

**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, pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

**II. RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA)  
AGENTS—INSULIN DRUGS**

*P&T Comments*

**A. Miscellaneous Insulin Delivery Devices: Valeritas V-Go (V-Go)—Relative Clinical Effectiveness and Conclusion**

V-Go is a disposable insulin delivery device approved for patients with diabetes mellitus. Unlike an insulin pump, V-Go does not require any tubing or catheters. The device is filled daily with rapid-acting insulin, allowing for continuous administration of basal insulin and optional bolus dosing. After 24 hours, the device is discarded and replaced with a new unit.

The advantages of using V-Go include convenience for the patient who desires increased control over their blood glucose levels and elimination of the need for multiple daily insulin injections. Compared to multiple insulin injections, V-Go may reduce prandial glycemic excursions.

There are no randomized controlled trials using the V-Go insulin delivery device compared to usual care with basal or basal/bolus insulin dosing using pens or vials. Limitations of the V-Go studies include small sample sizes (<140 patients enrolled), varied efficacy endpoints, short trial duration, and lack of published studies. Another limitation is that reports of patients requiring overall reduced total daily insulin doses was based on subjective patient-reported data and not on objective endpoints. Additionally, the discontinuation rates in the V-Go studies were high. Although the V-Go studies reported improvements in hemoglobin A1c- lowering, it is difficult to attribute those improvements to the V-Go device due to the lack of control groups and limitations in study design. Long-term data on whether the V-Go device improves patient adherence is lacking.

The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that the V-Go delivery device offers patient convenience because multiple daily insulin injections are not needed; however, it offers no clinically compelling advantages over existing UF insulin agents administered with pens or vials.

**B. Miscellaneous Insulin Delivery Devices: V-Go—Relative Cost-Effectiveness Analysis and Conclusion**

Cost-minimization analysis (CMA) was performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that the CMA showed V-Go was more costly than other combinations of basal/bolus insulin (e.g., Lantus/Novolog) currently on the UF.

**C. Miscellaneous Insulin Delivery Devices: V-Go—UF Recommendation**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) V-Go be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products.

**D. Miscellaneous Insulin Delivery Devices: V-Go—Prior Authorization (PA) Criteria**

Manual PA criteria were recommended at the August 2014 DoD P&T Committee meeting and implemented on November 14, 2014. The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) clarifying the PA criteria for V-Go.

PA criteria apply to all new users of the V-Go device.

Manual PA criteria:

1. Patient has Type 2 diabetes mellitus
2. Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily
3. Patient does not need less than 2 unit increments of bolus dosing
4. Patient has been maintained on stable basal insulin for at least 3 months (at dosages ranging from 20U to 40U)
5. Patient has been using prandial insulin for at least 3 months

**E. Miscellaneous Insulin Delivery Devices: V-Go—UF and PA Implementation Plan**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS).

### III. RECENTLY APPROVED U.S. FDA AGENTS—INSULIN DRUGS

#### *BAP Comments*

#### **A. Miscellaneous Insulin Delivery Devices: V-Go—UF Recommendation, PA Criteria, UF and PA Implementation Plan**

The P&T Committee's recommendations for Valeritas V-Go (V-Go) are listed above. This section is reserved for BAP discussion and comments.

*BAP Comment:*       Concur       Non-concur

Additional Comments and Dissent

### IV. RECENTLY APPROVED U.S. FDA AGENTS—PULMONARY DRUGS

#### *P&T Comments*

#### **A. Chronic Obstructive Pulmonary Disease (COPD): Umeclidinium/Vilanterol (Anoro Ellipta)—Relative Clinical Effectiveness and Conclusion**

Umeclidinium/vilanterol is the first fixed dose combination of a long-acting muscarinic agent (LAMA) with a long-acting beta agonist (LABA) to reach the market. Anoro Ellipta is indicated for maintenance treatment of COPD; in contrast, other products have the additional indication for reducing COPD exacerbations (Spiriva, Advair, and Breo Ellipta).

The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the main clinical benefits of umeclidinium/vilanterol are its superior improvements in forced expiration volume in 1 second (FEV<sub>1</sub>) compared to single ingredient inhalers, the convenience to patients of combining two long-acting bronchodilators into one inhaler, and once daily dosing. The COPD agents will be re-reviewed at an upcoming meeting for UF and Basic Core Formulary (BCF) placement. Additionally, the P&T Committee recommended adding the LAMA/LABA combinations to the Pulmonary II Drug Class, which includes other chemical entities used for treating COPD.

#### **B. COPD: Umeclidinium/Vilanterol (Anoro Ellipta)—Relative Cost-Effectiveness Analysis and Conclusion**

CMA was performed to evaluate umeclidinium/vilanterol (Anoro Ellipta) with other LAMA and LABA therapies in the treatment of COPD. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

CMA showed that the Anoro Ellipta fixed dose combination bronchodilator offers a cost-effective alternative to combining available LAMA and LABA inhalers.

**C. COPD: Umeclidinium/Vilanterol (Anoro Ellipta)—UF Recommendation**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) umeclidinium/vilanterol (Anoro Ellipta) be designated formulary on the UF, based on clinical and cost effectiveness.

**V. RECENTLY APPROVED U.S. FDA AGENTS—PULMONARY DRUGS**

*BAP Comments*

**A. COPD: Umeclidinium/Vilanterol (Anoro Ellipta)—UF Recommendation**

The P&T Committee’s recommendation for umeclidinium/vilanterol (Anoro Ellipta) is listed above. This section is reserved for BAP discussion and comments.

<p><i>BAP Comment:</i>      <input type="checkbox"/> Concur      <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissent</p>
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**VI. RECENTLY APPROVED U.S. FDA AGENTS—GLAUCOMA DRUGS**

*P&T Comments*

**A. Brinzolamide 1%/Brimonidine 0.2% Ophthalmic Suspension (Simbrinza)—Relative Clinical Effectiveness and Conclusion**

Brinzolamide/brimonidine ophthalmic suspension (Simbrinza) is the first fixed dose combination product for glaucoma that has components other than a beta blocker. It contains a carbonic anhydrase inhibitor (brinzolamide, Azopt) and an alpha 2 adrenergic antagonist (brimonidine, Alphagan).

The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) Simbrinza’s fixed combination offers a convenience to the patient versus using two drugs concomitantly, even though it requires dosing three times a day. Simbrinza also decreases intraocular pressure to a greater extent than the individual components administered alone.

**B. Brinzolamide 1%/Brimonidine 0.2% Ophthalmic Suspension (Simbrinza)—Relative Cost-Effectiveness Analysis and Conclusion**

CMA was performed to evaluate brinzolamide/brimonidine (Simbrinza) with other drugs used in the treatment of glaucoma. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA showed that brinzolamide/brimonidine (Simbrinza) was comparable to the UF carbonic anhydrase inhibitors and alpha adrenergic agonists when taken in combination.

**C. Brinzolamide 1%/Brimonidine 0.2% Ophthalmic Suspension (Simbrinza)—UF Recommendation**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) brinzolamide 1%/brimonidine 0.2% ophthalmic suspension (Simbrinza) be designated with formulary status on the UF, based on clinical and cost effectiveness.

**VII. RECENTLY APPROVED U.S. FDA AGENTS—GLAUCOMA DRUGS**

*BAP Comments*

**A. Brinzolamide 1%/Brimonidine 0.2% Ophthalmic Suspension (Simbrinza)—UF Recommendation**

The P&T Committee’s recommendation for brinzolamide 1%/brimonidine 0.2% ophthalmic suspension (Simbrinza) is listed above. This section is reserved for BAP discussion and comments.

*BAP Comment:*       Concur       Non-concur

Additional Comments and Dissent

**VIII. RECENTLY APPROVED U.S. FDA AGENTS—OPHTHALMIC NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)**

*P&T Comments*

**A. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—Relative Clinical Effectiveness and Conclusion**

Bromfenac 0.07% (Prolensa) is FDA-indicated for the treatment of postoperative inflammation and pain in patients following cataract surgery. It is the third bromfenac formulation to obtain FDA approval. The branded formulations of bromfenac 0.09% (Xibrom) dosed twice daily and bromfenac 0.09% (Bromday) dosed once daily (QD) have been discontinued by the manufacturer.

There are no head-to-head clinical trials comparing Prolensa with another ophthalmic NSAID. There is no data to show that Prolensa is better tolerated when compared to generic bromfenac 0.09% (Bromday) QD. While Prolensa offers the convenience of once daily dosing, generic Bromday is also dosed once daily.

The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that Prolensa does not offer clinically relevant advantages over the other UF ocular NSAIDs that are FDA-approved for use following cataract surgery.

**B. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—Relative Cost-Effectiveness Analysis and Conclusion**

CMA was performed to evaluate bromfenac 0.07% ophthalmic solution (Prolensa) with other ophthalmic NSAIDs on the UF. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that Prolensa was the most costly ocular NSAID.

**C. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Recommendation**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) bromfenac 0.07% ophthalmic solution (Prolensa) be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products.

**D. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Implementation Plan**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS.

**IX. RECENTLY APPROVED U.S. FDA AGENTS—OPHTHALMIC NSAIDs**

*BAP Comments*

**A. Bromfenac 0.07% Ophthalmic Solution (Prolensa)—UF Recommendation and UF Implementation Plan**

The P&T Committee’s recommendations for bromfenac 0.07% ophthalmic solution (Prolensa) are listed above. This section is reserved for BAP discussion and comments.

<p><i>BAP Comment:</i>      <input type="checkbox"/> Concur      <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissention</p>
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## X. UF CLASS REVIEWS—MULTIPLE SCLEROSIS (MS)

### *P&T Comments*

#### A. MS—Relative Clinical Effectiveness and Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the MS Drug Class, which is comprised of the following injectable and oral disease-modifying drugs:

- **Injectable:** Interferon beta-1b [Betaseron and Extavia subcutaneous (SC) injections], interferon beta-1a [Avonex intramuscular (IM) injection; Rebif SC injection], and, glatiramer [Copaxone 20 mg SC daily injection and 40 mg three times a week (TIW) SC injection]
- **Oral:** dimethyl fumarate (Tecfidera), fingolimod (Gilenya), and teriflunomide (Aubagio)

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following conclusions for the MS drugs:

1. For the injectables, no one interferon product is preferred over the other in terms of efficacy and safety. Interferon beta-1a IM (Avonex) is possibly less effective than the other interferons, based on the Oregon Drug Effectiveness Review Project (DERP, 2010).
2. In a Cochrane review (2014), similar outcomes (including clinical and magnetic resonance imaging activity measures) were reported when the interferons were compared to glatiramer (Copaxone) for treating patients with relapsing-remitting forms of MS. These findings differ from the DERP 2010 report, where Avonex was presented as less effective.
3. The Copaxone 40 mg TIW formulation has the convenience of less frequent administration than the 20 mg daily Copaxone formulation. However, the 40 mg TIW product has not been directly compared to the 20 mg daily formulation for efficacy or safety; trials are ongoing.
4. There are no head-to-head trials of one oral drug with another oral drug; placebo controlled studies were used to obtain FDA approval. Limited data from head-to-head trials of the injectables versus oral medications report the following:
  - Fingolimod produces a greater reduction in the annualized relapse rate (ARR) compared to interferon beta-1a IM (Avonex).
  - Teriflunomide (Aubagio) 14 mg and interferon beta-1a SC (Rebif) produced similar reductions in the ARR, while teriflunomide 7 mg was less effective than the 14 mg dose and Rebif.
  - There were no clinically relevant differences in the ARR when glatiramer (Copaxone) was compared to dimethyl fumarate (Tecfidera).
5. The Canadian Agency for Drugs in Technology and Health (CADTH, October 2013) reported the relative ARRs of the various MS treatments compared to

placebo. Fingolimod (Gilenya) and dimethyl fumarate (Tecfidera) had the lowest ARR; teriflunomide, interferon beta-1b SC (Betaseron), interferon beta-1a SC (Rebif), and glatiramer (Copaxone) all had similar ARRs; and, interferon beta-1a (Avonex) had the highest ARR.

6. The MS drugs have distinctly different adverse event profiles. Copaxone has the advantage of a pregnancy category B rating.
7. Dalfampridine (Ampyra) is an orally administered drug that is not disease-modifying; it is solely approved for symptom management to improve walking distance.
8. Due to their differing safety profiles and low degree of therapeutic interchangeability, several MS products are required on the UF to meet the needs of the MHS population.

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

A cost-effectiveness analysis (CEA) and BIA were performed to evaluate the MS Drug Class. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CEA results showed that, when considering the incremental cost-effectiveness ratios per relapse avoided, all scenarios were within a range considered to be cost-effective to the MHS. Ampyra was not included in the CEA as it is not a disease-modifying drug.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that all modeled scenarios demonstrated a similar level of cost avoidance for the MHS, with only slight differences between evaluated scenarios.

### **C. MS—UF Recommendation**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) the following:

- UF:
  - Interferon beta-1a SQ (Rebif and Rebif Rebidose)
  - Interferon beta-1a IM (Avonex)
  - Interferon beta-1b SC (Betaseron)
  - Interferon beta-1b SC (Extavia)
  - Dalfampridine (Ampyra)
  - Dimethyl fumarate (Tecfidera)
  - Fingolimod (Gilenya)
  - Glatiramer (Copaxone)
  - Teriflunomide (Aubagio)
- NF: None



**D. MS—PA Criteria**

Manual PA criteria recommended in November 2010 and November 2013 currently apply to fingolimod (Gilenya) and dimethyl fumarate (Tecfidera), respectively. The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) maintaining the current PA criteria for Tecfidera and revising the PA criteria for Gilenya due to recent updates in the package insert for cardiovascular toxicity.

Manual PA criteria:

- A documented diagnosis of relapsing forms of MS
- No current use of a disease-modifying therapy (e.g., interferon 1a or 1b or Copaxone)
- Avoid use in patients with significant cardiac history, including:
  - Patients with a recent history (within the past six months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization
  - Those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular block or sick sinus syndrome, unless they have a functioning pacemaker
  - Patients with a baseline QTc interval  $\geq 500$  ms
  - Those receiving treatment with class Ia or class III antiarrhythmic drugs

**E. MS—UF and PA Implementation Plan**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date no later than 30 days after signing of the minutes in all POS.

**XI. UF CLASS REVIEWS—MS**

*BAP Comments*

**A. MS—UF Recommendation, PA Criteria, UF and PA Implementation Plan**

The P&T Committee’s recommendations for the MS Drug Class are listed above. This section is reserved for BAP discussion and comments.

<p><i>BAP Comment:</i>      <input type="checkbox"/> Concur      <input type="checkbox"/> Non-concur</p> <p style="text-align: right; margin-top: 20px;">Additional Comments and Dissentation</p>
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## **XII. UF CLASS REVIEWS—SELF-MONITORING BLOOD GLUCOSE SYSTEM (SMBGS) TEST STRIPS**

### *P&T Comments*

#### **A. SMBGS Test Strips—Relative Clinical Effectiveness and Conclusion**

The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips. See the table at the end of this document for the full list of the SMBGS test strips in this class. SMBGS glucometers are not included as part of the TRICARE outpatient pharmacy benefit (they are included under the medical benefit) and are not the focus of the review.

U.S. Federal Government contracting requirements stated the following:

The Company shall ensure test strips are made available to all three Points of Service (Military Treatment Facilities, TRICARE Mail Order Pharmacy, and Retail Network). In accordance with industry practice, the Company shall make meters available to DoD beneficiaries at no additional charge or cost to the DoD beneficiary.

The FDA classifies SMBGS test strips and glucometers as medical devices rather than drugs. The clinical effectiveness review focused on differences in the technical aspects/attributes among the test strips and glucometers. The P&T Committee recommended that the potential test strips considered for inclusion on the UF should meet standards relating to such factors as FDA requirements for accuracy based on the International Organization for Standardization (ISO) 15197 guidelines from 2003, sample size, alternate site testing, result time, memory capacity, ease of calibration, customer support, downloading capabilities, and data management capabilities.

The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following for the SMBGS test strips:

- Potential SMBGS test strips considered for inclusion on the UF must meet all U.S. Federal Government contracting requirements and the technical factors listed above.
- Potential SMBGS test strips considered for inclusion on the UF included FreeStyle Lite; FreeStyle InsuLinx; Precision Xtra; ACCU-CHEK Aviva Plus; OneTouch Ultra Blue; OneTouch Verio; CONTOUR NEXT; TRUEtest; Nova Max; GLUCOCARD 01-SENSOR; GLUCOCARD Vital; and Prodigy No Coding.
- *Overall relative clinical effectiveness conclusion:* The P&T Committee concluded there were no clinically relevant differences between the 12 SMBGS test strips that were reviewed and met the contracting requirements and technical factors, and that any of the 12 test strips were acceptable for inclusion on the UF.

#### **B. SMBGS Test Strips—Relative Cost-Effectiveness Analysis and Conclusion**

CMA and budget impact analysis (BIA) were performed to evaluate the SMBGS test strips that were considered for inclusion on the UF. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- Results from a comprehensive cost analysis, which included a CMA and considered the cost of patient switching and related DoD administrative costs in addition to SMBGS test strip per unit costs, showed FreeStyle Lite and Precision Xtra test strips were the most cost-effective SMBGS test strips, followed by ACCU-CHEK Aviva Plus, GLUCOCARD Vital and GLUCOCARD 01-SENSOR, TRUEtest, Prodigy No Coding, CONTOUR NEXT, Nova Max, and all other SMBGS test strips. OneTouch Ultra Blue test strips were the least cost-effective.
- BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and UF or non-preferred and NF on the UF. BIA results showed the scenario with FreeStyle Lite and Precision Xtra designated as step-preferred on the UF and all remaining test strips designated NF and non-step preferred, where all current and new users are required to try FreeStyle Lite or Precision Xtra first, was the most cost-effective option for the Military Health System (MHS).

### **C. SMBGS Test Strips—UF Recommendation**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) the following:

- UF and step-preferred:
  - FreeStyle Lite
  - Precision Xtra
- NF and non-step preferred:
  - ACCU-CHEK Aviva Plus
  - GLUCOCARD 01-SENSOR
  - GLUCOCARD Vital
  - CONTOUR NEXT
  - FreeStyle InsuLinx
  - Nova Max
  - TRUEtest
  - Prodigy No Coding
  - OneTouch Verio
  - OneTouch Ultra Blue
  - All other test strips listed in the table at the end of this document with the exception of FreeStyle Lite and Precision Xtra
- This recommendation includes step therapy, which requires a trial of FreeStyle Lite or Precision Xtra prior to use of a NF test strip. The recommendation requires all current and new users of a non-preferred test strip try FreeStyle Lite or Precision Xtra, or meet the PA criteria for the non-preferred strips.

**D. SMBGS Test Strips—PA Criteria**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for all new and current users of NF test strips. The manual PA criteria requires a trial of FreeStyle Lite or Precision Xtra prior to the use of a NF test strip.

Manual PA Criteria—Non-preferred test strip allowed if:

- Patient is blind/severely visually impaired and requires a test strip used in a talking meter—Prodigy Voice, Prodigy AutoCode, Advocate Redicode
- Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter
  - Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump
  - Nova Max strip with Nova Max Link meter for Medtronic pump
  - For Retail Network Only: One Touch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump
  - For Retail Network Only: One Touch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump
- The patient has a documented physical or mental health disability requiring a special strip or meter. For example, the patient requires ACCU-CHEK Aviva Plus strip due to manual dexterity issues (Arthritis Association Seal of Approval)

**E. SMBGS Test Strips—UF and PA Implementation Plan**

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 120-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF and PA decisions.

**XIII. UF CLASS REVIEWS—SMBGS TEST STRIPS**

*BAP Comments*

**A. SMBGS Test Strips—UF Recommendation, PA Criteria, UF and PA Implementation Plan**

The P&T Committee’s recommendations for the SMBGS test strips are listed above. This section is reserved for BAP discussion and comments.

<p><i>BAP Comment:</i>      <input type="checkbox"/> Concur      <input type="checkbox"/> Non-concur</p> <p style="text-align: right; margin-top: 20px;">Additional Comments and Dissention</p>
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#### **XIV. UTILIZATION MANAGEMENT—HEPATITIS C VIRUS (HCV) AGENTS, DIRECT ACTING ANTIVIRALS (DAAs)**

##### ***P&T Comments***

##### **A. Ledipasvir/Sofosbuvir (Harvoni)—PA Criteria**

Ledipasvir 90 mg/sofosbuvir 400 mg (Harvoni) is a once daily fixed dose combination tablet that was approved by the FDA in October 2014 for the treatment of HCV genotype 1. It is the first FDA-approved interferon-free regimen indicated to treat HCV genotype 1. Harvoni will be reviewed as a new drug at an upcoming meeting.

PA criteria currently apply to the DAAs. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users of ledipasvir/sofosbuvir (Harvoni), consistent with FDA-approved labeling. Prior authorization will expire after 8–24 weeks based on the treatment regimen.

The full PA criteria are as follows:

- New users of ledipasvir/sofosbuvir (Harvoni) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their Harvoni prescriptions.
- Consult the AASLD/IDSA HCV guidelines ([www.hcvguidelines.org](http://www.hcvguidelines.org)) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

##### **Manual PA Criteria:**

- Age  $\geq$  18
- Has laboratory evidence of chronic HCV genotype 1 infection
  1. State the HCV genotype and HCV RNA viral load on the PA form
- Ledipasvir/sofosbuvir (Harvoni) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with Hepatitis B virus (HBV).

##### **Treatment Regimens and Duration of Therapy**

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 8 weeks or 12 weeks or 24 weeks, based on the treatment regimen selected.

<b>Genotype 1 Patient Populations</b>	<b>Treatment Duration</b>
Treatment naïve with or without cirrhosis	8* - 12 weeks
Treatment experienced** without cirrhosis	12 weeks
Treatment experienced** with cirrhosis	24 weeks

\*Consider treatment duration of 8 weeks in treatment-naïve patients without cirrhosis who have a pretreatment HCV RNA less than 6 million IU/mL.

\*\*Treatment-experienced patients who have failed treatment with either (a) peginterferon alfa plus ribavirin or (b) HCV protease inhibitor plus peginterferon alfa plus ribavirin

## **B. Simeprevir (Olysio)—PA Criteria**

PA criteria were recommended for Simeprevir (Olysio) at the May 2014 DoD P&T Committee meeting. Simeprevir received a new FDA indication in November 2014 as a component of an interferon-free combination treatment for chronic HCV genotype 1.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) revising the existing PA criteria for Olysio to include the expanded FDA-approved indication.

The full PA criteria are as follows:

- New users of simeprevir (Olysio) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- The FDA-approved indication of simeprevir + PEG-interferon + ribavirin for 24 to 48 weeks is not recommended for HCV treatment by the AASLD/IDSA. See [www.hcvguidelines.org](http://www.hcvguidelines.org).
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their simeprevir prescriptions.
- Consult the AASLD/IDSA HCV guidelines ([www.hcvguidelines.org](http://www.hcvguidelines.org)) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

### Manual PA Criteria:

- Age  $\geq$  18
- Has laboratory evidence of chronic HCV genotype 1 infection
- State the HCV genotype and HCV RNA viral load on the PA form
- If HCV genotype 1a, the patient is negative for NS3 Q80K polymorphism at baseline
- Simeprevir (Olysio) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with HIV or Hepatitis B virus (HBV).
- Not recommended for monotherapy

- The patient has not previously used a HCV protease inhibitor (boceprevir, telaprevir, or simeprevir)

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 12 weeks or 24 weeks, based on the treatment regimen selected.

<b>Genotype 1 Patient Populations</b>	<b>Treatments</b>	<b>Treatment Duration</b>
Treatment naïve or experienced* without cirrhosis	simeprevir 150 mg once daily sofosbuvir 300 mg once daily	12 weeks
Treatment naïve or experienced* with cirrhosis	simeprevir 150 mg once daily sofosbuvir 300 mg once daily	24 weeks

\*Treatment-experienced patients who have failed treatment with peginterferon alfa plus ribavirin but not a HCV protease inhibitor

Prior authorization expires at the end of treatment duration (12–24 weeks)

**XV. UTILIZATION MANAGEMENT—HCV AGENTS, DAAs**

*BAP Comments*

**A. Ledipasvir/Sofosbuvir (Harvoni) and Simeprevir (Olysio)—PA Criteria**

The P&T Committee’s recommendations for ledipasvir/sofosbuvir (Harvoni) and simeprevir (Olysio) are listed above.

This section is reserved for BAP discussion and comments.

<i>BAP Comment:</i>	<input type="checkbox"/> Concur <input type="checkbox"/> Non-concur	Additional Comments and Dissention
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## XVI. UTILIZATION MANAGEMENT—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBs)

### *P&T Comments*

#### A. Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel)—PA Criteria

The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class. Recently, adalimumab (Humira) received FDA approval for pediatric Crohn's disease in patients as young as six years and juvenile idiopathic arthritis (JIA) in patients as young as four years; apremilast (Otezla) received FDA approval for plaque psoriasis. PA criteria were updated for Humira and Otezla to reflect their new respective FDA indications. Accordingly, step therapy criteria for etanercept (Enbrel) were also revised since Enbrel and Humira are now indicated for the same age range in patients with JIA.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) revised manual and step therapy PA criteria for Humira and Otezla, consistent with the new FDA-approved product labeling, and an update to the PA criteria for Enbrel since Humira is now indicated for JIA.

The full PA criteria are as follows:

#### Adalimumab (Humira)

Coverage approved for patients  $\geq 18$  years with: (changes highlighted in bold)

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate
- Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade
- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

#### **Pediatric patients with:**

- **Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric patients: 2–17 years)**
- **Moderate to severely active Crohn's disease ( $\geq 6$  years)** who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate



Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan).

### **Apremilast (Otezla)**

- Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade
- Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

### **Pediatric patients with**

- **Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric patients: 2–17 years)**
- **Moderate to severely active Crohn's disease ( $\geq 6$  years)** who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate

Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan).

### **Etanercept (Enbrel)**

Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

#### Manual PA criteria:

If automated criteria are not met, coverage is approved for Enbrel if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative (Enbrel is prescribed for a patient with hepatitis C virus)

AND

Coverage approved for patients  $\geq 18$  years with:

- Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy

Coverage approved for pediatric patients (age 2–17) with:

- Moderate to severe active polyarticular Juvenile Idiopathic Arthritis

Coverage is NOT provided for concomitant use with other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)

## **XVII. UTILIZATION MANAGEMENT—TIBs**

### ***BAP Comments***

#### **A. Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel)—PA Criteria**

The P&T Committee’s recommendations for adalimumab (Humira), apremilast (Otezla), and etanercept (Enbrel) are listed above.

This section is reserved for BAP discussion and comments.

*BAP Comment:*       Concur       Non-concur

Additional Comments and Dissent

## **XVIII. UTILIZATION MANAGEMENT—PROSTATE CANCER DRUGS**

### ***P&T Comments***

#### **A. Enzalutamide (Xtandi)—PA Criteria**

Xtandi is an androgen receptor inhibitor that prolongs survival of metastatic castration-resistant prostate cancer. Manual PA criteria were recommended at the November 2012 P&T Committee meeting. The package insert for Xtandi was updated to state that prior treatment with docetaxel is no longer required.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an update to the manual PA criteria for Xtandi, consistent with the product’s labeling for treatment of metastatic castration-resistant prostate cancer.

The full PA criteria are as follows:

Coverage is approved if:

- Documented diagnosis of metastatic castration-resistant prostate cancer

No expiration date for the PA

## **XIX. UTILIZATION MANAGEMENT—PROSTATE CANCER DRUGS**

### ***BAP Comments***

#### **A. Enzalutamide (Xtandi)—PA Criteria**

The P&T Committee’s recommendation for Enzalutamide (Xtandi) is listed above.

This section is reserved for BAP discussion and comments.

*BAP Comment:*       Concur       Non-concur

Additional Comments and Dissent

## **XX. UTILIZATION MANAGEMENT—NON-INSULIN DIABETES MELLITUS DRUGS: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONIST (GLP1RAs)**

### ***P&T Comments***

#### **A. Exenatide Once Weekly Pen (Bydureon Pen)—PA Criteria**

Exenatide (Bydureon) is now available in a pre-filled pen, in addition to the original vial formulation. The manufacturer states that they do not intend to discontinue the original vial formulation. Both products are dosed once weekly. However, the cost of the Bydureon pen formulation is significantly higher than the Bydureon vials despite having the same dosing and FDA-approved indications. Exenatide (Byetta) is also available in a pen formulation that is dosed twice daily. Manual PA criteria were recommended for the Bydureon pen due to the cost and because other exenatide products (Bydureon vials and Byetta) are available on the UF. The GLP1RA Drug Subclass, including the Bydureon pen formulation, is scheduled for review at an upcoming meeting.

The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 1 absent) manual PA criteria for the Bydureon pen, requiring use of Bydureon vials first. Additionally, a trial of metformin or a sulfonylurea is also required, consistent with the PA criteria for other GLP1RAs.

The full PA criteria are as follows (changes highlighted in bold):

New GLP1RA users are required to try metformin or a sulfonylurea (SU) before receiving Byetta, Bydureon, or Victoza.

Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days, AND

Manual PA criteria, if automated criteria are not met: Byetta, Bydureon, or Victoza is approved (e.g., trial of metformin or SU is NOT required) if:

- 1) The patient has a confirmed diagnosis of Type 2 Diabetes Mellitus
- 2) The patient has experienced any of the following adverse events while receiving metformin: impaired renal function that precludes treatment with metformin or history of lactic acidosis.
- 3) The patient has experienced the following adverse event while receiving a SU: hypoglycemia requiring medical treatment.
- 4) The patient has a contraindication to both metformin and a SU.
- 5) The patient has had an inadequate response to metformin and a SU.
- 6) **Also for exenatide once weekly (Bydureon pen)**
  - **Coverage approved if patient has first tried Bydureon 2mg vial/cartridge first AND**
  - **Patient has dexterity issues and cannot assemble the Bydureon vial/cartridge**

**XXI. UTILIZATION MANAGEMENT—NON-INSULIN DIABETES MELLITUS DRUGS: GLP1RAs**

*BAP Comments*

**A. Exenatide Once Weekly Pen (Bydureon Pen)—PA Criteria**

The P&T Committee’s recommendation for the exenatide once weekly pen (Bydureon Pen) is listed above.

This section is reserved for BAP discussion and comments.

<p><i>BAP Comment:</i>      <input type="checkbox"/> Concur      <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissention</p>
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## **XXII. UTILIZATION MANAGEMENT—COMPOUND PRESCRIPTIONS**

### ***P&T Comments***

#### **A. Compound Prescriptions—PA Criteria**

The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant and increasing, and compounded medications have a high potential for inappropriate use. From June 2013 through May 2014, 140,000 beneficiaries filled 360,000 compounded prescriptions that totaled over \$410 million in expenditures at the Retail Network and Mail Order POS. In an effort to decrease inappropriate use and ensure safety for beneficiaries, PA criteria were proposed.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for all new and current users of compounds. Coverage will be approved if the prescriber provides the following information listed below and implementation of the PA will occur when a final recommendation is made.

1. What is the diagnosis?
2. Has the patient tried commercially available products for the diagnosis provided?  
Please state all products tried.
3. Is there a current national drug shortage of an otherwise commercially available product?
4. What is the proposed duration of therapy?

#### **AND**

The patient meets the following criteria:

- a) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market. (If True, proceed to (2); if False, claim rejects.)
- b) Each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided. (If True, proceed to (3); if False, claim rejects.)
- c) An FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication. (If True, Approved; if False, claim rejects.)

## **XXIII. UTILIZATION MANAGEMENT—COMPOUND PRESCRIPTIONS**

***BAP Comments***

**A. Compound Prescriptions—PA Criteria**

The P&T Committee’s recommendation for compound prescriptions is listed above.

This section is reserved for BAP discussion and comments.

<p><i>BAP Comment:</i>      <input type="checkbox"/> Concur      <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissent</p>
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## Table of Self-Monitoring Blood Glucose System Test Strips in the Class

FreeStyle Lite	Easy Touch	Reveal test strip
Freestyle Xtra	Easy Touch glucose	Relion Confirm Micro
ACCU-CHEK Aviva Plus	Easy Gluco	Relion Prime
GLUCOCARD 01-SENSOR	Easy Gluco G2 test strip	Rightest GS100 test strips
GLUCOCARD Vital	Element test strips	Rightest GS 300 test strips
CONTOUR NEXT	Element Plus	Rightest GS 550 test strips
FreeStyle Insulinx	Embrace	SmartDiabetes Xpres
Nova Max	Evencare test strip	Smartest test
TRUEtest	Evencare G2	Surechek test strips
Prodigy No Coding	EZ Smart	Surestep
OneTouch Verio	EZ Smart Plus Fast Take	Surestep Pro
OneTouch Ultra Blue	Fifty50 test strip	Sure test
ACCU-CHEK	Fora G20	Solus v2
ACCU-CHEK Active	Fora test strip	Telcare test strips
ACCU-CHEK Advantage	Fora v10	Tracer BG
ACCU-CHEK Aviva	Fora V12	TRUEtrack
ACCU-CHEK Comfort Curve	Fora V30a	TRUEtrack Smart System
ACCU-CHEK Instant	G-4 test strip	Ultima
ACCU-CHEK Smartview	GE blood glucose test	Ultratrak
AccuTrend glucose	GE100 blood glucose test strip	Ultratrak Pro
Acura test strips	GLUCOCARD Expression	Ultratrak Ultimate test strip
Advance test strips	GLUCOCARD X sensor	Victory
Advocate test strip	Glucolab	Wavesense AMP
Advocate Redi-Code	Glucose test strip	Wavesense Jazz
Advocate Redi-Code+	Glucometer Encore	Wavesense Presto
Ascensia Elite	Glucostix	
Assure 3	Infinity	
Assure 4	Keynote	
Assure Platinum	Liberty test strips	
Assure Pro	Micro	
BD test strips	Microdot	
BG-star	Neutek 2Tek test strips	
Blood glucose test strips	On Call Vivid test strip	
Blood glucose test strips – Leader	Optium	
Chemstrip BG	Optium EZ	
ChoiceDM G20	Pocketchem EZ	
ChoiceDM GD20	Precision PCX	
Clever Check	Precision PCX Plus	
Clever Choice test strips	Precision Point Of Care	
Clever Choice Pro	Precision QID	
Contour	Premium blood glucose	
Control	Prestige test	
Dextrostix reagent	Prestige smart system	
Easymax	Prodigy	
EasyPlus glucose test strips	Quintet	
EasyPlus mini strip	Quintet AC	
Easy Pro Plus	RefuAH Plus test strip	