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, 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—ANTI-GOUT DRUGS

P&T Comments

A. Anti-Gout Drugs—Relative Clinical Effectiveness and Conclusion

The P&T Committee evaluated the Anti-Gout Drug Class. This class has not been previously reviewed for UF placement. Drugs in the class include allopurinol (Zyloprim, generic), probenecid, colchicine (Colcrys), colchicine/probenecid, and febuxostat (Uloric). Allopurinol is currently designated as a Basic Core Formulary (BCF) product (pre-UF Rule decision).

The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following clinical effectiveness conclusions:

- Colchicine is a very old drug that is available in one branded formulation, (Colcrys), which has a patent extending to 2029.
- For an acute gout attack, clinical practice guidelines support colchicine as first line treatment, along with non-steroidal anti-inflammatory agents (NSAIDs) or prednisone. Treatment should be initiated within the first 24 hours of symptom onset.
- For chronic gout, urate-lowering therapy (ULT) with allopurinol or febuxostat is recommended as first line. Based on head-to-head trials, febuxostat (Uloric) 40 mg and allopurinol 300 mg were equally efficacious in lowering serum uric acid (sUA) to less than 6mg/dL in one study (CONFIRMS). Febuxostat 80 mg was superior to allopurinol 300 mg in lowering sUA to less than 6mg/dL in two studies (FACT and APEX).

- Higher doses of allopurinol (doses > 300mg), although not well studied, may be required in some patients to decrease sUA.
- Systematic reviews from the Cochrane group, and evidence-based organizations from Canada, the UK, and Europe recommend febuxostat as an alternative ULT in patients who cannot tolerate allopurinol.
- Use of colchicine for prophylaxis helps prevent gout flares during initiation of ULT. However, in published trials, gout flares increased when prophylaxis was discontinued. Guidelines recommend administering colchicine or NSAID prophylaxis for up to 6 months.
- Head-to-head studies show similar rates of adverse events with febuxostat and allopurinol.
- Febuxostat warnings from the U.S. Food and Drug Administration (FDA) include liver enzyme elevations. Liver function tests should be tested at initiation of therapy and monitored throughout treatment.
- Febuxostat warnings from the European Medicines Association (EMA) include the potential for increased cardiovascular (CV) events. According to the EMA, febuxostat should not be used in patients with ischemic heart disease or congestive heart failure, due to increased risk of CV events.
- In terms of clinical coverage, one anti-inflammatory agent (colchicine) and one xanthine oxidase inhibitor (allopurinol or febuxostat) is required on the UF to meet the needs of the majority of DoD beneficiaries.

B. Anti-Gout Drugs—Relative Cost-Effectiveness Analysis and Conclusion

Pharmacoeconomic analyses were performed for the Anti-Gout Drug Class, including cost-minimization analysis (CMA) and budget impact analyses (BIAs). The class was subdivided into chronic drugs (allopurinol and febuxostat) and acute drugs (colchicine). For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted.

The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) generic allopurinol (Zyloprim) was the most cost-effective of the chronic drugs, followed by branded febuxostat (Uloric), based on the weighted average cost per day of treatment across all three POS. Branded colchicine (Colcrys) was the only acute agent examined in the analysis; a cost analysis was conducted. CMA and BIA results showed that among available formulary options examined, scenarios where allopurinol (Zyloprim) is the BCF step-preferred agent, febuxostat (Uloric) is the NF non-preferred agent (with all current and new users required to try allopurinol first), and colchicine (Colcrys) is UF presented a maximum cost-avoidance projection.

C. Anti-Gout Drugs—UF Recommendation

The P&T Committee recommended (12 for, 4 opposed, 1 abstained, 0 absent) the following scenario for the UF, which is the most clinically and cost-effective option for the Military Health System (MHS):

- allopurinol be designated UF and step-preferred (e.g., "in front of the step");
- febuxostat (Uloric) be designated NF and non step-preferred (e.g., "behind the step"); and
- colchicine (Colcrys), probenecid, and the fixed dose combination of colchicine/probenecid be designated formulary on the UF and exempt from step therapy.
- This recommendation includes step therapy, which requires a trial of allopurinol prior to using febuxostat (Uloric) in all current and new users of febuxostat.

D. Anti-Gout Drugs—Prior Authorization (PA) Criteria

After extensive discussion, the P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) PA criteria for all current and new users of febuxostat (Uloric), requiring a trial of allopurinol prior to use of febuxostat. Coverage will be approved if the patient meets any of the following criteria:

1. Automated PA Criteria: The patient has received a prescription for allopurinol at any MHS pharmacy point service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order)] during the previous 180 days, AND

2. Manual PA Criteria: If automated criteria are not met, febuxostat (Uloric) is approved (e.g., a trial of allopurinol is not required) if:

    a) The patient has experienced any of the following issues with at least one of the following with allopurinol, which is not expected to occur with febuxostat (Uloric):

        (1) The patient has had an inadequate response to allopurinol (failure to achieve serum uric acid levels < 6 mg/day) after an adequate trial (at least 300 mg per day of allopurinol)

        (2) The patient has had intolerable adverse effects (e.g., hypersensitivity) to allopurinol

(3) The patient has a contraindication to allopurinol (e.g., renal impairment)

E. Anti-Gout Drugs—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service (POS); 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Additional recommendations made by the P&T Committee were to provide messaging to retail pharmacies to designate that PA and step therapy is required, with a trial of allopurinol prior to febuxostat (Uloric) and that the Anti-Gout Drug Class be added to the Rapid Response Program for the Retail Network and Mail Order Pharmacy.

III. UF CLASS REVIEWS—ANTI-GOUT DRUGS

BAP Comments

A. Anti-Gout Drugs—UF Recommendation

The P&T Committee recommended the following scenario for the UF, which is the most clinically and cost-effective option for the MHS:

- allopurinol be designated UF and step-preferred (e.g., "in front of the step");
- febuxostat (Uloric) be designated NF and non step-preferred (e.g., "behind the step"); and
- colchicine (Colcrys), probenecid, and the fixed dose combination of colchicine/probenecid be designated formulary on the UF and exempt from step therapy.
- This recommendation includes step therapy, which requires a trial of allopurinol prior to using febuxostat (Uloric) in all current and new users of febuxostat.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Anti-Gout Drugs—PA Criteria

After extensive discussion, the P&T Committee recommended PA criteria for all current and new users of febuxostat (Uloric), requiring a trial of allopurinol prior to use of febuxostat. Coverage will be approved if the patient meets any of the following criteria:

1. Automated PA Criteria: The patient has received a prescription for allopurinol at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days, AND

2. Manual PA Criteria: If automated criteria are not met, febuxostat (Uloric) is approved (e.g., a trial of allopurinol is not required) if:

    a) The patient has experienced any of the following issues with at least one of the following with allopurinol, which is not expected to occur with febuxostat (Uloric):

        (1) The patient has had an inadequate response to allopurinol (failure to achieve serum uric acid levels < 6 mg/day) after an adequate trial (at least 300 mg per day of allopurinol)

        (2) The patient has had intolerable adverse effects (e.g., hypersensitivity) to allopurinol

        (3) The patient has a contraindication to allopurinol (e.g., renal impairment)

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Anti-Gout Drugs—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Additional recommendations made by the P&T Committee were to provide messaging to retail pharmacies to designate that PA and step therapy is required, with a trial of allopurinol prior to febuxostat (Uloric) and that the Anti-Gout Drug Class be added to the Rapid Response Program for the Retail Network and Mail Order Pharmacy.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

IV. UF CLASS REVIEWS—PULMONARY II DRUGS

P&T Comments

A. Pulmonary II Drugs—Relative Clinical Effectiveness and Conclusion

The Pulmonary II Drug Class is comprised of two subclasses, the long-acting muscarinic agents (LAMAs), aclidinium inhaler (Tudorza) and tiotropium inhaler (Spiriva), and the chronic obstructive pulmonary disease (COPD) drugs [comprised of the short-acting muscarinic agents (SAMAs), short-acting beta agonist (SAMA/SABA) combinations and the phosphodiesterase type 4 (PDE-4) inhibitors].

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

The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following at the February 2013 meeting:

- Aclidinium inhaler (Tudorza) is the second LAMA on the market. The three clinical trials used to obtain FDA approval reported statistically significant improvement in spirometric endpoints, and two of the trials reported significantly fewer COPD exacerbations with aclidinium, compared to placebo.
- For aclidinium, the adverse event profile appears minimal, with primarily anticholinergic events reported. However, there is limited safety data with the 400 mcg approved dose. The FDA requires a prospective clinical trial to assess CV safety. Longer duration and larger comparative trials are needed to determine aclidinium's place in therapy.
- Several trials have shown the LAMA tiotropium (Spiriva) is associated with clinically significant improvements in spirometric endpoints and reductions in risk for COPD exacerbations. Tiotropium is also reported to reduce the proportion of patients hospitalized for COPD exacerbations.

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

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

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

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

B. Pulmonary II Drugs—Relative Cost-Effectiveness Analysis and Conclusion

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- CMA within the LAMA subclass showed that tiotropium (Spiriva) was more cost-effective than aclidinium (Tudorza). BIA results where Spiriva and Tudorza were designated UF resulted in the greatest cost-avoidance to the MHS.

- CMA was conducted within the COPD subclass, which includes the SAMAs, SABA/SAMA combination drugs, and PDE-4 inhibitors. The results showed ipratropium nebulized solution (Atrovent; generic) was the most cost-effective agent, followed by ipratropium/albuterol nebulized solution (DuoNeb; generic), ipratropium hydrofluoroalkane (HFA) MDI (Atrovent HFA), ipratropium/albuterol soft mist inhaler (Combivent Respimat), and roflumilast (Daliresp). Ipratropium/albuterol (Combivent) was not included in the cost-effectiveness analysis due to market discontinuation by December 2013. BIA projections for all scenarios were very similar.

C. Pulmonary II Drugs—UF Recommendation

The P&T Committee recommended (12 for, 1 opposed, 2 abstained, 2 absent) aclidinium inhaler (Tudorza), tiotropium inhaler (Spiriva), ipratropium nebulized solution (Atrovent; generic), ipratropium/albuterol nebulized solution (DuoNeb; generic), ipratropium HFA MDI (Atrovent HFA), ipratropium/albuterol soft mist inhaler (Combivent Respimat), and roflumilast (Daliresp) remain designated UF. Ipratropium/albuterol MDI (Combivent) will remain designated UF, pending discontinuation in December 2013.

V. UF CLASS REVIEWS—PULMONARY II DRUGS

BAP Comments

A. Pulmonary II Drugs—UF Recommendation

The P&T Committee recommended aclidinium inhaler (Tudorza), tiotropium inhaler (Spiriva), ipratropium nebulized solution (Atrovent; generic), ipratropium/albuterol nebulized solution (DuoNeb; generic), ipratropium HFA MDI (Atrovent HFA), ipratropium/albuterol soft mist inhaler (Combivent Respimat), and roflumilast (Daliresp) remain designated UF. Ipratropium/ albuterol MDI (Combivent) will remain designated UF, pending discontinuation in December 2013.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VI. RECENTLY APPROVED U.S. FDA AGENTS

P&T Comments

A. Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors—Canagliflozin (Invokana)

Relative Clinical Effectiveness Conclusion—Canagliflozin (Invokana) is a new diabetes drug with a novel mechanism of action and the first FDA-approved SGLT2 inhibitor. SGLT2 inhibitors are a new subclass of the Non-Insulin Diabetes Drug Class, which was originally reviewed in November 2010. The Non-Insulin Diabetes Drug Class also includes the following subclasses: biguanides (metformin), sulfonylureas, thiazolidinedione (TZD), dipeptidyl-

dipeptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 receptor agonists (GLP1RAs), pramlintide, dopamine agonists, meglitinides, and alpha glucosidase inhibitors.

The P&T Committee concluded (15 for, 1 opposed, 0 abstained, 1 absent):

- Efficacy of canagliflozin is limited to eight clinical trials, showing moderate decreases in hemoglobin A1c from baseline ranging from 0.63% (with insulin) to 1.11% (monotherapy in treatment-naïve patients).
- Canagliflozin has safety concerns of hypotension, impaired renal function, hyperkalemia, hypermagnesemia, hyperphosphatemia, increases in *l*ow-density lipoprotein (LDL) cholesterol and hemoglobin, hypoglycemia, urinary tract infections in both men and women, and genital mycotic infections.
- There is limited safety information available and no long-term outcomes trials have been completed to date with canagliflozin.
- Despite its unique mechanism of action to increase urinary glucose excretion, canagliflozin (Invokana) does not offer a clinically compelling advantage over the other non-insulin drugs included on the UF.

B. Non-Insulin Diabetes Drugs: SGLT2 Inhibitors—Canagliflozin (Invokana) Relative Cost-Effectiveness Analysis and Conclusion

The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that canagliflozin (Invokana) is not cost-effective compared to other non-insulin diabetes drugs currently available on the UF. CMA showed canagliflozin is more costly than metformin, glyburide, pioglitazone (Actos, generic), sitagliptin (Januvia), and exenatide (Byetta), in terms of cost per day of therapy.

C. Non-Insulin Diabetes Drugs: SGLT2 Inhibitors—Canagliflozin (Invokana) UF Recommendation

The P&T Committee recommended (13 for, 1 opposed, 1 abstained, 2 absent) canagliflozin (Invokana) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes and adverse event data, and cost disadvantage compared to UF products.

D. Non-Insulin Diabetes Drugs: SGLT2 Inhibitors—Canagliflozin (Invokana) PA Criteria

In the Non-Insulin Diabetes Drug Class, existing automated prior authorization (step therapy) requires a trial of metformin or a sulfonylurea**,** prior to the use of a DPP-4 inhibitor, a TZD, or a GLP1RA, based on positive efficacy and long-term outcomes data with metformin and the sulfonylureas.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) a trial of metformin, a sulfonylurea, or a DPP-4 inhibitor in all new and current users of SGLT2 inhibitors, canagliflozin (Invokana), due to the modest hemoglobin A1c lowering and safety concerns.

1. Automated PA criteria: The patient has filled a prescription for metformin, a sulfonylurea or a DPP4-inhibitor at any Military Health System (MHS) pharmacy point of service (POS) [military treatment facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.
2. Manual PA criteria, if automated criteria are not met: An SGLT2 inhibitor, canagliflozin (Invokana), is approved (e.g., trial of metformin or sulfonylurea or a DPP-4 inhibitor is NOT required) if:

    a) The patient has experienced any of the following adverse events on metformin: impaired renal function precluding treatment with metformin or history of lactic acidosis.

    b) The patient has experienced any of the following adverse events on sulfonylurea: hypoglycemia requiring medical treatment.

    c) The patient has had inadequate response to metformin or a sulfonylurea or a DPP-4 inhibitor.

    d) The patient has a contraindication to metformin or a sulfonylurea or a DPP-4 inhibitor.

E. Non-Insulin Diabetes Drugs: SGLT2 Inhibitors—Canagliflozin (Invokana) UF and PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) 1) 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 the UF and PA decisions.

VII. RECENTLY APPROVED U.S. FDA AGENTS

BAP Comments

A. Non-Insulin Diabetes Drugs: SGLT2 Inhibitors—Canagliflozin (Invokana) UF Recommendation

The P&T Committee recommended canagliflozin (Invokana) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes and adverse event data, and cost disadvantage compared to UF products.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Non-Insulin Diabetes Drugs: SGLT2 Inhibitors—Canagliflozin (Invokana) PA Criteria

In the Non-Insulin Diabetes Drug Class, existing automated prior authorization (step therapy) requires a trial of metformin or a sulfonylurea**,** prior to the use of a DPP-4 inhibitor, a TZD, or a GLP1RA, based on positive efficacy and long-term outcomes data with metformin and the sulfonylureas.

The P&T Committee recommended a trial of metformin, a sulfonylurea, or a DPP-4 inhibitor in all new and current users of SGLT2 inhibitors, canagliflozin (Invokana), due to the modest hemoglobin A1c lowering and safety concerns.

1. Automated PA criteria: The patient has filled a prescription for metformin, a sulfonylurea or a DPP4-inhibitor at any Military Health System (MHS) pharmacy point of service (POS) [military treatment facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.
2. Manual PA criteria, if automated criteria are not met: An SGLT2 inhibitor, canagliflozin (Invokana), is approved (e.g., trial of metformin or sulfonylurea or a DPP-4 inhibitor is NOT required) if:

    a) The patient has experienced any of the following adverse events on metformin: impaired renal function precluding treatment with metformin or history of lactic acidosis.

    b) The patient has experienced any of the following adverse events on sulfonylurea: hypoglycemia requiring medical treatment.

    c) The patient has had inadequate response to metformin or a sulfonylurea or a DPP-4 inhibitor.

    d) The patient has a contraindication to metformin or a sulfonylurea or a DPP-4 inhibitor.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Non-Insulin Diabetes Drugs: SGLT2 Inhibitors—Canagliflozin (Invokana) UF and PA Implementation Plan

The P&T Committee recommended 1) 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 the UF and PA decisions.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VIII. UTILIZATION MANAGEMENT

P&T Comments

A. Proton Pump Inhibitors (PPIs): Pantoprazole Change from Non-Preferred to Step-Preferred Status

The PPIs currently have PA criteria (step therapy) requiring a trial of omeprazole or esomeprazole (Nexium) prior to use of the other PPIs. Omeprazole and esomeprazole are BCF and step-preferred. In November 2012, the P&T Committee recommended reclassification of pantoprazole as formulary on the UF, due to availability of cost-effective generic formulations; pantoprazole remained non-preferred. The other PPIs, lansoprazole (Prevacid), rabeprazole (Aciphex), and omeprazole/sodium bicarbonate (Zegerid), are NF and non-preferred. The cost of generic pantoprazole tablets has continued to decline since November 2012. The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) revising the PA criteria to designate pantoprazole as step-preferred (i.e., in front of the step) on the UF.

IX. UTILIZATION MANAGEMENT

BAP Comments

A. PPIs: Pantoprazole Change from Non-Preferred to Step-Preferred Status

The P&T Committee recommended revising the PA criteria to designate pantoprazole as step-preferred (i.e., in front of the step) on the UF.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

X. UTILIZATION MANAGEMENT

P&T Comments

A. Antilipidemics-2: Icosapent ethyl (Vascepa)—PA Criteria

Icosapent ethyl (Vascepa) is the second prescription fish oil product marketed. Icosapent ethyl has the same FDA-approved labeling and dosing as omega-3-acid ethyl esters (Lovaza). Vascepa is not as effective as Lovaza at lowering triglycerides, but does not adversely affect LDL levels. PA criteria apply to Lovaza, limiting use to the FDA-approved indications, due to the large number of off-label, non-supportable uses. The P&T Committee recommended manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication; the manual PA criteria for Vascepa will be the same as criteria for Lovaza.

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication.

New and current users of Vascepa are required to undergo the PA process.

1. Manual PA Criteria—Vascepa is approved if:

    a) Patients Receiving Statins:

        (1) Patients with triglyceride (TG) Levels > 500 mg/dL AND

        (2) Inadequate TG-lowering response to a therapeutic trial of niacin (1-g/day), unable to tolerate niacin/fibrate or who are not a candidate for niacin/fibrate therapy * †

    b) Patients NOT Receiving Statins:

(1) Patients with TG Levels > 500 mg/dL AND

(2) Inadequate response to a therapeutic trial of monotherapy with both a fibrate and niacin (1-2 g/day), unable to tolerate a fibrate and niacin or who are not candidates for fibrates † and niacin therapy

c) Patients with TG <500 mg/dL or <500 mg/dL with an inadequate TG-lowering response to niacin or fibrates or who are unable to tolerate/are not candidates for niacin or fibrates

d) Coverage is not approved for the use of Vascepa for the treatment of other conditions, including: attention deficit hyperactivity disorder, Alzheimer's disease, bipolar disorder, Crohn's disease, cystic fibrosis, dementia, depression, inflammatory bowel disease, intermittent claudication, metabolic syndrome, osteoporosis, post-traumatic stress disorder, renal disease (IgA nephropathy), rheumatoid arthritis, schizophrenia, Type 2 diabetes mellitus, and ulcerative colitis.

* Not candidates for niacin: patients with a history of confirmed PUD (perforation, ulceration, or upper GIB), gouty attacks (presence of intra-articular uric acid crystals in the affected joint), and/or poorly controlled diabetes.

† Not candidates for fibrates: patients with hepatic or severe renal dysfunction, including primary biliary cirrhosis and preexisting gallbladder disease.

B. Antilipidemics-2: Icosapent ethyl (Vascepa)—PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS.

XI. UTILIZATION MANAGEMENT

BAP Comments

A. Antilipidemics-2: Icosapent ethyl (Vascepa)—PA Criteria

The P&T Committee recommended manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication; the manual PA criteria for Vascepa will be the same as criteria for Lovaza.

The P&T Committee recommended manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication.

New and current users of Vascepa are required to undergo the PA process.

1. Manual PA Criteria—Vascepa is approved if:

    a) Patients Receiving Statins:

        (1) Patients with triglyceride (TG) Levels > 500 mg/dL AND

        (2) Inadequate TG-lowering response to a therapeutic trial of niacin (1-g/day), unable to tolerate niacin/fibrate or who are not a candidate for niacin/fibrate therapy [*] [†]

    b) Patients NOT Receiving Statins:

        (1) Patients with TG Levels > 500 mg/dL AND

        (2) Inadequate response to a therapeutic trial of monotherapy with both a fibrate and niacin (1-2 g/day), unable to tolerate a fibrate and niacin or who are not candidates for fibrates [†] and niacin therapy

    c) Patients with TG <500 mg/dL or <500 mg/dL with an inadequate TG-lowering response to niacin or fibrates or who are unable to tolerate/are not candidates for niacin or fibrates

    d) Coverage is not approved for the use of Vascepa for the treatment of other conditions, including: attention deficit hyperactivity disorder, Alzheimer's disease, bipolar disorder, Crohn's disease, cystic fibrosis, dementia, depression, inflammatory bowel disease, intermittent claudication, metabolic syndrome, osteoporosis, post-traumatic stress disorder, renal disease (IgA nephropathy), rheumatoid arthritis, schizophrenia, Type 2 diabetes mellitus, and ulcerative colitis.

[*] Not candidates for niacin: patients with a history of confirmed PUD (perforation, ulceration, or upper GIB), gouty attacks (presence of intra-articular uric acid crystals in the affected joint), and/or poorly controlled diabetes.

[†] Not candidates for fibrates: patients with hepatic or severe renal dysfunction, including primary biliary cirrhosis and preexisting gallbladder disease.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Antilipidemics-2: Icosapent ethyl (Vascepa)—PA Implementation Plan

The P&T Committee recommended 1) 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