Beneficiary Advisory Panel Handout

Uniform Formulary Decisions

26 March 2015

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: Newer Sedative Hypnotics:

Recommended for Non-Formulary: Tasimelteon (Hetlioz)

Current Uniform Formulary Agents:

Step-preferred: zolpidem immediate release (Ambien generic), zaleplon (Sonata generic)

Non step-preferred: zolpidem extended release (Ambien CR), eszopiclone (Lunestra), doxepin (Silenor)

Non-Formulary Agents, non step-preferred: ramelteon (Rozerem), zolpidem sublingual (Edluar), zolpidem sublingual (Intermezzo)

Prior Authorization (PA) criteria: Manual PA recommended at August 2014 P&T Committee meeting and implemented on November 14, 2014. Revised PA criteria recommended.

The previous automated (step therapy) criteria requiring a trial of zolpidem IR or zaleplon no longer apply. Coverage is approved for all new users of Hetlioz, if all of the following criteria apply:

1. The patient is totally blind and has a documented diagnosis of non-24 sleep wake disorder.
2. The patient has had a trial of melatonin and either failed or had an adverse event.
3. The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers).

PA Criteria will expire after 6 months (if patient has not responded after 6 months, they will be deemed a non-responder.

Recommended Implementation Date: 60 days

Approximate Total Number of patients affected: 4 (MTF 0, Mail Order 0, Retail Network 4)

Class: Sodium Glucose Co-Transporter 2 Inhibitors

Recommended for Non-Formulary: empagliflozin (Jardiance)

Uniform Formulary Agents: SGLT-2 inhibitors: none

Other non-insulin diabetes drugs: metformin, sulfonylureas, sitagliptin (Januvia, Janumet), linagliptin (Tradjenta, Jentadueto), pioglitazone (Actos generic), exenatide (Byetta, Bydureon), liraglutide (Victoza)

Non-Formulary Agents: canagliflozin (Invokana), dapagliflozin (Farxiga)

Prior Authorization (PA) criteria: Step-therapy applies; must try metformin or a sulfonylurea (SU), and a dipeptidyl-dipeptidase-4 (DPP-4) inhibitor before empagliflozin (Jardiance).

Coverage for Jardiance approved if:

1. The patient has experienced any of the following issues on metformin:
   -impaired renal function precluding treatment with metformin
   -history of lactic acidosis
2. The patient has experienced any of the following issues on a sulfonylurea:
   -hypoglycemia requiring medical treatment
3. The patient has had inadequate response to metformin or a SU or a DPP-4 inhibitor.
4. The patient has a contraindication to metformin or a SU or DPP-4 inhibitor.

Recommended Implementation Date: 90 days

Total Number of patients affected: 913 (MTF 10, Mail Order 285, Retail Network 618)

Class: Antiplatelet Drugs

Recommended for Non-Formulary: vorapaxar (Zontivity)

Uniform Formulary Agents: clopidogrel (Plavix generic), prasugrel (Effient), ticagrelor (Brilinta), ticloplidine (Ticlid generic), cilostazol (Pletal generic) aspirin/dipyridamole (Aggrenox), pentoxifylline (Trental generic)

Non-Formulary Agents: none

Recommended Implementation Date: 90 days

Total Number of patients affected: 62 (MTF 2, Mail Order 35, Retail Network 25)

Class: Phosphodiesterase-5 Inhibitors

Recommended for Non-Formulary: avanafil (Stendra)

Uniform Formulary Agents: sildenafil (Viagra)

Non-Formulary Agents: tadalafil (Cialis), vardenafil (Levitra, Staxyn)

Prior Authorization (PA) criteria: Step-therapy applies; must try Viagra before Stendra. PA for ED not required for men over age 40 years.

Coverage for Stendra approved for erectile dysfunction, and a trial of Viagra is not required if:

1. Patient has tried Viagra and has had an inadequate response or was unable to tolerate treatment due to adverse effects.
2. Treatment with Viagra is contraindicated.
3. Patient is between 18 and 39 years of age and is being treated for ED of organic or mixed organic/psychogenic origin. Must try Viagra first or indicate inability to due to reasons stated above in 1 or 2.
4. Patient is between 18 and 39 years of age and is being treated for drug-induced ED where the causative drug cannot be altered or discontinued. Must try Viagra first or indicate inability to due to reasons stated above in 1 or 2.

Coverage is approved for Stendra for non-ED uses requiring daily therapy for preservation/restoration of erectile dysfunction after prostatectomy. PA expires after one year.

Recommended Implementation Date: 90 days

Total Number of patients affected: 576 (MTF 5, Mail Order 170, Retail Network 401)

Class: Proton Pump Inhibitors

<u>Recommended for Non-Formulary</u>: esomeprazole strontium

<u>Uniform Formulary Agents</u>:

Step-preferred: omeprazole (Prilosec generic) excluding 40mg Prilosec capsule; esomeprazole (Nexium)

Non step-preferred: Prilosec 40mg (brand), pantoprazole (Protonix generic)

<u>Non-Formulary Agents, non step-preferred</u>: lansoprazole (Prevacid) omeprazole bicarbonate (Zegerid), rabeprazole (Aciphex), dexlansoprazole (Kapidex/Dexilant)

<u>Prior Authorization (PA) criteria:</u> Step-therapy applies; must try omeprazole generic or Nexium first

Coverage for esomeprazole strontium approved if:

1. The patient has tried omeprazole, pantoprazole tablets, and esomeprazole magnesium (Nexium) and had an inadequate response.
2. The patient has tried omeprazole, pantoprazole tablets, and esomeprazole magnesium (Nexium) and was unable to tolerate it due to adverse effects.
3. Treatment with omeprazole, pantoprazole tablets, and esomeprazole magnesium (Nexium) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency).

Recommended Implementation Date: 90 days

Total Number of patients affected: 216 (MTF 1, Mail Order 32, Retail Network 183)

DRUG CLASS REVIEW

Class: Pulmonary Arterial Hypertension (PAH)

Uniform Formulary Agents:

Endothelin receptor antagonists: bosentan (Tracleer), ambrisentan (Letairis), macitentan (Opsumit)

Prostacyclins: treprostinil nebulized solution (Tvyaso), treprostinil tablets (Orenitram ER), iloprost (Ventavis)

PDE-5 Inhibitors:

Step-preferred: sildenafil 20 mg generic, sildenafil brand (Revatio)

Non step-preferred: tadalafil (Adcirca), riociguat (Adempas)

Non-Formulary Agents: none

Prior Authorization (PA) criteria: Step-therapy applies; must try sildenafil 20 mg generic or sildenafil brand (Revatio) first

Coverage for Adcirca or Adempas approved if:

1. For Adempas:

   -Patient has a documented diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH)

   -Patient has tried a PDE-5 inhibitor and failed or did not respond to therapy

   -Patient has experienced significant adverse effects from the PDE-5 inhibitor

2. For Adcirca:

   -Patient has tried a sildenafil 20 mg generic or sildenafil brand (Revatio) and failed or did not respond to therapy

3. For both Adempas and Adcirca:

   -Patient is not taking a nitrate drug

Recommended Implementation Date: 90 days – for PDE-5 inhibitor step-therapy

Approximate Total Number of patients affected for PDE-5 inhibitor step-therapy: Adcirca 149, Adempas 27

Class: Oral Oncology Agents Prostate Cancer

Uniform Formulary Agents:

Anti-Androgens: bicalutamide (Casodex generic), flutamide (Eulexin generic), nilutamide (Nilandron)

Survival Prolonging Agents: enzalutamide (Xtandi), abiraterone (Zytiga)

Non-Formulary Agents: none

Prior Authorization (PA) criteria: Manual PA criteria apply for Nilandron

Coverage for Nilandron is approved if:

1. Patient has experienced significant adverse effects or contraindication from bicalutamide or flutamide; or
2. Patient has experienced therapeutic failure with bicalutamide or flutamide; or
3. Patient has a diagnosis of metastatic prostate cancer (stage D2) disease and the patient has undergone orchiectomy.

Recommended Implementation Date: 90 days for Nilandron PA criteria

Approximate Total Number of patients affected for Nilandron PA: 41 (MTF 9, Mail Order 25, Retail Network 7)

Class: Transmucosal Immediate Release Fentanyl (TIRF) Products

Uniform Formulary Agents: fentanyl transmucosal lozenge (Actiq generic)

Non-Formulary Agents: fentanyl sublingual tablet (Abstral), fentanyl buccal tablets (Fentora), fentanyl nasal spray (Lazanda), fentanyl sublingual spray (Subsys)

Recommended Implementation Date: 90 days

Approximate Total Number of patients affected: 355

	MTF	Mail Order	Retail Network	Total
Abstral	0	0	34	34
Fentora	1	0	115	116
Lazanda	0	0	6	6
Subsys	0	0	199	199