criteria will be presented in the Utilization Management section.*

- Applying manual PA criteria to new users of Verzenio, Gocovri, Idhifa, Endari, Nerlynx, and Fycompa.

- Applying PA criteria to new and current users of Benlysta, ArmonAir RespiClick, Fiasp, Duzallo, Cotempla XR ODT, and FloLipid.

Full PA Criteria for the Newly-Approved Drugs per CFR 199.21(g)(5)

a. *TIBs: guselkumab (Tremfya)*

Changes made from the November 2017 meeting are in bold.

Step therapy and Manual PA Criteria apply to all new users of guselkumab (Tremfya).

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 Tremfya if:

- *Contraindications exist to Humira **and Cosentyx, and Stelara***
- *Inadequate response to Humira **and Cosentyx, and Stelara** (need for different anti-tumor necrosis factor [TNF] or non-TNF)*
- *There is no formulary alternative: patient requires a non-TNF TIB for symptomatic congestive heart failure (CHF)*
- *Adverse reactions to Humira **and Cosentyx, and Stelara** not expected with requested non step-preferred TIB*

AND

Coverage approved for patients ≥ 18 years with:

- *Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy* ***and have failed to respond to or lost response to other systemic therapies***

Off-label uses are not approved

Prior Authorization does not expire

Coverage is NOT provided for concomitant use with other TIBs.

b. HCV DAAs:

1) glecaprevir/pibrentasvir (Mavyret)

Manual PA criteria apply to new users of Mavyret.

Manual PA Criteria: coverage will be approved if all criteria are met:

- The patient is ≥ 18 years of age and diagnosed with chronic Hepatitis C Virus (HCV) infection
- Mavyret is prescribed in consultation with or by a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician
- The patient cannot use Harvoni (i.e. due to HCV GT2 or GT3)

Off-label uses are not approved

PA does not expire.

2) sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

Manual PA criteria apply to new users of Vosevi.

Manual PA Criteria: coverage will be approved if ALL of the following criteria are met:

- The patient is ≥ 18 years of age and diagnosed with Chronic Hepatitis C Virus (HCV) infection
- Vosevi is prescribed in consultation with or by a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician

- The patient has HCV genotype 1, 2, 3, 4, 5, or 6 AND has tried and failed treatment with a NS5A Inhibitor (e.g., daclatasvir (Daklinza), ledipasvir, ombitasvir, velpatasvir, elbasvir) OR
- The patient has HCV genotype 1a or 3 AND has tried and failed treatment with Sovaldi without a NS5A Inhibitor
- AND the patient does not have any of the following:
  a) Decompensated cirrhosis
  b) Moderate or severe hepatic impairment (Child-Pugh Class B or C)
  c) Severe renal impairment (eGFR <30 mL/min or End Stage Renal Disease)

Off-label uses are not approved

Prior Authorization does not expire.

3) Oral Oncologic Agents: abemaciclib (Verzenio)

Manual PA criteria apply to all new users of Verzenio

Manual PA criteria—Verzenio is approved if all of the following apply:

- The patient has a diagnosis of HR+, HER2 negative advanced or metastatic breast cancer
- Breast cancer has progressed during or after endocrine therapy
- The patient is using Verzenio and meets ALL of the following:

  a) Patient is postmenopausal and will use Verzenio in combination with fulvestrant OR
  b) The patient is premenopausal or perimenopausal and is receiving ovarian suppression with GnRH agonist AND Verzenio will be used in combination with fulvestrant OR
  c) Verzenio will be used as monotherapy and the patient has had prior chemotherapy for treatment of metastatic breast cancer

Off-label uses are not approved

Prior Authorization does not expire

4) Parkinson's Disease Drugs: amantadine ER tabs (Gocovri)
Manual PA criteria apply to all new users of Gocovri

Manual PA Criteria—Gocovri is approved if:

- The patient is ≥18 years old AND
- Has a diagnosis of Parkinson's Disease AND
- Has had therapeutic failure of a trial of amantadine 200 mg immediate release tablets administered twice daily

Off label uses are not approved

Prior Authorization does not expire

5) Oral Oncologic Agents: enasidenib (Idhifa)

Manual PA criteria apply to all new users of Idhifa.

Manual PA criteria—Idhifa is approved if all the following criteria are met:

- The patient is ≥18 years old and has a diagnosis of relapsed refractory acute myelogenous leukemia (AML)
- Patient exhibits the IDH2 mutation as determined by an FDA approved test
- Must be prescribed by or in consultation with hematologist or oncologist
- Idhifa is used in combination with standard chemotherapy protocols

Off-label uses are not approved

Prior Authorization expires at one year.

Renewal criteria: Idhifa will be approved for one year if the patient has not had disease progression.

6) Dietary Supplements: L-glutamine oral powder (Endari)

Manual PA criteria apply to new users of Endari.

Manual PA Criteria: coverage will be approved if ALL of the following criteria are met:

- Patient has a diagnosis of sickle cell anemia or Sickle ß thalassemia
- Age ≥ 5 years old
- Patient has had ≥ 2 sickle cell crises in the last 12 months
- Patient has had an inadequate treatment response to a 3 month trial of both hydroxyurea and blood transfusion therapy

Off-label uses are not approved

Prior Authorization does not expire.

7) **Oral Oncologic Agents: neratinib (Nerlynx)**

Manual PA criteria apply to all new users of Nerlynx

Manual PA criteria—Nerlynx is approved if meets all of the following:

- The patient is an adult ≥18 years of age with early stage HER2-overexpressed/amplified breast cancer
- Nerlynx is used following adjuvant trastuzumab-based therapy (preferably less than 1 year, but no more than 2 years after completion of trastuzumab (Herceptin)-based therapy.
- The patient has been counseled on significant adverse event profile
- Nerlynx is co-prescribed with an antidiarrheal to mitigate adverse events for at a minimum 2 months
- Patient has been counseled on the possibility of an unproven survival benefit gain with Nerlynx

Off-label uses are not approved

Prior Authorization expires after 18 months.

No renewal allowed, patient should not take more than a 365-day lifetime supply.

8) **Anticonvulsants/Antimania Agents: perampanel oral solutions (Fycompa O/S)**

Manual PA criteria apply to all new users of Fycompa O/S ≥18 years of age.

Manual PA criteria—Fycompa O/S is approved if:

- The patient cannot swallow perampanel tablets AND
- The patient has a diagnosis of epilepsy with partial-onset seizures w/wo secondarily generalized seizures OR
- The patient has a diagnosis of epilepsy with primary generalized tonic-clonic seizures

Off-label uses are not approved

Prior authorization does not expire

9) TIBs: belimumab (Benlysta)

Manual PA Criteria apply to all new and current users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta.

Manual PA criteria: Coverage is approved for Benlysta if all of the following are met:

- Benlysta is prescribed by or consultation with an specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist
- The patient is ≥18 years old
- The patient has a documented diagnosis of active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE
- The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)
- The patient does not have severe active lupus nephritis or severe active central nervous system lupus
- The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide

Off-label uses are not approved

Prior Authorization expires in one year.

Renewal PA Criteria: Benlysta will be approved on a yearly basis if the all of the following are met:

- Treatment with Benlysta has shown documented clinical benefit (i.e. improvement in number/frequency of flares, improvement in in Safety of Estrogen in Lupus Erythematosus National Assessment – SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.)
- The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)
- The patient does not have severe active lupus nephritis or severe active central nervous system lupus

The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide

10) Pulmonary I Agents—Inhaled Corticosteroids: fluticasone propionate (ArmonAir RespiClick)

PA criteria apply to all new and current users of ArmonAir RespiClick who are older than 12 years of age.

Manual PA criteria—ArmonAir RespiClick is approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if:

- The patient has experienced any of the following issues with either Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred ICS drug:
- The patient requires fluticasone and cannot manipulate BOTH the Flovent Diskus (active inhalation) or Flovent HFA MDI (passive inhalation)

Off-label uses are not approved

Prior Authorization does not expire.

11) Insulins Short-Acting Agents: insulin aspart (Fiasp)

Manual PA criteria apply to all new and current users of Fiasp.

Manual PA criteria: Coverage will be approved if all criteria are met:

- Patient has type 1 diabetes
- Patient has tried and failed insulin aspart (Novolog)
- Patient has tried and failed or is intolerant to insulin lispro (Humalog)
- Prescribed by or in consultation with an endocrinologist

Off-label uses are not approved
Prior authorization does not expire.

12) Antigout Agents—Chronic: lesinurad/allopurinol (Duzallo)

Manual PA criteria apply to all new and current users of Duzallo.

Manual PA criteria: Coverage will be approved if all criteria are met:

- The patient is ≥ 18 years of age
- The patient has chronic or tophaceous gout
- The patient has a creatinine clearance (CrCl) >45 mL/min
- The gout patient has not achieved target serum uric acid level despite maximally- tolerated therapy with allopurinol

Off-label uses are not approved

Prior authorization does not expire.

13) ADHD Drugs: methylphenidate ER orally dissolving tablets (Cotempla XR ODT)

Manual PA criteria apply to all new and current users of Cotempla XR-ODT.

Manual PA criteria: Coverage will be approved if ALL of the following criteria are met:

- Patient is between the ages of 6-17 years of age and has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient Must have tried and failed or has a contraindication to Adderall XR (generic)
- Patient must have tried and failed or has a contraindication to Concerta OROS (generic)
- Patient must have tried and failed or has a contraindication to methylphenidate ER oral suspension (Quillivant XR), or methylphenidate ER cap (Aptensio XR)

Off-label uses are not approved

Prior Authorization does not expire.

14) Antilipidemics-1s: simvastatin oral suspension (FloLipid)

PA criteria apply to all new and current users of FloLipid

Manual PA criteria—FloLipid is approved (e.g., trial of generic simvastatin, atorvastatin, pravastatin, lovastatin, or rosuvastatin tablets) is note required if:

- The provider writes in why the patient requires liquid simvastatin and cannot take simvastatin, atorvastatin, pravastatin, lovastatin, rosuvastatin tablets
- Acceptable responses include that the patient requires simvastatin and cannot swallow the statin tablets due to some documented medical condition , including dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience

Off-label uses are not approved

Prior Authorization does not expire

3. Newly-Approved Drugs per CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service.

Summary of Physician's Perspective

We continue to see an increasing number of new drugs requiring review at every meeting. Out of the 21 drugs reviewed at the November P&T Committee meeting, 11 were recommended for formulary status, and 10 recommended for non-formulary status.

Sixteen of the products have PA requirements, but 10 of the drugs have "grandfathering" where the PA will only apply to new users, with current users allowed to remain on therapy without having to fill out a PA form. For the six products where no grandfathering is recommended (where the PA will apply to both new and current users) there are formulary alternatives available.

For the 16 drugs where PAs were recommended, several of them fall into classes where there are existing PA requirements or step therapy requirements (such as for the oncology drugs, TIBs, hereditary angioedema, the inhaled steroid, and the Hep C drugs). Additionally, there are 7 drugs that are reformulations of existing products that are already on the formulary, (the insulin product, ADHD drug, Parkinson's disease drug, gout product, statin and anticonvulsant).

A PA was also recommended for the Lupus drug Benlysta to follow the FDA approved indication and safety monitoring.

Lastly a PA was recommended for Endari, which is the first prescription glutamine product approved by the FDA. Since the glutamine is available as a

dietary supplement, and often used to treat muscle soreness after exercise or GI problems, we wanted to ensure only patients with sickle cell disease would receive Endari, which is the indicated use.

Summary of Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, PA Criteria, and UF and PA Implementation Plan for the Newly Approved Drugs.

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

- **Newly-Approved Drugs per CFR 199.21(g)(5) – PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

III. UTILIZATION MANAGEMENT

A. ANTIDEPRESSANTS AND NON-OPIOD PAIN SYNDROME AGENT

1. Antidepressants and Non-Opiod Pain Syndrome Agents: Bupropion Hydrobromide (Aplenzin) – New Manual PA Criteria

Aplenzin is a branded formulation of bupropion ER approved for treating major depressive disorder and seasonal affective disorder. It was designated NF at the November 2009 meeting. Aplenzin contains a hydrobromide (HBr) salt, compared to the hydrochloride salt in Wellbutrin XL. The two formulations are bioequivalent. Cost-effective generic formulations of Wellbutrin are available and on the UF.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for Aplenzin, due to the significant cost differences and lack of clinically compelling benefits between Aplenzin and generic bupropion ER. New and current users of Aplenzin are required to try generic bupropion ER and a second antidepressant first.

Full PA Criteria:
Manual PA criteria apply to all new and current users of Aplenzin. Note that PA is not required for generic bupropion (Wellbutrin, Wellbutrin SR or Wellbutrin XL); providers are encouraged to consider changing the prescription to generic Wellbutrin XL.

Manual PA criteria: Coverage for Aplenzin is approved if ALL of the following apply:

- The patient is ≥18 years old
- The patient has clinically diagnosed major depressive disorder or seasonal affective disorder
- The patient must have tried and failed both of the following:

  a) generic bupropion ER (e.g., patient cannot take more than one tablet of generic bupropion) AND
  b) at least one generic selective serotonin reuptake inhibitor (SSRI) or other antidepressant

- Patient does not have a history of seizure disorder or bulimia

Off label uses are not approved (e.g., smoking cessation)

Prior Authorization expires after 1 year.

- Renewal PA criteria for continuation of therapy: PA is approved for an additional year if the patient has had an adequate clinical response and continues to be unable to take multiple tablets of generic bupropion.
- Renewal PA criteria is limited to one year.

2. Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplenzin)—New Manual PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that the manual PA for Aplenzin become effective on the first Wednesday after a 90-day implementation period in all points of service. Additionally, the P&T Committee recommended DHA send letters to the beneficiaries affected by this decision.

Summary of Physician's Perspective

Aplenzin is 40 times more expensive than generic bupropion formulations, and does not offer any clinical advantages over the generics.

Approximately 120 patients will be affected by the PA requirements, since the PA will apply to both new and current users ("no grandfathering"). Due to the fact that the disease being treated is depression, we felt that the affected patients should receive letters.

Summary of Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the New Manual PA Criteria and New Manual PA Implementation Plan for the Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplezin).

- **Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplezin) – New Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

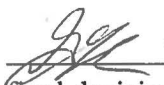
Director, DHA:

These comments were taken under consideration prior to my final decision

- **Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplezin) – New Manual PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

B. UPDATED MANUAL PA CRITERIA AND STEP THERAPY

1. Updated Manual PA Criteria and Step Therapy

Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications. The updated manual PA outlined below will apply to new users.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the manual PA criteria for Tafinlar, Mekinist, Zelboraf, Stelara, Eucrisa, and Cinryze, and updates to the step therapy and manual PA criteria for the GLP1RAs. All updated criteria apply to new users of these agents.

a. **Oral Oncological Agents: Dabrafenib (Tafinlar) and Trametinib (Mekinist)**

   Tafinlar and Mekinist were reviewed in August 2014 with manual PA criteria recommended. Criteria were updated to add the additional indication for non-small cell lung cancer (NSCLC).

   Off-label uses are not approved

b. **Oral Oncological Agents: Vemurafenib (Zelboraf)**—Zelboraf was reviewed in February 2012 with manual PA criteria recommended. Criteria were updated to add the additional indication for Erdheim-Chester Disease with BRAF V600 mutation.

   Off-label uses are not approved

c. **TIBs—Ustekinumab (Stelara)**—Stelara was reviewed in August 2014 with manual PA criteria recommended. Criteria were updated to add the additional indication for severe plaque psoriasis in patients 12 to 18 years old.

d. **Corticosteroids—Immune Modulators—Atopic Dermatitis Subclass: Crisaborole (Eucrisa)**—Eucrisa was reviewed in May 2017 with manual PA criteria recommended. Several atopic dermatitis agents are now available in generic formulations. Due to the significant cost differences between Eucrisa and formulary alternatives, the PA criteria were updated to include a two-week trial of at least two formulary medium to high potency topical steroids or a topical calcineurin inhibitor (e.g., tacrolimus, Elidel) prior to use of Eucrisa.

e. **Corticosteroids—Immune Modulators—Hereditary Angioedema (HAE) Subclass: Plasma-derived human C1 Esterase Inhibitor SQ (Haegarda) and IV (Cinryze)**—The HAE drugs were reviewed for formulary status in August 2017 and Haegarda was reviewed as a new drug during the November 2017 P&T Committee Meeting. Both Haegarda and Cinryze are indicated for prophylaxis of HAE episodes. The manual PA criteria were updated to prohibit concomitant use of Cinryze and Haegarda.

f. **Non-Insulin Diabetes Drugs: GLP1RAs—Step Therapy and Manual PA Criteria**—The NF and non-step-preferred GLP1RAs [lixisenatide (Adlyxin), liraglutide (Victoza), insulin degludec (Xultophy), insulin glargine/lixisenatide (Soliqua), exenatide microspheres BID (Byetta), and dulaglutide (Trulicity)] all require a trial of exenatide weekly (Bydureon) and albiglutide (Tanzeum). Tanzeum manufacturing will cease in June 2018. The step therapy and manual PA criteria for the GLP1RAs were updated to remove the requirement of a trial of Tanzeum. Additionally, the manual PA criteria for the UF and step-preferred products (Bydureon and Tanzeum) were updated to reflect the market discontinuation of Tanzeum, and to advise providers of this issue.

2. Updated Manual PA Criteria and Step Therapy—Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the current PAs for Tafinlar, Mekinist, Zelboraf, Stelara, Eucrisa, and Cinryze, and updates to the step therapy and manual PA criteria for the GLP1RAs become effective upon signing of the minutes in all points of service.

Summary of Physician's Perspective

At every meeting, we present updates to drugs with existing PAs to ensure the latest FDA indications or safety updates are included in our criteria. For this meeting, the majority of the updates are for new indications or an expanded pediatric age range (for Stelara). We regularly respond to requests from providers when they submit feedback on PA criteria.

For the GLP1 diabetes drugs, the PA changes are required to account for the market discontinuation of Tanzeum.

Summary of Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the Updated Manual PA Criteria and Step Therapy and Updated Manual PA Criteria and Step Therapy Implementation Plan.

- **Updated Manual PA Criteria and Step Therapy**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

- **Updated Manual PA Criteria and Step Therapy – Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent:0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

IV. BRAND OVER GENERIC AUTHORIZATION FOR MESALAMINE DELAYED RELEASE (LIALDA)

A. LIALDA

1. Lialda – Brand over Generic Requirement and Manual PA Criteria

TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Lialda product is more cost effective than the AB-rated generic formulations for mesalamine delayed release (DR), which were launched in June 2017. The manufacturer of Lialda has offered a Blanket Purchase Agreement (BPA). Therefore, the branded Lialda product will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 (generic) copayment will apply to Lialda. The "brand over generic" requirement for Lialda will be removed

administratively when it is no longer cost effective compared to the AB-rated generics.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) implementing the requirement to prefer the branded Lialda product over generic formulations. Manual PA criteria are required for generic mesalamine ER in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded Lialda product cannot be used.

PA Criteria

Manual PA criteria apply to all new users of generic Lialda. Note that brand Lialda is the preferred mesalamine delayed release product in DoD.

Manual PA Criteria: Coverage for generic mesalamine delayed release is approved if the following criteria is met:

- The provider has provided patient-specific justification as to why the brand Lialda product cannot be used.
- Acceptable reasons include the following, which have occurred or are likely to occur with the branded Lialda product: allergy to the branded Lialda; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues.

2. Lialda—Brand Copayment Change

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that the brand (Tier 2) formulary cost share for Lialda in the TRICARE Mail Order Pharmacy and the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share.

Summary of Physician's Perspective

The usual process for DoD is that when generic equivalents to branded products are introduced into the market, mandatory use of the generic is required. Occasionally, there are cases where the generic entrant is significantly more expensive than the existing branded product, so the "brand over generic" process is recommended. As an additional incentive for the brand product to be dispensed, the copay will decrease to the tier 1 (or generic) copay. This is the situation with Lialda.

When this process has been used in the past, there have been only rare instances where the manual PA to receive the generic product instead of the branded product has even been submitted. So overall, the patient will continue to receive the branded product.

The price of the generics will be monitored, so when it is no longer cost effective to continue dispensing the branded product, we will administratively remove this requirement, and go back to our usual process of preferring the generic.

Summary of Panel Questions and Comments

Mr. Hostettler asked when the co-pay change takes effect.

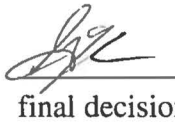
CAPT Von Berg replied that it already has.

There were no more questions or comments from the Panel. The Chair called for a vote on the Brand over Generic Requirements and Manual PA Criteria and the Brand Copayment change for Lialda.

- **Lialda – Brand over Generic Requirement and Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

- **Lialda – Brand Copayment Change**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

   These comments were taken under consideration prior to my final decision

V. RE-EVALUATION OF NF GENERICS

A. Re-evaluation of NF Generics

1. Re-evaluation of NF Generics—UF, PA, Step Therapy, and Implementation Plan

The P&T Committee recommended the following, effective upon signing of the minutes:

a. Returning the following product to UF status (16 for, 0 opposed, 0 abstained, 1 absent): *ADHD/Wakefulness*—armodafinil (Nuvigil, generics)

b. Removing the PA requirements for the following products, with reassessment in one year (12 for, 3 opposed, 0 abstained, 2 absent): *ADHD/Wakefulness*—armodafinil (Nuvigil, generics), modafinil (Provigil, generics)

c. Revising the PA criteria for the following product in new users (16 for, 0 opposed, 0 abstained, 1 absent): *ADHD/Wakefulness*—sodium oxybate (Xyrem). The full criteria are listed below.

d. Returning the following product to the UF, with step therapy requirements and PA criteria remaining unchanged (16 for, 0 opposed, 0 abstained, 1 absent): *BPH Agents*—dutasteride (Avodart, generics)

e. Designating the following products as UF and step-preferred, with pertinent updates made to the PA criteria for the non step-preferred RAAs (16 for, 0 opposed, 0 abstained, 1 absent): *RAAs*—irbesartan (Avapro, generics), irbesartan/HCTZ (Avalide, generics)

PA Criteria: ADHD/Wakefulness—sodium oxybate (Xyrem)

Changes from the November 2017 meeting are in BOLD

Manual PA criteria apply to all new users of Xyrem.

Manual PA Criteria: Coverage of Xyrem is approved if the following criteria are met:

- **The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND**

- **Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND**

- Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.

    - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing **OR**

- Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy **AND**

- **the patient has history of failure, contraindication, or intolerance of both of the following, modafinil, or armodafinil, AND stimulant- based therapy (amphetamine-based therapy or methylphenidate) AND**

- **Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)**

Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy.

PA expires after 1 year.

PA Renewal criteria: Xyrem will be renewed on a yearly basis if:

- **There is documentation demonstrating the patient has had a reduction in frequency of cataplexy attacks associated with Xyrem therapy OR**
- **There is documentation demonstrating the patient has had a reduction in the symptoms of excessive daytime sleepiness associated with Xyrem therapy AND**

Patient is not receiving a concomitant CNS depressant

Summary of Physician's Perspective

This is a continuing project where we look at drugs classes reviewed several years ago to see what the costs are for non-formulary products that now have generic equivalents available. We will also take a look at any existing manual PAs or step therapy as part of the process. Any new pertinent clinical information is also summarized.

For the narcolepsy drugs, the price for generic Nuvigil has fallen significantly, and is similar to the cost of generic Provigil. There was some discussion on the Committee as to whether the PAs for Nuvigil and Provigil should be removed, due to the large number of off-label uses. The recommendation was to remove the PAs for both products, but we will monitor the off-label usage and see if any change is needed in the future. For Xyrem, the original PA was approved in 2009, so updates to the PA criteria were needed to address some safety concerns.

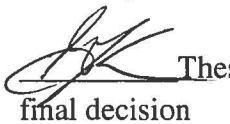
For the other two classes reviewed, BPH and the antihypertensives, the generic prices for dutasteride and irbesartan are now cost effective compared to the previous branded products.

Summary of Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the Re-evaluation of NF Generics – UF, PA, Step Therapy and Implementation Plan.

- **Re-evaluation of NF Generics – UF, PA, Step Therapy, and Implementation Plan**

  Director, DHA:

   These comments were taken under consideration prior to my final decision

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

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 the Panel discussions are listed below for easy reference. The term "BAP" in this summary refers to the "Uniform Formulary Beneficiary Advisory Panel," the group who's meeting in the subject of this report.

- ADHD – Attention Deficit Hyperactivity Disorder
- ANA – Antinuclear Antibodies
- ARI – Alpha Reductase Inhibitors
- BIA – Budget Impact Analysis
- BMI – Body Mass Index
- BPA – Blanket Purchase Agreement
- BPH – Benign Prostatic Hyperplasia
- CEA – Cost-Effectiveness Analysis
- CFR – Code of Federal Regulations
- CMA – Cost-Minimization Analysis
- COPD – Chronic Obstructive Pulmonary Disease
- CrCl – Creatinine Clearance
- CVD – Cardiovasular Disease
- DAAs – Direct Acting Antiviral
- DHA – Defense Health Agency
- FOB – Pharmacy Operations Division
- DR – Delayed Relase
- EPA – Eicosapentaenoic Acid
- ER – Extended Release
- FDA – Food Drug Administration
- GLP1-RAs – Glucagon-Like-1 Receptor Agonist
- GT2 – Genotype 2
- GT3 – Genotype 3
- HAE – Hereditary Angiodema
- HBr – Hydrobromide
- HCTZ- Hydrochloric Thiazide
- HCV DAAs – Hepatitis C Direct Acting Antiviral
- ICD – International Classification of Disease
- IR – Immediate Release
- JAMA – Journal of American Medical Association
- MHS – Military Health System
- MTF – Military Treatment Facility
- NASH – NonAlcoholic Steatohepatitis
- NCCN – National Comprehensive Cancer Network
- NDAA – Natioanl Defense Authorization Act

- NDCs – National Drug Codes
- NF – Non-Formulary
- NSCLC – Non-Small Cell Lung Cancer
- OTC – Over the Counter
- P&T – Pharmacy & Therapeutics
- PA – Prior Authorization
- RAAs – Renin-Andiotensin Antihypertensive Agents
- REMs – Risk Evaluation and Mitigation Strategies
- SC – Subcutaneously
- SELENA modified – Safety of Estrogen in Lupus Erythematosus National Assessment
- SLE – Systemic Lupus Erythematosus
- SR – Sustained Releaser
- SSRI – Serotonin Reuptake Inhibitor
- TIBs – Target Immunomodulatory Biologics
- TNF – Tumor Necrosis Factor
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- USPSTF – U.S. Preventative Service Task Force
- VTE – Venous Thromboembolism

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
January 4, 2018
Washington, D.C.

Present Panel Members

- Jon Ostrowski, Non Commissioned Officers Association, Chairperson
- Sarika Joshi, HealthNet Federal Services
- Theresa Buchanan, National Military Family Association
- Charles Hostettler, AMSUS, The Society of the Federal Health Professionals
- Suzanne Walker, Military Officers Association of America
- Richard Bertin, Commissioned Officers Association of the U.S. Public Health Service
- John Du Teil, U.S. Army Warrant Officers Association

The meeting was held at Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C., and CAPT Edward Norton, DFO, called the meeting to order at 9:10 A.M.

Agenda

The agenda for the meeting is as follows:

- Welcome and Opening Remarks
- Public Citizen Comments
- Therapeutic Class Reviews

    1. Drug Class Reviews

        a. Weight Loss Agents for Obesity
        b. Oncology Agents – Multiple Myeloma Subclass
        c. Vitamins – Prenatal Vitamins Subclass

    2. Newly-Approved Drugs per CFR 199.21(g)(5)

        a. abemaciclib (Verzenio) – Oral Oncology Agents for Breast Cancer
        b. amantadine ER (Gocovri) – Parkinson's Disease Drugs
        c. belimumab (Benlysta) – Immunosuppressive Agents – Systemic Lupus Erythematosus
        d. betrixaban (Bevyxxa) – Oral Anticoagulants
        e. plasma-derived human C1 esterase inhibitor SQ injection(Haegarda) Hereditary Angioedema
        f. delafloxacin (Baxdela) – Antibiotics – Quinolones

g. enasidenib (Idhifa) – Oral Oncology Agents for Acute Myelogenous Leukemia
h. fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta) – Pulmonary II Combination Agents – Chronic Obstructive Pulmonary Disease
i. fluticasone propionate (ArmonAir RespiClick) – Pulmonary I Agents – Inhaled Corticosteroids
j. glecaprevir/pibrentasvir (Mavyret) – Hepatitis C Virus Direct Acting Antivirals (HCV DAAs)
k. guselkumab (Tremfya) injection – Targeted Immunomodulatory Biologics (TIBs)
l. insulin aspart (Fiasp) – Insulins – Short-Acting Agents
m. L-glutamine (Endari) oral powder – Dietary Supplements
n. naldemedine (Symproic) – Gastrointestinal-2 Agents – Opioid Induced Constipation (OIC) Drugs
o. lesinurad/allopurinol (Duzallo) – Antigout Agents – Chronic
p. methylphenidate ER orally dissolving tablet (Cotempla XR ODT) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
q. neratinib (Nerlynx) – Oral Oncology Agents for Breast Cancer
r. nitisinone (Nityr) – Metabolic Replacement Agents
s. perampanel (Fycompa oral solution) – Anticonvulsants/Anti-Mania Agents
t. simvastatin oral suspension (FloLipid) – Antilipidemic-1s
u. sofosbuvir/velpatasvir/voxilaprevir (Vosevi) – HCV DAAs

3. Utilization Management Issues

a. Prior Authorization Criteria—New Criteria

- Antidepressants and Non-Opioid Pain Syndrome Agents—Bupropion hydrobromide (Aplenzin)

b. Prior Authorization Criteria—Updated Criteria

- Oral Oncological Agents: Dabrafenib (Tafinlar) and Trametinib (Mekinist)
- Oral Oncological Agents: Vemurafenib (Zelboraf)
- Targeted Immunomodulatory Biologics (TIBs): Ustekinumab (Stelara)
- Corticosteroids—Immune Modulators—Atopic Dermatitis Subclass: Crisaborole (Eucrisa)
- Corticosteroids—Immune Modulators—Hereditary Angioedema (HAE) Subclass: Plasma-derived C1 Esterase Inhibitor IV (Cinryze)
- Non-Insulin Diabetes Drugs: GLP1RAs—Step Therapy, Manual PA Criteria, and MN Criteria

4. Brand Over Generic Authorization for Mesalamine Delayed Release (Lialda): Prior Authorization and Co-pay Change

5. Re-evaluation of Generic Nonformulary Medications

   a. ADHD/Wakefulness Promoting Drugs: Wakefulness Promoting Drugs Subclass:

      - armodafinil (Nuvigil); modafinil (Provigil): UF status and PA criteria
      - sodium oxybate (Xyrem) updated PA criteria

   b. BPH Agents: 5-Alpha Reductase Inhibitors (5-ARI) Subclass

      - dutasteride (Avodart) UF status

   c. Renin-Angiotensin Antihypertensives

      - irbesartan (Avapro), irbesartan/HCTZ (Avalide) step therapy status

- 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

CAPT Edward Norton introduced himself as the Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP). The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on November 15th and 16th, 2017.

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

In addition, 10 U.S.C. Section 1074g, subsection c, also requires the Secretary to establish a UF 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. The Panel's comments must be

considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF.

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

The duties of the Uniform Formulary 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 to 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 in 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 for the Director of DHA. As guidance to the Panel regarding this meeting, CAPT Norton 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 for review, drugs recommended for the basic core formula (BCF) or specific pricing data, these items do not fall under the purview of the BAP.

The P&T Committee met for approximately 16 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 Formulary Management 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.

- When addressing the Panel or responding to questions, please use the microphone.

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

There were no individuals signed up this morning to provide comments to the BAP.

Chairman's Opening Remarks

Mr. Ostrowski thanks CAPT Norton; welcomes everyone, and thanks the panel members for their attendance. He looks forwards to the presentations.

DRUG CLASS REVIEW PRESENTATION

(PEC Script – CAPT VONBERG)

GOOD MORNING. I am CAPT Edward VonBerg, Chief of the Formulary Management Branch. Joining me is doctor and retired Army Colonel John Kugler, the Chairman of the Pharmacy & Therapeutics Committee, who will provide the physician perspective and comments on the recommendations made by the P&T Committee. Also joining us from the Formulary Management Branch today is Lt Col Ron Khoury, a family medicine physician and Chief P&T Section. I would also like to recognize Bryan Wheeler Assistant General Counsel and Col Paul Hoerner, Deputy Chief, Pharmacy Operation Division for DHA,

The DoD Formulary Management Branch supports the DoD P&T Committee by conducting the relative 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 (relative meaning in comparison to the other agents defined in the same class).

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) and (g)(5). Also note that nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

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 the following:

a. The P&T Committee reviewed three Uniform Formulary Drug Classes:

- the Weight Loss Agents;
- the Oncological Drug: Multiple Myeloma subclass; and
- the Prenatal Vitamins subclass
  A summary table of the UF drug class recommendations is found on page 37 of the background document. It also contains the numbers of the unique utilizers affected by the recommendations.

b. The P&T Committee also evaluated 21 Newly Approved Drug per CFR 199.21 (g)(5), which are currently in pending status and available under terms comparable to non-formulary drugs.

c. We will also discuss Prior Authorizations (PAs) for 9 drugs in 7 drug classes, plus one drug class with a step therapy modification.

- Antidepressants and Non-Opioid Pain Syndrome Agents
- Oral Oncologic Drugs
- Targeted Immunomodulatory Biologics
- Corticosteroids – Immune Modulators – Atopic Dermatitis Subclass
- Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass
- Gastrointestinal-2 Miscellaneous Agents
- Non-Insulin Diabetes Drugs – glucagon-like-1 receptor agonists (GLP1-RAs)

d. We discussed one product for brand over generic authorization.

e. There were 5 non formulary drugs with generic availability where we discussed the pertinent formulary status, step therapy and manual PA criteria.

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

UNIFORM FORMULARY DRUG CLASS REVIEWS

I. UF CLASS REVIEWS

(CAPT VONBERG)

A. WEIGHT LOSS AGENTS

1. Weight Loss Agents—Relative Clinical Effectiveness Analysis and Conclusion

Background—Prior to the National Defense Authorization Act (NDAA) 2017, weight loss agents were excluded from the TRICARE pharmacy benefit. An Interim Final Rule published on September 29, 2017, (DOD-2017-HA-RIN 0720) "authorizes coverage under TRICARE Prime and TRICARE Select for medically necessary treatment of obesity, even if it is the sole or major condition treated." Therefore, the P&T Committee evaluated the weight loss agents.

The medications approved for weight loss include both generic and branded products. The older generic drugs are phentermine (Adipex-P, generics), phendimetrazine immediate release (IR) and sustained release (SR) (Bontril, Bontril Slow Release, generics), benzphetamine (Didrex, generics), and diethylpropion (Tenuate, Tandil, generics). A branded, low-dose formulation of phentermine 8 mg (Lomaira) is now available. These older drugs are approved for up to 12 weeks of treatment. The clinical review focused on the newer branded drugs approved for long-term treatment of weight loss beyond 12 weeks.

The P&T Committee concluded (16 for, 1 opposed, 0 abstained, 0 absent) the following:

- Professional treatment guidelines from several organizations differ with respect to recommendations for weight loss. However, there is agreement among all the guidelines that comprehensive lifestyle intervention is the foundation of weight loss treatment. Pharmacotherapy may be offered to patients with a body mass index (BMI) ≥ 30 and to those with a BMI ≥ 27 who have obesity-associated comorbidities.

- The weight loss agents were primarily studied in placebo-controlled trials and vary significantly in their reported efficacy and safety. The individual trials also varied in the requirements for concurrent lifestyle interventions. All the trials included the percentage of patients who achieved a 5% reduction in weight from baseline over a 12- to 16-week period. For all the drugs, approximately 33% to 75% of patients achieved this endpoint, compared to 25% of patients receiving placebo.

- Phentermine/topiramate extended release (ER) (Qsymia) is a fixed-dose combination product that suppresses appetite. The safety concerns with Qsymia include the risk of congenital malformations, and cautions in patients with hypertension, elevated heart rate, or renal dysfunction.

- The fixed-dose combination of naltrexone SR/bupropion SR (Contrave) reduces cravings. Product labeling includes a black box warning advising against use in patients with major depression or psychiatric disorders. Contrave is not recommended in patients with a history of seizures, or uncontrolled hypertension, and in those taking opioids.

a) Lorcaserin is available in two formulations, immediate release (Belviq) and sustained release (Belviq XR). The mechanism by which lorcaserin induces weight loss is unknown. Patients with cardiac conditions, including congestive heart failure, bradycardia, heart valve problems, and second or third degree heart block, require close monitoring.

b) Orlistat (Xenical) is a lipase inhibitor administered with high-fat meals. It is the only weight loss drug approved for pediatric patients as young as 12 years of age. Xenical should be avoided in patients with gallbladder disease or malabsorption syndromes.

c) Liraglutide (Saxenda) is a glucagon-like peptide-1 receptor agonist (GLP1RA) that is administered subcutaneously (SC) once daily in a 3 mg dosage. It causes weight loss by increasing satiety. Liraglutide is also available in a 1.8 mg formulation (Victoza) for treating type 2 diabetes. In a two-year dose comparison study, the two dosages of liraglutide, 1.8 mg and 3 mg, were comparable in efficacy for weight loss.

d) Other GLP1RAs, including exenatide once weekly (Bydureon), have shown a decrease in weight from baseline when evaluated in type 2 diabetic patients. In the 26-week DURATION-6 trial, Bydureon reduced baseline weight by 2.7 kg, compared to 3.6 kg with Victoza; these differences between the drugs are statistically significant but not clinically relevant.

e) Qsymia is the only weight loss drug shown to cause a significant reduction in blood pressure. Reductions in hemoglobin A1c in type 2 diabetic patients have been reported with Contrave, Belviq, and Saxenda. In one trial, Qsymia showed a slowed rate of progression to type 2 diabetes compared to placebo.

f) Due to the lack of head-to-head trials with the weight loss agents, systematic reviews were evaluated to determine comparative clinical

efficacy. The Institute for Clinical & Economic Review in 2015 evaluated 17 placebo-controlled trials. Qsymia and Saxenda had the highest proportion of patients achieving a > 5% weight loss, followed by Contrave, and then Belviq. Discontinuations due to adverse drug reactions occurred most commonly with Qsymia (1.3%–16%) and Contrave (19%–29%). Xenical was not included in the analysis.

g) A 2016 Journal of the American Medical Association (JAMA) systematic review included 28 studies with the newer weight loss drugs. Qsymia and Saxenda had the highest odds of achieving a 5% weight loss followed by Contrave. Saxenda and Contrave had the highest discontinuation rate from adverse events.

h) Varied results were found when Military Health System providers were asked their opinions on prescribing weight loss drugs. The respondents were divided on whether a weight loss drug was needed on the formulary, with 43% responding "yes" versus 40% saying "no". More than half of providers (59%) stated a willingness to prescribe two agents separately in lieu of fixed-dose combinations.

i) Overall, these drugs have a modest effect on weight loss, and evidence for sustained weight loss beyond one to two years is minimal. Clinical comparisons between the individual drugs are difficult due to the differing mechanisms of action, lack of head-to-head trials, lack of long-term cardiovascular outcomes studies, and widely varying adverse event profiles. Discontinuations due to adverse events can be of concern.

2. Weight Loss Agents—Relative Cost-Effectiveness Analysis and Conclusion

Cost-minimization analysis (CMA), cost-effectiveness analysis (CEA), and budget impact analysis (BIA) were performed to evaluate the weight loss agents. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA and CEA results found that the generic agents including phentermine, phendimetrazine, benzphetamine, and diethylpropion were the most cost effective, followed by phentermine 8 mg tablets (Lomaira), phentermine/topiramate ER (Qsymia), lorcaserin (Belviq and Belviq XR), naltrexone SR/bupropion SR (Contrave), orlistat (Xenical), and liraglutide 3 mg injection (Saxenda).

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating the generic agents benzphetamine, diethylpropion,

phendimetrazine, and phentermine as formulary, with liraglutide 3 mg injection (Saxenda), lorcaserin (Belviq and Belviq XR), naltrexone SR/bupropion SR (Contrave), phentermine 8 mg tablets (Lomaira), phentermine/topiramate ER (Qsymia), and orlistat (Xenical) as NF, demonstrated significant cost avoidance for the MHS.

3. Weight Loss Agents—UF Recommendation

The P&T Committee recommended (15 for, 2 opposed, 0 abstained, 0 absent) the following:

a. UF

- benzphetamine (Didrex, generics)
- diethylpropion (Tenuate, Tandil, generics)
- phendimetrazine IR and SR (Bontril, Bontril SR, generics)
- phentermine (Adipex-P, generics)

b. NF

- liraglutide 3 mg injection (Saxenda)
- lorcaserin (Belviq, Belviq XR)
- naltrexone SR/bupropion SR (Contrave)
- orlistat (Xenical)
- phentermine 8 mg tablets (Lomaira)
- phentermine/topiramate ER (Qsymia)

4. Weight Loss Agents—Manual Prior Authorization (PA) Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for all the weight loss drugs, including the generic products, in all new and current users. In general, all the PAs have the following requirements: the patient is ≥ 18 years old; not pregnant; has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea); if the patient has impaired glucose tolerance or diabetes, they must have tried metformin first, or are concurrently taking metformin, have engaged in a trial of behavioral modification and dietary restriction for at least 6 months and have failed to achieve the desired weight loss; and will remain engaged throughout course of therapy to include after PA renewal. For Active Duty Service Members, the individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. Additionally, a trial of phentermine is required prior to use of the branded agents, unless the patient has significant cardiovascular disease or other contraindications to a stimulant. Off label uses are not approved.

In general, renewal PA criteria are required after 12 weeks for the generic products, and after four months for the products approved for long-term use (Belviq, Belviq XR, Contrave, Qsymia, Saxenda, and Xenical). The patient must have lost ≥ 5% of baseline body weight since starting medication for renewal. The PA will be renewed for an additional 12 months.

PA Criteria:

a. benzphetamine, diethylpropion, phendimetrazine IR and SR, phentermine

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* phentermine, phendimetrazine, benzphetamine, and diethylpropion.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents
- *Patient has a BMI ≥ 30 or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If the patient has impaired glucose tolerance or diabetes, the patient must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

PA expires after 3 months

Renewal PA Criteria: PA will be renewed for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*

- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

b. phentermine 8 mg tablets (Lomaira)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* phentermine 8 mg tablets (Lomaira).

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*

a) The patient requires a dose of phentermine less than 15 mg due to elevated baseline heart rate
b) Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents
c) Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)
d) Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy
e) For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy
f) Patient is not pregnant
g) If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin

Off-label uses are not approved

PA expires after 3 months

Renewal PA Criteria: Lomaira will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*

- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

c. phentermine/topiramate ER (Qsymia)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Qsymia.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Qsymia will be approved for an additional 12 months if the criteria discussed previously and the following are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*

- For patients initially receiving Qsymia 7.5mg/46mg: discontinue Qsymia, or escalate to 15mg/92mg if 3% baseline body weight is not achieved at after 12 weeks
- For patients receiving Qsymia 15mg/92mg: discontinue if 5% baseline body weight is not achieved at 12 weeks
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

d. naltrexone SR/bupropion SR (Contrave)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Contrave.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient has tried and failed to achieve a 5% reduction in baseline weight after a 12 week course of phentermine unless there is a history of cardiovascular disease (e.g. arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or significant contraindication to phentermine)
- Patient is not on concurrent opioid therapy and does not have a seizure disorder or uncontrolled hypertension
- Patient is not currently on an monoamine oxidase inhibitor (e.g., Emsam, Marplan, Nardil), or another formulation of bupropion or naltrexone
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Contrave will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

e. lorcaserin (Belviq, Belviq XR)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Belviq or Belviq XR.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient has tried and failed to achieve a 5% reduction in baseline weight after a 12 week course of phentermine unless there is a history of cardiovascular disease (e.g. arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or significant contraindication to phentermine)
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Belviq or Belviq XR will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

f. orlistat (Xenical)—Adults ≥ 18 Years of Age

Manual PA criteria (specific to-read only non-italicized) apply to all new and current users of Xenical.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- The patient has tried and failed or has a contraindication to ALL of the following: Qsymia, Contrave, and Belviq/Belviq XR
- The patient does not have chronic malabsorption syndrome or cholestasis
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*
- *If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin*

Off-label uses are not approved, including nonalcoholic steatohepatitis (NASH)

Prior Authorization expires after 4 months

Renewal PA Criteria: Xenical will be approved for an additional 12 months if the criteria discussed previously are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*

- *The patient has lost ≥ 5% of baseline body weight since starting medication*
- *The patient is not pregnant*

Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy

g. orlistat (Xenical)—Pediatric Patients 12 to 17 Years of Age

Manual PA criteria apply to all new and current users of Xenical.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- Patient is between the ages of 12 and 17 years old
- The patient currently has a BMI of ≥ 95th percentile for age and sex, OR if in ≥ 85th percentile but < 95th percentile for age and sex and has at least one severe co-morbidity (type 2 diabetes mellitus, premature cardiovascular disease) or has a strong family history of diabetes or premature cardiovascular disease (CVD)
- Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy
- *Patient is not pregnant*

Off-label uses are not approved

Prior Authorization expires after 4 months

Renewal PA Criteria: Xenical will be approved for an additional 12 months if the following are met:

- The patient is currently engaged in behavioral modification and on a reduced calorie diet
- The patient's current BMI percentile has decreased for age and weight (considering the patient is increasing in height and will have a different normative BMI from when Xenical was started) OR
- The patient currently has a BMI >85th percentile
- *The patient is not pregnant*

h. liraglutide 3 mg injection (Saxenda)

Manual PA criteria (specific to-read only non-italicized) *apply to all new and current users of* Saxenda.

Manual PA criteria—Agent approved if ALL of the following criteria are met:

- *Patient is ≥ 18 years old*
- Patient has tried and failed or has a contraindication to all of the following agents: Qsymia, Xenical, Contrave, and Belviq or Belviq XR
- If the patient is diabetic, must have tried and failed metformin and the preferred GLP1-RA (Bydureon)
- Concomitant use of Saxenda with another GLP1RA is not allowed (e.g., Bydureon, Byetta, Adlyxin, Victoza, Soliqua, Xultophy)
- The patient does not have a history of or family history of medullary thyroid cancer, or multiple endocrine neoplasia syndrome type 2
- *Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)*
- *Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy*
- *For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy*
- *Patient is not pregnant*

Off-label uses are not approved, including Diabetes Mellitus

Prior Authorization expires after 4 months

Renewal PA Criteria: Saxenda will be approved for an additional 12 months if the criteria discussed previously and the following are met:

- *The patient is currently engaged in behavioral modification and on a reduced calorie diet*
- Saxenda will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks
- *The patient is not pregnant*
- *Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy*

5. Weight Loss Agents—UF and 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 90-day implementation in all points of service.

6. Physician's Perspective

Unlike other drugs classes that have not yet been reviewed for formulary status, we don't know what the annual spend will be, since the weight loss agents have not previously been a covered TRICARE benefit.

There were two opposing votes for the formulary recommendation, as there was discussion as to whether any weight loss drug should be on the formulary, and also concern as to whether the individual service policies would be updated to reflect the new TRICARE Policy.

The justification to only have the generic products on the formulary was due to all the unknown variables that could affect utilization and cost, and the lack of long term efficacy data for the newer agents. The Committee felt that having only the generic products on the formulary will meet the clinical needs of DoD patients.

The Committee was unanimous in that all the weight loss drugs should require a PA, to reduce the risk of inappropriate use. Additionally the Committee strongly agreed that the PA criteria should require concurrent lifestyle intervention and include requirements for target BMIs, which is consistent with professional guidelines. The unique safety profiles of the individual drugs are also included in the PA criteria. For Saxenda, multiple products must be tried first, based on cost effectiveness.

The PA will apply to new and current users, since there are about 400 users of an obesity drug currently at the MTFs, primarily phentermine, followed by Saxenda.

This is an untested market, and the actual number of DoD patients who will fill a prescription for a weight loss drug is unknown at this time. We will watch the utilization for a year, and reassess if we need to re-review the class or update the PA criteria. Also several providers voiced that they had reservations about this drug class being included on the formulary; some of the reasons included that many providers lacked experience in prescribing these medications, and the fact that there is no magic bullet when it comes to weight loss.

7. Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria and UF and PA Implementation Plan for the Weight Loss Agents.

- **Weight Loss Agents – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Weight Loss Agents – Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Weight Loss Agents – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

B. ONCOLOGIC AGENTS: MULTIPLE MYELOMA SUBCLASS

(LT COL KHOURY)

1. Oncologic Agents: Multiple Myeloma Subclass – Relative Clinical Effectiveness Analysis and Conclusion

The P&T Committee evaluated the oral therapies for multiple myeloma; the subclass has not previously been reviewed for formulary status. Multiple myeloma is the 14th most common cancer, but represents only 1.8% of all new cancers diagnosed in the United States. The median age of diagnosis is 69 years, and there is a 50% 5-year mortality rate. The disease is characterized by a series of remissions and relapses, eventually progressing to treatment-refractory disease, and ultimately, patient demise.

The multiple myeloma drug class consists of five products: three immunomodulators, thalidomide (Thalomid), lenalidomide (Revlimid), and pomalidomide (Pomalyst); one proteasome inhibitor, ixazomib (Ninlaro); and, the histone deacetylase inhibitor panobinostat (Farydak). No generic alternatives exist for these branded agents, with the earliest patent or orphan drug expiration expected in 2027.

Despite the fact that multiple myeloma impacts only a small fraction of the MHS population, (<2,000 patients), the drugs account for $136 million in yearly expenditures. Expenditures are primarily driven by one product,

Revlimid, which has increased in price by 39% within the last 5 years, exceeding more than $100 million per year in expenditures.

Complexities in determining the relative clinical effectiveness of the multiple myeloma drugs include the use of concomitant intravenous chemotherapies that are not part of the TRICARE pharmacy benefit [e.g., bortezomib (Velcade), carfilzomib (Kyprolis)], the practice of combining therapies when patients relapse rather than replacing therapies, and the significant toxicities of the drugs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following for the Multiple Myeloma drugs:

- Multiple Myeloma is a complex and rapidly evolving field with management decisions based on several factors, including staging and grading of disease, cytogenetic profiles, patient response to previous therapy, and adverse event profiles. Treatment is not curative.

- The National Comprehensive Cancer Network (NCCN) guidelines support that the backbone of multiple myeloma therapy includes regimens comprised of triplet therapies (lenalidomide with Velcade and dexamethasone), proteasome inhibition, and immunomodulatory agents.

- Lenalidomide (Revlimid) is the preferred immunomodulatory agent across the full spectrum of disease course, from frontline therapy to the multi-relapsed or refractory state. Lenalidomide is also FDA approved for treating mantle cell lymphoma and myelodysplastic syndrome.

- Thalidomide (Thalomid) is reserved for very specific circumstances, largely related to its increased toxicity relative to lenalidomide. Thalidomide has a wide range of FDA-approved and off-label indications.

- Pomalidomide (Pomalyst) is reserved as an alternative regimen in relapsed/refractory disease that has not responded to treatment with lenalidomide.

- Ixazomib (Ninlaro) and panobinostat (Farydak) are indicated for relapsed/refractory disease after at least one previous therapy and demonstrate only modest efficacy. Panobinostat lacks an overall survival benefit and is poorly tolerated.

- Each of the multiple myeloma drugs is associated with significant toxicities that can be life threatening and frequently result in dosage reductions. The immunomodulators are well-known teratogens, with FDA requirements for a Risk Evaluation and Mitigation Strategies (REMS)

program; they also increase the risk for venous thromboembolism (VTE). Ninlaro and Pomalyst both cause thrombocytopenia and diarrhea. Finally, Farydak increases the risk of death via hemorrhagic, arrhythmogenic, and ischemic cardiac events.

2. Oncologic Agents: Multiple Myeloma Subclass—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed thalidomide (Thalomid) was the most cost-effective multiple myeloma drug, followed by ixazomib (Ninlaro), panobinostat (Farydak), lenalidomide (Revlimid), and pomalidomide (Pomalyst).

3. Oncologic Agents: Multiple Myeloma Subclass—UF Recommendation
The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the following, based on clinical and cost effectiveness:

a. UF:
- ixazomib (Ninlaro)
- lenalidomide (Revlimid)
- panobinostat (Farydak)
- pomalidomide (Pomalyst)
- thalidomide (Thalomid)

b. NF: None

4. Oncologic Agents: Multiple Myeloma Subclass—Manual PA Criteria
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new users of Ninlaro, Revlimid, Farydak and Pomalyst.

<u>Full PA Criteria</u>

a. ixazomib (Ninlaro)

Manual PA criteria apply to all new users of Ninlaro.

Manual PA criteria—Ninlaro is approved if all of the following apply:

- Patient is > 18 years old
- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient is diagnosed with multiple myeloma
- Patient must not have had disease progression with a bortezomib (Velcade) or carfilzomib (Kyprolis)–containing regimen

- One or more of the following must apply:
- Patient must have failed or not be candidate for Velcade AND Kyprolis
- Patient has failed or is not a candidate for Kyprolis and has high risk cytogenetics
- Patient will be starting Ninlaro as third (or higher) line of therapy
- Must be used in combination with lenalidomide (Revlimid), pomalildomide (Pomalyst), OR thalidomide (Thalomid)
- Must be used in combination with dexamethasone
- Must not be used concurrently with Velcade or Kyprolis

Off-label uses are not approved

Prior Authorization does not expire

b. lenalidomide (Revlimid)

Manual PA criteria apply to all new users of Revlimid.

- Manual PA criteria—Revlimid is approved if all of the following apply:
- Patient is > 18 years old
- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient has one of the following diagnoses:
  - Multiple myeloma
  - Mantle Cell Lymphoma refractory to at least 2 prior treatment regimens, one of which contains bortezomib (Velcade) OR at least 1 prior treatment regimen and has failed or has a contraindication to bortezomib
  - Myelodysplastic syndrome w/5q deletion with one or more of the following: symptomatic anemia, transfusion-dependent anemia, or anemia not controlled with an erythroid stimulating agent
- Patient is not on concurrent pomalidomide (Pomalyst) or thalidomide (Thalomid)
- PA will be approved for the following non-FDA approved indications:
- Relapsed/refractory multi-centric Castleman Disease not responding to non-lenalidomide management
  - Diffuse large B-cell lymphoma (Non-Hodgkin Lymphoma) as second-line (or subsequent) therapy relapsed/refractory to non-lenalidomide management
  - Follicular lymphoma (Non-Hodgkin Lymphoma)
  - Relapsed/refractory classical Hodgkin's lymphoma
  - Myelofibrosis refractory to or with contraindications to alternative therapies
  - Systemic light chain amyloidosis with organ involvement

Off-label uses other than those listed above are not approved
Prior Authorization does not expire

c. panobinostat (Farydak)

Manual PA criteria apply to all new users of Farydak.

Manual PA criteria—Farydak is approved if all of the following apply:

- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient is > 18 years old
- Patient is diagnosed with multiple myeloma that is relapsed or refractory
- Patient's disease is NOT refractory to all of the following drugs: bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)
- Patient will be starting Farydak as the third (or higher) line of therapy
- Patient's previous regimens include at least one regimen with bortezomib, carfilzomib OR ixazomib, AND at least one regimen with lenalidomide, pomalidomide, OR thalidomide
- Must be used in conjunction with dexamethasone
- Must be used in conjunction with a bortezomib, carfilzomib, OR Ninlaro-containing regimen
- Must meet ALL of the following requirements:
    - Platelet count > $100x10^9$/L
    - QTc < 450 msec
    - Patient has no evidence of acute or chronic ischemic disease on EKG and no history of MI or unstable angina within the last 6 months
- Patient must have access to anti-diarrheal therapy

Off-label uses are not approved

Prior Authorization expires after 12 months

Renewal PA Criteria: PA will be re-approved for an additional 6 months, if the patient has not yet completed 16 cycles of treatment

d. pomalidomide (Pomalyst)

Manual PA criteria apply to all new users of Pomalyst.

Manual PA criteria—Pomalyst is approved if all of the following apply:

- Patient is > 18 years old

- Must be prescribed by or in consultation with a hematologist or oncologist
- Patient is diagnosed with relapsed/refractory multiple myeloma that is refractory to lenalidomide AND all of the following must apply:
  - Patient has previously had a trial of a bortezomib, carfilzomib, OR Ninlaro-containing regimen
  - Patient will be starting Pomalyst as third (or higher) line of therapy
  - Must be used in combination with dexamethasone
- Patient is not using concurrent lenalidomide or thalidomide
- PA will be approved for the following non-FDA approved indications:
  - Myelofibrosis refractory to or with contraindications to alternative therapies (including lenalidomide) and erythropoietin levels > 500 mU/ml
  - Systemic light chain amyloidosis with organ involvement refractory to or with contraindications to alternative therapies including lenalidomide

Off-label uses other than those listed above are not approved

Prior Authorization does not expire

5. Oncologic Agents: Multiple Myeloma Subclass—UF and PA 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 60-day implementation period in all points of service.

6. Physician's Perspective

This is an extremely complicated disease to treat. As part of the clinical effectiveness review and PA criteria development, the Committee evaluated guidelines from the National Cancer Comprehensive Network (NCCN) and Mayo Clinic, individual clinical trial data, and several meta-analyses and systematic reviews, including one from the Institute for Clinical and Economic Reviews group.

Due to the risk of fetal malformations, there are strict requirements for Revlimid, thalidomide and Pomalyst. Dispensing is limited to one specialty pharmacy or about 6 MTF pharmacies who have satisfied the Risk Evaluation and Mitigation Strategy (REMS) REMS requirements.

All of the drugs were selected for formulary addition, as patients require access to multiple agents, due to the inevitable progression of the disease.

We have not previously had PA criteria for this drug class. PAs were recommended to highlight safety concerns and to ensure that the drugs are used for the FDA-approved indications. We did reach out to the oncology prescribers when developing the PA criteria. The PA criteria will only apply to new patients, so as not to disrupt patients who are currently undergoing therapy. Additionally, our data for DoD shows that patients are on these drugs for only 2 years.

7. Panel Questions and Comments

Mr. Hostettler asked for clarification on the 39% increase in the last 5 years by the product Revlimid. According to presentation, it exceeds more than $100 million per year in expenditures. Can you differentiate from mantle disease for multiple myeloma?

Lt Col Khoury responds the information is dependent on accurate coding. The majority were either FDA approved indications or off-label indications with the majority being on-label indications. I can get you exact numbers, but it's dependent on the ICD-9 codes. We wanted to ensure they were either on or off label. In the analysis, approximately 60 of the 1000, that we analyzed, did not have any of the on or off label indications. That could mean that they were on or off label not correctly on the agent or they were not correctly coded. Most were on and off label indications.

Mr. Hostettler asked if most of the patients were appropriately being treated.

Lt Col Khoury replied that 60 of them potentially were not. This is not a large class. While impact appears minimal, there are only 1000 patients in this class.

Mr. Hostettler asked if the recommendation is consistent with all of the guidelines that were reviewed.

Lt Col Khoury stated that they were.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Oncologic Agents: Multiple Myeloma Subclass.

- **Oncologic Agents: Multiple Myeloma Subclass – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Oncologic Agents: Multiple Myeloma Subclass – Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Oncologic Agents: Multiple Myeloma Subclass – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

C. VITAMINS: PRENATAL VITAMINS SUBCLASS

(CAPT VONBERG)

1. Vitamins: Prenatal Vitamins Subclass – Relative Clinical Effectiveness Analysis and Conclusion

Background—At the August 2017 meeting, the P&T Committee discussed the planned transition of multiple National Drug Codes (NDCs), including all legend prenatal vitamins, from prescription to non-prescription status in the First DataBank drug database. Actions recommended by the P&T Committee in response to this change were approved by the Director, DHA, on October 20, 2017, but are on hold due to recent litigation between outside parties concerning the change in status for these products. Therefore, prenatal vitamins currently listed as legend drugs remain a covered TRICARE pharmacy benefit, and thus were considered for formulary status. A total of 152 different prenatal vitamins (by brand name) were dispensed at any DoD point of service during Fiscal Year 2017.

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

- Prenatal vitamins are a low-cost intervention known to improve outcomes by preventing neural tube defects and providing adequate iron stores to prevent anemia and decrease nausea and vomiting during pregnancy.

- U.S. Preventive Services Task Force (USPSTF) guidelines recommend that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg of folic acid (Grade A recommendation).

- Continued TRICARE coverage of prenatal vitamins is highly desirable in order to ensure uninterrupted access to essential care.

- Provision of prenatal vitamins as part of the TRICARE pharmacy benefit is even more important for the MHS than civilian health plans, given worldwide assignment of female service members and beneficiaries to countries with variable availability of food products fortified with folic acid.

- In addition to iron and folic acid, prenatal vitamins may also contain additional components, including fatty acids [e.g., docosahexaenoic acid (DHA), omega-3, and eicosapentaenoic acid (EPA)] and calcium.

- Prenatal vitamins that provide alternative dosage forms (gummies, chewable, smaller capsule or tablet size, etc.), are available due to patient preference or marketing issues.

- Prenatal vitamins exhibit a high degree of therapeutic interchangeability.

7. Vitamins: Prenatal Vitamins Subclass—Relative Cost-Effectiveness Analysis and Conclusion

The relative cost-effectiveness analysis included identifying the highest volume, most cost-effective options that would provide a variety of formulations to meet the clinical needs of beneficiaries, based on ingredient cost and usage at each point of service (MTF, TRICARE Mail Order Pharmacy, Retail Network pharmacies). The Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following products (listed by brand name) comprise the highest volume, lowest cost options at all three points of service: Prenatal Vitamins Plus Low I, Prenatal Vitamin + Low Iron, Prenatal Plus, Preplus, Prenatal (OTC), Prenatal Vitamins (OTC), Prenatal Multi + DHA (OTC) and Prenatal Formula (OTC).

8. Vitamins: Prenatal Vitamins Subclass—UF Recommendation

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) placing the following legend products on the UF, with all other legend prenatal vitamins designated NF:

a. UF:
- Prenatal Vitamins Plus Low I
- Prenatal Vitamin + Low Iron
- Prenatal Plus
- Preplus

b. NF: All other legend prenatal vitamins.

c. Note that the products recommended for UF placement, listed above, include approximately 90% of the 30-day equivalent prescriptions dispensed for prenatal vitamins.

d. The products recommended for UF placement is different from, and thus supersedes, the list of agents identified as highest value in the August 2017 DoD P&T Committee minutes (available at https://health.mil/About-

MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes).

e. Selecting these agents facilitates the standardization of available agents in the Prenatal Vitamin subclass across DoD points of service.

9. Vitamins: Prenatal Vitamins Subclass—Prior Authorization Age and Gender Edit

Prenatal vitamins are not currently covered for male patients, and female patients older than 45 years of age, consistent with TRICARE coverage of legend prenatal vitamins for pregnancy-related use only. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current age and gender requirements for prenatal vitamins. The P&T Committee noted expert opinion stating that pregnancy was very rare past the age of 45, but agreed that the requirement should be overridden in such cases.

10. Vitamins: Prenatal Vitamins Subclass—UF and PA 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 points of service and, 2) DHA send letters to beneficiaries who are affected by the UF decision.

11. Physician's Perspective

Even though there is a question as to whether the prescription prenatal vitamins will remain legend products or change to OTC status, the Committee decided to go ahead and review the class, since they still remain part of the TRICARE benefit. The Committee also wanted to determine the UF status of the prescription products.

We have not previously reviewed the prenatal vitamins, since they include a mix of both prescription and OTC products. The vast majority (over 91%) of all prenatal vitamin prescriptions were dispensed at the MTFs, where there is about a 50-50 mix of OTC vs. prescription products dispensed. The Mail Order and Retail Network only dispense the legend products.

There were over 150 brand name and OTC products from 44 different manufacturers dispensed in the MHS. About 50% of the products have generic equivalents.

Although only four prescription products were recommended for addition to the formulary, the beneficiary impact of the products recommended for non-

formulary placement will only affect about 12% of the patients taking a prenatal vitamin.

7. Panel Questions and Comments

Mr. Hostettler asks for clarification on pending litigation. Will this recommendation become a permanent decision regardless of outcome of the litigation for the OTCs.

CAPT VonBerg asked for clarification.

Mr. Hostettler replied they are under consideration for OTC status. Will this decision change that they are being considered for OTC status or will we always have prenatal vitamins available for that age group?

CAPT VonBerg replied that the committee in the previous decision and the committee in this decision were consistent in saying that prenatal vitamins should be available. This applies to the prenatal vitamins in legend status. If they are in OTC status, the committee has been consistent in recommending that prenatal vitamins should be available either way. The P&T committee has the authority to select OTC agents.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation and UF and PA Implementation Plan for the Prenatal Vitamins Subclass.

- **Vitamins: Prenatal Vitamins Subclass – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Vitamins: Prenatal Vitamins Subclass – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

II. NEWLY-APPROVED DRUGS

(LT COL KHOURY)

A. NEWLY-APPROVED DRUGS PER CFR 199.21 (g)(5)

1. Newly-Approved Drugs per CFR 199.21(g)(5) – Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and

cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5).

2. Newly-Approved Drugs per CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

a. UF:

- abemaciclib (Verzenio) – Oral Oncology Agents for Breast Cancer
- belimumab (Benlysta) – Immunosuppressive Agents – Systemic Lupus Erythematosus
- plasma-derived human C1 esterase inhibitor SQ injection (Haegarda)– Hereditary Angioedema (HAE)
- enasidenib (Idhifa) – Oral Oncology Agents for Acute Myelogenous Leukemia
- fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta) – Pulmonary II Combination Agents – Chronic Obstructive Pulmonary Disease (COPD)
- glecaprevir/pibrentasvir (Mavyret) – Hepatitis C Virus Direct Acting Antivirals (HCV DAAs)
- L-glutamine (Endari) – Dietary Supplements
- naldemedine (Symproic) – Gastrointestinal-2 Agents – Opioid Induced Constipation (OIC) Drugs
- neratinib (Nerlynx) – Oral Oncology Agents for Breast Cancer
- nitisinone (Nityr) – Metabolic Replacement Agents
- perampanel (Fycompa oral solution) – Anticonvulsants/Anti-Mania Agents
- sofosbuvir/velpatasvir/voxilaprevir (Vosevi) – HCV DAAs

b. NF:

- amantadine ER (Gocovri) – Parkinson's Disease Drugs
- betrixaban (Bevyxxa) – Oral Anticoagulants
- delafloxacin (Baxdela) – Antibiotics – Quinolones
- fluticasone propionate (ArmonAir RespiClick) – Pulmonary I Agents – Inhaled Corticosteroids
- guselkumab (Tremfya) injection – Targeted Immunomodulatory Biologics (TIBs)
- insulin aspart (Fiasp) – Insulins – Short-Acting Agents
- lesinurad/allopurinol (Duzallo) – Antigout Agents – Chronic
- methylphenidate ER orally dissolving tablet (Cotempla XR ODT) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
- simvastatin oral suspension (FloLipid) – Antilipidemic-1s

3. Newly-Approved Drugs per CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Applying the same manual PA criteria for Tremfya in new users, as is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for Tremfya, a trial of both secukinumab (Cosentyx) and ustekinumab (Stelara) is required if the patient cannot be treated with Humira.

- Applying the same manual PA criteria to new users of Vosevi and Mavyret as is currently in place for the other non-step-preferred DAAs for chronic hepatitis C infection. Harvoni is the preferred agent.

- Revising the manual PA criteria for Haegarda in new users to not allow concomitant use with another C1 esterase inhibitor product. *The full PA criteria will be presented in the Utilization Management section.*

- Applying manual PA criteria to new users of Verzenio, Gocovri, Idhifa, Endari, Nerlynx, and Fycompa.

- Applying PA criteria to new and current users of Benlysta, ArmonAir RespiClick, Fiasp, Duzallo, Cotempla XR ODT, and FloLipid.

Full PA Criteria for the Newly-Approved Drugs per CFR 199.21(g)(5)

a. ***TIBs: guselkumab (Tremfya)***

Changes made from the November 2017 meeting are in bold.

Step therapy and Manual PA Criteria apply to all new users of guselkumab (Tremfya).

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 Tremfya if:

- *Contraindications exist to Humira* ***and Cosentyx, and Stelara***

- *Inadequate response to Humira **and Cosentyx, and Stelara** (need for different anti-tumor necrosis factor [TNF] or non-TNF)*
- *There is no formulary alternative: patient requires a non-TNF TIB for symptomatic congestive heart failure (CHF)*
- *Adverse reactions to Humira **and Cosentyx, and Stelara** not expected with requested non step-preferred TIB*

AND

Coverage approved for patients ≥ 18 years with:

- *Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy **and have failed to respond to or lost response to other systemic therapies***

Off-label uses are not approved

Prior Authorization does not expire

Coverage is NOT provided for concomitant use with other TIBs.

b. HCV DAAs:

1) glecaprevir/pibrentasvir (Mavyret)

Manual PA criteria apply to new users of Mavyret.

Manual PA Criteria: coverage will be approved if all criteria are met:

- The patient is ≥ 18 years of age and diagnosed with chronic Hepatitis C Virus (HCV) infection
- Mavyret is prescribed in consultation with or by a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician
- The patient cannot use Harvoni (i.e. due to HCV GT2 or GT3)

Off-label uses are not approved

PA does not expire.

2) sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

Manual PA criteria apply to new users of Vosevi.

Manual PA Criteria: coverage will be approved if ALL of the following criteria are met:

- The patient is ≥ 18 years of age and diagnosed with Chronic Hepatitis C Virus (HCV) infection
- Vosevi is prescribed in consultation with or by a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician
- The patient has HCV genotype 1, 2, 3, 4, 5, or 6 AND has tried and failed treatment with a NS5A Inhibitor (e.g., daclatasvir (Daklinza), ledipasvir, ombitasvir, velpatasvir, elbasvir) OR
- The patient has HCV genotype 1a or 3 AND has tried and failed treatment with Sovaldi without a NS5A Inhibitor
- AND the patient does not have any of the following:
  a) Decompensated cirrhosis
  b) Moderate or severe hepatic impairment (Child-Pugh Class B or C)
  c) Severe renal impairment (eGFR <30 mL/min or End Stage Renal Disease)

Off-label uses are not approved

Prior Authorization does not expire.

3) Oral Oncologic Agents: abemaciclib (Verzenio)

Manual PA criteria apply to all new users of Verzenio

Manual PA criteria—Verzenio is approved if all of the following apply:

- The patient has a diagnosis of HR+, HER2 negative advanced or metastatic breast cancer
- Breast cancer has progressed during or after endocrine therapy
- The patient is using Verzenio and meets ALL of the following:

  a) Patient is postmenopausal and will use Verzenio in combination with fulvestrant OR
  b) The patient is premenopausal or perimenopausal and is receiving ovarian suppression with GnRH agonist AND Verzenio will be used in combination with fulvestrant OR
  c) Verzenio will be used as monotherapy and the patient has had prior chemotherapy for treatment of metastatic breast cancer

Off-label uses are not approved

Prior Authorization does not expire

4) Parkinson's Disease Drugs: amantadine ER tabs (Gocovri)

Manual PA criteria apply to all new users of Gocovri

Manual PA Criteria—Gocovri is approved if:

- The patient is ≥18 years old AND
- Has a diagnosis of Parkinson's Disease AND
- Has had therapeutic failure of a trial of amantadine 200 mg immediate release tablets administered twice daily

Off label uses are not approved

Prior Authorization does not expire

5) Oral Oncologic Agents: enasidenib (Idhifa)

Manual PA criteria apply to all new users of Idhifa.

Manual PA criteria—Idhifa is approved if all the following criteria are met:

- The patient is ≥18 years old and has a diagnosis of relapsed refractory acute myelogenous leukemia (AML)
- Patient exhibits the IDH2 mutation as determined by an FDA approved test
- Must be prescribed by or in consultation with hematologist or oncologist
- Idhifa is used in combination with standard chemotherapy protocols

Off-label uses are not approved

Prior Authorization expires at one year.

Renewal criteria: Idhifa will be approved for one year if the patient has not had disease progression.

6) Dietary Supplements: L-glutamine oral powder (Endari)

Manual PA criteria apply to new users of Endari.

Manual PA Criteria: coverage will be approved if ALL of the following criteria are met:

- Patient has a diagnosis of sickle cell anemia or Sickle ß thalassemia
- Age ≥ 5 years old
- Patient has had ≥ 2 sickle cell crises in the last 12 months
- Patient has had an inadequate treatment response to a 3 month trial of both hydroxyurea and blood transfusion therapy

Off-label uses are not approved

Prior Authorization does not expire.

7) Oral Oncologic Agents: neratinib (Nerlynx)

Manual PA criteria apply to all new users of Nerlynx

Manual PA criteria—Nerlynx is approved if meets all of the following:

- The patient is an adult ≥18 years of age with early stage HER2-overexpressed/amplified breast cancer
- Nerlynx is used following adjuvant trastuzumab-based therapy (preferably less than 1 year, but no more than 2 years after completion of trastuzumab (Herceptin)-based therapy.
- The patient has been counseled on significant adverse event profile
- Nerlynx is co-prescribed with an antidiarrheal to mitigate adverse events for at a minimum 2 months
- Patient has been counseled on the possibility of an unproven survival benefit gain with Nerlynx

Off-label uses are not approved

Prior Authorization expires after 18 months.

No renewal allowed, patient should not take more than a 365-day lifetime supply.

8) Anticonvulsants/Antimania Agents: perampanel oral solutions (Fycompa O/S)

Manual PA criteria apply to all new users of Fycompa O/S ≥18 years of age.

Manual PA criteria—Fycompa O/S is approved if:

- The patient cannot swallow perampanel tablets AND
- The patient has a diagnosis of epilepsy with partial-onset seizures w/wo secondarily generalized seizures OR
- The patient has a diagnosis of epilepsy with primary generalized tonic-clonic seizures

Off-label uses are not approved

Prior authorization does not expire

9) TIBs: belimumab (Benlysta)

Manual PA Criteria apply to all new and current users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta.

Manual PA criteria: Coverage is approved for Benlysta if all of the following are met:

- Benlysta is prescribed by or consultation with an specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist
- The patient is ≥18 years old
- The patient has a documented diagnosis of active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE
- The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)
- The patient does not have severe active lupus nephritis or severe active central nervous system lupus
- The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide

Off-label uses are not approved

Prior Authorization expires in one year.

Renewal PA Criteria: Benlysta will be approved on a yearly basis if the all of the following are met:

- Treatment with Benlysta has shown documented clinical benefit (i.e. improvement in number/frequency of flares,

improvement in in Safety of Estrogen in Lupus Erythematosus National Assessment – SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.)
- The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)
- The patient does not have severe active lupus nephritis or severe active central nervous system lupus

The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide

10) Pulmonary I Agents—Inhaled Corticosteroids: fluticasone propionate (ArmonAir RespiClick)

PA criteria apply to all new and current users of ArmonAir RespiClick who are older than 12 years of age.

Manual PA criteria—ArmonAir RespiClick is approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if:

- The patient has experienced any of the following issues with either Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred ICS drug:
- The patient requires fluticasone and cannot manipulate BOTH the Flovent Diskus (active inhalation) or Flovent HFA MDI (passive inhalation)

Off-label uses are not approved

Prior Authorization does not expire.

11) Insulins Short-Acting Agents: insulin aspart (Fiasp)

Manual PA criteria apply to all new and current users of Fiasp.

Manual PA criteria: Coverage will be approved if all criteria are met:

- Patient has type 1 diabetes
- Patient has tried and failed insulin aspart (Novolog)
- Patient has tried and failed or is intolerant to insulin lispro (Humalog)

- Prescribed by or in consultation with an endocrinologist

Off-label uses are not approved

Prior authorization does not expire.

12) Antigout Agents—Chronic: lesinurad/allopurinol (Duzallo)

Manual PA criteria apply to all new and current users of Duzallo.

Manual PA criteria: Coverage will be approved if all criteria are met:

- The patient is ≥ 18 years of age
- The patient has chronic or tophaceous gout
- The patient has a creatinine clearance (CrCl) >45 mL/min
- The gout patient has not achieved target serum uric acid level despite maximally- tolerated therapy with allopurinol

Off-label uses are not approved

Prior authorization does not expire.

13) ADHD Drugs: methylphenidate ER orally dissolving tablets (Cotempla XR ODT)

Manual PA criteria apply to all new and current users of Cotempla XR-ODT.

Manual PA criteria: Coverage will be approved if ALL of the following criteria are met:

- Patient is between the ages of 6-17 years of age and has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient Must have tried and failed or has a contraindication to Adderall XR (generic)
- Patient must have tried and failed or has a contraindication to Concerta OROS (generic)
- Patient must have tried and failed or has a contraindication to methylphenidate ER oral suspension (Quillivant XR), or methylphenidate ER cap (Aptensio XR)

Off-label uses are not approved

Prior Authorization does not expire.

14) Antilipidemics-1s: simvastatin oral suspension (FloLipid)

PA criteria apply to all new and current users of FloLipid

Manual PA criteria—FloLipid is approved (e.g., trial of generic simvastatin, atorvastatin, pravastatin, lovastatin, or rosuvastatin tablets) is note required if:

- The provider writes in why the patient requires liquid simvastatin and cannot take simvastatin, atorvastatin, pravastatin, lovastatin, rosuvastatin tablets
- Acceptable responses include that the patient requires simvastatin and cannot swallow the statin tablets due to some documented medical condition , including dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience

Off-label uses are not approved

Prior Authorization does not expire

4. Newly-Approved Drugs per CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service.

5. Physician's Perspective

We continue to see an increasing number of new drugs requiring review at every meeting. Out of the 21 drugs reviewed at the November P&T Committee meeting, 11 were recommended for formulary status, and 10 recommended for non-formulary status.

Sixteen of the products have PA requirements, but 10 of the drugs have "grandfathering" where the PA will only apply to new users, with current users allowed to remain on therapy without having to fill out a PA form. For the six products where no grandfathering is recommended (where the PA will apply to both new and current users) there are formulary alternatives available.

For the 16 drugs where PAs were recommended, several of them fall into classes where there are existing PA requirements or step therapy requirements (such as for the oncology drugs, TIBs, hereditary angioedema, the inhaled steroid, and the Hep C drugs). Additionally, there are 7 drugs that are reformulations of existing products that are already on the formulary, (the

insulin product, ADHD drug, Parkinson's disease drug, gout product, statin and anticonvulsant).

A PA was also recommended for the Lupus drug Benlysta to follow the FDA approved indication and safety monitoring.

Lastly a PA was recommended for Endari, which is the first prescription glutamine product approved by the FDA. Since the glutamine is available as a dietary supplement, and often used to treat muscle soreness after exercise or GI problems, we wanted to ensure only patients with sickle cell disease would receive Endari, which is the indicated use.

6. Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, PA Criteria, and UF and PA Implementation Plan for the Newly Approved Drugs.

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Newly-Approved Drugs per CFR 199.21(g)(5) – PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

III. UTILIZATION MANAGEMENT

(CAPT VON BERG)

A. ANTIDEPRESSANTS AND NON-OPIOD PAIN SYNDROME AGENT

1. Antidepressants and Non-Opiod Pain Syndrome Agents: Bupropion Hydrobromide (Aplenzin) – New Manual PA Criteria

Aplenzin is a branded formulation of bupropion ER approved for treating major depressive disorder and seasonal affective disorder. It was designated NF at the November 2009 meeting. Aplenzin contains a hydrobromide (HBr) salt, compared to the hydrochloride salt in Wellbutrin XL. The two

formulations are bioequivalent. Cost-effective generic formulations of Wellbutrin are available and on the UF.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for Aplenzin, due to the significant cost differences and lack of clinically compelling benefits between Aplenzin and generic bupropion ER. New and current users of Aplenzin are required to try generic bupropion ER and a second antidepressant first.

Full PA Criteria:

Manual PA criteria apply to all new and current users of Aplenzin. Note that PA is not required for generic bupropion (Wellbutrin, Wellbutrin SR or Wellbutrin XL); providers are encouraged to consider changing the prescription to generic Wellbutrin XL.

Manual PA criteria: Coverage for Aplenzin is approved if ALL of the following apply:

- The patient is ≥18 years old
- The patient has clinically diagnosed major depressive disorder or seasonal affective disorder
- The patient must have tried and failed both of the following:

    a) generic bupropion ER (e.g., patient cannot take more than one tablet of generic bupropion) AND
    b) at least one generic selective serotonin reuptake inhibitor (SSRI) or other antidepressant

- Patient does not have a history of seizure disorder or bulimia

Off label uses are not approved (e.g., smoking cessation)

Prior Authorization expires after 1 year.

- Renewal PA criteria for continuation of therapy: PA is approved for an additional year if the patient has had an adequate clinical response and continues to be unable to take multiple tablets of generic bupropion.
- Renewal PA criteria is limited to one year.

2. Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplenzin)—New Manual PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that the manual PA for Aplenzin become effective on the first Wednesday after a 90-day implementation period in all points of service. Additionally,

the P&T Committee recommended DHA send letters to the beneficiaries affected by this decision.

3. Physician's Perspective

Aplenzin is 40 times more expensive than generic bupropion formulations, and does not offer any clinical advantages over the generics.

Approximately 120 patients will be affected by the PA requirements, since the PA will apply to both new and current users ("no grandfathering"). Due to the fact that the disease being treated is depression, we felt that the affected patients should receive letters.

4. Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the New Manual PA Criteria and New Manual PA Implementation Plan for the Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplezin).

- **Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplezin) – New Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Antidepressants and Non-Opioid Pain Syndrome Agents: Bupropion Hydrobromide (Aplezin) – New Manual PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

B. UPDATED MANUAL PA CRITERIA AND STEP THERAPY

(CAPT VON BERG)

1. Updated Manual PA Criteria and Step Therapy

Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications. The updated manual PA outlined below will apply to new users.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the manual PA criteria for Tafinlar, Mekinist, Zelboraf, Stelara, Eucrisa, and Cinryze, and updates to the step therapy and manual PA criteria for the GLP1RAs. All updated criteria apply to new users of these agents.

a. Oral Oncological Agents: Dabrafenib (Tafinlar) and Trametinib (Mekinist)

Tafinlar and Mekinist were reviewed in August 2014 with manual PA criteria recommended. Criteria were updated to add the additional indication for non-small cell lung cancer (NSCLC).

Off-label uses are not approved

b. Oral Oncological Agents: Vemurafenib (Zelboraf)—Zelboraf was reviewed in February 2012 with manual PA criteria recommended. Criteria were updated to add the additional indication for Erdheim-Chester Disease with BRAF V600 mutation.

Off-label uses are not approved

c. TIBs—Ustekinumab (Stelara)—Stelara was reviewed in August 2014 with manual PA criteria recommended. Criteria were updated to add the additional indication for severe plaque psoriasis in patients 12 to 18 years old.

d. Corticosteroids—Immune Modulators—Atopic Dermatitis Subclass: Crisaborole (Eucrisa)—Eucrisa was reviewed in May 2017 with manual PA criteria recommended. Several atopic dermatitis agents are now available in generic formulations. Due to the significant cost differences between Eucrisa and formulary alternatives, the PA criteria were updated to include a two-week trial of at least two formulary medium to high potency topical steroids or a topical calcineurin inhibitor (e.g., tacrolimus, Elidel) prior to use of Eucrisa.

e. Corticosteroids—Immune Modulators—Hereditary Angioedema (HAE) Subclass: Plasma-derived human C1 Esterase Inhibitor SQ (Haegarda) and IV (Cinryze)—The HAE drugs were reviewed for formulary status in August 2017 and Haegarda was reviewed as a new drug during the November 2017 P&T Committee Meeting. Both Haegarda and Cinryze are indicated for prophylaxis of HAE episodes. The manual PA criteria were updated to prohibit concomitant use of Cinryze and Haegarda.

f. Non-Insulin Diabetes Drugs: GLP1RAs—Step Therapy and Manual PA Criteria—The NF and non-step-preferred GLP1RAs [lixisenatide (Adlyxin), liraglutide (Victoza), insulin degludec (Xultophy), insulin glargine/lixisenatide (Soliqua), exenatide microspheres BID (Byetta), and dulaglutide (Trulicity)] all require a trial of exenatide weekly (Bydureon) and albiglutide (Tanzeum). Tanzeum manufacturing will cease in June 2018. The step therapy and manual PA criteria for the GLP1RAs were

updated to remove the requirement of a trial of Tanzeum. Additionally, the manual PA criteria for the UF and step-preferred products (Bydureon and Tanzeum) were updated to reflect the market discontinuation of Tanzeum, and to advise providers of this issue.

2. Updated Manual PA Criteria and Step Therapy—Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the current PAs for Tafinlar, Mekinist, Zelboraf, Stelara, Eucrisa, and Cinryze, and updates to the step therapy and manual PA criteria for the GLP1RAs become effective upon signing of the minutes in all points of service.

3. Physician's Perspective

At every meeting, we present updates to drugs with existing PAs to ensure the latest FDA indications or safety updates are included in our criteria. For this meeting, the majority of the updates are for new indications or an expanded pediatric age range (for Stelara). We regularly respond to requests from providers when they submit feedback on PA criteria.

For the GLP1 diabetes drugs, the PA changes are required to account for the market discontinuation of Tanzeum.

4. Panel Questions and Comments

There were no questions or comments from the Panel. The Chair called for a vote on the Updated Manual PA Criteria and Step Therapy and Updated Manual PA Criteria and Step Therapy Implementation Plan.

- **Updated Manual PA Criteria and Step Therapy**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Updated Manual PA Criteria and Step Therapy – Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

IV. BRAND OVER GENERIC AUTHORIZATION FOR MESALAMINE DELAYED RELEASE (LIALDA)

(CAPT VON BERG)

A. LIALDA

1. Lialda – Brand over Generic Requirement and Manual PA Criteria

TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Lialda product is more cost effective than the AB-rated generic formulations for mesalamine delayed release (DR), which were launched in June 2017. The manufacturer of Lialda has offered a Blanket Purchase Agreement (BPA). Therefore, the branded Lialda product will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 (generic) copayment will apply to Lialda. The "brand over generic" requirement for Lialda will be removed administratively when it is no longer cost effective compared to the AB-rated generics.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) implementing the requirement to prefer the branded Lialda product over generic formulations. Manual PA criteria are required for generic mesalamine ER in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded Lialda product cannot be used.

PA Criteria

Manual PA criteria apply to all new users of generic Lialda. Note that brand Lialda is the preferred mesalamine delayed release product in DoD.

Manual PA Criteria: Coverage for generic mesalamine delayed release is approved if the following criteria is met:

- The provider has provided patient-specific justification as to why the brand Lialda product cannot be used.
- Acceptable reasons include the following, which have occurred or are likely to occur with the branded Lialda product: allergy to the branded Lialda; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues.

2. Lialda—Brand Copayment Change

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that the brand (Tier 2) formulary cost share for Lialda in the TRICARE Mail Order Pharmacy and the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share.

3. Physician's Perspective

The usual process for DoD is that when generic equivalents to branded products are introduced into the market, mandatory use of the generic is required. Occasionally, there are cases where the generic entrant is significantly more expensive than the existing branded product, so the "brand over generic" process is recommended. As an additional incentive for the brand product to be dispensed, the copay will decrease to the tier 1 (or generic) copay. This is the situation with Lialda.

When this process has been used in the past, there have been only rare instances where the manual PA to receive the generic product instead of the branded product has even been submitted. So overall, the patient will continue to receive the branded product.

The price of the generics will be monitored, so when it is no longer cost effective to continue dispensing the branded product, we will administratively remove this requirement, and go back to our usual process of preferring the generic.

4. Panel Questions and Comments

Mr. Hostettler asked when the co-pay change takes effect.

CAPT Von Berg replied that it already has.

There were no more questions or comments from the Panel. The Chair called for a vote on the Brand over Generic Requirements and Manual PA Criteria and the Brand Copayment change for Lialda.

- **Lialda – Brand over Generic Requirement and Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Lialda – Brand Copayment Change**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

V. RE-EVALUATION OF NF GENERICS

(CAPT VON BERG)

A. Re-evaluation of NF Generics

1. Relative Clinical Effectiveness Analysis and Conclusion

Background—The DHA POD FMB monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs needs to be readdressed. The P&T Committee's process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, TMA, on July 24, 2007.

The P&T Committee reviewed the current utilization, formulary status, generic availability, comparative clinical effectiveness and relative cost effectiveness, including the weighted average cost per unit, for generically available NF agents in three previously reviewed drug classes: the ADHD/wakefulness promoting agents, benign prostatic hyperplasia (BPH) drugs, and renin-angiotensin antihypertensive agents (RAAs). Existing step therapy and manual PA requirements, and BCF designation were also discussed when pertinent.

Relative Clinical Effectiveness Conclusion and Relative Cost-Effectiveness Conclusion

For the topical antifungals, BPH agents, and RAAs, the P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusions from when the classes were originally reviewed for UF placement. The P&T Committee took into account new information for wakefulness-promoting agents. Specific comments, including the results of comparative cost reviews, are below:

a. ADHD/Wakefulness: Wakefulness Promoting Subclass

- *armodafinil (Nuvigil, generics); modafinil (Provigil, generics)*— Currently, armodafinil is NF (Tier 3) and modafinil is UF. The two drugs are now generically available from multiple manufacturers, with the same unit cost based on weighted average cost across all points of service. The unit cost for both products has dropped significantly from the previous brand cost.

  Current PA requirements are based primarily on the likelihood of their use for non-FDA approved indications that cannot be supported based on available evidence.

The P&T Committee reviewed an updated analysis of International Classification of Disease (ICD) 9/10 diagnosis codes for patients starting treatment with modafinil or armodafinil. A total of 67% of all patients have an ICD 9/10 code for an FDA-approved indication, which is a much lower rate of off-label use than in a 2012 MHS analysis.

- *sodium oxybate (Xyrem)*—There are no generic equivalents for sodium oxybate (Xyrem). Due to the significant abuse potential, Xyrem is only available under stringent restricted distribution requirements from a single pharmacy. The current manual PA restricts use to its two FDA-approved indications: excessive sleepiness associated with narcolepsy without cataplexy (which requires a trial of modafinil first) or treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. An analysis of MHS utilization by diagnostic codes suggests continued off-label use of sodium oxybate.

b. BPH Agents: 5-Alpha Reductase Inhibitors (5-ARI) Subclass

Dutasteride (Avodart, generics) and dutasteride/tamsulosin (Jalyn, generics) are NF and non-step-preferred, requiring a trial of finasteride (Proscar, generics) first. The P&T Committee noted that finasteride and dutasteride are highly therapeutically interchangeable for the treatment of BPH, and the combination product Jalyn offers no additional benefit compared to either of the individual components, or finasteride plus tamsulosin.

The weighted average cost per unit for Jalyn was substantially higher than that for finasteride, finasteride plus tamsulosin, or dutasteride plus tamsulosin as individual components. The weighted average cost per unit for generic dutasteride was slightly higher than that for finasteride.

c. RAAs

The nonformulary generic antihypertensives are still not cost effective relative to the generic formulary products. However, several products currently designated as UF and non-step-preferred were considered for UF and step-preferred status, given a number of factors to include the cost difference by points of service.

2. Re-evaluation of NF Generics—UF, PA, Step Therapy, and Implementation Plan

The P&T Committee recommended the following, effective upon signing of the minutes:

a. Returning the following product to UF status (16 for, 0 opposed, 0 abstained, 1 absent): *ADHD/Wakefulness*—armodafinil (Nuvigil, generics)

b. Removing the PA requirements for the following products, with reassessment in one year (12 for, 3 opposed, 0 abstained, 2 absent): *ADHD/Wakefulness*—armodafinil (Nuvigil, generics), modafinil (Provigil, generics)

c. Revising the PA criteria for the following product in new users (16 for, 0 opposed, 0 abstained, 1 absent): *ADHD/Wakefulness*—sodium oxybate (Xyrem). The full criteria are listed below.

d. Returning the following product to the UF, with step therapy requirements and PA criteria remaining unchanged (16 for, 0 opposed, 0 abstained, 1 absent): *BPH Agents*—dutasteride (Avodart, generics)

e. Designating the following products as UF and step-preferred, with pertinent updates made to the PA criteria for the non step-preferred RAAs (16 for, 0 opposed, 0 abstained, 1 absent): *RAAs*—irbesartan (Avapro, generics), irbesartan/HCTZ (Avalide, generics)

PA Criteria: ADHD/Wakefulness—sodium oxybate (Xyrem)

Changes from the November 2017 meeting are in BOLD

Manual PA criteria apply to all new users of Xyrem.

Manual PA Criteria: Coverage of Xyrem is approved if the following criteria are met:

- **The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND**
- **Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND**
- Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.

- Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing **OR**

- Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy **AND**

  - **the patient has history of failure, contraindication, or intolerance of both of the following, modafinil, or armodafinil, AND stimulant- based therapy (amphetamine-based therapy or methylphenidate) AND**

- **Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)**

Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy.

PA expires after 1 year.

PA Renewal criteria: Xyrem will be renewed on a yearly basis if:

- **There is documentation demonstrating the patient has had a reduction in frequency of cataplexy attacks associated with Xyrem therapy OR**
- **There is documentation demonstrating the patient has had a reduction in the symptoms of excessive daytime sleepiness associated with Xyrem therapy AND**

Patient is not receiving a concomitant CNS depressant

3. Physician's Perspective

This is a continuing project where we look at drugs classes reviewed several years ago to see what the costs are for non-formulary products that now have generic equivalents available. We will also take a look at any existing manual PAs or step therapy as part of the process. Any new pertinent clinical information is also summarized.

For the narcolepsy drugs, the price for generic Nuvigil has fallen significantly, and is similar to the cost of generic Provigil. There was some discussion on the Committee as to whether the PAs for Nuvigil and Provigil should be removed, due to the large number of off-label uses. The recommendation was to remove the PAs for both products, but we will monitor the off-label usage

and see if any change is needed in the future. For Xyrem, the original PA was approved in 2009, so updates to the PA criteria were needed to address some safety concerns.

For the other two classes reviewed, BPH and the antihypertensives, the generic prices for dutasteride and irbesartan are now cost effective compared to the previous branded products.

4. **Panel Questions and Comments**

There were no questions or comments from the Panel. The Chair called for a vote on the Re-evaluation of NF Generics – UF, PA, Step Therapy and Implementation Plan.

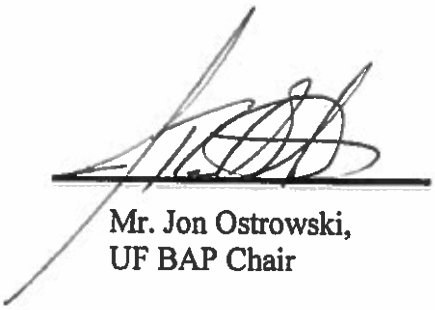
- **Re-evaluation of NF Generics – UF, PA, Step Therapy, and Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Mr. Ostrowski thanks CAPT Norton, the panel, and the audience.

CAPT Norton concludes the meeting.

Meeting Concludes



Mr. Jon Ostrowski,
UF BAP Chair

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 the Panel discussions are listed below for easy reference. The term "BAP" in this summary refers to the "Uniform Formulary Beneficiary Advisory Panel," the group who's meeting in the subject of this report.

- ADHD – Attention Deficit Hyperactivity Disorder
- ANA – Antinuclear Antibodies
- ARI – Alpha Reductase Inhibitors
- BIA – Budget Impact Analysis
- BMI – Body Mass Index
- BPA – Blanket Purchase Agreement
- BPH – Benign Prostatic Hyperplasia
- CEA – Cost-Effectiveness Analysis
- CFR – Code of Federal Regulations
- CMA – Cost-Minimization Analysis
- COPD – Chronic Obstructive Pulmonary Disease
- CrCl – Creatinine Clearance
- CVD – Cardiovasular Disease
- DAAs – Direct Acting Antiviral
- DHA – Defense Health Agency
- FOB – Pharmacy Operations Division
- DR – Delayed Relase
- EPA – Eicosapentaenoic Acid
- ER – Extended Release
- FDA – Food Drug Administration
- GLP1-RAs – Glucagon-Like-1 Receptor Agonist
- GT2 – Genotype 2
- GT3 – Genotype 3
- HAE – Hereditary Angiodema
- HBr – Hydrobromide
- HCTZ- Hydrochloric Thiazide
- HCV DAAs – Hepatitis C Direct Acting Antiviral
- ICD – International Classification of Disease
- IR – Immediate Release
- JAMA – Journal of American Medical Association
- MHS – Military Health System
- MTF – Military Treatment Facility
- NASH – NonAlcoholic Steatohepatitis
- NCCN – National Comprehensive Cancer Network
- NDAA – Natioanl Defense Authorization Act

- NDCs – National Drug Codes
- NF – Non-Formulary
- NSCLC – Non-Small Cell Lung Cancer
- OTC – Over the Counter
- P&T – Pharmacy & Therapeutics
- PA – Prior Authorization
- RAAs – Renin-Andiotensin Antihypertensive Agents
- REMs – Risk Evaluation and Mitigation Strategies
- SC – Subcutaneously
- SELENA modified – Safety of Estrogen in Lupus Erythematosus National Assessment
- SLE – Systemic Lupus Erythematosus
- SR – Sustained Releaser
- SSRI – Serotonin Reuptake Inhibitor
- TIBs – Target Immunomodulatory Biologics
- TNF – Tumor Necrosis Factor
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- USPSTF – U.S. Preventative Service Task Force
- VTE – Venous Thromboembolism