EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel Comments
8 January 2015

RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS—INSULIN DRUGS

1. Miscellaneous Insulin Delivery Device: Valeritas or V-Go.

A. V-Go UF Recommendation:

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** that V-Go be designated Non-Formulary (NF) due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products.

B. V-Go's Prior Authorization (PA) Criteria:

Manual PA criteria were recommended at the August 2014 DoD P&T Committee meeting and implemented on November 14, 2014. The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** clarifying the PA criteria for V-Go.

PA criteria apply to all new users of the V-Go device.

Manual PA criteria:

1. Patient has Type 2 diabetes mellitus
2. Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily
3. Patient does not need less than 2 unit increments of bolus dosing
4. Patient has been maintained on stable basal insulin for at least 3 months (at dosages ranging from 20U to 40U)
5. Patient has been using prandial insulin for at least 3 months

C. V-Go UF and PA Implementation Plan:

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS). Currently there are 55 patients receiving V-Go under the pharmacy benefit.

Summary of Physician Perspective:

The V-Go device is a new method to administer insulin. It is not a substitute for an insulin pump –the V-Go system does not have the capacity to contain the amount of insulin needed for most patients with type 1 diabetes.

There are very few studies available for the product, compared to the large amount of data published with insulin administered by vials or pens, or with a pump. V-Go is targeted primarily for patients with type 2 diabetes as a convenience – so they don't have to inject insulin doses throughout the day. However, the V-go device does require the patient to fill the device daily with insulin.

The P&T Committee reviewed the formulary status of V-Go on several civilian health care plans. The majority of plans do not cover V-Go, and two large health plans considered V-Go as "experimental and investigational, because its effectiveness has not been established or is unproven."

The P&T Committee was unanimous in recommending non-formulary placement for V-go. Additionally, one of the P&T Committee members is an endocrinologist.

PA criteria had been recommended for V-Go at the August 2014 P&T meeting, and at the November meeting the criteria were clarified to state the reasonable doses of insulin required for the device.

Summary of Panel Questions and Comments:

Several Panel members had questions regarding the V-Go insulin delivery device and how it is used. There were also question regarding available data regarding patient compliance and non-compliance due to the patient not injecting the medicine.

The presenter responded by stating that they did ask that question and look through the available data. Because the product is so new there are not studies that discuss whether the device will improve patients' adherence to their insulin therapy.

Without further discussion, the Chair asked for a vote on the Miscellaneous Insulin Delivery Device: Valeritas or V-Go:

A. V-Go's—UF Recommendation:

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

B. V-Go's —PA Criteria:

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

C. V-Go's UF AND PA Implementation Plan:

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS—PULMONARY DRUGS

1. Umeclidinium/Vilanterol (Anoro Ellipta)—UF Recommendations

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** Anoro Ellipta be designated formulary on the UF, based on clinical and cost effectiveness.

Summary of Physician's Perspective:

There are several inhalers available to treat patients with COPD, and many products contain combinations of drugs. Patients with COPD often require multiple medications to control their symptoms, and Anoro Ellipta is unique in that it contains two long-acting bronchodilators in one inhaler. The product is also dosed once daily, which can be a convenience to a patient with a complicated medication regimen.

There are several inhalers for COPD in the pipeline, which are likely to receive FDA approval this year. The P&T Committee will be evaluating these new products once they are launched, and the COPD drug class will likely be reviewed sometime in 2015.

There was no controversy here with the recommendation for Uniform Formulary status.

Summary of Panel Questions and Comment:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation for COPD: Umeclidinium/Vilanterol (Anoro Ellipta)

A. Umeclidinium/Vilanterol (Anoro Ellipta)—UF Recommendations

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS—GLAUCOMA DRUGS:

1. brinzolamide 1%/brimonidine 0.2% Ophthalmic Suspension (Simbrinza)—UF Recommendation

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** Simbrinza be designated with formulary status on the UF, based on clinical and cost effectiveness.

Summary of Physician's Perspective:

The Glaucoma drug class was last reviewed for formulary placement back in February 2007, and there haven't been many new drugs approved since then. Simbrinza is two older products combined into one medication.

Patients with glaucoma frequently need to administer eye drops several times a day. For Simbrinza, three times a day administration is still required. However, Simbrinza has advantages over the other combination eye drops (such as Cosopt and Combigan) in that it doesn't contain a beta blocker. Some patient with significant cardiac problems can have adverse effects from eye drops that contain a beta blocker.

There was no controversy here with the recommendation for Uniform Formulary placement for Simbrinza.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation for brinzolamide 1%/brimonidine 0.2% Ophthalmic Suspension (Simbrinza)

A. brinzolamide 1%/brimonidine 0.2% Ophthalmic Suspension (Simbrinza)—UF Recommendation

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS—OPHTHALMIC NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs):

1. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Recommendation:

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) Prolensa be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products. Currently there are about 8, 500 patients receiving Prolensa in the DoD.

2. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Recommendation:

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS.

Summary of Physician's Perspective:

There are several ocular NSAIDs available on the uniform formulary, including the generic bromfenac formulation that is dosed once daily.

One of the Committee members surveyed several former military providers in the community for their opinions on Prolensa. The majority opinion was that Prolensa didn't offer additional benefits over what is already available.

The Committee recommended non-formulary placement for Prolensa, based on the clinical analysis; the fact that the generic once daily product is on the formulary; and also based on cost effectiveness.

Summary of Panel questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation and Implementation Plan for the Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs):

A. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Recommendation

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

B. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Implementation Plan

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

UNIFORM FORMULARY DRUG CLASS REVIEW—MULTIPLE SCLEROSIS (MS)

1. MULTIPLE SCLEROSIS—UF Recommendation

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** the following:

- UF:
  - Interferon beta-1a SQ or Rebif and Rebif Rebidose
  - Interferon beta-1a IM or Avonex
  - Interferon beta-1b SC or Betaseron
  - Interferon beta-1b SC or Extavia
  - Dalfampridine or Ampyra
  - Dimethyl fumarate or Tecfidera
  - Fingolimod or Gilenya
  - Glatiramer or Copaxone
  - Teriflunomide or Aubagio
- NF: None

2. MULTIPLE SCLEROSIS—PA Criteria

Manual PA criteria recommended in November 2010 and November 2013 currently apply to Gilenya and Tecfidera, respectively. The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** maintaining the current PA criteria for Tecfidera and revising the PA criteria for Gilenya due to recent updates in the package insert for cardiovascular toxicity.

Gilenya's Manual PA criteria:

- A documented diagnosis of relapsing forms of MS
- No current use of a disease-modifying therapy (e.g., interferon 1a or 1b or Copaxone)
- Avoid use in patients with significant cardiac history, including:
  - Patients with a recent history (within the past six months) of class III/IV heart failure (symptoms with moderate activities levels), myocardial infarction (heart attack), unstable angina (chest pain with exertion), stroke, transient ischemic attack (mini stroke), or decompensated (symptomatic) heart failure requiring hospitalization
  - Those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular block or sick sinus syndrome (different types of severe heart rhythm problems), unless they have a functioning pacemaker
  - Patients with a baseline QTc interval ≥500 ms (heart rhythm problems)
  - Those receiving treatment with class Ia or class III antiarrhythmic drugs

3. MULTIPLE SCLEROSIS—UF and PA Implementation Plan

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** an effective date no later than 30 days after signing of the minutes in all POS.

Summary of Physician's Perspective:

All of these products are superior to placebo in treating patients with MS, but it is difficult to determine if one product has better efficacy over another product, since there are few head-to-head trials.

Several MTF neurologists provided their opinion on the MS drugs, and the overall consensus was that new patients are being started on oral therapy, and not an injection. This fact was supported by the results of an analysis of MHS prescribing trends that did confirm that new patients are primarily being started on the oral drugs. Other comments from the neurologists were that patients will stay on a regimen as long as it is working and the patient is "relapse-free". If there are side effects or the patient has a relapse, then the drug therapy will be changed. There was no preference stated for one interferon product over another.

The P&T Committee recommended that all the products be designated with Uniform Formulary status. The Committee recognized that several products are needed on the formulary, due to the complexity of the disease and also because the individual oral products have unique safety issues, which can be very important in determining which drug to use in a patient.

The PA criteria recommendations for Gilenya were due to safety issues, and reflect the information contained in the current package insert.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation, PA Criteria and Implementation Plan for the Multiple Sclerosis (MS) agents:

A. MULTIPLE SCLEROSIS—UF Recommendation

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

B. MULTIPLE SCLEROSIS—PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

C. MULTIPLE SCLEROSIS—UF and PA Implementation Plan

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

UNIFORM FORMULARY DRUG CLASS REVIEW—SELF-MONITORING BLOOD GLUCOSE SYSTEM (SMBGS) TEST STRIPS

1. SMBGS Test Strips—UF Recommendation:

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** the following:

- UF and step-preferred:
  - FreeStyle Lite
  - Precision Xtra

- NF and non-step preferred:

- ACCU-CHEK Aviva Plus
- GLUCOCARD 01-SENSOR
- GLUCOCARD Vital
- CONTOUR NEXT
- FreeStyle InsuLinx
- Nova Max
- TRUEtest
- Prodigy No Coding
- OneTouch Verio
- OneTouch Ultra Blue
- All other test strips listed in the table on page 23 of the Background Document, with the exception of FreeStyle Lite and Precision Xtra

This recommendation includes step therapy, which requires a trial of FreeStyle Lite or Precision Xtra prior to use of a NF test strip. The recommendation requires all current and new users of a non-preferred test strip try FreeStyle Lite or Precision Xtra, or meet the PA criteria for the non-preferred strips.

2. SMBGS Test Strips—PA Criteria

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** manual PA criteria for all new and current users of NF test strips. The manual PA criterion requires a trial of FreeStyle Lite or Precision Xtra prior to the use of a NF test strip.

Manual PA Criteria—A non-preferred test strip is allowed if:

1. Patient is blind/severely visually impaired and requires a test strip used in a talking meter – such as Prodigy Voice, Prodigy AutoCode, Advocate Redicode
2. Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter such as
    - Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump
    - Nova Max strip with Nova Max Link meter for Medtronic pump
    - For Retail Network Only: One Touch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump
    - For Retail Network Only: One Touch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump
3. The patient has a documented physical or mental health disability requiring a special strip or meter. For example, the patient requires ACCU-CHEK Aviva Plus strip due to manual dexterity issues (such as Arthritis Association Seal of Approval)

3. SMBGS Test Strips—UF and PA Implementation Plan

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 120-day implementation period in all POS; and the DHA will send a letter to beneficiaries affected by the UF and PA decisions.

Summary of Physician Perspective:

Because test strips are classified by the FDA as medical devices, rather than as drugs, there were different components for the review than what we usually discuss, including that the candidates had to meet the Federal Government contracting requirements. Additionally, rather than discussing efficacy and safety data, the technical attributes of the test strips were evaluated. The final candidates included 12 test strips, corresponding with 20 different blood glucose meters.

All of the candidate test strips work in meters that require very small amounts of blood, provide results quickly, and do not require manual coding by the patient. Most of the meters do have additional benefits, such as allowing patients to flag meal-time results, and also provide weekly and monthly summaries of results that can be downloaded to a computer.

The Committee did feel that one test strip would be adequate for all patients, even for special populations, such as pediatrics and pregnant women with gestational diabetes.

For the Uniform Formulary recommendation, the vote was unanimous that the Precision Extra and FreestyleLite test strips were the most cost-effective option, and thus were recommended to be the preferred strips in the MHS. The Committee felt that having all the other products as non-preferred and non-formulary would result in the greatest amount of cost-avoidance. The decision also took into account the cost of switching patients to a new test strip and meter.

The Prior Authorization criteria will allow those patients with special needs – such as visually impaired patients, or those on insulin pumps – to receive a non-formulary test strip.

We will work with the pharmaceutical manufacturer to ensure that the decision can be implemented with the least amount of hassle to the patient. Due to the numbers of patients affected by the decision, a 120-day implementation period is recommended.

Summary of Panel Questions and Comments:

The Panel members expressed concerns about the large beneficiary population as well as the age of the beneficiary population affected by this policy change. Approximately 97,000 patients will be affected which is approximately a 50% impact rate. As previously stated, a large number of the patients probably have Type 2 diabetes and are older patients. This could potentially set-up some chronic risks with patients who are not properly using the devices or getting a new strip and trying to use an older device.

They also fear that the discrepancies with the TRICARE Pharmacy benefit and the medical benefit will cause more of an obstacle for the beneficiary and providers to try to overcome. Patient compliance is also a concern. Because the test strips are not universal, the beneficiaries who have devices that don't match the test strips will be required to change both their meter and the strips. Going back to the providers and asking them to switch is going to cause the patient to not monitor their diabetes for a given period of time. Other

concerns are that the patients may incur secondary costs and cause patients to fall out of compliance. The Panel believes that this is a huge impact, huge undertaking and will cause undue consequences.

The Panel also expressed concerns about education and training of the beneficiary population affected especially those beneficiaries who are older and not affiliated with a MTF. The response is as follows and summarizes steps that will be taken during the implementation plan.

To assist with this transition, there are several training opportunities available. Training will be available for the beneficiaries impacted by the change at the military treatment facilities and the retail pharmacies. Per the industry standard, the meters are free. Patients may go to the diabetes clinic at the MTF and receive training from a physician clinic or a certified diabetes educator. All of the companies, included the ones selected for the Uniform Formulary recommendation, are offering extensive training on the internet and DVDs. Due to the confusion with the medical and pharmacy benefit, there is still the potential for a prescriber to prescribe a device that does not match the strips. Again, the hope is the 120 day implementation plan and the training opportunities will be provided adequate time for the providers to know the preferred TRICARE test strip.

The P&T recommended a 120 day implementation period to provide time to train the beneficiary population as well as the providers. Due to the language in the solicitation, patients will not be grandfathered.

There were previous decisions in 1999 and 2008. The Panel asked if the transition went smoothly with the two previous decisions. The response was that overall there are always people who believe that the transition did not go smoothly. We did not hear of any issues with the patients and beneficiaries receiving training on the new meter, swapping their meters, and getting the test strips.

Without further discussion, the Chair called for a vote on the UF Recommendation, PA Criteria, and the Implementation for the SMBGS Test Strips.

A. SMBGS—UF Recommendation

Concur: 4 Non-Concur: 3 Abstain: 0 Absent: 1

Director, DHA:

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

implement in 180 days.

B. SMBGS—PA Criteria

Concur: 4 Non-Concur: 3 Abstain: 0 Absent: 1

Director, DHA:

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

implement in 180 days

C. SMBGS—UF and PA Implementation Plan

Concur: 4 Non-Concur: 3 Abstain: 0 Absent: 1

Director, DHA:

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

implement in 180 days.

Additional Comments:

A. This recommendation has a very large impact on patients. Half of the beneficiaries impacted, who currently have diabetes, would have to make a significant change.

The Panel members requested short break and continued the discussion on the SMBGS. The comments and concerns are summarized in "Panel questions and comments" above

The Panel recommended:

1. Keeping the same vote of 4 concur and 3 non-concur with the following recommendations. (Panel vote is above)
2. The Panel recommended a one (1) year implementation period, and
3. That patients who currently have their meters and test strops be grandfathered for as long as they chose. This criterion applies to newly diagnosed patients and patients who have already changed their test strips for some other reason.

No further comments.

UTILIZATION MANAGEMENT—HEPATITIS C VIRUS (HCV) AGENTS, DIRECT ACTING ANTIVIRALS (DAAs)

1. Ledipasvir/Sofosbuvir (Harvoni's)—PA Criteria

Ledipasvir 90 mg/sofosbuvir 400 mg (Harvoni) is a once daily fixed dose combination tablet that was approved by the FDA in October 2014 for the treatment of HCV genotype 1. It is the first FDA-approved interferon-free regimen indicated to treat HCV genotype 1. Harvoni will be reviewed as a new drug at an upcoming meeting.

PA criteria currently apply to the DAAs. The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 1 absent)** manual PA criteria for new users of Harvoni, consistent with FDA-approved labeling. Prior authorization will expire after 8–24 weeks based on the treatment regimen.

The full PA criteria are as follows:

- New users of Harvoni are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their Harvoni prescriptions.
- Consult the American Association for the Study of Liver disease and Infectious Disease Society of America (AASLD/IDSA) HCV guidelines for the most up-to-date and comprehensive treatment for HCV. This guideline can be found on the internet at www.hcvguidelines.org and will be referred to as the HCV guideline for the remainder of this meeting. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age $\geq$ 18
- Has laboratory evidence of chronic HCV genotype 1 infection
    1. State the HCV genotype and HCV RNA viral load on the PA form
- Harvoni is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with Hepatitis B virus (HBV).

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 8 weeks or 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1 Patient Populations	Treatment Duration
Treatment naïve with or without cirrhosis	8* - 12 weeks

**Consider treatment duration of 8 weeks in treatment-naïve patients without cirrhosis who have a pretreatment HCV RNA less than 6 million IU/mL*

Genotype 1 Patient Populations	Treatment Duration
Treatment experienced** without cirrhosis	12 weeks
Treatment experienced** with cirrhosis	24 weeks

***Treatment-experienced patients who have failed treatment with either (a) peginterferon alfa plus ribavirin or (b) HCV protease inhibitor plus peginterferon alfa plus ribavirin*

2. Simeprevir (Olysio's) PA Criteria

PA criteria were recommended for Olysio at the May 2014 DoD P&T Committee meeting. Olysio received a new FDA indication in November 2014 as a component of an interferon-free combination treatment for chronic HCV genotype 1.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 1 absent)** revising the existing PA criteria for Olysio to include the expanded FDA-approved indication.

The full PA criteria are as follows:

- New users of Olysio are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- The FDA-approved indication of simeprevir + PEG-interferon + ribavirin for 24 to 48 weeks is not recommended for HCV treatment by the AASLD/IDSA. See www.hcvguidelines.org.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their simeprevir prescriptions.
- Consult the AASLD/IDSA HCV guidelines for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age $\geq$ 18
- Has laboratory evidence of chronic HCV genotype 1 infection
- State the HCV genotype and HCV RNA viral load on the PA form
- If HCV genotype 1a, the patient is negative for NS3 Q80K
- polymorphism at baseline

- Simeprevir (Olysio) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with HIV or Hepatitis B virus (HBV).
- Not recommended for monotherapy
- The patient has not previously used a HCV protease inhibitor (boceprevir, telaprevir, or simeprevir)

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 12 weeks or **24** weeks, based on the treatment regimen selected.

Genotype 1 Patient Populations	Treatments	Treatment Duration
Treatment naïve or experienced* without cirrhosis	simeprevir 150 mg once daily sofosbuvir 400 mg once daily	12 weeks
Treatment naïve or experienced* with cirrhosis	simeprevir 150 mg once daily sofosbuvir 400 mg once daily	24 weeks

*Treatment-experienced patients who have failed treatment with peginterferon alfa plus ribavirin but not a HCV protease inhibitor
Prior authorization expires at the end of treatment duration (12–24 weeks)

Summary of Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

Harvoni is the newest drug to treat hepatitis C. PA criteria apply to the other products in the class, including Sovaldi and Olysio. The Harvoni PA criteria reflect the indications and dosing listed in the package insert, and also reflects the guidelines from the AASLD/IDSA professional organizations.

Summary of Panel Questions and Comments:

The typo for the dosage of sofofbuvir is corrected. In the previous handout, the dosage was noted as 300 mg. Sofosbuvir does not come in a 300 mg tablet. The correct dosage is 400 mg.

The full PA criterion states that "patients are encouraged to use the Mail Order Pharmacy or the MTF to fill their prescriptions'. The Panel members asked about the process and if it was a recommendation to the provider.

In response, this is a recommendation to the provider. The PA forms are completed by the provider. Hepatitis is a rapidly expanding field. We want to be in consultation with the Hepatitis expert to get the most up-to-date treatment regimens. That is why we ask them to refer to the guidelines. For us, it would be best for the patient to receive their prescriptions through the Mail Order or the MTF.

Other questions from the Panel member are, in case of Harvoni, for people who are treatment naïve without cirrhosis, does the prior authorization do anything to actively direct the patient to the shorter treatment course of 8 weeks. Do we actually look at the viral load? More specifically, are we allowing the prescriber to make that determination or if the prior authorization dictates the shorter regimen if the patient qualifies.

In response, we do. Part of the initial, you have to break down the genotype because Hepatitis C, Genotype 1 treatment is different than Genotype 2, 3, 4, 5, or 6. You have to write down the Genotype. Typically, you will also have a viral load to confirm that you have Hepatitis C. The general way Hepatitis C is diagnosed is that you do a Hepatitis C antibody that comes back positive. The next step would be to do a viral load as well as the genotype subtyping. We ask for them to write that down on the piece of paper. There are spaces for that on the prior authorization. We are not recommending the 8 weeks. We would prefer the 8 weeks. But if the physician thinks they'd do better 12 weeks, they can continue to do 12 weeks. Prior authorization doesn't dictate. It's for the physician to consider. We would prefer it and obviously the shorter duration would be better. If the provider thinks it's longer, he doesn't have to justify anything. He just needs to write it down.

The Panel member commented that he would actually enforce that a little more strictly, but I defer to the P&T Committee.

In response, the data isn't as robust as the 12 weeks. There are other clinical factors in the treatment of Hepatitis C that would people in a higher risk group.

A. Ledipasvir/Sofosbuvir (Harvoni's)—PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

B. Simeprevir (Olysio's)—PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

UTILIZATION MANAGEMENT—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBs)

1. Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel's) PA Criteria

The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class. Recently, Humira received FDA approval for pediatric Crohn's disease (inflammation and irritation of the GI tract) in patients as young as six years and juvenile idiopathic arthritis (JIA – is pain, swelling and joint stiffness in childern) in patients as young as four years; Otezla received FDA approval for plaque psoriasis (large flaky skin rash). PA criteria were updated for Humira and Otezla to reflect their new respective FDA indications. Accordingly, step therapy criteria for Enbrel was also revised since Enbrel and Humira are now indicated for the same age range in patients with JIA.

The P&T Committee recommended (**17 for, 0 opposed, 0 abstained, 1 absent**) revised manual and step therapy PA criteria for Humira and Otezla, consistent with the new FDA-approved product labeling, and an update to the PA criteria for Enbrel since Humira is now indicated for JIA.

The full PA criteria are as follows:

A. <u>Humira</u>

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate
- Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade
- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

(the addition)

Pediatric patients with:

- **Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric patients: 2–17 years)**

- **Moderate to severely active Crohn's disease (≥ 6 years)** who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate

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

B. **Otezla**

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

  AND

- **Manual PA criteria:**

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

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

    AND

    Coverage approved for patients ≥ 18 years with:

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

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

C. **Enbrel**

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

during the previous 180 days.

AND

Manual PA criteria:

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

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative (Enbrel is prescribed for a patient with hepatitis C virus)

AND

Coverage approved for patients ≥ 18 years with:

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

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

- Moderate to severe active polyarticular Juvenile Idiopathic Arthritis

Coverage is NOT provided for concomitant use with other TIBs including, but not limited to Humira, Kineret, Cimzia, Enbrel , Simponi, Remicade, Orencia, Actemra, Xeljanz, Stelara, Otezla, or Rituxan.

Summary of Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

For the TIBs, all the products have PA criteria. This class was reviewed at the August 2014 P&T meeting, and the PA criteria recommended for Humira and Otezla reflect new indications approved by the FDA, and also a corresponding update to the Enbrel step therapy criteria

Summary of Panel Questions and Comment:

The Panel member states, "coverage is NOT provided for concomitant use with other TIBS…" Is this a drug/drug interaction that is being listed there? Or why is that listed here vs in other areas it's never been listed?

It's in the FDA indications that it's not covered. The main reason is that when you combine them, the efficacy does not increase. The risk of infections and side effects are remarkably increased. It's a safety issue and a clinical warning. That is why it's put on the PA.

Other concerns expressed by the Panel dealt with the process for beneficiaries being able to switch their medication. For instance, if a patient tries one of the medications, has an allergic reaction, and then needs to switch over to another medication; will "this paragraph" prohibit them from getting that medication that they now need?

No, clinically, you can switch them. You just can't use them together. As long as you stop your med then start the next one the next week and that does not seem to have a problem, there is literature to back that up.

Are there specific criteria that a provider will need to submit in order to justify "moderate or severe"? How does a provider determine if their patient has moderate or severe? Is there a process or system they are being asked to follow?

The provider is not required to provide documentation. The provider just has to provide it's a moderate rheumatoid arthritis. Typically, it would be the number of joints that are involved.

Without further discussion, the Chair called for a vote on the PA Criteria for Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel).

A. Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel) PA Criteria:

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

Notes: Correction to PA Criteria for Otezla noted and corrected on. Tackitt received written comments of Dr. Downs corrected statements on Otezla. It's been read into the record.

UTILIZATION MANAGEMEN—PROSTATE CANCER DRUGS

1. **Enzalutamide (Xtandi's)—PA Criteria**

Xtandi is an androgen receptor inhibitor that prolongs survival of metastatic castration-resistant prostate cancer. Manual PA criteria were recommended at the November 2012 P&T Committee meeting. The package insert for Xtandi was updated to state that prior treatment with docetaxel is no longer required.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 1 absent)** an update to the manual PA criteria for Xtandi, consistent with the product's labeling for treatment of metastatic castration-resistant prostate cancer.

The full PA criteria are as follows:

Coverage is approved if:

- There is a documented diagnosis of metastatic castration-resistant prostate cancer

  There is no expiration date for the PA. The drugs used to treat prostate cancer will be reviewed at the February 2015 P&T Committee meeting.

Summary of Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

PA criteria were revised for the prostate cancer drug Xtandi, to reflect that chemotherapy is no longer required, based on a recent update to the package insert.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the PA Criteria for Enzalutamide (Xtandi's)

A. Enzalutamide (Xtandi's)—PA Criteria:

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

UTILIZATION MANAGEMENT—NON-INSULIN DIABETES MELLITUS DRUGS: GLP1RAs

1. Exenatide Once Weekly Pen (Bydureon Pen)—PA Criteria

Bydureon is now available in a pre-filled pen, in addition to the original vial formulation. The manufacturer states that they do not intend to discontinue the original vial formulation. Both products are dosed once weekly. However, the cost of the Bydureon pen formulation is significantly higher than the Bydureon vials despite having the same dosing and FDA-approved indications. Exenatide (Byetta) is also available in a pen formulation that is dosed twice daily. Manual PA criteria were recommended for the Bydureon pen due to the cost and because other exenatide products (Bydureon vials and Byetta) are available on the UF. The GLP1RA Drug Subclass, including the Bydureon pen formulation, is scheduled for review at an upcoming meeting.

The P&T Committee recommended **(16 for, 1 opposed, 0 abstained, 1 absent)** manual PA criteria for the Bydureon pen, requiring use of Bydureon vials first. Additionally, a trial of metformin or a sulfonylurea is also required, consistent with the PA criteria for other GLP1RAs.

The full PA criteria are as follows:

New GLP1RA users are required to try metformin or a sulfonylurea before receiving Byetta, Bydureon, or Victoza.

Automated PA criteria:

The patient has received a prescription for metformin or sulfonylurea at any MHS pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days, AND

Manual PA criteria:

if automated criteria are not met:

Byetta, Bydureon, or Victoza is approved (e.g., trial of metformin or sulfonylurea is NOT required) if:

1) The patient has a confirmed diagnosis of Type 2 Diabetes Mellitus
2) The patient has experienced any of the following adverse events while receiving metformin: impaired renal function that precludes treatment with metformin or history of lactic acidosis.
3) The patient has experienced the following adverse event while receiving a SU: hypoglycemia requiring medical treatment.
4) The patient has a contraindication to both metformin and a SU.
5) The patient has had an inadequate response to metformin and a SU.

(new addition)

6) **Also for exenatide once weekly (Bydureon pen)**
   - **Coverage approved if patient has first tried Bydureon 2mg vial/cartridge first AND**
   - **Patient has dexterity issues and cannot assemble the Bydureon vial/cartridge**

Summary of Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date. The only case where there was not a unanimous vote was the PA criteria recommendation for the new Bydureon pen formulation. The one dissenting vote was due to the feeling that the PA criteria would not deter use of the pen over the vial formulation.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the PA Criteria for Exenatide Once Weekly Pen (Bydureon Pen)

A. Exenatide Once Weekly Pen (Bydureon Pen)—PA Criteria:

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

UTILIZATION MANAGEMENT—COMPOUND PRESCRIPTIONS

1. Compound Prescriptions'—PA Criteria

The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant and increasing, and compounded medications have a high potential for inappropriate use. From June 2013 through May 2014, 140,000 beneficiaries filled 360,000 compounded prescriptions that totaled over $410 million in expenditures at the Retail Network and Mail Order POS. In an effort to decrease inappropriate use and ensure safety for the beneficiaries, PA criteria were proposed.

The P&T Committee recommended **(16 for, 0 opposed, 0 abstained, 2 absent)** manual PA criteria for all new and current users of compounds. Coverage will be approved if the prescriber provides the following information listed below and implementation of the PA will occur when a final recommendation is made.

1. What is the diagnosis?
2. Has the patient tried commercially available products for the diagnosis provided? Please state all products tried.
3. Is there a current national drug shortage of an otherwise commercially available product?
4. What is the proposed duration of therapy?

AND

The patient meets the following criteria:

a) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market. (If True, proceed to (2); if False, claim rejects.)
b) Each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided. (If True, proceed to (3); if False, claim rejects.)
c) An FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication. (If True, Approved; if False, claim rejects.)

Summary of Physician's Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

For the compounds, the Committee did recommend unanimously to have PA criteria, to ensure that the compounded products are used in the most appropriate patients.

Summary of Panel Questions and Comments:

The Panel members expressed concerns regarding the lack of or short implementation period for the compounded medication with no plan or clear plan to notify the beneficiaries of the changes. They asked for statistics on beneficiaries that had been potentially harmed by compounded medications. Additional clarification was requested regarding the phrase "inappropriate use". Per the Panel member the term is vague. Also, did the P&T committee have any evidence that this was occurring within the beneficiary population that medications were being prescribed that was not consistent with a diagnosis?

The implementation date is at the discretion of the Director, DHA. It may occur any time after the minutes are signed. There was not a plan outlined to notify the affected beneficiary regarding the change in policy. In response to the question about inappropriate use, an example of appropriate use would be an FDA indication or that there is evidence based reason for using the medication for a disease. Appropriate treatment is defines as a "reflecting a linkage between a diagnosis and evidence-based treatment for that diagnosis". There is no data or statistics available to track the beneficiary population using compounded medication for a diagnosis inconsistent with the prescription.

Clarification was requested for some of the questions raised in the written statements provided by Richie's Specialty Pharmacy, PCCA, and Keystone Pharmacy, LLC. They asked if (1) off-label use was restricted with the change in policy; (2) does the policy change impact all compounded medications or the ones being made through bulk drug substances; (3) the number of beneficiaries that filled prescriptions and expectation how many the number will be reduced by if the policy is in place.

The PA criterion is for FDA approved medications and the off-labeling will not go through with this PA. The other compounded agents should go through the PA process without a problem. No, we don't have that number. Compounding is a very diverse group. The PA criterion is an attempt to take the first group and apply it to a single agent and try to make sure it is used appropriately and safe. This is idea for the PA criteria. I don't have numbers on it, but it would end up decreasing that number. We do know what the utilization was from that time period last year. Per the data in the presentation, from June 2013 through May 2014, 140,000 beneficiaries filled 360,000 compounded prescriptions. (see page 32)

Clarification was also requested about the manual PA criteria. What information was required and what information factored into the decision for approval of the PA.

The prescriber must provide the (1) the diagnosis; 2) if the patient has tried commercially available products for the diagnosis provided and state all products tried; (3) if there a current national drug shortage of an otherwise commercially available product; and (4) what is the proposed duration of therapy? The patient must meet the criteria summarized in a-c on page 33. It factors into the decision for approval of the PA. Also, please provide clarification regarding the claims process. Per the guidance in a, b, and c, "(If True, proceed to (2); if False, claim rejects.) (see page 33) So, the claim rejects upon presenting it at the point of sale because it needs a PA. Then, if it meets the criteria, it will be approved.

The Panel members asked how is the civilian sector, the Veterans Administration (VA) and Public Health Service handling compounded medications. Does the cover compounded medications?

A lot of public health plans do not cover compounded medications. According to the news media, other civilian health plans are implementing PAs for compounds. The VA does not have a retail pharmacy benefit. Their benefit only applies to mail order prescriptions or individual facilities. The difference in the TRICARE Pharmacy Benefit and the VA is that TRICARE does allow the retail pharmacy benefit. This is where the majority of the

prescriptions are being filled. The VA representation on the P&T Committee commented during the P&T committee meetings that they are using the same process but they have a specific list of covered compound medications. To our understanding, their approach is that they will provide "these specific compounds," period.

Without further discussion, the Chair called for a vote on the PA Criteria for Compounded Prescriptions

A. Compound Prescriptions'—PA Criteria:

Concur: 2 Non-Concur: 5 Abstain: 0 Absent: 1

Director, DHA:

☒ These comments were taken under consideration prior to my final decision.
Disapprove the P&T Committee recommendation pending consideration of the BAP recommendations and comments.

Additional comments and recommendations:

A. This is a very complex issue. I think the P&T Committee would benefit from some more in depth looking into this regarding what is currently being done in other parts of the industry as well as any sort of evidence on doing a study on persons who are currently in getting compounded medications to see if there are any adverse effects. Looking at the evidence that is already there is what I would recommend the P&T committee to do.

B. Maybe looking at how the costs are calculated at individual pharmacies. When you look at 410 million dollars, there are probably some ways to reduce that cost. The PA criteria, in my mind, are more like a hammer in trying to fix the problem. We need to be more judicious in what we really want to do to fix the problem.

C. I feel the lack of criteria for the implementation time as well as the communication of the beneficiaries impacts the decision here.

D. I support the P&T recommendation. It's ultimately in the beneficiaries best interest whenever possible that their medication is FDA approved and has gone through good manufacturing process. I would like this to be accompanied by additional notification to the beneficiaries.

There were no further comments from the panel.

Brief Listing of Acronyms Used in This Summary

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

- AASLD – American Association for the Study of Liver Disease
- ARR – Annualized Relapse Rate
- BAP – Beneficiary Advisory Panel
- BIA – Budget Impact Analysis
- CADTH – Canadian Agency for Drugs in Technology and Health
- CEA – Cost-Effectiveness Analysis
- CFR – Code of Federal Regulations
- CMA – Cost Minimization Analysis
- COPD – Chronic Obstructive Pulmonary Disease
- DERP – Drug Effectiveness Review Project
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DoD – Department of Defense
- FACA – Federal Advisory Committee Act
- FDA – Federal Drug Adminstration
- GLP1RA – Glucagon-Like Peptide-1 Receptor Agonists
- HBV – Hepatitis B Virus
- HCV – Hepatitis C Virus
- IDSA – Infectious Disease Society of America
- ISO – International Organization of Standardization
- LABA – Long-Acting Beta Agonist
- LAMA – Long-Acting Muscarinic Agent
- MHS – Military Health System
- MS – Multiple Sclerosis
- NDAA – National Defense Authorization Act
- NF – Non-Formulary
- NSAID – Non-Steroid Anti-Inflammatory Drug
- P&T – DoD Pharmacy & Therapeutic Committee
- PA – Prior Authoriztion
- PEG - Pegylated
- POS – Point of Sale
- RNA – Genetic Material
- SC - Subcutaneous
- SMBGS – Self-Monitoring Blood Glucose System
- SU - Sulfonylurea

- TIB – Targeted Immunomodulatory Biologics
- TIW – Three times a week
- TNF – Tumor Necrosis Factor
- TRICARE – Military Health Care System
- U - Units
- USC – United States Code
- V-GO - Veleritas

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January 2, 2015

Colonel J. Michael Spilker, DFO, Uniform
Formulary Beneficiary Advisory Panel
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

Delivered Via Email

Dear Colonel Spilker:

Please see my attached comments regarding the upcoming Beneficiary Advisory Panel ("BAP") meeting scheduled January 8, 2015.

Please share with members of the BAP and any other interested parties. Should you or any interested party have any questions that I might be of assistance answering, please feel free to contact me via my direct line (936) 588-5601, my mobile (936) 520-3202, or email at richie@richiespharmacy.com.

Very truly yours,

Richie Ray, R.Ph.
Pharmacist-In-Charge
President / CEO

Attachment

Information paper: Continued access to compounded medications for TRICARE beneficiaries

Background:

Since mid-June 2013, TRICARE has been reviewing its' position concerning coverage of compounded drug products prepared from bulk chemicals. Section 704 of the National Defense Authorization Act for Fiscal Year 2015 ("2015 NDAA"), executed in late 2014, provides flexibility for TRICARE to provide provisional coverage of emerging services and supplies (http://armedservices.house.gov/index.cfm/files/serve?File_id=926D63B6-5150-49EC-99EF-A59B9882526S).

In perceived stark contrast to this legislation, the recommendation of TRICARE's Pharmacy and Therapeutics Committee ("PTC") presented at the January 8, 2015 Beneficiary Advisory Panel meeting is to implement a manual Prior Authorization ("PA") process for all compounded drugs (http://www.tricare.mil/tma/pharmacy/BAP/Background%20Information_122214.pdf). Under the proposed PA process, coverage of a compounded drug will be approved if the prescriber provides the following information:

1. What is the diagnosis?
2. Has the patient tried commercially available products for the diagnosis provided? Please state all products tried.
3. Is there a current national drug shortage of an otherwise commercially available product?
4. What is the proposed duration of therapy?

AND the following criteria are also met:

a) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market. (If True, proceed to (2); if False, claim rejects.)
b) Each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided. (If True, proceed to (3); if False, claim rejects.)
c) An FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication. (If True, Approved; if False, claim rejects.)

Discussion:

Although the PA process proposed by the PTC appears to allow compounding from bulk chemicals[1], it is nevertheless very problematic for several reasons. First, the PA process applies to all compounded drugs, not just those medications compounded from a bulk chemical. Since

[1] If stated criteria (a) requires that each active ingredient derive from a commercially-available FDA-approved drug instead of a bulk drug powder produced in an FDA-registered facility, the provision that "the drugs have not been withdrawn for safety reasons" would be superfluous.

TRICARE has expressed concern only about compounding from bulk chemicals, why should the PA process be applied to other compounded medications as well? The PA process is a manual process, which results in increased costs and time delay, both of which restrict access to compounded drugs.

Second, the coverage criteria that "each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided" prohibits compounding a medication for ANY off-label use determined to be appropriate by the prescribing physician, and regardless of whether such use is supported by published clinical studies. Frequently, FDA-approved drugs are prescribed for diagnoses not included in the approved labeling for the drug. Such "off-label" prescribing and dispensing is not prohibited by federal or state law. This criteria imposes a restriction on compounded drugs that is not even imposed on FDA-approved drugs. Given that the primary purpose of compounded drugs is to provide medication to patients that cannot be, or have not been, effectively treated by FDA-approved drugs, it is unreasonable to impose such a limitation.

Third, the criteria that a compounded drug can only be provided if an FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication is also unduly restrictive. While it is true that most compounded drugs are prescribed and prepared for these reasons, it is not true that ALL compounded drugs meet these criteria. For example, compounded topical pain creams are frequently prescribed to avoid the systemic side-effects produced by oral opiates, including the potential for addiction to such drugs. This enables the patient to function and continue to work while receiving effective pain treatment. Such a situation does not clearly meet the stated criteria. Additionally, it is unclear how the criteria described in this paragraph will be evaluated by the PA reviewer since the prescriber is not asked to provide any information concerning these factors. Rather than listing specific criteria that must be met, the PA process should simply require that information be provided concerning the reason(s) that the prescriber has determined that a compounded drug is needed for the patient.

Fourth, despite the 2015 NDAA clear conduit to provide coverage of compounded drugs and TRICARE's self-proclaimed "most robust coverage" for the men and women who serve the United States, this PA process would make compounded drug coverage for TRICARE beneficiaries the most restrictive of any insurance plan throughout the entire country. Such a position is clearly contrary to the congressional intent expressed in Section 794 of the NDAA.

Conclusion:

Compounded medications play an important role in the health care industry. Compounding gives prescribers the ability to treat their patients' unique medical needs. Also, compounded medications fill in the gaps where commercial drugs fail to treat individuals. As a result, thousands of TRICARE beneficiaries currently rely on compounded medications to meet their individual needs that are not met by commercially available products. According to the information provided for the January 8, 2015 Beneficiary Advisory Panel meeting, approximately 140,000 TRICARE beneficiaries utilized compounded drugs from June 2013 to May 2014.

If TRICARE takes any action to deny, restrict, remove, or cancel this valuable component of its drug benefit, a significant number of military beneficiaries will be unable to obtain medications prescribed specifically for them by their treating physicians. As a result, patient health and quality of life could suffer as financial limitations on the commercial market will certainly prevent many individuals from filling their prescriptions as an out-of-pocket claim.

TRICARE is certainly concerned about the health and safety of its beneficiaries, and it has been demonstrated that compounded medications are of benefit to a large number of those beneficiaries. In response to pharmacy compounding safety concerns, both the FDA and state Boards of Pharmacy have implemented additional regulations. TRICARE has never claimed that medications compounded in accordance with state and FDA regulations actually pose a danger to recipients, nor are we aware of any empirical evidence demonstrating such a danger.

Our nation's heroes and their families deserve nothing less than our nation's best, so we must all strive to ensure their access to all necessary treatments and medications. TRICARE was created to ensure that our nation provides superior health support to military members and their families. Continued access to all compounded medications is critical to meet the health care needs of this population, such as a compounded medication to lower the incidence of respiratory infections or to treat invasive skin infections, burns, or even extreme circulatory issues that could potentially result in amputation if not treated appropriately.

We believe that the PA process recommended by the PTC is overly restrictive and must be reviewed and thoroughly evaluated with respect to its impact on TRICARE beneficiaries. Evidence-based compounding is part of the treatment regimen for tens of thousands of TRICARE beneficiaries, and it is essential that DOD conduct a more comprehensive analysis. We ask that you contact the DOD and request a delay in the implementation of this proposed policy change and that DOD initiate a study that examines beneficiary impact, possible alternative cost containment measures, and pharmacy best practices related to provision of compounded prescription drugs.

Comments to be submitted to the Federal Advisory Committee of Uniform Formulary Beneficiary Advisory Panel

To:
Col. J. Michael Spilker, DFO, Uniform
Formulary Beneficiary Advisory Panel
700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

Dear Col. Spilker,

Please find the attached comments to be submitted to be part of the record for the January 8, 2015 meeting of the Uniform Formulary Beneficiary Advisory Panel, We are interested in a couple of topics slated to be discussed on the agenda.

We plan on being in attendance at the meeting but wanted to make sure that the panel had a chance to review several of our concerns ahead of the meeting.

We look forward to participating in the meeting and make ourselves available to you and your staff should you have any questions regarding the items discussed in our comments.

Thank you in advance for the consideration of our comments,

Aaron R. Lopez, JD, FCLS
Senior Director Public Affairs

About PCCA
PCCA is an independent compounding pharmacy's complete resource for fine chemicals, devices, equipment, training and support. PCCA is the leader in US providing products, services and support to almost 4,000 pharmacist members throughout the United States, Canada, Australia and the United Kingdom. Serving compounding pharmacists since 1981, PCCA is headquartered in Houston, Texas. For more information, visit pccarx.com.

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Tricare P&T Committee Recommendations Impact Quality and Limit Access to Compounded Medications for Beneficiaries

Overview

PCCA is deeply concerned about the unintended consequences of the Department of Defense's Pharmacy and Therapeutics (P&T) Committee's recommendation to discontinue coverage of compounded medications prepared from bulk drug substances. The Committee has also recommended a rigorous Prior Authorization (PA) process for compounded medications, with one of the criteria for payment being that the active ingredient(s) must be "indicated by the FDA to treat the diagnosis provided." This is virtually impossible to satisfy and will limit access to compounded medications -- prescribed by physicians -- to our service members.

The Issues

- While this recommendation is likely rooted in a desire to achieve maximum cost containment, there are potentially serious unintended consequences that will negatively impact military beneficiaries.

- Since the FDA does NOT approve pure active pharmaceutical ingredients, but rather finished products for a specific indication, the only way to meet this criterion is to utilize finished FDA approved products as the starting material for a compounded preparation. While this may sound like a good idea, it actually presents physicochemical issues that impact quality & accuracy. It is more exacting to build a compounded preparation from pure active pharmaceutical ingredients (bulk drug substances) or, in layman terms, "from scratch."

- Finished FDA approved products contain excipients (fillers, binders, etc.) that may not be compatible with other desirable ingredients in the compounded preparation, or may affect the overall stability of the preparation. Some patients may also have sensitivities or allergies to these excipients and dyes.

- Additionally, finished FDA approved products have an allowable range of variance for active ingredient concentrations within the product, generally ± 10% of labeled potency. Thus, a pharmacist would be starting from a relative unknown. It is more accurate to make a compounded preparation from pure starting materials that can be weighed and measured precisely.

- FDA approved products, especially in pain management, are often prescribed for off-label uses. The requirement for compounded preparations, even if utilizing finished FDA approved products as starting ingredients, to match the active ingredient(s) with an approved indication is unprecedented, and creates a double standard when compared to non-compounded prescriptions. Also, because systems are not currently in place for all prescribers and pharmacies to consistently collect and report this information, this requirement would certainly

cause a lot of issues and can negatively impact access and "troop readiness," which is a primary focus for DOD and MHS leadership.

- Compounded medications serve a valuable medical need by providing patients and their practitioners with a therapeutic alternative when manufactured drugs cannot satisfy clinical objectives and no alternative therapies exist. Examples include complex pain syndromes or wounds associated with combat injuries.

- If TRICARE initiates a requirement to only pay for compounds made from finished FDA approved products, and that these products have an indication that matches the patient's diagnosis, many military beneficiaries will be forced to make difficult decisions about whether to pay for these products out of pocket and incur financial hardship or to forgo a reasonable and necessary treatment when no viable alternative exists.

Discussion

- If cost containment is the objective, there are less disruptive ways to achieve cost-savings while preserving beneficiary access to compounded drug products. Instead of instituting an onerous PA process that is virtually impossible to satisfy, TRICARE could reduce pharmacy reimbursement for compounded medications by utilizing reimbursement schedules similar to those in commercial markets. With this approach, the compounded medications would continue to be covered, made in a manner that is appropriate, but reimbursed at a lower rate. Cost savings to DOD could be significant.

- Only paying for compounded preparations utilizing FDA approved finished products as a starting point reduces overall quality of the compound, as described above. In fact, the United States Pharmacopeia (USP)[1], in chapter <795>, states that[2]: "A United States Pharmacopeia (USP), National Formulary (NF), or Food Chemicals Codex (FCC) *substance* is the recommended source of ingredients for compounding all preparations." It goes on to describe points of consideration when using manufactured products as a starting material. It states: "When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components." The expert committee that wrote this chapter recognized the potential challenges of working with finished products as a starting point.

- The PA process currently being recommended by the P&T committee also states that[3]: "a) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market."

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[1] The USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries. http://www.usp.org/about-usp

[2] http://www.usp.org/sites/default/files/usp_pdf/EN/gc795.pdf

[3] http://www.tricare.mil/tma/pharmacy/BAP/Background%20Information_122214.pdf

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
January 08, 2015
Washington, D.C.

Present Panel Members

- Robert Duane Tackitt, the Association of Military Surgeons US - Chairperson
- Michael Anderson, United Healthcare
- Theresa Buchanan, the National Military Family Association
- Sandra Delgado, Humana
- Bryan Hammons, Express Scripts, Inc.
- Katherine O'Neill-Tracy, the Military Office Association of America
- John Wagoner – HealthNet Federal Services

Absent:

- Mr. Robert Lewis, Chief Warrant and Warrant Officers Association

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. Colonel Mike Spilker called the proceedings to order at 9:00 A.M. The Panel convened to review and comment on the therapeutic drug class recommendations resulting from the November 19 & 20 Department of Defense (DoD) Pharmacy and Therapeutics Committee meeting held in San Antonio, TX.

Agenda

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

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

  - Designated Newly Approved Drugs
    - Insulin Drugs: Miscellaneous Insulin Devices – V-Go
    - Pulmonary Drugs: Chronic Obstructive Pulmonary Disease – umeclidinium/vilanterol inhaler (Anoro Ellipta)
    - Glaucoma Drugs – brinzolamide 1% brimodidine 0.2% ophthalmic suspension (Simbrinza)
    - Ophthalmic Non-Steroid Anti-Inflammatory Drugs (NSAIDs) – Prolensa

  - Drug Class Reviews:
    - Multiple Sclerosis Drugs (MS)
    - Self-Monitoring Blood Glucose System (SMBGS) Test Strips

- Utilization Management Issues
  - Prior Authorization Criteria
    - Hepatitis C Virus Drugs: Direct Acting Antivirals – ledipasvir/sofosbuvir (Harvoni) and simeprevir (Olysio)
    - Targeted Immunomodulatory Biologics (TIBs) – adalimumab (Humira), apremilast (Otezla), and etanercept (Enbrel)
    - Prostate Cancer Drugs – enzalutamide (Xtandi)
    - Non-Insulin Diabetes Mellitus Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) – exenatide once weekly pen formulation (Bydureon pen)
    - Compounded Prescriptions

- Panel Discussions

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

Opening Remarks

Col Mike Spilker introduced himself as the Designated Federal Officer for the Uniform Formulary Beneficiary Advisory Panel. The panel convened to comment on the recommendations of the DoD P&T Committee meeting, which occurred on November 19 & 20, 2014.

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

In addition, 10 U.S.C. Section 1074g, subsection c, also requires the Secretary to establish a UF Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. Comments of the panel must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF.

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

The duties of the 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 subsequent recommended 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 prepare comments for 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, Colonel Spilker said the role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the department appreciates that the BAP may be interested in the drug class selected for review, drugs recommended for the basic core formulary (BCF) or specific pricing data, these topics do not fall under the purview of the BAP.

The P&T Committee met for approximately 12 hours conducting it's review of the drug class recommendations 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 will be 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.
- Audience participation is limited to private citizens who signed up to address the Panel.
- Members of the Pharmacy Operations 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.

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

Written statements were received prior to the meeting from the following and distributed to the Panel for consideration:

- Mr. Richie Ray, R.PH of Richie's Specialty Pharmacy
- Mr. Aaron R Lopez of Professional Compounding Centers of America
- Mr. Jeffrey Clark of Keystone Pharmacy, LLC

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

Chairman's Opening Remarks

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

DRUG CLASS REVIEW PRESENTATION:

(PEC Script – CAPT Downs)

Good morning. I am CAPT Walter Downs, Chief 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 comment on the recommendations made by the P&T Committee. Also joining us from the Formulary Management Branch today is Dr. Angela Allerman, a clinical pharmacist and Deputy Chief of the P&T Operations; MAJ Kevin Ridderhoff, Deputy Chief of the Formulary Management Branch; Lt Col Ann McManis, Deputy Chief of the Purchase Operations Branch; CAPT Ed Norton, Deputy Chief of Clinical Utilization Branch and LT Kendra Jenkins, Purchase Operations Branch. I would also like to recognize Mr. Paul Hutter, Associate Deputy General Counsel for the DHA.

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

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

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

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

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

3) The DoD P&T Committee's Uniform Formulary recommendation is based upon its collective professional judgment when considering the analyses from both the relative clinical- and relative cost-effectiveness evaluations. The Committee reviewed

   a. 1 newly approved insulin delivery device – Valeritas or V-Go
   b. 3 newly approved drugs. They are - umeclidinium / vilanterol combination inhaler (Anoro Ellipa) from the chronic obstructive pulmonary disease (COPD) drug class; -brinzolamide 1% / brimonidine 0.2% ophthalmic suspension (Simbrenza) from the glaucoma drug class; -and bromfenac 0.07% ophthalmic solution (Prolensa) from the ophthalmic non-steroidal anti-inflammatory (NSAIDs) drug class.
   c. Finally, the P&T Committee reviewed 2 Drug Classes: Multiple Sclerosis (MS) and Self-Monitoring Blood Glucose Test Strips

   We will also discuss Prior Authorizations for:

   a. 2 Hepatitis C direct agent agents: ledipasvir - sofosbuvir fixed dose combination (Harvoni) and simeprevir (Olysio);
   b. 3 targeted immunomodulatory biologic agents (TIBs): adalimumab (Humira), apremilast (Otezla) and etanercept (Enbrel) to reflect update FDA indications;
   c. enzalutamide (Xtandi) an oral prostate cancer drug;
   d. exenatide pen (Bydureon Pen), a non-insulin diabetes mellitus drug, glucagon-like peptide-1 receptor agonist (GLP1RA) subclass;
   e. and finally a prior authorization for compound prescriptions

4) There were no NDAA Section 703 drugs reviewed at this meeting.

5) 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.

We have given you a handout that includes the Uniform Formulary recommendations for all the drugs discussed today; these are found on pages 2 through 5. We will be using trade names as much as possible, so you can refer to your handout throughout the presentation.

I. RECENTLY APPROVED U.S. FDA AGENTS- Miscellaneous Insulin Delivery Device: Valeritas or V-GO

P &T Comments

(Dr. Allerman)

A. **Miscellaneous Insulin Delivery Device: Valeritas or V-Go. The Relative Clinical Effectiveness and Conclusion is as follows:**

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

The advantages of using V-Go include convenience for the patient who desires increased control over their blood glucose levels and elimination of the need for multiple daily insulin injections. Compared to multiple insulin injections, V-Go may reduce prandial glycemic excursions.

There are no randomized controlled trials using the V-Go insulin delivery device compared to usual care with basal or basal/bolus insulin dosing using pens or vials. Limitations of the V-Go studies include small sample sizes (<140 patients enrolled), varied efficacy endpoints, short trial duration, and lack of published studies. Another limitation is that reports of patients requiring overall reduced total daily insulin doses was based on subjective patient-reported data and not on objective endpoints. Additionally, the discontinuation rates in the V-Go studies were high. Although the V-Go studies reported improvements in hemoglobin A1c- lowering, it is difficult to attribute those improvements to the V-Go device due to the lack of control groups and limitations in study design. Long-term data on whether the V-Go device improves patient adherence is lacking.

The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that the V-Go delivery device offers patient convenience because multiple daily insulin injections are not needed; however, it offers no clinically compelling advantages over existing UF insulin agents administered with pens or vials.

B. **V-Go's Relative Cost-Effectiveness Analysis and Conclusion:**

Cost-minimization analysis (CMA) was performed. The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** that the CMA showed V-Go was more costly than other combinations of basal/bolus insulin (i.e., Lantus/Novolog) that are currently on the UF.

C. **V-Go UF Recommendation**:

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** that V-Go be designated Non-Formulary (NF) due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products.

D. V-Go's Prior Authorization (PA) Criteria:

Manual PA criteria were recommended at the August 2014 DoD P&T Committee meeting and implemented on November 14, 2014. The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** clarifying the PA criteria for V-Go.

PA criteria apply to all new users of the V-Go device.

Manual PA criteria:

1. Patient has Type 2 diabetes mellitus
2. Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily
3. Patient does not need less than 2 unit increments of bolus dosing
4. Patient has been maintained on stable basal insulin for at least 3 months (at dosages ranging from 20U to 40U)
5. Patient has been using prandial insulin for at least 3 months

E. V-Go UF and PA Implementation Plan:

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS). Currently there are 55 patients receiving V-Go under the pharmacy benefit.

Physician Perspective:

The V-Go device is a new method to administer insulin. It is not a substitute for an insulin pump –the V-Go system does not have the capacity to contain the amount of insulin needed for most patients with type 1 diabetes.

There are very few studies available for the product, compared to the large amount of data published with insulin administered by vials or pens, or with a pump. V-Go is targeted primarily for patients with type 2 diabetes as a convenience – so they don't have to inject insulin doses throughout the day. However, the V-go device does require the patient to fill the device daily with insulin.

The P&T Committee reviewed the formulary status of V-Go on several civilian health care plans. The majority of plans do not cover V-Go, and two large health plans considered V-Go as "experimental and investigational, because its effectiveness has not been established or is unproven."

The P&T Committee was unanimous in recommending non-formulary placement for V-go. Additionally, one of the P&T Committee members is an endocrinologist.

PA criteria had been recommended for V-Go at the August 2014 P&T meeting, and at the November meeting the criteria were clarified to state the reasonable doses of insulin required for the device.

Panel Questions and Comments:

Several Panel members had questions regarding the V-Go insulin delivery device and how it is used. There were also question regarding available data regarding patient compliance and non-compliance due to the patient not injecting the medicine.

The presenter responded by stating that they did ask that question and look through the available data. Because the product is so new there are not studies that discuss whether the device will improve patients' adherence to their insulin therapy.

Without further discussion, the Chair asked for a vote on the Miscellaneous Insulin Delivery Device: Valeritas or V-Go:

A. V-Go's UF Recommendation:

Concur: 7	Non-Concur: 0	Abstain: 0	Absent: 1

B. V-Go's Prior Authorization (PA) Criteria:

Concur: 7	Non-Concur: 0	Abstain: 0	Absent: 1

C. V-Go's UF AND PA Implementation Plan:

Concur: 7	Non-Concur: 0	Abstain: 0	Absent: 1

II. RECENTLY APPROVED U.S. FDA AGENTS – Pulmonory Drugs: Umeclidinium/Vilanterol (Anoro Ellipta) from the Chronic Obstructive Pulmonary Disease (COPD).

P & T Comments

(Dr. Downs)

A. Anoro Ellipta's Relative Clinical Effectiveness and Conclusion

Anoro Ellipta is the first fixed dose combination of a long-acting muscarinic agent (LAMA) with a long-acting beta agonist (LABA) to reach the market. Anoro Ellipta is indicated for maintenance treatment of COPD; in contrast, other products have the additional indication for reducing COPD exacerbations (Spiriva, Advair, and Breo Ellipta).

The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** the main clinical benefits of Anoro Ellipta are its superior improvements in forced expiration volume in 1 second (FEV_1 is a pulmonary function test that measures the volume of air exhaled over 1 second) compared to single ingredient inhalers, the convenience to patients of combining two long-acting bronchodilators into one inhaler, and once daily dosing. The COPD agents will be re-reviewed at an upcoming meeting for UF placement. Additionally, the P&T Committee recommended adding the LAMA/LABA combinations to the Pulmonary II Drug Class, which includes other chemical entities used for treating COPD

B. Anoro Ellipta's Relative Cost-Effectiveness Analysis and Conclusion

A CMA was performed to evaluate Anoro Ellipta with other LAMA and LABA therapies in the treatment of COPD. The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** the following:

CMA showed that the Anoro Ellipta fixed dose combination bronchodilator offers a cost-effective alternative to combining available LAMA and LABA inhalers.

C. Anoro Ellipta's UF Recommendations

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** Anoro Ellipta be designated formulary on the UF, based on clinical and cost effectiveness.

Physician's Perspective:

There are several inhalers available to treat patients with COPD, and many products contain combinations of drugs. Patients with COPD often require multiple medications to control their symptoms, and Anoro Ellipta is unique in that it contains two long-acting bronchodilators in one inhaler. The product is also dosed once daily, which can be a convenience to a patient with a complicated medication regimen.

There are several inhalers for COPD in the pipeline, which are likely to receive FDA approval this year. The P&T Committee will be evaluating these new products once they are launched, and the COPD drug class will likely be reviewed sometime in 2015.

There was no controversy here with the recommendation for Uniform Formulary status.

Panel Questions and Comment:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation for COPD: Umeclidinium/Vilanterol (Anoro Ellipta)

A. Anoro Ellipta's UF Recommendation

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

III. RECENTLY APPROVED U.S. FDA AGENTS – GLAUCOMA DRUGS: brinzolamide 1%/brimonidine 0.2% Ophthalmic Suspension (Simbrinza)

(P & T Comment)

Dr. Allerman

A. Simbrinza's Relative Clinical Effectiveness and Conclusion

Brinzolamide/brimonidine ophthalmic suspension (Simbrinza) is the first fixed dose combination product for glaucoma that has components other than a beta blocker. It contains a carbonic anhydrase inhibitor (brinzolamide, Azopt) and an alpha 2 adrenergic agonist (brimonidine, Alphagan).

The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** Simbrinza's fixed combination offers a convenience to the patient versus using two drugs concomitantly, even though it requires dosing three times a day. Simbriniza also decreases intraocular pressure to a greater extent than the individual components administered alone.

B. Simbrinza's Relative Cost-Effectiveness Analysis and Conclusion

A CMA was performed to evaluate Simbrinza with other drugs used in the treatment of glaucoma. The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** the following:

- The CMA showed that Simbrinza was comparable to the UF carbonic anhydrase inhibitors and alpha adrenergic agonists when taken in combination.

C. Simbrinza's UF Recommendation

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** Simbrinza be designated with formulary status on the UF, based on clinical and cost effectiveness.

Physician's Perspective:

The Glaucoma drug class was last reviewed for formulary placement back in February 2007, and there haven't been many new drugs approved since then. Simbrinza is two older products combined into one medication.

Patients with glaucoma frequently need to administer eye drops several times a day. For Simbrinza, three times a day administration is still required. However, Simbrinza has advantages over the other combination eye drops (such as Cosopt and Combigan) in that it doesn't contain a beta blocker. Some patient with significant cardiac problems can have adverse effects from eye drops that contain a beta blocker.

There was no controversy here with the recommendation for Uniform Formulary placement for Simbrinza.

Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation for brinzolamide 1%/brimonidine 0.2% Ophthalmic Suspension (Simbrinza)

A. Simbrinza's UF Recommendation

Concur: 7	Non-Concur: 0	Abstain: 0	Absent: 1

VIII. RECENTLY APPROVED U.S. FDA AGENTS—bromfenac 0.075 Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs):

(P & T Comments)

Dr. Downs

A. Prolensa's Relative Clinical Effectiveness and Conclusion:

Bromfenac 0.07% (Prolensa) is FDA-indicated for the treatment of postoperative inflammation and pain in patients following cataract surgery. It is the third bromfenac formulation to obtain FDA approval. The branded formulations of bromfenac 0.09%, Xibrom which is dosed twice daily and Bromday which is dosed

once daily have both been discontinued by the manufacturer. There are no head-to-head clinical trials comparing Prolensa with another ophthalmic NSAID. There is no data to show that Prolensa is better tolerated when compared to once daily generic bromfenac 0.09% or Bromday. While Prolensa offers the convenience of once daily dosing, generic Bromday is also dosed once daily.

The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that Prolensa does not offer clinically relevant advantages over the other UF ocular NSAIDs that are FDA-approved for use following cataract surgery.

B. Prolensa's Relative Cost-Effectiveness Analysis and Conclusion:

CMA was performed to evaluate Prolensa's with other ophthalmic NSAIDs on the UF. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that Prolensa was the most costly ocular NSAID.

C. Bromfenac 0.07% Ophthalmic Solution (Prolensa) — UF Recommendation:

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) Prolensa be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products. Currently there are about 8, 500 patients receiving Prolensa in the DoD.

D. Prolensa's UF Implementation Plan:

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS.

Physician's Perspective:

There are several ocular NSAIDs available on the uniform formulary, including the generic bromfenac formulation that is dosed once daily.

One of the Committee members surveyed several former military providers in the community for their opinions on Prolensa. The majority opinion was that Prolensa didn't offer additional benefits over what is already available.

The Committee recommended non-formulary placement for Prolensa, based on the clinical analysis; the fact that the generic once daily product is on the formulary; and also based on cost effectiveness.

Panel questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation and Implementation Plan for the Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs):

A. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Recommendation

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

B. Prolensa's UF Implementation Plan

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

X. UF DRUG CLASS REVIEW—MULTIPLE SCLEROSIS (MS)

(P & T Comments)

Dr. Downs

A. MS Relative Clinical Effectiveness and Conclusion is a follows:

The P&T Committee evaluated the relative clinical effectiveness of the MS Drug Class, which is comprised of the following injectable and oral disease-modifying drugs:

- **Injectable** agents are interferon beta-1b [Betaseron and Extavia subcutaneous (SC) injections], interferon beta-1a [Avonex intramuscular (IM) injection; Rebif SC injection], and, glatiramer [Copaxone 20 mg SC daily injection and 40 mg three times a week (TIW) SC injection]

- **Oral** agents are dimethyl fumarate (Tecfidera), fingolimod (Gilenya), and teriflunomide (Aubagio)

The P&T Committee recommended **(16 for, 0 opposed, 0 abstained, 2 absent)** the following conclusions for the MS drugs:

1. For the injectables, no one interferon product is preferred over the other in terms of efficacy and safety. Avonex is possibly less effective than the other interferons, based on the Oregon Drug Effectiveness Review Project (DERP, 2010).

2. In a Cochrane review (2014), similar outcomes (including clinical and magnetic resonance imaging activity measures) were reported when the interferons were

compared to Copaxone for treating patients with relapsing-remitting forms of MS. These findings differ from the DERP 2010 report, where Avonex was presented as less effective.

3. The Copaxone 40 mg three times a week formulation has the convenience of less frequent administration than the 20 mg daily Copaxone formulation. However, the 40 mg three times a week product has not been directly compared to the 20 mg daily formulation for efficacy or safety; trials are ongoing.

4. There are no head-to-head trials of one oral drug with another oral drug; placebo controlled studies were used to obtain FDA approval. Limited data from head-to-head trials of the injectables versus oral medications report the following:

   - Fingolimod produces a greater reduction in the **annualized relapse rate (ARR)** compared to Avonex. For the annual relapse rate, a "lower" number is better

   - Aubagio 14 mg and Rebif produced similar reductions in the ARR, while Aubagio 7 mg was less effective than the 14 mg dose and Rebif.

   - There were no clinically relevant differences in the ARR when Copaxone was compared to Tecfidera.

5. The Canadian Agency for Drugs in Technology and Health (CADTH, October 2013) reported the relative ARRs of the various MS treatments compared to placebo. Gilenya and Tecfidera had the lowest ARRs; Aubagio, Betaseron, Rebif, and Copaxone all had similar ARRs; and Avonex had the highest ARR.

6. The MS drugs have distinctly different adverse event profiles. Copaxone has the advantage of a pregnancy category B rating.

7. Dalfampridine (Ampyra) is an orally administered drug that is not disease-modifying; it is solely approved for symptom management to improve walking distance.

8. Due to their differing safety profiles and low degree of therapeutic interchangeability, several MS products are required on the UF to meet the needs of the Military Health System (MHS) population.

B. MS Relative Cost-Effectiveness Analysis and Conclusion

A cost-effectiveness analysis (CEA) and budget impact analysis (BIA) were performed to evaluate the MS Drug Class. The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** the following:

- The CEA showed that, when considering the incremental cost-effectiveness ratios per relapse avoided, all scenarios were within a range considered to be cost-effective to the MHS. Ampyra was not included in the CEA as it is not a disease-modifying drug.

- A BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF. The BIA showed that all modeled scenarios demonstrated a similar level of cost avoidance for the MHS, with only slight differences between evaluated scenarios.

C. MS UF Recommendation

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** the following:

- UF:
  - Interferon beta-1a SQ or Rebif and Rebif Rebidose
  - Interferon beta-1a IM or Avonex
  - Interferon beta-1b SC or Betaseron
  - Interferon beta-1b SC or Extavia
  - Dalfampridine or Ampyra
  - Dimethyl fumarate or Tecfidera
  - Fingolimod or Gilenya
  - Glatiramer or Copaxone
  - Teriflunomide or Aubagio

- NF: None

D. MS PA Criteria

Manual PA criteria recommended in November 2010 and November 2013 currently apply to Gilenya and Tecfidera, respectively. The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** maintaining the current PA criteria for Tecfidera and revising the PA criteria for Gilenya due to recent updates in the package insert for cardiovascular toxicity.

Gilenya's Manual PA criteria:

- A documented diagnosis of relapsing forms of MS
- No current use of a disease-modifying therapy (e.g., interferon 1a or 1b or Copaxone)
- Avoid use in patients with significant cardiac history, including:
  - Patients with a recent history (within the past six months) of class III/IV heart failure (symptoms with moderate activities levels), myocardial infarction (heart attack), unstable angina (chest pain with

exertion), stroke, transient ischemic attack (mini stroke), or decompensated (symptomatic) heart failure requiring hospitalization
- Those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular block or sick sinus syndrome (different types of severe heart rhythm problems), unless they have a functioning pacemaker
- Patients with a baseline QTc interval ≥500 ms (heart rhythm problems)
- Those receiving treatment with class Ia or class III antiarrhythmic drugs

E. MS' UF and PA Implementation Plan

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** an effective date no later than 30 days after signing of the minutes in all POS.

Physician's Perspective:

All of these products are superior to placebo in treating patients with MS, but it is difficult to determine if one product has better efficacy over another product, since there are few head-to-head trials.

Several MTF neurologists provided their opinion on the MS drugs, and the overall consensus was that new patients are being started on oral therapy, and not an injection. This fact was supported by the results of an analysis of MHS prescribing trends that did confirm that new patients are primarily being started on the oral drugs. Other comments from the neurologists were that patients will stay on a regimen as long as it is working and the patient is "relapse-free". If there are side effects or the patient has a relapse, then the drug therapy will be changed. There was no preference stated for one interferon product over another.

The P&T Committee recommended that all the products be designated with Uniform Formulary status. The Committee recognized that several products are needed on the formulary, due to the complexity of the disease and also because the individual oral products have unique safety issues, which can be very important in determining which drug to use in a patient.

The PA criteria recommendations for Gilenya were due to safety issues, and reflect the information contained in the current package insert.

Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the UF Recommendation, PA Criteria and Implementation Plan for the Multiple Sclerosis (MS) agents:

A. MS—UF Recommendation

Concur: 7	Non-Concur: 0	Abstain: 0	Absent: 1

B. MS—PA Criteria

Concur: 7	Non-Concur: 0	Abstain: 0	Absent: 1

C. MS—UF and PA Implementation Plan

Concur: 7	Non-Concur: 0	Abstain: 0	Absent: 1

XI. UF DRUG CLASS REVIEW—SELF-MONITORING BLOOD GLUCOSE SYSTEM (SMBGS) TEST STRIPS

(P & T Comments)

Dr Allerman

A. Blood Glucose Test Strips Relative Clinical Effectiveness and Conclusion

The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips. The Background Document on page 23 has the full list of the SMBGS test strips in this class.

SMBGS glucometers are not included as part of the TRICARE outpatient pharmacy benefit (they are included under the medical benefit) and are not the focus of the review.

U.S. Federal Government contracting requirements stated the following:

> *The Company shall ensure test strips are made available to all three Points of Service (Military Treatment Facilities, TRICARE Mail Order Pharmacy, and Retail Network). In accordance with industry practice, the Company shall make meters available to DoD beneficiaries at no additional charge or cost to the DoD beneficiary.*

The FDA classifies SMBGS test strips and glucometers as medical devices rather than drugs. The clinical effectiveness review focused on differences in the technical aspects/attributes among the test strips and glucometers. The P&T Committee recommended that the potential test strips considered for inclusion on the UF should meet standards relating to such factors as FDA requirements for accuracy based on the International Organization for Standardization (ISO) 15197 guidelines from 2003, sample size, alternate site testing, result time, memory capacity, ease of calibration, customer support, downloading capabilities, and data management capabilities.

The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** the following for the SMBGS test strips:

- Potential SMBGS test strips considered for inclusion on the UF must meet all U.S. Federal Government contracting requirements and the technical factors listed above.

- Potential SMBGS test strips considered for inclusion on the UF included FreeStyle Lite; FreeStyle InsuLinx; Precision Xtra; ACCU-CHEK Aviva Plus; OneTouch Ultra Blue; OneTouch Verio; CONTOUR NEXT; TRUEtest; Nova Max; GLUCOCARD 01-SENSOR; GLUCOCARD Vital; and Prodigy No Coding.

  - *Overall relative clinical effectiveness conclusion:* The P&T Committee concluded there were no clinically relevant differences between the 12 SMBGS test strips that were reviewed and met the contracting requirements and technical factors, and that any of the 12 test strips were acceptable for inclusion on the UF.

B. SMBGS Test Strips—Relative Cost-Effectiveness Analysis and Conclusion

A CMA and BIA were performed to evaluate the SMBGS test strips that were considered for inclusion on the UF. The P&T Committee concluded **(18 for, 0 opposed, 0 abstained, 0 absent)** the following:

- Results from a comprehensive cost analysis, which included a CMA and considered the cost of patient switching and related DoD administrative costs in addition to SMBGS test strip per unit costs, showed FreeStyle Lite and Precision Xtra test strips were the most cost-effective SMBGS test strips, followed by ACCU-CHEK Aviva Plus, GLUCOCARD Vital and GLUCOCARD 01-SENSOR, TRUE test, Prodigy No Coding, CONTOUR NEXT, Nova Max, and all other SMBGS test strips. OneTouch Ultra Blue test strips were the least cost-effective.

- A BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and UF or non-preferred and NF on the UF. BIA results showed the scenario with FreeStyle Lite and Precision Xtra designated as step-preferred on the UF, and all remaining test strips designated NF and non-step preferred, where all current and new users are required to try FreeStyle Lite or Precision Xtra first, was the most cost-effective option for the MHS.

C. SMBGS Test Strips UF Recommendation

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** the following:

- UF and step-preferred:
  - FreeStyle Lite

- Precision Xtra

- NF and non-step preferred:
  - ACCU-CHEK Aviva Plus
  - GLUCOCARD 01-SENSOR
  - GLUCOCARD Vital
  - CONTOUR NEXT
  - FreeStyle InsuLinx
  - Nova Max
  - TRUEtest
  - Prodigy No Coding
  - OneTouch Verio
  - OneTouch Ultra Blue
  - All other test strips listed in the table on page 23 of the Background Document, with the exception of FreeStyle Lite and Precision Xtra

- This recommendation includes step therapy, which requires a trial of FreeStyle Lite or Precision Xtra prior to use of a NF test strip. The recommendation requires all current and new users of a non-preferred test strip try FreeStyle Lite or Precision Xtra, or meet the PA criteria for the non-preferred strips.

D. SMBGS Test Strips PA Criteria

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** manual PA criteria for all new and current users of NF test strips. The manual PA criterion requires a trial of FreeStyle Lite or Precision Xtra prior to the use of a NF test strip.

Manual PA Criteria—A non-preferred test strip is allowed if:

1. Patient is blind/severely visually impaired and requires a test strip used in a talking meter – such as Prodigy Voice, Prodigy AutoCode, Advocate Redicode
2. Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter such as
   - Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump
   - Nova Max strip with Nova Max Link meter for Medtronic pump
   - For Retail Network Only: One Touch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump
   - For Retail Network Only: One Touch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump
3. The patient has a documented physical or mental health disability requiring a special strip or meter. For example, the patient requires ACCU-CHEK Aviva Plus strip due to manual dexterity issues (such as Arthritis Association Seal of Approval)

E. SMBGS Test Strips' UF and PA Implementation Plan

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 120-day implementation period in all POS; and the DHA will send a letter to beneficiaries affected by the UF and PA decisions.

Physician Perspective:

Because test strips are classified by the FDA as medical devices, rather than as drugs, there were different components for the review than what we usually discuss, including that the candidates had to meet the Federal Government contracting requirements. Additionally, rather than discussing efficacy and safety data, the technical attributes of the test strips were evaluated. The final candidates included 12 test strips, corresponding with 20 different blood glucose meters.

All of the candidate test strips work in meters that require very small amounts of blood, provide results quickly, and do not require manual coding by the patient. Most of the meters do have additional benefits, such as allowing patients to flag meal-time results, and also provide weekly and monthly summaries of results that can be downloaded to a computer.

The Committee did feel that one test strip would be adequate for all patients, even for special populations, such as pediatrics and pregnant women with gestational diabetes.

For the Uniform Formulary recommendation, the vote was unanimous that the Precision Extra and FreestyleLite test strips were the most cost-effective option, and thus were recommended to be the preferred strips in the MHS. The Committee felt that having all the other products as non-preferred and non-formulary would result in the greatest amount of cost-avoidance. The decision also took into account the cost of switching patients to a new test strip and meter.

The Prior Authorization criteria will allow those patients with special needs – such as visually impaired patients, or those on insulin pumps – to receive a non-formulary test strip.

We will work with the pharmaceutical manufacturer to ensure that the decision can be implemented with the least amount of hassle to the patient. Due to the numbers of patients affected by the decision, a 120-day implementation period is recommended.

Panel Questions and Comments:

The Panel members expressed concerns about the large beneficiary population as well as the age of the beneficiary population affected by this policy change. Approximately 97,000 patients will be affected which is approximately a 50% impact rate. As previously stated, a large number of the patients probably have Type 2

diabetes and are older patients. This could potentially set-up some chronic risks with patients who are not properly using the devices or getting a new strip and trying to use an older device.

They also fear that the discrepancies with the TRICARE Pharmacy benefit and the medical benefit will cause more of an obstacle for the beneficiary and providers to try to overcome. Patient compliance is also a concern. Because the test strips are not universal, the beneficiaries who have devices that don't match the test strips will be required to change both their meter and the strips. Going back to the providers and asking them to switch is going to cause the patient to not monitor their diabetes for a given period of time. Other concerns are that the patients may incur secondary costs and cause patients to fall out of compliance. The Panel believes that this is a huge impact, huge undertaking and will cause undue consequences.

The Panel also expressed concerns about education and training of the beneficiary population affected especially those beneficiaries who are older and not affiliated with a MTF. The response is as follows and summarizes steps that will be taken during the implementation plan.

To assist with this transition, there are several training opportunities available. Training will be available for the beneficiaries impacted by the change at the military treatment facilities and the retail pharmacies. Per the industry standard, the meters are free. Patients may go to the diabetes clinic at the MTF and receive training from a physician clinic or a certified diabetes educator. All of the companies, included the ones selected for the Uniform Formulary recommendation, are offering extensive training on the internet and DVDs. Due to the confusion with the medical and pharmacy benefit, there is still the potential for a prescriber to prescribe a device that does not match the strips. Again, the hope is the 120 day implementation plan and the training opportunities will be provided adequate time for the providers to know the preferred TRICARE test strip.

The P&T recommended a 120 day implementation period to provide time to train the beneficiary population as well as the providers. Due to the language in the solicitation, patients will not be grandfathered.

There were previous decisions in 1999 and 2008. The Panel asked if the transition went smoothly with the two previous decisions. The response was that overall there are always people who believe that the transition did not go smoothly. We did not hear of any issues with the patients and beneficiaries receiving training on the new meter, swapping their meters, and getting the test strips.

Without further discussion, the Chair called for a vote on the UF Recommendation, PA Criteria, and the Implementation for the SMBGS Test Strips.

A. SMBGS—UF Recommendation

Concur: 4	Non-Concur: 3	Abstain: 0	Absent: 1

B. SMBGS—PA Criteria

Concur: 4	Non-Concur: 3	Abstain: 0	Absent: 1

C. SMBGS—UF and PA Implementation Plan

Concur: 4	Non-Concur: 3	Abstain: 0	Absent: 1

Additional Comments:

A. This recommendation has a very large impact on patients. Half of the beneficiaries impacted, who currently have diabetes, would have to make a significant change.

The Panel members requested short break and continued the discussion on the SMBGS. The comments and concerns are summarized in "Panel questions and comments" above.

The Panel recommended:

1. Keeping the same vote of 4 concur and 3 non-concur with the following recommendations. (Panel vote is above)
2. The Panel recommended a one (1) year implementation period, and
3. That patients who currently have their meters and test strops be grandfathered for as long as they chose. This criterion applies to newly diagnosed patients and patients who have already changed their test strips for some other reason.

No further comments.

XII. UTILIZATION MANAGEMENT—HEPATITIS C VIRUS (HCV) AGENTS, DIRECT ACTING ANTIVIRALS (DAAs)

(P & T Comments)

Dr. Downs

A. Ledipasvir/Sofosbuvir (Harvoni's) PA Criteria

Ledipasvir 90 mg/sofosbuvir 400 mg (Harvoni) is a once daily fixed dose combination tablet that was approved by the FDA in October 2014 for the treatment of HCV genotype 1. It is the first FDA-approved interferon-free regimen indicated to

treat HCV genotype 1. Harvoni will be reviewed as a new drug at an upcoming meeting.

PA criteria currently apply to the DAAs. The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 1 absent)** manual PA criteria for new users of Harvoni, consistent with FDA-approved labeling. Prior authorization will expire after 8–24 weeks based on the treatment regimen.
The full PA criteria are as follows:

- New users of Harvoni are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their Harvoni prescriptions.
- Consult the American Association for the Study of Liver disease and Infectious Disease Society of America (AASLD/IDSA) HCV guidelines for the most up-to-date and comprehensive treatment for HCV. This guideline can be found on the internet at www.hcvguidelines.org and will be referred to as the HCV guideline for the remainder of this meeting. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1 infection
    1. State the HCV genotype and HCV RNA viral load on the PA form
- Harvoni is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with Hepatitis B virus (HBV).

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 8 weeks or 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1 Patient Populations	**Treatment Duration**
Treatment naïve with or without cirrhosis	8* - 12 weeks

**Consider treatment duration of 8 weeks in treatment-naïve patients without cirrhosis who have a pretreatment HCV RNA less than 6 million IU/mL*

Genotype 1 Patient Populations	Treatment Duration
Treatment experienced** without cirrhosis	12 weeks
Treatment experienced** with cirrhosis	24 weeks

***Treatment-experienced patients who have failed treatment with either (a) peginterferon alfa plus ribavirin or (b) HCV protease inhibitor plus peginterferon alfa plus ribavirin*

B. Simeprevir (Olysio's) PA Criteria

PA criteria were recommended for Olysio at the May 2014 DoD P&T Committee meeting. Olysio received a new FDA indication in November 2014 as a component of an interferon-free combination treatment for chronic HCV genotype 1.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 1 absent)** revising the existing PA criteria for Olysio to include the expanded FDA-approved indication.

The full PA criteria are as follows:

- New users of Olysio are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- The FDA-approved indication of simeprevir + PEG-interferon + ribavirin for 24 to 48 weeks is not recommended for HCV treatment by the AASLD/IDSA. See www.hcvguidelines.org.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their simeprevir prescriptions.
- Consult the AASLD/IDSA HCV guidelines for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age $\geq$ 18
- Has laboratory evidence of chronic HCV genotype 1 infection
- State the HCV genotype and HCV RNA viral load on the PA form
- If HCV genotype 1a, the patient is negative for NS3 Q80K
- polymorphism at baseline
- Simeprevir (Olysio) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with HIV or Hepatitis B virus (HBV).
- Not recommended for monotherapy

- The patient has not previously used a HCV protease inhibitor (boceprevir, telaprevir, or simeprevir)

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 12 weeks or **24** weeks, based on the treatment regimen selected.

Genotype 1 Patient Populations	**Treatments**	**Treatment Duration**
Treatment naïve or experienced* without cirrhosis	simeprevir 150 mg once daily sofosbuvir 400 mg once daily	12 weeks
Treatment naïve or experienced* with cirrhosis	simeprevir 150 mg once daily sofosbuvir 400 mg once daily	24 weeks

*Treatment-experienced patients who have failed treatment with peginterferon alfa plus ribavirin but not a HCV protease inhibitor
Prior authorization expires at the end of treatment duration (12–24 weeks)

Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

Harvoni is the newest drug to treat hepatitis C. PA criteria apply to the other products in the class, including Sovaldi and Olysio. The Harvoni PA criteria reflect the indications and dosing listed in the package insert, and also reflects the guidelines from the AASLD/IDSA professional organizations.

Panel Questions and Comments:

The typo for the dosage of sofofbuvir is corrected. In the previous handout, the dosage was noted as 300 mg. Sofosbuvir does not come in a 300 mg tablet. The correct dosage is 400 mg.

The full PA criterion states that "patients are encouraged to use the Mail Order Pharmacy or the MTF to fill their prescriptions'. The Panel members asked about the process and if it was a recommendation to the provider.

In response, this is a recommendation to the provider. The PA forms are completed by the provider. Hepatitis is a rapidly expanding field. We want to be in consultation with the Hepatitis expert to get the most up-to-date treatment regimens. That is why we ask them to refer to the guidelines. For us, it would be best for the patient to receive their prescriptions through the Mail Order or the MTF.

Other questions from the Panel member are, in case of Harvoni, for people who are treatment naïve without cirrhosis, does the prior authorization do anything to actively direct the patient to the shorter treatment course of 8 weeks. Do we actually look at the viral load? More specifically, are we allowing the prescriber to make that determination or if the prior authorization dictates the shorter regimen if the patient qualifies.

In response, we do. Part of the initial, you have to break down the genotype because Hepatitis C, Genotype 1 treatment is different than Genotype 2, 3, 4, 5, or 6. You have to write down the Genotype. Typically, you will also have a viral load to confirm that you have Hepatitis C. The general way Hepatitis C is diagnosed is that you do a Hepatitis C antibody that comes back positive. The next step would be to do a viral load as well as the genotype subtyping. We ask for them to write that down on the piece of paper. There are spaces for that on the prior authorization. We are not recommending the 8 weeks. We would prefer the 8 weeks. But if the physician thinks they'd do better 12 weeks, they can continue to do 12 weeks. Prior authorization doesn't dictate. It's for the physician to consider. We would prefer it and obviously the shorter duration would be better. If the provider thinks it's longer, he doesn't have to justify anything. He just needs to write it down.

The Panel member commented that he would actually enforce that a little more strictly, but I defer to the P&T Committee.

In response, the data isn't as robust as the 12 weeks. There are other clinical factors in the treatment of Hepatitis C that would people in a higher risk group.

A. Ledipasvir/Sofosbuvir (Harvoni's) PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

B. Simeprevir (Olysio's) PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

XIII. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBs)

(P & T Comments)

Dr. Downs

A. Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel's) PA Criteria

The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class. Recently, Humira received FDA approval for pediatric Crohn's disease (inflammation and irritation of the GI tract) in patients as young as six years and juvenile idiopathic arthritis (JIA – is pain, swelling and joint stiffness in childern) in patients as young as four years; Otezla received FDA approval for plaque psoriasis (large flaky skin rash). PA criteria were updated for Humira and Otezla to reflect their new respective FDA indications. Accordingly, step therapy criteria for Enbrel was also revised since Enbrel and Humira are now indicated for the same age range in patients with JIA.

The P&T Committee recommended (**17 for, 0 opposed, 0 abstained, 1 absent**) revised manual and step therapy PA criteria for Humira and Otezla, consistent with the new FDA-approved product labeling, and an update to the PA criteria for Enbrel since Humira is now indicated for JIA.

The full PA criteria are as follows:

Humira

Coverage approved for patients ≥ 18 years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate
- Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade
- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

(the addition)

Pediatric patients with:

- **Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric patients: 2–17 years)**
- **Moderate to severely active Crohn's disease (≥ 6 years)** who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate

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

Otezla

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

AND

- **Manual PA criteria:**

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

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

AND

Coverage approved for patients $\geq$ 18 years with:

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

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

Enbrel

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

AND

Manual PA criteria:

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

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative (Enbrel is prescribed for a patient with hepatitis C virus)

AND

Coverage approved for patients ≥ 18 years with:

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

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

- Moderate to severe active polyarticular Juvenile Idiopathic Arthritis

Coverage is NOT provided for concomitant use with other TIBs including, but not limited to Humira, Kineret, Cimzia, Enbrel , Simponi, Remicade, Orencia, Actemra, Xeljanz, Stelara, Otezla, or Rituxan.

Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

For the TIBs, all the products have PA criteria. This class was reviewed at the August 2014 P&T meeting, and the PA criteria recommended for Humira and Otezla reflect new indications approved by the FDA, and also a corresponding update to the Enbrel step therapy criteria

Panel Questions and Comment:

The Panel member states, "coverage is NOT provided for concomitant use with other TIBS..." Is this a drug/drug interaction that is being listed there? Or why is that listed here vs in other areas it's never been listed?

It's in the FDA indications that it's not covered. The main reason is that when you combine them, the efficacy does not increase. The risk of infections and side effects

are remarkably increased. It's a safety issue and a clinical warning. That is why it's put on the PA.

Other concerns expressed by the Panel dealt with the process for beneficiaries being able to switch their medication. For instance, if a patient tries one of the medications, has an allergic reaction, and then needs to switch over to another medication; will "this paragraph" prohibit them from getting that medication that they now need?

No, clinically, you can switch them. You just can't use them together. As long as you stop your med then start the next one the next week and that does not seem to have a problem, there is literature to back that up.

Are there specific criteria that a provider will need to submit in order to justify "moderate or severe"? How does a provider determine if their patient has moderate or severe? Is there a process or system they are being asked to follow?

The provider is not required to provide documentation. The provider just has to provide it's a moderate rheumatoid arthritis. Typically, it would be the number of joints that are involved.

Without further discussion, the Chair called for a vote on the PA Criteria for Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel).

A. Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel) PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

Notes: Correction to PA Criteria for Otezla noted and corrected on. Tackitt received written comments of Dr. Downs corrected statements on Otezla. It's been read into the record.

XIV. UTILIZATION MANAGEMENT/PROSTATE CANCER DRUGS

(P & T Comments)

Dr. Allerman

A. Enzalutamide (Xtandi's)—PA Criteria

Xtandi is an androgen receptor inhibitor that prolongs survival of metastatic castration-resistant prostate cancer. Manual PA criteria were recommended at the November 2012 P&T Committee meeting. The package insert for Xtandi was updated to state that prior treatment with docetaxel is no longer required.

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 1 absent)** an update to the manual PA criteria for Xtandi, consistent with the product's labeling for

treatment of metastatic castration-resistant prostate cancer.

The full PA criteria are as follows:

Coverage is approved if:

- There is a documented diagnosis of metastatic castration-resistant prostate cancer

There is no expiration date for the PA. The drugs used to treat prostate cancer will be reviewed at the February 2015 P&T Committee meeting.

Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

PA criteria were revised for the prostate cancer drug Xtandi, to reflect that chemotherapy is no longer required, based on a recent update to the package insert.

Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the PA Criteria for Enzalutamide (Xtandi's)

A. Enzalutamide (Xtandi's) PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

XV. UTILIZATION MANAGEMENT: Non-Insulin Diabetes Mellitus Drugs: GLP1RAs

(P & T Comments)

Dr. Allerman

A. Exenatide Once Weekly Pen (Bydureon Pen) PA Criteria

Bydureon is now available in a pre-filled pen, in addition to the original vial formulation. The manufacturer states that they do not intend to discontinue the original vial formulation. Both products are dosed once weekly. However, the cost of the Bydureon pen formulation is significantly higher than the Bydureon vials despite having the same dosing and FDA-approved indications. Exenatide (Byetta) is also

available in a pen formulation that is dosed twice daily. Manual PA criteria were recommended for the Bydureon pen due to the cost and because other exenatide products (Bydureon vials and Byetta) are available on the UF. The GLP1RA Drug Subclass, including the Bydureon pen formulation, is scheduled for review at an upcoming meeting.

The P&T Committee recommended **(16 for, 1 opposed, 0 abstained, 1 absent)** manual PA criteria for the Bydureon pen, requiring use of Bydureon vials first. Additionally, a trial of metformin or a sulfonylurea is also required, consistent with the PA criteria for other GLP1RAs.

The full PA criteria are as follows:

New GLP1RA users are required to try metformin or a sulfonylurea before receiving Byetta, Bydureon, or Victoza.

Automated PA criteria:

The patient has received a prescription for metformin or sulfonylurea at any MHS pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days, AND

Manual PA criteria:

if automated criteria are not met:

Byetta, Bydureon, or Victoza is approved (e.g., trial of metformin or sulfonylurea is NOT required) if:

1) The patient has a confirmed diagnosis of Type 2 Diabetes Mellitus
2) The patient has experienced any of the following adverse events while receiving metformin: impaired renal function that precludes treatment with metformin or history of lactic acidosis.
3) The patient has experienced the following adverse event while receiving a SU: hypoglycemia requiring medical treatment.
4) The patient has a contraindication to both metformin and a SU.
5) The patient has had an inadequate response to metformin and a SU.

   (new addition)

6) **Also for exenatide once weekly (Bydureon pen)**
   - **Coverage approved if patient has first tried Bydureon 2mg vial/cartridge first AND**
   - **Patient has dexterity issues and cannot assemble the Bydureon vial/cartridge**

Physician Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.
The only case where there was not a unanimous vote was the PA criteria recommendation for the new Bydureon pen formulation. The one dissenting vote was due to the feeling that the PA criteria would not deter use of the pen over the vial formulation.

Panel Questions and Comments:

There were no questions or comments from the Panel members. Without further discussion, the Chair asked for a vote on the PA Criteria for Exenatide Once Weekly Pen (Bydureon Pen)

A. Exenatide Once Weekly Pen (Bydureon Pen) PA Criteria

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1

XVI. UTILIZATION MANAGEMENT: COMPOUND PRESCRIPTIONS

(P & T Comments)

Dr. Downs

A. Compound Prescriptions' PA Criteria

The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant and increasing, and compounded medications have a high potential for inappropriate use. From June 2013 through May 2014, 140,000 beneficiaries filled 360,000 compounded prescriptions that totaled over $410 million in expenditures at the Retail Network and Mail Order POS. In an effort to decrease inappropriate use and ensure safety for the beneficiaries, PA criteria were proposed.

The P&T Committee recommended **(16 for, 0 opposed, 0 abstained, 2 absent)** manual PA criteria for all new and current users of compounds. Coverage will be approved if the prescriber provides the following information listed below and implementation of the PA will occur when a final recommendation is made.

1. What is the diagnosis?
2. Has the patient tried commercially available products for the diagnosis provided? Please state all products tried.

3. Is there a current national drug shortage of an otherwise commercially available product?
4. What is the proposed duration of therapy?
   AND

   The patient meets the following criteria:

   a) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market. (If True, proceed to (2); if False, claim rejects.)
   b) Each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided. (If True, proceed to (3); if False, claim rejects.)
   c) An FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication. (If True, Approved; if False, claim rejects.)

Physician's Perspective:

The Utilization Management section contains PA criteria for several products. The Committee does monitor for new FDA approved drugs, and updated indications for drugs where PA criteria already exist. This section is to ensure that PA criteria are kept up to date.

For the compounds, the Committee did recommend unanimously to have PA criteria, to ensure that the compounded products are used in the most appropriate patients.

Panel Questions and Comments:

The Panel members expressed concerns regarding the lack of or short implementation period for the compounded medication with no plan or clear plan to notify the beneficiaries of the changes. They asked for statistics on beneficiaries that had been potentially harmed by compounded medications. Additional clarification was requested regarding the phrase "inappropriate use". Per the Panel member the term is vague. Also, did the P&T committee have any evidence that this was occurring within the beneficiary population that medications were being prescribed that was not consistent with a diagnosis?

The implementation date is at the discretion of the Director, DHA. It may occur any time after the minutes are signed. There was not a plan outlined to notify the affected beneficiary regarding the change in policy. In response to the question about inappropriate use, an example of appropriate use would be an FDA indication or that there is evidence based reason for using the medication for a disease.

Appropriate treatment is defines as a "reflecting a linkage between a diagnosis and evidence-based treatment for that diagnosis". There is no data or statistics available to track the beneficiary population using compounded medication for a diagnosis inconsistent with the prescription.

Clarification was requested for some of the questions raised in the written statements provided by Richie's Specialty Pharmacy, PCCA, and Keystone Pharmacy, LLC. They asked if (1) off-label use was restricted with the change in policy; (2) does the policy change impact all compounded medications or the ones being made through bulk drug substances; (3) the number of beneficiaries that filled prescriptions and expectation how many the number will be reduced by if the policy is in place.

The PA criterion is for FDA approved medications and the off-labeling will not go through with this PA. The other compounded agents should go through the PA process without a problem. No, we don't have that number. Compounding is a very diverse group. The PA criterion is an attempt to take the first group and apply it to a single agent and try to make sure it is used appropriately and safe. This is idea for the PA criteria. I don't have numbers on it, but it would end up decreasing that number. We do know what the utilization was from that time period last year. Per the data in the presentation, from June 2013 through May 2014, 140,000 beneficiaries filled 360,000 compounded prescriptions. (see page 32)

Clarification was also requested about the manual PA criteria. What information was required and what information factored into the decision for approval of the PA.

The prescriber must provide the (1) the diagnosis; 2) if the patient has tried commercially available products for the diagnosis provided and state all products tried; (3) if there a current national drug shortage of an otherwise commercially available product; and (4) what is the proposed duration of therapy? The patient must meet the criteria summarized in a-c on page 33. It factors into the decision for approval of the PA. Also, please provide clarification regarding the claims process. Per the guidance in a, b, and c, "(If True, proceed to (2); if False, claim rejects.) (see page 33) So, the claim rejects upon presenting it at the point of sale because it needs a PA. Then, if it meets the criteria, it will be approved.

The Panel members asked how is the civilian sector, the Veterans Administration (VA) and Public Health Service handling compounded medications. Does the cover compounded medications?

A lot of public health plans do not cover compounded medications. According to the news media, other civilian health plans are implementing PAs for compounds. The VA does not have a retail pharmacy benefit. Their benefit only applies to mail order prescriptions or individual facilities. The difference in the TRICARE Pharmacy Benefit and the VA is that TRICARE does allow the retail pharmacy benefit. This is where the majority of the prescriptions are being filled. The VA representation on the P&T Committee commented during the P&T committee meetings that they are

using the same process but they have a specific list of covered compound medications. To our understanding, their approach is that they will provide "these specific compounds," period.

Without further discussion, the Chair called for a vote on the PA Criteria for Compounded Prescriptions

A. Compound Prescriptions' PA Criteria:

Concur: 2 Non-Concur: 5 Abstain: 0 Absent:1

Additional comments and recommendations:

A. This is a very complex issue. I think the P&T Committee would benefit from some more in depth looking into this regarding what is currently being done in other parts of the industry as well as any sort of evidence on doing a study on persons who are currently in getting compounded medications to see if there are any adverse effects. Looking at the evidence that is already there is what I would recommend the P&T committee to do.

B. Maybe looking at how the costs are calculated at individual pharmacies. When you look at 410 million dollars, there are probably some ways to reduce that cost. The PA criteria, in my mind, are more like a hammer in trying to fix the problem. We need to be more judicious in what we really want to do to fix the problem.

C. I feel the lack of criteria for the implementation time as well as the communication of the beneficiaries impacts the decision here.

D. I support the P&T recommendation. It's ultimately in the beneficiaries best interest whenever possible that their medication is FDA approved and has gone through good manufacturing process. I would like this to be accompanied by additional notification to the beneficiaries.

There were no further comments from the panel.

Col Spilker adjourns meeting at 11:35 a.m.

Robert Duane Tackitt

(Conclusion of the meeting)

Brief Listing of Acronyms Used in This Summary

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

- AASLD – American Association for the Study of Liver Disease
- ARR – Annualized Relapse Rate
- BAP – Beneficiary Advisory Panel
- BIA – Budget Impact Analysis
- CADTH – Canadian Agency for Drugs in Technology and Health
- CEA – Cost-Effectiveness Analysis
- CFR – Code of Federal Regulations
- CMA – Cost Minimization Analysis
- COPD – Chronic Obstructive Pulmonary Disease
- DERP – Drug Effectiveness Review Project
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DoD – Department of Defense
- FACA – Federal Advisory Committee Act
- FDA – Federal Drug Adminstration
- GLP1RA – Glucagon-Like Peptide-1 Receptor Agonists
- HBV – Hepatitis B Virus
- HCV – Hepatitis C Virus
- IDSA – Infectious Disease Society of America
- ISO – International Organization of Standardization
- LABA – Long-Acting Beta Agonist
- LAMA – Long-Acting Muscarinic Agent
- MHS – Military Health System
- MS – Multiple Sclerosis
- NDAA – National Defense Authorization Act
- NF – Non-Formulary
- NSAID – Non-Steroid Anti-Inflammatory Drug
- P&T – DoD Pharmacy & Therapeutic Committee
- PA – Prior Authoriztion
- PEG - Pegylated
- POS – Point of Sale
- RNA – Genetic Material
- SC - Subcutaneous
- SMBGS – Self-Monitoring Blood Glucose System
- SU - Sulfonylurea

- TIB – Targeted Immunomodulatory Biologics
- TIW – Three times a week
- TNF – Tumor Necrosis Factor
- TRICARE – Military Health Care System
- U - Units
- USC – United States Code
- V-GO - Veleritas

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January 2, 2015

Colonel J. Michael Spilker, DFO, Uniform
Formulary Beneficiary Advisory Panel
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

Delivered Via Email

Dear Colonel Spilker:

Please see my attached comments regarding the upcoming Beneficiary Advisory Panel ("BAP") meeting scheduled January 8, 2015.

Please share with members of the BAP and any other interested parties. Should you or any interested party have any questions that I might be of assistance answering, please feel free to contact me via my direct line (936) 588-5601, my mobile (936) 520-3202, or email at richie@richiespharmacy.com.

Very truly yours,

Richie Ray, R.Ph.
Pharmacist-In-Charge
President / CEO

Attachment

Information paper: Continued access to compounded medications for TRICARE beneficiaries

Background:

Since mid-June 2013, TRICARE has been reviewing its' position concerning coverage of compounded drug products prepared from bulk chemicals. Section 704 of the National Defense Authorization Act for Fiscal Year 2015 ("2015 NDAA"), executed in late 2014, provides flexibility for TRICARE to provide provisional coverage of emerging services and supplies (http://armedservices.house.gov/index.cfm/files/serve?File_id=926D63B6-5E50-49FC-99EF-A59B98825265).

In perceived stark contrast to this legislation, the recommendation of TRICARE's Pharmacy and Therapeutics Committee ("PTC") presented at the January 8, 2015 Beneficiary Advisory Panel meeting is to implement a manual Prior Authorization ("PA") process for all compounded drugs (http://www.tricare.mil/tma/pharmacy/BAP/Background%20Information_122214.pdf). Under the proposed PA process, coverage of a compounded drug will be approved if the prescriber provides the following information:

1. What is the diagnosis?
2. Has the patient tried commercially available products for the diagnosis provided? Please state all products tried.
3. Is there a current national drug shortage of an otherwise commercially available product?
4. What is the proposed duration of therapy?

AND the following criteria are also met:

a) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market. (If True, proceed to (2); if False, claim rejects.)
b) Each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided. (If True, proceed to (3); if False, claim rejects.)
c) An FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication. (If True, Approved; if False, claim rejects.)

Discussion:

Although the PA process proposed by the PTC appears to allow compounding from bulk chemicals[1], it is nevertheless very problematic for several reasons. First, the PA process applies to all compounded drugs, not just those medications compounded from a bulk chemical. Since

[1] If stated criteria (a) requires that each active ingredient derive from a commercially-available FDA-approved drug instead of a bulk drug powder produced in an FDA-registered facility, the provision that "the drugs have not been withdrawn for safety reasons" would be superfluous.

TRICARE has expressed concern only about compounding from bulk chemicals, why should the PA process be applied to other compounded medications as well? The PA process is a manual process, which results in increased costs and time delay, both of which restrict access to compounded drugs.

Second, the coverage criteria that "each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided" prohibits compounding a medication for ANY off-label use determined to be appropriate by the prescribing physician, and regardless of whether such use is supported by published clinical studies. Frequently, FDA-approved drugs are prescribed for diagnoses not included in the approved labeling for the drug. Such "off-label" prescribing and dispensing is not prohibited by federal or state law. This criteria imposes a restriction on compounded drugs that is not even imposed on FDA-approved drugs. Given that the primary purpose of compounded drugs is to provide medication to patients that cannot be, or have not been, effectively treated by FDA-approved drugs, it is unreasonable to impose such a limitation.

Third, the criteria that a compounded drug can only be provided if an FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication is also unduly restrictive. While it is true that most compounded drugs are prescribed and prepared for these reasons, it is not true that ALL compounded drugs meet these criteria. For example, compounded topical pain creams are frequently prescribed to avoid the systemic side-effects produced by oral opiates, including the potential for addiction to such drugs. This enables the patient to function and continue to work while receiving effective pain treatment. Such a situation does not clearly meet the stated criteria. Additionally, it is unclear how the criteria described in this paragraph will be evaluated by the PA reviewer since the prescriber is not asked to provide any information concerning these factors. Rather than listing specific criteria that must be met, the PA process should simply require that information be provided concerning the reason(s) that the prescriber has determined that a compounded drug is needed for the patient.

Fourth, despite the 2015 NDAA clear conduit to provide coverage of compounded drugs and TRICARE's self-proclaimed "most robust coverage" for the men and women who serve the United States, this PA process would make compounded drug coverage for TRICARE beneficiaries the most restrictive of any insurance plan throughout the entire country. Such a position is clearly contrary to the congressional intent expressed in Section 794 of the NDAA.

Conclusion:

Compounded medications play an important role in the health care industry. Compounding gives prescribers the ability to treat their patients' unique medical needs. Also, compounded medications fill in the gaps where commercial drugs fail to treat individuals. As a result, thousands of TRICARE beneficiaries currently rely on compounded medications to meet their individual needs that are not met by commercially available products. According to the information provided for the January 8, 2015 Beneficiary Advisory Panel meeting, approximately 140,000 TRICARE beneficiaries utilized compounded drugs from June 2013 to May 2014.

If TRICARE takes any action to deny, restrict, remove, or cancel this valuable component of its drug benefit, a significant number of military beneficiaries will be unable to obtain medications prescribed specifically for them by their treating physicians. As a result, patient health and quality of life could suffer as financial limitations on the commercial market will certainly prevent many individuals from filling their prescriptions as an out-of-pocket claim.

TRICARE is certainly concerned about the health and safety of its beneficiaries, and it has been demonstrated that compounded medications are of benefit to a large number of those beneficiaries. In response to pharmacy compounding safety concerns, both the FDA and state Boards of Pharmacy have implemented additional regulations. TRICARE has never claimed that medications compounded in accordance with state and FDA regulations actually pose a danger to recipients, nor are we aware of any empirical evidence demonstrating such a danger.

Our nation's heroes and their families deserve nothing less than our nation's best, so we must all strive to ensure their access to all necessary treatments and medications. TRICARE was created to ensure that our nation provides superior health support to military members and their families. Continued access to all compounded medications is critical to meet the health care needs of this population, such as a compounded medication to lower the incidence of respiratory infections or to treat invasive skin infections, burns, or even extreme circulatory issues that could potentially result in amputation if not treated appropriately.

We believe that the PA process recommended by the PTC is overly restrictive and must be reviewed and thoroughly evaluated with respect to its impact on TRICARE beneficiaries. Evidence-based compounding is part of the treatment regimen for tens of thousands of TRICARE beneficiaries, and it is essential that DOD conduct a more comprehensive analysis. We ask that you contact the DOD and request a delay in the implementation of this proposed policy change and that DOD initiate a study that examines beneficiary impact, possible alternative cost containment measures, and pharmacy best practices related to provision of compounded prescription drugs.

Appendix 3 01/08/2015 BAP Meeting Minutes

Comments to be submitted to the
Federal Advisory Committee of Uniform Formulary Beneficiary Advisory Panel

To:
Col. J. Michael Spilker, DFO, Uniform
Formulary Beneficiary Advisory Panel
700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

Dear Col. Spilker,

Please find the attached comments to be submitted to be part of the record for the January 8, 2015 meeting of the Uniform Formulary Beneficiary Advisory Panel. We are interested in a couple of topics slated to be discussed on the agenda.

We plan on being in attendance at the meeting but wanted to make sure that the panel had a chance to review several of our concerns ahead of the meeting.

We look forward to participating in the meeting and make ourselves available to you and your staff should you have any questions regarding the items discussed in our comments.

Thank you in advance for the consideration of our comments,

Aaron R. Lopez, JD, FCLS
Senior Director Public Affairs

About PCCA
PCCA is an independent compounding pharmacy's complete resource for fine chemicals, devices, equipment, training and support. PCCA is the leader in US providing products, services and support to almost 4,000 pharmacist members throughout the United States, Canada, Australia and the United Kingdom. Serving compounding pharmacists since 1981, PCCA is headquartered in Houston, Texas. For more information, visit pccarx.com.

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Tricare P&T Committee Recommendations Impact Quality and Limit Access to Compounded Medications for Beneficiaries

Overview

PCCA is deeply concerned about the unintended consequences of the Department of Defense's Pharmacy and Therapeutics (P&T) Committee's recommendation to discontinue coverage of compounded medications prepared from bulk drug substances. The Committee has also recommended a rigorous Prior Authorization (PA) process for compounded medications, with one of the criteria for payment being that the active ingredient(s) must be "indicated by the FDA to treat the diagnosis provided." This is virtually impossible to satisfy and will limit access to compounded medications -- prescribed by physicians -- to our service members.

The Issues

- While this recommendation is likely rooted in a desire to achieve maximum cost containment, there are potentially serious unintended consequences that will negatively impact military beneficiaries.

- Since the FDA does NOT approve pure active pharmaceutical ingredients, but rather finished products for a specific indication, the only way to meet this criterion is to utilize finished FDA approved products as the starting material for a compounded preparation. While this may sound like a good idea, it actually presents physicochemical issues that impact quality & accuracy. It is more exacting to build a compounded preparation from pure active pharmaceutical ingredients (bulk drug substances) or, in layman terms, "from scratch."

- Finished FDA approved products contain excipients (fillers, binders, etc.) that may not be compatible with other desirable ingredients in the compounded preparation, or may affect the overall stability of the preparation. Some patients may also have sensitivities or allergies to these excipients and dyes.

- Additionally, finished FDA approved products have an allowable range of variance for active ingredient concentrations within the product, generally ± 10% of labeled potency. Thus, a pharmacist would be starting from a relative unknown. It is more accurate to make a compounded preparation from pure starting materials that can be weighed and measured precisely.

- FDA approved products, especially in pain management, are often prescribed for off-label uses. The requirement for compounded preparations, even if utilizing finished FDA approved products as starting ingredients, to match the active ingredient(s) with an approved indication is unprecedented, and creates a double standard when compared to non-compounded prescriptions. Also, because systems are not currently in place for all prescribers and pharmacies to consistently collect and report this information, this requirement would certainly