DECISION PAPER

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

February 2013

I. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Newer Sedative Hypnotic-1 (SED-1s) Agents—Zolpidem Sublingual Low-Dose Tablets (Intermezzo)

Relative Clinical Effectiveness Conclusion—Intermezzo is a new low-dose zolpidem sublingual (SL) formulation available in 1.75 mg and 3.5 mg tablets. The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that despite its unique FDA labeling for middle-of-the-night awakening compared to the other SED-1s and the potential for less next-day impairment, zolpidem SL low dose (Intermezzo) does not offer a clinically compelling advantage over the other SED-1s included on the Uniform Formulary (UF).

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that zolpidem SL low dose (Intermezzo) is not cost-effective when compared to other SED-1s included on the UF. The relative cost minimization analysis (CMA) ranking of the comparator SED-1s (ranked from most cost-effective to least cost-effective) revealed that zolpidem immediate release (IR) (Ambien IR, generics) < zaleplon (Sonata, generics) < zolpidem ER (Ambien CR, generics) < zolpidem SL (Edluar)< ramelteon (Rozerem) < zolpidem SL low dose (Intermezzo).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) zolpidem sublingual low dose (Intermezzo) be designated nonformulary (NF) due to the lack of compelling clinical advantages and cost disadvantage compared to UF products.

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following MN criteria for zolpidem SL low dose (Intermezzo): there is no alternative formulary agent—the patient has swallowing difficulties and requires a product for middle-of-the-night awakening.

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***
Existing automated prior authorization (step therapy) requires a trial of generic zolpidem IR or zaleplon, the step-preferred agents, prior to the other SED-1s in new users. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria should apply to Intermezzo. Coverage would be approved if the patient met any of the following criteria:

   a) Automated PA criteria: The patient has filled a prescription for zolpidem IR or zaleplon at any Military Health System (MHS) pharmacy point of service (POS) [military treatment facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

   b) Manual PA criteria: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is July 17, 2013.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

II. UF DRUG CLASS REVIEWS

A. Topical Pain Agents

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

- Lidocaine 5% patch (Lidoderm) is effective for the management of its orphan indication, postherpetic neuralgia (PHN). There is insufficient evidence supporting use of Lidoderm for other neuropathies (e.g., diabetic neuropathy, HIV-associated neuropathy, complex regional pain syndrome); however, several professional guidelines support its use. There is a paucity of data regarding use

of Lidoderm for other off-label conditions, including widespread or deep pain conditions such as fibromyalgia or chronic pain associated with osteoarthritis.

- A review of MHS prescribing trends showed a high discontinuation rate for Lidoderm, with a similar prevalence between unique user new starts and discontinuations. A Pharmacy Outcomes Research Team (PORT) analysis showed that Lidoderm is commonly prescribed in the MHS for off-label, non-supportable uses (e.g., musculoskeletal pain) that are not associated with neuropathic pain.
- There are no head-to-head trials comparing the topical diclofenac products (Voltaren gel, Pennsaid drops, and Flector patch) in terms of efficacy or safety. However, indirect evidence suggests the agents are highly interchangeable with regard to efficacy. Limited evidence suggests the agents are as effective as oral diclofenac.
- The incidence of gastrointestinal (GI) adverse events is lower with the topical diclofenac products compared to oral nonsteroidal anti-inflammatory drugs (NSAIDs), offering a potential advantage for patients with a history of GI bleeding or peptic ulcers.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that among topical diclofenac products, diclofenac gel (Voltaren) was the most cost-effective, based on the weighted average cost per day of treatment across all three POS, followed by diclofenac drops (Pennsaid) and diclofenac patch (Flector). Results from the CMA and budget impact analyses (BIAs) showed that the scenario where Lidocaine patch (Lidoderm) and diclofenac gel (Voltaren) were designated UF, with diclofenac drops (Pennsaid) and patch (Flector) designated NF, was the most cost-effective for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) lidocaine 5% patch (Lidoderm) and diclofenac 1% gel (Voltaren) remain designated with formulary status on the UF, and recommended NF status for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector), based on clinical and cost effectiveness.
2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) that none of the topical pain agents be designated BCF. Because the topical pain agents are a subclass of the Pain Agents, there is no requirement to designate a topical agent with BCF status. Several pain agents (narcotic analgesics and oral NSAIDs) are included on the BCF. The cost-effectiveness analysis revealed no financial benefit to the MHS for placement of the topical pain agents on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector). (See Appendix B for full MN criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—After extensive discussion, the P&T Committee recommended (12 for, 4 opposed, 1 abstained, 0 absent) manual PA criteria apply to all current and new users of lidocaine 5% patch (Lidoderm). Coverage is approved for patients who have a diagnosis of postherpetic neuralgia, other peripheral neuropathic pain, and for patients with non-neuropathic pain where an occupational or clinical reason exists and other analgesics are contraindicated. Coverage is not approved for other uses of Lidoderm. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is August 14, 2013.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Pulmonary II Drugs

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

- Aclidinium inhaler (Tudorza) is the second long-acting muscarinic agent (LAMA) on the market. The three clinical trials used to obtain FDA approval reported statistically significant improvement in spirometric endpoints, and two of the trials reported significantly fewer chronic obstructive pulmonary disease (COPD) exacerbations with aclidinium, compared to placebo.
- For aclidinium, the adverse event profile appears minimal, with primarily anticholinergic events reported. However, there is limited safety data with the 400 mcg approved dose. The FDA is requiring a prospective clinical trial to

assess cardiovascular safety. Longer duration and larger comparative trials are needed to determine aclidinium's place in therapy.

- Several trials have shown the LAMA tiotropium (Spiriva) is associated with clinically significant improvements in spirometric endpoints and reductions in risk for COPD exacerbations. Tiotropium is also reported to reduce the proportion of patients hospitalized for COPD exacerbations.

- Reports of a possible link between tiotropium and adverse cardiovascular (CV) events including death, stroke, and myocardial infarction have not been confirmed in prospective trials.

- Roflumilast (Daliresp) is the first oral selective inhibitor of phosphodiesterase type 4 marketed in the United States. Its FDA indication is limited to reducing the incidence of COPD exacerbations in patients with severe COPD. In two clinical trials, roflumilast was associated with statistically significant reductions in the rate of COPD exacerbations.

- For roflumilast, safety issues identified by the FDA included psychiatric events (including suicide), weight loss, GI upset and severe diarrhea, and nasal tumors. However, the FDA did not require additional prospective safety studies. A risk evaluation and mitigation strategy program was not required.

- Albuterol/ipratropium inhaler (Combivent Respimat) is the new propellant-free inhaler that is replacing the ozone-depleting chlorofluorocarbon (CFC)-containing Combivent metered dose inhaler (MDI). The clinical trial used to obtain FDA approval showed Combivent Respimat was non-inferior to Combivent CFC MDI in terms of improvements in spirometric endpoints.

Relative Cost-Effectiveness Conclusion—The P&T Committee reviewed proposed condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

C. Oral Anticoagulants

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following for warfarin, dabigatran (Pradaxa), and rivaroxaban (Xarelto). Apixaban (Eliquis) will be reviewed at an upcoming P&T meeting due to recent FDA approval in late 2012.

- The newer oral anticoagulants (NOACs) dabigatran and rivaroxaban have advantages of predictable anticoagulant effect, fixed dosing, and fewer drug interactions compared to warfarin (Coumadin, generic). Advantages of warfarin

include its long history of use, reliable reversal agent (vitamin K), and adverse effects that are predictable and manageable.

- The NOACs offer a convenience to patients; laboratory monitoring for efficacy and dietary restrictions are not required. More data is needed in patients with renal and hepatic impairment. No reversal agent is available with the NOACs.
- In non-valvular atrial fibrillation (Afib), dabigatran and apixaban were superior to poorly controlled warfarin at preventing stroke and systemic embolism, including hemorrhagic stroke; rivaroxaban was non-inferior to poorly controlled warfarin for these outcomes. Intracranial bleeding was lower with dabigatran, rivaroxaban, and apixaban compared to warfarin.
- For venous thromboembolism (VTE) prevention following orthopedic surgery, rivaroxaban was superior to enoxaparin at preventing symptomatic deep venous thrombosis (DVT), but at the cost of increased bleeding. For prevention of VTE recurrence following DVT or pulmonary embolism (PE), rivaroxaban in two trials was non-inferior to enoxaparin/warfarin for preventing recurrent VTE, with no difference in bleeding, and was superior to placebo in one trial for extended therapy for 6–12 months.
- Due to a lack of head-to-head trials, there is insufficient evidence to determine if one NOAC has advantages over the others.
- Patients require education and clinical monitoring to ensure appropriate use and avoid adverse reactions with the NOACs. Bleeding is a concern with all the NOACs, and dabigatran is associated with dyspepsia and major GI bleeding. For warfarin, a high risk of falls is not associated with risk of subsequent major bleeding.
- It remains to be determined whether the NOACs will increase the numbers of patients currently undertreated for stroke prevention in Afib. Also unknown is whether NOACs will improve persistence rates for anticoagulation therapy.

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

- Anticoagulant agents for stroke prevention in non-valvular AFib—CMA results showed that, in all scenarios, warfarin, including drug monitoring costs, was the least costly agent. Cost-effectiveness analysis (CEA) results showed that the incremental cost-effectiveness ratios per life year gained with dabigatran and rivaroxaban in relation to warfarin were in a range that could be considered cost-effective to the MHS.
- Anticoagulant agents for DVT/PE prophylaxis in hip and knee replacement surgery—CMA results demonstrated that rivaroxaban was a cost-effective

alternative compared to enoxaparin, based on analysis of the average weighted price per day of therapy at all three POS.

- BIA results—Scenarios where all drugs remain on the UF resulted in the greatest cost-avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) warfarin (Coumadin, generic), dabigatran (Pradaxa), and rivaroxaban (Xarelto) remain formulary on the UF.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining warfarin (Coumadin, generic) on the BCF. MTFs are highly encouraged to purchase the contracted warfarin generic product.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

III. UTILIZATION MANAGEMENT

A. PA

1. **Tretinoin Age Limits**—The P&T Committee reviewed the current age limits for tretinoin, which does not allow use in patients older than 35 years. While treatment for acne is covered by TRICARE benefits, cosmetic services and supplies are excluded from the benefit, including treatments for photoaging of the skin.

   a) ***COMMITTEE ACTION: TRETINOIN AGE LIMITS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing the age limit for tretinoin products that are not exclusively labeled for cosmetic use at all 3 MHS POS (MTF, Mail Order, and the Retail Network). Acne can occur beyond age 35. Treatment for acne is covered by TRICARE benefits and low-cost tretinoin generic formulations are available. Tretinoin products/derivatives specifically indicated for cosmetic use as a result of the aging process (e.g., Renova, Refissa, Avage) remain excluded from the Pharmacy benefit.

2. **Zolpidem Gender-Based Dosing**—The P&T Committee discussed whether PA criteria are needed for zolpidem products, given new recommendations from the FDA in January 2013 regarding dosing in women. For women, lower dosing is recommended, as blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. A review of MHS prescriptions in the last six months of 2012 showed significant use of the higher zolpidem dosages in women.

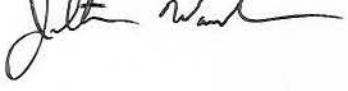
    a) ***COMMITTEE ACTION: ZOLPIDEM GENDER-BASED DOSING*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to not institute gender-based dosing PA criteria for zolpidem products, and to instead educate providers of the new recommendations, and notify patients via beneficiary newsletters of the concerns regarding impaired driving and activities requiring mental alertness the morning after use. The P&T Committee recommended re-evaluating this issue in six months to review MHS prescribing trends and whether additional measures are necessary.

B. Quantity Limits (QLs)

1. The P&T Committee reviewed quantity limit proposals for four products: aclidinium oral inhaler (Tudorza) for COPD, beclomethasone dipropionate nasal inhaler (Qnasl) for seasonal and perennial allergic rhinitis, ponatinib (Iclusig) tablets for treatment of patients with chronic myelogenous leukemia (CML), and cabozantinib (Cometriq) for patients with progressive, metastatic medullary thyroid cancer. QLs are recommended due to either existing QLs in the class to prevent wastage (inhalers) or due to high cost/adverse event profiles with subsequent need for dosage changes.

    a) ***COMMITTEE ACTION: ACLIDINIUM (TUDORZA), BECLOMETHASONE (QNASAL), PONATINIB (ICLUSIG) and CABOZANTINIB (COMETRIQ) QLs***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for aclidinium oral inhaler (Tudorza), beclomethasone dipropionate nasal inhaler (Qnasl), ponatinib tablets (Iclusig), and cabozantinib (Cometriq), based on FDA-approved labeling. (See Appendix D.)

Director, TMA, Decision: ☒ Approved ☐ Disapproved



Approved, but modified as follows:

VI. ITEMS FOR INFORMATION

A. Options for Future DoD P&T Committee Meetings—Given the current budget restrictions regarding travel, the P&T Committee discussed options for future meetings, including Defense Connect Online (DCO) web conferences. Items of concern voiced by the P&T Committee if DCO teleconferences were implemented in lieu of in-person meetings included maintaining confidentiality of the contracted pricing solicitations, likelihood of interruption/inattention, decreased engagement by P&T Committee members, and potential lost opportunities for cost-avoidance, which would ultimately negatively impact TRICARE beneficiaries.

B. Cost-Effectiveness Modeling Review—The P&T Committee reviewed an analysis of previous UF economic evaluations that compared the performance of cost modeling projections and budget impact analyses to actual observed costs in the MHS. Overall, the evaluated cost-effectiveness models performed suitably, demonstrating expenditure and utilization trends that were similar between modeled outcomes and actual results. Possible factors contributing to variance between the modeled outcomes and actual results were discussed. Potential improvements identified during the review will be incorporated into future cost modeling scenarios and processes.

C. Smoking Cessation Program Final Rule—As of the meeting date, the Smoking Cessation Final Rule has not yet been published in the Code of Federal Regulations. The Proposed Rule provides that smoking cessation pharmaceutical agents, including FDA-approved over-the-counter pharmaceutical agents, will be available through the TRICARE Mail Order Pharmacy or the MTF. Until publication of the Final Rule, all UF/BCF recommendations for smoking cessation products from the May 2012 DoD P&T Committee meeting remain on hold.

D. POS Analysis Update—The PORT provided an update on MHS prescribing trends by point of service. The results showed that for branded medications considered maintenance products (e.g., used for chronic conditions and not specialty medications), drug costs (30-day equivalent prescriptions) would have been about 27%–31% lower, if all prescriptions that were filled and dispensed in the Retail Network had instead been dispensed at the MTFs or at the Mail Order. In contrast, drug costs would have been about 13%–18% higher if generic drugs dispensed in the Retail Network had instead been dispensed in the MTFs or Mail Order.

E. **New TRICARE Pharmacy Copayments**—The P&T Committee was briefed on new pharmacy co-pays that were implemented in February 2013. At the Mail Order POS, co-pays for Tier 1 drugs (generics) remain $0, with co-pays of $13 for Tier 2 products (preferred brands) and $43 for Tier 3 products (non-preferred brands). The new co-pays in the Retail Network are $5 (Tier 1), $17 (Tier 2) and $44 (Tier 3). In the Mail Order, one co-pay applies for up to a 90-day supply, and one co-pay applies for up to a 30-day supply in the Retail Network.

F. **Step Therapy Safety Net**—The P&T Committee was briefed on the Rapid Response Step Therapy "Safety Net" Program implemented in September 2012. The program was initiated to educate beneficiaries affected by a step therapy reject and to educate providers regarding step-preferred drugs. The program targets beneficiaries who have not received a prescription fill for either a step-preferred or non step-preferred drug, after the initial reject. Since implementation, the MHS successful cases averaged 38.30%, which is similar to successful cases reported in commercial programs. Updates on the program will be periodically provided to the P&T Committee.

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

Jonathan Woodson, M.D.
Director

13 May 2013
Date

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE MINUTES AND RECOMMENDATIONS

February 2013

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 20 and 21, 2013, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is found in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2012 Minutes**—Jonathon Woodson M.D., Director, approved the minutes for the November 2012 DoD P&T Committee meeting on February 13, 2013.
2. **Clarification to the November 2012 Minutes—Prior Authorization (PA) Implementation Date for enzalutamide (Xtandi) and abiratone (Zytiga):** The November minutes were clarified to state March 20, 2013, is the effective implementation date for PA criteria applicable to enzalutamide (Xtandi) and abiratone (Zytiga).

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Newer Sedative Hypnotic-1 (SED-1s) Agents—Zolpidem Sublingual Low Dose Tablets (Intermezzo)

Relative Clinical Effectiveness—Intermezzo is a new low-dose zolpidem sublingual

(SL) formulation available in 1.75 mg and 3.5 mg tablets. Women should not receive Intermezzo doses larger than 1.75 mg. Intermezzo is specifically approved for treatment of insomnia characterized by middle-of-the-night waking followed by difficulty returning to sleep. In one study, there was a statistically significant improvement in sleep latency and total sleep time with Intermezzo versus placebo for middle-of-the-night awakening, but another placebo-controlled trial found no differences in total sleep time. No studies have been completed with an active comparator.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) despite its unique FDA labeling for middle-of-the-night awakening compared to the other SED-1s and the potential for less next-day impairment, zolpidem SL low dose (Intermezzo) does not offer a clinically compelling advantage over the other SED-1s included on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that zolpidem SL low dose (Intermezzo) is not cost-effective when compared to other SED-1s included on the UF. The relative cost minimization analysis (CMA) ranking of the comparator SED-1s (ranked from most cost-effective to least cost-effective) revealed that zolpidem immediate release (IR) (Ambien IR, generics) < zaleplon (Sonata, generics) < zolpidem ER (Ambien CR, generics) < zolpidem SL (Edluar)< ramelteon (Rozerem) < zolpidem SL low dose (Intermezzo).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) zolpidem sublingual low dose (Intermezzo) be designated NF due to the lack of compelling clinical advantages and cost disadvantage compared to UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following MN criteria for zolpidem SL low dose (Intermezzo): there is no alternative formulary agent—the patient has swallowing difficulties and requires a product for middle-of-the-night awakening.

3. ***COMMITTEE ACTION: PA CRITERIA***—Existing automated prior authorization (step therapy) requires a trial of generic zolpidem IR or zaleplon, the step-preferred agents, prior to the other SED-1s in new users. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria should apply to Intermezzo. Coverage would be approved if the patient met any of the following criteria:

a) Automated PA criteria: The patient has filled a prescription for zolpidem IR or zaleplon at any Military Health System (MHS) pharmacy point of service (POS) [military treatment facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

b) Manual PA criteria: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is July 17, 2013.

V. UF DRUG CLASS REVIEWS

A. Topical Pain Agents

Background and Relative Clinical Effectiveness—The P&T Committee evaluated the Topical Pain agents subclass, which is comprised of lidocaine 5% patch (Lidoderm), diclofenac 1% gel (Voltaren), diclofenac 1.5% solution (Pennsaid), and diclofenac 1.3% patch (Flector).

The Topical Pain agents are a subclass of the Pain Agents UF drug class, which includes the Narcotic Analgesics and oral Non-Steroidal Anti-Inflammatory drugs (NSAIDs).

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

- Extensive review of the literature provided limited evidence regarding efficacy and safety of the topical pain agents.
- Lidoderm is effective as first line and/or combination therapy for the management of its orphan indication—postherpetic neuralgia (PHN). There is insufficient evidence supporting use of Lidoderm for other neuropathies (e.g., diabetic neuropathy, HIV-associated neuropathy, complex regional pain syndrome); however, several professional guidelines support its use. There is a paucity of data regarding use of Lidoderm for other off-label conditions, including widespread or deep pain conditions such as fibromyalgia or chronic pain associated with osteoarthritis.

- A review of MHS prescribing trends showed a high discontinuation rate for Lidoderm, with a similar prevalence between unique user new starts and discontinuations.
- Topical diclofenac formulations (Voltaren gel, Pennsaid drops, and Flector patch) are effective in managing superficial pain associated with osteoarthritis of the knee and wrist, and superficial pain associated with sprains, strains, and contusions.
- There are no head-to-head trials comparing the topical diclofenac products in terms of efficacy or safety. However, indirect evidence suggests the agents are highly interchangeable with regard to efficacy. Limited evidence suggests the agents are as effective as oral diclofenac.
- The incidence of gastrointestinal (GI) adverse events is lower with the topical diclofenac products compared to oral NSAIDs, offering a potential advantage for patients with a history of GI bleeding or peptic ulcers.
- Systemic side effects are uncommon and the most common adverse events are application site reactions, including pruritis with Lidoderm, and dry skin, erythema and pruritis with the topical diclofenac products.
- Flector is indicated for short-term use associated with acute musculoskeletal injury and is likely to be used in a younger population than Voltaren gel or Pennsaid drops.
- Pennsaid is indicated only for osteoarthritis of the knee and clinical usefulness may be limited by multiple daily dosing (four times daily).
- A Pharmacy Outcomes Research Team (PORT) analysis reviewing ICD-9 codes associated with Lidoderm prescriptions in the MHS revealed significant overlap for diagnoses associated with neuropathic and musculoskeletal pain. Only 3% of prescriptions were written for patients with the FDA-approved PHN indication. Up to 49% of patients receiving Lidoderm prescriptions had no neuropathic diagnosis: 39% had musculoskeletal diagnoses without neuropathic diagnoses and 10% had neither neuropathic nor musculoskeletal diagnostic codes. This suggests that Lidoderm is commonly used in the MHS for off-label use that is not associated with neuropathic pain.

Relative Cost-Effectiveness Analysis and Conclusion—Pharmacoeconomic analyses were performed for the Topical Pain Agent subclass, including CMA and budget impact analyses (BIAs). For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted.

The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that among topical diclofenac products, diclofenac gel (Voltaren) was the most cost-effective, based

on the weighted average cost per day of treatment across all three POS, followed by diclofenac drops (Pennsaid), and diclofenac patch (Flector). Results from the CMA and BIAs showed that the scenario where Lidocaine patch (Lidoderm) and diclofenac gel (Voltaren) were designated UF, with diclofenac drops (Pennsaid) and patch (Flector) designated NF, was the most cost-effective for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) lidocaine 5% patch (Lidoderm) and diclofenac 1% gel (Voltaren) remain designated with formulary status on the UF, and recommended NF status for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector), based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) that none of the topical pain agents be designated BCF. Because the topical pain agents are a subclass of the Pain Agents, there is no requirement to designate a topical agent with BCF status. Several pain agents (narcotic analgesics and oral NSAIDs) are included on the BCF. The cost-effectiveness analysis revealed no financial benefit to the MHS for placement of the topical pain agents on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector). (See Appendix B for full MN criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—After extensive discussion, the P&T Committee recommended (12 for, 4 opposed, 1 abstained, 0 absent) manual PA criteria apply to all current and new users of lidocaine 5% patch (Lidoderm). Coverage is approved for patients who have a diagnosis of postherpetic neuralgia, other peripheral neuropathic pain, and for patients with non-neuropathic pain where an occupational or clinical reason exists and other analgesics are contraindicated. Coverage is not approved for other uses of Lidoderm. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is August 14, 2013.

B. Pulmonary II Drugs

Background and Relative Clinical Effectiveness—The Pulmonary II Drug Class is comprised of aclidinium inhaler (Tudorza), tiotropium inhaler (Spiriva), roflumilast tablets (Daliresp), ipratropium (Atrovent HFA inhaler; Atrovent nebulized solution), and ipratropium/albuterol (Combivent, Combivent Respimat and DuoNeb nebulized solution). The two inhalation solutions, ipratropium (Atrovent) and ipratropium/ albuterol (DuoNeb), are available in generic formulations.

Combivent metered dose inhaler (MDI) is one of the last available chlorofluorocarbon (CFC) MDIs on the market and will have supplies exhausted by December 2013. Its replacement is Combivent Respimat, a new CFC- and propellant-free formulation.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following clinical effectiveness conclusions:

- With regard to the long-acting muscarinic agents (LAMAs), aclidinium (Tudorza) and tiotropium (Spiriva), and the short-acting muscarinic agent (SAMA), ipratropium (Atrovent HFA), the P&T Committee concluded the following:
  - Aclidinium (Tudorza) is a dry powder inhaler (DPI) administered twice daily. The three clinical trials used to obtain FDA approval reported statistically significant improvement in lung function/spirometric endpoints [forced expiratory volume in 1 second (FEV_1)] compared with placebo at 12 weeks. Two of the trials reported statistically significant reductions in chronic obstructive pulmonary disease (COPD) exacerbations versus placebo.
  - In a small-dose ranging trial with 30 participants lasting for 15 days, there was no significant difference between aclidinium and tiotropium in terms of improvements in spirometric endpoints (FEV_1).
  - For aclidinium, the adverse event profile appears minimal, with primarily anticholinergic events reported. However, there is limited safety data with the approved 400 mcg dose. The FDA is requiring a prospective clinical trial to assess cardiovascular (CV) safety. Longer duration and larger comparative trials are needed to determine aclidinium's place in therapy.
  - Tiotropium is formulated as a DPI administered once daily. Several trials have documented tiotropium is associated with clinically significant improvements in FEV_1 and forced vital capacity compared with placebo or ipratropium. Additional benefits include reductions in the risk for COPD exacerbations as well as reduced hospitalizations due to COPD exacerbations.
  - Reports of a possible link between tiotropium and adverse CV events including death, stroke, and myocardial infarction (MI) were first raised in

2008, based on meta-analysis and retrospective analyses of health claims data. New data based on a large 4-year prospective trial (UPLIFT) and other analyses does not support an association with tiotropium and CV adverse events.

  - The other common adverse effects of tiotropium are anticholinergic in nature. There are reports of incorrect administration of the inhaler, with patients swallowing the capsule, instead of administering it via the HandiHaler device.
  - Ipratropium has been marketed since 1995. Review of the clinical literature for efficacy did not add substantial new information. For safety, while there may be a possible signal between ipratropium use and CV adverse events, the data is limited due to study design (cohort studies), influence of underlying CV disease, and presence of underlying pulmonary cancers.

- With regard to the SAMA/LAMA combination products, Combivent Respimat demonstrated similar improvements in FEV_1 as Combivent CFC MDI in the clinical trial used to obtain FDA approval. Some older patients or those with hand joint problems may require assistance for the initial assembly of the Combivent Respimat inhaler and cartridge. Combining bronchodilators may improve efficacy and decrease the risk of side effects, as compared to maximizing the dose of a single bronchodilator, and also provide a convenience to the patient. The safety profile of Combivent Respimat is similar to Combivent CFC MDI.
- Roflumilast (Daliresp) is the first oral phosphodiesterase type 4 inhibitor marketed in the United States, and is administered once daily. It has a narrow FDA indication, limited to reducing the incidence of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.
- Roflumilast should not be used to treat acute bronchospasm, as it has modest effects on FEV_1, is not a bronchodilator, and instead has anti-inflammatory actions. Combining roflumilast with a long-acting bronchodilator [salmeterol (Serevent) or tiotropium] results in improvements in FEV_1. The two trials used to obtain FDA approval reported roflumilast reduced COPD exacerbation rates by 15%–19% compared to placebo.
- For roflumilast, safety issues identified by the FDA included psychiatric events (including suicide), weight loss, GI upset and severe diarrhea, and nasal tumors. However, the FDA did not require additional prospective safety studies. A risk evaluation and mitigation strategy program was not required.

Relative Cost-Effectiveness Analysis, Relative Cost-Effectiveness Conclusion, UF Recommendation, BCF Recommendation—The P&T Committee reviewed proposed

condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

C. Oral Anticoagulants

Background and Relative Clinical Effectiveness—The Oral Anticoagulant Drug Class is comprised of warfarin (Coumadin, generic), and the newer oral anticoagulants (NOACs) dabigatran (Pradaxa) and rivaroxaban (Xarelto). Another NOAC, apixaban (Eliquis) was approved in December 2012, and will be evaluated as a new drug at an upcoming meeting. Warfarin has been designated a BCF drug since before 1998, prior to implementation of the Uniform Formulary Rule in 2005.

Dabigatran, rivaroxaban, and apixaban are approved for stroke prevention in patients with non-valvular atrial fibrillation (Afib). Rivaroxaban has additional indications for prophylaxis of venous thromboembolism (VTE) in patients following hip or knee replacement surgery, and is also indicated to prevent recurrent VTE in patients with deep vein thrombosis (DVT) or pulmonary embolism (PE).

A PORT analysis showed that MHS users of dabigatran have a mean age of 76 years and 91% of patients have an ICD-9 diagnosis code for Afib. MHS users of rivaroxaban have a mean age of 70 years and 41% of patients have an ICD-9 diagnosis code for Afib versus 39% of patients with a diagnosis code for hip of knee replacement surgery.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following clinical effectiveness conclusions:

- The NOACs dabigatran and rivaroxaban have advantages of predictable anticoagulant effect, fixed dosing, and fewer drug interactions compared to warfarin (Coumadin, generic). Advantages of warfarin include its long history of use, reliable reversal agent (vitamin K), and adverse effects that are predictable and manageable.
- The NOACs offer a convenience to patients; laboratory monitoring for efficacy and dietary restrictions are not required. More data is needed in patients with renal and hepatic impairment. No reversal agent is available with the NOACs.
- In non-valvular Afib, dabigatran and apixaban were superior to poorly controlled warfarin (time in therapeutic range < 65.5%) at preventing stroke and systemic embolism, including hemorrhagic stroke; rivaroxaban was non-inferior to poorly controlled warfarin for these outcomes. Intracranial bleeding was lower with dabigatran, rivaroxaban, and apixaban compared to warfarin.
- For VTE prevention following orthopedic surgery, rivaroxaban was superior to enoxaparin at preventing symptomatic DVT, but at the cost of increased bleeding. Dabigatran and apixaban were similar to enoxaparin at VTE

prevention; no difference in bleeding was noticed with dabigatran, but a lower risk of bleeding was shown with apixaban versus enoxaparin.

- For prevention of VTE recurrence following DVT or PE, rivaroxaban in two trials was non-inferior to enoxaparin/warfarin for preventing recurrent VTE, with no difference in bleeding, and was superior to placebo in one trial for extended therapy. Dabigatran in one trial was non-inferior to enoxaparin/warfarin for preventing recurrent VTE, with no difference in bleeding. Apixaban was superior to placebo for prevention of recurrent VTE over 12 months (extended therapy) in one trial.
- Due to a lack of head-to-head trials, there is insufficient evidence to determine if one NOAC has advantages over the others for stroke prevention in non-valvular Afib, prophylaxis of VTE following hip or knee replacement surgery, or for prevention of VTE recurrence following DVT or PE.
- Patients require education and clinical monitoring to ensure appropriate use and avoid adverse reactions with the NOACs. Bleeding is a concern with all the NOACs, and dabigatran is associated with dyspepsia and major GI bleeding. For warfarin, a high risk of falls is not associated with risk of subsequent major bleeding.
- It remains to be determined whether the NOACs will increase the numbers of patients currently undertreated for stroke prevention in Afib. Also unknown is whether NOACs will improve persistence rates for anticoagulation therapy.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee evaluated the relative cost-effectiveness of the anticoagulant agents for stroke prevention in non-valvular Afib and for prophylaxis of VTE in patients undergoing knee or hip replacement surgery. CMAs were performed for both indications. Additionally, a cost-effectiveness analysis (CEA) evaluated the agents for stroke prevention in Afib.

- For the anticoagulant drugs, CMAs were used to compare the anticoagulant drug costs including relevant drug monitoring costs (e.g., international normalized ratio testing for warfarin and office visits).
- The CEA model was constructed based on comparisons of relevant clinical trial data from systematic reviews. The CEA model assessed the potential impact of anticoagulant treatment on the occurrence of stroke, bleeding, MI, and mortality. Results were reported as an incremental cost-effectiveness ratio (ICER) comparing the additional costs per life year gained with the NOACs dabigatran (Pradaxa) and rivaroxaban (Xarelto) in relation to warfarin.
- For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted. BIA results were presented to

the P&T Committee. The MHS projected budgetary impact varied depending on which medication was selected for BCF, UF, or NF status.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 against, 0 abstained, 0 absent) the following:

- Anticoagulant agents for stroke prevention in non-valvular AFib—CMA results showed that, in all scenarios, warfarin (Coumadin, generic), including drug monitoring costs, was the least costly agent. CEA results showed that the ICERs per life year gained with dabigatran and rivaroxaban in relation to warfarin were in a range that could be considered cost-effective to the MHS.
- Anticoagulant agents for DVT/PE prophylaxis in hip and knee replacement surgery—CMA results demonstrated that rivaroxaban (Xarelto) was a cost-effective alternative compared to enoxaparin (Lovenox), based on analysis of the average weighted price per day of therapy at all three POS.
- BIA results—Scenarios where all drugs remain on the UF resulted in the greatest cost-avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) warfarin (Coumadin, generic), dabigatran (Pradaxa), and rivaroxaban (Xarelto) remain formulary on the UF.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining warfarin (Coumadin, generic) on the BCF. MTFs are highly encouraged to purchase the contracted warfarin generic product.

VI. UTILIZATION MANAGEMENT

A. PAs

1. **Tretinoin Age Limits**—The P&T Committee reviewed the current age limits for tretinoin, which does not allow use in patients older than 35 years. While treatment for acne is covered by TRICARE benefits, cosmetic services and supplies are excluded from the benefit, including treatments for photoaging of the skin.

a) ***COMMITTEE ACTION: TRETINOIN AGE LIMITS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing the age limit for tretinoin products that are not exclusively labeled for cosmetic use at all 3 MHS POS (MTF, Mail Order, and the Retail Network). Acne can occur beyond age 35 years. Treatment for acne is covered by TRICARE benefits and low-cost tretinoin generic formulations are available. Tretinoin products/derivatives specifically indicated for cosmetic use as a result of the aging process (e.g., Renova, Refissa, Avage) remain excluded from the Pharmacy benefit.

2. **Zolpidem Gender-Based Dosing**—The P&T Committee discussed whether PA criteria are needed for zolpidem products, given new recommendations from the FDA in January 2013 regarding dosing in women. For women, lower dosing is recommended, as blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. A review of MHS prescriptions in the last six months of 2012 showed significant use of the higher zolpidem dosages in women.

   a) ***COMMITTEE ACTION: ZOLPIDEM GENDER-BASED DOSING*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to not institute gender-based dosing PA criteria for zolpidem products, and to instead educate providers of the new recommendations, and notify patients via beneficiary newsletters of the concerns regarding impaired driving and activities requiring mental alertness the morning after use. The P&T Committee recommended re-evaluating this issue in six months to review MHS prescribing trends and whether additional measures are necessary.

B. Quantity Limits (QLs)

1. The P&T Committee reviewed quantity limit proposals for four products: aclidinium oral inhaler (Tudorza) for COPD, beclomethasone dipropionate nasal inhaler (Qnasl) for seasonal and perennial allergic rhinitis, ponatinib (Iclusig) tablets for treatment of patients with chronic myelogenous leukemia (CML), and cabozantinib (Cometriq) for patients with progressive, metastatic medullary thyroid cancer. QLs are recommended due to either existing QLs in the class to prevent wastage (inhalers) or due to high cost/adverse event profiles with subsequent need for dosage changes.

a) ***COMMITTEE ACTION: ACLIDINIUM (TUDORZA), BECLOMETHASONE (QNASAL) PONATINIB (ICLUSIG) and CABOZANTINIB (COMETRIQ) QLs***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for aclidinium oral inhaler (Tudorza), beclomethasone dipropionate nasal inhaler (Qnasl), ponatinib tablets (Iclusig), and cabozantinib (Cometriq), based on FDA-approved labeling. (See Appendix D.)

VII. ITEMS FOR INFORMATION

A. Options for Future DoD P&T Committee Meetings—Given the current budget restrictions regarding travel, the P&T Committee discussed options for future meetings, including Defense Connect Online (DCO) web conferences. Items of concern voiced by the P&T Committee if DCO teleconferences were implemented in lieu of in-person meetings included maintaining confidentiality of the contracted pricing solicitations, likelihood of interruption/inattention, decreased engagement by P&T Committee members, and potential lost opportunities for cost-avoidance, which would ultimately negatively impact TRICARE beneficiaries.

B. Cost-Effectiveness Modeling Review—The P&T Committee reviewed an analysis of previous UF economic evaluations that compared the performance of cost modeling projections and budget impact analyses to actual observed costs in the MHS. Overall, the evaluated cost-effectiveness models performed suitably, demonstrating expenditure and utilization trends that were similar between modeled outcomes and actual results. Possible factors contributing to variance between the modeled outcomes and actual results were discussed. Potential improvements identified during the review will be incorporated into future cost modeling scenarios and processes.

C. Smoking Cessation Program Final Rule—As of the meeting date, the Smoking Cessation Final Rule has not yet been published in the Code of Federal Regulations. The Proposed Rule provides that smoking cessation pharmaceutical agents, including FDA-approved over-the-counter pharmaceutical agents, will be available through the TRICARE Mail Order Pharmacy or the MTF. Until publication of the Final Rule, all UF/BCF recommendations for smoking cessation products from the May 2012 DoD P&T Committee meeting remain on hold.

D. POS Analysis Update—The PORT provided an update on MHS prescribing trends by point of service. The results showed that for branded medications considered maintenance products (e.g., used for chronic conditions and not specialty

medications), drug costs (30-day equivalent prescriptions) would have been about 27%–31% lower, if all prescriptions that were filled and dispensed in the Retail Network had instead been dispensed at the MTFs or at the Mail Order. In contrast, drug costs would have been about 13%–18% higher if generic drugs dispensed in the Retail Network had instead been dispensed in the MTFs or Mail Order.

E. **New TRICARE Pharmacy Copayments**—The P&T Committee was briefed on new pharmacy co-pays that were implemented in February 2013. At the Mail Order POS, co-pays for Tier 1 drugs (generics) remain $0, with co-pays of $13 for Tier 2 products (preferred brands) and $43 for Tier 3 products (non-preferred brands). The new co-pays in the Retail Network are $5 (Tier 1), $17 (Tier 2) and $44 (Tier 3). In the Mail Order, one co-pay applies for up to a 90-day supply, and one co-pay applies for up to a 30-day supply in the Retail Network.

F. **Step Therapy Safety Net**—The P&T Committee was briefed on the Rapid Response Step Therapy "Safety Net" Program implemented in September 2012. The program was initiated to educate beneficiaries affected by a step therapy reject and to educate providers regarding step-preferred drugs. The program targets beneficiaries who have not received a prescription fill for either a step-preferred or non step-preferred drug, after the initial reject. Since implementation, the MHS successful cases averaged 38.30%, which is similar to successful cases reported in commercial programs. Updates on the program will be periodically provided to the the P&T Committee.

VIII. ADJOURNMENT

The meeting adjourned at 1145 hours on February 21, 2013. The next meeting will be in May 2013.

Appendix A—Attendance: February 2013 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Implementation Status of UF Recommendations/Decisions Summary

Appendix F—Table of Abbreviations

Appendix A—Attendance: February 2013 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CDR Joe Lawrence, MSC	Director, DoD Pharmacoeconomic Center (Recorder)
Col George Jones, BSC	Deputy Chief, Pharmaceutical Operations Directorate
COL Peter Bulatao, MS for COL John Spain, MS	Army, Pharmacy Officer
Col Mike Spilker, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
COL Ted Cieslak, MC	Army, Physician at Large
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CDR Brian King, MC for CAPT Walter Downs, MC	Navy, Internal Medicine Physician
LTC Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
COL Bruce Lovins, MC	Army, Family Practice Physician
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Jeremy King, MC	Air Force, OB/GYN Physician
CDR Eileen Hoke, MC	Navy, Pediatrics
Dr. Miguel Montalvo	TRICARE Regional Office-South Chief of Clinical Operations Division and Medical Director
Nonvoting Members Present	
Mr. David Hurt	Associate General Counsel, TMA
COL Todd Williams, MS	Defense Medical Materiel Program Office
CDR Jay Peloquin, MSC via DCO	Defense Logistics Agency Troop Support
Guests	
Mr. Bill Davies via DCO	TRICARE Management Activity, Pharmaceutical Operations Directorate
CDR Matthew Baker, USPHS	Indian Health Service

Appendix A—Attendance (continued)

Guests	
Stephani Folts	Student, University of Incarnate Word Feik School of Pharmacy
Brian Hettler	Student, University of Incarnate Word Feik School of Pharmacy
Others Present	
LTC Chris Conrad, MS	DoD Pharmacoeconomic Center
LCDR Marisol Martinez, USPHS	DoD Pharmacoeconomic Center
LCDR Joshua Devine, USPHS	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
Lt Col Melinda Henne, MC	DoD Pharmacoeconomic Center
LCDR Ola Ojo, MSC	DoD Pharmacoeconomic Center
LCDR Linh Quach, MSC	DoD Pharmacoeconomic Center
Maj David Folmar, BSC	DoD Pharmacoeconomic Center
MAJ Misty Cowan, MC	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Amy Lugo via DCO	DoD Pharmacoeconomic Center
Dr. Teresa Anekwe via DCO	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Dean Valibhai	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacoeconomic Center
LT Kendra Jenkins, USPHS	Pharmacy Resident
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Mr. Kirk Stocker	DoD Pharmacy Outcomes Research Team contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Zolpidem sublingual low dose (Intermezzo) **Newer Sedative Hypnotic-1 (SED-1s)**	• No alternative formulary agent – patient has swallowing difficulties and requires a product for middle-of-the-night awakening.
• Diclofenac 1.5% solution (Pennsaid) **Topical Pain Medications**	• Patient has experienced significant adverse effects from ALL of the formulary medications that are not expected to occur with the nonformulary topical pain medication (e.g., patient had intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs). • Formulary agents result or are likely to result in therapeutic failure (e.g., patient had intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs). • No alternative formulary agent – patient requires topical agent with dimethyl sulfoxide (DMSO) to aid in skin absorption.
• Diclofenac 1.3% patch (Flector) **Topical Pain Medications**	• Patient has experienced significant adverse effects from ALL of the formulary medications that are not expected to occur with the nonformulary topical pain medication (e.g., patient experienced intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs). • No alternative formulary agent – patient requires use of patch for treatment of pain associated with acute strain/sprain and cannot use oral NSAIDs or diclofenac gel products.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
▪ Zolpidem sublingual low dose (Intermezzo) **Newer Sedative Hypnotics-1 (SED-1s)**	A trial of generic zolpidem IR or zaleplon is required for new users of Intermezzo. Automated PA criteria – The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Manual PA criteria – The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.
▪ Lidocaine 5% patch (Lidoderm) **Topical Pain Medications**	New and current users of Lidoderm are required to undergo the PA process. Manual PA criteria Lidoderm is approved if: – The patient has a diagnosis of postherpetic neuropathy – The patient has a diagnosis of another form of peripheral neuropathy – The patient has a diagnosis of other pain (non-neuropathic) and an occupational or clinical reason exists and other analgesics are contraindicated • Coverage for other uses of Lidoderm is not approved.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• aclidinium oral inhaler (Tudorza) **Pulmonary Disease II Drugs – Long-Acting Muscarinic Agent**	• Retail: 1 inhalers/30 days • Mail Order and MTF: 3 inhalers/90 days
• beclomethasone dipropionate aerosol nasal inhaler (Qnasl) **Nasal Allergy Drugs**	• Retail: 1 inhalers/30 days • Mail Order and MTF: 3 inhalers/90 days
• ponatinib (Iclusig) **Oral Chemotherapy Agents for chronic myelogenous leukemia**	• 15 mg tablets: – Retail: 90 tabs/30 days – Mail Order and MTF: 135 tabs/45 days • 45 mg tablets: – Retail: 30 tabs/30 days – Mail order and MTF: 45 tabs/45 days
• cabozantinib (Cometriq) **Oral Chemotherapy Agents for metastatic medullary thyroid cancer**	• 140, 100 and 60 mg daily dose cartons – Retail: 4 packs/30 days – Mail Order: 8 packs /45 days

Appendix E—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2013	**Topical Pain Medications**	UF Class Review	None	▪ Lidocaine 5% patch (Lidoderm) ▪ Diclofenac 1% gel (Voltaren)	▪ Diclofenac 1.3% patch (Flector) ▪ Diclofenac 1.5% solution (Pennsaid)	Pending signing of the minutes/ 90 days	PA applies	PA for Lidoderm applies to new and current users (see Appendix C)
Feb 2013	**Oral Anticoagulants**	UF Class review	Warfarin	▪ Dabigatran (Pradaxa) ▪ Rivaroxaban (Xarelto)	▪ N/A (no drugs designated nonformulary	Pending signing of the minutes	-	-
Feb 2013	**Newer Sedative Hypnotics-1 (SED-1s)**	New Drug	Zolpidem IR	▪ Zolpidem ER ▪ Eszopiclone (Lunesta) ▪ Doxepin (Silenor) ▪ Zaleplon	▪ **Zolpidem sublingual low dose (Intermezzo) recommended for NF placement Feb 2013** ▪ Rozerem (Ramelteon) ▪ Zolpidem sublingual (Edluar)	Pending signing of the minutes/ 60 days	PA applies	Step therapy (Automated PA); requires trial of zolpidem IR or zaleplon before any other SED-1

TRICARE Formulary Search tool: http://www.pec.ha.osd.mil/formulary_search.php

Appendix F—Table of Abbreviations

Afib	atrial fibrillation
ASD(HA)	Assistant Secretary of Defense for Health Affairs
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	cost-effectiveness analysis
CFC	chlorofluorocarbon
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
CV	cardiovascular
DCO	Defense Connect Online
DoD	Department of Defense
DMSO	dimethyl sulfoxide
DPI	dry powder inhaler
DVT	deep vein thrombosis
ER	extended release
FDA	U.S. Food and Drug Administration
FEV_1	forced expiratory volume in 1 second
GI	gastrointestinal
ICER	incremental cost-effectiveness ratio
IR	immediate release
MI	myocardial infarction
MDI	metered dose inhaler
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NAOCs	newer oral anticoagulants
NF	nonformulary
NSAIDs	nonsteroidal anti-inflammatory drugs
P&T	Pharmacy and Therapeutics
PA	prior authorization
PE	pulmonary embolism
PEC	Pharmacoeconomic Center
PHN	postherpetic neuralgia
PORT	Pharmacy Outcomes Research Team
POS	points of service
QLs	quantity limits
SED-1s	newer sedative hypnotic-1 agents
LAMA	long-acting muscarinic agent
SAMA	short-acting muscarinic agent
SL	sublingual
UF	Uniform Formulary
VTE	venous thromboembolism