EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP) Comments
19 September 2013

The Uniform Formulary (UF) Beneficiary Advisory Panel (BAP) commented on the recommendations from the DoD Pharmacy and Therapeutics Committee August 2013 Meeting.

1. UF CLASS REVIEWS – CORTICOSTEROID IMMUNE MODULATORS (TOPICAL STEROIDS):

A. Corticosteroid Immune Modulators (Topical Steroids) - UF Recommendation: The P&T Committee recommended (9 for, 3 opposed, 1 abstained, 1 absent) all topical steroid products be designated formulary on the UF, with the exception of the products listed below that are designated NF

- **High Potency**: augmented betamethasone dipropionate 0.05% cream, ointment, gel, and lotion (Diprolene, Diprolene AF, generics); clobetasol 0.05% cream, ointment, solution, foam, gel, shampoo, lotion, and spray (Clobex, Cormax, Olux, Temovate, generics); desoximetasone 0.05% and 0.25% cream, ointment, gel, and spray (Topicort, generics); fluocinonide 0.05% cream, ointment, gel, and solution (Lidex, generics); flurandrenolide 4mcg/sq cm tape (Cordran); halobetasol 0.05% cream, ointment, lotion, and combinations (Halonate, Ultravate, generics)

- **Medium Potency**: betamethasone dipropionate 0.05% cream and lotion (Diprosone, generics); betamethasone valerate 0.1% cream and ointment (Valisone, generics); desonide 0.05% ointment (Desowen, generics); desoximetasone 0.05% cream (Topicort, generics); fluocinolone 0.025% cream and ointment (Synalar, generics); fluticasone 0.005% ointment and 0.05% cream and lotion (Cutivate, generics); hydrocortisone butyrate 0.1% ointment and solution (Locoid, generics); hydrocortisone valerate 0.2% cream and ointment (Westcort, generics); mometasone 0.1% cream, ointment, and solution (Elocon, generics); prednicarbate 0.1% cream and ointment (Dermatop, generics); triamcinolone 0.025%, 0.05%, 0.1% and 0.5% cream, ointment, and lotion (Kenalog, generics); triamcinolone 0.015% spray (Kenalog)

- **Low Potency**: alclometasone 0.05% cream and ointment (Aclovate, generics); desonide 0.05% cream (Desowen, generics); fluocinolone 0.01% cream, solution, and oil (Synalar, Derma-Smoothe, generics); hydrocortisone 1% and 2% cream, ointment, and lotion

and the following topical steroids be designated NF on the UF:

- **NF High Potency products:** amcinonide 0.1% ointment (Cyclocort, generics); diflorasone 0.05% cream and ointment (Apexicon, generics); fluocinonide 0.1% cream (Vanos);

halcinonide 0.1% cream and ointment (Halog);

- **NF Medium Potency products:** amcinonide 0.1% cream and lotion (Cyclocort, generics); betamethasone valerate 0.12% foam (Luxiq, generics); clocortolone 0.1% cream (Cloderm); desonide 0.05% lotion (Desowen, generics); hydrocortisone probutate 0.1% cream (Pandel); hydrocortisone butyrate 0.1% cream and lotion (Locoid); triamcinolone with emollient #45, 0.1% cream kit (Pediaderm TA);

- **NF Low Potency products:** desonide 0.05% foam (Verdeso) and 0.05% gel (Desonate); fluocinolone 0.01% shampoo (Capex); hydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC).

***Summary of Physician's Perspective*:**

The Topical Steroids had not previously been reviewed by the P&T Committee and there are several products on the market with varying formulations, so a Uniform Formulary review was in order.

For the Uniform Formulary decision, a wide selection of products from the high, mid, and low potency classes were chosen. The products selected for the non-formulary status were not cost effective. The Committee did recommend keeping one of the Coopman Class C drugs for patients with allergies; desoximetasibe (Topicort) a high potency drug was recommended for inclusion on the UF.

The reasons for the opposing votes all centered around the decision regarding fluocinolone cream and solution (Synalar). Synalar was recommended for Uniform Formulary status, due to the number of unique utilizers and because it is approved for use in the pediatric population. The opposing view was that there are no other agents, including mometasone, that are approved for pediatrics, and that Synalar should be designated as non-formulary.

***Summary of Panel Vote/Comments*:**

Dr. Salom corrected a statement made during the presentation. The desonide foam is 0.05% not 0.5%. Dr. Meade acknowledged the correction.

Dr. Khurana asked Dr. Kugler to repeat the information presented regarding the opposing votes and the other agents available for use. Dr. Kugler answered that they thought that mometasone would be suitable but the majority of the committee disagreed.

Dr. Sampel stated looking at the utilization; we can see the breakdown by generic theme. Dr. Sampsel asked if Dr. Meade would provide information about the fluocinonide 0.5% cream and removing the 0.1% cream concerning the % of the market share affected. Dr Meade stated that the % of the affected items was small; in most cases it was a specific strength was a small part of the market. Generics in the subclass had a higher market share then the affected product. Dr. Sampsel clarified by stating that the majority of the users were in the low market share.

- Without further discussion, the Panel voted on the UF Recommendations as follows:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA: ☒ *These comments were taken under consideration prior to my final decision.*

B. Corticosteroid Immune Modulators (Topical Steroids) - UF Implementation Plan Recommendations:

The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 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 decision.

- Without further discussion, the Panel voted on the PA Criteria as follows:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA: ☒ *These comments were taken under consideration prior to my final decision.*

2. UF CLASS REVIEWS — SELF-MONITORING BLOOD GLUCOSE SYSTEM (SMBGS) TEST STRIPS

A. Self-Monitoring Blood Glucose System (SMBGS) Test Strips - UF Recommendation:

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) the following:

- Formulary and step-preferred on the UF:
  - Precision Xtra (Abbott)
  - FreeStyle Lite (Abbott)
  - FreeStyle InsuLinx (Abbott)
- Non formulary and non-step preferred on the UF:
  - ACCU-CHEK Aviva Plus (Roche)
  - GLUCOCARD 01-Sensor (Arkray)
  - GLUCOCARD Vital (Arkray)
  - CONTOUR NEXT (Bayer)
  - NovaMax (Nova)

- TRUEtest (Nipro Diagnostics)
- Prodigy No Coding (Prodigy)
- One Touch Verio
- One Touch Ultra
- The following test strips are also NF.

GLUCOSE TEST STRIP; ACCU-CHEK ADVANTAGE, PRECISION PCX, BD TEST STRIPS, ACCU-CHEK, PRODIGY, ACCU-CHEK INSTANT, CHEMSTRIP BG, DEXTROSTIX REAGENT, ASCENSIA ELITE, FIFTY50 TEST STRIP, OPTIUM EZ, FORA G20, PRECISION POINT OF CARE, FORA TEST STRIP, PRESTIGE TEST, FORA V10, EASYMAX, FORA V30A, FIFTY50 TEST STRIP, PRESTIGE SMART SYSTEM, GLUCOSTIX, TRACER BG, GLUCOMETER ENCORE, MICRODOT, ASSURE PRO, ELEMENT TEST STRIPS, SMARTEST TEST, ASSURE PLATINUM, EVENCARE G2, CLEVER CHOICE TEST STRIPS, EZ SMART, RIGHTEST GS100 TEST STRIPS, EZ SMART PLUS, SURESTEP PRO, FAST TAKE, OPTIUM EZ, FORA G20, PRECISION POINT OF CARE, FORA TEST STRIP, PRESTIGE TEST, EASY PRO PLUS, ASSURE 3, RIGHTEST GS550 TEST STRIPS, ACCU-CHEK ACTIVE, SURECHEK TEST STRIPS, EASYGLUCO, ADVOCATE REDI-CODE, CONTROL, ADVOCATE REDI- CODE+, ASSURE 4, ULTIMA, OPTIUM, ULTRATRAK, POCKETCHEM EZ, VICTORY, ACURA TEST STRIPS, WAVESENSE JAZZ, BG-STAR, ACCUTREND GLUCOSE, GLUCOLAB, BLOOD GLUCOSE TEST, EASY TOUCH, ADVOCATE TEST STRIP, RIGHTEST GS300 TEST STRIPS, ADVANCE TEST STRIPS, SMARTDIABETES XPRES, TEST STRIP, SOLUS V2 TEST STRIPS, SURESTEP, TELCARE, LIBERTY TEST STRIPS, MICRO, INFINITY, TRUETRACK SMART SYSTEM, INFINITY TEST STRIPS, CLEVER CHOICE PRO, KEYNOTE, ULTRATRAK PRO, GE100 BLOOD GLUCOSE TEST STRIP, WAVESENSE AMP, WAVESENSE PRESTO, GLUCOCARD EXPRESSION, PRECISION PCX PLUS, PRECISION Q-I-D, Glucocard X sensor, CONTOUR, ACCU- CHEK AVIVA, TRUE TRACK, ACCU-CHEK

COMFORT CURVE, ACCU-CHEK SMARTVIEW, RELION CONFIRM MICRO, RELION PRIME, WAVESENSE PRESTO, EMBRACE, CLEVER CHECK

- This recommendation includes step therapy, which requires a trial of one of the Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra) prior to use of a non-formulary test strip in all current and new users of a non-formulary test strip.

Summary of Physician's Perspective:

The test strips were selected for evaluation, since it had been 5 years since the last review, and because there have been improvements in technology in both the test strips and meters. 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– 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 Committee updated the technical requirements at the May meeting, and the final candidates included 10 test strips, corresponding with 17 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 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.

We also surveyed both MTF providers and the Managed Care Support Contractors. One question asked whether a particular strip or meter was required for special patient populations, including pediatric patients, those with gestational diabetes, or patients receiving insulin – the overwhelming response was that one test strip would be adequate for all patients.

For the Uniform Formulary recommendation, the vote was unanimous that the Abbott Precision Extra, Insulinx and Freestyle Lite 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. Additionally the Committee recognized that for patients currently on a non-formulary test strip, this decision allows them to be upgraded to a new test strip and meter with some potential benefits (such as no coding required) at no cost.

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.

Because of the large numbers of patients affected by the decision, there were specific

recommendations made to work with the pharmaceutical manufacturer to ensure that the decision can be implemented with the least amount of hassle to the patient. A detailed implementation plan is being developed, and patients will be notified of how to obtain the required test strip and meter via several routes, including beneficiary letters, and publication of 1-800 numbers and websites.

Summary of Panel Vote/Comments:

The Panel members expressed concern regarding the 120 day implementation period. Due to the large beneficiary population (approximately 45,000) affected by the change, they believed that the implementation period should be extended to 180 days.

The major topics of discussion centered on (1) the education of the patients; (2) how the patients would receive the new meters; (3) questions received by the call centers at ESI; and (4) if there would enough meters available on the first day of implementation. In response, Dr. Meade stated that this will be an extensive beneficiary communication plan and stated that he was open to suggestions. At present, they plan to target the various websites (TMA and Pharmaceutical Manufacturer's website); provide information to beneficiaries using 1-800-numbers; health fair package; ask the staff at the Military Treatment Facilities to distribute the meters; and ask the providers who write prescriptions for TRICARE beneficiaries to provide information as well as distribute meters during the patient's doctor's visits.

When asked about the patient population using the retail pharmacies, Dr. Meade indicated that information/education would be provided by using 1-800-numbers, pre-positioning in the physician's offices and making products available at the pharmacies.

The discussion ended by Dr. Salom stating that he could see problems coordinating the medical benefit and the implementation period. Dr. Khurana agreed that the 120 day implementation period was not enough time to implement this change.

** The Panel members contributing to this discussion were Dr. Ira Salom, Dr. Amit Khurana, Dr. Elizabeth Sampsel, Ms. Lisa Le Gette and Mr. Duane Tackitt

- Without further discussion, the Panel voted on the UF recommendations as follows:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA:

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

B. Self-Monitoring Blood Glucose System (SMBGS) Test Strips – PA Criteria Recommendation:

The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for all new and current users of a non-formulary SMBG test strip, requiring a trial of FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra prior to the use of a non-formulary SMBG test strip.

- Patient is blind/severely visually impaired and requires a test strip used in a talking meter - Prodigy Voice, Prodigy AutoCode, Advocate Redicode

- Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter

    - Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump
    - NovaMax strip with NovaMax Link meter for Medtronic pump
    - One Touch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump
    - OneTouch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump

- The patient has a documented physical or mental health disability requiring a special strip or meter.

- The patient is receiving peritoneal dialysis or the intravenous immune globulin (IVIG) preparation Octagam and the provider is concerned about the GDH-PQQ.

- Without further discussion, the Panel voted on the PA Criteria as follows:

  Concur: 9 Non-concur: 1 Abstain: 0 Absent: 0

Director, TMA:

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

C. Self-Monitoring Blood Glucose System (SMBGS) Test Strips - UF Implementation Plan Recommendations:

The P&T Committee recommended (11 for, 1 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 120-day implementation period in all POS; 2) TMA send a letter to beneficiaries affected by the UF and PA decisions.

Additional Panel Questions and Comments:

The Panel discussed a six (6) month extension of the 120 implementation period. Dr. Sampsel ask for clarification as to why a 6 month extension was needed and requested

more details regarding how the new users would receive their self-monitoring glucose strips.

In response to Dr. Sampsel's questions, Dr. Salom stated the new users would get their test strips from Abbott and the 180 day conversion would be for people who already have a meter. The 6 month extension would also provide time for users (new and current) and practitioners for transition and education on the use of the test strips.

The Panel agreed that more time was needed to implement this change. Dr. Salom recommended (1) the effective date of the first Wednesday after a 180 day implementation period to all points of service for those beneficiaries who are currently using self-monitoring glucose strips. (2) the effective date of the first Wednesday after the 120 day implementation period to all points of service for those beneficiaries newly placed on the self-monitoring glucose strips.

Dr. Sampsel asked if DoD technology would support the recommended change. Prior to proposing the recommendations, the Panel agreed that more research should be conducted to ensure that current technology would support the recommendation. Dr. Salom made an editorial change stating that the Panel members were not sure that DoD technology would support the 120 day and the 180 day recommendation.

- Without further discussion, the Panel voted on the PA Criteria as follows:

  Concur: 0 Non-concur: 10 Abstain: 0 Absent: 0

Director, TMA: *These comments were taken under consideration prior to my final decision.*

3. UTILIZATION MANAGEMENT:

A. Injectable Corticotropin (HP Acthar Gel) – PA Criteria

Injectable corticotrophin has been commercially available since 1952, but now is only marketed as a proprietary product, HP Acthar Gel. The P&T Committee established manual PA criteria for all new and current users of HP Acthar Gel, limiting use to infantile spasms (West Syndrome) for patients less than 24 months old at initiation of treatment and not previously treated with corticotropin. Additional uses for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies (kidney disease) may be permitted on appeal.

The following uses for Acthar Gel are considered unsupportable: dermatomyositis (a connective-tissue disease characterized by inflammation of the muscles and the skin), polymyositis (chronic inflammation of the muscles), psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis (chronic inflammatory disease of spine, peripheral joints and other bones structures), sarcoidosis (involving abnormal collections of chronic inflammatory cells that can form as nodules in multiple

organs), serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis (the immune system attacks the body's cells and tissue, resulting in inflammation and tissue damage).

1. **Injectable Corticotropin (HP Acthar Gel) - PA Criteria Recommendations:**

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) manual PA criteria for all current and new users of HP Acthar Gel, limiting use to the specific FDA-approved indication of infantile spasms (West Syndrome). Prior Authorization will expire after 30 days for infantile spasms; retreatment is not covered. Use for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies will be on appeal only. Other uses of HP Acthar Gel are considered unsupportable.

Summary of Physician's Perspective:

The active ingredient in Acthar Gel, corticotropin, has been available commercially since 1952, however this specific product is now marketed by only one company. There is a generic product available, but it is only approved for use as a diagnostic agent, so Acthar Gel is the only product available on the market approved for clinical use.

There was an extensive discussion of the published efficacy data for all the FDA-approved and off-label uses, and whether the off-label uses met the TRICARE criteria for coverage of unproven drugs. The recommendation was unanimous for the PA criteria to cover supportable uses of the drug, and to not cover the non-supportable uses. The Committee wanted the PA criteria to be implemented as quickly as possible, so a 30-day implementation period was recommended.

***Summary of Panel Vote/Comments*:**

Dr. Salom asked if this drug was in wide use or had a large population of users. Dr. Meade stated that there were a total of 300 users.

- Without further discussion, the Panel voted on the UF Recommendations:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA:

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

2. **Injectable Corticotropin (HP Acthar Gel) – PA Implementation Plan Recommendations:**

The P&T Committee recommended (8 for, 3 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this PA decision.

- Without further discussion, the Panel voted on the PA Criteria as follows:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

  Director, TMA:

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

B. Antiemetics: Doxylamine/Pyridoxine (Diclegis):

Diclegis contains 10 mg of doxylamine and 10 mg of pyridoxine and is FDA-approved for treating pregnant women experiencing nausea and vomiting. The P&T Committee recommended manual PA criteria for all new users of Diclegis. Diclegis is limited to use for management of nausea and vomiting during pregnancy (NVP) and excluded for the treatment of hyperemesis gravidarum. Patients must have tried at least one nonpharmacologic treatment (e.g., ginger, acupressure, high-protein bedtime snack) and OTC pyridoxine. An alternate antiemetic (e.g., ondansetron) should be considered prior to Diclegis.

1. **Antiemetics: Doxylamine/Pyridoxine (Diclegis) - PA Criteria:**

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) that manual PA criteria apply to new users of Diclegis who are being treated for nausea and vomiting during pregnancy. The PA will expire after nine months. (See Appendix E for full criteria.)

Manual PA Criteria—pyridoxine/doxylamine (Diclegis) is approved if:

a. The patient has not had relief of symptoms after trying a nonpharmacologic method to manage nausea and vomiting during pregnancy,

   AND

b. The patient has not had relief of symptoms after trying OTC pyridoxine for management of nausea and vomiting during pregnancy

Providers are encouraged to consider an alternate antiemetic (e.g., ondansetron) prior to prescribing Diclegis.

Summary of Physician's Perspective:

Diclegis is a new drug that is really an old drug – it contains the same ingredients as Bendectin, which was removed from the market in 1983. Diclegis contains two products that have been used for decades for nausea and vomiting in pregnancy – Unisom and pyridoxine, or Vitamin B6. Both Unisom and pyridoxine are OTC drugs.

The decision was unanimous to have PA criteria for Dicelgis. The PA criteria do reflect current guidelines in recommending non-pharmacologic treatments prior to use of Diclegis.

***Summary of Panel Vote/Comments*:**

There were no questions or comments from the Panel.

- Without further discussion, the Panel voted on the UF Recommendations:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA:

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

2. **Antiemetics: Doxylamine/Pyridoxine (Diclegis) - PA Implementation Plan Recommendations:**

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS.

There were no questions or comments from the Panel.

- Without further discussion, the Panel voted on the UF Recommendations:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA:

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

C. **Targeted Immunomodulatory Biologics (TIBs): Ustekinumab (Stelara) and Golimumab (Simponi):**

PA criteria currently apply to the Targeted Immunomodulatory Biologics (TIBs). Ustekinumab was previously limited to injection by health care professionals, but is now available in pre-filled syringes labeled for patient self-administration for treatment of plaque psoriasis. Also, the FDA recently approved a new indication for golimumab for treatment of moderate to severe ulcerative colitis.

1. **TIBs: Ustekinumab (Stelara) and Golimumab (Simponi) – PA Criteria::**

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) PA criteria for ustekinumab for plaque psoriasis and golimumab for ulcerative colitis, consistent with the products' labeling. (See Appendix E for full criteria.)

a) Manual PA Criteria— Ustekinumab (Stelara) is approved for:

1) Patients older than age 18 with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

b) Manual PA Criteria—Golimumab (Simponi) is approved for:

1) Patients older than age 18 with moderately to severely active ulcerative colitis that has not responded to other treatments or who require continuous steroids.

2) Coverage is not provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia or Rituxan.

***Summary of Physician's Perspective*:**

There was no controversy here. The P&T Committee does routinely update PA criteria for new indications or for new drugs in a class where there are PA criteria already in place. This is part of the usual "housekeeping" activities to ensure PA criteria reflect current package insert labeling.

***Summary of Panel Vote/Comments*:**

Dr. Salom asked if an implementation plan was discussed. Dr. Meade stated that is was effective the first Wednesday after a 60-day implementation in all POS

- Without further discussion, the Panel voted on the revised PA Criteria as follows:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA: 

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

2. **TIBS: Ustekinumab (Stelara) and Golimumab (Simponi) – PA Implementation Plan**:

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS.

- Without further discussion, the Panel voted on the revised PA Criteria as follows:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA: 

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

A. FISCAL YEAR 2008 NATIONAL DEFENSE AUTHORIZATION ACT, SECTION 703 DRUGS:

1) **SECTION 703**—The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not compliant with Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity in MTFs. These NF drugs will remain available in the Mail Order POS without pre-authorization.

a. SECTION 703: Drugs Designated Non-formulary:

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 1 absent) to designate (or maintain) the products in (listed by manufacturer) as non-formulary on the Uniform Formulary:

BAUSCH & LOMB RX
Besivance ophth susp
FOUGERA
Methscopamine
GRACEWAY PHARMA
Zyclara Cr
KEDRION
Gammaked inj

MEDA PHARMA
- Dymista

NEUROGESX, INC.
- Qutenza

NOVARTIS CONSUMER
- Transderm Scop

OTSUKA AMERICA
- Pletal

PATRIOT PHARMA
- Haldol Inj
- Itraconazole Tabs/Caps
- Ketoconazole Shampoo
- Galantamine Tabs
- Tramadol ER Tabs

PHARMADERM
- Oxistat Products
- Cutivate lotion
- Temovate Products

RHODES PHARM
- Hydromorphone
- Tramadol ER

SANDOZ
- Calcitonin Nasal Spray
- Calcium Acetate
- Carbamazepine XR
- Lansoprazole
- Losartan
- Losartan/HCTZ
- Oxcarbazepine Susp
- Sumatriptan Nasal Spray
- Valsartan/HCTZ
- Metoprolol/HCTZ
- Rivastigmine

STIEFEL LABS
- Veltin

UNITED RESEARCH LAB
- Glycopyrrolate Tabs
- Nisoldipine ER

VIROPHARMA INC
- Vancocin Caps

Summary of Physician's Perspective:

No comments

Summary of Panel Vote/Comments:

The Panel was concerned about the number of beneficiaries affected by this recommendation as well as education regarding the use of another generic drug. In response to Dr. Salom's question, Dr. Meade stated that approximately 45,000 beneficiaries were affected. The majority of those patients are acute users meaning they used the drug one (1) time. Per the implementation plan, letter will be sent to beneficiaries affected by this change and alternate generics will be provided in the letter.

Dr. Salom also asked if the numbers would decrease as companies come into compliance. Dr. Meade stated that the companies would be removed from the list as they came into compliance.

Dr. Crum asked if the information comes in on the transactions from the retail pharmacy identify the maker. Dr. Meade stated that the product number at the pharmacy is an NDC number which is specific drug and dose.

- Without further discussion, the Panel voted on the PA Criteria as follows:

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA:

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

b. SECTION 703 - PA Criteria:

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) the following Pre-Authorization Criteria for the drugs listed as non-formulary in Appendix G: 1) Obtaining the product from the home delivery would be detrimental to the patient and 2) For branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any point of service other than retail network pharmacies.

- Without further discussion, the Panel voted on the Implementation Plan as follows::

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA:

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

c. SECTION 703 - Implementation Plan Recommendation:

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 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 these decisions.

- Without further discussion, the Panel voted on the Implementation Plan as follows::

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Director, TMA:

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

5. **For information only**

   A. **Angiotensin Receptor Blockers (ARBs)/Direct Renin Inhibitor**—The P&T committee considered the merits of formulary action in the Angiotensin Receptor Blockers, Direct Renin Inhibitors and respective fixed dose combination products drug classes. Based on current pricing agreements and pending availability of new generic entrants, the P&T committee opted not to take any formulary action at this time.

Letter

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July 24, 2013

RADM Thomas McGinnis, USPHS
Chief, DoD Pharmacy Programs
TRICARE Management Activity
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Falls Church, VA 22402

Dear RADM McGinnis:

Thank you for your offer to get our comments in front of the committee in a public format so they can be recorded into the minutes and presented to the Director of TRICARE Management Activity.

As of this morning, I received an email that TRICARE is extending its coverage on compounded drugs for 180 days. I am very happy to hear this news and would like to see compounded drugs remain in place without limits. TRICARE has made a promise of healthcare to us, and the coverage of compounded medicines matters to us whom TRICARE had made that promise.

In the case of progesterone and testosterone, there are particular concerns. Manufactured capsules of progesterone come only in 100 to 200 mg doses and are an immediate release formula. Compounded progesterone comes in a dosage specific to the patient and has a slow release. This is much healthier to those who wish to neither be under or overdoses, not to mention the benefit of release over time.

Manufacturers only produce testosterone for women as a monthly injectable. This is unacceptable for many reasons, but particularly because of the unhealthy peaks and valleys in the drug's distribution over a month's cycle. Compounding pharmacies can produce testosterone for women as a topical cream or a sublingual tablet. This is a much healthier delivery system and the dosage is specific to the individual

I have focused on those two, but in general, I am an advocate of compounding for all. Compounded medications are allergy-friendly, available in personalized dosage, and may assist in avoiding many of the negative systemic effects of commercially available drugs.

I urge the board to make this 180-day extension of compounded medicines a permanent one.

Sincerely,

Terry Ciotti Galo.

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
September 19, 2013
Washington D.C.

Panel Members Present

- Ira Salom - Chairman
- John Crum
- Elizabeth Sampsel
- Robert Duane Tackitt
- Robert L. Lewis
- Steven Hein
- Amit Khurana
- Kathryn Buchta
- Lisa Le Gette
- Katherine O'Neill-Tracy

New Panel Member

- Mr. Robert Lewis

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington D.C. Commander Lawrence, Designated Federal Officer (DFO), called the proceedings to order at 9:00 A.M. CDR Lawrence indicated that the Panel has been convened to review and comment on the therapeutic drug class recommendations resulting from the August 14 & 15, 2013 Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee meeting held in San Antonio, TX.

Agenda

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

- Welcome and Opening Remarks
- Public Citizen Comments
- Review and Panel discussion of P&T Committee recommendations for the following therapeutic drug classes.

  - *Drug Class Reviews*

- Corticosteroid Immune Modulators (Topical Steroids)
- Self-Monitoring Blood Glucose System (SMBGS) Test Strips

➢ *Utilization Management Issues*

- Prior Authorization Criteria
  - Injectible Corticotropin (HP Acthar Gel)
  - Doxylamine/Pyridoxine (Diclegis)
  - Targeted Immunomodulatory Biologics
    - Ustekinumab (Stelara)
    - Golimumab (Simponi)

➢ *2008 Section 703 Actions*

Opening Remarks

Commander Lawrence indicated that Title 10 United States Code (U.S.C.) 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 UF. 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, TRICARE Management Activity (TMA) before establishing the UF or implementing changes to the UF. The Panel's meetings are conducted in accordance with 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, TMA, 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, TMA before making a final decision.

- To hold quarterly meetings in an open forum. The Panel may not hold meetings except at the call of or with the advance approval of the DFO 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, TMA.

As guidance to the Panel regarding this meeting, CDR Lawrence 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 classes 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 its reviews of the drug class recommendations presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website.

Detailed minutes of this meeting are being prepared. The BAP minutes, the DoD P&T Committee meeting minutes and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO next provided the ground rules for conducting the meeting:

- All discussions take place in the open public forum. There is to be no committee discussion outside the room, during breaks or at lunch.

- Audience participation is limited to private citizens who signed up to address the Panel.

- Members of the Pharmacoeconomic Center (PEC) and the 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.

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

Private Citizen Comments

The DFO stated there are no private citizens signed up to comment. However, a letter from Mr. Terry Ciotti Gallo was distributed to the committee for consideration.

Chairman's Opening Remarks

The DFO next turned the meeting over to Dr. Ira Salom who opened the meeting for the first drug class review presentation.

DRUG CLASS REVIEW PRESENTATIONS:

(PEC Script - Dr. Meade)

I'm Dave Meade, Director of Clinical Operations at the Pharmacoeconomic Center (PEC). Joining me is Doctor and retired Army Colonel John Kugler, the chairman of the P & T Committee, who will provide the physician perspective and comment on the recommendation made by the P & T Committee. Also joining us is CAPT Nina Sood, Chief of Staff, Pharmaceutical Operations Director.

The DoD Pharmacoeconomic Center 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.

a. 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 two Uniform Formulary Drug Classes (or sub-classes) gout agents and chronic obstructive pulmonary disease agents (Pulm 2) Additionally, one newly approved drug was reviewed – canagliflozin (Invokana)

3) The DoD P & T Committee's recommendation as to the effective date of the agents being changed from formulary tier to the non-formulary tier of the Uniform Formulary. 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've given you a handout which includes the Uniform Formulary recommendations for all the drugs discussed today; these are found on pages 2 through 5. There are tables and utilization figures for each of the drug classes. We'll be using trade names as much as possible, so you can refer to your handout throughout the presentation.

I. UF DRUG CLASS REVIEWS - Corticosteroid Immune Modulators (Topical Steroids)

(PEC Script - Dr. Meade)

P&T Comments:

A. Corticosteroid Immune Modulators (Topical Steroids) - Background and Relative Clinical Effectiveness:

The P&T Committee has never evaluated the Corticosteroid Immune Modulators (Topical Steroids) Drug Class. The drug class is comprised of 22 individual chemical entities, available in over 100 different formulations and vehicles. The Stoughton-Cornell classification system, which divides the drugs into seven classes based on their vasoconstrictive properties, was used to further divide the drugs into high- (classes 1 and 2), medium- (classes 3, 4, and 5), and low-potency agents (classes 6 and 7). Over-the-counter (OTC) products are excluded from the class.

B. Corticosteroid Immune Modulators (Topical Steroids) - Relative Clinical Effectiveness Conclusion:

The P&T Committee agreed (14 for, 0 opposed, 0 abstained, 0 absent) with the following conclusions:

- For all of the topical steroids, there is very limited generalizable data. Heterogeneity of the data (the mix of design and measures) precludes direct and indirect comparisons. A product formulated for hair (e.g., foam, shampoo) from each potency class is desirable for inclusion on the UF.

- Safety issues are considered class effects.

- A Coopman Class C product (e.g., desoximetasone, clocortolone) is less likely to cause an allergic response, compared with Coopman Classes A (hydrocortisone, hydrocortisone acetate) and D1 (clobetasol, betamethasone, diflurasone, fluticasone, mometasone, aclometasone) agents, and is required for inclusion on the UF.

- For the high-potency topical steroids, none of the products offer unique advantages in terms of efficacy or safety over other agents in the high-potency class. Products in the high potency subclass can be seen on page 2 of your handout.

    - Clobetasol is offered in more vehicles and is more extensively studied than the other high-potency products.
    - Fluocinonide was frequently mentioned as required for inclusion on the UF in a survey of Military Health System (MHS) providers.
    - Flurandrenolide tape has several unique therapeutic uses.
    - Clobetasol, halobetasol, augmented betamethasone dipropionate, and fluocinonide 1% cream products have package-labeled weekly exposure limits.

- Products in the medium potency subclass are listed on page 3 of your handout. For the medium-potency topical steroids, the following conclusions were made:

    - Triamcinolone is offered in more vehicles, is more extensively studied, and more frequently mentioned as required for inclusion on the UF in the MHS provider survey than the other medium-potency agents. It has a modest risk of skin atrophy.
    - Triamcinolone (Kenalog Spray) is the only spray product in the medium-potency class.
    - The Pediaderm TA combination product co-packages triamcinolone with an emollient vehicle. There are no compelling advantages to using the co-packaged product versus using triamcinolone and a comparable emollient sold separately.
    - There is weak evidence that clocortolone may have less risk of hypothalamic-pituitary-adrenal axis (part of the endocrine system responsible for the regulation of metabolism) suppression than other medium- potency steroids.
    - Hydrocortisone butyrate and fluticasone propionate are the only medium-potency agents labeled for use in children as young as three months of age.
    - Fluticasone propionate, mometasone, and prednicarbate have the most favorable therapeutic indices among the medium-potency steroids.
    - Desonide ointment and lotion, betamethasone valerate, and hydrocortisone valerate were frequently favorably mentioned in the MHS provider survey as required for inclusion on the UF.

- For the low-potency topical steroids, there is no evidence to support clinically meaningful differences in efficacy or safety among the agents. Products in the low potency subclass are listed on page 4 of your handout.

    - Hydrocortisone was more frequently favorably mentioned in the MHS provider survey than the other low-potency agents.

- The Pediaderm HC combination product co-packages hydrocortisone with an emollient vehicle. There are no compelling advantages to using the co-packaged product versus using hydrocortisone and a comparable emollient sold separately.
- Derma-Smoothe/FS, a fluocinolone acetonide shampoo product, has the theoretical risk of inducing a peanut allergy.
- Desonate Gel, Verdeso Foam, and Capex Shampoo all remain uniquely branded, without clinical advantages over the other generic low-potency topical steroids.

C. **Corticosteroid Immune Modulators (Topical Steroids) - Relative Cost-Effectiveness Analysis and Conclusion**:

A pharmacoeconomic analysis, including cost minimization analysis (CMA), was performed for the topical steroids within each potency class (high, medium, and low). CMA results showed that designating cost-effective agents from within each potency class as formulary on the UF yielded the most cost-effective results for the MHS.

The P&T Committee concluded (13 for, 0 opposed, 1 abstained, 0 absent) that, for each topical steroid potency class, there were specific agents, strengths, and dosage forms determined to be cost-effective based on the weighted average cost per day of treatment across all three points of service (POS).

1) **Corticosteroid Immune Modulators (Topical Steroids) - UF Recommendation:**

The P&T Committee recommended (9 for, 3 opposed, 1 abstained, 1 absent) all topical steroid products be designated formulary on the UF, with the exception of the products listed below that are designated NF

- **High Potency**: betamethasone dipropionate 0.05% cream, ointment, gel, and lotion (Diprolene, Diprolene AF, generics); clobetasol 0.05% cream, ointment, solution, foam, gel, shampoo, lotion, and spray (Clobex, Cormax, Olux, Temovate, generics); desoximetasone 0.05% and 0.25% cream, ointment, gel, and spray (Topicort, generics); fluocinonide 0.05% cream, ointment, gel, and solution (Lidex, generics); flurandrenolide 4mcg/sq cm tape (Cordran); halobetasol 0.05% cream, ointment, lotion, and combinations (Halonate, Ultravate, generics)

- **Medium Potency**: betamethasone dipropionate 0.05% cream and lotion (Diprosone, generics); betamethasone valerate 0.1% cream and ointment (Valisone, generics); desonide 0.05% ointment (Desowen, generics); desoximetasone 0.05% cream (Topicort, generics); fluocinolone 0.025% cream and ointment (Synalar, generics); fluticasone 0.005% ointment and 0.05% cream and lotion (Cutivate, generics); hydrocortisone butyrate 0.1% ointment and solution (Locoid, generics); hydrocortisone valerate 0.2% cream and ointment (Westcort, generics); mometasone 0.1% cream, ointment, and solution (Elocon, generics); prednicarbate 0.1% cream and ointment (Dermatop,

generics); triamcinolone 0.025%, 0.05%, 0.1% and 0.5% cream, ointment, and lotion (Kenalog, generics); triamcinolone 0.015% spray (Kenalog)

- **Low Potency**: alclometasone 0.05% cream and ointment (Aclovate, generics); desonide 0.05% cream (Desowen, generics); fluocinolone 0.01% cream, solution, and oil (Synalar, Derma-Smoothe, generics); hydrocortisone 1% and 2% cream, ointment, and lotion

and the following topical steroids be designated NF on the UF:

- **NF High Potency products:** amcinonide 0.1% ointment (Cyclocort, generics); diflorasone 0.05% cream and ointment (Apexicon, generics); fluocinonide 0.1% cream (Vanos); halcinonide 0.1% cream and ointment (Halog);

- **NF Medium Potency products:** amcinonide 0.1% cream and lotion (Cyclocort, generics); betamethasone valerate 0.12% foam (Luxiq, generics); clocortolone 0.1% cream (Cloderm); desonide 0.05% lotion (Desowen, generics); hydrocortisone probutate 0.1% cream (Pandel); hydrocortisone butyrate 0.1% cream and lotion (Locoid); triamcinolone with emollient #45, 0.1% cream kit (Pediaderm TA);

- **NF Low Potency products:** desonide 0.05% foam (Verdeso) and 0.05% gel (Desonate); fluocinolone 0.01% shampoo (Capex); hydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC).

2) **Corticosteroid Immune Modulators (Topical Steroids) - UF Implementation Period:**

The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 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 decision.

D. **Corticosteroid Immune Modulators (Topical Steroids) - Physician's Perspective:**

The Topical Steroids had not previously been reviewed by the P&T Committee and there are several products on the market with varying formulations, so a Uniform Formulary review was in order.

For the Uniform Formulary decision, a wide selection of products from the high, mid, and low potency classes were chosen. The products selected for the non-formulary status were not cost effective. The Committee did recommend keeping one of the Coopman Class C drugs for patients with allergies; desoximetasibe (Topicort) a high potency drug was recommended for inclusion on the UF.

The reasons for the opposing votes all centered around the decision regarding fluocinolone cream and solution (Synalar). Synalar was recommended for Uniform Formulary status, due to the number of unique utilizers and because it is approved for use in the pediatric

population. The opposing view was that there are no other agents, including mometasone, that are approved for pediatrics, and that Synalar should be designated as non-formulary.

E. **Corticosteroid Immune Modulators (Topical Steroids) – Panel Questions and Comments:**

Dr. Salom corrected a statement made during the presentation. The desonide foam is 0.05% not 0.5%. Dr. Meade acknowledged the correction.

Dr. Khurana asked Dr. Kugler to repeat the information presented regarding the opposing votes and the other agents available for use. Dr. Kugler answered that they thought that mometasone would be suitable but the majority of the committee disagreed.

Dr. Sampel stated looking at the utilization, we can see the breakdown by generic theme. Dr. Sampsel asked if Dr. Meade would provide information about the fluocinonide 0.5% cream and removing the 0.1% cream concerning the % of the market share affected. Dr Meade stated that the % of the affected items was small; in most cases it was a specific strength was a small part of the market. Generics in the subclass had a higher market share then the affected product. Dr. Sampsel clarified by stating that the majority of the users were in the low market share.

F. **Corticosteroid Immune Modulators (Topical Steroids) – Panel Vote on the UF Recommendations:**

The Chair called read the P&T Committee UF Recommendation on the Corticosteroid Immune Modulators (Topical Steroids) drug class.

The P&T Committee recommended that the following topical steroid products be designated formulary on the UF:

- **High Potency**: betamethasone dipropionate 0.05% cream, ointment, gel, and lotion (Diprolene, Diprolene AF, generics); clobetasol 0.05% cream, ointment, solution, foam, gel, shampoo, lotion, and spray (Clobex, Cormax, Olux, Temovate, generics); desoximetasone 0.05% and 0.25% cream, ointment, gel, and spray (Topicort, generics); fluocinonide 0.05% cream, ointment, gel, and solution (Lidex, generics); flurandrenolide 4mcg/sq cm tape (Cordran); halobetasol 0.05% cream, ointment, lotion, and combinations (Halonate, Ultravate, generics)

- **Medium Potency**: betamethasone dipropionate 0.05% cream and lotion (Diprosone, generics); betamethasone valerate 0.1% cream and ointment (Valisone, generics); desonide 0.05% ointment (Desowen, generics); desoximetasone 0.05% cream (Topicort, generics); fluocinolone 0.025% cream and ointment (Synalar, generics); fluticasone 0.005% ointment and 0.05% cream and lotion (Cutivate, generics); hydrocortisone butyrate 0.1% ointment and solution (Locoid, generics); hydrocortisone valerate 0.2% cream and ointment (Westcort, generics); mometasone 0.1% cream, ointment, and solution (Elocon,

generics); prednicarbate 0.1% cream and ointment (Dermatop, generics); triamcinolone 0.025%, 0.05%, 0.1% and 0.5% cream, ointment, and lotion (Kenalog, generics); triamcinolone 0.015% spray (Kenalog)

- **Low Potency**: alclometasone 0.05% cream and ointment (Aclovate, generics); desonide 0.05% cream (Desowen, generics); fluocinolone 0.01% cream, solution, and oil (Synalar, Derma-Smoothe, generics); hydrocortisone 1% and 2% cream, ointment, and lotion

and the following topical steroids be designated NF on the UF:

- **High Potency**: amcinonide 0.1% ointment (Cyclocort, generics); diflorasone 0.05% cream and ointment (Apexicon, generics); fluocinonide 0.1% cream (Vanos); halcinonide 0.1% cream and ointment (Halog)

- **Medium Potency**: amcinonide 0.1% cream and lotion (Cyclocort, generics); betamethasone valerate 0.12% foam (Luxiq, generics); clocortolone 0.1% cream (Cloderm); desonide 0.05% lotion (Desowen, generics); hydrocortisone probutate 0.1% cream (Pandel); hydrocortisone butyrate 0.1% cream and lotion (Locoid); triamcinolone with emollient #45, 0.1% cream kit (Pediaderm TA)

- **Low Potency**: desonide 0.05% foam (Verdeso) and 0.05% gel (Desonate); fluocinolone 0.01% shampoo (Capex); hydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC)

There was no further discussion by the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

G. **Corticosteroid Immune Modulators (Topical Steroids) — UF Implementation Plan**

The Chair called for a vote on the Topical Steriod drug class Implementation Plan.

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS); and, 2) TMA send a letter to beneficiaries affected by the UF decision.

There was no further discussion by the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

II. UF CLASS REVIEW: Self-Monitoring Blood Glucose System (SMBGS) Test Strips

(PEC Script - Dr. Meade)

P&T Comments

A. Self-Monitoring Blood Glucose System (SMBGS) Test Strips - Background and Relative Clinical Effectiveness:

The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips, including the attributes of the test strips and glucometers. The SMBGS test strips were previously reviewed for UF placement in August 2008. The primary goal for this review is to ensure uniform availability of quality SMBGS test strips across the MHS (MTF, Retail, and Mail Order POS). 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; however, provisions have been made to provide SMBGS glucometers at no cost to MHS beneficiaries. Product utilization is seen in figure 4 on page 5 of your handout.

The FDA classifies SMBGS test strips and glucometers as medical devices, rather than drugs, thus the focus of the clinical effectiveness review centers on differences in the technical aspects/attributes among the products. Candidates for inclusion on the UF must meet all minimum required technical standards and U.S. Federal Government contracting requirements. The P&T Committee reviewed the existing technical requirements approved in May 2007, and recommended updates to the criteria.

B. Self-Monitoring Blood Glucose System (SMBGS) Test Strips - Relative Clinical Effectiveness Conclusion:

The P&T Committee agreed (14 for, 0 opposed, 0 abstained, 0 absent) on the following for the minimum technical requirements and U.S. Federal Government contracting requirements for the SMBGS test strips.

- *U.S. Federal Government contracting requirements*: SMBGS test strips eligible for inclusion on the UF must be available at all three POS and must be compliant with the Trade Agreements Act. Corresponding SMBGS glucometers must also be compliant with the Trade Agreements Act. Manufacturers of SMBGS glucometers will be required to provide DoD beneficiaries with a no-cost glucometer.

- *Minimum technical requirements*: Candidate SMBGS test strips eligible for inclusion on the UF must meet the following minimum technical requirements:

    - Accuracy: must meet FDA standards for accuracy based on the International Organization for Standardization (ISO) 15197 guidelines. During the August 2013 meeting, newly proposed ISO standards were presented to the P&T Committee.

However, the current 2003 ISO 15197 standard remains effective and there is no change regarding this minimum technical requirement.
    - Sample size of $\leq$ 1 microliter
    - Alternate site testing: more than one alternate site approved.
    - Result time: $\leq$ 10 seconds
    - Memory capacity: $\geq$ 250 readings
    - Ease of use: glucometer must be easy to code/calibrate, have a large visual display, and be easy to handle for patients with dexterity issues.
    - Clinical support: 24-hour helpline available, for beneficiaries residing outside the continental United States.
    - Downloading capabilities: results must be downloadable
    - Data management capabilities: data management capabilities required (e.g., software, cloud computing).

- *SMBG strips meeting the final technical and U.S. Federal Government contracting requirements*: The SMBG test strips meeting the final technical and U.S. Federal Government contracting requirements are Abbott FreeStyle Lite, Abbbot FreeStyle InsuLinx, Abbott Precision Xtra; Roche ACCU-CHEK Aviva Plus; Bayer CONTOUR NEXT; Nipro Diagnostics TRUEtest; Nova Nova Max; Arkray Glucocard 01-Sensor, Akray Glucocard Vital; and Prodigy Prodigy No Coding.

- *MHS Provider Opinion*: MTF and Managed Care Support Contractors (MCSCs) were surveyed for their opinions on the SMBGS test strips and glucometers. The majority of the respondents ranked meter accuracy as the most important attribute. The majority of MTF respondents stated one glucometer was adequate to meet their needs, while the MCSCs requested availability of more than one glucometer to allow the patient options.

- *Overall relative clinical effectiveness conclusion:* The Committee concluded that any of the 10 final SMBGS test strip candidates were acceptable for inclusion on the UF. There are no clinically relevant differences between the 10 SMBGS test strips meeting the final technical and U.S. Federal Government contracting requirements set forth by the P&T Committee.

C. **Self-Monitoring Blood Glucose System (SMBGS) Test Strips - Relative Cost-Effectiveness Analysis and Conclusion**:

CMA and budget impact analysis (BIA) were performed for SMBGS test strips that met all minimum required technical standards and U.S. Federal Government contracting requirements. CMA was performed for the following manufacturer's products: Abbott (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra), Roche (ACCU-CHEK Aviva Plus), Bayer (CONTOUR NEXT), Nipro Diagnostics (TRUEtest), Nova (Nova Max), ARKRAY (GLUCOCARD 01-SENSOR, GLUCOCARD Vital), and Prodigy (Prodigy No Coding) test strips. For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted.

The P&T Committee concluded (12 for, 0 opposed, 1 abstained, 1 absent) the Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra) were the most cost-effective SMBGS products, based on the weighted average cost per strip across all three POS, followed by (ranked in order from most cost effective to least cost effective). Arkray (GLUCOCARD 01-SENSOR, GLUCOCARD Vital), Bayer (CONTOUR NEXT), Nipro (TRUEtest), Roche (ACCU-CHEK Aviva Plus), Prodigy (Prodigy No Coding), and Nova (Nova Max) products.

Among the formulary options evaluated, CMA and BIA results showed the most cost-effective scenario designated Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra) as the UF step-preferred test strip "suite" with all other SMBGS test strips designated NF and non-preferred, where all current and new users are required to first try an Abbott test strip.

1) **Self-Monitoring Blood Glucose System (SMBGS) Test Strips - UF Recommendation:**

   The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) the following:

   - Formulary and step-preferred on the UF:
     - Precision Xtra (Abbott)
     - FreeStyle Lite (Abbott)
     - FreeStyle InsuLinx (Abbott)
   - Non formulary and non-step preferred on the UF:
     - ACCU-CHEK Aviva Plus (Roche)
     - GLUCOCARD 01-Sensor (Arkray)
     - GLUCOCARD Vital (Arkray)
     - CONTOUR NEXT (Bayer)
     - NovaMax (Nova)
     - TRUEtest (Nipro Diagnostics)
     - Prodigy No Coding (Prodigy)
     - One Touch Verio
     - One Touch Ultra
     - All other test strips
   - This recommendation includes step therapy, which requires a trial of one of the Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra) prior to use of a non- formulary test strip in all current and new users of a non-formulary test strip.

2) **Self-Monitoring Blood Glucose System (SMBGS) Test Strips - PA Criteria**:

The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for all new and current users of a non-formulary SMBG test strip, requiring a trial of FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra prior to the use of a non-formulary SMBG test strip.

3) **Self-Monitoring Blood Glucose System (SMBGS) Test Strips – Quantity Limits (QLs)**:

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs/days supply limits for the SMBGS test strips, limiting use to 150 strips/30-day supply in the Retail Network, and 450 strips/90-day supply via Mail Order.

4) **Self-Monitoring Blood Glucose System (SMBGS) Test Strips - UF and PA Implementation Period:**

The P&T Committee recommended (11 for, 1 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 120-day implementation period in all POS; 2) TMA send a letter to beneficiaries affected by the UF and PA decisions.

D. **Self-Monitoring Blood Glucose System (SMBGS) Test Strips – Physician's Perspective:**

The test strips were selected for evaluation, since it had been 5 years since the last review, and because there have been improvements in technology in both the test strips and meters. 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– 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 Committee updated the technical requirements at the May meeting, and the final candidates included 10 test strips, corresponding with 17 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 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.

We also surveyed both MTF providers and the Managed Care Support Contractors. One question asked whether a particular strip or meter was required for special patient populations, including pediatric patients, those with gestational diabetes, or patients receiving insulin – the overwhelming response was that one test strip would be adequate for all patients.

For the Uniform Formulary recommendation, the vote was unanimous that the Abbott Precision Extra, Insulinx and Freestyle Lite 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. Additionally the Committee recognized that for patients currently on a non-formulary test strip, this decision allows them to be upgraded to a new test strip and meter with some potential benefits (such as no coding required) at no cost.

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.

Because of the large numbers of patients affected by the decision, there were specific recommendations made to work with the pharmaceutical manufacturer to ensure that the decision can be implemented with the least amount of hassle to the patient. A detailed implementation plan is being developed, and patients will be notified of how to obtain the required test strip and meter via several routes, including beneficiary letters, and publication of 1-800 numbers and websites.

E. **Self-Monitoring Blood Glucose System (SMBGS) Test Strips – Panel Questions and Comments:**

The Panel members expressed concern regarding the 120 day implementation period. Due to the large beneficiary population (approximately 45,000) affected by the change, they believed that the implementation period should be extended to 180 days.

The major topics of discussion centered on (1) the education of the patients; (2) how the patients would receive the new meters; (3) questions received by the call centers at ESI; and (4) if there would enough meters available on the first day of implementation. In response, Dr. Meade stated that this will be an extensive beneficiary communication plan and stated that he was open to suggestions. At present, they plan to target the various websites (TMA and Pharmaceutical Manufacturer's website); provide information to beneficiaries using 1-800-numbers; health fair package; ask the staff at the Military Treatment Facilities to distribute the meters; and ask the providers who write prescriptions for TRICARE beneficiaries to provide information as well as distribute meters during the patient's doctor's visits.

When asked about the patient population using the retail pharmacies, Dr. Meade indicated that information/education would be provided by using 1-800-numbers, pre-positioning in the physician's offices and making products available at the pharmacies.

The discussion ended by Dr. Salom stating that he could see problems coordinating the medical benefit and the implementation period. Dr. Khurana agreed that the 120 day implementation period was not enough time to implement this change.

** The Panel members contributing to this discussion were Dr. Ira Salom, Dr. Amit Khurana, Dr. Elizabeth Sampsel, Ms. Lisa Le Gette and Mr. Duane Tackitt

F. **Self-Monitoring Blood Glucose System (SMBGS) Test Strips – Panel Vote on the UF Recommendations:**

The Chair called for the vote on the Uniform Formulary recommendations on the Self-Monitoring Blood Glucose System (SMBGS) Test Strips.

The P&T Committee recommended the following:

- Formulary and step-preferred on the UF:
  - Precision Xtra (Abbott)
  - FreeStyle Lite (Abbott)
  - FreeStyle InsuLinx (Abbott)
- Non formulary and non-step preferred on the UF:
  - ACCU-CHEK Aviva Plus (Roche)
  - GLUCOCARD 01-Sensor (Arkray)
  - GLUCOCARD Vital (Arkray)
  - CONTOUR NEXT (Bayer)
  - NovaMax (Nova)
  - TRUEtest (Nipro Diagnostics)
  - Prodigy No Coding (Prodigy)
  - One Touch Verio
  - One Touch Ultra
  - The following test strips are also NF:

    GLUCOSE TEST STRIP; ACCU-CHEK ADVANTAGE, PRECISION PCX, BD TEST STRIPS, ACCU-CHEK, PRODIGY, ACCU-CHEK INSTANT, CHEMSTRIP BG, DEXTROSTIX REAGENT, ASCENSIA ELITE, FIFTY50 TEST STRIP, OPTIUM EZ, FORA G20, PRECISION POINT OF CARE, FORA TEST STRIP, PRESTIGE TEST, FORA V10, EASYMAX, FORA V30A, FIFTY50 TEST STRIP, PRESTIGE SMART SYSTEM, GLUCOSTIX, TRACER BG, GLUCOMETER ENCORE, MICRODOT, ASSURE PRO, ELEMENT TEST STRIPS, SMARTEST TEST, ASSURE PLATINUM, EVENCARE G2, CLEVER CHOICE TEST STRIPS, EZ SMART, RIGHTEST

GS100 TEST STRIPS, EZ SMART PLUS, SURESTEP PRO, FAST TAKE, OPTIUM EZ, FORA G20, PRECISION POINT OF CARE, FORA TEST STRIP, PRESTIGE TEST, EASY PRO PLUS, ASSURE 3, RIGHTEST GS550 TEST STRIPS, ACCU-CHEK ACTIVE, SURECHEK TEST STRIPS, EASYGLUCO, ADVOCATE REDI-CODE, CONTROL, ADVOCATE REDI-CODE+, ASSURE 4, ULTIMA, OPTIUM, ULTRATRAK, POCKETCHEM EZ, VICTORY, ACURA TEST STRIPS, WAVESENSE JAZZ, BG-STAR, ACCUTREND GLUCOSE, GLUCOLAB, BLOOD GLUCOSE TEST, EASY TOUCH, ADVOCATE TEST STRIP, RIGHTEST GS300 TEST STRIPS, ADVANCE TEST STRIPS, SMARTDIABETES XPRES, TEST STRIP, SOLUS V2 TEST STRIPS, SURESTEP, TELCARE, LIBERTY TEST STRIPS, MICRO, INFINITY, TRUETRACK SMART SYSTEM, INFINITY TEST STRIPS, CLEVER CHOICE PRO, KEYNOTE, ULTRATRAK PRO, GE100 BLOOD GLUCOSE TEST STRIP, WAVESENSE AMP, WAVESENSE PRESTO, GLUCOCARD EXPRESSION, PRECISION PCX PLUS, PRECISION Q-I-D, Glucocard X sensor, CONTOUR, ACCU- CHEK AVIVA, TRUE TRACK, ACCU-CHEK COMFORT CURVE, ACCU-CHEK SMARTVIEW, RELION CONFIRM MICRO, RELION PRIME, WAVESENSE PRESTO, EMBRACE, CLEVER CHECK

- This recommendation includes step therapy, which requires a trial of one of the Abbott test strips (FreeStyle Life, FreeStyle InsuLinx, or Precision Xtra) Priof to use of a non-formulary test strip in all current and new users of a non-formulary test stip.

There was no further discussion by the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

G. **Self-Monitoring Blood Glucose System (SMBGS) Test Strip —Prior Authorization (PA) Criteria**

The Chair next called for a vote on the Prior Authorization (PA) Criteria for the SMBGS Test Strips.

The P&T Committee recommended the following manual PA criteria for all new and current users of a non-formulary SMBG test strip, requiring a trial of FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra prior to the use of a non-formulary SMBG test strip. :

- Patient is blind/severely visually impaired and requires a test strip used in a talking meter - Prodigy Voice, Prodigy AutoCode, Advocate Redicode

- Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter

    - Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump
    - NovaMax strip with NovaMax Link meter for Medtronic pump
    - One Touch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump
    - OneTouch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump

- The patient has a documented physical or mental health disability requiring a special strip or meter.

- The patient is receiving peritoneal dialysis or the intravenous immune globulin (IVIG) preparation Octagam and the provider is concerned about the GDH-PQQ.

There is no further discussion from the Panel.

The BAP voted:

Concur: 9 Non-concur: 1 Abstained: 0 Absent: 0

H. Self-Monitoring Blood Glucose System (SMBGS) Test Strip —Implementation Period

The Chair called for the vote on the SMBGS Test Strips Implementation Plan.

The P&T Committee recommended 1) an effective date of the first Wednesday after a 120-day implementation period in all POS; and 2) TMA will send a letter to beneficiaries affected by the UF and PA decisions.

Additional Panel Discussion:

The Panel discussed a six (6) month extension of the 120 implementation period. Dr. Sampsel ask for clarification as to why a 6 month extension was needed and requested more details regarding how the new users would receive their self-monitoring glucose strips.

In response to Dr. Sampsel's questions, Dr. Salom stated the new users would get their test strips from Abbott and the 180 day conversion would be for people who already have a meter. The 6 month extension would also provide time for users (new and current) and practitioners for transition and education on the use of the test strips.

The Panel agreed that more time was needed to implement this change. Dr. Salom recommended (1) the effective date of the first Wednesday after a 180 day implementation period to all points of service for those beneficiaries who are currently using self-monitoring glucose strips. (2) the effective date of the first Wednesday after the 120 day implementation period to all points of service for those beneficiaries newly placed on the self-monitoring glucose strips.

Dr. Sampsel asked if DoD technology would support the recommended change. Prior to proposing the recommendations, the Panel agreed that more research should be conducted to ensure that current technology would support the recommendation. Dr. Salom made an editorial change stating that the Panel members were not sure that DoD technology would support the 120 day and the 180 day recommendation.

There were no further discussions from the Panel

The BAP Voted:

Concur: 0 Non-concur: 10 Abstained: 0 Absent: 0

III. UTILIZATION MANAGEMENT

(PEC Script - Dr. Meade)

P&T Comments

A. *P*rior Authorizations

1. **Injectable Corticotropin (HP Acthar Gel)**:

Injectable corticotrophin has been commercially available since 1952, but now is only marketed as a proprietary product, HP Acthar Gel. The P&T Committee established manual PA criteria for all new and current users of HP Acthar Gel, limiting use to infantile spasms (West Syndrome) for patients less than 24 months old at initiation of treatment and not previously treated with corticotropin. Additional uses for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies (kidney disease) may be permitted on appeal.

The following uses for Acthar Gel are considered unsupportable: dermatomyositis (a connective-tissue disease characterized by inflammation of the muscles and the skin),

polymyositis (chronic inflammation of the muscles), psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis (chronic inflammatory disease of spine, peripheral joints and other bones structures), sarcoidosis (involving abnormal collections of chronic inflammatory cells that can form as nodules in multiple organs), serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis (the immune system attacks the body's cells and tissue, resulting in inflammation and tissue damage).

a. **Injectable Corticotropin (HP Acthar Gel) - PA Criteria:**

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) manual PA criteria for all current and new users of HP Acthar Gel, limiting use to the specific FDA-approved indication of infantile spasms (West Syndrome). Prior Authorization will expire after 30 days for infantile spasms; retreatment is not covered. Use for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies will be on appeal only. Other uses of HP Acthar Gel are considered unsupportable.

b. Injectable Corticotropin (HP Acthar Gel) - PA Implementation Plan:

The P&T Committee recommended (8 for, 3 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this PA decision.

c. Injectable Corticotropin (HP Acthar Gel) - Physician's Perspective:

The active ingredient in Acthar Gel, corticotropin, has been available commercially since 1952, however this specific product is now marketed by only one company. There is a generic product available, but it is only approved for use as a diagnostic agent, so Acthar Gel is the only product available on the market approved for clinical use.

There was an extensive discussion of the published efficacy data for all the FDA-approved and off-label uses, and whether the off-label uses met the TRICARE criteria for coverage of unproven drugs. The recommendation was unanimous for the PA criteria to cover supportable uses of the drug, and to not cover the non-supportable uses. The Committee wanted the PA criteria to be implemented as quickly as possible, so a 30-day implementation period was recommended.

d. **Injectable Corticotropin (HP Acthar Gel) – Panel Questions and Comments:**

Dr. Salom asked if this drug was in wide use or had a large population of users. Dr. Meade stated that there were a total of 300 users.

e. **Injectable Corticotropin (HP Acthar Gel) – Panel Vote on the PA Recommendations:**

The Chair called for a vote on the Prior Authorization Criteria for the Injectable Corticotropin (HP Acthar Gel).

The P&T Committee recommended manual PA criteria for all current and new users of HP Acthar Gel, limiting use to the specific FDA-approved indication of infantile spasms (West Syndrome). Prior Authorization will expire after 30 days for infantile spasms; retreatment is not covered. Use for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies will be on appeal only. Other uses of HP Acthar Gel are considered unsupportable and not covered.

There was no further discussion by the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

f. **Injectable Corticotropin (HP Acthar Gel) —PA Implementation Plan**

The Chair called for a vote on the Prior Authorization Implementation Plan for the Injectable Corticotropin (HP Acthar Gel).

The P&T Committee recommended an effective date of the first Wednesday after a 30-day implementation period in all POS; and 2) TMA send a letter to beneficiaries affected by this PA decision.

There was no further discussion from the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

2. **Antiemetics: Doxylamine/Pyridoxine (Diclegis)**:

Diclegis contains 10 mg of doxylamine and 10 mg of pyridoxine and is FDA-approved for treating pregnant women experiencing nausea and vomiting. The P&T Committee recommended manual PA criteria for all new users of Diclegis. Diclegis is limited to use for management of nausea and vomiting during pregnancy (NVP) and excluded for the treatment of hyperemesis gravidarum. Patients must have tried at least one nonpharmacologic treatment (e.g., ginger, acupressure, high-protein bedtime snack) and OTC pyridoxine. An alternate antiemetic (e.g., ondansetron) should be considered prior to Diclegis.

a. **Antiemetics: Doxylamine/Pyridoxine (Diclegis) - PA Criteria:**

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) that manual PA criteria apply to new users of Diclegis who are being treated for nausea and vomiting during pregnancy. The PA will expire after nine months. (See Appendix E for full criteria.)

b. **Antiemetics: Doxylamine/Pyridoxine (Diclegis) - PA Implementation Plan:**

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS.

c. **Antiemetics: Doxylamine/Pyridoxine (Diclegis) – Physician's Perspective:**

Diclegis is a new drug that is really an old drug – it contains the same ingredients as Bendectin, which was removed from the market in 1983. Diclegis contains two products that have been used for decades for nausea and vomiting in pregnancy – Unisom and pyridoxine, or Vitamin B6. Both Unisom and pyridoxine are OTC drugs.

The decision was unanimous to have PA criteria for Dicelgis. The PA criteria do reflect current guidelines in recommending non-pharmacologic treatments prior to use of Diclegis.

d. Antiemetics: Doxylamine/Pyridoxine (Diclegis) – Panel Questions and Comments:

There were no questions or comments from the Panel.

e. Antiemetics: Doxylamine/Pyridoxine (Diclegis) – Panel Vote on the PA Criteria:

The Chair called for a vote on the Prior Authorization Criteria for the Antiemetics: Doxylamine/Pyridoxine (Diclegis).

The P&T Committee recommended that manual PA criteria apply to new users of Diclegis who are being treated for nausea and vomiting during pregnancy. The PA will expire after nine months.

1. **Manual PA Criteria**—pyridoxine/doxylamine (Diclegis) is approved if:

a. The patient has not had relief of symptoms after trying a nonpharmacologic method to manage nausea and vomiting during pregnancy,

AND

b. The patient has not had relief of symptoms after trying OTC pyridoxine for management of nausea and vomiting during pregnancy

Providers are encouraged to consider an alternate antiemetic (e.g., ondansetron) prior to prescribing Diclegis.

There was no further discussion from the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

f. **Antiemetics: Doxylamine/Pyridoxine (Diclegis) —PA Implementation Plan**

The Chair called a vote on the Antiemetics: Doxylamine/Pyridoxine (Diclegis implementation plan:

The P&T Committee recommended an effective date of the first Wednesday after a 60- day implementation period in all POS.

There was no further discussion from the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

3. **Targeted Immunomodulatory Biologics (TIBs): Ustekinumab (Stelara) and Golimumab (Simponi)**:

PA criteria currently apply to the Targeted Immunomodulatory Biologics (TIBs). Ustekinumab was previously limited to injection by health care professionals, but is now available in pre-filled syringes labeled for patient self-administration for treatment of plaque psoriasis. Also, the FDA recently approved a new indication for golimumab for treatment of moderate to severe ulcerative colitis.

a. **TIBs: Ustekinumab (Stelara) and Golimumab (Simponi) – PA Criteria:**:

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) PA criteria for ustekinumab for plaque psoriasis and golimumab for ulcerative colitis, consistent with the products' labeling. (See Appendix E for full criteria.)

b. **TIBS: Ustekinumab (Stelara) and Golimumab (Simponi) – PA Implementation Plan**:

The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS.

c. TIBS: Ustekinumab (Stelara) and Golimumab (Simponi) – Physician's Perspective:

There was no controversy here. The P&T Committee does routinely update PA criteria for new indications or for new drugs in a class where there are PA criteria already in place. This is part of the usual "housekeeping" activities to ensure PA criteria reflect current package insert labeling.

d. **TIBS: Ustekinumab (Stelara) and Golimumab (Simponi) – Panel Questions and Comments:**

Dr. Salom asked if an implementation plan was discussed. Dr. Meade stated that is was effective the first Wednesday after a 60-day implementation in all POS

e. **TIBS: Ustekinumab (Stelara) and Golimumab (Simponi) – Panel Vote on the PA Criteria:**

The Chair next read the Prior Authorization Criteria on the TIBS: Ustekinumab (Sterara) and Golumumab (Simponi) drug class.

The P&T Committee recommended PA criteria for ustekinumab for plaque psoriasis, and golimumab for ulcerative colitis, consistent with the products' labeling.

1. Manual PA Criteria— ustekinumab (Stelara) is approved for:

   a) Patients older than age 18 with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

2. Manual PA Criteria—golimumab (Simponi) is approved for:

   a) Patients older than age 18 with moderately to severely active ulcerative colitis that has not responded to other treatments or who require continuous steroids.

   b) Coverage is not provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia or Rituxan.

There was no further discussion from the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

f. **TIBS: Ustekinumab (Stelara) and Golimumab (Simponi) —PA Implementation Plan**

The Chair called for a vote on the TIBs: Ustekinumab (Stelara) Implementation Plan.

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period in all POS.

There was no further discussion from the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

IV. SECTION 703

A. **Section 703—**The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not compliant with Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity in MTFs. These NF drugs will remain available in the Mail Order POS without pre-authorization.

1. **Section 703: DRUGS DESIGNATED NF**:

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 1 absent) to designate (or maintain) the products in (listed by manufacturer) as non-formulary on the Uniform Formulary:

BAUSCH & LOMB RX
Besivance ophth susp
FOUGERA
Methscopamine
GRACEWAY PHARMA
Zyclara Cr
KEDRION
Gammaked inj

MEDA PHARMA
Dymista
NEUROGESX, INC.
Qutenza
NOVARTIS CONSUMER
Transderm Scop
OTSUKA AMERICA
Pletal
PATRIOT PHARMA
Haldol Inj
Itraconazole Tabs/Caps
Ketoconazole Shampoo
Galantamine Tabs
Tramadol ER Tabs
PHARMADERM
Oxistat Products
Cutivate lotion
Temovate Products
RHODES PHARM
Hydromorphone
Tramadol ER
SANDOZ
Calcitonin Nasal Spray
Calcium Acetate
Carbamazepine XR
Lansoprazole
Losartan
Losartan/HCTZ
Oxcarbazepine Susp
Sumatriptan Nasal Spray
Valsartan/HCTZ
Metoprolol/HCTZ
Rivastigmine
STIEFEL LABS
Veltin
UNITED RESEARCH LAB
Glycopyrrolate Tabs
Nisoldipine ER
VIROPHARMA INC
Vancocin Caps

2. **Section 703: Prior Authorization Criteria:**

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) the following Pre-Authorization Criteria for the drugs listed as non-formulary in Appendix G: 1) Obtaining the product from the home delivery would be detrimental to the patient and 2)

For branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any point of service other than retail network pharmacies.

3. **Section 703: UF and Implementation Period:**

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 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 these decisions.

4. **Section 703: Physician's Perspective:**

No comments

5. **Section 703: Panel Questions and Comments:**

The Panel was concerned about the number of beneficiaries affected by this recommendation as well as education regarding the use of another generic drug. In response to Dr. Salom's question, Dr. Meade stated that approximately 45,000 beneficiaries were affected. The majority of those patients are acute users meaning they used the drug one (1) time. Per the implementation plan, letter will be sent to beneficiaries affected by this change and alternate generics will be provided in the letter.

Dr. Salom also asked if the numbers would decrease as companies come into compliance. Dr. Meade stated that the companies would be removed from the list as they came into compliance.

Dr. Crum asked if the information comes in on the transactions from the retail pharmacy identify the maker. Dr. Meade stated that the product number at the pharmacy is an NDC number which is specific drug and dose.

6. **Section 703: Panel vote on the UF Recommendation**

The Chair called a vote for the Section 703 UF Recommendations

The P&T Committee recommended to designate the following products (listed by manufacturer) as non-formulary on the Uniform Formulary, due to noncompliance with Section 703.

BAUSCH & LOMB RX
Besivance ophth susp

FOUGERA
Methscopolamine tablets

GRACEWAY PHARMA
- Zyclara Cr

KEDRION
- Gammaked inj

MEDA PHARMA
- Dymista

NEUROGESX, INC.
- Qutenza

NOVARTIS CONSUMER
- Transderm Scop

OTSUKA AMERICA
- Pletal

PATRIOT PHARMA
- Haldol Inj
- Itraconazole Tabs/Caps
- Ketoconazole Shampoo
- Galantamine Tabs
- Tramadol ER Tabs

PHARMADERM
- Oxistat Products
- Cutivate lotion
- Temovate Products

RHODES PHARM
- Hydromorphone
- Tramadol ER

SANDOZ
- Calcitonin Nasal Spray
- Calcium Acetate
- Carbamazepine XR
- Lansoprazole
- Losartan
- Losartan/HCTZ
- Oxcarbazepine Susp
- Sumatriptan Nasal Spray
- Valsartan/HCTZ
- Metoprolol/HCTZ
- Rivastigmine

STIEFEL LABS
- Veltin

UNITED RESEARCH LAB

Glycopyrrolate Tabs
Nisoldipine ER

VIROPHARMA INC

Vancocin Cap

There was no further discussion from the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

7. **Section 703—PA Criteria**

The P&T Committee recommended the following Pre-Authorization Criteria for the non-formulary drugs not in compliance with Section 703: 1) obtaining the product from home delivery would be detrimental to the patient; and 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient.

There was no further discussion from the Panel.

The BAP voted:

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

8. **Section 703—PA Implementation Plan**

P&T Committee recommended 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 these decisions.

There was no further discussion from the Panel.

The BAP voted;

Concur: 10 Non-concur: 0 Abstained: 0 Absent: 0

V. **For information only**

A. **Angiotensin Receptor Blockers (ARBs)/Direct Renin Inhibitor—**The P&T committee considered the merits of formulary action in the Angiotensin Receptor Blockers, Direct Renin Inhibitors and respective fixed dose combination products drug classes. Based on current pricing agreements and pending availability of new generic entrants, the P&T committee opted not to take any formulary action at this time**.**

CLOSING STATEMENTS

Dr. Salom thanked Commander Lawrence for his service to the BAP. This was his last meeting.

Ira Salom MD

Dr. Ira Salom, Chair

Appendix 1 09/19/2013 BAP Meeting Minutes

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 Advisory Panel," the group whose meeting is the subject of this report.

- ARBS – Angiotensin Receptor Blockers
- ASD(HA)—Assistant Secretary of Defense for Health Affairs
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- CEA — Cost-effectiveness analysis
- CFR — Code of Federal Regulations
- CMA — Cost-Minimization Analysis
- CPG — Clinical Practice Guideline
- DFO — Designated Federal Officer
- DoD — Department of Defense
- ECF — Extended Core Formulary
- ESI — Express-Scripts, Inc.

- FACA — Federal Advisory Committee Act
- FDA — U.S. Food and Drug Administration
- GDH-PQQ – Glucose Dehydrogenase-Pyroloquinolinequinone Interaction
- ISO – International Organization for Standardization
- IVIG – Intravenous Immune Glogulin
- MCSC – Managed Care Support Contractors
- MDI — Metered Dose Inhaler
- MHS — Military Health System
- MTF — Military Treatment Facility
- NF — Non-formulary
- NVP – Nausea and Vomiting During Pregnancy
- OTC — Over the counter
- PA — Prior Authorization
- P&T Committee — DoD Pharmacy and Therapeutics Committee
- PDTS — Pharmacy Data Transaction Service
- PEC — DoD Pharmacoeconomic Center
- PORT — Pharmacy Outcomes Research Team
- POS — Point of Service
- SMBFGS – Self-Monitoring Blood Glucose System
- TIBS – Targeted Immunomodulatory Biologics
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TPHARM — TRICARE Pharmacy Program
- TRRx — TRICARE Retail Pharmacy Program
- TZD — Thiazolidedione
- UF — DoD Uniform Formulary
- ULT — Urate-Lowering Therapy
- USC — United States Code
- VA — U.S. Department of Veterans Affairs

Letter

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July 24, 2013

RADM Thomas McGinnis, USPHS
Chief, DoD Pharmacy Programs
TRICARE Management Activity
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22402

Dear RADM McGinnis:

Thank you for your offer to get our comments in front of the committee in a public format so they can be recorded into the minutes and presented to the Director of TRICARE Management Activity.

As of this morning, I received an email that TRICARE is extending its coverage on compounded drugs for 180 days. I am very happy to hear this news and would like to see compounded drugs remain in place without limits. TRICARE has made a promise of healthcare to us, and the coverage of compounded medicines matters to us whom TRICARE had made that promise.

In the case of progesterone and testosterone, there are particular concerns. Manufactured capsules of progesterone come only in 100 to 200 mg doses and are an immediate release formula. Compounded progesterone comes in a dosage specific to the patient and has a slow release. This is much healthier to those who wish to neither be under or overdoses, not to mention the benefit of release over time.

Manufacturers only produce testosterone for women as a monthly injectable. This is unacceptable for many reasons, but particularly because of the unhealthy peaks and valleys in the drug's distribution over a month's cycle. Compounding pharmacies can produce testosterone for women as a topical cream or a sublingual tablet. This is a much healthier delivery system and the dosage is specific to the individual

I have focused on those two, but in general, I am an advocate of compounding for all. Compounded medications are allergy-friendly, available in personalized dosage, and may assist in avoiding many of the negative systemic effects of commercially available drugs.

I urge the board to make this 180-day extension of compounded medicines a permanent one.

Sincerely,

Terry Ciotti Galo.