EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel Meeting

September 25, 2024

For the August 2024 DoD Pharmacy and Therapeutics Committee Meeting

The Uniform Formulary Beneficiary Advisory Panel (UF BAP) convened at 10:00 A.M. EDT on September 25, 2024 via teleconference. The current meeting took place approximately over 2 hours. The information presented included the recommendations from the August 2024 DoD Pharmacy and Therapeutics (P&T) Committee meeting.

The detailed meeting information is found starting on page 7.

I. UNIFORM FORMULARY (UF) CLASS REVIEW—LEUKEMIA AND LYMPHOMA AGENTS: BRUTON TYROSINE KINASE INHIBITORS (BTKI) SUBCLASS

A. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—UF Recommendation

- UF
  - acalabrutinib (Calquence)
  - ibrutinib (Imbruvica)
  - pirtobrutinib (Jaypirca)
  - zanubrutinib (Brukinsa)
- NF - None
- Completely Excluded - None

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

B. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—Manual PA Criteria

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

C. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—UF, PA, and Implementation Period

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

II. UF CLASS REVIEW—ANTILIPIDEMIC-1s: STATINS AND NON-STATINS AND COMBINATIONS

A. Antilipidemic-1s: Statins and Non-Statins and Combinations—UF Recommendation

- UF
  - atorvastatin
  - fluvastatin
  - lovastatin
  - pravastatin
  - simvastatin
  - rosuvastatin
  - fluvastatin ER *moves from NF to UF*
- NF
  - Altoprev
  - Livalo and generic
  - Zypitamag
  - Atorvaliq suspension
  - Ezallor sprinkle capsules
  - Flolipid suspension
- Complete exclusion - None

Non-statins and Combinations

- UF
  - Nexletol *moves from NF to UF*
  - Nexlizet *moves from NF to UF*
  - Vytorin *moves from NF to UF*
  - ezetimibe

- atorvastatin/amlodipine
- NF - None
- Complete exclusion
  - Roszet

UF BAP Comments

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

B. Antilipidemic-1s: Statins and Non-Statins and Combinations—Manual PA Criteria

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

C. Antilipidemic-1s: Statins and Non-Statins and Combinations—UF, PA, and Implementation Period

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

III. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

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

- UF
  - Libervant
  - Iqirvo
  - Xolremdi
  - Myhibbin suspension
  - Rextovy nasal spray
  - Rezdiffra

- Winrevair
- Tyenne
- Ojemda

- NF
  - Simlandi
  - Voydeya
  - Duvyzat
  - Opsynvi
  - Zituvimet authorized generic
  - Spevigo
- Completely Excluded
  - Humira Cordavis

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

IV. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—WHITE BLOOD CELL STIMULANTS (WBC)—EFLAPEGRASTIM-XNST (ROLVEDON)

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

V. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) – ENDOCRINE AGENTS MISCELLANEOUS—LANREOTIDE 120 mg/0.5 mL SYRINGE AND PAIN AGENTS: PAIN TOPICAL—LIDOCAINE 5% PATCH (TRIDACAINE I, II, AND III, LIDOCAN IV AND V)

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

VI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEW FDA-APPROVED INDICATIONS

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

VII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR REASONS OTHER THAN NEW INDICATIONS

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

VIII. BRAND OVER GENERIC AUTHORIZATION, TIER 1 COPAY FOR ADDITION FOR MIRABEGRON (MYRBETRIQ) AND REMOVAL FOR TOPIRAMATE (TROKENDI XR) AND IMPLEMENTATION PLAN

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

IX. UTILIZATION MANAGEMENT: HEPATITIS C VIRUS (HCV) DIRECT ACTING ANTIVIRALS (DAAS) SUBCLASS PA CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

There were no questions or comments from the Panel.

- Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:

[redacted] The comments outlined above were taken under consideration my final decision.

Uniform Formulary Beneficiary Advisory
Panel Virtual Meeting Summary Minutes
September 25, 2024

Panel Members Present

- Dr. Pamela Schweitzer, Commissioned Offices Association of the US Public Health Service, Chair
- Ms. Holly Daily, the Association of the United States Army
- Dr. Karen Dager, PharmD, Health Net Federal Services
- Dr. Betsaida Guzman, PharmD, Veterans of Foreign Wars
- Dr. Jay Peloquin, PharmD, Express Scripts, Inc.
- Dr. Jennifer Soucy, PharmD, US Family Health Plan, Martins Point Services

Designated Federal Officer (Non-Voting): CAPT Tiffany Cline, USN

DHA HCO and Pharmacy Operations Division Participants (Non-Voting)

- Dr. John Kugler, MD, Chief, Clinical Support Division: DoD P&T Committee Chair
- Edward VonBerg, PharmD, BCPS, Chief, Pharmacy Operations Division, Formulary Management (POD FMB)
- CDR Elizabeth Hall, POD FMB
- CDR Giao Phung, POD FMB
- Maj Angelina Escano, POD FMB
- Angela Allerman, PharmD, BCPS, POD FMB
- Heather Johnson, PharmD, BCPS, POD FMB
- Ms. Megan Gemunder, Office of General Counsel
- Mr. Dennis Dyke, Office of General Counsel
- CAPT P. Thien Nguyen, DFO Alternate

Agenda is found starting on page 14.

Panel Discussion

The Uniform Formulary Beneficiary Advisory Panel (UF BAP) members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the UF BAP members will concur or non-concur on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. The UF BAP will provide comments on their vote as directed by the Panel Chair. Comments to the Director, DHA, or their designee will be considered before making a final UF decision.

Opening Remarks

CAPT Cline introduced herself as the Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (UF BAP). The UF BAP

has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on August 7-8, 2024.

CAPT Cline then indicated Title 10, United States Code, (U.S.C.) § section 1074g, subsection b requires the Secretary of Defense to establish a DoD Uniform Formulary (UF) of pharmaceutical agents and establishes the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

In addition, 10 U.S.C. § Section 1074g, subsection c, also requires the Secretary to establish a UF BAP to review and comment on the development of the Uniform Formulary. The UF BAP includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. The UF BAP's comments must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF. The UF BAP's meetings are conducted in accordance with the Federal Advisory Committee Act (FACA).

CAPT Cline then outlined the duties of the UF BAP which include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and to subsequently recommend changes. Comments to the Director, DHA, regarding recommended formulary status, preauthhorizations, and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.
- To hold quarterly meetings in an open forum. The UF BAP may not hold meetings except at the call of or with the advance approval of the DFO in consultation with the Chairperson of the UF BAP.
- To prepare minutes of the proceeding and prepare comments for the Secretary or his designee regarding the UF or changes to the formulary. The minutes will be available on the website and comments will be prepared for the Director, DHA.

The DFO provided guidance regarding this meeting.

- The role of the UF BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the Department of Defense appreciates that the UF BAP may be interested in the drug classes selected for review or specific pricing data, these topics do not fall under the purview of the UF BAP.
- The P&T Committee met for approximately 15.5 hours conducting its reviews of the drug class recommendations that will be presented today. Since this meeting is considerably shorter, the UF BAP will not receive the same extensive information that is presented to the P&T Committee members. However, the UF BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the UF BAP are available on the TRICARE website.

- Detailed minutes of this meeting are being prepared. The UF BAP meeting minutes, the DoD P&T Committee meeting minutes, and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO provided some ground rules for conducting the virtual meeting:

- The meeting will be conducted in a remote access format.
- All discussions take place in open public forum.
- There is to be no committee discussion outside the virtual forum or during breaks.
- Audience participation is limited to private citizen comments received in writing prior to the meeting.
- Participants will be joined in a listen only mode.
- To ensure that there are not disruptions to discussion and as a precaution, please mute your phones.

Panel and Presenter Guidance

- When asking or responding to questions:
  - Panel members are asked to state their name prior to asking your questions.
  - Presenters or anyone responding to a question are asked to state their name prior to responding.
  - The meeting is being recorded. Please speak clearly.
- Members of the Formulary Management Branch and the P&T Committee are available to answer questions related to the UF BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure the minutes accurately reflect relevant facts, regulations, or policy.

CAPT Cline introduced the individual Panel members (see list above) and noted house- keeping considerations.

Private Citizen Comments: No private citizen comments were received.

The meeting was handed over to the Panel Chair Dr. Pamela Schweitzer for her opening remarks.

Chair's Opening Remarks

Dr. Schweitzer welcomed the BAP panel members to the meeting. She stated that she appreciates all the panel members representing the voice of their beneficiaries for their organizations and also the time spent to prepare for this meeting, especially with the time needed to review the materials. She gave a shout out to the team that prepared this lengthy meeting. Then she turned the meeting over to the FMB.

Dr. VonBerg's Opening Remarks

The meeting then proceeded with comments from Dr. Ed VonBerg, Chief of the Formulary Management Branch, who introduced the team speaking (see list above).

Uniform Formulary Review Process: In accordance with 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) or their designee, on formulary or complete exclusion status, prior authorization (PA), pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) or complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

The DoD Formulary Management Branch supports the P&T Committee by conducting the relative clinical effectiveness analyses and relative cost effectiveness analyses of the drugs and drug classes under review and consideration by the P&T Committee for the Uniform Formulary.

The goal of this presentation is not to provide you with the same in-depth analyses presented to the P&T Committee, but a summary of the processes and analyses presented to the P&T Committee. The cost-effective analyses will be general in nature since we are unable to disclose the actual costs used in the economic models.

The full presentations then started. Following some of the sections the DoD P&T Committee physician perspective was provided by Dr. John Kugler and is included starting on page 14. The information starting on page 17 includes the full meeting information.

Closing Remarks

Dr. Schweitzer stated she appreciated the P&T Committee making things easier and considering things like the automated lookback for the drugs, and having the specialist be able to have the PAs approved without having to jump through extra steps. She also commended the members of the P&T Committee for considering the beneficiary perspective and the prescriber perspective.

Dr. Peloquin also commented that the streamlining of some of the questions in the PA criteria is something historically that this panel has talked through with the volume of questions and criteria that are asked. For this meeting he saw a lot of automated lookbacks which he felt was great for the beneficiaries and providers. He also stated that removing some of the practice types of questions and streamlining the criteria to requiring specifically why the required information is needed to make the appropriate decision for the appropriate patient and product is a good step forward.

Dr. VonBerg then thanked the UF BAP Panel members for their comments on the DoD P&T

Committee recommendations.

CAPT Cline closed the meeting by thanking Dr. Schweitzer and Dr. Peloquin for their remarks. She also thanked the Panel members for their commitment and time serving on the UF BAP panel to improve the TRICARE pharmacy benefit. She also expressed her warmest thanks for the Panel's devotion to the health and well-being of our nation's military and to providing our service members, veterans and families with the best possible pharmacy benefit. CAPT Cline then declared the meeting closed.

The meeting adjourned at 11:47 AM EDT.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

[redacted]

Chairperson, UFBA

DoD P&T Committee Physician Perspective

Dr. John Kugler's comments on the formulary recommendations followed selected individual sections and are outlined below:

Drug Class Reviews

Leukemia And Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass

- This class was last reviewed in August 2021, and since that time there is one new entrant. The four products in the class were all designated as formulary and this maintains a variety of treatment options for the various oncology indications.
- Since a preferred product was not selected, if there are investigational agents that reach the market, then they can also be added to the formulary, based on clinical and cost effectiveness.
- Substantial changes were made to the existing PA forms. The P&T Committee is aware of the provider time and effort needed for completing the PA forms. The PAs were streamlined to reduce the number of clinical criteria. The PAs were also updated for the provider to include additional information for off-label uses that are supported by the NCCN.
- Additionally, for Calquence and Brukinsa, the automated specialist bypass was added, which allows the oncologist or hematologist to bypass the PA. An analysis of MHS prescribing did show that there is appropriate prescribing by specialists. There are several other oncology drugs which will be presented in the Utilization Management section where this automated specialist bypass was added.

Antilipidemic-1s: Statins And Non-Statins And Combinations

- The statins are a well-established class that have been reviewed several times previously. The only branded products remaining in the class all contain a parent statin as one of the ingredients. There was no new data to support moving the branded products to formulary status, so they will all remain nonformulary.
- For the non-statins, the data with the newest product, Nexletol, was reviewed for the primary prevention indication. Nexletol and Nexlizet will move to UF status.
- The PA was updated to allow the new indication for primary prevention for Nexletol and Nexlizet, however, a trial of a PCSK-9 inhibitor will be required first in new patients. Patients currently receiving Nexletol and Nexlizet will be able to continue current therapy. An automated look back for a PCSK-9 inhibitor will apply to reduce administrative burden.
- The PAs for the PCSK-9 inhibitors were also updated. The changes made will also align with updates that the VA has made.

New Drugs

- For the new drugs, there were 16 total drugs reviewed, with 9 were designated as UF and 6 as NF. The one drug that was completely excluded is a private label brand of Humira distributed by CVS.
- There was a continuing trend for several of the drugs to treat specialty conditions, including rare diseases or oncology indications. For the PAs, criteria were added where there is already existing criteria in the class, or where specialist prescribing is required. Specialists are consulted when establishing the PA criteria.
- There were also two biosimilars reviewed, one for Humira and also Tyenne, which is the first biosimilar for Actemra. Biosimilar drug approvals continue to increase. The P&T Committee continues to review biosimilars and will address interchangeability more in the future.

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AGENDA

Uniform Formulary Beneficiary Advisory Panel (UF BAP)
For the August 2024 Department of Defense Pharmacy and Therapeutics Committee Meeting
September 25, 2024 at 10:00 AM Eastern Daylight Time

Virtual Meeting

- **General session starts at 10:00 AM Eastern Daylight Time**
- **Roll Call**
- **Therapeutic Class Reviews**

  Members of the Defense Health Agency (DHA) Pharmacy Operations Division (POD) Formulary Management Branch (FMB) will present relative clinical and cost-effective analyses along with the Department of Defense (DoD) Pharmacy & Therapeutics Committee (P&T) recommendations for the Uniform Formulary (UF) and any recommended complete exclusion candidates.

  The DoD P&T Committee made recommendations for the following drugs/drug classes during the August 2024 meeting.

- **Drug Class Reviews**
  - *Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors*
  - *Antilipidemic-1s Class*
    - *Statin Subclass*
    - *Non-statins and Combinations Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *adalimumab (Cordavis Humira)—Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor Inhibitors*
  - *adalimumab-ryvk (Simlandi)—TIBs: Tumor Necrosis Factor Inhibitors (TNFs)*
  - *danicopan (Voydeya)—Hematological Agents*
  - *diazepam (Libervant)—Anticonvulsants-Antimania Agents*
  - *elafibranor (Iqirvo)—Gastrointestinal-2 Agents*
  - *givinostat (Duvyzat)—Corticosteroids-Immune Modulators*
  - *macitentan/tadalafil (Opsynvi)—Pulmonary Arterial Hypertension*
  - *mavorixafor (Xolremdi)—Hematological Agents*
  - *mycophenolate mofetil (Myhibbin)—Immunosuppressives*
  - *naloxone (Rextovy)—Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists*
  - *resmetirom (Rezdiffra)—Gastrointestinal-2 Agents*

- *sitagliptin/metformin (Zituvimet authorized generic)—Diabetes Non-Insulin: Dipeptidyl/Peptidase 4 (DPP-4) Inhibitors*
- *sotatercept-csrk (Winrevair)—Pulmonary Arterial Hypertension Agents*
- *spesolimab-sbzo (Spevigo)—TIBs: Miscellaneous Interleukins*
- *tocilizumab-aazg (Tyenne)—TIBs: Non-TNFs*
- *tovorafenib (Ojemda)—Oncological Agents*

➢ **Utilization Management Issues**

- **Prior Authorization (PA) Criteria—New Manual Prior Authorization (PA) Criteria**
  - *White Blood Cell Stimulants: eflapegrastim-xnst (Rolvedon)*
- **PA Criteria —Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**
  - *Endocrine Agents Miscellaneous: lanreotide 120 mg/0.5 mL syringe*
  - *Pain Agents —Topical Pain: lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V)*
- **PA Criteria—Updated PA Criteria for New FDA-Approved Indications**
  - *Atopy: Oral JAK-1—upadacitinib (Rinvoq)*
  - *Atopy—benralizumab (Fasenra)*
  - *TIBs: Non-TNFs—vedolizumab (Entyvio)*
  - *TIBs: Non-TNFs—sarilumab (Kevzara)*
  - *Metabolic Agents Miscellaneous—maralixibat (Livmarli)*
- **PA Criteria—Updated PA Criteria for Reasons Other Than New Indications**
  - *Corticosteroids-Immune Modulators: Adrenocorticotrophic Hormones corticotropin (Acthar Gel SelfJect)*
  - *Antiemetic-Antivertigo Agents—doxylamine/pyridoxine (Diclegis, Bonjesta)*
  - *Oncological Agents—trametinib (Mekinist), dabrafenib (Tafinlar), neratinib (Nerlynx), vemurafenib (Zelboraf), venetoclax(Venclexta), nilutamide (Nilandron), belzutifan (Welireg), tucatinib (Tukysa), glasdegib (Daurismo), erdafitinib (Balversa), and the Prostate Cancer drugs abiraterone (generic and Zytiga), enzalutamide (Xtandi), darolutamide, (Nubeqa), and apalutamide (Erleada)*
  - *TIBs: Non-TNFs—anakinra (Kineret)*
  - *Sleep Disorders: Wakefulness Promoting Agents—solriamfetol (Sunosi)*
  - *Sleep Disorders: Wakefulness Promoting Agents—pitolisant (Wakix)*
  - *TIBs: TNFs— adalimumab (Humira)*
  - *TIBs: Non-TNFs — secukinumab (Cosentyx)*

- *TIBs: Non-TNFs—tocilizumab (Actemra)*

- **Brand Over Generic PA Authorization and Tier 1 copay**
  - *Overactive Bladder Agents—mirabegron (Myrbetriq)*
  - *Anticonvulsant and Anti-Mania Agents—topiramate ER (Trokendi XR)*

- **PA Updates for Hepatitis C Virus Direct-Acting Antivirals Subclass**
  - *glecaprevir/pibrentasvir (Mavyret)*
  - *sofosbuvir/velpatasvir (Epclusa)*
  - *ledipasvir/sofosbuvir (Harvoni)*
  - *elbasvir/grazoprevir (Zepatier)*
  - *sofosbuvir (Sovaldi)*
  - *sofosbuvir/velpatasvir/voxilaprevir (Vosevi)*

- **Panel Discussions**

  The UF BAP members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will concur or non-concur on the recommendations of the DoD P&T Committee concerning the establishment of the UF and subsequent recommended changes. The Panel will provide comments on their vote as directed by the Panel Chairman. Comments to the Director, DHA, or their designee will be considered before making a final UF decision.

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
FROM THE AUGUST 2024 MEETING

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING SEPTEMBER 25, 2024

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with 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) or their designee, on formulary or complete exclusion status, prior authorizations (PAs), pre-authorizations, and the effective date for a pharmaceutical agent's change from formulary to nonformulary (NF) or to complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEW—LEUKEMIA AND LYMPHOMA AGENTS: BRUTON TYROSINE KINASE INHIBITORS (BTKI) SUBCLASS

P&T Comments

A. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—Relative Clinical Effectiveness Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the BTKi subclass, which was previously reviewed for formulary status in August 2021. The agents within the class include ibrutinib (Imbruvica), acalabrutinib (Calquence), zanubrutinib (Brukinsa), and pirtobrutinib (Jaypirca).

The BTKi agents are used for a variety of oncologic disease states, however the review specifically focused on treatment of chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL).

The comprehensive evidence review included information from individual clinical trial data, guidelines from the National Cancer Comprehensive Network (NCCN), available meta-analyses, FDA-labeling, current Military Health System (MHS) patterns of use, and MHS provider feedback.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

Clinical Practice Guidelines

- NCCN treatment recommendations are similar for CLL/SLL and diverge based on the presence or absence of deletion (17p) and/or TP53 mutation.
- For patients with or without deletion (17p) and/or TP 53 mutation, first-line treatment of CLL/SLL includes Imbruvica, Calquence, and Brukinsa.

Jaypirca is reserved for treatment of refractory CLL/SLL patients who have received at least two other systemic therapies, including a BTKi.

- Two of the newer agents, Calquence and Brukinsa, are suggested as a preferred regimen for CLL/SLL due to their more favorable toxicity profiles compared to Imbruvica.

Efficacy

- Imbruvica and Calquence are the earliest approved agents, offering more robust long-term data, while Brukinsa has ongoing extension data.
- Indirect comparison between agents is challenging due to the varying study treatment arms, trial durations, and inclusion criteria for high-risk features.
- There is limited head-to-head data between agents for the various treatment pathways required for CLL/SLL treatment.
- Where data is available, by indirect comparison, via network meta-analysis, and in head-to-head trials, Imbruvica, Calquence, and Brukinsa do not appear to have clinically relevant differences in efficacy.

Safety

- While the safety profiles largely overlap, each drug has unique features requiring specialists to tailor their treatment choice based on patient comorbidities.
- Imbruvica carries overall higher rates of adverse reactions including nausea, rash, bruising and fatigue, compared to Calquence and Brukinsa. Calquence is more likely associated with headache while Brukinsa uniquely requires no dose modification for patients with severe renal failure.

Other Factors

- Imbruvica is available in a variety of formulations, including capsules, oral suspension and tablets and is dosed once daily. It also covers the most FDA-approved and off-label indications.
- Calquence and Brukinsa are each available as a single formulation and may be given either once or twice daily.
- Jaypirca is indicated for relapsed or refractory treatment of CLL/SLL.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, at least one BTKi agent for the specific indication of CLL/SLL treatment is required on the formulary.

B. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—Relative Cost Effectiveness Analysis and Conclusion

The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (19 for, 0 opposed, 0

abstained, 1 absent) the following:

- CMA results showed that acalabrutinib (Calquence) is the most cost effective BTKi agent, followed by zanubrutinib (Brukinsa), ibrutinib (Imbruvica), and pirtobrutinib (Jaypirca).
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the agents in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

C. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—UF Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following.

- UF
  - acalabrutinib (Calquence)
  - ibrutinib (Imbruvica)
  - pirtobrutinib (Jaypirca)
  - zanubrutinib (Brukinsa)
- NF - None
- Completely Excluded - None

D. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—Manual PA Criteria

Existing PA criteria currently apply to all four drugs. For the Imbruvica tablet formulation, further justification is required on the PA to state why the capsules cannot be used first. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the changes below.

- For all four BTKi drugs, the PA criteria were streamlined in the sections pertaining to FDA-indications and safety monitoring.
- For Imbruvica, the current criteria preferring the capsules over the tablets was removed.
- For Calquence and Brukinsa, if prescribing physician specialty is identified as an oncologist or hematologist during adjudication, no PA will be required. The provider's specialty is identified through an automated system that searches for specific specialty information in the claim. This will hereafter be referred to as automated specialist bypass. Manual PA will also allow approval solely based on the prescribing physician being identified as an oncologist or hematologist. Additionally, for prescriptions initially written by an oncologist or hematologist, an automated drug lookback for Calquence or Brukinsa will allow PA approval if the patient has received the drug in the past

720 days, to allow continuation of therapy for prescriptions subsequently written by non-specialists.

The Manual PA criteria is as follows. Changes from the August 2024 meeting are in bold and strikethrough.

1. acalabrutinib (Calquence)

Automated PA Criteria: When prescribed by a hematologist or oncologist, prior authorization is not required. Once therapy is initiated by a hematologist or oncologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.

Manual PA criteria apply to all new users of Calquence

Manual PA Criteria: **If automated criteria are not met for hematologist or oncologist specialist prescribing, coverage is approved if all criteria are met:**

- **If the physician is a hematologist or oncologist, PA is approved OR**
- **If the prescriber is not a hematologist or oncologist and the drug is prescribed in consultation with a hematologist/oncologist, then continue with the questions below:**
- Patient is 18 years of age or older
- ~~Drug is prescribed by or in consultation with a hematologist/oncologist~~
- **Patient has a diagnosis of either chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or Mantle Cell Lymphoma (MCL) and received at least one prior therapy**
- ~~Patient meets one of the following categories:~~
  - ~~Patient must have pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1 that had a short response duration to prior therapy (< median progression-free survival).~~
  - ~~Patient will use acalabrutinib as frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation~~
    - ~~Patient fits one of following categories:~~
      - ~~Frail patient with significant comorbidity (not able to tolerate purine analogues)~~
      - ~~Patient ≥ 65 years old with significant comorbidity~~

- ~~Patients < 65 years old~~
- ~~Patient will use acalabrutinib as frontline or relapsed refractory therapy for CLL/SLL with del(17p)/TP53 mutation~~

- ~~If the patient has CLL, the patient's disease has no evidence of a BTK C481S mutation nor prior ibrutinib refractory disease~~
- ~~Patient must not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec~~
- ~~Monitor for bleeding, infection, cardiac arrhythmias, and cytopenias~~
- ~~If the patient is female and of childbearing potential, advise the patient of the risk of significant fetal harm~~
- ~~Female patients will not breastfeed during treatment and for at least 2 weeks following cessation of treatment~~
- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis:~~ **To facilitate approval, please list the diagnosis, guideline version and page number** _____.

Other non-FDA-approved uses are not approved, except as noted above
PA does not expire

2. ibrutinib capsules, tablets and oral suspension (Imbruvica)

Manual PA apply to all new users of Imbruvica

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

- ~~The provider acknowledges that Imbruvica capsules are more cost effective than Imbruvica tablets for TRICARE patients (at the 140 mg and 280 mg strengths).~~
- ~~If the Rx is for Imbruvica tablets at the 140 mg or 280 mg strengths, please state why the patient cannot take the capsule formulation_____, then continue with the PA criteria below.~~
- ~~If the Rx is for the Imbruvica capsules or for the higher strengths of Imbruvica tablets (420 mg and 560 mg), please continue with the PA criteria below.~~
- Drug is prescribed by or in consultation with a hematologist/oncologist
- Patient is 1 ~~to 17 years of age~~ **year of age or older** with a diagnosis

of chronic graft-versus-host disease OR

- Patient is 18 years of age or older **and has a diagnosis of either chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or Waldenström's macroglobulinemia (WM)**
- ~~Will be used in one of the following contexts:~~
  - ~~Pretreatment to limit the number of cycles of RhyperCVAD/rituximab maintenance therapy for Mantle Cell Lymphoma~~
  - ~~Second line (or subsequent therapy) for Mantle Cell Lymphoma~~
  - ~~Second line (or subsequent therapy) for Marginal Zone Lymphoma~~
  - ~~Second line (or subsequent therapy) for non-germinal center B cell-like Diffuse Large B-Cell Lymphoma if unable to receive chemotherapy~~
    - ~~Frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation~~
    - ~~Patient fits one of the following categories:~~
      - ~~Frail patient with significant comorbidity (not able to tolerate purine analogues)~~
      - ~~Patient ≥ 65 years old with significant comorbidity~~
      - ~~Patients < 65 years old~~
  - ~~Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation~~
  - ~~Waldenström macroglobulinemia~~
  - ~~Chronic graft-versus-host disease~~
- ~~Monitor for bleeding, infection, hypertension, cardiac arrhythmias, cytopenias, and Tumor Lysis Syndrome~~
- ~~If the patient is female, she is not pregnant or planning to become pregnant~~
- ~~Breastfeeding female patients will be advised that the potential harm to the infant is unknown~~
- ~~All patients (males and females) of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation~~
- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis:~~ **To facilitate approval, please list the diagnosis, guideline version and page number _____.**

Other non-FDA-approved uses are not approved, except as noted above
PA does not expire

3. pirtobrutinib (Jaypirca)

Manual PA criteria apply to all new users of pirtobrutinib (Jaypirca).

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

- Patient is 18 years of age or older
- Drug is prescribed by or in consultation with a hematologist or oncologist
- Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) OR
- Patient has chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) and has received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor
- ~~Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias~~
- ~~Patient will use sun protection in sun-exposed areas~~
- ~~Female patients of childbearing age and are not pregnant confirmed by (-) HCG~~
- ~~Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment~~
- ~~Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment~~
- The diagnosis Is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis: _~~ **To facilitate approval, please list the diagnosis, guideline version and page number:_____.**

Other non-FDA approved uses are not approved, except as noted above
PA does not expire

4. zanubrutinib (Brukinsa)

Automated PA Criteria: When prescribed by a hematologist or oncologist, prior authorization is not required. Once therapy is initiated by a hematologist or oncologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.

Manual PA criteria apply to all new users of pirtobrutinib (Brukinsa).

Manual PA Criteria**: If automated criteria are not met for hematologist or oncologist specialist prescribing, coverage is approved if all criteria are met:**

- **If the physician is a hematologist or oncologist, PA is approved OR**
- **If the prescriber is not a hematologist or oncologist and the drug is prescribed in consultation with a hematologist/oncologist, then continue with the questions below:**
- Patient is 18 years of age or older
- ~~Drug is prescribed by or in consultation with a hematologist/oncologist~~
- Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) OR
- Patient has Waldenström's macroglobulinemia (WM) ~~a rare non-Hodgkin lymphoma~~ OR
- Patient has relapsed or refractory marginal zone lymphoma (MZL) **and has**~~who have~~ received at least 1 anti-CD20-based regimen OR
- Patient has chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- ~~Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias~~
- ~~Patient will use sun protection in sun-exposed areas~~
- ~~Female patients of childbearing age and are not pregnant confirmed by (-) HCG.~~
- ~~Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment~~
- ~~Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment~~
- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.~~If so, please list the diagnosis:~~ **To facilitate approval, please list the diagnosis, guideline version and page number** _____.

Other non-FDA approved uses are not approved, except as noted above

PA does not expire

E. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—UF, PA, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date the first Wednesday 60 days after signing of the minutes in all points of service.

III. UF DRUG CLASS REVIEW—LEUKEMIA AND LYMPHOMA AGENTS: BRUTON TYROSINE KINASE INHIBITORS (BTKI) SUBCLASS

UF BAP Comments

A. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—UF Recommendation

The P&T Committee recommended formulary status as discussed above.

- UF
  - acalabrutinib (Calquence)
  - ibrutinib (Imbruvica)
  - pirtobrutinib (Jaypirca)
  - zanubrutinib (Brukinsa)
- NF - None
- Completely Excluded - None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—Manual PA Criteria

The P&T Committee recommended manual PA criteria in new users as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKi) Subclass—UF, PA, and Implementation Period

The P&T Committee recommended an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—ANTILIPIDEMIC-1s: STATINS AND NON-STATINS AND COMBINATIONS

P&T Comments

A. Antilipidemic-1s: Statins and Non-Statins and Combinations—Relative Clinical Effectiveness Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the Antilipidemic-1 drug class, comprised of the statins along with the non-statins and combinations subclasses. For the statins, there is significant generic availability, with only five branded products remaining. The non-statins include ezetimibe, bempedoic acid, bempedoic acid/ezetimibe and combinations with statins. The evidence review focused on the low-density lipoprotein (LDL)-lowering effects of the products, published cardiovascular (CV) outcomes data, and recent data available with bempedoic acid.

Note the proprotein convertase subtilisin/kexin type-9 (PCSK9) inhibitors were reviewed for formulary status in May 2023, and were not included here.

The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Statins

- Since the last class review in 2013, statin therapy remains the key component of treating hyperlipidemia to reduce adverse CV outcomes of coronary heart disease (CHD), myocardial infarction (MI), and stroke in the primary and secondary prevention settings.
- In terms of adverse effects, the prevalence of complete statin intolerance might often be overestimated. Most patients can tolerate a statin and many patients reporting statin intolerance may be experiencing a nocebo effect (where there are perceived negative symptoms experienced by patients when anticipating a treatment to be harmful).
- In order to meet the needs of MHS patients, atorvastatin, simvastatin, pravastatin, and rosuvastatin are required on the formulary due to compelling clinical evidence from CV outcomes trials and recommendations from the 2018 Multi-Society guidelines. Inclusion of these products will allow for differences in safety profiles and drug interactions. Positive CV outcomes have also been reported with fluvastatin and lovastatin, although fewer trials are available. Robust published CV outcomes data is lacking for pitavastatin.
- The remaining branded products, lovastatin extended release (ER) (Altoprev), atorvastatin oral suspension (Atorvaliq), simvastatin oral suspension (FloLipid), rosuvastatin sprinkle capsules (Ezallor), and pitavastatin magnesium (Zypitamag) do not offer compelling clinical advantages compared to the other generic statins.

Non-statins and Combinations

- The 2022 American College of Cardiology (ACC) Expert Consensus Decision Pathway for non-statins continue to support use of high intensity statins first-line for patients with atherosclerotic cardiovascular disease (ASCVD) (secondary prevention setting) and in the primary prevention setting.
    - PCSK-9 inhibitors either alone or with ezetimibe can be considered in patients receiving maximally tolerated statin therapy who require a greater than 50% reduction in LDL cholesterol.
- Bempedoic acid (Nexletol) is a non-statin that when used as monotherapy reduces LDL to a similar extent as ezetimibe (Zetia) by 18%-20%. The LDL-lowering approaches 38% when bempedoic acid is added on to ezetimibe (Nexlizet).
- The results of a CV outcomes trial (CLEAR OUTCOMES) showed bempedoic acid benefitted adults with CV disease or those at high risk for CV disease who were statin intolerant. The majority of the patients (70%) had existing CV disease (secondary prevention). The outcomes were primarily driven by a reduction in non-fatal myocardial infarction (MI) and coronary revascularization; the reduction in stroke or CV death was not statistically significant.
    - Limitations to the trial include the use of low dose statins in 25% of patients, the high drop-out rate (approximately 29%), the high baseline LDL level of 139 mg/dL, and the homogenous patient population.
    - The CLEAR OUTCOMES trials results have not yet been incorporated into the professional guidelines.
- The long-term adverse event profile of bempedoic acid is unknown, however the rate of statin-associated muscle symptoms appears similar to placebo. Unique adverse events associated with bempedoic acid include gout, renal impairment and elevated hepatic enzymes.
- Use of PCSK-9 inhibitors prior to bempedoic acid should be considered due to current ACC guideline recommendations, their ability to reduce LDL cholesterol by more than 60% and the more favorable safety profile based on published CV outcomes trials.
- Bempedoic acid should be reserved for use in patients with statin intolerance or those who have failed to reach LDL goals after ezetimibe and PCSK-9 inhibitor.
- Ezetimibe is recognized in most professional society guidelines as the first statin add-on or in those who cannot tolerate a statin, due to its generic availability and well tolerated adverse event profile.
- The fixed dose combination of simvastatin/ezetimibe has positive CV outcomes data from the IMPROVE-IT trial.
- The remaining branded products, atorvastatin/amlodipine and rosuvastatin/ezetimibe (Roszet) do not provide compelling clinical

evidence compared to the other drugs in the subclass.

B. Antilipidemic-1s: Statins and Non-Statins and Combinations—Relative Cost Effectiveness Analysis and Conclusion

A cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

For the statins

- The committee reviewed the CMA results for atorvastatin, atorvastatin oral suspension (Atorvaliq), fluvastatin, lovastatin ER (Altoprev), lovastatin, pitavastatin calcium (Livalo, generics), pitavastatin magnesium (Zypitamag), pravastatin, rosuvastatin, rosuvastatin sprinkle (Ezallor), simvastatin oral suspension (Flolipid), and simvastatin.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the statin agents in accordance with the formulary recommendation below demonstrated benefit to the MHS.

For the non-statins and combinations

- The committee reviewed the CMA results for amlodipine/atorvastatin, bempedoic acid (Nexletol), bempedoic acid/ezetimibe (Nexlizet), ezetimibe, ezetimibe/rosuvastatin (Roszet, generics), and ezetimibe/simvastatin.

- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the non-statin and combination agents in accordance with the formulary recommendation below demonstrated cost-avoidance for the MHS.

C. Antilipidemic-1s: Statins and Non-Statins and Combinations—UF Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following.

Statins

- UF
  - atorvastatin
  - fluvastatin
  - lovastatin
  - pravastatin

- simvastatin
- rosuvastatin
- fluvastatin ER *moves from NF to UF*

- NF
  - lovastatin ER (Altoprev)
  - pitavastatin calcium (Livalo, generic)
  - pitavastatin magnesium (Zypitamag)
  - atorvastatin oral suspension (Atorvaliq)
  - rosuvastatin sprinkle capsules (Ezallor)
  - simvastatin oral suspension (Flolipid)
- Complete exclusion - None

Non-statins and Combinations

- UF
  - Nexletol *moves from NF to UF*
  - Nexlizet *moves from NF to UF*
  - Vytorin *moves from NF to UF*
  - ezetimibe
  - atorvastatin/amlodipine
- NF - None
- Complete exclusion
  - Roszet

D. Antilipidemic-1s: Statins and Non-Statins and Combinations—Manual PA Criteria

For the statins, automated step therapy have been in place for the branded products (Livalo, Zypitamag, Altoprev, Lescol XL, Altoprev, Atorvaliq, FloLipid, and Ezallor) for several years, requiring a trial of generic statin first. For the non-statins, current PA criteria for bempedoic acid allows use only in the secondary prevention setting, plus requires a trial of concurrent statin and ezetimibe prior to use, unless the patient has statin intolerance or a contraindication to statin. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Statins

- Maintaining the current automated step therapy for pitavastatin calcium (Livalo, generic) and pitavastatin magnesium (Zypitamag), requiring a trial of generic statins first.

- Removing the PA for fluvastatin ER (Lescol XL)
- Maintaining the current manual PA criteria for Atorvaliq, FloLipid and Ezallor

Non-statins and Combinations

- For bempedoic acid, maintaining the requirement for ezetimibe plus maximally tolerated statin unless there is a contraindication or statin intolerance; expanding the criteria to include primary prevention in high-risk patients; and requiring concurrent PCSK-9 inhibitor. There will be automated drug look back for a PCSK-9 inhibitor (Repatha or Praluent). The updated PA criteria will apply to new patients.
- Updates to the PA for the PCSK-9 inhibitors evolocumab (Repatha) and alirocumab (Praluent) were also recommended, to include use for patients at high risk for ASCVD, based on the PA updates for bempedoic acid.
- Removing the PA for simvastatin/ezetimibe (Vytorin, generic) and atorvastatin/amlodipine (Caduet, generic)

The Manual PA criteria is as follows. Updates from the August 2024 meeting are in bold.

1. bempedoic acid (Nexletol), bempedoic acid/ezetimibe (Nexlizet)

PA criteria apply to new users of Nexletol and Nexlizet.

<u>Automated PA criteria:</u> The patient has filled a prescription for Repatha or Praluent at any MHS pharmacy point of service (MTFs, retail pharmacies, or network TRICARE Mail Order Pharmacy) during the previous 720 days.

<u>Manual PA Criteria</u>: **If automated PA criteria are not** met Nexletol or Nexlizet is approved if all criteria are met:

- The drug is prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization)
- Patient has one of the following diagnoses:
  - Patient has established atherosclerotic cardiovascular disease (ASCVD) including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attack (TIA) or peripheral arterial disease (PAD), OR
  - **Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following:**
    - **type 1 or type 2 diabetes or**

        - **10-year ASCVD risk score (Pooled Cohort Equation – PCE)>20% or Reynolds Risk score > 30% or SCORE risk score>7.5% over 10 yrs.** *or*
        - **Coronary calcium score >400 Agatston units at any time in the past OR**
    - Patient has Heterozygous Familial Hypercholesterolemia (HeFH)
- For Nexletol:
    - Patient is taking concurrent ezetimibe OR
    - Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks AND
    - Patient is on concurrent statin therapy at the maximum tolerated dose and dose hasn't reached LDL goals or
    - Patient is statin intolerant based on one of the following:
        - Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, muscle cramps), with at least 2 statins OR
        - History of creatine kinase (CK) levels greater than 10 x the upper limit of normal (ULN) unrelated to statin use OR
        - History of statin-associated rhabdomyolysis
        - Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) **AND**
    - **Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR**
    - **Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCK-9 inhibitor**
- For Nexlizet:
    - Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) AND
    - Patient is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal OR
    - Patient is statin intolerant based on one of the following:
        - Patient has experienced intolerable (muscle pain, cramp) with at least 2 statins OR
        - History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use OR
        - History of statin-associated rhabdomyolysis OR

- Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy)

- **Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR**
- **Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCK-9 inhibitor**

Non-FDA-approved uses are not allowed
Prior authorization does not expire

2. evolocumab (Repatha), alirocumab (Praluent)

Changes from August 2024 meeting are in BOLD and strikethrough. Note that there were no changes to the PA criteria for patients with existing ASCVD, homozygous familial hypercholesterolemia (HoFH), or heterozygous familial hypercholesterolemia (HeFH). For Praluent, there were no changes to the requirement for a trial of Repatha first.

Manual PA criteria apply to all new users of Repatha

Manual PA Criteria: evolocumab (Repatha) is approved if all criteria are met:

For patients at high risk for ASCVD

- **The patient has LDL >190 mg/dL or**
- **Patient has diabetes and LDL <190 mg/dL or**
- **Patient with LDL 70 to 189 mg/dL and an estimated 10-year risk for ASCVD >7.5% or**
- **Patients with LDL < 190 mg/dL and evidence of significant subclinical atherosclerosis defined as:**
  - **Significant atherosclerotic plaque observed in an asymptomatic patient on any of the following diagnostic studies: coronary artery calcification noted on computed tomography (CT) studies, including calcium scoring, cardiac CT coronary angiography, chest CT for ruling out pulmonary embolism, chest CT for lung cancer screening, or diagnostic chest CT; carotid plaque noted on carotid ultrasound or angiography; or abnormal ankle-brachial index or plaque noted on peripheral arterial angiography. AND**
- The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR
- The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR

- If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND
- The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy.

PA does not expire

3. atorvastatin 20 mg/5 mL suspension (Atorvaliq), rosuvastatin sprinkle (Ezallor Sprinkle), simvastatin oral suspension (Flolipid), pitavastatin calcium (Livalo, generics), pitavastatin magnesium (Zypitamag)

Note no changes were made to the existing PA criteria.

E. Antilipidemic-1s: Statins and Non-Statins and Combinations—UF, PA, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date the first Wednesday 90 days after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEW—ANTILIPIDEMIC-1S: STATINS AND NON-STATINS AND COMBINATIONS

UF BAP Comments

A. Antilipidemic-1s: Statins and Non-Statins and Combinations—UF Recommendation

The P&T Committee recommended formulary status as discussed above.

Statins

- UF
  - atorvastatin
  - fluvastatin
  - lovastatin
  - pravastatin
  - simvastatin
  - rosuvastatin
  - fluvastatin ER *moves from NF to UF*
- NF
  - Altoprev

- Livalo and generic
- Zypitamag
- Atorvaliq suspension
- Ezallor sprinkle capsules
- Flolipid suspension

- Complete exclusion - None

Non-statins and Combinations

- UF
  - Nexletol *moves from NF to UF*
  - Nexlizet *moves from NF to UF*
  - Vytorin *moves from NF to UF*
  - ezetimibe
  - atorvastatin/amlodipine
- NF - None
- Complete exclusion
  - Roszet

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Antilipidemic-1s: Statins and Non-Statins and Combinations—Manual PA Criteria

The P&T Committee recommended manual PA criteria in new users as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Antilipidemic-1s: Statins and Non-Statins and Combinations—UF, PA, and Implementation Period

The P&T Committee recommended an effective date the first Wednesday 90 days after signing of the minutes in all points of service.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VI. 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 (20 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
  - diazepam buccal film (Libervant) – Anticonvulsants – Antimania Agents
  - elafibranor (Iqirvo) – Gastrointestinal-2 Agents
  - mavorixafor (Xolremdi) – Hematological Agents
  - mycophenolate mofetil 200 mg/mL oral suspension (Myhibbin) – Immunosuppressives
  - naloxone 4 mg nasal spray (Rextovy) – Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists
  - resmetirom (Rezdiffra) – Gastrointestinal-2 Agents
  - sotatercept-csrk (Winrevair) – Pulmonary Arterial Hypertension Agents
  - tocilizumab-aazg syringe (Tyenne) – TIBs: Non-Tumor Necrosis Factor Inhibitors
  - tovorafenib (Ojemda) – Oncological Agents
- NF
  - adalimumab-ryvk (Simlandi) – TIBs: Tumor Necrosis Factor Inhibitors
  - danicopan (Voydeya) – Hematological Agents
  - givinostat (Duvyzat) – Corticosteroids-Immune Modulators
  - macitentan/tadalafil (Opsynvi) – Pulmonary Arterial Hypertension Agents
  - sitagliptin/metformin authorized generic (Zituvimet) – Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors
  - spesolimab-sbzo syringe (Spevigo) – TIBs: Miscellaneous Interleukins

- Completely Excluded
  - adalimumab (Cordavis Humira) – TIBs: Tumor Necrosis Factor Inhibitors

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

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria.

- Applying manual PA criteria to new users of the oncology/hematology drugs Voydeya, Xolremdi, and Ojemda; and for new users of Iqirvo, Duvyzat, Rezdiffra, and Winrevair.
- Applying manual PA criteria to new and current users of Opsynvi, requiring a trial of the individual components separately.
- Applying manual PA criteria to new users of Spevigo requiring a trial of Humira and Cosentyx first.
- Applying manual PA criteria to new users of Tyenne requiring a trial of Humira for moderate to severely active RA and active polyarticular juvenile idiopathic arthritis (pJIA) first. Additionally, a trial of Tyenne will be required before the originator Actemra formulation in new users.
- Applying manual PA criteria to new and current users of the Humira biosimilar Simlandi, similar to what is in place for the other Humira biosimilars. A trial of the Humira branded product is required first as per the February 2023 P&T Committee meeting minutes.
- Applying manual PA criteria to new users of Zituvimet authorized generic, requiring a trial of Januvia, similar to the other NF, non-step-preferred DPP-4 inhibitors in the class.

The Manual PA criteria is as follows:

1. adalimumab-ryvk (Simlandi)

Manual PA criteria apply to all new and current users of the Humira biosimilar.

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

- Provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations
- Provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient
  - Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Humira biosimilar
- If patient is younger than 18 years of age, coverage is provided for

moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease

- If indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must 2 years of age or older
- If indication is moderate to severe Crohn's disease patient must be 6 years of age or older AND must have had an inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates [such as, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [such as, azathioprine], etc. unless they have fistulizing Crohn's disease

- If patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, and hidradenitis suppurativa
  - If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease
  - If indication is ankylosing spondylitis the patient must have had an inadequate response to at least two NSAIDs over a period of at least 2 months
- Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira
- Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed)
- Patient is not receiving other targeted immunomodulatory biologics with Humira, including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab ~~(Stelara),~~ abatacept (Orencia), anakinra (Kineret), tocilizumab ~~(Actemra),~~ tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER)

Non-FDA approved uses are NOT approved, except if indication is approved for Humira, it is approved for a biosimilar

PA does not expire

2. danicopan (Voydeya)

Manual PA criteria apply to all new users of danicopan (Voydeya).

- Manual PA criteria: Coverage is approved if all criteria are met:
- Prescribed by a hematologist/oncologist
- Patient is 18 years of age or older
- Patient has documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Patient has tried and failed monotherapy with a C5 inhibitor for six months (e.g., eculizumab, ravulizumab), and has residual anemia
- Patient will receive C5 inhibitor therapy (eculizumab, ravulizumab) concurrently with Voydeya
- Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and Risk Evaluation and Mitigation Strategies (REMS) requirements
- Patient is not receiving C3 or Complement Factor B inhibitors with Voydeya, including but not limited to the following: iptacopan (Fabhalta), or pegcetacoplan (Empaveli)

Non-FDA approved uses are NOT approved

PA expires after 6 months then annually

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for another year if all the criteria are met:

- Patient has documentation of positive clinical response including increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis.

3. elafibranor (Iqirvo)

Manual PA criteria apply to all new users of elafibranor (Iqirvo).

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
- Patient has a diagnosis of primary biliary cholangitis (PBC)
- Diagnosis has been confirmed by at least TWO of the following:
  - alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values

- positive anti-mitochondrial antibodies (AMAs)
- histologic evidence of PBC from a liver biopsy

- Patient been receiving ursodiol therapy for one year or greater and has had an inadequate response OR
- Patient is unable to tolerate ursodiol therapy
- Patient has a contraindication to, intolerability to, or has failed a trial of obeticholic acid (Ocaliva)

Non-FDA approved uses are NOT approved

PA expires after 1 year

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- Patient has responded to Iqirvo as determined by the prescribing physician (for example, improved biochemical markers of PBC: alkaline phosphatase, bilirubin, gamma-glutamyl transpeptidase, aspartate aminotransferase, alanine aminotransferase)

4. givinostat (Duvyzat)

Manual PA criteria apply to all new users of givinostat (Duvyzat)

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

- Patient is 6 years of age or older
- Prescribed by a neurologist
- Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) that has been confirmed by genetic testing or muscle biopsy
- Patient is ambulatory
- Patient has a contraindication to, intolerability to, or has failed a trial of deflazacort (Emflaza)
- Provider acknowledges the FDA safety alerts, warnings, precautions, drug interactions, and monitoring recommendations for the requested medication

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

5. macitentan/tadalafil (Opsynvi)

Manual PA criteria apply to all new and current users of macitentan and tadalafil (Opsynvi).

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with cardiologist or a pulmonologist
- Patient has had a right heart catheterization with documentation provided

- Results of right heart catheterization confirm diagnosis of World Health Organization (WHO) Group 1 PAH
- Patient has WHO Functional Class II or III PAH
- If patient is a female, then prescriber is enrolled in Risk Evaluation and Mitigation Strategy (REMS) program
- Female patient is not pregnant
- Females of childbearing age are using adequate contraception up to 1 month after therapy
- Provider must describe why the patient requires a fixed dose combination and cannot take the individual components separately (write-in)
  - Acceptable responses include the following: the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are NOT approved

PA does not expire

6. mavorixafor (Xolremdi)

Manual PA criteria apply to all new users of mavorixafor (Xolremdi).

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

- Patient is 12 years of age or older
- Prescribed by an immunologist or hematologist
- Patient has diagnosis of WHIM syndrome
- Patient's diagnosis has been confirmed by genotype variant of CXCR4
- Patient has absolute neutrophil count (ANC) ≤ 400 cells/microliter

Non-FDA approved uses are NOT approved

PA expires after 6 months

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- Patient has documentation of positive clinical response defined as one of the following:
  - improvement in absolute neutrophil count (ANC)
  - decrease in infections

7. resmetirom (Rezdiffra)

Manual PA criteria apply to all new users of resmetirom (Rezdiffra).

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with hepatologist or gastroenterologist
- Patient has biopsy-proven non-alcoholic steatohepatitis (NASH) OR
- Patient has fibrosis stage of F2 or F3 diagnosed with appropriate assessment (e.g., FibroScan, MRI-PDFF)
- The patient has metabolic risk factors that are managed by standard of care (e.g., lifestyle modifications, glucagon-like peptide 1-receptor agonists (semaglutide, tirzepatide), or statins)

Non-FDA approved uses are NOT approved

PA expires in 1 year

Renewal Criteria: Initial TRICARE approval is required for renewal. Rezdiffra is approved for an additional year if all criteria are met:

- Patient has documentation of positive clinical response to include improvement in fibrosis or stabilization of fibrosis AND
- Patient has continued consultation with a hepatologist or gastroenterologist

8. sitagliptin/metformin (Zituvimet authorized generic)

Manual PA criteria apply to all new users of sitagliptin and metformin (Zituvimet authorized generic).

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

- Provider acknowledges that Januvia and its combination products are DoD's preferred dipeptidyl peptidase-4 inhibitor and are available to TRICARE beneficiaries without requiring prior authorization
- Provider must document why the patient cannot use the brand Januvia or Janumet XR. (write-in)
  - Acceptable responses include that the patient has had an adverse reaction to an excipient in brand Januvia, Janumet or Janumet XR that would not be likely to occur with sitagliptin/metformin authorized generic

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

9. sotatercept-csrk (Winrevair)

Manual PA criteria apply to all new users of sotatercept-csrk (Winrevair).

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with cardiologist or pulmonologist
- Patient has documented diagnosis of WHO group 1 PAH
- Patient has WHO functional class II or III PAH
- Patient has had right heart catheterization
- Documentation provided to confirm that patient has had right heart catheterization and confirms diagnosis of WHO Group 1 PAH
- Documentation is provided to confirm the patient is on stable background therapy for PAH (i.e., monotherapy, double therapy, triple therapy)
- Documentation is provided to confirm patient has been on stable doses of diuretics for more than 90 days
- Females of childbearing potential must use contraception up to 4 months after the last dose

Non-FDA approved uses are NOT approved

PA does not expire

10. spesolimab-sbzo syringe (Spevigo)

Manual PA criteria apply to all new users of spesolimab-sbzo (Spevigo) .

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

- Prescribed by a dermatologist
- Patient is 12 years of age or older and weighs 40 kilograms or greater
- Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent.
- The patient has had an inadequate response to Humira OR
- The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
- The patient has a contraindication to Humira AND
- The patient had an inadequate response to Cosentyx OR
- The patient experienced an adverse reaction to Cosentyx that is not expected to occur with the requested agent OR
- The patient has a contraindication to Cosentyx
- Patient has had an inadequate response to non-biologic systemic therapy. (For example – cyclosporine, methotrexate, acitretin, isotretinoin, systemic glucocorticoids, or mycophenolate)
- Patient has generalized pustular psoriasis and is not currently experiencing a flare as defined by a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1

- Patient has history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past while on biologic suppressive maintenance therapy
- Coverage is NOT provided for concomitant use with other TIBs including, but not limited to: certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), ustekinumab (Stelara), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), tildrakizumab (Ilumya), risankizumab (Skyrizi)

Non-FDA approved uses are NOT approved

PA expires in 1 year

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional year if all the criteria are met:

- Patient has had a documented reduction in generalized pustular psoriasis symptoms or
- Patient has had a reduction in generalized pustular psoriasis flares

11. tocilizumab-aazg syringe (Tyenne)

Manual PA criteria apply to all new users of tocilizumab-aazg (Tyenne).

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

- Provider acknowledges the Department of Defense's preferred targeted immune biologic is Humira
- The patient has had an inadequate response to Humira OR
- The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
- The patient has a contraindication to Humira AND
- Patient has moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs OR
- Patient has active polyarticular Juvenile Idiopathic Arthritis (pJIA) OR
- Patient has a diagnosis for which adalimumab is not approved including
  - Giant cell arteritis OR
  - Systemic sclerosis-associated lung disease OR
  - Patient has systemic Juvenile Idiopathic Arthritis (sJIA) OR
  - If "other" diagnosis, please provide appropriate literature-based support documentation for the indication and utilization
- Patient is not receiving other targeted immunomodulatory biologics with Tyenne

Non-FDA approved uses are NOT approved, except as noted above

PA does not expire

12. tovorafenib (Ojemda)

Manual PA criteria apply to all new users of tovorafenib (Ojemda).

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

- Prescribed by or in consultation with a hematologist/oncologist
- Patient has pediatric low-grade glioma
- Patient has relapsed or refractory disease
- Tumor is positive for one of the following: BRAF fusion, BRAF rearrangement, BRAF V600 mutation
- The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.

Other non-FDA approved uses are NOT approved except as noted above

PA does not expire

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

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF, NF and Completely Excluded Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service.

VII. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

UF BAP Comments

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

The P&T Committee recommended the formulary status for the newly approved drugs as discussed above.

- UF
  - Libervant
  - Iqirvo
  - Xolremdi
  - Myhibbin suspension
  - Rextovy nasal spray

- Rezdiffra
- Winrevair
- Tyenne
- Ojemda

- NF
  - Simlandi
  - Voydeya
  - Duvyzat
  - Opsynvi
  - Zituvimet authorized generic
  - Spevigo
- Completely Excluded
  - Humira Cordavis

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

The P&T Committee recommended implementation period of two weeks as discussed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—WHITE BLOOD CELL STIMULANTS (WBC)—EFLAPEGRASTIM-XNST (ROLVEDON)

P&T Comments

A. New Manual PA Criteria

White Blood Cell Stimulants—eflapegrastim-xnst (Rolvedon)

Rolvedon was FDA approved in September 2022. Initially Rolvedon required administration by a healthcare professional and was covered under the TRICARE medical benefit. In June 2023, the FDA updated the Rolvedon label to allow for self-administration therefore, it now falls under TRICARE pharmacy benefit coverage, and will be designated as UF. The committee reviewed PA criteria for Rolvedon, based on existing step therapy in the WBC stimulant class.

In reviewing available clinical data, Rolvedon demonstrated noninferior efficacy and similar adverse effects compared to pegfilgrastim. Rolvedon is less cost-effective than the step-preferred pegfilgrastims. PA criteria for Rolvedon will require use of all the step-preferred WBC stimulants first in new users.

The New Manual PA criteria is as follows:

eflapegrastim-xnst (Rolvedon)

Updates from the August 2024 meeting are in bold.

Manual PA criteria apply to all new users of pegfilgrastim (Neulasta) and pegfilgrastim (Neulasta OnPro, **and eflapegrastim-xnst (Rolvedon).**

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

- Provider acknowledges that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) are the TRICARE preferred pegfilgrastims and are available without a prior authorization.
- Drug is prescribed by or in consultation with a hematologist/oncologist
- Patient requires use of an on-body injector (Neulasta OnPro) because the patient/caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration OR
- Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) and is expected to respond to the requested medication

PA does not expire

B. PA Criteria and Implementation Plan—eflapegrastim-xnst (Rolvedon)

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) PA criteria in new users of eflapegrastim-xnst (Rolvedon) prefilled syringe, requiring use of the step-preferred WBC stimulants first. The new PA will become effective the first Wednesday 60 days after the signing of the minutes.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—WHITE BLOOD CELL STIMULANTS—EFLAPEGRASTIM-XNST (ROLVEDON)

UF BAP Comments

The P&T Committee recommended PA criteria in new users of Rolvedon prefilled syringe as outlined above. The new PA will become effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

P&T Comments

A. Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)—lanreotide 120 mg/0.5 mL syringe

Manual PA criteria were recommended for six recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

a) **Endocrine Agents Miscellaneous—lanreotide 120 mg/0.5 mL syringe—** Other versions of lanreotide 120 mg/0.5 mL syringe are available, including Somatuline Depot, that are more cost-effective than this version made by a sole manufacturer.

b) **Pain Agents: Pain Topical—lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V)—**Numerous other more cost-effective lidocaine 5% patches are available.

The Manual PA criteria is as follows:

1. lanreotide 120 mg/ 0.5 mL syringe

Manual PA criteria apply to all new and current users of lanreotide acetate 120 mg injection.

Manual PA criteria: Lanreotide acetate 120 mg injection is approved if all criteria are met:

- Provider acknowledges that this drug has been identified as having cost-effective alternatives and Somatuline Depot is available without prior authorization.
- Provider must explain why the patient cannot use the 120 mg

Somatuline Depot brand.
- Acceptable responses include if the patient has a hypersensitivity to an excipient in the brand that is not found in the generic

Non-FDA-approved uses are not approved

Prior authorization does not expire

2. lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V)

Updates from the August 2024 meeting are in bold.

Manual PA criteria apply to all new and current users of lidocaine 5% patch (DermacinRx).

Lidocan, Lidocan II, Lidocan III, **Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, Tridacaine III**).

Manual PA criteria: lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III) is approved if all criteria are met:

- Provider acknowledges other formulations of lidocaine 5% patch are available without prior authorization.
- Provider must explain why the patient requires DermacinRx Lidocan, Lidocan II, Lidocan III, **Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, or Tridacaine III** and cannot take the cost-effective generic lidocaine 5% formulations.
    - Acceptable responses include that the patient has failed a trial of at least 3 other preferred generic lidocaine 5% patches; examples of failure include a documented allergy to an inactive ingredient or the patch not adhering to skin

Non-FDA-approved uses are not approved

Prior authorization does not expire

B. New PA Criteria for Drugs Not Subject to 32 CFR 199.21(G)(5) and Implementation Plan

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for lanreotide 120 mg/0.5 mL syringe, lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

XI. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

UF BAP Comments

The P&T Committee recommended manual PA for lanreotide 120 mg/0.5 mL syringe, lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V as stated above and an effective date the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA APPROVED INDICATIONS

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

a) **Atopy: Oral JAK-1—upadacitinib (Rinvoq)—**The manual PA were updated to allow for use in polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older and to expand the psoriatic arthritis indication to include pediatric patients 2 years of age and older. Both indications are for use in patients who have had an inadequate response or intolerance to one or more tumor necrosis factor inhibitors. A trial of Humira will be required for both indications.

b) **Atopy—benralizumab (Fasenra)**—The manual PA criteria for Fasenra were expanded to include patients 6 years of age or older with severe asthma with an eosinophilic phenotype.

c) **TIBs: Non-TNFs—vedolizumab (Entyvio)—**The manual PA criteria were updated to allow use of Entyvio to treat Crohn's Disease in adults.

d) **TIBs: Non-TNFs—sarilumab (Kevzara)—**Kevzara is now indicated for the treatment of active polyarticular JIA in patients who weight at least 63 kg. The manual PA were updated to reflect this new indication.

e) **Metabolic Agents Miscellaneous—maralixibat (Livmarli)—**The manual PA criteria were updated to allow for use in patients 12 months of age and older with cholestatic pruritus due to Progressive Familial Intrahepatic Cholestasis.

B. Updated Manual PA Criteria and Implementation Period for New FDA Approved Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent)

updates to the manual PA criteria for Rinvoq, Fasenra, Entyvio, Kevzara, and Livmarli in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA IMPLEMENTATION PERIOD FOR NEW FDA APPROVED INDICATIONS

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Rinvoq, Fasenra, Entyvio, Kevzara, and Livmarli above in new users and an implementation effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

A. Updated PA Criteria for Reasons other than New Indications

a) **Corticosteroids-Immune Modulators: Adrenocorticotrophic Hormones—corticotropin (Acthar Gel SelfJect)—**The manual PA criteria were updated to exclude use of the new Acthar Gel SelfJect formulation for the treatment of infantile spasms, as it is not FDA approved for this indication.

b) **Antiemetic-Antivertigo Agents—doxylamine/pyridoxine (Diclegis, Bonjesta)—**The PA was updated to inform prescribers that the more cost-effective OTC doxylamine is available under the TRICARE pharmacy benefit without a copay at the MTF and retail points of service; a prescription is required for coverage.

c) **Oncological Agents—trametinib (Mekinist), dabrafenib, (Tafinlar), neratinib (Nerlynx), vemurafenib (Zelboraf), venetoclax (Venclexta), nilutamide (Nilandron), belzutifan (Welireg), tucatinib (Tukysa), glasdegib (Daurismo), erdafitinib (Balversa) and Prostate Cancer drugs—abiraterone (generic and Zytiga), enzalutamide (Xtandi), darolutamide (Nubeqa), and apalutamide (Erleada)—**Based on a review of MHS data and feedback from providers, several oncology PA were reviewed in order to standardize and streamline the criteria. Future meetings will address the other oncology PAs.

As part of this standardization effort, the following actions were

taken: adding the requirement that the PAs be written by appropriate specialist in the PAs that lacked this, editing the NCCN guideline question to cite specific guideline version and page number to ease approvals for new indications, updating indications to more closely match FDA label language, and removing lengthy clinical monitoring and counseling questions based on provider feedback.

For the prostate cancer drug abiraterone (Zytiga and generic), automated specialist bypass and drug lookback criteria were added to allow PA approval if the prescriber is an oncologist, hematologist or urologist and continuation by a non-specialist.

d) **TIBs: Non-TNFs—anakinra (Kineret)—**The manual PA criteria for Kineret were updated to allow for treatment of Adult-onset Still's Disease (AOSD) without requiring a trial of Humira. This update is based on the approved indication in Europe, updates from the 2024 British Society of Rheumatology treatment recommendations of AOSD, available clinical data, and specialist feedback.

e) **Sleep Disorders: Wakefulness Promoting Agents—solriamfetol (Sunosi)—**The manual PA criteria were updated to allow for alternative treatments and prescribing providers for patients with obstructive sleep apnea and excessive daytime sleepiness. This update is based on review of current guidelines and literature, as well as specialist feedback. Additional edits were made to better align the Sunosi PA with existing PA criteria in the class.

f) **Sleep Disorders: Wakefulness Promoting Agents—pitolisant (Wakix)—**The manual PA criteria were updated to allow use in children as young as 6 years for the updated indication of narcolepsy with excessive daytime sleepiness. Additional edits were made to better align the Wakix PA with existing PA criteria in the class.

g) **TIBs: TNFs—adalimumab (Humira)—**At the May 2023 meeting, automated specialist bypass PA criteria were added to Humira to allow for rheumatologists to bypass PA requirements. At this meeting, the automated specialist bypass was expanded to include dermatologists and gastroenterologists. Additionally, the manual PA criteria were expanded to allow for off-label use of Humira for generalized pustular psoriasis (GPP) in children and adults based on guidelines and provider feedback.

h) **TIBs: Non-TNFs—secukinumab (Cosentyx)—**Similar to Humira, the manual PA criteria for Cosentyx were updated to allow for off-label use of Humira for generalized pustular psoriasis (GPP) in children and adults based on guidelines and provider feedback.

i) **TIBs: Non-TNFs—tocilizumab (Actemra)—**The manual PA and MN criteria for Actemra were updated due to the recent availability of a cost-effective tocilizumab biosimilar (see new drugs section on

page 20). The PA updates require a trial of the biosimilar tocilizumab-aazg (Tyenne) prior to Actemra. Other updates were made to standardize the PA, consistent with what was done with other TIBs (e.g., removing the monitoring and counseling questions).

B. Updated PA Criteria and Implementation Period for Reasons other than New Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Acthar Gel, Diclegis, Bonjesta, Mekinist, Nerlynx, Nilutamide, Tafinlar, Zelboraf, Venclexta, Welireg, Tukysa, Daurismo, Balversa, Xtandi, Nubeqa, abiraterone, Kineret, Sunosi, Wakix, Humira, Cosentyx, and Actemra in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XV. UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for drugs listed above, and implementation effective the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVI. BRAND OVER GENERIC AUTHORIZATION, TIER 1 COPAY FOR ADDITION FOR MIRABEGRON (MYRBETRIQ) AND REMOVAL FOR TOPIRAMATE (TROKENDI XR) AND IMPLEMENTATION PLAN

P&T Comments

Overactive Bladder Agents: Mirabegron (Myrbetriq) tablets are designated as UF and require a PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. The branded Myrbetriq tablets will continue to be dispensed at all three points of service, and the generics will only be available with prior authorization. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Myrbetriq tablets. The effective date will be no later than 60 days after the signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

Anticonvulsant and Anti-Mania Agents: topiramate ER (Trokendi XR): At the May 2023 P&T meeting, brand over generic criteria and a Tier 1 copay were recommended for topiramate ER (Trokendi XR). At this time, the branded Trokendi XR is no longer more cost-effective than the generics, and the Tier 1 copay and brand over generic PA criteria for Trokendi XR will be removed at all three points of service, with an implementation plan of

no later than 60 days after signing of the minutes.

XVII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR ADDITION FOR MIRABEGRON (MYRBETRIQ) AND REMOVAL FOR TOPIRAMATE (TROKENDI XR) AND IMPLEMENTATION PLAN

UF BAP Comments

The branded Myrbetriq tablets will continue to be dispensed as outlined above. The Tier 1 copay for brand Myrbetriq is recommended.

The branded Trokendi XR is no longer more cost-effective than the generics, and the Tier 1 copay and brand over generic PA criteria for Trokendi XR will be removed at all three points of service.

Implementation will occur no later than 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVIII. UTILIZATION MANAGEMENT: HEPATITIS C VIRUS (HCV) DIRECT ACTING ANTIVIRALS (DAAS) SUBCLASS PA CRITERIA AND IMPLEMENTATION PLAN

P&T Comments

A. HEPATITIS C VIRUS (HCV) DIRECT ACTING ANTIVIRALS (DAAS) SUBCLASS

The HCV DAA subclass was reviewed in May 2015, February 2017, and most recently in August 2018. A summary of the utilization trends and cost of the HCV DAAs were presented during the August 2024 meeting. The Committee also reviewed the 2023 American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidelines for HCV.

Based on the above, provider feedback, and changes in commercial practice, several changes were recommended for the PA criteria and QLs for the HCV DAAs. These changes included removing the PA requirements for glecaprevir/pibrentasvir (Mavyret) and adding automated specialist bypass criteria allowing HCV specialists to bypass the PA for sofosbuvir/velpatasvir (Epclusa), ledipasvir/sofosbuvir (Harvoni), elbasvir/grazoprevir (Zepatier), sofosbuvir (Sovaldi), and sofosbuvir/velpatasvir/voxilaprevir (Vosevi).

Additionally, the PA criteria were streamlined by removing the requirement for minimum age and HCV diagnosis. For Epclusa, non-specialists will be able to prescribe without specialist consultation for all patients except for patients with both genotype 3 and cirrhosis. Harvoni, Zepatier, Vosevi, and Sovaldi will still require prescribing by or in consultation with a specialist. For Vosevi and Sovaldi, non-specialists will only be able to prescribe for retreatment.

The PA criteria is as follows:

1. **sofosbuvir/velpatasvir (Epclusa)**

   Updates from the August 2024 meeting are in bold and strikethrough.

   PA criteria: Epclusa is approved if all criteria are met:*Note: The branded agent on the top of this form is the preferred agent for TRICARE. If the authorized generic of Epclusa is required, please stop filling out this form and complete the separate PA form specific for the authorized generic product.

   Note: Mavyret does not require prior authorization

   Automated PA Criteria: When prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician, PA is approved.

   Manual PA Criteria: **If automated criteria are not met for gastroenterologist, hepatologist infectious disease physician or liver transplant physician specialist prescribing, coverage is approved if all criteria are met:**

   - ~~Patient is 3 years of age or older~~
   - ~~Patient has laboratory evidence of chronic HCV~~
   - ~~What is the HCV genotype~~
   - **If the physician is a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician, PA is approved OR**
   - **If the prescriber is not a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician sthen continue with the questions below.**
   - ~~**Prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician OR**~~
   - **Patient has a detectable hepatitis C viral load AND**
     - Patient is not cirrhotic OR
     - Patient is cirrhotic with non-genotype 3 hepatitis c virus (HCV) infection OR
     - Patient is cirrhotic with genotype 3 HCV infection and the prescription is prescribed in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician

   Non-FDA-approved uses are not approved
   Prior authorization ~~does not expire~~ **expires in 1 year. PA must be resubmitted.**

2. **ledipasvir/sofosbuvir (Harvoni), elbasvir/grazoprevir (Zepatier)**

   Updates from the August 2024 meeting are in bold and strikethrough.

PA criteria: PA is approved if all criteria are met: *Note: The branded Harvoni on the top of this form is the preferred ledipasvir/sofosbuvir for TRICARE. If the authorized generics of Harvoni is required, please stop filling out this form and complete the separate PA form specific for the authorized generic product. **Note: Mavyret does not require prior authorization**

Automated PA Criteria: When prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician, PA is approved.

Manual PA Criteria: **If automated criteria are not met for gastroenterologist, hepatologist infectious disease physician or liver transplant physician specialist prescribing, coverage is approved if all criteria are met:**

- ~~Patient is 3 years of age or older (Harvoni) or 12 Years of age and older or weighing at least 30 kg (Zepatier)~~
- ~~Patient has laboratory evidence of chronic HCV~~
- ~~What is the HCV genotype?~~
- **If the physician is a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician, PA is approved OR**
- **If the prescriber is not a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician and the drug is prescribed in consultation with a specialist, then continue with the questions below.**
- ~~**Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician AND**~~
- **Patient has a detectable hepatitis C viral load AND**
  - **For Harvoni, patient has genotype 1, 4, 5, or 6 hepatitis C virus (HCV) infection OR**
  - **For Zepatier, patient has genotype 1 or 4 HCV infection**

Non-FDA-approved uses are not approved

Prior authorization ~~does not expire~~ **expires in 1 year. PA must be resubmitted.**

3. **sofosbuvir (Sovaldi), sofosbuvir/velpatasvir/voxilaprevir (Vosevi)**

   Updates from the August 2024 meeting are in bold and strikethrough.

   PA criteria: PA is approved if all criteria are met. **Note: Mavyret does not require prior authorization**

   Automated PA Criteria: When prescribed by a gastroenterologist,

hepatologist, infectious diseases physician, or a liver transplant physician, PA is approved.

Manual PA Criteria: **If automated criteria are not met for gastroenterologist, hepatologist infectious disease physician or liver transplant physician specialist prescribing, coverage is approved if all criteria are met:**

- ~~Patient is 3 years of age or older (Sovaldi) or 18 Years of age and older (Vosevi)~~
- ~~Patient has laboratory evidence of chronic HCV~~
- ~~What is the HCV genotype?~~
- **If the physician is a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician, PA is approved OR**
- **If the prescriber is not a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician and the drug is prescribed in consultation with a specialist, then continue with the questions below.**
- ~~**Prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician OR**~~
- **Patient has a detectable hepatitis C viral load AND**
- ~~The patient does not have an 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 was previously treated with an~~ **Medication is for retreatment of hepatitis C virus (HCV) that has failed treatment with a** regimen containing an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir). OR
- ~~Patient has previously been treated with an~~ **Medication is for retreatment of hepatitis C virus (HCV) that has failed treatment with a** regimen containing sofosbuvir with or without an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir).

Non-FDA-approved uses are not approved
PA ~~does not expire~~ **expires in 1 year. PA must be resubmitted.**

B. HCV DAAs MAVYRET PA REMOVAL, PA UPDATED CRITERIA, AND IMPLEMENTATION PERIOD

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent)

updates to the PA criteria for Epclusa, Harvoni, Zepatier, Sovaldi and Vosevi, with an implementation of the first Wednesday 60 days after signing of the minutes at all points of service.

XIX. UTILIZATION MANAGEMENT: HEPATITIS C VIRUS (HCV) DIRECT ACTING ANTIVIRALS (DAAS) SUBCLASS PA AND IMPLEMENTATION PLAN

UF BAP Comments

PA changes included removing the requirements for Mavyret and adding automated specialist bypass criteria allowing HCV specialists to bypass the PA for Epclusa, Harvoni, Zepatier, Sovaldi, and Vosevi, and an implementation of the first Wednesday 60 days after signing of the minutes at all points of service.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***