EXECUTIVE SUMMARY

Uniform Formulary (UF) Beneficiary Advisory Panel (BAP)

March 22, 2017

I. INTERIM MEETING: UF CLASS REVIEWS—PROTON PUMP INHIBITORS (PPIs)

PPIs—UF Recommendation

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) esomeprazole (Nexium brand and generics) be designated NF and non-step-preferred. No change was recommended to the formulary status for the other PPIs. The formulary recommendation is as follows:

- UF and step-preferred:
  - omeprazole (Prilosec generics)
  - pantoprazole (Protonix generics)
  - rabeprazole tablets (Aciphex generics)
- UF and non-step-preferred
  - omeprazole 40 mg capsule (Prilosec)
  - rabeprazole sprinkles (Aciphex sprinkles)
- NF and non-step-preferred:
  - esomeprazole (Nexium brand and generics)
  - esomeprazole strontium
  - dexlansoprazole (Dexilant)
  - lansoprazole (Prevacid)
  - omeprazole/sodium bicarbonate (Zegerid)
- This recommendation includes step therapy (automated PA), which requires a trial of omeprazole, pantoprazole, and rabeprazole in new and current users presenting with a prescription for esomeprazole, and in new users presenting with a prescription for one of the other non-formulary PPIs.
- As part of this recommendation, the current Tier 1 copayment for Nexium will move to the Tier 3 non-formulary copayment at the Retail Network and Mail Order Pharmacy.

1. PPIs—Automated (Step Therapy) and Manual PA Criteria

The existing automated PA (step therapy) requires a trial of omeprazole, Nexium, pantoprazole, or rabeprazole prior to use of a non-formulary PPI.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) modifying the existing step therapy and manual PA criteria to require all new and current users of esomeprazole to try omeprazole, pantoprazole, and rabeprazole first.

Full PA Criteria:

PPIs: esomeprazole (Nexium)

PA criteria apply to all new and current users of esomeprazole (Nexium).

Automated PA criteria: The patient has filled a prescription for omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole tablets (Aciphex, generics) at any Military Health Service (MHS) pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order), during the previous 180 days.

AND

Manual PA criteria: A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole (Aciphex, generics) is NOT required if:

- The patient has tried omeprazole, pantoprazole tablets, and rabeprazole tablets (Aciphex, generics), and the patient had an inadequate response.
- The patient has tried omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics), and the patient was unable to tolerate them due to adverse effects.
- Treatment with omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency).

2. PPIs—UF and PA Implementation Period

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday that occurs no later than 90 days after signing of the minutes in all points of service; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

Summary of Physician Perspective:

- The PPIs were handled in an interim P&T meeting, due to the need to react quickly to a contract cancellation. Since the last PPI class review in 2007, several cost-effective generic products have entered the market. The class is highly therapeutically interchangeable, and now there will be three equally efficacious products on the formulary.
- The patients who require Nexium or one of the other non-step preferred products will go through the usual process for obtaining a non-formulary drug, by meeting the PA criteria. The PPIs will work no differently than what we have done with other drug classes.

- Approximately 178,000 patients will be affected by the formulary recommendation. We will work with the DHA Strategic Communications division to have additional beneficiary outreach, including publishing information on the DHA website, along with the usual beneficiary letters. We want to notify patients as quickly as possible about this recommendation.

Summary of Panel Questions and comments:

Ms. Le Gette has a few questions. She asks for clarification on the UF and step preferred. Is that an AND or and OR?

CAPT VonBerg replied it's an AND.

Ms. Le Gette stated, they have to try all three before they can get one of the products. What is the reason for putting the 40 mg behind the step on the Prilosec?
CAPT VonBerg replied that the Prilosec 40mg has always been behind the step. No change.

Ms. Le Gette stated that she didn't realize that it had always been behind the step. She further commented that there have been discussions regarding the timeline being no longer than 90 days. This drug, from a benefits stand point, has tons of rules in place to include special co-pays, PA on the generic and a change to the generic. Regarding set up, we are looking at 4-5 weeks to get all the rules changed. She wanted to make that comment that the changes are not something that can be done in a couple of days. Setting up in the system from an adjudication stand point will take time.

Ms. Le Gette asked if there were any more thoughts about the communication plan. Currently, we send letters to the affected population. However, if the implementation period is 90 days, will there be two (2) mailings to the beneficiary. What is the level of involvement from STRATCOM? I know there are a lot of hands on this one because lots the folks know about the contract cancellation.

CAPT Von Berg replied we are working on several things in addition to the letters. STRATCOM is engaged. All of the MTF's have been notified already. Several outreaches have been done earlier than normal.

CAPT Norton stated that VADM Bono has reached out to the MSOs and VSOs.

CAPT Von Berg added that papers are going up to the Hill so everyone will be notified in plenty of time to work through this issue. We understand there are a lot of issues to resolve.

Ms. Hostettler commented, there are a lot of patients affected and the implementation period is short. He was curious about a Nexium 40. Will they be brought back to a 20?

CAPT VonBerg stated that there are no instructions on any doses.

Dr. Anderson asked if the communication plan included prescribers.

CAPT VonBerg replied there are networks throughout the MTFs and TRICARE. Some of the processes are normal things that are done. This is not the first time there has been a change to this drug class. A change occurred in 2007. A 90-day implementation period is normal. It allows time to send the letters and the affected population to make the transition.

Ms. Buchanan asked if the contract cancellation restricts the implementation period to the 90 days. There are so many people who have to be notified, and a lot of the beneficiaries are affected. Is it possible to consider 180 days?

CAPT Von Berg replied yes.

Mr. Hostettler commented that from his experience, the MTF piece is easy to get done. The retail or mail is not as easily changed. I would suggest lengthening the implementation time.

Ms. Le Gette commented that she knows that it doesn't make it 100% better but the processes at the mail order are a little better. Because we are dispensing pharmacy, we are required to clear the reject. We reach out to the physician to make those changes to see (1) can we convert to one of the preferred products or (2) have the physician walk through the PA. We do have to clear the rejects ourselves in mail order. It doesn't go back to the patient.

CAPT VonBerg stated about 50% is mail order.

Ms. Le Gette replied the good thing about the letters is that the beneficiary has the information. They can show the letter to their doctor and proactively take action before the reject hits. That's the whole purpose, educating and providing the beneficiaries with the pharma-alternatives. We won't send the script back that is rejected.

Mr. Hostettler replied that a similar process happens in retail.

Ms. Le Gette said that a pharmacist cannot call in with a prior authorization. It has to be the physician. In retail, we have to rely on the pharmacist to say there is a prior authorization.

Mr. Hostettler commented that's my point. It is not an easy process.

Dr. Anderson stated he'll defer to legal on this whether it's in the purview of the BAP. I was wondering in terms of contracting. Has there been any consideration given to not allowing Pharma companies to exit agreements during the plan year? It

would be ideal from a beneficiary perspective if we could re-visit the exit terms of the agreements.

Mr. Wheeler responds that they'll have to explore that. The contractor will have to access, and we will build a larger window. We can look into that.

Dr. Anderson states that it's pretty common in Medicare plans to not allow the Pharma companies to exist during the plan year. The reason he mentions this is because it is in the interest of the beneficiary to stabilize the contracts. If these disruptive events would occur on Jan 1st, we wouldn't have to deal with these types of issues.

Mr. Wheeler stated that he would discuss with CAPT VonBerg.

The Chair called for a vote on the UF Recommendation, Automated (Step Therapy) and Manual PA Criteria and Implementaion for the Proton Pump Inhibitors.

- **PPIs – UF Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 4

  Director, DHA:

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

- **PPIs - Automated (Step Therapy) and Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 4

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- **PPIs - UF and PA Implementation Plan**

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***Additional Panel Questions and Comments*:**

Ms. Le Gette commented that this has been an advantageous contract to the MHS. It is obvious that the impact due to the cancellation of the contract will be big. There have

been discussions regarding the timeline. We don't have any cost data, for obvious reasons. However, we do know that this is basically going to happen anyway. Given in budget times, we have to consider the financial piece. The longer we wait, the more people get on the drug; the more people are disrupted. Therefore, I'm leaning more towards the 90-day implementation period. It's going to be a "pull-off-the-band aid" no matter when it happens.

Mr. Hostettler stated he has another recommendation: (1) in 90 days, stop new users from getting the drug, and (2) give current users a 180-day implementation plan to transition. In my opinion, this is a good compromise, to delay the implementation period for current users.

Dr. Anderson states that Mr. Hostettler prefers a longer implementation period and you have heard our comments regarding the implementation plan. I am also sensitive to the cost. I'm sure they are significant.

CAPT VonBerg replies exponential.

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P&T Comments – CAPT VonBerg

A. PPIs—Relative Clinical Effectiveness and Conclusion

Background—Following the February 2017 DoD P&T Committee meeting, the Pharmacy Operations Division became aware of a contract cancellation that would significantly impact MHS expenditures for the PPI Drug Class. An interim meeting was held to determine the clinical and cost-effectiveness, and UF status of the PPIs. The PPIs were previously evaluated for UF status at the May 2007 meeting. Current automated PA (step therapy) requiring a trial of omeprazole, esomeprazole (Nexium), pantoprazole, or rabeprazole applies to new users presenting with a prescription for a non-formulary PPI.

Relative Clinical Effectiveness Conclusion—At the May 2007 meeting, the P&T Committee reviewed evidence across a wide range of disease states and, in summary, concluded that PPIs appear very similar with regard to efficacy, safety, and tolerability. Recent updates to the safety of the PPIs were presented at the November 2016 P&T Committee meeting. There have been three drug safety communications from the FDA relating to long-term safety concerns with the PPIs as a class. The P&T Committee did not find new clinical evidence that would alter the conclusion from 2007 that the PPIs are highly therapeutically interchangeable. Risks of long-term use (>1 year) without a clear indication for use could outweigh the benefits of the PPIs. Deprescribing should be considered for appropriate patients.

B. PPIs—Relative Cost-Effectiveness Analysis and Conclusion

The current costs for the PPIs were evaluated. Nexium brand is exponentially more expensive than therapeutically equivalent generic PPIs.

C. PPIs—UF Recommendation

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D. PPIs—Automated (Step Therapy) and Manual PA Criteria

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ADDITIONAL COMMENTS:

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CAPT VonBerg replies exponential.

Dr. Kevin J. Sommers
Alternate Chairperson
Uniform Formulary Beneficiary
Advisory Panel