

**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 (CFR) 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—PANCREATIC ENZYME REPLACEMENT THERAPY**

*P&T Comments*

**A. Pancreatic Enzyme Replacement Therapy—Relative Clinical Effectiveness Analysis and Conclusion**

*Background*—The class was most recently reviewed for UF status in February 2014. Since the last review, the drug class name was changed from “Pancreatic Enzyme Products” to “Pancreatic Enzyme Replacement Therapy (PERT)” to align with accepted nomenclature in the clinical literature. The drugs in the class all contain various amounts of lipase, amylase, and protease and are available under the trade names of Creon, Pancreaze, Pertzye, Ultresa, Viokace, and Zenpep.

The products were reviewed for the U.S. Food and Drug Administration (FDA)-approved indication of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis or other conditions; other uses (e.g., pain relief from pancreatitis) were not reviewed.

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

- Creon, Pancreaze, Ultresa, and Zenpep are formulated as capsules containing delayed release enteric-coated microspheres, while Pertzye capsules contain enteric-coated microspheres with a bicarbonate buffer.
- Viokace is an uncoated tablet that is not approved for use in pediatrics; it requires administration with a proton pump inhibitor to prevent degradation in the stomach.
- Based on a 2016 Cochrane Review in patients with cystic fibrosis, Creon, Pancreaze, Zenpep, Viokace, Ultresa, and Pertzye are effective at improving fat malabsorption in patients with EPI, when compared to placebo.
- The 2016 Cochrane review found no difference between Creon and other enteric-coated microsphere products in the endpoints of change in weight, stool frequency, abdominal pain, or fecal fat excretion. Creon was superior to the tablet formulation (Viokace) in only one endpoint, decreasing stool frequency.

- Zenpep has the largest number of dosage strengths available, but multiple capsules can be used to obtain individualized patient dosing. Creon and Zenpep both have higher strengths available. All the products except for Viokace provide dosing for infants.
- Creon has the greatest number of FDA-approved indications and the highest Military Health System (MHS) utilization.
- Although Pertzye is the only product with gastrostomy (G)-tube administration information contained in the package insert, instructions are available for G-tube administration with Creon, Viokace, and Zenpep.
- There is a high degree of therapeutic interchangeability among the PERT products, and having one on the formulary is sufficient to meet the needs of MHS patients.

#### **B. PERT—Relative Cost-Effectiveness Analysis and Conclusion**

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

- CMA results showed that Creon was the most cost-effective agent in the PERT class.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Creon as formulary and step-preferred; Viokace as UF and non-step-preferred; and Pertzye, Pancreaze, Ultresa, and Zenpep as NF and non-step-preferred demonstrated significant cost avoidance for the MHS.

#### **C. PERT—UF Recommendation**

The P&T Committee recommended (15 for, 1 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

- UF and step-preferred
  - Creon
- UF and non-step-preferred
  - Viokace tablet
- NF and non-step-preferred
  - Pancreaze
  - Pertzye
  - Ultresa
  - Zenpep
- This recommendation includes step therapy, which requires a trial of Creon prior to use of Viokace and the NF non-step-preferred PERT drugs in all new and current users.

#### **D. PERT—Manual PA Criteria**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the non-step-preferred products, requiring a trial of Creon first in all new and current users. Note that PA is not needed for Creon, and the step-therapy requirements will be included in the manual PA.

Manual PA Criteria: Pancreaze, Pertzye, Ultresa, Viokace, and Zenpep are approved if any of the following criteria are met:

- The patient has failed an adequate trial of Creon, defined as at least two dose adjustments done over a period of at least four weeks OR
- The patient is  $\leq 2$  years old and a sufficient trial of Creon was unsuccessful OR
- For Viokace: the patient requires an uncoated tablet due to actual or suspected dissolution issues with enteric coating of Creon

PA does not expire.

#### **E. PERT—Tier 1 Cost Share**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) lowering the current tier 2 cost share for Creon to the generic tier 1 cost share.

The authority for this recommendation is codified in 32 CFR 199.21(j)(3), which states that "when a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate." The objective is to maximize use of Creon in the TRICARE Mail Order pharmacy and Retail Network, given its significantly lower cost relative to the other PERT products. Lowering the cost-share for Creon will provide a greater incentive for beneficiaries to use the most cost-effective PERT formulation in the purchased care points of service.

#### **F. PERT—UF, PA, and Tier 1 Cost Share Implementation Plan**

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

### **III. UF CLASS REVIEWS—PERT**

#### ***BAP Comments***

##### **A. PERT—UF Recommendation**

The P&T Committee recommended the following:

- UF and step-preferred
  - Creon
- UF and non-step-preferred
  - Viokace tablet
- NF and non-step-preferred

- Pancreaze
- Pertzye
- Ultresa
- Zenpep

<i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur
<b>Additional Comments and Dissension</b>

**B. PERT—Manual PA Criteria**

The P&T Committee recommended manual PA criteria for the non-step-preferred products, requiring a trial of Creon first in all new and current users. PA is not needed for Creon, and the step-therapy requirements will be included in the manual PA. The full PA criteria were stated previously.

<i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur
<b>Additional Comments and Dissension</b>

**C. PERT—Tier 1 Cost Share**

The P&T Committee recommended lowering the current tier 2 cost share for Creon to the generic tier 1 cost share.

<i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur
<b>Additional Comments and Dissension</b>

**D. PERT—UF, PA, and Tier 1 Cost Share Implementation Plan**

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

*BAP Comment:*

Concur

Non-concur

Additional Comments and Dissension

#### IV. GROWTH STIMULATING AGENTS

##### *P&T Comments*

##### **A. Growth Stimulating Agents—Relative Clinical Effectiveness Analysis and Conclusion**

*Background*—The Growth Stimulating Agents (GSAs) were last reviewed at the August 2007 DoD P&T Committee meeting. All the products contain recombinant human growth hormone (rhGH), or somatropin. Since the 2007 review, two products (Zorbitive and Tev-Tropin) were discontinued, and one product, Zomacton, has entered the market. There are no generic products in the class.

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

- The products are all bioidentical and equally biopotent to each other.
- Head-to-head trials show equivalency in pharmacokinetic profiles, efficacy, and safety.
- The GSA products all offer 5 mg and 10 mg dosing options, pen devices, small needle gauges (29-, 30-, and 31-gauge), a needle-guard option, patient support programs, home nurse education, instructional websites, and an emergency hotline number.
- The GSA products differ in terms of their FDA-approved indications; storage requirements (refrigeration vs. room temperature); preservative (benzyl alcohol vs. metacresol vs. phenol); delivery devices, smallest available dosage increment; and reconstitution or device assembly steps required prior to administration. None of these differences impact patient outcomes.
- Advantages of Norditropin FlexPro include that it has the greatest number of FDA-approved indications (seven); it does not require refrigeration or mixing prior to administration; it contains phenol as a preservative; and it is administered in a pen device that is convenient and easy to use. It can also deliver small increments in dosage, down to 0.025 mg with the 5 mg pen.
- One advantage of Genotropin is the availability of the low-dose, single-use MiniQuick formulation that can deliver the lowest dosage options for children. However, all the products can deliver low dosages.
- Norditropin FlexPro, Nutropin, Omnitrope, and Saizen are pre-mixed formulations that are convenient for patients.

- Disadvantages of Saizen, Serostim, Zomacton, and Omnitrope include the benzoyl alcohol preservative, which is toxic to neonates and infants. However, alternate formulation options are available for these products.
- Zomacton is the only product available in a needle-free device.
- Overall, the GSA products have a high degree of therapeutic interchangeability, based on MHS provider opinion, systematic reviews, meta-analyses, and professional treatment guidelines.

**B. GSAs—Relative Cost-Effectiveness Analysis and Conclusion**

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

- CMA showed that Zomacton, Omnitrope, and Norditropin FlexPro were the most cost-effective products in the GSA class.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Norditropin FlexPro as formulary and step-preferred demonstrated the greatest cost avoidance for the MHS.

**C. GSAs—UF Recommendation**

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following, based on clinical and cost effectiveness:

- UF and step-preferred
  - Norditropin FlexPro
- UF and non-step-preferred
  - Omnitrope
  - Zomacton
- NF and non-step-preferred
  - Genotropin and Genotropin MiniQuick
  - Humatrope
  - Nutropin AQ Nuspin
  - Saizen
  - Serostim
- This recommendation includes step therapy, which requires a trial of Norditropin FlexPro prior to use of the non-step-preferred GSAs in all new and current users.

**D. GSAs—Manual PA Criteria**

PA criteria currently apply to the GSAs. The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) updating the current PA criteria for the class to include the updated safety warning for use of a GSA in patients with Prader-Willi syndrome and obstructive sleep apnea and to require the prescription to be written by the appropriate subspecialist. Additionally the step therapy requirements for trial of Norditropin FlexPro in all new and current users will be included in the manual PA. Use of the non-

step-preferred products is allowed if the patient has a contraindication or has experienced an adverse reaction to Norditropin FlexPro, and then Omnitrope and Zomacton, before moving to NF agents.

Manual PA Criteria: Norditropin FlexPro, Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, and Zomacton are approved if:

- The patient is younger than 18 years of age and has the following indications:
  - Growth hormone deficiency
  - Small for Gestational Age
  - Chronic Renal Insufficiency **associated with growth failure**
  - Prader-Willi Syndrome (**in patients with negative sleep study for obstructive sleep apnea**)
  - Turner Syndrome
  - Noonan's Syndrome
  - Short stature homeobox (ShoX) gene mutation
- For patients younger than 18 years of age who do not have one of the indications above, the diagnosis must be documented
- For patients younger than 18 years of age, the prescription is written by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment
- The patient is older than 18 years of age and has the following indications:
  - Growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood
  - Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) wasting/cachexia
  - Short Bowel Syndrome
- For patients older than 18 years of age, the prescription is written by or **in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist).**

AND

For Omnitrope and Zomacton: In addition to the above criteria, the following criteria applies to current users of Omnitrope and Zomacton:

- The patient has a contraindication to Norditropin FlexPro OR
- The patient has experienced an adverse reaction to Norditropin FlexPro that is not expected with Omnitrope or Zomacton (e.g., because of different preservative) OR
- For Zomacton: the patient prefers a needle-free device (Zomacton)

AND

For Genotropin, Humatrope, Nutropin AQ Nuspin, Saizen, and Serostim: In addition to the above criteria, the following criteria applies to new and current users of Genotropin, Humatrope, Nutropin AQ Nuspin, Saizen, and Serostim:

- The patient has a contraindication to Norditropin FlexPro AND Omnitrope AND Zomacton OR
- The patient has experienced an adverse reaction to Norditropin FlexPro AND Omnitrope AND Zomacton that is not expected with the non-step-preferred product (e.g., because of different preservative)

Note that all possible preservative formulations are available between Norditropin FlexPro, Omnitrope, and Zomacton.

Note that patient preference for a particular device is insufficient grounds for approval of Genotropin, Humatrope, Nutropin AQ Nuspin, Saizen, or Serostim.

- Use of a GSA is not approved for idiopathic short stature, the normal ageing process, obesity, or depression
- Use of a GSA is not approved for other non-FDA-approved uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment)
- Concomitant use of multiple GSAs is not approved

PA expires in one year.

#### **E. GSAs—Tier 1 Cost Share**

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) lowering the current tier 2 cost share for Norditropin FlexPro to the generic tier 1 cost share, under the authority previously discussed on page 3.

#### **F. GSAs—UF, PA, and Tier 1 Cost Share Implementation Plan**

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following: 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service and 2) DHA send letters to beneficiaries who are affected by the UF decision.

### **V. GSAs**

#### ***BAP Comments***

##### **A. GSAs—UF Recommendation**

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

- UF and step-preferred
  - Norditropin FlexPro
- UF and non-step-preferred
  - Omnitrope
  - Zomacton
- NF and non-step-preferred
  - Genotropin and Genotropin MiniQuick



- Humatrope
- Nutropin AQ Nuspin
- Saizen
- Serostim

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur	<b>Additional Comments and Dissension</b>
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**B. GSAs—Manual PA Criteria**

The P&T Committee recommended updating the current PA criteria for the class to include the updated safety warning for use of a GSA in patients with Prader-Willi syndrome and obstructive sleep apnea and to require the prescription to be written by the appropriate subspecialist. Additionally the step therapy requirements for trial of Norditropin FlexPro in all new and current users will be included in the manual PA. The full PA criteria were stated previously.

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur	<b>Additional Comments and Dissension</b>
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**C. GSAs—Tier 1 Cost Share**

The P&T Committee recommended lowering the current tier 2 cost share for Norditropin FlexPro to the generic tier 1 cost share.

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur	<b>Additional Comments and Dissension</b>
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**D. GSAs—UF, PA, and Tier 1 Cost Share Implementation Plan**

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service and 2) DHA send letters to beneficiaries who are affected by the UF decision.

*BAP Comment:*

Concur

Non-concur

Additional Comments and Dissension

## VI. GASTROINTESTINAL-2 AGENTS OPIOID-INDUCED CONSTIPATION SUBCLASS

### *P&T Comments*

#### **A. Gastrointestinal-2 Agents: Opioid-Induced Constipation Subclass—Relative Clinical Effectiveness Analysis and Conclusion**

*Background*—The P&T Committee evaluated the peripherally acting mu opioid receptor antagonists (PAMORAs) for opioid-induced constipation (OIC). The products are a subclass of the Gastrointestinal-2 (GI-2); the subclass has not been reviewed previously for formulary status. The drugs in the class include methylnaltrexone (Relistor), naldemedine (Symproic), and naloxegol (Movantik) and are all indicated for treating OIC. Relistor is also available in an injection for treatment of OIC in the palliative care setting.

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

- The PAMORAs inhibit the action of opioids in the GI tract, which decreases constipation, but still maintain the analgesic effects from the mu receptors in the central nervous system.
- According to professional treatment guidelines, scheduled doses of a stimulant laxative, (e.g., bisacodyl/senna) with or without a stool-softener (e.g., docusate), a high fiber diet, increased fluid intake, moderate exercise and opioid dosage reduction to the minimum effective dose are recommended as first-line options for OIC.
- Limitations to the evidence for efficacy of the OIC drugs include the lack of a validated minimally clinically important difference in study endpoints, the allowance of concomitant or “rescue” laxative doses, and the short duration of the trials (less than three months). Additionally, in the trials leading to FDA approval for the OIC drugs, there were differing inclusion and exclusion criteria, especially with regard to intensity of opioid dosing.
- Given the varying efficacy endpoints and lack of head-to-head trials, there is insufficient evidence to conclude that one PAMORA is more effective than another or associated with fewer adverse events.
- There is no long-term safety data available with the OIC drugs. The FDA is requiring cardiovascular outcomes trials (CVOTs) for the PAMORAs to evaluate CV mortality, non-fatal myocardial infarction, and stroke. Results from the CVOTs are pending.
- Advantages of Symproic include once daily dosing and no need to adjust the dose in patients with renal dysfunction. Symproic is available in one tablet strength, so

dose titration is not required. However, disadvantages include rare cases of rash and hypersensitivity reactions reported in the clinical trials leading to FDA approval and CYP3A4 drug interactions.

- Movantik can be crushed and placed down a nasogastric tube and is also dosed once daily. Disadvantages include that the 12.5 mg dosage was not statistically significant in one trial; it requires renal and hepatic dosing adjustment; and it has CYP3A4 drug interactions.
- Advantages of the methylnaltrexone (Relistor) tablets include the lack of CYP3A4 drug interactions. However, only one phase III trial is available for the oral tablet.
- MHS provider feedback supported use of traditional laxative therapy as first-line therapy for OIC.

#### **B. GI-2 Agents: OIC Subclass—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 Symproic was the most cost-effective OIC drug, followed by Movantik, and Relistor.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating Symproic and Movantik as formulary with Relistor as NF demonstrated significant cost avoidance for the MHS.

#### **C. GI-2 Agents: OIC Subclass—UF Recommendation**

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

- UF
  - Symproic
  - Movantik
- NF
  - Relistor tablets and injection

#### **D. GI-2 Agents: OIC Subclass—Manual PA Criteria**

PA criteria currently apply to Relistor and Movantik, which requires a trial of two traditional laxatives and a trial of lubiprostone (Amitiza) prior to use of an OIC drug. For new users of Symproic and Movantik, the P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining the requirement for a trial of over-the-counter (OTC) laxatives, and removing the requirement for a trial of Amitiza, based on the treatment guidelines from the American Gastroenterological Association where PAMORAs are recommended specifically for laxative-refractory patients.

The Committee also recommended updating the existing manual PA criteria for Relistor tablets to require a trial of Amitiza and both Symproic and Movantik, due to the relatively limited amount and low quality evidence available. The PA criteria for Relistor tablets will apply to

new and current users. PA is not required for Relistor injection, as this product is limited to the palliative care setting.

### Manual PA criteria

#### **1. Movantik and Symproic**

Manual PA criteria apply to new users of Movantik and Symproic.

Manual PA criteria: Approved if all criteria are met:

- The patient is 18 years of age or older with a diagnosis of OIC AND
- The patient is currently taking an opioid agonist AND
- The patient is not on other opioid antagonists (naloxone not including rescue agents, naltrexone, etc.) AND
- The patient has either failed or not tolerated two or more of the following:
  - At least one stimulant laxative (sennosides or bisacodyl) AND
  - At least one osmotic laxative (Miralax, lactulose, or magnesium citrate) AND
- The patient does not have a known or suspected gastrointestinal obstruction or is not at increased risk of recurrent obstruction AND
- The patient is not currently on strong CYP3A4 inducers inhibitors (e.g., clarithromycin, ketoconazole)

Non-FDA-approved uses are not approved.

PA expires in one year.

Renewal PA criteria: Coverage will be approved for an additional year if all of the following apply:

- The patient continues to take opioids AND
- The patient continues lifestyle modifications including regular use of a stimulant laxative (e.g., bisacodyl, senna), a high fiber diet, increased fluid intake, moderate exercise, and opioid dose de-escalation to minimum effective dose
- The patient is responding in a meaningful manner (e.g., improvement of at least one additional spontaneous bowel movement per week over baseline)

#### **2. Relistor tablets**

Manual PA criteria apply to new and current users of Relistor tablets.

Manual PA criteria: Approved if all criteria are met:

- The patient is 18 years of age or older with a diagnosis of OIC AND
- The patient is currently taking an opioid agonist AND
- The patient is not on other opioid antagonists (naloxone not including rescue agents, naltrexone, etc.) AND
- The patient has either failed or not tolerated two or more of the following:

- At least one stimulant laxative (sennosides or bisacodyl) AND
- At least one osmotic laxative (Miralax, lactulose, or magnesium citrate) AND
- The patient has tried and failed Movantik AND
- The patient has tried and failed Symproic AND
- The patient has tried and failed Amitiza AND
- The patient does not have a known or suspected gastrointestinal obstruction or is not at increased risk of recurrent obstruction AND
- The patient is not currently on strong CYP3A4 inducers/inhibitors (e.g., clarithromycin, ketoconazole)

Non-FDA-approved uses are not approved.  
PA expires in one year.

Renewal PA criteria: Coverage will be approved for an additional year if all of the following apply:

- The patient continues to take opioids AND
- The patient continues lifestyle modifications including regular use of a stimulant laxative (e.g., bisacodyl, senna), a high fiber diet, increased fluid intake, moderate exercise, and opioid dose de-escalation to minimum effective dose
- The patient is responding in a meaningful manner (e.g., improvement of at least one additional spontaneous bowel movement per week over baseline)

#### **E. GI-2 Agents: OIC Subclass—UF and PA Implementation Plan**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:  
1) an effective date of the first Wednesday after a 60-day implementation period in all points of service and 2) DHA send letters to beneficiaries who are affected by the UF decision.

### **VII. GI-2 AGENTS: OIC SUBCLASS**

#### *BAP Comments*

#### **A. GI-2 Agents: OIC Subclass—UF Recommendation**

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

- UF
  - Symproic
  - Movantik
- NF
  - Relistor tablets and injection

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur	
			Additional Comments and Dissension

**B. GI-2 Agents: OIC Subclass—Manual PA Criteria**

For new users of Symproic and Movantik, the P&T Committee recommended maintaining the requirement for a trial of OTC laxatives and removing the requirement for a trial of Amitiza.

The Committee also recommended updating the existing manual PA criteria for Relistor tablets in new and current users to require a trial of Amitiza and both Symproic and Movantik.

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur	
			Additional Comments and Dissension

**C. GI-2 Agents: OIC Subclass—UF and PA Implementation Plan**

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period in all points of service and 2) DHA send letters to beneficiaries who are affected by the UF decision.

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur	
			Additional Comments and Dissension

**VIII. NEWLY APPROVED DRUGS PER 32 CFR 199.21(G)(5)**

*P&T Comments*

**A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—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 per 32 CFR 199.21(g)(5)—UF Recommendation**

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

- UF:

- apalutamide (Erleada) – Oral Oncologic Agent for Prostate Cancer
  - bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy) – Antiretrovirals for HIV
  - efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi) – HIV
  - efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi Lo) – HIV
  - ibrutinib tablets (Imbruvica) – Oral Oncologic Agent for mantle cell lymphoma and chronic lymphocytic leukemia, new formulation (note that Imbruvica capsules were already designated as uniform formulary prior to the Innovator Rule established in August 2015)
  - insulin lispro (Admelog) – Short-Acting Insulin for Diabetes Mellitus
  - lamivudine/tenofovir disoproxil fumarate (Cimduo) – Antiretrovirals for HIV
  - netarsudil 0.02% ophthalmic solution (Rhopressa) – Glaucoma Agents
  - tezacaftor/ivacaftor (Symdeko) – Cystic Fibrosis Agents
  - vancomycin oral solution (Firvanq) – Gastrointestinal-2 agents: Miscellaneous for *Clostridium difficile* associated diarrhea or enterocolitis
- NF:
    - clobetasol propionate 0.025% cream (Impoiz) – High Potency Corticosteroids-Immune Modulators for Moderate to Severe Plaque Psoriasis
    - desmopressin nasal spray (Noctiva) – Miscellaneous Endocrine Agent for nocturia due to nocturnal polyuria
    - doxylamine succinate/pyridoxine ER tablets (Bonjesta) – Antiemetic-Antivertigo Agents
    - ertugliflozin (Steglatro) – Non-Insulin Diabetes Drugs – Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor
    - ertugliflozin/sitagliptin (Steglujan) – Non-Insulin Diabetes Drugs –SGLT2 Inhibitor
    - glycopyrrolate inhalation solution (Lonhala Magnair) – Pulmonary-2: Long-Acting Muscarinic Agents (LAMAs) for Chronic Obstructive Pulmonary Disease
    - pitavastatin magnesium (Zypitamag) – Antilipidemic-Is (LIP-Is)
    - secnidazole (Solosec) – Miscellaneous Anti-Infective for bacterial vaginosis in adult women

### C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

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

- Applying the same manual PA criteria for Steglatro, Segluomet, and Steglujan in new and current users as is currently in place for the other non-step-preferred SGLT2 inhibitors. Patients must first try the step-preferred SGLT2 inhibitor empagliflozin (Jardiance, Glyxambi, Synjardy or Synjardy XR).

- Applying the same step therapy and manual PA criteria to new and current users of Zypitamag as is currently in place for pitavastatin (Livalo). Step therapy for the Antilipidemic I's drug class requires a trial of a generic statin at comparable low-density lipoprotein (LDL) lowering capability.
- Applying manual PA criteria to new and current users of Impoyz cream, Lonhala Magnair inhalation solution, Noctiva nasal spray, and Rhopressa ophthalmic solution.
- Applying manual PA criteria to new users of Bonjesta, Erleada, and Symdeko.
- Applying manual PA criteria to new users of Imbruvica tablets and capsules.

***INTERIM P&T COMMITTEE MEETING***—Following the May 2018 P&T Committee meeting, the Committee became aware that Imbruvica capsules would remain on the market. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) to revise the PA for Imbruvica to require a trial of Imbruvica capsules first in new users, prior to use of the tablets; as shifting patients to the tablet formulation unnecessarily reduces dosage titration options

Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5)

**1. Erleada**

Manual PA criteria apply to all new users of Erleada. Coverage will be approved if all criteria are met:

- The patient has a diagnosis of non-metastatic castration-resistant prostate cancer (as shown by a negative CT scan of abdomen/pelvis and/or negative bone scan) AND
- Patients should be co-prescribed gonadotropin-releasing hormone analog therapy concurrently OR patients should have had bilateral orchiectomy AND
- Erleada is prescribed by or in consultation with an oncologist or urologist

Non-FDA-approved uses are not approved.

PA expires in one year.

Renewal criteria: Erleada will be continued for another year if:

- The patient continues to be free of metastases
- No toxicities have developed
- The patient has not had disease progression requiring subsequent therapy (such as abiraterone [Zytiga])

**2. Impoyz**

Manual PA applies to all new and current users of Impoyz.

Manual PA criteria: Coverage will be approved if all criteria are met:

- Patient has moderate to severe plaque psoriasis AND
- Patient is  $\geq 18$  years old AND



- Patient is not a candidate for or has failed phototherapy AND
- Contraindications exist to all formulary high-potency topical steroids OR
- Patient has had an inadequate response to all formulary high-potency topical steroids OR
- Patient has had an adverse effect to each of the formulary high-potency topical steroids

Non-FDA-approved uses are not approved.

PA expires in 30 days.

Renewal Criteria: Renewal of therapy is not allowed.

### 3. Noctiva

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

Manual PA criteria: Coverage will be approved if all criteria are met:

- The patient  $\geq 50$  years old (only the low dose is allowed for patients  $> 65$  years old)
- Causes of nocturia have been evaluated, nocturnal polyuria is confirmed with a 24-hour urine collection, and the patient has experienced at least two nocturia episodes per night for  $\geq 6$  months
- The patient is not currently taking any of the following medications:
  - loop diuretics, thiazide diuretics, systemic or inhaled corticosteroids, lithium, alpha1-adrenoceptor antagonists, 5-alpha reductase inhibitors (5-ARIs), anticholinergics, antispasmodics, sedative/hypnotic agents, NSAIDs, selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), antidepressants, anti-epileptics, opioids, or SGLT2s
- The patient has normal sodium level (135-145 meq/L) prior to the initiation of therapy, the sodium level is rechecked after one week of therapy, and another sodium level is rechecked after one month of therapy
- The patient does not have the following conditions:
  - acute or chronic rhinitis
  - atrophy of nasal mucosa
  - renal impairment (eGFR  $< 50$  mL/min)
  - hyponatremia or history of hyponatremia
  - polydipsia
  - nocturnal enuresis
  - syndrome of inappropriate antidiuretic hormone (SIADH)
  - congestive heart failure (New York Heart Association II-IV)
  - uncontrolled hypertension or uncontrolled diabetes mellitus

Non-FDA-approved uses are not approved.  
PA expires in six months.

Renewal criteria: Coverage will be approved for an additional six months if all of the following apply:

- Patient has not developed any of the above conditions
- Patient is not taking any of the above medications
- Patient has shown a reduction in nocturia episodes

#### **4. Bonjesta**

Manual PA criteria apply to all new users of Bonjesta.

Manual PA criteria: Bonjesta is approved if all criteria are met:

- The patient has a diagnosis of nausea and vomiting associated with pregnancy
- The patient has tried at least one non-pharmacologic treatment (for example, ginger, acupressure, high protein bedtime snack) and failed to obtain relief of symptoms
- The patient has tried OTC doxylamine and pyridoxine and failed to obtain relief of symptoms
- The provider has considered a change to an alternate anti-emetic (e.g., ondansetron) prior to prescribing Bonjesta

Non-FDA-approved uses are not approved.  
PA will expire after nine months.

#### **5. Steglatro, Segluromet, and Steglujan**

Manual PA criteria apply to all new and current users of Steglatro, Segluromet, and Steglujan.

Manual PA criteria: Coverage will be approved if all criteria are met:

- For Steglatro and Steglujan: The patient must have had an inadequate response or experienced significant adverse events, or have a contraindication to metformin AND
  - For Steglatro, Segluromet, and Steglujan: The patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, and Synjardy XR) and had an inadequate response or experienced significant adverse events, or have a contraindication to empagliflozin OR
  - For Steglujan: The patient must have had an inadequate response to sitagliptin alone

Non-FDA-approved uses are not approved.  
PA does not expire.

#### **6. Lonhala Magnair**

Manual PA is required for all new and current users of Lonhala Magnair inhalation solution (starter kit and refill kit).

Lonhala Magnair is approved if all criteria are met:

- The patient has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) AND
- The patient has tried and failed an adequate course of a nebulized Short-Acting Muscarinic Antagonist (e.g., ipratropium) AND
- The patient has tried and failed an adequate course of Spiriva Respimat AND
- The patient has tried and failed an adequate course of therapy of at least one of the following dry powder inhalers: Tudorza Pressair, Incruse Ellipta, Spiriva Handihaler, or Seebri Neohaler OR
- The patient cannot generate the peak inspiratory flow needed to activate at least one of the following dry powder inhalers: Tudorza Pressair, Incruse Ellipta, Spiriva Handihaler, or Seebri Neohaler

Non-FDA-approved uses are not approved.  
PA does not expire.

## 7. Imbruvica tablets and capsules

Manual PA criteria apply to all new users of Imbruvica tablets and capsules.

Manual PA criteria: Coverage will be approved if all criteria are met:

- Imbruvica capsules are the DoD-preferred formulation for Imbruvica.
  - **If the prescription is for Imbruvica capsules, please continue to the criteria below.**
  - **If the prescription is for Imbruvica tablets, provide documentation as to why the capsule formulation cannot be used, and then continue with the criteria below.**
- The patient is  $\geq 18$  years old
- The patient has laboratory evidence of and pathologic confirmation of one of the following:
  - Mantle Cell Lymphoma
  - Marginal Zone Lymphoma
  - Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia  $\pm 17p$  deletion
  - Waldenström's macroglobulinemia
  - Chronic Graft versus Host Disease
- Imbruvica is prescribed by or in consultation with a hematologist/oncologist

Non-FDA-approved uses are not approved.  
PA does not expire.

## 8. Rhopressa

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

Manual PA criteria: Rhopressa is approved if all criteria are met:

- The patient has a diagnosis of ocular hypertension or open-angle glaucoma
- The prescription is written by an ophthalmologist or an optometrist
- The patient has had a trial of appropriate duration of two different formulary options from different glaucoma drug classes, in combination or separately, and has not reached intraocular pressure target goals as defined by the provider. The drug classes include:
  - prostaglandin analogs (latanoprost or bimatoprost)
  - beta blockers (Betoptic, Betoptic-S, Ocupress, Betagan, Optipranolol)
  - alpha2-adrenergic agonists (brimonidine, apraclonidine)
  - topical carbonic anhydrase inhibitors [dorzolamide (Trusopt)]

Non-FDA-approved uses are not approved.

PA does not expire.

## 9. Zypitamag

All new users of Zypitamag must try a preferred statin at appropriate LDL lowering first.

Automated PA Criteria:

- The patient has received a prescription for a preferred agent (generic atorvastatin, simvastatin, pravastatin, fluvastatin, lovastatin, pravastatin or rosuvastatin) targeting similar LDL reduction (LDL lowering between 30% to 50%, LDL lowering < 30%) at any MHS pharmacy point of service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days

AND

Manual PA Criteria: If automated criteria are not met, Zypitamag is approved (e.g., trial of generic statin is NOT required) if:

- The patient has tried a preferred statin with similar LDL reduction (moderate or low intensity) and was unable to tolerate it due to adverse effects
- The patient is taking a drug that is metabolized by CYP3A4 is unable to take pravastatin or rosuvastatin

PA does not expire.

## 10. Symdeko

Manual PA criteria apply to all new users of Symdeko.

Manual PA Criteria: Symdeko is approved if ALL of the following criteria are met:

- Symdeko is prescribed for the treatment of cystic fibrosis in patient ages 12 years and older.
- The patient meets one of the following criteria:
  - The patient is homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test.
  - The patient has at least one specific gene mutation in the CFTR gene that is responsive to Symdeko as detected by an FDA-approved CF mutation test.
  - The CF-related gene mutation, based on FDA-approved testing, must be documented.
- Symdeko is not approved for use in combination with other CFTR modulators (e.g., Orkambi, Kalydeko).

Non-FDA-approved uses are not approved.  
PA does not expire.

**D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service.

**IX. NEWLY APPROVED DRUGS PER 32 CFR 199.21(G)(5)**

*BAP Comments*

**A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation**

The P&T Committee recommended the following:

- UF:
  - Erleada
  - Biktarvy
  - Symfi
  - Symfi Lo
  - Imbruvica
  - Admelog
  - Cimduo
  - Rhopressa
  - Symdeko
  - Firvanq
- NF:
  - Impoyz
  - Noctiva
  - Bonjesta

- Steglatro
- Segluromet
- Steglujan
- Lonhala Magnair
- Zypitamag
- Solosec

*BAP Comment:*       Concur       Non-concur

**Additional Comments and Dissension**

**B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria**

The P&T Committee recommended the PA criteria for the new drugs as stated previously. The recommendations are as follows:

- Applying the same manual PA criteria for Steglatro, Segluromet, and Steglujan in new and current users as is currently in place for the other non-step-preferred SGLT2 inhibitors. Patients must first try the step-preferred SGLT2 inhibitor.
- Applying the same step therapy and manual PA criteria to new and current users of Zypitamag as is currently in place for Livalo.
- Applying manual PA criteria to new and current users of Impoyz cream, Lonhala Magnair inhalation solution, Noctiva nasal spray, and Rhopressa ophthalmic solution.
- Applying manual PA criteria to new users of Bonjesta, Erleada, Symdeko, and Imbruvica tablets and capsules.
- Requiring a trial of Imbruvica capsules first in new users, prior to use of the tablets.

*BAP Comment:*       Concur       Non-concur

**Additional Comments and Dissension**

**C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation**

The P&T Committee recommended an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service.

*BAP Comment:*

Concur

Non-concur

Additional Comments and Dissension

## X. UTILIZATION MANAGEMENT

### *P&T Comments*

#### A. PA Criteria and Step Therapy

The P&T Committee recommended updates to the step therapy and manual PA criteria for several drugs due to a variety of reasons, including expanded FDA indications and feedback from the field. The updated manual PAs outlined below will apply to new users.

- 1. Antiemetic-Antivertigo Agents: doxylamine succinate and pyridoxine hydrochloride ER (Diclegis)**—Diclegis PA criteria were first recommended at the August 2014 DoD P&T Committee Meeting. PA criteria were reviewed and updated to require a trial of both OTC doxylamine and pyridoxine before use of Diclegis.
- 2. Targeted Immunomodulatory Biologics (TIBs): abatacept (Orencia)**—The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Orencia was recently approved by the FDA for treatment of polyarticular Juvenile Idiopathic Arthritis (JIA) in patients two year or older. PA criteria were updated to add the additional indication JIA in pediatric patients.
- 3. Targeted Immunomodulatory Biologics (TIBs): secukinumab (Cosentyx)**—Cosentyx was approved by the FDA in January 2015 for treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Since then, three additional indications were approved by the FDA: psoriatic arthritis, psoriasis of the scalp, and most recently ankylosing spondylitis in January 2018. The PA criteria were updated to add the additional FDA indications.
- 4. Oncological Agents: abiraterone acetate (Zytiga)**—In April 2011, the FDA approved Zytiga for use in combination with prednisone for the treatment of metastatic castration-resistant prostate cancer in patients who have received prior chemotherapy containing docetaxel. PA criteria for Zytiga were recommended at the November 2012 meeting, consistent with the FDA labeling. The FDA has subsequently updated the approved labeling for patients with metastatic high-risk castration-sensitive prostate cancer receiving concomitant prednisone. The PA criteria were updated to add the additional FDA indication and to require that the patient receive concomitant therapy with a gonadotropin-releasing hormone (GnRH) analog or have had bilateral orchiectomy.
- 5. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists/Insulin Combination: insulin glargine/lixisenatide (Xultophy) and insulin degludec/liraglutide (Soliqua)**—Xultophy and Soliqua were reviewed in May 2017, and step therapy and manual PA criteria applied. Insulin glargine (Lantus) is the

preferred basal insulin. The Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA) class was reviewed in February 2018, and exenatide weekly (Bydureon/BCise) and dulaglutide (Trulicity) were designated as the preferred products. The PA criteria for Xultophy and Soliqua were updated to include provider acknowledgement of the preferred basal insulin and GLP1RAs.

- 6. Parkinson’s Disease Drugs: amantadine hydrochloride extended release (Gocovri)**—Gocovri was reviewed as a new drug during the November 2017 P&T Committee meeting, and PA criteria were recommended requiring the patient to have failed and tried amantadine immediate release (IR) 200 mg BID. Since this recommendation, feedback was received from neurologists that patients are not always able to tolerate a 400 mg daily dose of amantadine immediate release (IR). The PA criteria for Gocovri were updated to allow a trial of a lower dose of amantadine IR (300 mg daily in divided doses) to qualify for Gocovri.
- 7. Oncological Agents: abemaciclib (Verzenio)**—Verzenio was first reviewed at the November 2017 P&T Committee meeting, and PA criteria were recommended for treatment of metastatic breast cancer. The PA criteria were updated to add the new FDA indication for use in postmenopausal women when used in combination with an aromatase inhibitor (i.e., anastrozole/letrozole) as initial endocrine-based therapy.
- 8. Targeted Immunomodulatory Biologics (TIBs): apremilast (Otezla)**—The current PA criteria for the TIBs does not allow combination therapy with other TIBs, due to overlapping mechanisms of action and risk of enhanced toxicity. Otezla has a mechanism of action unique to the TIBs; it is a phosphodiesterase-4 (PDE4) inhibitor, which is an enzyme that breaks down cyclic adenosine monophosphate (cAMP). FDA labeling for Otezla does not specify that it cannot be utilized in combination with other TIB agents, and it has a low risk of immunosuppression. The PA criteria for Otezla were updated to allow use in combination with the other TIBs (e.g., in a patient requiring Humira for treatment of RA and Otezla for treatment of plaque psoriasis), if the provider provides documented evidence as to why combination therapy is required.

#### **B. Updated Manual PA Criteria**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Diclegis, Orencia, Cosentyx, Zytiga, Xultophy, Soliqua, Gocovri, Verzenio, and Otezla. All updated PA criteria apply to new users.

#### **C. Updated Manual PA Criteria and PA Renewal Criteria—PA Implementation Plan**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) updates to the current PAs for Diclegis, Orencia, Cosentyx, Zytiga, Xultophy, Soliqua, Gocovri, Verzenio, and Otezla become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.

### **XI. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA AND STEP THERAPY**

#### ***BAP Comments***



**A. Updated Manual PA Criteria and PA Renewal Criteria**

The P&T Committee recommended updates to the manual PA criteria for Diclegis, Orenzia, Cosentyx, Zytiga, Xultophy, Soliqua, Gocovri, Verzenio, and Otezla, as stated above.

<i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur
Additional Comments and Dissension

**B. Updated Manual PA Criteria and PA Renewal Criteria—PA Implementation Plan**

The P&T Committee recommended the updates to the PA criteria for the drugs discussed above become effective on the first Wednesday two weeks after the signing of the minutes.

<i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur
Additional Comments and Dissension

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

*P&T Comments*

The P&T Committee reviewed four drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were 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.

**A. Drugs Designated as NF**

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following products be designated NF on the UF:

- Aurobindo Pharma: armodafinil (*New Drug Application-authorized generic*) 200 mg tablet
- Quinn Pharmaceuticals: mercaptopurine (*NDA-authorized generic*) 50 mg tablet
- Noden Pharma: aliskiren (Tekturna) 150 mg tablet; 300 mg tablet
- Noden Pharma: aliskiren-hydrochlorothiazide (Tekturna HCT) 150-12.5 mg tablet, 150-25 mg tablet, 300-12.5 mg tablet, 300-25 mg tablet

**B. Preauthorization Criteria**

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs of armodafinil, mercaptopurine, Tekturna, and Tekturna HCT:

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.

**NOTE:** Should the mail order requirement impact availability of a drug, the P&T Committee will allow an exception to the Section 703 rule.

**C. Implementation Plan**

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following: 1) an effective date of the first Wednesday after a 90-day implementation period for the Section 703 non-compliant NDCs of armodafinil, mercaptopurine, Tekturna, and Tekturna HCT and 2) DHA send letters to beneficiaries affected by this decision.

**XIII. SECTION 703 NDAA FY 2008**

*BAP Comments*

**A. Drugs Designated NF**

The P&T Committee recommended the following four products be designated NF on the UF: armodafinil, mercaptopurine, Tekturna, and Tekturna HCT.

<i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur
<b>Additional Comments and Dissension</b>

**B. Pre-Authorization Criteria**

The P&T Committee recommended the following pre-authorization criteria for the four Section 703 non-compliant drugs:

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.

<i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur
<b>Additional Comments and Dissension</b>

**C. Implementation Period**

The P&T Committee recommended the following: 1) an effective date of the first Wednesday after a 90-day implementation period and 2) DHA send letters to beneficiaries affected by this decision.

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur	
			<b>Additional Comments and Dissension</b>

**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 2018	<b>Pancreatic Enzyme Replacement Therapy</b>	UF Class Review  Class previously reviewed Feb 2011, Feb 2014	<u>UF Step-Preferred</u> <ul style="list-style-type: none"> <li>▪ Creon</li> </ul> <u>UF Non-Step-Preferred</u> <ul style="list-style-type: none"> <li>▪ Viokace</li> </ul>	<u>NF Non-Step-Preferred</u> <ul style="list-style-type: none"> <li>▪ Pancreaze</li> <li>▪ Pertzye</li> <li>▪ Ultresa</li> <li>▪ Zenpep</li> </ul>	90 days	<ul style="list-style-type: none"> <li>▪ A trial of Creon is required first in all new and current users</li> <li>▪ Manual PA criteria applies to all new and current users</li> <li>▪ No PA required for Creon</li> </ul> <u>Unique Users Affected</u> Mail 558 MTF 237 Retail 487 Total 1,282
May 2018	<b>Growth Stimulating Agents</b>	UF Class Review  Class previously reviewed in Aug 2007	<u>UF Step-Preferred</u> <ul style="list-style-type: none"> <li>▪ Norditropin FlexPro</li> </ul> <u>UF Non-Step-Preferred</u> <ul style="list-style-type: none"> <li>▪ Omnitrope</li> <li>▪ Zomacton</li> </ul>	<u>NF Non-Step-Preferred</u> <ul style="list-style-type: none"> <li>▪ Genotropin</li> <li>▪ Humatrope</li> <li>▪ Nutropin</li> <li>▪ Saizen</li> <li>▪ Serostim</li> </ul>	90 days	<ul style="list-style-type: none"> <li>▪ Must try Norditropin FlexPro first in all new and current users. Then must use Omnitrope and Zomacton (either order) before moving to NF agents (Genotropin, Humatrope, Nutropin, Saizen, and Serostim)</li> <li>▪ Manual PA criteria applies to all new and current users</li> </ul> <u>Unique Users Affected</u> Mail 1,242 MTF 515 Retail 73 Total 1,830

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implement Date	Notes and Unique Users Affected
May 2018	<b>GI-2 Agents Opioid Induced Constipation (OIC) Subclass</b>	UF Class Review  Subclass not reviewed; class reviewed Nov 2015	<u>UF</u> <ul style="list-style-type: none"> <li>▪ naldemedine (Symproic)</li> <li>▪ naloxegol (Movantik)</li> </ul>	<u>NF</u> <ul style="list-style-type: none"> <li>▪ methylnaltrexone (Relistor) tablet and injection</li> </ul>	60 days	<ul style="list-style-type: none"> <li>▪ Manual PAs and QLs apply</li> <li>▪ PA applies: must try two OTC laxatives before use of an OIC drug.</li> <li>▪ Must try Movantik, Symproic and Amitiza before use of the nonformulary product Relistor</li> </ul> <p><u>Unique Users Affected:</u>  Mail 114  MTF 38  Retail 163  Total 315</p>