DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, TRICARE® Management Activity (TMA), on formulary status, pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. UF CLASS REVIEWS—CORTICOSTEROID IMMUNE MODULATORS (TOPICAL STEROIDS)

P&T Comments

A. Topical Steroids—Relative Clinical Effectiveness and Conclusion

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.

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 generic low-potency topical steroids.

B. 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).

C. Topical Steroids—UF Recommendation

The P&T Committee recommended (9 for, 3 opposed, 1 abstained, 2 absent) that the following topical steroid products be designated formulary on the UF:

- **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 nonformulary (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)

D. Topical Steroids—UF Implementation Plan

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 POS; and, 2) TMA send a letter to beneficiaries affected by the UF decision.

III. UF CLASS REVIEWS—TOPICAL STEROIDS

BAP Comments

A. Topical Steroids—UF Recommendation

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)

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Topical Steroids—UF 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

P&T Comments

A. SMBGS Test Strips—Relative Clinical Effectiveness and Conclusion

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.

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 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 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.

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

CMA and budget impact analysis (BIA) were performed for the 10 SMBGS test strips that met all minimum required technical standards and U.S. Federal Government contracting requirements. CMA and budget impact analyses (BIA) was performed. 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

C. 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)
- 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
  - 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, ONE 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 nonformulary test strip in all current and new users of a nonformulary test strip.

D. SMBGS Test Strips—Prior Authorization (PA) Criteria

The P&T Committee recommended (12 for, 0 opposed, 1abstained, 1 absent) the following 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.

- 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
    - OneTouch 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 glucose dehydrogenase-pyrroloquinolinequinone interaction (GDH-PQQ.

E. SMBGS Test Strips—UF and PA Criteria

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/

V. UF CLASS REVIEWS—SMBGS TEST STRIPS

BAP Comments

A. SMBGS Test Strips—UF Recommendation

The P&T Committee recommended 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
    - 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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. SMBGS Test Strips—Prior Authorization (PA) Criteria

The P&T Committee recommended the following 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. :

- 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
    - OneTouch 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. SMBGS Test Strips—UF and PA Criteria

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 send a letter to beneficiaries affected by the UF and PA decisions.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VI. UTILIZATION MANAGEMENT

P&T Comments

A. Injectable Corticotropin: HP Acthar Gel—PA Criteria

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.

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.

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.

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.

VII. UTILIZATION MANAGEMENT

BAP Comments

A. Injectable Corticotropin: HP Acthar Gel—PA Criteria

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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Injectable Corticotropin: HP Acthar Gel—PA Implementation Plan

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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VIII. UTILIZATION MANAGEMENT

P&T Comments

A. Antiemetics: Doxylamine/Pyridoxine (Diclegis)—PA Criteria

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 and excluded for the treatment of hyperemesis gravidarum.

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.

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.

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.

IX. UTILIZATION MANAGEMENT

BAP Comments

A. Antiemetics: Doxylamine/Pyridoxine (Diclegis)—PA Criteria

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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

X. UTILIZATION MANAGEMENT

P&T Comments

A. Targeted Immunomodulatory Biologics (TIBs): Ustekinumab (Stelara) and Golimumab (Simponi)—PA Criteria

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.

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.

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.

B. TIBs: Ustekinumab (Stelara)—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.

XI. UTILIZATION MANAGEMENT

BAP Comments

A. TIBs: Ustekinumab (Stelara)—PA Criteria

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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. TIBs: Ustekinumab (Stelara)—PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XII. FISCAL YEAR 2008 NATIONAL DEFENSE AUTHORIZATION ACT, SECTION 703

P&T Comments

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 pre-authorization criteria do not apply to any point of service other than retail network pharmacies.

A. Section 703—UF Recommendation

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) to designate the following products (listed by manufacturer) as nonformulary on the Uniform Formulary, due to noncompliance with Section 703.

BAUSCH & LOMB RX
Besivance ophth susp
FOUGERA
Methscopolamine tabs
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

B. Section 703PA—PA Criteria

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) the following Pre-Authorization Criteria for the nonformulary 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.

C. Section 703PA—Implementation Plan

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) 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.

XIII. UTILIZATION MANAGEMENT

BAP Comments

A. Section 703—UF Recommendation

The P&T Committee recommended to designate the following products (listed by manufacturer) as nonformulary 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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Section 703—PA Criteria

The P&T Committee recommended the following Pre-Authorization Criteria for the nonformulary 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention