DECISION PAPER

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

August 2013

I. UNIFORM FORMULARY DRUG CLASS REVIEWS

A. Corticosteroid Immune Modulators (Topical Steroids)

Background and Relative Clinical Effectiveness Conclusion—The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee evaluated the Corticosteroid Immune Modulators (Topical Steroids) Drug Class. The drugs were categorized into high- (classes 1 and 2), medium- (classes 3, 4, and 5), and low-potency agents (classes 6 and 7). Appendix B lists all products in the Topical Steroids Drug Class and their respective potency classifications, formulations, and generic availability.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the following conclusions:

- There is very limited generalizable data for all of the topical steroids. Heterogeneity of the data 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.
- The medium-potency topical steroid 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.

- For the low-potency topical steroids, there is no evidence to support clinically meaningful differences in efficacy or safety among the 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.
    - Desonate Gel, Verdeso Foam, and Capex Shampoo all remain uniquely branded, without clinical advantages over the other generic low-potency topical steroids

Relative Cost-Effectiveness 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, 0 abstained, 1 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. ***COMMITTEE ACTION: UNIFORM FORMULARY (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 nonformulary (NF) (See Appendix H):
    - **Nonformulary 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. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) maintaining fluocinonide 0.05% cream and triamcinolone acetate 0.1% cream on the BCF. Additionally, the P&T Committee recommended adding fluocinonide 0.05% ointment, clobetasol 0.05% cream, clobetasol 0.05% ointment, and triamcinolone acetate 0.1% ointment to the BCF.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for all topical steroids that were designated as NF. (See Appendix D for full MN criteria.)

4. ***COMMITTEE ACTION: 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. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

Director, DHA, Decision:  ☒Approved ☐ Disapproved

Approved, but modified as follows:

B. 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. Appendix C lists the products in the SMBGS Test Strips Drug Class. Candidates for inclusion on the UF met all minimum required technical standards and U.S. Federal Government contracting requirements.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following 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 minimum technical requirements in the areas of accuracy, sample size, alternate site testing, result time, memory capacity, ease of use, customer support, downloading capabilities, and data management capabilities. See pages 15-16 for detailed technical requirements. 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.
- *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 FreeStyle Lite (Abbott), FreeStyle InsuLinx (Abbott), Precision Xtra (Abbott); ACCU-CHEK Aviva Plus (Roche); CONTOUR NEXT (Bayer); TRUEtest (Nipro Diagnostics); Nova Max (Nova); Glucocard 01-Sensor (Arkray), Glucocard Vital (Akray); and Prodigy No Coding (Prodigy).
- *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.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (12 for, 0 opposed, 0 abstained, 2 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 budget impact analysis (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. ***COMMITTEE ACTION: 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)
    - Nonformulary 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 listed in Appendix C (with the exception of FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra)
    - 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 nonformulary test strip in all current and new users of a nonformulary test strip.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) designating FreeStyle Lite (Abbott) with BCF status, based on clinical and cost-effectiveness, and removing Precision Xtra (Abbott) from the BCF. Note: Precision Xtra (Abbott) is designated with Uniform Formulary status and is step-preferred on the UF.

3. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1abstained, 1 absent) manual PA criteria for all new and current users of a nonformulary SMBG test strip, requiring a trial of FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra prior to the use of a nonformulary SMBG test strip. (See Appendix E for full criteria).

4 ***COMMITTEE ACTION: 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.

5. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for the NF SMBGS test strips. (See Appendix D for full MN criteria.)

6. ***COMMITTEE ACTION: 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; and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is March 12, 2014.

Director, DHA, Decision: ☒Approved □ Disapproved

Approved, but modified as follows:

Considering the comments of the Beneficiary Advisory Panel, implementation period is 180 days. Effective date is May 7, 2014.

II. UTILIZATION MANAGEMENT

A. Prior Authorizations

1. **Injectable Corticotropin (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 may be permitted on appeal.

   The following uses for Acthar Gel are considered unsupportable: dermatomyositis, polymyositis, psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis), sarcoidosis, serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis.

   a) ***COMMITTEE ACTION: 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 and not covered. (See Appendix E for full criteria.)

b) ***COMMITTEE ACTION: HP ACTHAR GEL PA IMPLEMENTATION***—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. Based on the P&T Committee's recommendation, the effective date is December 11, 2013.

2. **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.

   a) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (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) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (DICLEGIS) PA IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

3. **Targeted Immunomodulatory Biologics: 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) ***COMMITTEE ACTION: 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) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI PA IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

B. Quantity Limits

1. **Targeted Immunomodulatory Biologics: Ustekinumab (Stelara) and Golimumab (Simponi)**—QLs currently apply to the TIBs. The P&T Committee evaluated QLs for ustekinumab for the new indication of plaque psoriasis for patient self administration, and for golimumab for the new indication of ulcerative colitis.

   a) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI) QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for Stelara and Simponi, as outlined in Appendix F, consistent with FDA-approved product labeling.

2. **Oral Chemotherapy Drugs: Dabrafenib (Tafinlar), Trametinib (Mekinist), and Afatinib (Glotrif)**—The P&T Committee evaluated QLs for several oral chemotherapy drugs, including dabrafenib (Tafinlar), indicated for treatment of treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations; trametinib (Mekinist) for treatment of unresectable or metastatic melanoma with BRAF V600E mutations; and afatinib (Glotrif) for first-line treatment of metastatic non-small cell lung cancer whose tumors have specific mutations. QLs exist for several other oral chemotherapy agents.

   a) ***COMMITTEE ACTION: TAFINLAR, MEKINST, AND GLOTRIF QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for dabrafenib (Tafinlar), trametinib (Mekinist), and afatinib (Glotrif) as outlined in Appendix F, consistent with FDA-approved product labeling.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

III. Fiscal Year 2008 National Defense Authorization Act, 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. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) to designate the products in Appendix G (listed by manufacturer) as nonformulary on the Uniform Formulary.

2. ***COMMITTEE ACTION: PRE-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 nonformulary in Appendix G: 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. These pre-authorization criteria do not apply to any point of service other than retail network pharmacies.

3. ***COMMITTEE ACTION: UF AND PRE-AUTHORIZATION 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 the these decisions. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

Director, DHA, Decision: ☒Approved □ Disapproved

Approved, but modified as follows:

Patriot Pharmaceuticals has now signed a pricing agreement for all of its covered drugs. Qutenza patch and Zyclara cream are also now covered by a pricing agreement. Therefore, the Patriot Pharmaceuticals products listed in Appendix G, Qutenza patch, and Zyclara cream are excluded from this action.

SUBMITTED BY:

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

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

7 NOV 2013
Date

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE MINUTES AND RECOMMENDATIONS

August 2013

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 14 and 15, 2013, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is found in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May Minutes**—Jonathon Woodson M.D., Director, TRICARE® Management Activity (TMA), approved the minutes for the May 2013 DoD P&T Committee meeting on August 6, 2013.
2. **Changes to the May 2013 Minutes:**
    a) **Emergency Contraceptives**—The Director's decision was that due to over-the-counter availability of levonorgestrel 1.5 mg (Plan B One-Step) without age restrictions, no emergency contraceptives shall be included on the Basic Core Formulary (BCF). However, Military Treatment Facilities (MTFs) shall carry Plan B One-Step and provide it no cost.

III. REQUIREMENTS

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

IV. UF DRUG CLASS REVIEWS

A. Corticosteroid Immune Modulators (Topical Steroids)

Background and Relative Clinical Effectiveness—The P&T Committee 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. Appendix B lists all products in the Corticosteroid Immune Modulators (Topical Steroids) Drug Class and their respective potency classifications, formulations, and generic availability.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the following conclusions:

- For all of the topical steroids, there is very limited generalizable data. Heterogeneity of the data 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.
    - 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.
- 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 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.
  - 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.

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, 0 abstained, 1 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. ***COMMITTEE ACTION: 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 (See Appendix G):

    - **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. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) maintaining fluocinonide 0.05% cream and triamcinolone acetate 0.1% cream on the BCF. Additionally, the P&T Committee recommended adding fluocinonide 0.05% ointment, clobetasol 0.05% cream, clobetasol 0.05% ointment, and triamcinolone acetate 0.1% ointment to the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for all topical steroids that were designated as NF. (See Appendix D for full MN criteria.)

4. ***COMMITTEE ACTION: 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. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

B. 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. Appendix C lists the products in the SMBGS Test Strips Drug Class.

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.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (17 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.
- Customer 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.

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, 0 abstained, 2 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. ***COMMITTEE ACTION: 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)
    - Nonformulary 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 listed in Appendix C (with the exception of FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra)
    - 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 nonformulary test strip in all current and new users of a nonformulary test strip.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) designating FreeStyle Lite (Abbott) with BCF status, based on clinical and cost-effectiveness, and removing Precision Xtra (Abbott) from the BCF. Note: Precision Xtra (Abbott) is designated with Uniform Formulary status and is step-preferred on the UF.

3. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1abstained, 1 absent) manual PA criteria for all new and current users of a nonformulary SMBG test strip, requiring a trial of FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra prior to the use of a nonformulary SMBG test strip. (See Appendix E for full criteria).

4 ***COMMITTEE ACTION: 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.

5. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for the NF SMBGS test strips. (See Appendix D for full MN criteria.)

6. ***COMMITTEE ACTION: 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. Based on the P&T Committee's recommendation, the effective date is March 12, 2014.

V. UTILIZATION MANAGEMENT

A. PAs

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 may be permitted on appeal.

The following uses for Acthar Gel are considered unsupportable: dermatomyositis, polymyositis, psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis), sarcoidosis, serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis.

a) ***COMMITTEE ACTION: 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. (See Appendix E for full criteria.)

b) ***COMMITTEE ACTION: HP ACTHAR GEL PA IMPLEMENTATION***—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. Based on the P&T Committee's recommendation, the effective date is December 11, 2013.

2. **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) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (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) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (DICLEGIS) PA IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

3. **Targeted Immunomodulatory Biologics: 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) ***COMMITTEE ACTION: 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) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI PA IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

B. QLs

1. **Targeted Immunomodulatory Biologics: Ustekinumab (Stelara) and Golimumab (Simponi)**—QLs currently apply to the TIBs. The P&T Committee evaluated QLs for ustekinumab for the new indication of plaque psoriasis for patient self administration, and for golimumab for the new indication of ulcerative colitis.

a) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI) QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for Stelara and Simponi, as outlined in Appendix F, consistent with FDA-approved product labeling.

2. **Oral Chemotherapy Drugs: Dabrafenib (Tafinlar), Trametinib (Mekinist), and Afatinib (Glotrif)**—The P&T Committee evaluated QLs for several oral chemotherapy drugs, including dabrafenib (Tafinlar), indicated for treatment of treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations; trametinib (Mekinist) for treatment of unresectable or metastatic melanoma with BRAF V600E mutations; and afatinib (Glotrif) for first-line treatment of metastatic non-small cell lung cancer whose tumors have specific mutations. QLs exist for several other oral chemotherapy agents.

   a) ***COMMITTEE ACTION: TAFINLAR, MEKINST, AND GLOTRIF QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for dabrafenib (Tafinlar), trametinib (Mekinist), and afatinib (Glotrif) as outlined in Appendix F, consistent with FDA-approved product labeling.

VI. 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. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) to designate the products in Appendix G (listed by manufacturer) as nonformulary on the Uniform Formulary

2. ***COMMITTEE ACTION: PRE-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 nonformulary 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. ***COMMITTEE ACTION: UF AND PRE-AUTHORIZATION 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 the these decisions. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

VII. OVERVIEWS

Overviews of the following four drug class were presented to the P&T Committee: the Inhaled Corticosteroids/Long-Acting Beta Agonists, the Inhaled Short-Acting Beta Agonists, the Antilipidemic-1 Agents (LIP-1s), and the Benign Prostatic Hyperplasia drugs comprised of the 5-alpha-reductase inhibitors and alpha blockers. The P&T Committee provided expert opinion regarding those clinical outcomes considered most important for the PEC to use in contract solicitation, and for completing the clinical effectiveness reviews and developing the appropriate cost-effectiveness models. The clinical and economic analyses of these classes will be presented at an upcoming meeting.

VIII. ITEMS FOR INFORMATION

A. Bulk Chemicals In Compounded Medications—The P&T Committee was presented with an update and will be given a full presentation at an upcoming meeting.

B. FY13 TRICARE Pharmacy Copayments—The P&T Committee was briefed on the initial impact of new pharmacy copayments implemented in February 2013 on pharmaceutical utilization in the Military Health System. The analysis included the first 5 months of data following copayment increases for Tier 2 products (preferred brands) and Tier 3 products (non-preferred brands) in the Retail Network and at Mail Order. The results showed preliminary evidence that the increase in copays (from $25 to $43 in Mail Order/$44 in the Retail Network) for Tier 3 medications appeared to be associated with declining use of these products, with about a 10% reduction over the first 5 months. However, the new copays did not appear to be associated with any major changes in use of medications overall (i.e., across all Tiers). Additional updates will be provided to the P&T Committee as data becomes available.

C. 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.

D. **Prior Authorization (PA) Implementation date for canagliflozin (Invokana)**—The implementation date for PA criteria applicable to canagliflozin (Invokana) was changed to September 25, 2013.

IX. ADJOURNMENT

The meeting adjourned at 1015 hours on August 15, 2013. The next meeting will be in November 2013.

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

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drug Class

Appendix C—Self-Monitoring Blood Glucose System Test Strips Products in Class

Appendix D—Table of Medical Necessity

Appendix E—Table of Prior Authorization Criteria

Appendix F—Table of Quantity Limits

Appendix G—Table of Drugs Designated NF due to Section 703

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

Appendix I—Table of Abbreviations

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

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CDR Joe Lawrence, MSC	Director, DoD Pharmacoeconomic Center (Recorder)
Col George Jones, BSC	Deputy Chief, Pharmaceutical Operations Directorate
COL John Spain, MS	Army, Pharmacy Officer
Col Mike Spilker, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
LTC Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Dr. Miguel Montalvo	TRICARE Regional Office-South Chief of Clinical Operations Division and Medical Director
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. David Hurt	Associate General Counsel, TMA
LCDR Tiffany Scott, MSC, via DCO	Defense Logistics Agency Troop Support
Capt Richard Caballero, via DCO	Defense Logistics Agency Troop Support
Capt Randall Sweeney, via DCO	Defense Logistics Agency Troop Support
Guests	
Mr. Bill Davies via DCO	TRICARE Management Activity, Pharmaceutical Operations Directorate
CDR Matthew Baker, USPHS, by phone	Indian Health Service
CAPT Jamie Kersten	Navy Medicine Training Support Center
LCDR David Sohl	University of Texas Masters Student

Appendix A—Attendance (continued)

Others Present	
LTC Chris Conrad, MS	DoD Pharmacoeconomic Center
LCDR Marisol Martinez, USPHS	DoD Pharmacoeconomic Center
LCDR Joshua Devine, USPHS	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
LCDR Linh Quach, MSC	DoD Pharmacoeconomic Center
Lt Col Melinda Henne, MC	DoD Pharmacoeconomic Center
Maj David Folmar, BSC	DoD Pharmacoeconomic Center
MAJ Misty Cowan, MC	DoD Pharmacoeconomic Center
LT Kendra Jenkins, USPHS	DoD Pharmacoeconomic Center
HM1 Nichole Moraldo	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Dean Valibhai	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacoeconomic Center
Dr. Amy Lugo via DCO	DoD Pharmacoeconomic Center
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Mr. Kirk Stocker	DoD Pharmacy Outcomes Research Team contractor
Andrew Delgado	University of Texas Health Science Center/University of Texas College of Pharmacy Student
Yuna Bae via DCO	University of Maryland School of Pharmacy Student
Christopher Bender via DCO	Lake Erie College of Osteopathic Medicine School of Pharmacy Student

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drugs in the Class (For UF decision see Appendix H)

Generic	Brand Generic	Strengths & formulations	Patent Exp
High-Potency Steroids (Classes 1 and 2)			
Clobetasol Propionate	Clobex Temovate/-E Olux/-E Generics: Yes (lotion/ointment/solution/ shampoo/ ointment/gel/foam)	0.05% Lotion, Shampoo, Spray 0.05% Oint, Soln, Gel, Cream 0.05% Foam 0.05% Ointment, Soln, Gel, Cream 0.05% Cream	9/2017–6/2019 -- 3/2016–9/2019 -- -- --
Diflorasone diacetate	*Psorcon/-E; Apexicon E** Generic: Yes	0.05% Ointment 0.05% Cream 0.05% Cream with Emollient	-- -- --
Halobetasol propionate	*Halac, Halonate, Halonate PAC** Ultravate/-PAC Generics: Yes	0.05% Cream, Ointment, Foam Combinations with Lactates	-- --
Flurandrenolide	Cordran Generics: No	4mcg/sq cm Tape	--
Desoximetasone	Topicort Generics: Yes	0.25% Cream, Ointment, Spray 0.05% Gel	-- --
Fluocinonide/-Emollient	Vanos, *Lidex/-E** Generics: Yes	0.1% Cream 0.05% Gel, Cream, Oint, Soln	-- --
Halcinonide	Halog Generics: Halog is generic	0.1% Cream, Ointment	--
Betamethasone dipropionate augmented	Diprolene/-AF Generics: Yes	0.05% Cream, Lotion, Ointment 0.05% Gel (generic only)	
Amcinonide	Cyclocort Generics: Yes	0.1% Ointment	--

*** italicized medications are branded products (reference listed drugs) that are not currently marketed.**

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drugs in the Class (For UF decision see Appendix H)

Generic	Brand Generic	Strengths & formulations	Patent Exp
Medium-Potency Steroids (Classes 3, 4, 5)			
Amcinonide	**Cyclocort** **Generics: Yes**	**0.1% Cream, Lotion**	
Betamethasone dipropionate	Diprosone Generics: Yes	0.05% Cream 0.05% Lotion (generic only)	--
Betamethasone valerate	Beta-Val, Luxiq, Valisone Generics: Yes (ointment)	0.1% Cream, Lotion 0.12% Foam	Luxiq: 3/2016–5/2017 --
Clocortalone pivalate	Cloderm Generics: No	0.1% Cream	--
Desonide	Desowen Generics: Yes	0.05% Ointment, Lotion	--
Desoximetasone	Topicort Generics: Yes	0.05% Cream	--
Fluocinolone	Synalar Generics: Yes (cream/ointment)	0.025% Cream	--
Flurandrenolide	Cordran Generics: No	0.05% Cream, Lotion	--
Fluticasone propionate	Cutivate Generics: Yes	0.05% Cream, Lotion 0.005% Ointment	--
Hydrocortisone butyrate	Locoid Locoid Lipocream Generics: Yes (lotion/ointment/solution)	0.1% Cream (brand only), Ointment, Solution, Lotion 0.1% Cream	Lotion: 1/2025–12/2026 Cream: 6/2014
Hydrocortisone probutate	Pandel Generics: No	0.1% Cream	--
Hydrocortisone valerate	Brand: *Westcort** Generics: Yes	0.2% Cream, Ointment	--
Mometasone furoate	Elocon Generics: Yes	0.1% Ointment, Cream, Solution	--
Prednicarbate	Dermatop Generics: Yes	0.1% Cream, Ointment	--
Triamcinolone acetate	Aristocort HP Kenalog Trianex Kenalog Triderm Triacet Generics: Yes (cream/ointment/lotion)	0.5% Cream 0.025%, 0.1%, 0.5% Cream 0.025%, 0.1% Lotion 0.025%; 0.1% Ointment 0.147 mg/g Topical Spray 0.1% Cream 0.05% Ointment	-- -- -- -- -- --
Triamcinolone Acetonide	Aristocort A Pediaderm TA Generics: Yes	0.5% Cream 0.1% Cream	-- --

*** italicized medications are branded products (reference listed drugs) that are not currently marketed.**

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drugs in the Class (For UF decision see Appendix H)

Generic	Brand Generic	Strengths & formulations	Patent Exp
Low Potency Steroids (Class 6 and 7)			
Alclometosone dipropionate	Aclovate Generics: Yes	0.05% Cream, Ointment	--
Desonide	Desonate Desowen Verdeso Generics: Yes	0.05% Gel 0.05% Cream 0.05% Foam	08/2020 -- 09/2016
Fluocinolone acetonide	Capex Derma-Smoothe/FS Synalar Generics: Yes	0.01% Shampoo 0.01% Oil 0.01% Solution	-- -- --
Hydrocortisone	Ala-Cort Ala-Scalp Nutracort, Stie-Cort Synacort Texacort Pediaderm HC Generics: Yes	1% Lotion, Cream 2% Lotion 1%, 2.5% Lotion 1%, 2% Cream 2.5% Solution 2% Lotion + Emollient	-- -- -- -- -- --
Hydrocortisone acetate	Microcort Carmol HC, U-Cort Pramosone Epifoam Generics: Yes	2%, 2.5% Cream 1% Cream + 10% Urea 0.5%, 1% Cream + 1% Pramoxine 1%, 2.5% Lotion + 1% Pramoxine 1% Aerosol +1% Pramoxine	-- -- -- -- --

Appendix C—Self-Monitoring Blood Glucose System Test Strips Products in the Class

FREESTYLE LITE (ABBOTT)	ACCU-CHEK AVIVA
FREESTYLE INSULINX (ABBOTT)	ACCU-CHEK COMFORT CURVE
PRECISION XTRA (ABBOTT)	ACCU-CHEK SMARTVIEW
ACCU-CHEK AVIVA PLUS (ROCHE)	ACCUTREND GLUCOSE
GLUCOCARD 01-SENSOR (ARKRAY)	ACURA TEST STRIPS
GLUCOCARD (ARKRAY)	ADVANCE TEST STRIPS
CONTOUR NEXT (BAYER)	ADVOCATE REDI-CODE
NOVAMAX (NOVA)	ADVOCATE REDI-CODE+
TRUETEST (NIPRO DIAGNOSTICS)	ADVOCATE TEST STRIP
PRODIGY NO CODING (PRODIGY)	ASSURE 4
ACCU-CHEK	BG-STAR
ACCU-CHEK ACTIVE	BLOOD GLUCOSE TEST
ACCU-CHEK ADVANTAGE	CLEVER CHECK
ACCU-CHEK INSTANT	CLEVER CHOICE PRO
ASCENSIA ELITE	CONTOUR
ASSURE 3	CONTROL
ASSURE PLATINUM	EASY TOUCH
ASSURE PRO	EASYGLUCO
BD TEST STRIPS	EMBRACE
CHEMSTRIP BG	GE100 BLOOD GLUCOSE TEST STRIP
CLEVER CHOICE TEST STRIPS	GLUCOCARD EXPRESSION
DEXTROSTIX REAGENT	GLUCOCARD X SENSOR
EASY PRO PLUS	GLUCOLAB
EASYMAX	INFINITY
ELEMENT TEST STRIPS	INFINITY TEST STRIPS
EVENCARE G2	KEYNOTE
EZ SMART	LIBERTY TEST STRIPS
EZ SMART PLUS	MICRO
FAST TAKE	ONE TOUCH ULTRA
FIFTY50 TEST STRIP	ONE TOUCH VERIO
FORA G20	OPTIUM
FORA TEST STRIP	POCKETCHEM EZ
FORA V10	PRECISION PCX PLUS
FORA V30A	PRECISION Q-I-D
GLUCOMETER ENCORE	RELION CONFIRM MICRO
GLUCOSE TEST STRIP	RELION PRIME
GLUCOSTIX	RIGHTEST GS300 TEST STRIPS
MICRODOT	SMARTDIABETES XPRES
OPTIUM EZ	SOLUS V2 TEST STRIPS
PRECISION PCX	SURESTEP
PRECISION POINT OF CARE	TELCARE
PRESTIGE SMART SYSTEM	TEST STRIP
PRESTIGE TEST	TRUE TRACK
PRODIGY	TRUETRACK SMART SYSTEM
RIGHTEST GS100 TEST STRIPS	ULTIMA
RIGHTEST GS550 TEST STRIPS	ULTRATRAK
SMARTEST TEST	ULTRATRAK PRO
SURECHEK TEST STRIPS	VICTORY
SURESTEP PRO	WAVESENSE AMP
TRACER BG	WAVESENSE JAZZ
	WAVESENSE PRESTO

Appendix D—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• 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) **High Potency Topical Steroids**	• Use of the formulary agent is contraindicated • All other formulary agents have resulted in therapeutic failure. Formulary alternatives include the high potency topical steroids - clobetasol, augmented betamethasone dipropionate, desoximetasone, fluocinonide 0.05%, halobetasol propionate.
• 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) **Medium Potency Topical Steroids**	• Use of all other medium potency formulary agents is contraindicated, and using a high potency agent would incur unacceptable risk. • All other Mid Potency formulary agents have resulted in therapeutic failure and using a High Potency agent would incur unacceptable risk. • For clocortolone, the patient requires a Coopman Class C agent, and desoximetasone is contraindicated. Formulary alternatives include the high potency and medium potency topical steroids
• Desonide 0.05% foam (Verdeso) • Desoinde 0.05 gel (Desonate) • Fluocinolone 0.01% shampoo (Capex) • Hydrocortisone with emoliient #45, 2% lotion kit (Pediaderm HC) **Low Potency Topical Steroids**	• Use of all other low potency formulary agents, including over-the-counter topical steroids are contraindicated and using a higher potency agent would incur unacceptable risk. • All other low potency formulary topical steroids have resulted in therapeutic failure and using a higher potency agent would incur unacceptable risk. • For Desonide 0.05% foam (Verdeso) and fluocinolone 0.01% shampoo (Capex), requires a trial of fluocinolone oil (Derma-Smoothe/FS) unless patient has a contraindication specifically to Derma-Smoothe/FS Formulary alternatives include high, medium, and low potency topical steroids
• ACCU-CHEL Aviva Plus (Roche) • GLUCOCARD 01-Sensor (Arkray) • GLUCOCARD Vital (Arkray) • CONTOUR NEXT (Bayer) • NovaMAx (Nova) • TRUEtest (Nipro Diagnostics) • Prodigy No Coding (Prodigy) • One Touch Ultra (Lifescan) • One Touch Verio (Lifescan) • All other test strips listed in Appendix C with the exception of FreeStyle Lite, FreeStyle InsuLinx, and Precision Xtra **SMBG System Test Strips**	• No alternative formulary agent. o Patient is blind/severely visually impaired and requires a test strip used in a talking meter - Prodigy Voice, Prodigy AutoCode, Advocate Redicode. o Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter. o The patient has a documented physical or mental health disability requiring a special strip meter. o Provider is concerned about the glucose dehydrogenase-pyrroloquinolinequinone interaction (GDH-PQQ) and the patient is taking IVIG Octagam.

Appendix E—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• 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 Ultra (Lifescan) • One Touch Verio (Lifescan) • All other SMBG test strips listed in Appendix C, with the exception of FreeStyle Lite, FreeStyle InsuLinx, and Precision Xtra **Self-Monitoring Blood Glucose (SMBG) Test Strips**	New and current users of the nonformulary test strips are required to try FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra Manual PA Criteria—Non-Preferred test strip allowed if: • 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 o Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump o NovaMax strip with NovaMax Link meter for Medtronic pump o OneTouch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump o 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 glucose dehydrogenase-pyrroloquinolinequinone interaction (GDH-PQQ)
• Injectable Corticotropin (HP Acthar Gel)	All new and current users of HP Acthar Gel are required to undergo Prior Authorization. Manual PA Criteria • Coverage is approved for infantile spasms (West Syndrome) in the following patients: Patient is less than 24 months old at initiation of treatment, and has no previous treatment with corticotrophin. Prior Authorization will expire in 30 days. Retreatment is not covered. • Coverage for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout and protein-wasting nephropathies—may be permitted on appeal. Prior Authorization will expire in 21 days for multiple sclerosis; 14 days for acute gout; and 6 months for protein-wasting nephropathies. • Coverage is not provided for the following uses: dermatomyositis, polymyositis, psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis), sarcoidosis, serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis

Drug / Drug Class	Prior Authorization Criteria
• pyridoxine/doxylamine (Diclegis) **Antiemetics**	All new users of Diclegis are required to try a nonpharmacologic method for management of nausea and vomiting during pregnancy AND OTC pyridoxine before receiving pyridoxine/doxylamine (Diclegis). Manual PA criteria—Pyridoxine/doxylamine (Diclegis) is approved if: • The patient has not had relief of symptoms after trying a nonpharmacologic method to manage nausea and vomiting during pregnancy, AND • 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 pyrodixone/doxylamine. Prior Authorization will expire after 9 months.
• Ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy No expiration date for Prior Authorization
• Golimumab (Simponi) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with • Moderate to severely active rheumatoid arthritis and active psoriatic arthritis, active ankylosing spondylitis • **Moderate to severely active ulcerative colitis that has not responded to other treatments or who require continuous steroids** • Coverage NOT provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia, or Rituxan No expiration date for Prior Authorization

Appendix F—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
Self-Monitoring Blood Glucose Test Strips (all products)	▪ Retail: 150 strips/30-day supply ▪ Mail Order and MTF: 450 strips/90-day supply
• Ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail: 2 pre-filled syringes (45 mg/0.5 mL; 90 mg/1.0 mL) or 2 vials (45 mg; 90 mg) /30 days ▪ Mail: 2 pre-filled syringes (45 mg/0.5 mL; 90 mg/1.0 mL) or 2 vials (45 mg; 90 mg) /56 days
• Golimumab (Simponi) **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail: 3 syringes (3 mL) /30 days ▪ Mail: 4 syringes (4mL) /56 days
• Dabrafenib (Tafinlar) **Oral chemotherapy drug**	50 mg and 75 mg capsules ▪ Retail: 120 capsules/30 days ▪ Mail Order: 240 capsules/60 days
• Trametinib (Mekinist) **Oral chemotherapy drug**	2 mg tablets ▪ Retail: 30 tablets/30 days ▪ Mail Order: 60 tablets/60 days 0.5 mg ▪ Retail: 120 tablets/30 days ▪ Mail Order 240 tablets/60 days
• Afatinib (Glotrif) **Oral chemotherapy drug**	40mg, 30mg, 20mg tablets ▪ Retail: 30 tablets/30 days ▪ Mail Order: 60 tablets/60 days

Appendix G—Drugs Designated as NF due to Section 703

Manufacturer	Drugs
Bausch & Lomb Rx	Besivance ophthalmic suspension
Fougera	methscopolamine tablets
Graceway Pharma	Zyclara cream
Kedrion	Gammaked injection
Meda Pharma	Dymista nasal spray
Neurogesx, Inc	Qutenza patch
Novartis Consumer	Transderm Scop
Otsuka America	Pletal
Patriot Pharma	Haldol injection; 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

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

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2013	**Topical Steroids**	UF Class Review	▪ clobetasol 0.05% cream and ointment ▪ fluocinonide 0.05% cream and ointment ▪ triamcinolone acetate 0.1% cream and ointment	▪ aclometasone 0.05% cream, ointment (Aclovate, generics) ▪ augmented betamethasone dipropionate 0.05% cream, ointment, gel & lotion (Diprolene, Diprolene AF, generics) ▪ betamethasone dipropionate 0.05% cream & lotion (Diprosone, generics) ▪ betamethasone valerate 0.1% cream, ointment & lotion (Valisone, generics) ▪ clobetasol 0.05% solution, foam, gel, shampoo, lotion & spray (Clobex, Olux, Temovate, generics) ▪ desonide 0.05% cream & ointment (Desowen, generics) ▪ desoximetasone 0.05% & 0.25% cream, ointment, gel, & spray (Topicort, generics) ▪ fluocinonide 0.05%, gel, and solution (Lidex, generics) ▪ fluocinolone acetonide 0.01% oil, solution (Derma-Smoothe/FS, generics) ▪ fluocinolone 0.025% cream & ointment (Synalar, generics) ▪ flurandrenolide 4mcg/sq cm tape (Cordran) ▪ flurandrenolide 0.05% cream, lotion (Cordran, generics) ▪ fluticasone 0.005% ointment, & 0.05% cream & lotion (Cutivate, generics)	**High potency** ▪ mcinonide 0.1% ointment (Cyclocort, generics) ▪ iflorasone 0.05% cream & ointment (Apexicon, generics) ▪ luocinonide 0.1% cream (Vanos) ▪ alcinonide 0.1% cream & ointment (Halog) **Medium potency** ▪ mcinonide 0.1% cream & lotion (Cyclocort, generics) ▪ etamethasone valerate 0.12% foam (Luxiq, generics) ▪ locortolone 0.1% cream (Cloderm) ▪ esonide 0.05% lotion (Desowen, generics) ▪ hydrocortisone probutate 0.1% cream (Pandel) ▪ ydrocortisone butyrate 0.1% cream & lotion (Locoid) ▪	Pending signing of the minutes/ 60 days	N/A	-

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
				▪ halobetasol 0.05% cream, ointment, lotion foam, & combinations (Halonate, Ultravate, generics) ▪ hydrocortisone 1%, 2% &2.5% cream, solution & lotion (excludes Pediaderm HC) ▪ hydrocortisone acetate 2% & 2.5% cream (Microcort-HC) generics ▪ hydrocortisone butyrate 0.1% ointment & solution (Locoid) ▪ hydrocortisone valerate 0.2% cream and ointment (Westcort, generics) ▪ mometasone 0.1% cream, ointment & solution (Elocon, generics) ▪ prednicarbate 0.1% cream & ointment (Dermatop, generics) ▪ triamcinolone acetate 0.025%, 0.05%, 0.1%, & 0.5% cream, ointment & lotion (excludes Pediaderm TA) ▪ triamcinolone acetate 0.015% spray (Kenalog) ▪ triamcinolone acetonide 0.5% cream (Artistocort A, generics)	riamcinolone acetonide with emollient #45, 0.1% cream kit (Pediaderm TA) **Low potency** ▪ esonide 0.05% foam (Verdeso) & 0.05% gel (Desonate) ▪ luocinolone 0.01% shampoo (Capex) **Low potency (continued)** ▪ ydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC)			

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2013	**Self-Monitoring Blood Glucose System (SMBS) test strips**	UF Class Review	▪ FreeStyle Lite (Abbott)	Uniform Formulary and Step-Preferred ▪ FreeStyle Lite (Abbott) ▪ FreeStyle InsuLinx (Abbott) ▪ Precision Xtra (Abbott)	Nonformulary and non-step preferred ▪ ACCU-CHEK Aviva Plus (Roche) ▪ GLUCOCARD 01-SENSOR (Arkray) ▪ GLUCOCARD (Arkray) ▪ CONTOUR NEXT (Bayer) ▪ NovaMax (Nova) ▪ TRUEtest (Nipro) ▪ Prodigy No Coding (Prodigy) ▪ One Touch Ultra (Lifescan) ▪ One Touch Verio (Lifescan) ▪ All other test strips listed in Appendix C, with the exception of Freestyle Lite, Freestyle InsuLinx, and Precision Xtra	Pending signing of the minutes / 120 days	Step therapy requires a trial of an Abbott test strip (FreeStyle Lite, FreeStyle InsunLinx, or Precision Xtra) in all new and current users of the nonformulary strips	▪ FreeStyle Lite added to the BCF ▪ PrecisionXtra removed from the BCF, but still UF and step-preferred

Appendix I—Table of Abbreviations

ARBs	Angiotensin Receptor Blockers
ASD(HA)	Assistant Secretary of Defense for Health Affairs
BCF	Basic Core Formulary
BIA	budget impact analysis
BPH	benign prostatic hyperplasia
CMA	cost minimization analysis
DoD	Department of Defense
DRIs	Direct Renin Inhibitors
FDA	U.S. Food and Drug Administration
GDH-PQQ	glucose dehydrogenase-pyrroloquinolinequinone
ISO	International Organization for Standardization
LIP-1s	Antilipidemic-1s Drug Class
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
MCSCs	Managed Care Support Contractors
NF	nonformulary
NVP	nausea and vomiting in pregnancy
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PEC	Pharmacoeconomic Center
PORT	Pharmacy Outcomes Research Team
POS	points of service
QLs	quantity limits
SMBGS	Self-Monitoring Blood Glucose System (SMBGS)
TMA	TRICARE Management Activity
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary