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—HEPATITUS C VIRUS (HCV) DRUGS

P&T Comments

A. HCV Drugs: Direct-Acting Antivirals (DAAs) Subclass—Relative Clinical Effectiveness and Conclusion

Background—The HCV DAAs Subclass was last reviewed for UF placement in May 2015. The standard of care for all HCV genotypes is oral therapy consisting of a cocktail of DAAs that are most commonly used in fixed-dose combinations and are based on their synergistic mechanisms of action. Hepatitis C treatments are classified into sofosbuvir-based regimens and non-sofosbuvir (protease inhibitor) based regimens:

- **Sofosbuvir-Based Regimens**:
  - sofosbuvir (Sovaldi) plus daclatasvir (Daklinza)
  - sofosbuvir (Sovaldi) plus simeprevir (Olysio)
  - sofosbuvir/ledipasvir (Harvoni)
  - sofosbuvir/velpatasvir (Epclusa)

  Note that sofosbuvir is not used as monotherapy.

- **Non-Sofosbuvir (Protease Inhibitor) Based Regimens**:
  - paritaprevir/ritonavir/ombitasvir and dasabuvir (Viekira Pak)
  - paritaprevir/ritonavir/ombitasvir/dasabuvir extended release (Viekira XR)
  - paritaprevir/ritonavir/ombitasvir (Technivie)
  - grazoprevir/elbasvir (Zepatier)

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- HCV Genotype 1 (GT1): There are currently six regimens recommended for treatment of genotype 1 chronic HCV: Epclusa, Harvoni, Sovaldi plus Daklinza, Sovaldi plus Olysio, Viekira (Viekira Pak and Viekira XR), and Zepatier. These drugs provide all-oral (interferon-free) therapies with sustained virologic response at 12 weeks (SVR12) ranging from 94% to 100%. Viekira Pak and Viekira XR require co-administration with ribavirin in some patients. GT1 is the most common HCV genotype in the United States.
- HCV Genotype 2 (GT2) and Genotype 3 (GT3)
    - Epclusa or Sovaldi plus Daklinza are regimens for patients with GT2 or GT3. Epclusa is the primary treatment regimen for both genotypes, as it represents an all-oral (interferon-free), and ribavirin-free therapy with SVR12 generally exceeding 95%. The only head-to-head trial of the HCV DAAs (ASTRAL-2) demonstrated superiority of Epclusa to Sovaldi plus ribavirin in patients with GT2. Genotype 3 cirrhotic patients are the most difficult to treat and require the addition of ribavirin to Epclusa.
    - For GT3, Sovaldi plus Daklinza represents an all-oral (interferon-free) therapy with SVR12 rates generally exceeding 89%. The SVR12 is significantly reduced in patients with cirrhosis, thus Sovaldi plus Daklinza is no longer the most effective regimen for this population.
- HCV Genotype 4 (GT4): Epclusa, Harvoni, Zepatier, and Technivie are regimens for patients with genotype 4 chronic HCV. Technivie is solely indicated for patients with GT4. It is only used in patients without cirrhosis and is indicated in combination with ribavirin.
- Ribavirin may be used with some of the other HCV DAAs indicated in HCV GT1 or GT4 to shorten the course of therapy, or when certain baseline factors are present (e.g., treatment experienced patients or those with cirrhosis).
- There are no studies directly comparing Sovaldi plus Daklinza, Epclusa, Harvoni, Viekira, and Zepatier. Indirect comparisons of the individual clinical trials enrolling similar patient populations (i.e., treatment-naïve or treatment-experienced, with or without cirrhosis) show similar efficacy as assessed by SVR12.
- Due to the rapidly evolving field of hepatitis C, the use of these products outside of their FDA-labeled indications is common. The American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) Hepatitis C Guidelines (www.HCVguidelines.org) is a resource that experts reference for the most current information on HCV treatment.
- In the absence of head-to-head trials with all the DAAs, HCV treatment is based on individual patient characteristics, such as the HCV genotype and subtype, treatment history, stage of hepatic fibrosis, presence or absence of resistance-associated variants (RAVs), comorbidities, concomitant medications, and cost.

B. HCV Drugs: DAAs Subclass—Relative Cost-Effectiveness Analysis and Conclusion

Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that sofosbuvir/ledipasvir (Harvoni) was the most cost-effective HCV DAA regimen, followed by grazoprevir/elbasvir (Zepatier), sofosbuvir/velpatasvir (Epclusa), paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira Pak), paritaprevir/ritonavir/ombitasvir/dasabuvir XR (Viekira XR), sofosbuvir (Sovaldi), paritaprevir/ritonavir/ombitasvir (Technivie), daclatasvir (Daklinza), and simeprevir (Olysio).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating sofosbuvir/ ledipasvir (Harvoni) as formulary and step-preferred, with all other DAA agents as formulary and non step-preferred, demonstrated the largest estimated cost avoidance for the Military Health System (MHS).

C. HCV Drugs: DAAs Subclass—UF Recommendation

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- **UF and Step-Preferred:**
  - sofosbuvir/ledipasvir (Harvoni)
- **UF and Non Step-Preferred:**
  - daclatasvir (Daklinza)
  - grazoprevir/elbasvir (Zepatier)
  - paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira Pak)
  - paritaprevir/ritonavir/ombitasvir/dasabuvir ER (Viekira XR)
  - paritaprevir/ritonavir/ombitasvir (Technivie)
  - simeprevir (Olysio)
  - sofosbuvir (Sovaldi)
  - sofosbuvir/velpatasvir (Epclusa)
- **NF:** No products

Note that as part of this recommendation, all new users of an HCV DAA are required to try Harvoni first.

D. HCV Drugs: DAAs Subclass—Manual Prior Authorization (PA) Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new users of a HCV DAA prior to use of a non step-preferred product (Daklinza, Epclusa, Olysio, Sovaldi, Technivie, Viekira XR, Viekira Pak, Zepatier). The step therapy requirement for a trial of Harvoni in all new users is included in the manual PA criteria. A manual PA is also required for Harvoni. Coverage for the HCV DAAs is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

A trial of Harvoni is not required if:

- Contraindications exist to Harvoni (advanced kidney disease with a creatinine clearance < 30 mL/min).
- The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is not expected with the requested non step-preferred HCV DAA (e.g., concurrent use of high-dose proton pump inhibitor).
- The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is not expected with the requested non step-preferred HCV DAA.
- There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 or HCV GT3).

Full PA Criteria

1. HCV DAA Drug: sofosbuvir/ledipasvir (Harvoni)

   Coverage approved for patients ≥ 18 years with:

   - A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
   - Laboratory evidence of chronic hepatitis C
     - Document HCV RNA viral load
   - Has hepatitis C genotype 1, 4, 5 or 6
   - Does not have advanced kidney disease (CrCl < 30 mL/min)

   Applies to new users only

   Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

   PA expires after 365 days.

2. HCV DAA Drug: sofosbuvir (Sovaldi)

   Manual PA criteria:

   - Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for sofosbuvir (Sovaldi) unless:
     - Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min])
     - The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with the requested non step- preferred HCV DAA (e.g., concurrent high-dose PPI)
     - The patient has experienced or is likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step- preferred HCV DAA

- There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 or GT3)

AND

Coverage approved for patients ≥ 18 years with:

- A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Laboratory evidence of chronic hepatitis C
  - Document HCV RNA viral load
- Has hepatitis C genotype 1, 2, 3 or 4
- Used in combination with another HCV DAA (not used as monotherapy)
- Does not have advanced kidney disease (CrCl < 30 mL/min)

Applies to new users only.

Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

PA expires after 365 days.

3. HCV DAA Drug: simeprevir (Olysio)

Manual PA criteria:

- Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for simeprevir (Olysio) if:
  - Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min])
  - The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
  - The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step- preferred HCV DAA
  - There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)

AND

Coverage approved for patients ≥ 18 years with:

- A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Laboratory evidence of chronic hepatitis C
  - Document HCV RNA viral load
- Has hepatitis C genotype 1
- Used in combination with sofosbuvir (not used as monotherapy)
- Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C)

Applies to new users only.

Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

PA expires after 365 days.

4. HCV DAA Drug: daclatasvir (Daklinza)

Manual PA criteria:

- Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for daclatasvir (Daklinza) if:
    - Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min])
    - The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
    - The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step- preferred HCV DAA
    - There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)

AND

Coverage approved for patients ≥ 18 years with:

- A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Laboratory evidence of chronic hepatitis C
    - Document HCV RNA viral load
- Has hepatitis C genotype 3
- Used in combination with sofosbuvir (not used as monotherapy)
- Does not have advanced kidney disease (CrCl < 30 mL/min)

Applies to new users only.

Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

PA expires after 365 days.

5. HCV DAA Drug: sofosbuvir/velpatasvir (Epclusa)

Manual PA criteria:

- Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for sofosbuvir / velpatasvir (Epclusa) if:

- Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min])
- The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
- The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step- preferred HCV DAA
- There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)

AND

Coverage approved for patients ≥ 18 years with:

- A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Laboratory evidence of chronic hepatitis C
  - Document HCV RNA viral load
- Has hepatitis C genotype 1, 2, 3, 4, 5 or 6
- Does not have advanced kidney disease (CrCl < 30 mL/min)

Applies to new users only.

Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

PA expires after 365 days.

6. HCV DAA Drug: paritaprevir/ritonavir/ombitasvir (Technivie)

Manual PA criteria:

- Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for paritaprevir / ritonavir / ombitasvir (Technivie) if:
  - Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min])
  - The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
  - Has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA
  - There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)

AND

Coverage approved for patients ≥ 18 years with:

- A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Laboratory evidence of chronic hepatitis C
    - Document HCV RNA viral load
- Has hepatitis C genotype 4
- Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C)
- Does not have cirrhosis

Applies to new users only.

Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

PA expires after 365 days.

7. HCV DAA Drugs: paritaprevir/ritonavir/ombitasvir/dasabuvir Pak (Viekira Pak) and paritaprevir/ritonavir/ombitasvir/dasabuvir XR (Viekira XR)

   Manual PA criteria:

   - Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for paritaprevir / ritonavir / ombitasvir / dasabuvir Pak (Viekira Pak) or paritaprevir / ritonavir/ombitasvir / dasabuvir XR (Viekira XR) if:
       - Contraindications exist to Harvoni (e.g., advanced kidney disease [CrCl < 30 mL/min])
       - The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
       - The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step- preferred HCV DAA
       - There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)

   AND

   Coverage approved for patients ≥ 18 years with:

   - A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
   - Laboratory evidence of chronic hepatitis C
       - Document HCV RNA viral load
   - Has hepatitis C genotype 1
   - Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C)

   Applies to new users only.

Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

PA expires after 365 days.

8. HCV DAA Drug: grazoprevir/elbasvir (Zepatier)

   Manual PA criteria:

   - Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for grazoprevir / elbasvir (Zepatier) if:
     - Contraindications exist to Harvoni (e.g., advanced kidney disease [CrCl < 30 mL/min])
     - The patient is likely to experience significant adverse reactions or drug-drug interaction to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
     - The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step- preferred HCV DAA
     - There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)

   AND

   Coverage approved for patients ≥ 18 years with:

   - The prescription is written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
   - Laboratory evidence of chronic hepatitis C
     - Document HCV RNA viral load
   - Has hepatitis C genotype 1 or 4
   - Testing for NS5A resistance in HCV GT 1a prior to treatment
   - Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C)

   Applies to new users only.

   Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

   PA expires after 365 days.

E. HCV Drugs: DAAs Subclass—UF and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation.

III. UF CLASS REVIEWS—HCV DRUGS

BAP Comments

A. HCV Drugs: DAAs Subclass—UF Recommendation

The P&T Committee recommended the following:

- **UF and Step-Preferred:**
  - Harvoni

- **UF and Non Step-Preferred:**
  - Daklinza
  - Epclusa
  - Olysio
  - Sovaldi
  - Technivie
  - Viekira Pak
  - Viekira XR
  - Zepatier

- **NF:** No products

Note that as part of this recommendation, all new users of an HCV DAA are required to try Harvoni first.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. HCV Drugs: DAAs Subclass—Manual PA Criteria

The P&T Committee recommended manual PA criteria for new users of a HCV DAA prior to use of a non step-preferred product. The step therapy requirement for a trial of Harvoni in all new users is included in the manual PA criteria. A manual PA is also required for Harvoni. Coverage for the HCV DAA products is only allowed for FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

A trial of Harvoni is not required if:

- Contraindications exist to Harvoni (advanced kidney disease with a creatinine clearance < 30 mL/min).

- The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is not expected with the requested non step-preferred HCV DAA (e.g., concurrent use of high-dose proton pump inhibitor).
- The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is not expected with the requested non step-preferred HCV DAA.
- There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 or HCV GT3).

The full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. HCV Drugs: DAAs Subclass—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—ANTIBIOTICS

P&T Comments

A. Antibiotics: Tetracycline Drugs Subclass—Relative Clinical Effectiveness and Conclusion

Background—The P&T Committee evaluated the tetracycline antibiotics for formulary placement. Doxycycline hyclate (Vibramycin, Vibra-Tabs) and minocycline immediate release (Minocin) are available in generic formulations. The newer entrants to the subclass all contain doxycycline or minocycline as the active ingredient, and are marketed with different salt forms, special packaging, release mechanisms (immediate release [IR] versus sustained release [SR] versus delayed release [DR]), or dosing strategies from the traditional generic products.

The clinical and cost-effectiveness evaluations focused on the use of doxycycline and minocycline for treatment of acne and rosacea. Use of the tetracycline antibiotics for treating infections was not addressed in the clinical review. The clinical effectiveness of tetracycline and demeclocycline were not reviewed; these products will remain on the UF due to unique clinical niches for treating rickettsial infections and syndrome of inappropriate antidiuretic hormone (SIADH) secretion, respectively. Additionally, use of doxycycline for deployment purposes is not affected by this formulary recommendation.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following for the tetracyclines:

- Tetracycline, minocycline, and doxycycline are all effective in the treatment of moderate to severe acne and rosacea.
- Professional treatment guidelines for papulopustular rosacea recommend doxycycline 50 mg to 100 mg, minocycline 50 mg to 100 mg, or doxycycline 40 mg IR/DR (Oracea) as second-line therapy following topical medications, but there are concerns of conflict of interest with the guideline's authors.
- A 2015 Cochrane review evaluating doxycycline for treating rosacea found no significant difference in effectiveness between doxycycline 100 mg and 40 mg IR/DR (Oracea). There were significantly fewer adverse effects with the 40 mg lower dose; however, the results were based on low quality evidence and the clinical relevance of these results is questionable. There was high quality evidence to support efficacy of generic doxycycline 100 mg.
- Solodyn was originally developed as an extended-release (ER) minocycline formulation to reduce potential vestibular adverse effects associated with rapid absorption of generic minocycline IR formulations. However, pharmacokinetic studies showed the absorption profile for Solodyn does not differ significantly from that of minocycline IR.
- There are no head-to-head trials comparing the efficacy or safety of minocycline ER (Solodyn) with generic minocycline IR products for treating acne. A Cochrane review from 2015 concluded there was no data to support minocycline ER formulations are safer than standard minocycline IR preparations.
- Overall, there is little evidence to support advantages of the newer doxycycline and minocycline products over the traditional generic formulations in terms of salt (monohydrate versus hyclate), dosage form (tablet versus capsule versus scored tablets), release mechanisms (IR versus ER versus DR), or dosing strategy (1 mg/kg dosing with minocycline ER versus traditional 50 mg or 100 mg dosing).

B. Antibiotics: Tetracycline Drugs Subclass—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that doxycycline monohydrate (generic), doxycycline hyclate (generic), and minocycline IR (generic) were the most cost-effective oral

tetracyclines, followed by doxycycline 40 mg IR/DR (Oracea brand), doxycycline hyclate modified polymer coat (Doryx MPC), tetracycline (generic), doxycycline hyclate (Morgidox), demeclocycline (generic), doxycycline 40 mg IR/DR (Oracea generic), doxycycline hyclate (Targadox), doxycycline monohydrate (Monodoxyne NL), minocycline ER (Solodyn generic), minocycline ER (Solodyn brand), doxycycline hyclate (Acticlate), doxycycline hyclate (Doryx), doxycycline monohydrate (Monodox), and doxycycline monohydrate (Adoxa), in order from most cost effective to least cost effective.

- BIA was performed to evaluate the potential impact of designating selected agents as formulary (and step-preferred) or NF (and non step-preferred) on the UF. All modeled scenarios show savings against the current baseline. BIA results showed that designating doxycycline monohydrate (generic), doxycycline hyclate (generic), and minocycline (generic) as formulary and step-preferred, with the remaining products as NF and non step-preferred demonstrated the most cost-effective option for the MHS.

C. Antibiotics: Tetracycline Drugs Subclass—UF Recommendation

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

- UF and Step-Preferred:
  - doxycycline hyclate IR 50 mg, 75 mg, 100 mg, 150 mg, 200 mg tabs and caps (generic)
  - doxycycline monohydrate IR 50 mg, 75 mg, 100 mg, 150 mg, 200 mg tabs and caps (generic)
  - minocycline IR 50mg, 75 mg, 100 mg tabs and caps (generic)
- NF and Non Step-Preferred:
  - doxycycline hyclate 75 mg unscored and 150 mg scored tabs, and 75 mg caps (Acticlate)
  - doxycycline hyclate 50 mg, 100 mg, 150 mg, and 200 mg DR tabs (Doryx and generic)
  - doxycycline hyclate 60 mg and 120 mg DR modified polymer coat tabs (Doryx MPC)
  - doxycycline hyclate 50 mg tabs (Targadox)
  - doxycycline hyclate 50 mg, 100 mg caps (Morgidox)
  - doxycycline monohydrate 40 mg IR/DR caps (Oracea and generics)
  - doxycycline monohydrate 50 mg, 75 mg, 150 mg caps (Monodoxyne NL)
  - doxycycline monohydrate 50 mg, 75 mg, 100 mg tabs, 150 mg caps (Adoxa)
  - doxycycline monohydrate 75 mg, 100 mg caps (Monodox)
  - minocycline ER 45 mg, 90 mg, 135 mg tabs (generics)
  - minocycline ER 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg tabs (Solodyn)

- Note that as part of this recommendation, all new users of a non step-preferred product will be required to try a generic step-preferred doxycycline and/or minocycline product first.

- UF and not subject to the Step Therapy requirements:
  - doxycycline calcium/monohydrate 25 mg/5 mL, 50 mg/5 mL suspension (generic)
  - tetracycline hydrochloride 250 mg, 500 mg caps and 125 mg/5 mL suspension (generic)
  - demeclocycline hydrochloride 150 mg and 300 mg caps (generic)
  - Note that children under the age of 13 are exempt from step therapy.

D. Antibiotics: Tetracycline Drugs Subclass—Automated PA (Step Therapy) and Manual PA Criteria

The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 0 absent) step therapy and manual PA criteria for the subclass. All new and current users of a NF, non step-preferred doxycycline or minocycline product are required to first try one generic doxycycline IR (not including doxycycline 40 mg IR/DR) and one generic minocycline IR product for acne and rosacea, prior to use of the non step-preferred products.

The branded products of Doryx, Doryx MPC, and Acticlate will be allowed for treatment of susceptible infections, if the patient has failed or had clinically significant adverse events to generic doxycycline IR products.

Note that children under age 13 are exempt from the step therapy requirement, as are patients receiving tetracycline, doxycycline suspension, or demeclocycline.

<u>Full PA Criteria</u>

Oral Tetracycline Agents:
- doxycycline hyclate 75 mg and 150 mg (Acticlate)
- doxycycline hyclate 50, 100, 150, 200 mg DR (Doryx and generic)
- doxycycline hyclate 60 mg and 120 mg DR modified polymer coat (Doryx MPC)
- doxycycline hyclate 50 mg (Targadox)
- doxycycline hyclate 50 mg, 100 mg (Morgidox)
- doxycycline monohydrate 40 mg IR/DR (Oracea and generics)
- doxycycline monohydrate 50 mg, 75 mg, 150 mg (Monodoxyne NL)
- doxycycline monohydrate 50mg, 75 mg, 100 mg tabs & 150 mg (Adoxa)
- doxycycline monohydrate 75 mg, 100 mg (Monodox)
- minocycline ER 45 mg, 90 mg, 135 mg ER (generics)
- minocycline DR 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg (Solodyn)

Prior authorization applies to both new and current users of non-preferred tetracycline oral agents.

Automated PA Criteria:

- Patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) **AND** one generic minocycline IR product at any Military Treatment Facility, retail network pharmacy, or the mail order pharmacy in the previous 180 days

Manual PA Criteria: If automated PA criteria are not met, the non step-preferred product is allowed if:

Acne Vulgaris or Rosacea

- For Acticlate, Doryx, Doryx MPC, Targadox, Monodox, Morgidox, Monodoxyne NL: The patient has tried and had an inadequate response to or failed to tolerate the following:
  - one generic immediate-release doxycycline product (hyclate or monohydrate salt) AND
  - one generic immediate-release minocycline product

- For Oracea and generic 40 mg IR/DR: The patient has rosacea with inflammatory lesions (papules and pustules) or ocular rosacea symptoms AND
  - has tried generic immediate-release doxycycline (does not include doxycycline 40 mg IR/DR) and had an inadequate response or could not tolerate it due to gastrointestinal adverse events AND
  - has not responded to topical rosacea treatments, including metronidazole 1% gel

- For Solodyn or generic minocycline ER: The patient has acne with inflammatory lesions AND
  - the patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events

Susceptible Infections

- For Doryx, Doryx MPC, and Acticlate: if used for susceptible infections, the patient has failed or had clinically significant adverse events to generic IR doxycycline

PA expires in 365 days.

E. Antibiotics: Tetracycline Drugs Subclass—UF and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 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.

V. UF CLASS REVIEWS—ANTIBIOTICS

BAP Comments

A. Antibiotics: Tetracycline Drugs Subclass—UF Recommendation

The P&T Committee recommended the following:

- UF and Step-Preferred:
  - doxycycline hyclate IR tabs and caps (generic)
  - doxycycline monohydrate IR tabs and caps (generic)
  - minocycline IR tabs and caps (generic)

- NF and Non Step-Preferred:
  - Acticlate
  - Doryx brand and generic
  - Doryx MPC
  - Targadox
  - Morgidox
  - Oracea brand and generics
  - Monodoxyne NL
  - Adoxa
  - Monodox
  - minocycline ER generics
  - Solodyn

- Note that as part of this recommendation, all new users of a non step-preferred product will be required to try a generic step-preferred doxycycline and/or minocycline product first.

- UF and not subject to the Step Therapy requirements:
  - doxycycline calcium/monohydrate suspension (generic)
  - tetracycline hydrochloride suspension (generic)
  - demeclocycline hydrochloride caps (generic)
  - Note that children under the age of 13 are exempt from step therapy.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Antibiotics: Tetracycline Drugs Subclass—Automated PA (Step Therapy) and Manual PA Criteria

The P&T Committee recommended step therapy and manual PA criteria for the subclass. All new and current users of a NF, non step-preferred doxycycline or minocycline product are required to first try one generic doxycycline IR (not including doxycycline

40 mg IR/DR) and one generic minocycline IR product for acne and rosacea, prior to use of the non step-preferred products.

The branded products of Doryx, Doryx MPC, and Acticlate will be allowed for treatment of susceptible infections, if the patient has failed or had clinically significant adverse events to generic doxycycline IR products.

Note that children under age 13 are exempt from the step therapy requirement, as are patients receiving tetracycline, doxycycline suspension, or demeclocycline.

The full automated and manual PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Antibiotics: Tetracycline Drugs Subclass—UF and PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

VI. INTERIM MEETING: UF CLASS REVIEWS—PROTON PUMP INHIBITORS (PPIs)

P&T Comments

A. PPIs—Relative Clinical Effectiveness and Conclusion

Background—Following the February 2017 DoD P&T Committee meeting, the Pharmacy Operations Division became aware of a contract cancellation that would significantly impact MHS expenditures for the PPI Drug Class. An interim meeting was held to determine the clinical and cost-effectiveness, and UF status of the PPIs. The PPIs were previously evaluated for UF status at the May 2007 meeting. Current automated PA (step therapy) requiring a trial of omeprazole, esomeprazole (Nexium), pantoprazole, or rabeprazole applies to new users presenting with a prescription for a nonformulary PPI.

Relative Clinical Effectiveness Conclusion—At the May 2007 meeting, the P&T Committee reviewed evidence across a wide range of disease states and, in summary, concluded that PPIs appear very similar with regard to efficacy, safety, and tolerability. Recent updates to the safety of the PPIs were presented at the November 2016 P&T Committee meeting. There have been three drug safety communications from the FDA relating to long-term safety concerns with the PPIs as a class. The P&T Committee did not find new clinical evidence that would alter the conclusion from 2007 that the PPIs are highly therapeutically interchangeable. Risks of long-term use (>1 year) without a clear indication for use could outweigh the benefits of the PPIs. Deprescribing should be considered for appropriate patients.

B. PPIs—Relative Cost-Effectiveness Analysis and Conclusion

The current costs for the PPIs were evaluated. Nexium brand is exponentially more expensive than therapeutically equivalent generic PPIs.

C. PPIs—UF Recommendation

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) esomeprazole (Nexium brand and generics) be designated NF and non step-preferred. The formulary recommendation is as follows:

- UF and step-preferred:
  - omeprazole (Prilosec generics)
  - pantoprazole (Protonix generics)
  - rabeprazole tablets (Aciphex generics)
- UF and non step-preferred
  - omeprazole 40 mg capsule (Prilosec)
  - rabeprazole sprinkles (Aciphex sprinkles)
- NF and non step-preferred:
  - esomeprazole (Nexium brand and generics)
  - esomeprazole strontium
  - dexlansoprazole (Dexilant)
  - lansoprazole (Prevacid)
  - omeprazole/sodium bicarbonate (Zegerid)
- This recommendation includes step therapy (automated PA), which requires a trial of omeprazole, pantoprazole, and rabeprazole in new and current users presenting with a prescription for esomeprazole, and in new users presenting with a prescription for one of the other nonformulary PPIs.
- As part of this recommendation, the current Tier 1 copayment for Nexium will move to the Tier 3 nonformulary copayment at the Retail Network and Mail Order Pharmacy.

D. PPIs—Automated (Step Therapy) and Manual PA Criteria

The existing automated PA (step therapy) requires a trial of omeprazole, Nexium, pantoprazole, or rabeprazole prior to use of a nonformulary PPI.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) modifying the existing step therapy and manual PA criteria to require all new and current users of esomeprazole to try omeprazole, pantoprazole, and rabeprazole first.

Full PA Criteria:

PPIs: esomeprazole (Nexium)

PA criteria apply to all new and current users of esomeprazole (Nexium).

Automated PA criteria: The patient has filled a prescription for omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole tablets (Aciphex, generics) at any Military Health Service (MHS) pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order), during the previous 180 days.

AND

Manual PA criteria: A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole (Aciphex, generics) is NOT required if:

- The patient has tried omeprazole, pantoprazole tablets, and rabeprazole tablets (Aciphex, generics), and the patient had an inadequate response.
- The patient has tried omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics), and the patient was unable to tolerate them due to adverse effects.
- Treatment with omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency).

E. PPIs—UF and PA Implementation Period

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday that occurs no later than 90 days after signing of the minutes in all points of service; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

VII. INTERIM MEETING: UF CLASS REVIEWS—PROTON PUMP INHIBITORS (PPIs) *BAP Comments*

A. PPIs—UF Recommendation

The P&T Committee recommended esomeprazole (Nexium brand and generics) be designated NF and non step-preferred. No change was recommended to the formulary status for the other PPIs. The formulary recommendation is as follows:

- UF and step-preferred:
  - Prilosec generics
  - Protonix generics
  - Aciphex generics
- UF and non step-preferred
  - Prilosec 40 mg capsule
  - Aciphex sprinkles
- NF and non step-preferred:
  - Nexium brand and generics
  - esomeprazole strontium
  - Dexilant
  - Prevacid
  - Zegerid
- This recommendation includes step therapy (automated PA), which requires a trial of omeprazole, pantoprazole, and rabeprazole in new and current users presenting with a prescription for esomeprazole, and in new users presenting with a prescription for one of the other nonformulary PPIs.
- As part of this recommendation, the current Tier 1 copayment for Nexium will move to the Tier 3 nonformulary copayment at the Retail Network and Mail Order Pharmacy.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. PPIs—Automated (Step Therapy) and Manual PA Criteria

The existing automated PA (step therapy) requires a trial of omeprazole, Nexium, pantoprazole, or rabeprazole prior to use of a nonformulary PPI.

The P&T Committee recommended modifying the existing step therapy and manual PA criteria to require all new and current users of esomeprazole to try omeprazole, pantoprazole, and rabeprazole first.

The full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. PPIs—UF and PA Implementation Period

The P&T Committee recommended an effective date of the first Wednesday that occurs no later than 90 days after signing of the minutes in all points of service and DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

VIII. SECTION 702, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR 2015 (FY15): RECENTLY-APPROVED DRUGS/ABBREVIATED REVIEWS (INNOVATOR DRUGS)

P&T Comments

A. Section 702, NDAA FY15: Recently-Approved Drugs/Abbreviated Reviews (Innovator Drugs)—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the recently-approved drugs reviewed according to Section 702, NDAA FY15.

B. Section 702, NDAA FY15: Recently-Approved Drugs/Abbreviated Reviews (Innovator Drugs)—UF Recommendation

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- **UF**:
  - Hepatitis B Agents: tenofovir alafenamide (Vemlidy)
  - Oral Oncologic Agents: rucaparib (Rubraca)

- **NF:**
    - Basal Insulins: insulin glargine (Basaglar KwikPen)
    - Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA): lixisenatide (Adlyxin)
    - GLP1RA: lixisenatide/insulin glargine (Soliqua)
    - Ophthalmic-1 Nonsteroidal Anti-inflammatory Drugs (NSAIDs): bromfenac 0.075% ophthalmic solution (BromSite)
    - Vitamin D Analogs: calcifediol (Rayaldee)

C. Section 702, NDAA FY15: Recently-Approved Drugs/Abbreviated Reviews (Innovator Drugs)—GLP1RAs Lixisenatide (Adlyxin) and Lixisenatide/Insulin Glargine (Soliqua) Step Therapy and Manual PA Criteria

Step therapy currently applies to the GLP1RAs Subclass, requiring a trial of exenatide weekly injection (Bydureon) and albiglutide weekly injection (Tanzeum) first, before the other non step-preferred GLP1RAs (Byetta, Victoza, or Trulicity).

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) step therapy and manual PA criteria for Adlyxin and Soliqua in new and current users. Patients will be required to try metformin or a sulfonylurea, and Bydureon and Tanzeum, before Adlyxin or Soliqua. Additionally, for Soliqua, patients will be required to be on basal insulin at a dosage of less than 60 units daily.

Full PA Criteria

1. GLP1RA: lixisenatide (Adlyxin)

   All new and current users of Adlyxin 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 Adlyxin must try Bydureon and Tanzeum first.

   Automated PA criteria: The patient has received a prescription for metformin or SU at any MHS pharmacy point of service (military treatment facilities, retail network pharmacies, or mail order) during the previous 180 days,

   AND

   Manual PA criteria: If automated PA criteria are not met, Adlyxin is approved (e.g., trial of metformin or SU is NOT required) if:
   - The patient has a confirmed diagnosis of Type 2 diabetes mellitus
   - The patient has experienced any of the following issues on metformin:
     - impaired renal function precluding treatment with metformin
     - history of lactic acidosis

- The patient has experienced any of the following issues on a SU:
    - hypoglycemia requiring medical treatment

- The patient has had inadequate response to metformin or a SU
- The patient has a contraindication to metformin or a SU

AND

In addition to the above criteria regarding metformin and SU, the following PA criteria would apply specifically to new and current users of Adlyxin:

- The patient has had an inadequate response to Bydureon and Tanzeum.

Prior Authorization does not expire.
Off-label uses are not approved.

2. GLP1RA: lixisenatide/insulin glargine (Soliqua)

   Manual PA criteria apply to all new and current users of lixisenatide/insulin glargine.

   Manual PA Criteria: Coverage will be approved if the following:

   - Soliqua 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 (< 60 units daily)
   - 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.

D. Section 702, NDAA FY15: Recently-Approved Drugs/Abbreviated Reviews (Innovator Drugs)—UF and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date upon signing of the minutes in all points of service.

IX. SECTION 702, NDAA FY15: RECENTLY-APPROVED DRUGS/ABBREVIATED REVIEWS (INNOVATOR DRUGS)

BAP Comments

A. Section 702, NDAA FY15: Recently-Approved Drugs/Abbreviated Reviews (Innovator Drugs)—UF Recommendation

The P&T Committee recommended the following:

- **UF**:
  - Vemlidy
  - Rubraca

- **NF:**
  - Basaglar KwikPen
  - Adlyxin
  - Soliqua
  - BromSite
  - Rayaldee

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Section 702, NDAA FY15: Recently-Approved Drugs/Abbreviated Reviews (Innovator Drugs)—Adlyxin and Soliqua Step Therapy and Manual PA Criteria

The P&T Committee recommended step therapy and manual PA criteria for Adlyxin and Soliqua in new and current users. Patients will be required to try metformin or a sulfonylurea, and Bydureon and Tanzeum, before Adlyxin or Soliqua. Additionally, for Soliqua, patients will be required to be on basal insulin at a dosage of less than 60 units daily.

The full step therapy and manual PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Section 702, NDAA FY15: Recently-Approved Drugs/Abbreviated Reviews (Innovator Drugs)—UF and PA Implementation Plan

The P&T Committee recommended an effective date upon signing of the minutes in all points of service.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

X. UTILIZATION MANAGEMENT—EPINEPHRINE AUTO-INJECTORS

P&T Comments

A. Epinephrine Auto-Injectors—Manual PA Criteria

The Auvi-Q, Adrenaclick, and EpiPen auto-injectors all contain epinephrine and are used in allergic emergencies, including anaphylaxis. An authorized generic formulation of EpiPen from Mylan Pharmaceuticals is now available and manufactured by the same pharmaceutical company as the originator product. The manufacturer of the authorized generic to Adrenaclick cannot produce sufficient supply to keep up with demand. The Auvi-Q device includes audible voice instructions and has a needle that automatically retracts following injection. Auvi-Q will be re-introduced in mid-February 2017, after market withdrawal in October 2015, due to reports the device failed to deliver a reliable dose of epinephrine.

A cost analysis and BIA favored dispensing the EpiPen brand auto-injector at the Military Treatment Facility and Mail Order points of service, whereas in the Retail Pharmacy Network the EpiPen authorized generic is most cost-effective. The Auvi-Q auto-injector is prohibitively more expensive than the other products.

Due to the significant cost differences based on point of service dispensing, the P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria apply to all new and current users of all formulations of EpiPen at the Retail Pharmacy Network; Adrenaclick at all points of service; the Mylan authorized generic at the TRICARE Mail Order Pharmacy and military treatment facilities; and in all new users of Auvi-Q at all points of service (note that there are no current users of Auvi-Q). Patients will be required to try the EpiPen branded product at the TRICARE Mail Order Pharmacy and military treatment facilities, or the authorized EpiPen generic formulation from Mylan Pharmaceuticals at the Retail Pharmacy Network, prior to use of any other epinephrine auto-injector product. The provider must document a patient-specific justification as to why the preferred agent is not acceptable. Prior authorization will not expire.

Full PA Criteria:

Respiratory Agents, Miscellaneous:

- epinephrine auto-injector (Auvi-Q, EpiPen, and Adrenaclick)

Patients will be required to try the EpiPen branded product at the Military Treatment Facility and TRICARE Mail Order Pharmacy, or the Mylan authorized generic EpiPen formulation at the Retail Network, prior to use of any other epinephrine auto-injector product.

Manual PA criteria—Coverage will be approved if:

- The provider documents a patient-specific reason why the patient cannot use the preferred product.

PA does not expire.

B. Epinephrine Auto-Injectors—PA Implementation Period

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the new manual PA for the epinephrine auto-injectors (Auvi-Q, EpiPen [brand and generic], and Adrenaclick [generic]) become effective on the first Wednesday that occurs no later than 90 days after signing of the minutes in all points of service, and that DHA send letters to patients currently receiving an epinephrine auto-injector in the Retail Network who are affected by this recommendation.

XI. UTILIZATION MANAGEMENT—EPINEPHRINE AUTO-INJECTORS

BAP Comments

A. Epinephrine Auto-Injectors—Manual PA Criteria

The P&T Committee recommended manual PA criteria apply to all new and current users of all formulations of EpiPen at the Retail Pharmacy Network; Adrenaclick at all points of service; the Mylan authorized generic at the TRICARE Mail Order Pharmacy and military treatment facilities; and in all new users of Auvi-Q at all points of service. Patients will be required to try the EpiPen branded product at the TRICARE Mail Order Pharmacy and military treatment facilities, or the authorized EpiPen generic formulation from Mylan Pharmaceuticals at the Retail Pharmacy Network, prior to use of any other epinephrine auto-injector product. The provider must document a patient-specific justification as to why the preferred agent is not acceptable. Prior authorization will not expire.

The full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Epinephrine Auto-Injectors—PA Implementation Plan

The P&T Committee recommended the new manual PA for the epinephrine auto-injectors (Auvi-Q, EpiPen [brand and generic], and Adrenaclick [generic]) become effective on the first Wednesday that occurs no later than 90 days after signing of the minutes in all points of service, and DHA send letters to patients currently receiving an epinephrine auto-injector in the Retail Network who are affected by this recommendation.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XII. UTILIZATION MANAGEMENT—ORAL ONCOLOGY AGENTS

P&T Comments

A. Oral Oncology Agents: Palbociclib (Ibrance)—Updated Manual PA Criteria

Ibrance was approved by the FDA in February 2015 for specific types of metastatic breast cancer. Manual PA criteria were recommended at the May 2016 meeting and implemented on November 2, 2016. An additional use as second-line therapy after endocrine-based treatment and in combination with fulvestrant was recently approved. The criteria were updated to add the new indication.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updating the manual PA criteria for new users.

Full PA Criteria:

Oral Oncology Agents: palbociclib (Ibrance)

Changes from February 2017 P&T Committee Meeting are in BOLD

Manual PA criteria apply to all new users of Ibrance.

Manual PA criteria—Ibrance is approved if:

A. Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND
B. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
C. The patient meets ONE of the following criteria (i, ii, iii, or iv):
    i. The patient is a postmenopausal woman and Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR
    ii. The patient is a premenopausal or perimenopausal woman and meets the following conditions (a and b):
        a. The patient is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]), surgical bilateral oophorectomy, or ovarian irradiation; AND
        b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole;

OR

    iii. The patient is a man and meets the following conditions (a and b):
        a. The patient is receiving a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]); AND
        b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole.

OR

iv. The patient is a pre-, peri-, or post-menopausal woman and has disease progression following endocrine therapy and is using palbociclib in combination with fulvestrant (Faslodex).

Other Non-FDA approved uses are not approved.

Prior Authorization does not expire.

B. Oral Oncology Agents: Palbociclib (Ibrance)—PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the updated manual PA for Ibrance become effective on the first Wednesday after a 90-day implementation period in all points of service.

XIII. UTILIZATION MANAGEMENT—ORAL ONCOLOGY AGENTS

BAP Comments

A. Oral Oncology Agents: Palbociclib (Ibrance)—Updated Manual PA Criteria

The P&T Committee recommended updating the manual PA criteria for new users.

The full updated PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Oral Oncology Agents: Palbociclib (Ibrance)—PA Implementation Plan

The P&T Committee recommended the updated manual PA for Ibrance 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

XIV. UTILIZATION MANAGEMENT—ANTICONVULSANT AND ANTI-MANIA DRUGS

P&T Comments

A. Anticonvulsant and Anti-Mania Drugs: Topiramate ER (Trokendi XR)—Updated Manual PA Criteria

Trokendi XR and Qudexy XR are branded ER formulations of topiramate dosed once daily. Generic topiramate IR formulations have been marketed since 1996. Manual PA criteria were recommended for Trokendi XR and Qudexy XR in August 2014 to limit use of the branded topiramate ER products to their FDA-approved indications for seizures and appropriate age ranges. A trial of topiramate IR (generic Topamax IR) is required first. Trokendi XR is expected to receive FDA approval for use in migraine headache prophylaxis in March 2017.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updating the manual PA criteria for Trokendi XR to include use as prophylaxis in migraine headache after an inadequate response, or adverse event with topiramate IR.

Full PA Criteria

Anticonvulsants and Anti-Mania Agents: topiramate (Trokendi XR)

February 2017 updates are in BOLD

Manual PA criteria apply to all new users of Trokendi XR and Qudexy XR:

- Coverage approved for
    - Partial onset seizure and 1° generalized tonic-clonic seizures in patients ≥ 10 years
    - Lennox-Gastaut seizures in patients ≥ 6 years for Trokendi ER and age ≥ 2 years for Qudexy XR
    - Adjunctive therapy for partial onset seizure or primary generalized tonic clonic seizure in patients 2 years of age or older (Qudexy XR) or 6 years and older (Trokendi XR).
    - **Migraine prophylaxis in adults (Trokendi XR)**
- Coverage not approved for
    - Non-FDA approved indications, including weight loss and migraine headache (for Qudexy XR only)
- Patient is required to try topiramate first, unless the following has occurred:
    - Inadequate response not expected to occur with Trokendi XR or Qudexy XR
    - Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR

Prior Authorization does not expire.

B. Anticonvulsant and Anti-Mania Drugs: Topiramate ER (Trokendi XR)—PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the updated manual PA for Trokendi XR become effective on the first Wednesday after a 90-day implementation period in all points of service.

XV. UTILIZATION MANAGEMENT—ANTICONVULSANT AND ANTI-MANIA DRUGS

BAP Comments

A. Anticonvulsant and Anti-Mania Drugs: Topiramate ER (Trokendi XR)—Updated Manual PA Criteria

The P&T Committee recommended updating the manual PA criteria for Trokendi XR to include use as prophylaxis in migraine headache after an inadequate response, or adverse event with topiramate IR.

The full updated PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Anticonvulsant and Anti-Mania Drugs: Topiramate ER (Trokendi XR)—PA Implementation Plan

The P&T Committee recommended the updated manual PA for Trokendi XR 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

XVI. UTILIZATION MANAGEMENT—TESTOSTERONE REPLACEMENT THERAPIES (TRTs)

P&T Comments

A. TRTs—Updated Manual PA Criteria

The testosterone replacement therapies were reviewed for formulary placement in August 2012, with testosterone transdermal 2% gel pump (Fortesta) designated as step-preferred. All other TRT products are non step-preferred.

Updated step therapy and manual PA criteria are needed since publication of the Final Rule/technical amendment (81 FR 61068-61098), removing certain regulatory exclusions for the treatment of gender dysphoria for TRICARE beneficiaries. This rule change permits coverage of all nonsurgical medically necessary and appropriate care in the treatment of gender dysphoria. See the Final Rule for TRICARE Mental Health and Substance Use Disorder Treatment published on September 2, 2016 at https://www.gpo.gov/fdsys/pkg/FR-2016-09-02/pdf/2016-21125.pdf.

The P&T Committee recommended (14 for, 2 opposed, 1 abstained, 0 absent) updating the manual PA criteria for the topical and buccal TRT products to allow for use in patients undergoing female to male gender reassignment (endocrinologic masculinization), as outlined in the Final Rule and the TRICARE Policy Manual 6010.57-M.

Full PA Criteria:

1. TRT (step-preferred product): testosterone 2% gel pump (Fortesta)

   February 2017 updates are in BOLD
   Manual PA criteria apply to all users of transdermal and buccal testosterone replacement products.

   - Coverage approved for male patients if:
     - Patient is male over the age of 17 years AND
     - Patient has a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND
     - The patient is experiencing symptoms usually associated with hypogonadism
   - **Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:**
     - **Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND**
     - **Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the DSM; AND**
     - **Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment); AND**
     - **Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous**

psychotherapy addressing gender transition as an intervention for gender dysphoria; AND

- **For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding.**

Prior authorization does not expire.

2. TRT (non step-preferred products):

   - transdermal patch (Androderm)
   - transdermal gel tubes (Testim)
   - buccal tablets (Striant)
   - nasal gel (Natesto)
   - transdermal gel (Vogelxo)
   - transdermal gel and gel pump (Androgel 1%, 1.62%)
   - transdermal solution (Axiron)

   February 2017 updates are in BOLD
   Manual PA criteria apply to all users of transdermal and buccal testosterone replacement products.

   - Coverage approved for male patients if:
     - Patient is male over the age of 17 years AND
     - Patient has a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND
     - The patient is experiencing symptoms usually associated with hypogonadism AND
     - The patient has tried Fortesta (testosterone 2% gel) for a minimum of 90 days AND failed to achieve total testosterone levels above 400 ng/dL (labs drawn 2 hours after Fortesta application) AND without improvement in symptoms. OR
     - The patient has a contraindication or relative contraindication to Fortesta that does not apply to the requested agent. OR
     - The patient has experienced a clinically significant skin reaction to Fortesta that is not expected to occur with the requested agent. OR
     - The patient requires a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members (for Androderm, Natesto, or Striant only).
   - **Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:**
     - **Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND**

- **Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the DSM; AND**
- **Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment); AND**
- **Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria; AND**
- **For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding. AND**
- **Does the patient have a contraindication or relative contraindication to Fortesta that does not apply to the requested agent? OR**
- **Has the patient experienced a clinically significant skin reaction to Fortesta that is not expected to occur with the requested agent? OR**
- **If the request is for Androderm, Natesto, or Striant, does the patient require a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members?**

Prior authorization does not expire.

B. TRTs—PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the updated manual PA for the TRTs become effective on the first Wednesday after a 90-day implementation period in all points of service.

XVII. UTILIZATION MANAGEMENT—TRTs

BAP Comments

A. TRTs—Updated Manual PA Criteria

The P&T Committee recommended updating the manual PA criteria for the topical and buccal TRT products to allow for use in patients undergoing female to male gender reassignment (endocrinologic masculinization), as outlined in the Final Rule and the TRICARE Policy Manual 6010.57-M.

The full updated PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. TRTs—PA Implementation Plan

The P&T Committee recommended the updated manual PA for the TRTs 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

XVIII. FORMULARY STATUS UPDATE—ANTILIPIDEMIC-1s (LIP-1s)

P&T Comments

A. LIP-1s: Rosuvastatin—Step Therapy

The statins included in the Antilipidemic-1s Drug Class were most recently reviewed for formulary status in November 2013. Rosuvastatin (Crestor) was designated UF and non step-preferred, requiring a trial of a generic statin with equivalent low-density lipoprotein lowering intensity. Cost-effective generic formulations for rosuvastatin are now available and a Joint National Contract with the U.S. Department of Veterans Affairs will become effective on March 13, 2017.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) designating rosuvastatin as UF and step-preferred. The corresponding PA forms for the non step-preferred statins will be updated to reflect the status of rosuvastatin as step-preferred, with implementation effective upon signing of the minutes.

XIX. FORMULARY STATUS UPDATE—LIP-1s

BAP Comments

A. LIP-1s: Rosuvastatin—Step Therapy

The P&T Committee recommended designating rosuvastatin as UF and step-preferred. The corresponding PA forms for the non step-preferred statins will be updated to reflect the status of rosuvastatin as step-preferred, with implementation effective upon signing of the minutes.

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	Imple-mentation	Notes & Unique Utilizers Affected
Feb 2017	**Hepatitis C Virus (HCV) Agents – Direct Acting Antivirals (DAAs) Subclass**	UF subclass review Previously reviewed May 2015; Nov 2012	**UF Step-Preferred** ▪ ledipasvir/sofosbuvir (Harvoni) **UF Non Step-Preferred** ▪ daclatasvir (Daklinza) ▪ sofosbuvir / velpatasvir (Epclusa) ▪ simeprevir (Olysio) ▪ sofosbuvir (Sovaldi) ▪ paritaprevir / ritonavir/ ombitasvir (Technivie) ▪ paritaprevir / ritonavir/ ombitasvir/ dasabuvir XR (Viekira XR) ▪ paritaprevir /ritonavir/ ombitasvir / dasabuvir Pak (Viekira Pak) ▪ grazoprevir / elbasvir (Zepatier)	None	Pending signing of the minutes / 30 days	▪ Manual PA required ▪ Must try Harvoni first in all new users before the other HCV DAAs ▪ Step therapy applies to all new users of non step-preferred products ▪ Coverage only allowed for FDA-approved indications ▪ PA expires after 365 days
Feb 2017	**Antibiotics: Tetracyclines Subclass**	UF subclass; not previously reviewed	**UF Step-Preferred** ▪ doxycycline hyclate 100 mg caps (generic) ▪ doxycycline hyclate IR 50 mg, 75 mg, 150 mg, 200 mg tabs and caps (generic) ▪ doxycycline hyclate IR 100 mg tabs (generic) ▪ doxycycline monohydrate IR 50 mg, 75 mg, 100 mg, 150 mg, 200 mg tabs and caps (generic) ▪ minocycline IR 50 mg, 75 mg, 100 mg tabs and caps (generic) **UF –Not Subject to Step** ▪ doxycycline calcium/ monohydrate 25 mg/5 mL, 50 mg/5 mL suspension (generic) ▪ tetracycline 250 mg, 500 mg caps ▪ demeclocycline HCl 150 mg, 300 mg caps (generic)	**NF – Non Step-Preferred** ▪ doxycycline hyclate (Acticlate) ▪ doxycycline hyclate DR (Doryx) ▪ doxycycline hyclate DR modified polymer coat (Doryx MPC) ▪ doxycycline hyclate (Targadox) ▪ doxycycline hyclate (Morgidox) ▪ doxycycline monohydrate 40 mg IR/DR (Oracea and generics) ▪ doxycycline monohydrate (Monodoxyne NL) ▪ doxycycline monohydrate (Adoxa) ▪ doxycycline monohydrate (Monodox) ▪ minocycline ER 45 mg, 90 mg, 135 mg ER (generics) ▪ minocycline ER 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg (Solodyn)	Pending signing of the minutes / 90 days	▪ Step therapy applies ▪ Manual PA required for all new and current users of a non step-preferred product ▪ Doryx, Doryx MPC, and Acticlate will be allowed for treatment of susceptible infections, if the patient has failed or had clinically significant adverse events to generic doxycycline IR products ▪ Children under the age of 13 are exempt from step therapy Unique Users Affected ▪ Retail: 3,923 ▪ Mail: 2,148 ▪ MTF: 896 **Total: 6,967**

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Imple-mentation	Notes & Unique Utilizers Affected
Mar 2017 Interim	**Proton Pump Inhibitors (PPIs)**	UF class review	**UF Step-Preferred** ▪ omeprazole (Prilosec generics); excludes 40 mg branded product ▪ pantoprazole (Protonix, generics) ▪ rabeprazole tabs (Aciphex generics) **UF and Non Step-Preferred** ▪ omeprazole 40 mg cap (Prilosec) ▪ rabeprazole sprinkles (Aciphex sprinkles)	**NF and Non Step-Preferred** ▪ **esomeprazole (Nexium brand and generic)** ▪ esomeprazole strontium ▪ dexlansoprazole (Dexilant) ▪ lansoprazole (Prevacid) ▪ omeprazole/sodium bicarbonate (Zegerid)	Pending signing of the minutes / NF no later than 90 days	▪ Nexium removed from the UF and made NF and non step-preferred ▪ Pantoprazole generic added to the UF ▪ PA criteria and step therapy apply to all new and current users of esomeprazole (Nexium) ▪ All new and current users of Nexium must try omeprazole, pantoprazole, and rabeprazole first Unique Users Affected ▪ Retail: 23,679 ▪ Mail: 154,443 ▪ MTF: 160,717 **Total: 338,839**

TRICARE Formulary Search tool: http://www.express-scripts.com/tricareformulary
MTF: military treatment facility
UUs: unique utilizers

February 2017 Drugs with Prior Authorization Criteria
Unique Utilizers Affected Per Drug

Drug	MTF	Mail Order	Retail	Total
Epinephrine Auto-Injectors (Mylan, brand and generic; Lineage generic)	16,499	2,771	7,529	26,799