

Beneficiary Advisory Panel Handout

Uniform Formulary Decisions

6 April 2016

Purpose: The purpose of this handout is to provide the BAP members with a reference document for the clinical effective presentation for each Uniform Formulary (UF) decision.

NEW DRUG REVIEWS

Class: Non-Basal Insulins

Recommended for Non-formulary:

- **Inhaled human insulin (Afrezza)**

Current Uniform Formulary Agents:

- Regular human insulin (Novolin R)
- NPH human insulin (Novolin N)
- 70/30 human insulin (Novolin 70/30)
- Insulin aspart (Novolog)
- Insulin aspart 70/30 (Novolog Mix)
- Insulin lispro (Humalog)

Current Non-Formulary Agents:

- None

Recommended Implementation Date: 90 days

Approximate Total Number of patients affected:

Afrezza: Total: 81 (MTF 7; Mail Order 42; Retail 32)

Class: Non-Steroidal Anti-Inflammatory Agents (NSAIDs)

Recommended for Non-formulary:

- **Indomethacin low dose 20 mg and 40 mg capsules (Tivorbex)**

Current Uniform Formulary Agents:

- ibuprofen tablets and suspension (generic)
- indomethacin (Indocin, generic)
- meloxicam (Mobic, generic)
- celecoxib (Celebrex, generic)
- diclofenac/misoprostol (Arthrotec)
- diclofenac potassium tablets (Cataflam generic)
- diclofenac sodium tablets (Voltaren generic)
- generics for the following: diflunisal, etodolac, fenoprofen, flurbiprofen, ketoprofen, ketorolac, meclofenamate, nabumetone, oxaprozin, piroxicam, sulindac, tolmetin
- naproxen sodium (Anaprox, generic)
- naproxen/esomeprazole (Vimovo)

Current Non-Formulary Agents:

- diclofenac low dose 18 and 35 mg capsules (Zorvolex)
- diclofenac potassium liquid filled capsules (Zipsor) 25 mg
- diclofenac potassium powder packets 50 mg (Cambia)
- naproxen sodium ER (Naprelan CR, generic) ER tabs and dosing card

- mefenamic acid (Ponstel, generic) 250 mg

Recommended Implementation Date: 90 days

Approximate Total Number of patients affected:

Tivorbex: Total: 145 (MTF 0; Mail Order 43; Retail 102)

Class: Ophthalmic-1: Antihistamines/Mast Cell Stabilizers

Recommended for Non-formulary:

- **olopatadine 0.7% ophthalmic solution (Pazeo)**

Current Uniform Formulary Agents:

- olopatadine 0.1% (Patanol, generic)
- olopatadine 0.2% (Pataday)
- bepotastine (Bepreve)
- azelastine (Optivar, generic)
- Epinastine (Elestat)

Current Non-Formulary Agents:

- alcaftadine (Lastacaft)

Recommended Implementation Date: 90 days

Approximate Total Number of patients affected:

Pazeo: Total: 2,863 (MTF 562; Mail Order 1,740; Retail 561)

Class: Pulmonary IIs – Long-Acting Beta Agonists

Recommended for Uniform Formulary:

- **olodaterol oral inhaler (Striverdi)**

Current Uniform Formulary Agents:

- salmeterol (Serevent Diskus)
- formoterol (Foradil)
- arformoterol nebulized solution (Brovana)

Current Non-Formulary Agents:

- indacaterol nebulized solution (Arcapta Neohaler)
- formoterol nebulized solution (Perforomist)

Recommended Implementation Date: Not applicable

Approximate Total Number of patients affected: Not applicable

DRUG CLASS REVIEWS

Class: Contraceptive Agents: Oral Contraceptive Products (OCPs) and Miscellaneous Contraceptives

Recommended for Uniform Formulary

- levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen (Jolesa, Quasense, Introvale, and Setlakin [equivalent to discontinued Seasonale])
- norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Microgestin Fe 1/20; generics)
- norethindrone acetate 1 mg/EE 20 mcg (Microgestin 1/20 [21-day]; generics)
- drospirenone 3 mg/EE 20 mcg (Yaz; generics)
- levonorgestrel 0.1 mg/EE 20 mcg (Sronyx; Lutera; generics)
- norgestrel 0.3 mg/EE 30 mcg (Low-Ogestrel; generics [equivalent to discontinued Lo/Ovral 28])
- norethindrone acetate 1.5 mg/EE 30 mcg ferrous fumarate (Microgestin Fe 1.5/30; generics; [equivalent to Loestrin Fe 1.5/30])
- norethindrone acetate 1.5 mg/EE 30 mcg (Microgestin 1.5/30; generics; [equivalent to Loestrin 1.5/30])
- desogestrel 0.15 mg/EE 30 mcg (Reclipsen; Ortho-Cept; generics)
- levonorgestrel 0.15 mg/EE 30 mcg (Levora-28; generics)
- drospirenone 3 mg/EE 30 mcg (Yasmin; generics)
- ethynodiol diacetate 1 mg/EE 35 mcg (Zovia 1-35E; generics)
- norethindrone 0.5 mg /EE 35 mcg (Notrel 0.5/35; generics)
- norgestimate 0.25 mg/EE 35 mcg (Mononessa; generics)
- norethindrone 1 mg/EE 35 mcg (Norinyl 1+35; generics)
- norethindrone 1 mg + mestranol 50 mcg/EE 50 mcg (Norinyl 1+50; generics)
- norgestrel 0.5 mg/EE 50 mcg (Ogestrel; generics)
- ethynodiol diacetate 1 mg/EE 50 mcg (Zovia 1-50E; generics)
- norethindrone 0.5/1 mg + EE 35 mcg (Necon 10/11; [equivalent to discontinued Ortho Novum])
- desogestrel 0.15 mg + EE 20/10 mcg (Azurette; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 25 mcg (Ortho Tri-Cyclen Lo; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 35 mcg (TriNessa; generics)
- norethindrone 0.5/0.75/1 mg + EE 35 mcg (Necon 7/7/7; generics)
- norethindrone 0.5/1/0.5 mg + EE 35 mcg (Leena; generics)
- levonorgestrel 0.05/0.075/0.125 mg + EE 30/40/30 mcg (Trivora-28; generics)
- desogestrel 0.1/0.125/0.15 mg + EE 25 mcg (Velivet; generics)
- levonorgestrel 0.15 mg + EE 20/25/30/10 mcg (Quartette)
- norethindrone 0.35 mg (Nor-Q-D; Ortho Micronor; generics)
- etonogestrel 0.12 mg + EE 15 mcg vaginal ring (per day [NuvaRing])
- norelgestromin 150 mcg + EE 35 mcg transdermal system (per day [Xulane]; equivalent to discontinued Ortho Evra patch)
- depot medroxyprogesterone acetate 150 mg/mL IM vials (Depo-Provera vials; generic)
- depot medroxyprogesterone acetate 150 mg/mL IM syringes (Depo-Provera syringes; generic)
- depot medroxyprogesterone acetate 104 mg/0.65 mL SC (Depo-SubQ Provera 104)

Recommended for Non-Formulary

- norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate chewable (Minastrin 24 Fe chewable)
- norethindrone acetate 0.8 mg/EE 25 mcg ferrous fumarate chewable (Generess Fe chewable; generics)
- drospirenone 3 mg/EE 20 mcg levomefolate (Beyaz)
- norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Lomedia 24 Fe; generics)
- drospirenone 3 mg/EE 30 mcg levomefolate (Safyral)
- norethindrone 0.4 mg/EE 35 mcg (Balziva; generics)
- norethindrone 0.4 mg/EE 35 mcg ferrous fumarate chewable (Wymzya Fe chewable; generics)
- levonorgestrel 0.09 mg/EE 20 mcg (Amethyst; generics)
- levonorgestrel 0.15 mg/EE 30/10 mcg (Camrese; generics)
- levonorgestrel 0.1 mg/EE 20/10 mcg (Camrese Lo; generics)
- norethindrone acetate 1 mg/EE 10 mcg ferrous fumarate (Lo Loestrin Fe)
- norethindrone acetate 1 mg/EE 20/30/35 mcg ferrous fumarate (Tri-Legest Fe; generics)
- dienogest 2/3 mg and estradiol valerate 3/2/2/1 mg (Natazia)

Prior Authorization criteria recommended for the chewable formulations (Minastrin 24 Fe, Generess FE, and Wymzya, – see BAP Background Information

Recommended Implementation Date: 90 days

Approximate Total Number of patients affected for the newly designated Nonformulary OCPs.

Note that these are prescriptions dispensed in calendar year 2015

Minastrin 24 Fe chewable: approximately 5,401

Generess Fe chewable: approximately 32,373

Class: Antifungals: Topical Antifungal Lacquers

Recommended for Uniform Formulary

- ciclopirox 8% topical solution (Penlac, generic)

Recommended for Non-Formulary

- efinaconazole 10% topical solution (Jublia)
- tavaborole 5% topical solution (Kerydin)

Prior Authorization criteria recommended – see BAP Background Information

Recommended Implementation Date for Prior Authorization: 90 days

Approximate Total Number of patients affected by Prior Authorization:

Jublia and Kerydin: 17,322 Total

Class: Ophthalmic Anti-Inflammatory/Immunomodulatory Agents – Ophthalmic Immunomodulatory Agents

Recommended for Uniform Formulary

- Cyclosporine 0.05% ophthalmic emulsion (Restasis)

Recommended for Non-Formulary

- None

Prior Authorization criteria recommended –see BAP Background Information

Recommended Implementation Date for Prior Authorization: 90 days

Approximate Total Number of patients affected by Prior Authorization:

Restasis: 8,323

Innovator Drugs – currently in pending tier 3 (non-formulary) status

Recommended for Uniform Formulary

- Metabolic Replacement Agents: Asfotase alfa injection (Strensiq). Note that Prior Authorization is recommended; total number of patients affected: 3
- Anti-retrovirals: Elvitegravir/cobicistat/emtricitabine/tenofovir/raltegravir (Genvoya)
- Alcohol Deterrents/Narcotic Antagonists: Naloxone nasal spray (Narcan Nasal)
- Pulmonary Arterial Hypertension Agents: Selexipag (Uptravi)
- Binders/Chelators/Antidotes/Overdose Agents: Patiromer (Veltassa)
- Oral Oncology Agents—Metastatic Melanoma: Cobimetinib (Cotellic)
- Oral Oncology Agents—Multiple Myeloma: Ixazomib (Ninlaro)
- Oral Oncology Agents—Non-Small Cell Lung Cancer (NSCLC): Osimertinib (Tagrisso)
- Oral Oncology Agents—Lung Cancer: Alectinib (Alecensa)
- Antihemophilic Agents: Coagulation Factor X injection (Coagadex)
- Antihemophilic Agents: Antihemophilic factor, recombinant (rFVIII) injection (Adynovate)

Recommended for Non-Formulary

- Anti-platelet Agents: Aspirin ER 162.5 mg (Durlaza)
- Non-steroidal Anti-inflammatory Drugs: Meloxicam low dose 5 mg and 10 mg (Vivlodex)
- Anti-emetics: Rolapitant (Varubi)
- Basal Insulins: Insulin degludec (Tresiba)
- Attention Deficit Hyperactivity Disorder (ADHD)—Stimulants: Amphetamine ER oral suspension (Dyanavel XR)
- Pulmonary II—LABAs: Glycopyrrolate oral inhaler (Seebri Neohaler)
- Pulmonary II—Long-Acting Beta Agonists/Long-Acting Muscarinic Agents (LABAs/LAMAs): Indacaterol/glycopyrrolate oral inhaler (Utibron Neohaler)

Recommended Implementation Date: Upon signing of the minutes

Prior Authorizations

Numbers of patients affected:

- Gastrointestinal -2 Miscellaneous – Eluxadoline (Viberzi): Total 45 (MTF 0, Mail Order 2, Retail 43)
- Atypical Antipsychotics – Brexpiprazole (Rexulti): Total 571 (MTF 11, Mail Order 124, Retail 436)
- Anticonvulsants – Lacosamide (Vimpat): Total 3,011 (MTF 460, Mail Order 798, Retail 1,753)
- Renin-Angiotensin Antihypertensives – Sacubitril/valsartan (Entresto): Total 603 (MTF 36, Mail Order 274, Retail 293)