Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
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TO: Maine Drug Utilization Review Board
DATE: July 1, 2025
RE: Maine DUR Board Meeting minutes from June 10, 2025

ATTENDANCE	UNEXCUSED	EXCUSED	IN-PERSON	REMOTELY
Linda Glass, MD	X			
Kathleen Polonchek, MD		X		
Erin Ackley, PharmD.				X
John Deason, PharmD.				X
Caitlin Morrow, PharmD.				X
Non –Voting				
Mike Ouellette, R.Ph., Optum			X	
Roberta Capp, MD, Optum			X	
Jan Wright, MaineCare			X	
Courtney Pladsen, MaineCare				X

Guests of the Board: Gavin Gillespie PharmD, Optum

CALL TO ORDER: 6:00PM

The meeting was called to order at 6:00 PM.

MAINECARE UPDATE - JAN WRIGHT

Jan reminded the Committee that to be compliant with the 21st Century Cures Act, effective September 1, 2025, the Office of MaineCare Services (OMS) will no longer process prescriptions by prescribers who are not enrolled in the MaineCare program.

PUBLIC COMMENTS

Elena Fernandez from Vertex Pharmaceutical: Highlighted the attributes of Journavx

Annie Vong from Abbvie: Highlighted the attributes of Vyalev

Omer Aziz from Teva Pharmaceutical: Highlighted the attributes of Epysqli and Selarsdi

Shirley Quach from Novartis: Highlighted the attributes of Vanrafia

OLD BUSINESS

None.

CONSENT AGENDA

DUR MINUTES

Approval of March 11, 2025, DUR meeting minutes

NEW CANCER MEDICATIONS

Recommendation: Add Aucatzyl, Datroway, Gomekli, Grafapex, Revuforj, and Romvimza to non-preferred.

Criteria: All non-preferred: A clinical PA is required to confirm appropriate clinical indication for the individual drug request. Specific to each drug, all age, clinical testing requirements, previous step therapies, adjunctive drug therapy requirements, and response without disease progression will also be evaluated for clinical appropriateness. The standard for the appropriate indication will include the FDA label as well as current NCCN guidelines.

BIOSIMILARS

Recommendation: Add Soliris Biosimilars Bkemv and Epysqli to non-preferred.

Criteria: Updated criteria for a diagnosis of generalized myasthenia gravis (gMG): must have confirmation that patients are anti-acetylcholine receptor (AChR) antibody positive.

Recommendation: Add Stelara Biosimilars Otulfi, Pyzchiva, Selarsdi, Steqeyma, and Yesintek to non-preferred.

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.

Board Decision: The Board unanimously approved the above recommendations as presented.

NEW BUSINESS

RETRODUR

Introduction of a Biosimilar PDL cost saving initiative
This initiative analyzes inclusion of Biosimilar PDL into the MaineCare benefit to see if changes affected utilization and cost benefit. Biosimilar PDL is where the State does indicate a preference among similar drugs on the medical benefit.

We will use paid, non-reversed Medicaid pharmacy and medical claims from the inception of the Biosimilar PDL excluding members with Part D, TPL and Maine RX coverage.

For members taking products listed on the MaineCare Biosimilar PDL (Bevacizumab, Infliximab, Pegfilgrastim, Rituximab and Trastuzumab) we will analyze medical and pharmacy claims, looking at number of preferred and nonpreferred prescriptions and analyze and evaluate the cost savings, the shift of branded products to the biosimilar preferred product other contributing factors to utilization of or not to the Biosimilar products after starting the Biosimilar PDL.

Data Presentation: The effect of Hemlibra on the cost and quality of care in Hemophilia A patients
Hemlibra (emicizumab), a bispecific - and factor X -directed antibody is used to treat factor VIII deficient patients (hemophilia A), with or without inhibitors. It activates the coagulation cascade downstream of the factor VIII activating pathway, thereby negating the need for factor VIII for normal coagulation. It was initially developed for patients with inhibitors to factor VIII, which usually develop after only a few exposures to factor products, to reduce the need for immune tolerance with very high doses of factor and to avoid the used of

bypassing agents, such as NovoSeven. However, it is now routinely used as the initial prophylactic treatment in children born with hemophilia, due to the ease of subcutaneous administration and only rare incidences of inhibitor development. If bleeding occurs, traditional factor replacement is used. Hemlibra may be given weekly, every other week or monthly. In children, it prevents the need for central line placement with the risks of infection and prevents in all patients the need for IV prophylaxis several times a week. The medical and scientific advisory council (MASAC) of the National Bleeding Disorders Foundation recommends Hemlibra as one possible prophylactic agent for the treatment of patients with factor VIII deficiency.

While Hemlibra is more costly per month than traditional factor infusions, it is possible that patient quality of life improvement and the overall cost of care for patients is decreased, due to better compliance with prophylaxis (no IV required), less development of inhibitors, which are more costly to treat, and less use of medical care, such as hospitalizations for infections from central lines, bleeds, and trauma-related care.

We will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2023, excluding members with Part D, TPL and Maine RX coverage. For members taking Hemlibra during SFY 23, we will analyze medical claims, looking at number and cost of hospitalizations, ER visits, factor use and provider visits for the year prior to starting Hemlibra and 1 year after starting the medication in those who had been on traditional factor prophylaxis prior to starting Hemlibra, to see if the increased cost of Hemlibra is offset by decreased utilization of medical care, including factor use.

Among the five members who received Hemlibra for twelve consecutive months, 80% had previously received factor therapy for a full year within the ten years preceding Hemlibra initiation. For those with multiple years of factor replacement therapy, the average number of prescriptions and associated costs were calculated for years with complete 12-month data. Prior to initiating Hemlibra, the average number of factor therapy prescriptions was 17 per year, compared to an average of 3 prescriptions per year following Hemlibra initiation.

Overall, there was an 81% reduction in factor replacement utilization and a 90% reduction in associated costs over the 12 months following Hemlibra initiation. Despite the decrease in factor therapy use, the average number of Hemlibra prescriptions was 1.4 per month. Consequently, the total pharmacy costs—including both factor and non-factor therapies—increased by an average of 33% per patient.

For members with incomplete Hemlibra data, the analysis focused on those with at least six months of continuous treatment. Among these individuals, the average number of factor replacement prescriptions was 1.25 per patient. These findings suggest that these four members likely did not experience acute bleeding episodes. However, as with the broader cohort, the lack of access to medical claims data limits the ability to confirm whether factor replacement was administered during medical visits.

Based on the available data, patients receiving Hemlibra therapy demonstrate a notable reduction in the utilization of traditional factor replacement therapies, as evidenced by pharmacy claims. This suggests a shift in treatment patterns, with Hemlibra effectively reducing the need for frequent factor infusions. However, despite this reduction in factor replacement utilization, the overall expenditures associated with hemophilia treatment have increased. This rise in pharmacy costs for the hemophilia therapeutic class is likely attributable to the increase in utilization of Hemlibra itself, which can significantly exceed the cost of conventional therapies, particularly for patients who were previously on prophylactic factor regimens.

Furthermore, while Hemlibra has shown strong clinical efficacy, especially in reducing bleeding episodes among patients with inhibitors, the full scope of its impact on patient quality of life and healthcare resource utilization—such as hospital or infusion center visits—remains unclear due to incomplete medical claims data. This lack of comprehensive data limits the ability to fully assess the broader clinical and economic benefits of

Hemlibra. Although to offset the costs of Hemlibra, it would have needed to save on average 16 hospitalizations per year.

Recommendation: Based on findings, recommendations moving forward include addition of prior authorization clinical criteria to Hemlibra and referral of members receiving this therapy to the pharmacy care management (PCM) program.

NEW DRUG REVIEW

Attruby (Acoramidis); **PDL Category** – Neurologics-hATTR Agents

Attruby® is a transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization. The efficacy of Attruby® was demonstrated in a randomized, double-blind, placebo-controlled study. The primary composite endpoint included all-cause mortality (ACM) and cumulative frequency of cardiovascular-related hospitalizations (CVH) over 30 months, analyzed hierarchically using the stratified F-S test. The F-S test demonstrated a statistically significant reduction (p=0.018) in ACM and cumulative frequency of CVH in the Attruby® arm as compared with placebo. Attruby® offers a new treatment option for patients with this disease. Other agents considered comparators of Attruby® include tafamidis and vutrisiran. Direct comparisons have not been found between tafamidis, acoramidis, or vutrisiran, but in patients with ATTR cardiac amyloidosis these treatments reduce the risk of hospitalization while tafamidis and vutrisiran reduce the risk of mortality.

Recommendation: Add Attruby to non-preferred

Criteria: Prior Authorization required for appropriate diagnosis

Inzirqo (Hydrochlorothiazide) suspension; **PDL Category** – Diuretics.

Inzirqo® is a thiazide diuretic indicated for the treatment of hypertension in adult and pediatric patients alone or in combination with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction. It is also indicated for the treatment of edema associated with congestive heart failure, hepatic cirrhosis, and renal disease, including the nephrotic syndrome in adult and pediatric patients. It is supplied as a powder for oral suspension and must be reconstituted prior to dispensing. HCTZ is currently available as a capsule or tablet; thus, Inzirqo® offers providers and patients with an available dosage alternative.

Recommendation: Add Inzirqo to non-preferred

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists**.**

Journavx (Suzetrigine); **PDL Category** – Analgesics-Misc.

Journavx® is a sodium channel blocker indicated for the treatment of moderate to severe acute pain in adults. Use Journavx® for the shortest duration, consistent with individual patient treatment goals. Use of Journavx® for the treatment of moderate to severe acute pain has not been studied beyond 14 days. The efficacy of Journavx® for the treatment of moderate to severe acute pain in adults was established in two randomized, double-blind, placebo- and active-controlled trials of acute post-operative pain, one following full abdominoplasty and the other following bunionectomy. Efficacy for both studies was evaluated by the time-

weighted sum of the pain intensity difference from 0 to 48 hours (SPID48) in the Journavx® group compared to the placebo group, and then to the HB/APAP group. Results suggested that treatment with Journavx® demonstrated statistically significant superior reduction in pain compared to placebo in both studies. Per the full text study by Bertoch et al[2], neither study attained the first key secondary endpoint of superiority of suzetrigine as compared with HB/APAP on SPID48. No data is available for long-term safe and effective use.

Recommendation: Add Journavx to non-preferred

Criteria: Patient must have documented clinical reason as to why they are unable to use acetaminophen and NSAIDS (which can include Cox-II inhibitors)

Kebilidi (Eldocagene Exuparvovec-tneq); **PDL Category** – AADC Deficiency Agent

Kebilidi® is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. This indication is approved under accelerated approval based on the change from baseline in gross motor milestone achievement at 48 weeks post-treatment. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. Kebilidi® is for single-dose intraputaminal infusion only. The efficacy of Kebilidi® was assessed in one open-label, single arm study that included 13 patients treated with Kebilidi® and compared to an external untreated natural history cohort of 43 pediatric patients with severe AADC deficiency who had at least one motor milestone assessment after 2 years of age. The main efficacy outcome measure was gross motor milestone achievement assessed at week 48, and this was assessed in 12 of the 13 patients treated, as one dropped out of the study prior to week 48. Sixty-seven percent of treated patients (8/12) achieved a new gross motor milestone at week 48. Kebilidi® is the first FDA approved gene therapy for AADC deficiency.

Recommendation: Add Kebilidi to non-preferred

Criteria: Prior Authorization required for appropriate diagnosis

Qfitlia (Fitusiran Sodium); **PDL Category** – Antihemophilic Agent, Non-Factor Replacement Therapy

Qfitlia® is an antithrombin-directed small interfering ribonucleic acid indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors. It is for subcutaneous use only, to be administered every 2 months. It has a box warning regarding thrombotic events and acute and recurrent gallbladder disease. The efficacy of Qfitlia® prophylaxis using AT-DR in ATLAS-OLE compared to on-demand BPA or CFC control data from studies ATLAS-INH and ATLAS-A/B were reported. The ABR for all treated bleeds in patients with inhibitors for Qfitlia® AT-DR as compared with on-demand BPA was significantly in favor of Qfitlia® ($p=0.0006$). The ABR for all treated bleeds in patients without inhibitors for Qfitlia® AT-DR vs on-demand CFC was significantly in favor of Qfitlia® ($p<0.0001$).

Recommendation: Add Qfitlia to non-preferred

Criteria: Create new PDL Category for placement of non-factor replacement products, including: Hemlibra, Alhemo, Hympavzi, and Qfitlia. Clinical Prior Authorization required for appropriate diagnosis. Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.

Onapgo (apomorphine) injection and **Vyalev** (foscarbidopa/foslevodopa) injection; **PDL Category** – Parkinsons – Dopaminergics/CarbII/Levo

Onapgo® is a dopaminergic agonist indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease. It is for subcutaneous use by infusion only and is not substitutable for apomorphine products intended for intermittent use. A double-blind, randomized, placebo-controlled trial assessed the safety and efficacy of Onapgo® SC infusion in patients with Parkinson's disease who had motor fluctuations while receiving carbidopa/levodopa and other concomitant medications to treat PD. The primary efficacy endpoint was the change in total daily OFF time assessed from baseline to the end of the 12-week treatment period based on patient diaries. A key secondary endpoint was the change in daily ON time without troublesome dyskinesia from baseline to the end of the 12-week treatment period. Results suggested that there was a statistically significant reduction in the amount of daily OFF time in patients treated with Onapgo® compared to placebo (p=0.0114), and there was also a statistically significant increase in daily ON time without troublesome dyskinesia in patients treated with Onapgo® compared to placebo (p=0.0188). This is the first FDA approved continuous subcutaneous apomorphine infusion indicated for motor fluctuations in adults with advanced Parkinson's disease.

Vyalev® is a combination of foscarbidopa (an aromatic amino acid decarboxylation inhibitor) and foslevodopa (an aromatic amino acid) indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease. It is for subcutaneous administration only, preferably in the abdomen, via the Vyafuser pump. Patients selected for treatment with Vyalev® should be capable of understanding and using the delivery system themselves or with assistance from a caregiver. In addition, patients should be trained on the proper use of Vyalev® and the delivery system prior to starting. Vyalev® is contraindicated in patients who are currently taking a non-selective monoamine oxidase (MAO) inhibitor or have recently (within 2 weeks) taken a nonselective MAO inhibitor. The efficacy of Vyalev® was assessed in a randomized, double-blind, double-dummy, active-controlled multicenter study that included adults with advanced PD who were responsive to levodopa treatment, had motor fluctuations inadequately controlled by their current medications, and who experienced a minimum of 2.5 hours of "Off" time per day as assessed by PD diaries. The primary clinical outcome measure was the mean change from baseline to week 12 in the total daily mean "On" time without troublesome dyskinesia (defined as "On" time without dyskinesia plus "On" time with non-troublesome dyskinesia) based on PD diary. Results suggested that Vyalev® demonstrated statistically significant improvements from baseline to week 12 in "On" time without troublesome dyskinesia compared with the oral IR carbidopa/levodopa group (p=0.0083). Vyalev® is the only FDA-approved subcutaneous 24-hour continuous infusion of levodopa-based therapy to treat motor fluctuations with advanced Parkinson's disease.

Recommendation: Add Onapgo and Vyalev to non-preferred

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists**.**

Raldesy (Trazodone) solution; **PDL Category** – Antidepressants – Selected SSRI's and Others

Raldesy® is a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of major depressive disorder (MDD) in adults. It has a box warning regarding suicidal thoughts and behaviors, and is contraindicated in patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue. The efficacy of Raldesy® for the treatment of MDD in adults is based

on studies of trazadone tablets. Trazadone tablets have been available for numerous years but Raldesy® provides patients with another dosage formulation option, as it is the only FDA-approved oral liquid trazodone.

Recommendation: Add Raldesy to non-preferred

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.

Tezruly (Terazosin) solution; **PDL Category** – Benign Prostatic Hyperplasia (BPH)

Tezruly® is an alpha-1 adrenoceptor antagonist indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males, as well as for the treatment of hypertension alone or with other antihypertensive agents, to lower blood pressure in adults. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction. Tezruly®, like other alpha-1-adrenoceptor antagonists, can cause marked lowering of blood pressure, especially postural hypotension, and syncope in association with the first dose or first few days of therapy. To decrease the chance of syncope or excessive hypotension, start treatment with a 1mg dose of terazosin, given at bedtime. Higher doses (e.g., 2mg to 10mg) are not indicated as initial therapy. Advise patients to avoid situations, such as driving or hazardous tasks, where injury could result should syncope occur during initiation of therapy. There were no new clinical studies found in the Tezruly® prescribing information. The studies were the same as those found in the terazosin capsules prescribing information. Tezruly® offers prescribers and patients another treatment option. It is the first oral terazosin solution.

Recommendation: Add Tezruly to non-preferred

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists**.**

Tryngolza (olezarsen); **PDL Category** – Familial Hypercholesterolemia and Hypertriglyceridemia

Tryngolza® is an apoC-III-directed antisense oligonucleotide indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). Patients with FCS have very high triglyceride levels, which leads to an increased risk of potentially fatal pancreatitis as well as increased risk of cardiovascular disease (CVD).[2] Because of impairment in the clearance of postprandial lipids, patients with FCS respond poorly to standard TG-lowering medications including fibrates or omega-3 fatty acids and require a lifelong very low-fat diet, which prevents the formation of chylomicrons.[3,4] Patients with FCS typically have TG concentrations >20 mmol/L (1770 mg/dL) and continue to experience symptoms despite good dietary compliance and adherence to available medications.[5,6] Tryngolza® is for once monthly subcutaneous injection. The efficacy of Tryngolza® was demonstrated in a randomized, double-blind, placebo-controlled study that included adults with genetically identified FCS and fasting TG levels ≥880mg/dL. The primary endpoint was the percent change in fasting TG from baseline to month 6 (average of weeks 23, 25, and 27) compared to placebo. Results suggested that the difference between Tryngolza® and placebo was statistically significant in favor of Tryngolza® (-42.5%, p=0.0084). Tryngolza® is the first FDA-approved treatment for adults with FCS.

Recommendation: Add Tryngolza to non-preferred

Criteria: Tryngolza requires fasting triglycerides of ≥ 880 mg/dL and confirmed genetically identified familial chylomicronemia syndrome (FCS)

Vanrafia (Atrasentan); **PDL Category** – Hematological Agents - IgAN

Vanrafia® is an endothelin receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Vanrafia® slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. It has a box warning regarding embryo-fetal toxicity, as it may cause major birth defects if used during pregnancy. Exclude pregnancy prior to the start of treatment. In addition, use effective contraception before the start of treatment, during treatment, and for two weeks after treatment discontinuation. If pregnancy occurs, discontinue Vanrafia®. The efficacy of Vanrafia® was assessed in a randomized, double-blind, placebo-controlled study that included adults with biopsy-proven primary IgAN, an eGFR ≥30ml/min/1.73m^2, and urine protein ≥1g/day on a stable dose of maximally tolerated renin angiotensin system inhibitor. The primary endpoint was the percent reduction in UPCR at week 36 relative to baseline, and results suggested that Vanrafia® had a statistically significant greater percentage reduction in UPCR at week 36 as compared with placebo ($p<0.0001$; NNT 3). Generally, supportive care, including blood pressure control and reduction of proteinuria with renin-angiotensin system inhibition, as well as treatment of dyslipidemia and lifestyle modification, is the initial management of primary IgAN. If proteinuria persists even with ACE inhibitor or ABR treatment, then it is suggested to add an SGLT2 inhibitor, an ERA (atrasentan), or sparsentan.[2] Vanrafia® is a selective endothelin type A receptor antagonist that provides another treatment option to be added to supportive care.

Recommendation: Add Vanrafia to non-preferred

Criteria: PA required to confirm FDA approved indication. Vanrafia is for adults with biopsy proven primary IgAN AND eGFR>=30 cc/min/1.73m3 AND urine protein >=1 g/day AND on stable dose of maximally tolerated renin-angiotensin system inhibitor

Xromi (hydroxyurea) solution; **PDL Category** – Sickle Cell Disease

Xromi® is an antimetabolite indicated to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients aged 6 months of age and older with sickle cell anemia with recurrent moderate to severe painful crises. It has a box warning regarding myelosuppression and malignancies. Monitor blood counts at baseline and throughout treatment and advise sun protection and monitor patients for malignancies. The efficacy of Xromi® has been established for its approved indication based on an adequate and well-controlled study of hydroxyurea capsules in adult patients with sickle cell anemia with recurrent moderate to severe pain crises and additional pharmacokinetic data from a single-arm, open-label study of Xromi® in pediatric patients aged 10 months to less than 18 years with sickle cell anemia, who were treatment naïve or had not received hydroxyurea in the 6 months prior to enrollment. Xromi provides a new dosage formulation for providers and patients with sickle cell anemia with recurrent moderate to severe painful crises.

Recommendation: Add Xromi to non-preferred

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists**.**

Zunveyl (Benzgalantamine); **PDL Category** – Alzheimer – Cholinomimetics/Others

Zunveyl® is a cholinesterase inhibitor indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults. It is prodrug of galantamine, which has been available in various dosage forms for many years. The efficacy of Zunveyl® is based upon 3 bioavailability studies in healthy adults comparing galantamine IR tablets and galantamine ER capsules to Zunveyl®. Zunveyl® is available as a delayed-release tablet, with the potential to be better tolerated due to minimal absorption in the GI tract. A cholinesterase inhibitor agent (donepezil, galantamine, or rivastigmine) is suggested for patients with newly diagnosed mild to moderate AD.

Recommendation: Add Zunveyl to non-preferred

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists**.**

Board Decision: The Board unanimously approved the above recommendations as presented.

FDA SAFETY ALERTS

FDA Requires Warning About Rare But Severe Itching After Stopping Long-Term Use of Oral Allergy Medicines Cetirizine or Levocetirizine (Zyrtec, Xyzal, and other trade names)
Click here for a direct link to the FDA Safety Communication.

Board Decision: No action needed.

ADJOURNMENT: 8:30PM

The next meeting will be held on September 9, 2025 | 6 – 8:30pm hybrid