

**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—CORTICOSTEROIDS-IMMUNE MODULATORS:
ATOPIC DERMATITIS**

P&T Comments

A. Corticosteroids-Immune Modulators: Atopic Dermatitis—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the atopic dermatitis subclass, which has not been previously reviewed for formulary placement. The products in the subclass include tacrolimus 0.03% and 0.01% ointment (Protopic, generics), pimecrolimus 1% cream (Elidel), crisaborole 2% ointment (Eucrisa), and dupilumab injection (Dupixent). Other drugs used for treating atopic dermatitis, such as topical corticosteroids and systemic immunomodulatory agents were not included in this review.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

Professional Treatment Guidelines for Atopic Dermatitis

- The American Academy of Dermatology (AAD) 2014 guidelines recommend topical emollients as the basis for atopic dermatitis therapy. When additional intervention is required, topical corticosteroids are considered first-line therapies for mild to severe atopic dermatitis, while topical calcineurin inhibitors (pimecrolimus and tacrolimus) are considered second-line after topical corticosteroids.
- Concerns regarding adverse effects with topical corticosteroids include adrenal suppression, striae, and skin atrophy. Evidence from large systematic reviews show that mild to moderate potency corticosteroids pose little to no risk to patients when used appropriately. However, “steroid phobia” can affect patient compliance.
- For severe to uncontrolled atopic dermatitis, systemic therapies are options and include cyclosporine, azathioprine, mycophenolate, and methotrexate.

- The AAD 2017 consensus statement regarding the utilization of systemic therapy in patients with moderate to severe atopic dermatitis recommended use of topical treatments and phototherapy, prior to systemic therapy. Overall, no one therapy was preferred over the others, and individual patient factors should guide treatment selection.
- Crisaborole and dupilumab are not yet mentioned in the AAD guidelines.

Topical Calcineurin Inhibitors (TCIs): pimecrolimus and tacrolimus

- Pimecrolimus (Elidel) is FDA-approved for treating mild to moderate atopic dermatitis, while tacrolimus (Protopic) is approved for moderate to severe atopic dermatitis. Both drugs are approved for use in children as young as two years of age.
- A 2016 AAD meta-analysis concluded that the TCIs and topical corticosteroids show similar rates of improvement of dermatitis and treatment success, but TCIs are associated with a higher incidence of adverse events including skin burning and pruritus on application.
- A 2007 Cochrane review reported moderate- to high-potency corticosteroids and tacrolimus 0.1% were more effective than pimecrolimus. Similar results were reported in a 2015 Cochrane review that concluded tacrolimus 0.1% was more effective than low-potency corticosteroids, pimecrolimus 1%, and tacrolimus 0.03%.
- The product labeling for TCIs contains a black box warning for rare case reports of malignancy. A study published in JAMA Dermatology (2015) evaluated rates of cancer in over 7,400 pediatric pimecrolimus users. The authors concluded it was unlikely that pimecrolimus was associated with an increased risk of malignancy. No skin-related cancers were reported.

Topical Phosphodiesterase (PDE)-4 inhibitor: crisaborole (Eucrisa)

- Crisaborole (Eucrisa) is a non-steroidal phosphodiesterase (PDE)-4 inhibitor indicated for patients as young as 2 years of age with mild to moderate atopic dermatitis. In the two controlled trials used for FDA approval, crisaborole treatment resulted in statistically significant improvement in atopic dermatitis signs and symptoms, compared to placebo vehicle. Although the results were statistically significant, the drugs provided only modest clinical benefit. There are no trials available comparing crisaborole with topical corticosteroids or the TCIs.
- The 2017 Institute for Clinical and Economic Review (ICER) review of crisaborole noted that there is not an agreed-upon definition of “mild-to-moderate” or “moderate-to-severe” atopic dermatitis. ICER also concluded that for patients with mild to moderate atopic dermatitis, there is inadequate evidence on both the relative efficacy and safety of crisaborole compared to other treatment options.
- Common side effects for crisaborole include burning and itching on application.

- Overall, despite the novel mechanism of action, crisaborole has no compelling advantages over the current formulary drugs used for atopic dermatitis.

Systemic therapy: dupilumab injection (Dupixent)

- Dupilumab is an interleukin-4/interleukin-13 antagonist monoclonal antibody indicated for moderate to severe atopic dermatitis that is not adequately controlled with topical prescription therapies. The 2017 ICER review concluded there was high certainty that dupilumab provides at least a small net health benefit relative to treatment with emollients, with or without continued failed topical treatments. Additionally, there was moderate certainty that the net health benefit of dupilumab is comparable or better than that provided by cyclosporine.
- Limitations to dupilumab include the lack of comparative trials with standard systemic treatments, the lack of long-term safety data, and the fact that it is only approved for use in adults. Pediatric trials are ongoing.
- The most common side effects for dupilumab are injection-site reactions and conjunctivitis.
- Dupilumab has fewer known side effects and monitoring requirements compared to azathioprine, cyclosporine, methotrexate, and mycophenolate.

B. Atopic Dermatitis—Relative Cost-Effectiveness Analysis and Conclusion

Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the atopic dermatitis agents. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic tacrolimus was the most cost-effective atopic dermatitis drug, followed by pimecrolimus (Elidel), branded tacrolimus (Protopic), crisaborole ointment (Eucrisa), and dupilumab injection (Dupixent).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating pimecrolimus (Elidel), tacrolimus, and dupilumab (Dupixent) as formulary, with crisaborole (Eucrisa) as NF demonstrated significant cost avoidance for the Military Health System (MHS).

C. Atopic Dermatitis—UF Recommendation

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

- UF
 - pimecrolimus (Elidel)
 - dupilumab (Dupixent)
 - tacrolimus (Protopic, generics)
- NF
 - crisaborole (Eucrisa)

D. Atopic Dermatitis—Manual Prior Authorization (PA) Criteria

Manual PA criteria for both crisaborole ointment and dupilumab injection were recommended at the May 2017 P&T Committee meeting. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) updating the current PA criteria for dupilumab (Dupixent), to require a trial of phototherapy, if feasible, in all new users, due to the AAD 2017 consensus statement on systemic therapies. The Committee also recommended maintaining the current manual PA criteria for crisaborole (Eucrisa), which requires a two-week trial of at least two formulary medium to high potency topical corticosteroids or a TCI first.

1. Eucrisa

No changes from the November 2017 meeting

Manual PA criteria apply to all new users of Eucrisa.

Manual PA criteria: Coverage is approved if all of the following criteria are met:

- Patient has mild to moderate atopic dermatitis
- Prescribed by a dermatologist, allergist, or immunologist
- Patient has a contraindication to, intolerability to, or failed treatment with a two-week trial of at least one medium to high potency topical corticosteroid

AND

- Patient has a contraindication to, intolerability to, or failed treatment with a two-week trial of a second agent including
 - An additional medium - high potency topical corticosteroid OR
 - Topical calcineurin inhibitor (i.e., tacrolimus, Elidel)

Non-FDA-approved uses are NOT approved.

PA does not expire.

2. Dupixent

August 2018 updates are in BOLD.

Manual PA criteria apply to all new users of Dupixent.

Manual PA criteria: Coverage will be approved for initial therapy for 6 months if all criteria are met:

- Patient has moderate to severe or uncontrolled atopic dermatitis
- Patient must be 18 years of age or older
- Prescribed by a dermatologist, allergist, or immunologist
- Patient has a contraindication to, intolerability to, or failed treatment with at least **ONE** high potency/class 1 topical corticosteroid
- Patient has a contraindication to, intolerability to, or failed treatment with at least **ONE** systemic immunosuppressant

- **Patient has a contraindication to, intolerability to, inability to access treatment, or failed treatment with Narrowband UVB phototherapy**

Non-FDA-approved uses are NOT approved.

PA expires after 6 months.

Renewal PA criteria: coverage will be approved indefinitely for continuation of therapy if:

- The patient has had a positive response to therapy, e.g., an Investigator’s Static Global Assessment (ISGA) score of clear (0) or almost clear (1)

E. Atopic Dermatitis—UF and PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service.

III. UF CLASS REVIEWS—ATOPIC DERMATITIS

BAP Comments

A. Atopic Dermatitis—UF Recommendation

The P&T Committee recommended the following:

- UF
 - Elidel
 - Dupixent
 - Protopic, generics
- NF
 - Eucrisa

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

The P&T Committee recommended updating the current PA criteria for Dupixent, to require a trial of phototherapy, if feasible, in all new users. The Committee also recommended maintaining the current manual PA criteria for Eucrisa. The full PA criteria were stated previously.

BAP Comment:

Concur

Non-concur

Additional Comments and Dissension

C. Atopic Dermatitis—UF and PA Implementation Plan

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

BAP Comment:

Concur

Non-concur

Additional Comments and Dissension

IV. HEPATITIS C VIRUS (HCV) DIRECT-ACTING ANTIVIRALS (DAAs)

P&T Comments

A. Hepatitis C Virus (HCV) Direct-Acting Antivirals (DAAs)—Relative Clinical Effectiveness Analysis and Conclusion

Background—The HCV DAAs subclass has previously been reviewed for formulary placement three times, most recently in February 2017. Two products, glecaprevir/pibrentasvir (Mavyret) and sofosbuvir/velpatasvir/voxilaprevir (Vosevi), were reviewed as new drugs at the November 2017 P&T Committee meeting. Since the last review, simplification of HCV treatment has occurred, including introduction of additional regimens lasting only 8 weeks, FDA approval of additional single-tablet regimens, and the availability of additional pangenotypic therapies.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

- There were no major changes to the clinical effectiveness conclusion from the February 2017 meeting.
- The first-line HCV DAAs are Epclusa, Harvoni, and Mavyret.
- Advantages of Harvoni include approval for treatment courses as short as 8 weeks in treatment-naïve patients with HCV genotype (GT) 1, availability as a single tablet dosed once daily, and approval for use in patients with decompensated cirrhosis. Patients with GT 4, 5, and 6 require 12-week treatment courses. Harvoni should remain designated as UF, due to existing high utilization in DoD, provider familiarity, and the fact that the majority of MHS patients with HCV have GT 1.
- Advantages of Epclusa include that it was the first pangenotypic HCV DAA marketed, it is dosed as a single tablet once daily, and it has an improved resistance profile. It

remains an option of HCV therapy for treatment-naïve patients, but requires a 12-week course of therapy. It can be used in patients with decompensated cirrhosis.

- Mavyret was the third pangenotypic HCV DAA to receive FDA approval. It provides an 8-week course of therapy in treatment-naïve patients and treatment-experienced patients who do not have cirrhosis. Mavyret can also be used in patients with moderate to severe renal disease, including those on dialysis. It is dosed as three tablets once daily, and must be given with food.
- Vosevi was the second pangenotypic HCV DAA approved. It is reserved for use in treatment-experienced patients, and fills a unique niche for this population. It is dosed as a single tablet once daily for 12 weeks in most patients. It is not indicated for patients with moderate to severe renal dysfunction, including those with end-stage renal disease (ESRD).
- Daklinza, Olysio, Sovaldi, and Zepatier are no longer the standard of care for HCV, due to their longer treatment courses, limited genotype coverage, unfavorable tolerability and toxicity profiles, and/or higher pill burden.
- 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, comorbidities, concomitant medications, and cost.

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

CMA and BIA were performed to evaluate the HCV DAA agents. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that glecaprevir/pibrentasvir (Mavyret), sofosbuvir/velpatasvir (Epclusa), and ledipasvir/sofosbuvir (Harvoni) were the most cost-effective HCV DAAs, followed by grazoprevir/elbasvir (Zepatier), paritaprevir/ritonavir/ombitasvir (Technivie), paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira Pak and Viekira XR), sofosbuvir/velpatasvir/voxilaprevir (Vosevi), daclatasvir (Daklinza), and sofosbuvir (Sovaldi).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Mavyret, Epclusa, Harvoni, Technivie, Viekira, Viekira XR, and Vosevi as formulary, and Daklinza, Olysio, Sovaldi, and Zepatier as NF demonstrated the largest cost avoidance for the MHS.

C. HCV DAAs—UF Recommendation

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

- UF
 - sofosbuvir/velpatasvir (Epclusa)
 - ledipasvir/sofosbuvir (Harvoni)
 - glecaprevir/pibrentasvir (Mavyret)
 - paritaprevir/ritonavir/ombitasvir (Technivie)

- paritaprevir/ritonavir/ombitasvir/dasabuvir tablets pak (Viekira Pak)
- paritaprevir/ritonavir/ombitasvir/dasabuvir XR tablets (Viekira XR)
- sofosbuvir/velpatasvir/voxilaprevir (Vosevi)
- NF
 - daclatasvir (Daklinza)
 - simeprevir (Olysio)
 - sofosbuvir (Sovaldi)
 - grazoprevir/elbasvir (Zepatier)
- Note that as part of this recommendation, the current requirement for a trial of Harvoni prior to another HCV DAA (“step therapy”) has been removed. Additionally, no HCV DAA products were recommended for Extended Core Formulary (ECF) addition. For the HCV drug class, ribavirin 200 mg capsules and peginterferon alfa-2a (Pegasys) were designated ECF in November 2012.

D. HCV DAAs—Manual PA Criteria

Manual PA criteria is currently required for all the HCV DAAs, including the use of Harvoni as the step-preferred product. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) revising the manual PA criteria for new users of Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira XR, Viekira Pak, and Zepatier, to remove the Harvoni step therapy requirement, and simplify the PA criteria by having these drugs on the same PA form.

Additionally, the P&T Committee recommended maintaining separate PA criteria for Vosevi, since it is reserved for treatment-experienced patients. Minor updates to the Vosevi PA criteria were also recommended for new users, including removal of the Harvoni step. Coverage for any HCV DAA is only allowed for the FDA-approved indications or as outlined in the American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD/IDSA) HCV guidelines (www.HCVguidelines.org).

1. Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira XR, Viekira Pak, and Zepatier

Changes from the August 2018 meeting will replace current PA criteria in place for the HCV DAAs. Note that the Harvoni step therapy requirement has been removed.

Manual PA criteria apply to all new users of Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira Pak, Viekira XR, and Zepatier.

Manual PA criteria: The HCV DAA is approved if all of the following criteria are met:

- ≥ 18 years of age
- Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician
- Patient has laboratory evidence of hepatitis C virus infection

- The HCV genotype is documented (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6)

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

PA expires in 1 year.

2. Vosevi

Changes from the November 2017 meeting are in strikethrough; August 2018 updates are in BOLD and strikethrough.

Manual PA criteria apply to all new users of Vosevi.

Manual PA criteria: Vosevi is approved if all the following criteria are met:

- ≥ 18 years of age and diagnosed with chronic hepatitis C virus (HCV)
- Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Laboratory evidence of chronic hepatitis C
- The HCV genotype is documented. (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6)
- The patient does not have estimated glomerular filtration rate (eGFR) ≤ 30 mL/min or end-stage renal disease (ESRD) requiring hemodialysis
- The patient will not be receiving concomitant therapy with other hepatitis C drugs or rifampin
- The treatment course will not exceed the maximum duration of treatment of 12 weeks
- **Patient has one of the following:**
 - **Patient has HCV GT 1, 2, 3, 4, 5, or 6 and was previously treated with an HCV regimen containing an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir).**
 - OR**
 - **Patient has HCV GT 1a or 3 and has previously been treated with an HCV regimen containing sofosbuvir with or without an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir).**
- ~~• Patient cannot use Harvoni (due to HCV GT2 or GT3) other agents (due to decompensation, etc.)~~

AND

- ~~• Previously treated with an NS5A inhibitor OR~~

- ~~HCV GT 1a or 3 and treated with sofosbuvir without an NS5A inhibitor~~

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 1 year; complete original PA form for renewal of therapy.

E. HCV DAAs—UF and PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, and 2) DHA send letters to beneficiaries who are affected by the UF decision.

V. HCV DAAs

BAP Comments

A. HCV DAAs—UF Recommendation

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

- UF
 - Epclusa
 - Harvoni
 - Mavyret
 - Technivie
 - Viekira XR and Viekira Pak
 - Vosevi
- NF
 - Daklinza
 - Olysio
 - Sovaldi
 - Zepatier

<p><i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissension</p>
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B. HCV DAAs—Manual PA Criteria

The P&T Committee recommended revising the manual PA criteria for new users of all the drugs except Vosevi, to remove the Harvoni step therapy requirement, and simplify the PA criteria by having these drugs on the same PA form.

Additionally, the P&T Committee recommended maintaining separate PA criteria for Vosevi, since it is reserved for treatment-experienced patients. Minor updates to the

Vosevi PA criteria were also recommended for new users, including removal of the Harvoni step. The full PA criteria were stated previously.

<p><i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissension</p>

C. HCV DAAs—UF and PA Implementation Plan

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

<p><i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissension</p>

**VI. CORTICOSTEROIDS-IMMUNE MODULATORS:
ADRENOCORTICOTROPIC HORMONES (ACTH)**

P&T Comments

**A. Corticosteroids-Immune Modulators: Adrenocorticotrophic Hormones (ACTH)—
Relative Clinical Effectiveness Analysis and Conclusion**

Background—The P&T Committee previously evaluated the ACTH subclass at the February 2018 meeting. The ACTH subclass is comprised solely of injectable corticotropin (H.P. Acthar Gel). The Committee designated H.P. Acthar with UF status, with manual PA allowing use exclusively for infantile spasms or exacerbation of multiple sclerosis (MS) and only after failure of or intolerance to a course of corticosteroids.

At this meeting, the P&T Committee reviewed additional information received from providers and the FDA as it relates to the clinical effectiveness and safety of H.P. Acthar. There was no change to the cost effectiveness conclusion, Uniform Formulary recommendation, or PA criteria from the February 2018 P&T Committee meeting.

A comprehensive review of the evidence for H.P. Acthar Gel’s efficacy for infantile spasms, multiple sclerosis exacerbation, other uses, and safety and tolerability across all indications and usages was performed for the February 2018 P&T Committee meeting. That comprehensive body of evidence guided the P&T’s decision-making in that meeting.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

- Infantile Spasms

- New information was presented that reaffirms and strengthens the clinical conclusions reached by the P&T Committee at the February 2018 meeting, including the following:
 - Patients with infantile spasms require urgent treatment that is better facilitated by oral corticosteroids, which are widely available, rather than the administratively burdensome H.P. Acthar Gel, due to the limited distribution requirements by the manufacturer.
 - High-dose oral corticosteroids were reaffirmed as a frontline treatment alongside H.P. Acthar Gel and vigabatrin (Sabril).
- MS Exacerbation
 - Fundamentals of inflammation were reviewed, reaffirming the appropriateness of the requirement that patients try and fail the safer and more effective corticosteroid treatment option prior to approval of H.P. Acthar Gel for each multiple sclerosis exacerbation.
- Other Uses
 - There was no new data to support changing the original recommendation that uses other than infantile spasms and MS exacerbation be excluded from TRICARE coverage.¹
- Safety
 - No new information was presented that helped allay the concerns of the Committee regarding the safety profile of H.P. Acthar Gel. New data, however, did cause the Committee to have more safety concerns than previously concluded.
- Other Factors
 - A review of coverage of H.P. Acthar Gel by several commercial health care plans performed for the February 2018 P&T Committee meeting found significant limitations or outright exclusions of H.P. Acthar Gel.
 - For the August 2018 meeting, the P&T Committee reviewed an update to several national health care plans and health systems' coverage policies. Of the 50 pharmacy benefit managers (PBMs) reviewed in the update, 9 health care plans did not cover H.P. Acthar Gel for any indication for their respective beneficiaries.
 - Several prominent health care plans and health systems require a trial of oral corticosteroids prior to using H.P. Acthar Gel for infantile spasms. These include Intermountain Health System in Utah and leading Academic Centers of Excellence in Pediatric Neurology, such as Johns Hopkins and UCLA.
 - The P&T Committee reviewed prior decisions in other drug classes where the recommendation was to require a trial of a drug lacking FDA approval for a

¹ As with any drug, an appeal is available for an eligible covered beneficiary or network or uniformed provider on behalf of the beneficiary to establish clinical justification for the use of a pharmaceutical agent that is not on the Uniform Formulary. See 10 U.S.C. § 1074g.

particular diagnosis prior to use of a drug that carries FDA approval for that particular diagnosis. One example is that patients with Duchenne’s Muscular Dystrophy are required to try or have intolerance to prednisone prior to using deflazacort (Emflaza) [February 2017 DoD P&T Committee Meeting].

- Overall, the Committee evaluated the additional information presented and agreed that no new evidence was presented that would change the clinical conclusions reached by the P&T Committee at the February 2018 meeting. In fact, additional information for treatment of infantile spasms further confirmed the appropriateness of a trial of corticosteroids and the importance of early treatment, before using H.P. Acthar Gel. Additional safety concerns for H.P. Acthar Gel were raised by the new information. No changes to the existing manual PA criteria for H.P. Acthar Gel were recommended.

**VII. CORTICOSTEROIDS-IMMUNE MODULATORS:
ADRENOCORTICOTROPIC HORMONES (ACTH)**

BAP Comments

**A. Corticosteroids-Immune Modulators: Adrenocorticotrophic Hormones (ACTH)—
Maintain Current UF Status and PA Criteria**

The P&T Committee evaluated the additional information presented and agreed that no new evidence was presented that would change the clinical conclusions reached by the P&T Committee at the February 2018 meeting. Additional safety concerns were raised. The Committee agreed that no changes were recommended to the Uniform Formulary recommendation or the existing manual PA criteria for H.P. Acthar Gel from the February 2018 P&T Committee meeting.

<p><i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissension</p>

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

P&T Comments

**A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Relative Clinical Effectiveness
and Relative Cost-Effectiveness Conclusions**

The P&T Committee agreed (group 1 and 3: 14 for, 0 opposed, 0 abstained, 0 absent; group 2: 13 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent and group 2: 13 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
 - abiraterone acetate micronized (Yonsa) – Oral Oncologic Agent for Prostate Cancer
 - avatrombopag (Doptelet) – Hematological Agent: Platelets for Thrombocytopenia in Chronic Liver Disease
 - baricitinib (Olumiant) – Targeted Immunomodulatory Biologic (TIB) for Rheumatoid Arthritis
 - binimetinib (Mektovi) – Oral Oncologic Agent for Metastatic Melanoma
 - encorafenib (Braftovi) – Oral Oncologic Agent for Metastatic Melanoma
 - epoetin-alfa-epbx (Retacrit) injection – Hematological Agent: Red Blood Cell Stimulant for Erythropoiesis
 - erenumab-aooe (Aimovig) injection – Migraine Agent (calcitonin gene-related peptide [CGRP]) for Migraine Headache Prophylaxis
 - fostamatinib (Tavalisse) – Hematological Agent: Platelets for Chronic Immune Thrombocytopenia
 - hydroxyurea (Siklos) tablets – Hematological Agent: Sickle Cell Anemia Agent for Sickle Cell Anemia in Pediatrics
 - pegvaliase-pqpz (Palynziq) injection – Miscellaneous Metabolic Agent for Phenylketonuria
 - tolvaptan (Jynarque) – Miscellaneous Nephrology Agent for Rapidly Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD)
- NF:
 - amantadine extended release tablets (Osmolex ER) – Parkinson’s Agent
 - estradiol (Imvexxy) vaginal insert – Miscellaneous Gynecological Agent for Dyspareunia
 - levonorgestrel/ethinyl estradiol/ferrous (Balcoltra) – Oral Combined Contraceptive Agent
 - lofexidine (Lucemyra) – Alpha 2 Antagonist for Mitigation of Symptoms of Opioid Withdrawal
 - oxycodone IR (Roxybond) – Narcotic Analgesic Abuse Deterrent Formulation for Pain

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

The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent and group 2: 13 for, 0 opposed, 0 abstained, 1 absent) the following:

- Applying manual PA criteria to new users of Yonsa, Osmolex ER, Doptelet, Olumiant, Imvexxy, Mektovi, Braftovi, Lucemyra, Aimovig, Siklos, and Palynziq.
- Applying manual PA criteria to new and current users of Tavalisse and Jynarque.

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

1. abiraterone acetate micronized (Yonsa)

Manual PA criteria apply to all new users of Yonsa.

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

- Provider is aware that Yonsa may have different dosing and food effects than other abiraterone acetate products, due to the risks of medication errors and overdose
- Patient has documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)
- Patient must receive concomitant therapy with methylprednisolone
- The patient is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had bilateral orchiectomy

Non-FDA-approved uses are NOT approved, with exception for treatment in patients with metastatic high-risk castration-sensitive prostate cancer (mHRCSPC).

PA does not expire.

2. amantadine extended release tablets (Osmolex ER)

Manual PA criteria apply to all new users of Osmolex ER.

Manual PA criteria: Osmolex ER is approved if all criteria are met:

- Patient is aged 18 years and older
- Patient has a diagnosis of either Parkinson's disease or drug-induced extrapyramidal symptoms
- Patient has had therapeutic failure of a trial of amantadine 300 mg per day given in divided doses using immediate release tablets.

Non-FDA-approved uses are NOT approved.

PA does not expire.

3. avatrombopag (Doptelet)

Manual PA criteria apply to all new users of Doptelet.

Manual PA criteria: Avatrombopag (Doptelet) is approved if all criteria are met:

- Age ≥ 18
- Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet count less than $50 \times 10^9/L$)
- Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag
- Patient has no evidence of current thrombosis
- The drug is prescribed by or in consultation with a gastroenterologist

Non-FDA-approved uses are NOT approved.

PA expires in 60 days.

4. baricitinib (Olumiant)

Manual PA criteria apply to all new users of Olumiant.

Manual PA criteria: Baricitinib (Olumiant) is approved if all criteria are met:

- Provider acknowledges that Humira is the preferred TIB to treat rheumatoid arthritis
- Provider acknowledges that if a JAK inhibitor is desired, Xeljanz/Xeljanz XR is an alternative to baricitinib (Olumiant) without the black box warning risk of thrombosis
- Age \geq 18
- Has diagnosis of moderate to severe active rheumatoid arthritis
- Has a contraindication, inadequate response, or had an adverse reaction to adalimumab (Humira)
- Has a contraindication, inadequate response, or had an adverse reaction to methotrexate
- Has no history of thromboembolic disease
- Is not receiving other potent immunosuppressants (e.g., azathioprine or cyclosporine)
- May not be used concomitantly with other TIB agents except for Otezla
- Must be prescribed by or in consultation with a rheumatologist

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

5. **binimetinib (Mektovi)**

Manual PA criteria apply to all new users of Mektovi.

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

- Age \geq 18 years
- Has unresectable or metastatic melanoma
- Has confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test
- Mektovi is being taken in combination with Braftovi
- Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)
- Prescribed by or in consultation with an oncologist

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

6. **encorafenib (Braftovi)**

Manual PA criteria apply to all new users of Braftovi.

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

- Age \geq 18 years
- Has unresectable or metastatic melanoma

- Has confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test
- Braftovi is being taken in combination with Mektovi
- Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)
- Prescribed by or in consultation with an oncologist

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

7. **erenumab-aooe (Aimovig) injection**

Manual PA criteria apply to all new users of Aimovig.

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

- Patient \geq 18 years old and not pregnant
- Must be prescribed by or in consultation with a neurologist
- Patient has a migraine diagnosis with at least 8 migraine days per month for 3 months
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
 - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
 - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol
 - Prophylactic antidepressants: amitriptyline, venlafaxine

Non-FDA-approved uses are NOT approved.
PA expires after 6 months.

Renewal criteria: coverage will be approved indefinitely for continuation of therapy if:

- The patient has shown improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication)

8. **estradiol (Imvexxy) vaginal insert**

Manual PA criteria apply to all new users of Imvexxy.

Manual PA criteria: Imvexxy is approved for 1 year if all criteria are met:

- Patient is a postmenopausal woman with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy
- Patient has tried and failed or has a contraindication to a low dose vaginal estrogen preparation (e.g., Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem)
- Patient does not have any of the following:
 - Undiagnosed abnormal genital bleeding

- Pregnant or breastfeeding
- History of breast cancer or currently has breast cancer
- History of thromboembolic disease or currently has thromboembolism

Non-FDA-approved uses are NOT approved.
PA expires in 1 year.

Renewal criteria: Coverage is approved for an additional year if:

- Patient has an improvement in dyspareunia symptom severity

9. fostamatinib (Tavalisse)

Manual PA criteria apply to all new and current users Tavalisse.

Manual PA criteria: Fostamatinib (Tavalisse) is approved if all criteria are met:

- Age ≥ 18
- Has diagnosis of chronic primary idiopathic thrombocytopenic purpura (ITP) whose disease has been refractory to at least one previous therapy (including IVIG, thrombopoietin(s), corticosteroids, and/or splenectomy)
- Has laboratory evidence of thrombocytopenia with average [platelet] count less than $30 \times 10^9/L$ over three discrete tests
- Has no evidence of active or chronic infection
- Has no evidence of secondary thrombocytopenia
- Does not have uncontrolled hypertension
- Has had no cardiovascular event (including but not limited to MI, unstable angina, PE, CVA, and/or NYHA Stage III or IV CHF) within the last 6 months
- Has no evidence of neutropenia or lymphocytopenia
- Prescribed by or in consultation with a hematologist/oncologist
- Tavalisse is not being used concomitantly with other chronic ITP therapy

Non-FDA-approved uses are NOT approved.
PA expires in 120 days.

Renewal criteria: Fostamatinib (Tavalisse) can be renewed for an additional year if all criteria are met:

- Has demonstrated a response to fostamatinib (Tavalisse) as defined by a sustained platelet count $> 50 \times 10^9/L$ or an increase in platelet count by $\geq 20 \times 10^9/L$ above baseline. Sustained is defined by two separate tests (at least 2 or more weeks apart) meeting either or both of the aforementioned criteria
- Has no evidence of active or chronic infection
- Has no evidence of secondary thrombocytopenia
- If patient carries a diagnosis of hypertension, it is well controlled according to national guidelines (e.g., JNC 8)

- Has had no cardiovascular event (including but not limited to MI, unstable angina, PE, CVA, and/or NYHA Stage III or IV CHF) within the last 6 months
- Has no evidence of neutropenia or lymphocytopenia.
- Prescribed by or in consultation with a hematologist/oncologist

10. hydroxyurea (Siklos)

Manual PA criteria apply to all new users of Siklos older than 18 years of age.

Automated PA criteria: Siklos will be approved for patients \leq 18 years of age.

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

- Age \geq 19 years
- The provider documents a patient-specific reason why the patient cannot use the preferred product (generic hydroxyurea or Droxia).
- Acceptable responses would include.
 - The patient has a diagnosis of sickle cell disease AND has swallowing difficulties
- Note that use of Siklos for malignancy (e.g., chronic myelocytic leukemia or other cancers) is not approved

Non-FDA-approved uses are NOT approved.

PA expires after 1 year.

Renewal criteria: Coverage will be approved indefinitely if all of the following apply:

- Patient continues to have swallowing difficulties that preclude the use of hydroxyurea 200 mg, 300 mg, 400 mg, or 500 mg capsules
- Patient has been monitored and has had at least two laboratory draws in the last year and has not developed hematologic toxicity (Toxic hematologic ranges: Neutrophils $<$ 2,000/mm³; platelets $<$ 80,000/mm³; hemoglobin $<$ 4.5 g/dL; and reticulocytes $<$ 80,000/mm³ if hemoglobin is $<$ 9 g/dL)
- Patient has achieved a stable dose with no hematologic toxicity for 24 weeks

11. lofexidine (Lucemyra)

Manual PA criteria apply to all new users of Lucemyra.

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

- Lucemyra is prescribed for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation
- Patient is \geq 18 years old
- Lucemyra will not be prescribed for longer than 14 days
- The provider documents a patient-specific reason why the patient cannot use the preferred product, clonidine. Acceptable responses include that

the patient has experienced orthostatic hypotension or severe bradycardia with previous clonidine use

Non-FDA-approved uses are NOT approved (e.g., blood pressure control, nicotine withdrawal, Tourette syndrome, or ADHD).
PA expires after 3 months.

Renewal criteria: Renewal of therapy will not be allowed

12. pegvaliase-pqpz (Palynziq)

Manual PA criteria apply to all new users of Palynziq.

Manual PA criteria: Palynziq is approved for initial therapy if all criteria are met:

- Patient is ≥ 18 years of age
- Patient has uncontrolled blood phenylalanine concentrations > 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, or prior treatment with Kuvan [sapropterin dihydrochloride tablets and powder for oral solution])
- Palynziq is prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses on the treatment of metabolic diseases)
- Provider acknowledges and has educated the patient on the risk of anaphylaxis
- Patient has a prescription for self-administered SQ epinephrine
- Patient is not using Palynziq concomitantly with Kuvan

Non-FDA-approved uses are NOT approved.
PA expires in 6 months.

Renewal criteria (maintenance/continuation therapy): Coverage will be approved for 1 year if:

- The patient's blood phenylalanine concentration is ≤ 600 micromol/L OR
- The patient has achieved a $\geq 20\%$ reduction in blood phenylalanine concentration from pre-treatment baseline (i.e., blood phenylalanine concentration before starting Palynziq therapy) AND
- Patient is not using Palynziq concomitantly with Kuvan

13. tolvaptan (Jynarque)

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

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

- Age ≥ 18
- Jynarque is prescribed by or in consultation with a nephrologist
- Provider acknowledges that Jynarque requires liver function monitoring with evaluation of transaminases and bilirubin before initiating treatment, at 2 weeks and 4 weeks after initiation, then continuing monthly for the first 18 months and every 3 months thereafter
- Patient has rapidly progressing autosomal dominant polycystic kidney disease (ADPKD, defined as reduced or declining renal function [i.e.,

glomerular filtration rate {GFR} less than or equal to 65 mL/min/1.73 m²] and high total kidney volume [i.e., greater than or equal to 750ml])

- Patient does not have Stage 5 chronic kidney disease (CKD) [GFR < 15 mL/min/1.73 m²]
- Patient is not receiving dialysis
- Patient is not currently taking Samsca (tolvaptan)

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

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

The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent; and group 2: 13 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday two weeks after signing of the minutes in all points of service.

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

BAP Comments

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

The P&T Committee recommended the following:

- UF:
 - Yonsa
 - Doptelet
 - Olumiant
 - Mektovi
 - Braftovi
 - Retacrit injection
 - Aimovig injection
 - Tavalisse
 - Siklos
 - Palynziq injection
 - Jynarque
- NF:
 - Osmolex ER
 - Invexxy vaginal insert
 - Balcoltra
 - Lucemyra
 - Roxybond

BAP Comment: Concur Non-concur

Additional Comments and Dissension

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

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

- Applying manual PA criteria to new users of Mektovi, Braftovi, Yonsa, Olumiant, Osmolex ER, Siklos, Doptelet, Palynziq, Invexxy, Aimovig, and Lucemyra.
- Applying manual PA criteria to new and current users of Tavalisse and Jynarque.

BAP Comment: Concur Non-concur

Additional Comments and Dissension

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

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

BAP Comment: Concur Non-concur

Additional Comments and Dissension

X. UTILIZATION MANAGEMENT

P&T Comments

A. PA Criteria and Step Therapy

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

- 1. Epinephrine Auto-Injectors: Auvi-Q Temporary Removal of Manual PA Criteria**—The Auvi-Q device includes audible voice instructions and has a needle that automatically retracts following injection. Manual PA criteria were previously recommended for all epinephrine auto-injectors, including Epi-Pen, generic epinephrine auto-injectors, and Auvi-Q, at the February 2017 P&T Committee meeting. The PA requirements for Epi-Pen were administratively removed on May 23, 2018, due to a

national shortage. There have been continued shortages of Epi-Pen, and intermittent availability of generic epinephrine auto-injectors.

Although Auvi-Q is significantly more expensive than Epi-Pen, the manual PA requirements for Auvi-Q will be temporarily lifted, but re-instated administratively when the supply of Epi-Pen and generic epinephrine auto-injectors has stabilized. The Committee acknowledged, however, that it is doubtful that the current Auvi-Q supply will support the volume required to replace Epi-Pen.

- 2. Renin Angiotensin Antihypertensive Agents (RAAs): candesartan and candesartan/HCTZ Step-Therapy**—Step therapy in the RAAs class requires a trial of losartan, telmisartan, valsartan, or irbesartan, or their respective combinations with hydrochlorothiazide (HCTZ), prior to use of non-step-preferred angiotensin receptor blockers (ARBs). Two ARBs, candesartan and irbesartan, are approved for treating heart failure with reduced ejection fraction (HFrEF), in addition to hypertension. Candesartan and candesartan/HCTZ are currently designated as UF but non-step-preferred.

There is currently a national recall of valsartan, due to contamination with a carcinogen. There is no immediate risk to patients currently taking valsartan. However, availability of valsartan lots not affected by the recall are in limited supply, and it remains uncertain as to when the shortage will be resolved.

A group of MHS cardiologists has requested removing the step therapy requirement for candesartan, due to the valsartan recall. Cost-effective formulations of candesartan and candesartan/HCTZ are now available. Candesartan and candesartan/HCTZ will now be designated as step-preferred, with the step therapy criteria and medical necessity criteria for the remaining non-step-preferred RAAs updated accordingly.

- 3. Oncological Agents for unresectable or metastatic melanoma: dabrafenib (Tafinlar), trametinib (Mekinist), and vemurafenib (Zelboraf) Manual PA criteria**—These drugs are approved for treating unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. They are exclusively used in unique pair combinations of a specific BRAF drug with a specific mitogen-activated extracellular signal regulated kinase (MEK) inhibitor. Due to the risk of enhanced toxicity if other combinations of BRAF with MEK inhibitors are administered together, the PA criteria were updated to prevent the use of concurrent therapies outside of the FDA-approved combination.

Criteria were also updated for dabrafenib (Tafinlar) and trametinib (Mekinist) to include the new FDA-approved indication for combination use for locally advanced or metastatic anaplastic thyroid cancer without satisfactory locoregional treatment options.

- 4. Oncological Agents: Prostate II - enzalutamide (Xtandi)**—In August 2012, manual PA criteria were recommended for Xtandi. PA criteria were updated in February 2015 to remove the co-administration requirement of docetaxel. Xtandi is now FDA-approved for treatment of castration-resistant prostate cancer, and does not require the presence of metastatic disease. Additionally, the PA criteria were also updated to

include new product labeling that requires the patient receive concomitant therapy with a gonadotropin-releasing hormone (GnRH) analog, or have had bilateral orchiectomy.

- 5. Targeted Immunomodulatory Biologics (TIBs): Tofacitinib (Xeljanz/Xeljanz XR)**—The TIBs were reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Xeljanz was originally approved for treating rheumatoid arthritis. In February 2018, PA criteria were updated to add the indication for active psoriatic arthritis in adults. The PA criteria were further expanded to include a new FDA-approved indication of ulcerative colitis.

B. Updated Manual PA Criteria

The P&T Committee recommended the following:

- (12 for, 0 opposed, 0 abstained, 2 absent) to temporarily remove the manual PA criteria for Auvi-Q, until adequate supply of the Epi-Pen auto-injector has been established.
- (14 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria and step therapy for candesartan and candesartan/HCTZ.
- (13 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Tafenlar, Mekinist, Zelboraf, Xeljanz/Xeljanz XR, and Xtandi.

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

The P&T Committee recommended the following implementation periods:

- (12 for, 0 opposed, 0 abstained, 2 absent) and (14 for, 0 opposed, 0 abstained, 0 absent) To administratively implement the removal of manual PA requirements for Auvi-Q and to designate candesartan and candesartan/HCTZ as step-preferred.
- (13 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PAs for Tafenlar, Mekinist, Zelboraf, Xeljanz, Xeljanz XR, and Xtandi become effective on the first Wednesday two weeks after the signing of the minutes.

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

BAP Comments

A. Updated Manual PA Criteria and PA Renewal Criteria

The P&T Committee recommended updates to the manual PA criteria for Auvi-Q, candesartan and candesartan/HCTZ, Tafenlar, Mekinist, Zelboraf, Xtandi, and Xeljanz/Xeljanz XR, as stated above.

<p><i>BAP Comment:</i> <input type="checkbox"/> Concur <input type="checkbox"/> Non-concur</p> <p style="text-align: right;">Additional Comments and Dissension</p>

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

The P&T Committee recommended that the temporary removal of the Auvi-Q PA criteria, and the step therapy changes for candesartan and candesartan/HCTZ would occur administratively. The P&T Committee also recommended the updates to the PA criteria for the remainder of the drugs discussed above become effective on the first Wednesday two weeks after the 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	Implement Date	Notes and Unique Users Affected
Aug 2018	Corticosteroids -Immune Modulators: Atopic Dermatitis	UF Class Review	<u>UF</u> <ul style="list-style-type: none"> ▪ dupilumab (Dupixent) injection 	<u>NF</u> <ul style="list-style-type: none"> ▪ crisaborole (Eucrisa) ointment 	2 weeks after signing of the minutes	<ul style="list-style-type: none"> ▪ Manual PA criteria applies to all new users for dupilumab (Dupixent) ▪ Updates made to the Dupixent PA ▪ No changes recommended to the current Eucrisa PA criteria <p><u>Unique Users Affected</u> None</p>
Aug 2018	Hepatitis C Virus Direct-Acting Antivirals	UF Class review Class previously reviewed in Feb 2017, May 2015, Nov 2012; New drug review in Nov 2017	<u>UF</u> <ul style="list-style-type: none"> ▪ sofosbuvir/velpatasvir (Epclusa) ▪ ledipasvir/sofosbuvir (Harvoni) ▪ glecaprevir/pibrentasvir (Mavyret) ▪ paritaprevir/ritonavir/ombitasvir (Technivie) ▪ paritaprevir/ritonavir/ombitasvir/dasabuvir XR tablets (Viekira XR) ▪ dasabuvir tablets pak (Viekira Pak) ▪ sofosbuvir/velpatasvir/voxilaprevir (Vosevi) 	<u>NF</u> <ul style="list-style-type: none"> ▪ daclatasvir (Daklinza) ▪ simeprevir (Olysio) ▪ sofosbuvir (Sovaldi) ▪ grazoprevir/elbasvir (Zepatier) 	60 days	<ul style="list-style-type: none"> ▪ Manual PA required ▪ Previous requirement for step therapy with Harvoni removed ▪ PA criteria simplified for all the DAAs except Vosevi ▪ Vosevi separate PA form due to unique FDA indication <p><u>Unique Users Affected</u> Mail – 3 MTF – 3 Retail – 5 Total – 11</p>