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, Defense Health Agency (DHA), on formulary status, prior authorization (PA), pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) status are received from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. UF CLASS REVIEWS—PULMONARY-1 DRUG CLASS: PULMONARY MISCELLANEOUS SUBCLASS

P&T Comments

A. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—Relative Clinical Effectiveness and Conclusion

Background—The IPF drugs have not been previously reviewed for UF status. Currently, there are manual prior authorization (PA) requirements in place since February 2016 for both nintedanib (Ofev) and pirfenidone (Esbriet).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- IPF is difficult to diagnose and has limited therapeutic options. Nintedanib (Ofev) and pirfenidone (Esbriet) are the first therapeutic advances for the disease, and provide different mechanisms of action. How Ofev and Esbriet slow the decline of lung function in IPF is not fully understood.
- There are no studies directly comparing nintedanib and pirfenidone. These two drugs may delay disease progression; however, the most appropriate subset of IPF patients who will respond to therapy and who will tolerate the adverse effects is difficult to predict.
- While neither agent is curative, FDA approval was based on studies showing Ofev and Esbriet may reduce the rate of inexorable decline in lung function that is the hallmark of IPF.
- Available meta-analyses suggest that Ofev and Esbriet favorably affect endpoints of lung function including forced vital capacity over 52 weeks. Overall, the available evidence suggests these two drugs have similar efficacy when compared to placebo.

- The most commonly reported adverse events for Ofev and Esbriet include gastrointestinal (GI) effects. Esbriet uniquely can cause rash/photosensitivity, while Ofev is rated as pregnancy Category D. Esbriet should not be used in patients with renal dysfunction, and is associated with more drug interactions.
- Both products are associated with significant discontinuation rates, and may require dosage reductions or temporary stoppage due to adverse effects.

B. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—Relative Cost-Effectiveness Analysis and Conclusion

Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that pirfenidone (Esbriet) was the most cost-effective IPF agent, followed by nintedanib (Ofev).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating pirfenidone (Esbriet) as formulary and step-preferred, with nintedanib (Ofev) as formulary and non step-preferred, demonstrated the largest estimated cost avoidance for the Military Health System (MHS).

C. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—UF Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- **UF and Step-Preferred:** pirfenidone (Esbriet)
- **UF and Non Step-Preferred:** nintedanib (Ofev)
- **NF:** no products

Note that as part of this recommendation, all new users of an IPF agent are required to try Esbriet first.

D. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—Manual Prior Authorization (PA) Criteria

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updating the current manual PA criteria to require a trial of pirfenidone (Esbriet) in new users, prior to use of nintedanib (Ofev). The step therapy requirement for a trial of Esbriet in new users is included in the manual PA criteria.

Updated PA Criteria

1. nintedanib (Ofev)

Changes from the May 2017 meeting are in BOLD

All new users of nintedanib (Ofev) are required to try pirfenidone (Esbriet) first.

Pirfenidone (Esbriet) is the preferred IPF agent; coverage is approved for nintedanib (Ofev) if:

- **The patient has had a trial of pirfenidone (Esbriet) and either:**
  - **Failed therapy with Esbriet due to progression of IPF, e.g. improvement or effectiveness of therapy is defined by a less than 10% decline in percent predicted forced vital capacity (FVC) OR**
  - **Experienced intolerable adverse effects (e.g., rash, photosensitivity; GI AEs) OR**
- **The patient has clinical factors where Esbriet is not appropriate**
  - **The patient is taking a drug which will interact with Esbriet that does not interact with Ofev [moderate to strong CYP inhibitors – CYP 450-1A2 (e.g., fluvoxamine)] OR**
  - **The patient has end stage renal disease (ESRD) on dialysis**

E. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation.

III. UF CLASS REVIEWS—PULMONARY-1 DRUG CLASS: PULMONARY MISCELLANEOUS SUBCLASS

BAP Comments

A. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—UF Recommendation

The P&T Committee recommended the following:

- **UF and Step-Preferred:** Esbriet
- **UF and Non Step-Preferred:** Ofev
- **NF:** no products

Note that as part of this recommendation, all new users of an IPF agent are required to try Esbriet first.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—Manual PA Criteria

The P&T Committee recommended updating the current manual PA criteria to require a trial of Esbriet in new users, prior to use of Ofev. The step therapy requirement for a trial of Esbriet in all new users is included in the manual PA criteria.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass: Idiopathic Pulmonary Fibrosis (IFP) Drugs—UF and PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 30-day implementation.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

IV. UF CLASS REVIEWS—OPHTHALMIC-1s

P&T Comments

A. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—Relative Clinical Effectiveness and Conclusion

Background—The Ophthalmic-1 Dual Acting Antihistamine and Mast Cell Stabilizer (AH/MCS) Drug Class was previously reviewed for UF status in August 2010. Ketotifen (Zaditor, generic) is available over-the-counter (OTC) and was not included in the review.

Three products containing the active ingredient olopatadine are available. Olopatadine 0.1% (Patanol) is administered twice daily, is available as a generic formulation, and is the current BCF selection for the class. Olopatadine 0.2% (Pataday) has been marketed since 2004 and is administered once daily; generic formulations are expected later this year. Olopatadine 0.7% (Pazeo) entered the market in 2015 and is administered once daily; it was designated NF at the February 2016 meeting.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 1 opposed, 0 abstained, 0 absent) the following for the ophthalmic AH/MCS:

- The ophthalmic AH/MCS are the standard of care for treating the signs and symptoms of allergic conjunctivitis. Allergic conjunctivitis is a highly seasonal condition, and MHS utilization for the class reflects this variability.
- Clinical practice guidelines from the American Academy of Ophthalmology and the American Optometric Association recommend the AH/MCS as first-line therapy for acute and chronic allergic conjunctivitis. The guidelines do not prefer one product over another.
- A 2015 Cochrane review and 2016 meta-analysis concluded there is insufficient evidence to discern whether one AH/MCS is the more effective than another. Olopatadine may be more effective than OTC ketotifen, but less effective than alcaftadine; however, these differences among products may not be clinically relevant.
- In terms of efficacy and safety, head-to-head studies show olopatadine 0.1% (Patanol) is comparable to olopatadine 0.2% (Pataday). Olopatadine 0.7% (Pazeo) reduced ocular itching to a greater extent than olopatadine 0.2%; however, although these results were statistically significant 24 hours following administration (when the next daily dose is due), the result did not meet the threshold for clinical significance.
- With regard to safety and tolerability, the overall adverse event rate is low. All the products can cause burning, stinging, headaches, dry eye, blurred vision, and hyperemia. Bepotastine (Bepreve) may cause taste perversion in up to 25% of patients.
- There is no new data to change the conclusion from the previous review that the AH/MCS are highly therapeutically interchangeable.

B. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic azelastine (Optivar) was the most cost-effective AH/MCS, followed by generic epinastine (Elestat), brand olopatadine 0.7% (Pazeo), generic olopatadine 0.1% (Patanol), brand olopatadine 0.1% (Patanol), brand emedastine (Emadine), brand bepotastine (Bepreve), brand alcaftadine (Lastacaft), and brand olopatadine 0.2% (Pataday).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating generic

olopatadine 0.1% (Patanol), generic azelastine (Optivar), generic epinastine (Elestat), and brand olopatadine 0.7% (Pazeo) as UF, and brand emedastine (Emadine), brand bepotastine (Bepreve), brand alcaftadine (Lastacaft), and brand olopatadine 0.2% (Pataday) as NF, demonstrated the largest estimated cost avoidance for the MHS.

C. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—UF Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

- **UF:**
    - olopatadine 0.1% (generic Patanol)
    - olopatadine 0.7% (Pazeo)
    - azelastine 0.05% (generic Optivar)
    - epinastine 0.05% (generic Elestat)

- **NF:**
    - olopatadine 0.2% (Pataday)
    - alcaftadine 0.25% (Lastacaft)
    - bepotastine 1.5% (Bepreve)
    - emedastine 0.05% (Emadine)

D. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—Manual PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the dual acting AH/MCS. All new and current users of a NF product, olopatadine 0.2% (Pataday), Lastacaft, Bepreve, and Emadine, require a trial of two formulary products within the past 90 days, unless the patient has experienced intolerable adverse events from the formulary products, or is pregnant.

Full PA Criteria

Manual PA criteria apply to all new and current users of Lastacaft, Bepreve, Emadine, and olopatadine 0.2% (Pataday).

- The patient has ocular symptoms of allergic conjunctivitis AND
    - The patient has tried and failed two formulary alternatives (olopatadine 0.1%, olopatadine 0.7% (Pazeo), azelastine, or epinastine) in the last 90 days, OR
    - Use of two formulary alternatives (olopatadine, azelastine, or epinastine) has resulted in intolerable adverse effects, OR
    - The patient is pregnant (for Lastacaft and Emadine only)

PA does not expire.

E. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period and, 2) DHA send letters to beneficiaries who are affected by the UF decision.

V. UF CLASS REVIEWS—OPHTHALMIC-1s

BAP Comments

A. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—UF Recommendation

The P&T Committee recommended the following, based on clinical and cost effectiveness:

- **UF:**
  - generic Patanol
  - Pazeo
  - generic Optivar
  - generic Elestat

- **NF:**
  - Pataday
  - Lastacaft
  - Bepreve
  - Emadine

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—Manual PA Criteria

The P&T Committee recommended manual PA criteria for the dual acting AH/MCS. All new and current users of a NF product, Pataday, Lastacaft, Bepreve, and Emadine require a trial of two formulary products within the past 90 days, unless the patient has experienced intolerable adverse events from the formulary products, or is pregnant.

The full manual PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers—UF and PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period and DHA send letters to beneficiaries who are affected by the UF decision.

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

VI. NEWLY-APPROVED DRUGS PER CFR 199.21 (g)(5) (INNOVATOR DRUGS)

P&T Comments

A. Newly-Approved Drugs—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5).

B. Newly-Approved Drugs—UF Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- **UF:**
  - deflazacort (Emflaza) – Corticosteroids – Immune Modulators – for Duchenne Muscular Dystrophy (DMD)
  - deutetrabenazine (Austedo) – Neurological Agents Miscellaneous for Huntington's Disease
  - dupilumab (Dupixent) – Corticosteroids – Immune Modulators – Immune Modulators Subclass for Atopic Dermatitis
  - ribociclib (Kisqali) – Oral Oncologic Agents for Breast Cancer
  - telotristat (Xermelo) – GI-2 Miscellaneous Agents

- **NF:**
  - crisaborole (Eucrisa) – Corticosteroids – Immune Modulators – Immune Modulators Subclass for Atopic Dermatitis
  - insulin degludec/liraglutide (Xultophy) – Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA)

- morphine sulfate extended release (Arymo ER) – Narcotic Analgesics and Combinations
- oxymetazoline (Rhofade) – Acne Agents – Topical Acne and Rosacea Agents Subclass
- plecanatide (Trulance) – GI-2 Miscellaneous Agents

C. Newly-Approved Drugs—PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- Applying the same manual PA criteria for insulin degludec/liraglutide (Xultophy) in new and current users, as is currently in place for insulin glargine/lixisenatide (Soliqua) and the other non step-preferred GLP1RAs. Patients must first try metformin or a sulfonylurea, and exenatide weekly injection (Bydureon) and albiglutide weekly injection (Tanzeum) prior to Xultophy. Additionally, for Xultophy, patients are required to be on basal insulin at a dosage of less than 50 units daily.

- Applying the same step therapy and manual PA criteria for topical oxymetazoline (Rhofade) in new and current users as is currently in place for the non step-preferred topical rosacea products. Patients must first try one generic metronidazole step-preferred formulation and topical azelaic acid prior to Rhofade.

- Applying PA criteria to the following: new and current users of crisaborole (Eucrisa), dupilumab (Dupixent), deflazacort (Emflaza), plecanatide (Trulance), and telotristat (Xermelo);and in new users of deutetrabenazine (Austedo) and ribociclib (Kisqali).

Full PA Criteria for the Newly-Approved Drugs

1. Crisaborole (Eucrisa) – Corticosteroids – Immune Modulators – Immune Modulators Subclass

Manual PA criteria apply to all new and current users of Eucrisa.

Manual PA Criteria: coverage will be approved if:

- Patient has mild to moderate atopic dermatitis AND
- Prescribed by a dermatologist AND
- Patient has a contraindication to, intolerability to, or failed treatment with at least one high potency / class 1 topical corticosteroid.

Off-label uses are NOT approved.

PA does not expire.

2. Dupilumab (Dupixent) – Corticosteroids – Immune Modulators – Immune Modulators Subclass

Manual PA criteria apply to all new and current users of Dupixent.

Manual PA Criteria: Coverage will be approved for initial therapy for 6 months if:

- Patient has moderate to severe or uncontrolled atopic dermatitis AND
- Patient must be 18 years of age or older AND
- Prescribed by a dermatologist AND
- Patient has a contraindication to, intolerability to, or failed treatment with at least **ONE** high potency / class 1 topical corticosteroid AND
- Patient has a contraindication, intolerability to, or failed treatment with at least **ONE** systemic immunosuppressant.

PA expires after 6 months.

Renewal PA Criteria: Coverage will be approved indefinitely for continuation of therapy if:

1. The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear (1)

Off-label uses are NOT approved.

3. Deflazacort (Emflaza) – Corticosteroids – Immune Modulators

Manual PA criteria apply to all new and current users of Emflaza.

Manual PA Criteria: Coverage will be approved for one year if all criteria are met:

1. Patient has a diagnosis of Duchenne Muscular Dystrophy AND
2. Prescribed by a neurologist AND
3. Patient is age 5 or greater AND
4. Patient has tried prednisone for at least 6 months and has experienced at least one of the following adverse events:
    - Unmanageable weight gain OR
    - Patient has experienced severe behavioral adverse events that requires a reduction in prednisone dose

Off-label uses are NOT approved.

PA does not expire.

4. Plecanatide (Trulance) – GI-2 Miscellaneous Drugs

Manual PA criteria apply to all new and current users of Trulance.

Manual PA Criteria: Coverage approved if:

1. Patient is ≥ 18 years of age AND

2. Patient has clinically diagnosed chronic idiopathic constipation AND
3. Patient does not have gastrointestinal obstruction AND
4. Patient has failed or is intolerant to linaclotide (Linzess) AND
5. Dual therapy with another guanylate cyclase-C agonist is not allowed.

Off-label uses are not approved.
PA expires in one year.

- PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Trulance will be approved if there has been improvement in constipation symptoms and NO dual therapy with another guanylate cyclase-C agonist.

Renewal PA criteria is limited to one year.

5. Telotristat (Xermelo) – GI-2 Miscellaneous Drugs

Manual PA criteria apply to all new and current users of Xermelo.
Manual PA Criteria: Coverage approved for one year if all criteria are met:

1. Patient has diagnosis of carcinoid syndrome diarrhea.
2. Patient has had an inadequate treatment response to at least a 3-month trial of somatostatin analog therapy.
3. Telotristat must be used in combination with a somatostatin analog (i.e., octreotide or lanreotide).
4. Patient has ≥ 4 bowel movements daily.

Off-label uses are NOT approved.
PA expires in one year.

- PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Xermelo will be approved when
  a) used in combination with a somatostatin analog,
  b) decrease from baseline in amount of average daily bowel movements,
  c) prescriber agrees to continue to assess the patient for severe constipation and abdominal pain and discontinue the medication if either develops,
  d) no severe constipation or abdominal pain develops.

- Renewal PA criteria is limited to one year.

6. Liraglutide/Insulin Degludec (Xultophy) – Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)

All new and current users of Xultophy are required to try metformin or a sulfonylurea

(SU) before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin or a sulfonylurea first.

Additionally, Bydureon and Tanzeum are the preferred agents in the GLP1RA Subclass. New and current users of Xultophy must try Bydureon and Tanzeum first.

Manual PA Criteria: Coverage will be approved if the following criteria are met:

- Xultophy is used as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus inadequately controlled on a basal insulin (< 50 units daily)
- Patient has tried and failed therapy with metformin or sulfonylurea AND
- The patient has had an inadequate response to Bydureon AND
- The patient has had an inadequate response to Tanzeum.

Prior Authorization does not expire.

Off-label uses are not approved.

7. Deutetrabenazine (Austedo) – Neurological Agents Miscellaneous

Manual PA criteria apply to all new users of Austedo.

Manual PA Criteria: Coverage approved for initial therapy for one year if all criteria are met:

1. Prescribed by or in consultation with a neurologist
2. Patient has a diagnosis of chorea associated with Huntington's Disease
3. Patient is not actively suicidal
4. Patient does not have depression, or is being adequately treated for depression
5. Patient does not have severe hepatic impairment
6. Patient is not taking any of the following:
    - MAOI inhibitor within the past 14 days
    - reserpine
    - tetrabenazine (Xenazine) or another VMAT-2 inhibitor
7. Patient has had an adequate trial of tetrabenazine for 12 weeks and had one of the following:
    - Experienced treatment failure
    - Experienced an adverse event that is not expected to occur with Austedo

PA expires in one year.

Manual PA Criteria (Renewal Criteria): Coverage approved indefinitely for continuation of therapy if all criteria are met:

1. Patient has demonstrated improvement in chorea based on clinician assessment and is being monitored for depression and suicidal ideation

Off-label uses are NOT approved (Tourette's, tardive dyskinesia, dystonia).

8. Oxymetazoline (Rhofade) – Topical Acne and Rosacea Agents: Miscellaneous Topical Agents

Manual PA Criteria apply to all new and current users of Rhofade.

Automated PA Criteria:

The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion, or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days

Manual PA Criteria: If automated PA criteria are not met, Rhofade will be approved if:

The patient is at least 18 years of age and has the following diagnosis:

- For Rhofade, the patient has persistent facial erythema of rosacea AND
- The patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, 0.75% lotion or 0.75% cream) AND
- The patient has tried and failed topical azelaic acid 15%

PA expires in one year

Off-label uses are not approved

9. Ribociclib (Kisqali) – Oral Oncologic Agents

Manual PA criteria apply to all new users of Kisqali.
Manual PA Criteria: Kisqali is approved if:

1. Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND
2. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
3. The patient is postmenopausal woman and will be used as first-line endocrine therapy in combination with an aromatase inhibitor.

Off-label uses are not approved.

PA does not expire.

D. Newly-Approved Drugs—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date upon signing of the minutes in all points of service, including the new PAs for dupilumab (Dupixent), crisaborole (Eucrisa), deflazacort (Emflaza), plecanatide

(Trulance), telotristat (Xermelo), liraglutide/insulin degludec (Xultophy), deutetrabenazine (Austedo), oxymetazoline (Rhofade), and ribociclib (Kisqali).

VII. NEWLY-APPROVED DRUGS PER CFG 199.21 (g)(5)

BAP Comments

A. Newly-Approved Drugs—UF Recommendation

The P&T Committee recommended the following:

- **UF:**
  - Emflaza
  - Austedo
  - Dupixent
  - Kisqali
  - Xermelo

- **NF:**
  - Eucrisa
  - Xultophy
  - Arymo ER
  - Rhofade
  - Trulance

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Newly-Approved Drugs—PA Criteria

The P&T Committee recommended the following:

Applying the same manual PA criteria for Xultophy in new and current users, as is currently in place for Soliqua and the other non step-preferred GLP1RAs. Patients must first try metformin or a sulfonylurea, and Bydureon and Tanzeum prior to Xultophy. Additionally, for Xultophy, patients are required to be on basal insulin at a dosage of less than 50 units daily.

- Applying the same step therapy and manual PA criteria for Rhofade in new and current users as is currently in place for the non step-preferred topical rosacea products. Patients must first try one generic metronidazole step-preferred formulation and topical azelaic acid prior to Rhofade.

- Applying PA criteria to the following: new and current users of Eucrisa, Dupixent, Emflaza, Trulance, and Xermelo; and in new users of Austedo and Kisqali.

- The full PA criteria for these newly-approved agents were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Newly-Approved Drugs—UF and PA Implementation Plan

The P&T Committee recommended an effective date upon signing of the minutes in all points of service, including the new PAs for Dupixent, Eucrisa, Emflaza, Trulance, Xermelo, Xultophy, Austedo, Rhofade, and Kisqali.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

VIII. UTILIZATION MANAGEMENT—NON-INSULIN DIABETES DRUG: BIGUANIDES

P&T Comments

A. Non-Insulin Diabetes Drug: Biguanides—Metformin Extended Release (ER), Fortamet, and Glumetza—New Manual PA Criteria

Fortamet and Glumetza are branded formulations of metformin ER (Glucophage XR), which were designated as NF at the November 2010 meeting, and maintained as NF in August 2016. Glumetza and Fortamet are available in 500 mg and 1000 mg tablets while generic metformin ER products are available in 500 mg and 750 mg tablets.

Due to the significant cost differences between Fortamet and Glumetza and generic metformin ER, and the lack of clinically compelling benefits over generic metformin ER, the Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA in all new and current users of Glumetza and Fortamet. The patient will be required to try generic metformin ER first. Prior authorization will not expire.

Full PA Criteria:

Manual PA criteria apply to all new and current users of Fortamet and Glumetza.

The provider must explain why the patient cannot take two generic 500mg ER tablets separately (for patients taking requiring 1000 mg metformin ER).

PA will be approved if patient is on a dose-alternating schedule (e.g., 500 mg alternating with 1000 mg every other day).

PA does not expire.
Off-label uses are not approved.

B. Non-Insulin Diabetes Drug: Biguanides—Metformin Extended Release (ER), Fortamet, and Glumetza—Manual PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the new manual PA for extended-release metformin (Fortamet, Glumetza, generics) become effective on the first Wednesday after a 90-day implementation period in all points of service.

IX. UTILIZATION MANAGEMENT—NON-INSULIN DIABETES DRUG: BIGUANIDES

BAP Comments

A. Non-Insulin Diabetes Drug: Biguanides—Metformin Extended Release (ER), Fortamet, and Glumetza—New Manual PA Criteria

Due to the significant cost differences between Fortamet and Glumetza and generic metformin ER, and the lack of clinically compelling benefits over generic metformin ER, the Committee recommended new manual PA in all new and current users of Glumetza and Fortamet. The patient will be required to try generic metformin ER first. Prior authorization will not expire.

The full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Non-Insulin Diabetes Drug: Biguanides—Metformin Extended Release (ER), Fortamet, and Glumetza—Manual PA Implementation Plan

The P&T Committee recommended the new manual PA for Fortamet, Glumetza, and generics become effective on the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

X. UTILIZATION MANAGEMENT—DIURETICS CARBONIC ANHYDRASE INHIBITOR

P&T Comments

A. Diuretics Carbonic Anhydrase Inhibitor: Dichlorphenamide (Keveyis)—New Manual PA Criteria

Keveyis is an orphan drug approved for treating primary hyperkalemic or hypokalemic periodic paralysis, or related variants. The active ingredient dichlorphenamide was first marketed in 1958 under the brand name Daranide, but discontinued from the market. Keveyis was FDA-approved in August 2015, but just recently launched.

Acetazolamide is commonly used off-label for this condition, but only one published retrospective trial is available. FDA approval for Keveyis was based on two clinical trials enrolling a total of 65 patients. The mechanism of action of Keveyis for treating periodic paralysis is unknown.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) new manual PA criteria for Keveyis, requiring a diagnosis of hypo- or hyperkalemic periodic paralysis as outlined in the product labeling, and a trial of acetazolamide. Prior authorization will expire after two months. If the patient has responded to therapy, then Keveyis will be approved indefinitely.

Full PA Criteria:

Manual PA criteria apply to all new and current users of Keveyis for treatment of Hypo/Hyperkalemic Periodic Paralysis (HypoPP/HyperPP) and Related Variants.

Manual PA Criteria: Initial Therapy. Keveyis is approved for 2 months if the patient meets the following criteria (i, ii, iii, iv, and v):

i. Patient has a confirmed diagnosis of primary hypokalemic or hyperkalemic periodic paralysis by meeting at least ONE of the following (a, b, or c):

   a) Patient with HypoPP has had a serum potassium concentration of less than 3.5 mEq/L during a paralytic attack; OR for patient with HyperPP, patient has had an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack; OR for patient with HyperPP, patient has had a serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L;

   OR

b) Patient has a family history of the condition; OR

c) Patient has a genetically confirmed skeletal muscle calcium or sodium channel mutation; AND

ii. Patient has had improvements in paralysis attack symptoms with potassium intake; AND

iii. Patient has tried and failed oral acetazolamide therapy (e.g., Diamox tablets, Diamox Sequels extended-release capsules, generics); AND

iv. According to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient; AND

v. Keveyis is prescribed by or in consultation with a neurologist or a physician who specializes in the care of patients with primary periodic paralysis (e.g., muscle disease specialist, or Physical Medicine and Rehabilitation [PMNR]).

PA expires after two months.

Renewal Manual PA Criteria:

- Patients Continuing Therapy. Keveyis is approved indefinitely if the patient has responded to Keveyis (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.

Off-label uses are not approved.

B. Diuretics Carbonic Anhydrase Inhibitor: Dichlorphenamide (Keveyis)—PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the new manual PA for dichlorphenamide (Keveyis) become effective on the first Wednesday after a 90-day implementation period in all points of service.

XI. UTILIZATION MANAGEMENT—DIURETICS CARBONIC ANHYDRASE INHIBITOR

BAP Comments

A. Diuretics Carbonic Anhydrase Inhibitor: Dichlorphenamide (Keveyis)—New Manual PA Criteria

The P&T Committee recommended new manual PA criteria for Keveyis, requiring a diagnosis of hypo- or hyperkalemic periodic paralysis as outlined in the product labeling, and a trial of acetazolamide. Prior authorization will expire after two months. If the patient has responded to therapy, then Keveyis will be approved indefinitely.

The full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Diuretics Carbonic Anhydrase Inhibitor: Dichlorphenamide (Keveyis)—PA Implementation Plan

The P&T Committee recommended the new manual PA for dichlorphenamide (Keveyis) become effective on the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XII. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

P&T Comments

The P&T Committee recommended updated manual PA criteria for nine drugs from seven classes. Updates to the manual PA criteria were recommended for a variety of reasons, including expanded FDA-approved indications, FDA safety alerts, or availability of low cost generics for NF drugs in classes where there is existing step therapy.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updates to the current PAs for eluxadoline (Viberzi), topiramate ER (Qudexy XR), pregabalin (Lyrica), ledipasvir/sofosbuvir (Harvoni), sofosbuvir (Sovaldi), fluticasone/azelastine (Dymista), eszopiclone (Lunesta), and zolpidem ER (Ambien CR); and the P&T Committee recommended (12 for, 0 opposed, 0 abstained, and 4 absent) the updated manual PA criteria for mirabegron (Myrbetriq). The updated manual PA for all the drugs discussed will apply to new users.

A. Updated Manual PA Criteria

1. Gastrointestinal-2 Miscellaneous Agents: Eluxadoline (Viberzi)

Viberzi was reviewed in February 2016 with manual PA criteria recommended. An update to the manual PA criteria was recommended, based on a recent FDA safety alert. Patients who have had a cholecystectomy will be excluded from using Viberzi.

<u>Updated PA Criteria</u>

- **Patient does not have a history of cholecystectomy.**

2. **Anticonvulsants and Anti-Mania Drugs: Topiramate ER (Qudexy XR)**
   Qudexy XR was reviewed in May 2016 with manual PA criteria recommended. Criteria were updated to add the additional indication for migraine prophylaxis.

   Updated PA Criteria

   Changes from the May 2017 meeting are in BOLD and strikethrough

   - Coverage approved for **Migraine prophylaxis in adults (**Trokendi XR and **Qudexy XR)**

   - Coverage not approved for non-FDA approved indications, including ~~migraine headache and~~ weight loss

3. **Non-Opioid Pain Syndromes: Pregabalin (Lyrica)**
   Lyrica was reviewed in November 2011 with step therapy and manual PA criteria recommended. A trial of gabapentin is required prior to use of Lyrica, except in patients with seizure disorders. The manual PA criteria were updated to require a trial of duloxetine in addition to gabapentin for disorders not related to seizures or post-herpetic neuralgia.

   Updated PA Criteria

   Changes from the May 2017 meeting are in BOLD and will apply to new users of Lyrica.

   - Indication: Seizure disorder **and post-herpetic neuralgia** – (no changes to the criteria for these indications)

   OR

   - **Indication: Non-seizure related disorder (diabetic peripheral neuropathy and fibromyalgia)**
     - The patient has tried and failed gabapentin therapy (trial of Gralise or Horizant does not qualify) **AND**
     - **Patient has tried and failed duloxetine**
     - The patient has a contraindication to gabapentin or **duloxetine** that is not expected to occur with pregabalin
     - The patient experienced adverse events with gabapentin or **duloxetin**e that are not expected to occur with pregabalin
     - The patient previously responded to pregabalin and changing to gabapentin or **duloxetine** would incur unacceptable risk

4. **Hepatitis C Virus Direct-Acting Antivirals: Ledipasvir/Sofosbuvir (Harvoni) and Sofosbuvir (Sovaldi)**
   The direct-acting antivirals were most recently reviewed for formulary status in February 2017. The manual PA criteria were updated to reflect FDA approval in children 12 years of age and older.

   Updated PA Criteria for both ledipasvir/sofosbuvir (Harvoni) and sofosbuvir (Sovaldi)

   Coverage approved for patients **≥ 12 years**

5. **Nasal Allergy Drugs: Fluticasone/Azelastine (Dymista)**
   Dymista was reviewed in May 2014, with step therapy and manual PA criteria recommended. Currently, a trial of one step-preferred formulary nasal allergy drug (nasal formulations of generic fluticasone, flunisolide, azelastine, or ipratropium) is required prior to use of Dymista. Since the May 2014 class review, several nasal allergy drugs are now available in generic formulations, or OTC. Criteria were updated to include a trial of at least two formulary step-preferred drugs prior to use of Dymista.

   Updated PA Criteria
   Changes from May 2017 meeting are in BOLD

   Manual PA Criteria: Dymista is approved (e.g., trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is NOT required) if:

   - Patient has experienced any of the following issues with **at least two** of the following step-preferred nasal allergy drugs (fluticasone propionate, flunisolide, azelastine, or ipratropium), which is not expected to occur with the non-preferred nasal allergy drugs

     - inadequate response to the step-preferred drugs
     - intolerable adverse effects (persistent epistaxis, significant nasal irritation, pharyngitis)
     - contraindication

6. **Sedative Hypnotic-1s: Newer Sedative Hypnotics—Eszopiclone (Lunesta) and Zolpidem ER (Ambien CR)**
   Lunesta and Ambien CR were reviewed in May 2012 with the newer sedative hypnotics drug class, and both drugs are designated as UF and non step-preferred. Step therapy for the class requires a trial of a step-preferred drug (zolpidem IR or zaleplon) prior to use of non step-preferred agents. Cost-effective generic formulations of Lunesta and Ambien CR are now available.

   The step therapy criteria and manual criteria for the newer sedative hypnotics were updated to remove step therapy for eszopiclone and zolpidem ER. Eszopiclone and zolpidem ER will be step-preferred agents in addition to zolpidem IR and zaleplon. Step therapy remains for non step-preferred agents including Rozerem, Intermezzo,

Edluar, Silenor, and Zolpimist. Belsomra and Hetlioz have additional manual PA criteria.

Updated PA Criteria

Changes from May 2017 meeting are in BOLD

Manual PA Criteria: Coverage is approved if: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR, zaleplon, **zolpidem ER, or eszopiclone**.

7. OAB Drugs: Mirabegron (Myrbetriq)

The OAB drugs were most recently reviewed for formulary status in November 2012, with step therapy requiring a 12-week trial of one cost-effective generic formulation of tolterodine ER, oxybutynin ER, or trospium IR prior to use of the non step-preferred drugs. Mirabegron was reviewed as a new drug at the May 2014 meeting, and was designated as UF and non step-preferred. Since the previous P&T Committee review, several cost-effective generic formulations of other OAB drugs have entered the market.

Overactive bladder is characterized by a high placebo response rate, and benefits are seen with behavioral therapies. There do not appear to be clinically relevant differences in efficacy between mirabegron and the antimuscarinic OAB drugs, based on meta-analyses and clinical practice guidelines.

The manual PA criteria for mirabegron were updated to recommend a trial of two formulary step-preferred products first. The criteria will continue to allow patients who are at significant risk for central nervous system effects from antimuscarinic drugs to receive mirabegron. The criteria were also updated to reflect package insert cautions regarding use in patients with compromised renal function. Additionally, a trial of behavioral interventions (including pelvic floor muscle training in women and bladder training) is recommended, based on the clinical practice guidelines.

Updated PA Criteria

C**hanges from May 2017 meeting are in BOLD**

Manual PA Criteria—If automated criteria are not met, Myrbetriq is approved if:

1. Patient has confirmed diagnosis of OAB with symptoms of urge incontinence, urgency, and urinary frequency **AND**
2. **Patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, AND**
3. Patient has had a 12-week trial with **2** formulary step-preferred products and had therapeutic failure **OR**

4. Patient has experienced central nervous system AEs with oral OAB medications **OR** is at increased risk for such central nervous system effects due to comorbid conditions or other medications, **AND**
5. **Patient does not have a creatinine clearance (CrCl) < 15 mL/min OR**
6. If CrCl 15-29 mL/min, dosage does not exceed 25 mg daily

B. Updated Manual PA Criteria PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updates to the current PAs for eluxadoline (Viberzi), topiramate ER (Qudexy XR), pregabalin (Lyrica), ledipasvir/sofosbuvir (Harvoni), sofosbuvir (Sovaldi), fluticasone/azelastine (Dymista) and the step therapy changes for eszopiclone (Lunesta) and zolpidem ER (Ambien CR) and recommended (12 for, 0 opposed, 0 abstained, 0 absent) the manual PA update for mirabegron (Myrbetriq) become effective upon signing of the minutes in all points of service.

XIII. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

BAP Comments

A. Updated Manual PA Criteria

The P&T Committee recommended the updated PAs for Viberzi, Qudexy XR, Lyrica, Harvoni, Sovaldi, Dymista, Lunesta, Ambien CR and Myrbetriq.

The updated PA criteria were all stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Updated Manual PA Criteria PA Implementation Plan

The P&T Committee recommended updates to the current PA for Viberzi, Qudexy XR, Lyrica, Harvoni, Sovaldi, Dymista and Myrbetriq, and the step therapy changes for Lunesta, and Ambien CR become effective upon signing of the minutes in all points of service.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XIV. RE-EVALUATION OF NF GENERICS

P&T Comments

A. Re-evaluation of Generics—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee reviewed the current utilization, formulary status, generic availability, comparative clinical effectiveness, and relative cost effectiveness, including the weighted average cost per unit, for all generically available NF agents in two previously reviewed UF drug classes: the antidepressants, and the testosterone replacement therapies.

The P&T Committee concluded that for the drug classes, there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusions from when the classes were originally reviewed for UF placement. Specific comments, including the results of comparative cost reviews, are below:

- *Selective Serotonin Reuptake Inhibitors (SSRIs): Fluoxetine tablets and capsules* Fluoxetine is available in several formulations, including tablets and capsules, products with special packaging for Premenstrual Dysphoric Disorder (PMDD) (Sarafem) and a higher dosing strength for weekly administration (Prozac Weekly). Fluoxetine capsules are substantially more cost effective than these other formulations of fluoxetine. The vast majority of utilization across all POS is for the lowest cost generic fluoxetine capsules.
- *Testosterone Replacement Therapy (TRT):* This class was last reviewed in August of 2012, and the P&T Committee agreed there are no clinically relevant differences in efficacy or safety among available products, since they all contain testosterone. Fortesta (testosterone gel) was designated as UF and the sole step-preferred product. Androgel 1% and 1.62% gel were designated as NF and non step-preferred. As of May 2017, a number of the TRT products have become generically available, including Fortesta, Testim, Androgel 1% gel, and Androgel 1.62% gel. However, only generic Androgel 1% is now comparable to Fortesta in terms of weighted average cost across points of service and less costly than Fortesta at MTFs.

B. Re-evaluation of Generics—UF Recommendations and Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following actions, to become effective upon signing of the minutes:

1. Selective Serotonin Reuptake Inhibitors: All fluoxetine capsules currently designated as NF will be returned to UF status.

2. Testosterone Replacement Therapies: Androgel 1% gel will be returned to UF status and designated as step-preferred, with appropriate changes made to PA criteria to require an unsuccessful trial, contraindication, or intolerance to either Fortesta or generic Androgel 1% before receiving a non-preferred product.

XV. RE-EVALUATION OF NF GENERICS

BAP Comments

A. Re-evaluation of Generics—UF Recommendations and Implementation Plan

The P&T Committee recommended the following, effective upon signing of the minutes:

1. Selective Serotonin Reuptake Inhibitors: All fluoxetine capsules currently designated as NF will be returned to formulary status.
2. Testosterone Replacement Therapy: Androgel 1% gel will be returned to UF status and designated as step-preferred, with appropriate changes made to PA criteria to require an unsuccessful trial, contraindication, or intolerance to either Fortesta or generic Androgel 1% before receiving a non-preferred product.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XVI. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

P&T Comments

A. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee reviewed one drug from a pharmaceutical manufacturer that was not included on a DoD Retail Refund Pricing Agreement; this drug was not in compliance with FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail POS and medical necessity at MTFs. These NF drugs will remain available in the mail order POS without pre-authorization.

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) the following product be designated NF on the UF:

- CSL Behring LLC: antihemophilic factor, recombinant single chain (Afstyla) 500 units, 1000 units, 2000 units, and 3000 units injection

B. Section 703, NDAA FY08—Pre-Authorization Criteria

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) the following pre-authorization criteria for Afstyla:

1. Obtaining the product by home delivery would be detrimental to the patient; and,
2. For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.

These pre-authorization criteria do not apply to any other POS other than retail network pharmacies.

Should the mail order requirement impact availability of a drug, the P&T Committee will allow an exception to the Section 703 rule. The following drug will not be available in the Mail Order:

- Afstyla (antihemophilic factor, recombinant single chain), 500 units, 1000 units, 2000 units, and 3000 units subcutaneous injection is only available in the Retail Network.

C. Section 703, NDAA FY08—Implementation Plan

The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) an effective date of the first Wednesday after a 90-day implementation period for Afstyla and DHA send letters to beneficiaries affected by this decision.

XVII. SECTION 703, NDAA FY08

BAP Comments

A. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee recommended the following product be designated NF on the UF:

- Afstyla injection

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Section 703 NDAA FY08—Pre Authorization Criteria

The P&T Committee recommended the pre authorization criteria for Afstyla as previously presented.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Section 703, NDAA FY08—Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period for Afstyla and DHA send letters to beneficiaries affected by this decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implement Date	Notes and Unique Users Affected
May 2017	**Pulmonary-1 Agents – Pulmonary Miscellaneous Subclass**	UF subclass review	**UF Step-Preferred** ▪ pirfenidone (Esbriet) **UF Non Step-Preferred** ▪ nintedanib (Ofev)	▪ None	30 days	▪ Manual PA required ▪ Must try Esbriet first in all new users before Ofev
May 2017	**Ophthalmic-1 – Antihistamine and Dual Acting Antihistamine/ Mast Cell (AH/MCS) Stabilizers Subclass**	UF subclass; previously reviewed August 2010	▪ olopatadine 0.1% (Patanol generic) ▪ olopatadine 0.7% (Pazeo) ▪ azelastine 0.05% (Optivar generic) ▪ epinastine 0.05% (Elestat generic)	▪alcaftadine 0.25% (Lastacaft) ▪bepotastine 1.5% (Bepreve) ▪emedastine 0.05% (Emadine) ▪olopatadine 0.2% (Pataday)	90 days	▪ Manual PA required ▪ Note: Patanol moves to NF status, and Pazeo moves to UF status Unique Users Affected ▪ Retail: 10,688 ▪ Mail: 5,100 ▪ MTF: 17,244 **Total: 33,032**

May 2017 Drugs with New Prior Authorization Criteria
Unique Utilizers Affected Per Drug

Drug	MTF	Mail Order	Retail	Total
Non-Insulin Diabetes Drugs Biguanides Metformin ER (Fortamet)	254	3,203	1,008	4,465
Non-Insulin Diabetes Drugs Biguanides Metformin ER (Glumetza)	91	1,705	211	2,007
Diuretics Dichlorphenamide (Keveyis)	0	0	1	1