

Managed Care Pharmacy and Medical Drug Policies Public Comments

Date	Item Number and Policy	My question/comment
4/24/2026 6 13:44	2026-HB-MED-656 Forzinity (elamipretide)	<p>Thank you for the opportunity to comment on Elamipretide in the context of Barth syndrome. I want to thank the committee for the time and rigor that went into developing the current policy. Below are two points related to the draft policy that may be helpful.</p> <ol style="list-style-type: none"> 1. Elamipretide is a mitochondrial cardiolipin-binding agent that improves mitochondrial structure and function. It is approved to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg, with no age restriction in the label. We respectfully request reconsideration of the policy's age requirement (>12 years), as it is not aligned with the approved indication. 2. Some states require reauthorization for Elamipretide use every 6 months. However, available data suggests that a longer duration of therapy, approximately 9 months, is needed to demonstrate efficacy. We respectfully request reconsideration of reauthorization after 12 months.
4/15/2026 6 13:56	2026-LHCC-MED-939 Aflibercept (Eylea, Eylea HD) and Biosimilars)	<p>To Whom It May Concern,</p> <p>I am writing to strongly support the inclusion of Eylea HD on the Louisiana Medicaid formulary.</p> <p>Eylea HD represents an important advancement in anti-VEGF therapy and is increasingly considered a standard of care for the treatment of retinal vascular diseases, including diabetic macular edema, retinal vein occlusion, and neovascular (wet) age-related macular degeneration. Its extended durability allows for longer intervals between injections while maintaining excellent visual and anatomic outcomes.</p> <p>For the Louisiana Medicaid population, inclusion of Eylea HD would offer several meaningful benefits:</p> <ul style="list-style-type: none"> • Improved patient adherence, particularly in populations with transportation and access challenges • Reduced treatment burden for patients, caregivers, and clinics • Potential overall cost efficiency through fewer injections and clinic visits • Clinical flexibility for physicians to individualize treatment based on patient response

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		<p>Given the chronic nature of these conditions and the significant risk of irreversible vision loss without adequate treatment, access to longer-acting, evidence-based therapies is critical. Adding Eylea HD to the formulary would enhance our ability to deliver high-quality, patient-centered care to Medicaid beneficiaries across Louisiana.</p> <p>Thank you for your consideration.</p> <p>Sincerely,</p> <p>Adam C Janot, MD, FASRS</p> <p>Vitreoretinal Institute</p> <p>Baton Rouge, Gonzales, Alexandria</p>
3/13/2026 8:37	2026-PHARM-18 Pain Management - Antimigraine Agents, CGRP Antagonists	<p>In March 2024, the American Headache Society (AHS) updated its guidance, now recommending CGRP therapies as first-line options for migraine prevention, without requiring patients to have previously tried and failed other preventive medications. This recommendation is based on extensive evidence supporting the efficacy, safety, and tolerability of CGRP-targeted therapies.</p> <p>Qulipta is currently the only oral preventive CGRP indicated for both chronic and episodic migraine. With three approved dosage strengths, Qulipta offers dosing flexibility to address individual patient needs, such as drug-drug interactions or renal dysfunction.</p> <p>Studies show that the leading reasons for discontinuation of oral preventive migraine medications—“including antidepressants, beta-blockers, and calcium channel blockers”—are side effects (35.6%-47.1%), lack of efficacy (40.8%-45.2%), and satisfactory resolution (8.5%-13.9%). Due to these discontinuation rates, patients frequently cycle through various preventive medications, which leads to more physician and hospital visits, significantly increasing overall healthcare costs compared to consistent, effective therapy.</p>

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		<p>We respectfully ask the board to remove step therapy requirements for Qulipta in alignment with AHS guidelines, so that patients with chronic and/or episodic migraine can access appropriate preventive treatment sooner.</p> <p>Thank you for your consideration.</p>
<p>3/10/2026 12:52</p>	<p>2026-LHCC-MED-900 Atezolizumab (Tecentriq)</p>	<p>Dear Louisiana Healthcare Connections Clinical Policy Review Team:</p> <p>This evidence submission pertains to the Louisiana Department of Health (LDH) pharmacy and medical drug policy open comment process for new or updated data relevant to the recently posted "Atezolizumab (Tecentriq), Atezolizumab-Hyaluronidase (Tecentriq Hybreza)" clinical policy. Please consider the enclosed information on the use of Tecentriq and Tecentriq Hybreza in patients with Small Cell Lung Cancer (SCLC) and Alveolar Soft Part Sarcoma (ASPS) for your policy updating needs.</p> <p>Specific Change Requests (3) & Supporting Scientific Evidence:</p> <p>Section, Page, Text/Criteria</p> <ul style="list-style-type: none"> - FDA-Approved Indication(s): small cell lung cancer (SCLC), Page 1 - Initial Approval Criteria: Section I.B.4 (Small Cell Lung Cancer), Page 3 <p>Request #1:</p> <ul style="list-style-type: none"> - Please update the text in the above SCLC sections to reflect the recent FDA-approval of Tecentriq/Tecentriq Hybreza for 1L maintenance in patients with ES-SCLC (Centene Clinical Policy # CP.PHAR.235)

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		<p>Scientific Evidence and FDA Clearance:</p> <ul style="list-style-type: none"> - In October 2025, the FDA approved both Tecentriq and Tecentriq Hybreza in combination with lurbinectedin for the maintenance treatment of adult patients with ES-SCLC whose disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza, carboplatin and etoposide.[1,2] - Updating this criterion ensures Medicaid beneficiaries have access to the newly approved maintenance combination regimen. <p>Please refer to the product prescribing information for the full FDA-approved indications and safety information, available below:</p> <p>https://www.gene.com/download/pdf/tecentriq_prescribing.pdf</p> <p>https://www.gene.com/download/pdf/tecentriq_hybreza_prescribing.pdf</p> <p>Genentech is not the manufacturer of lurbinectedin, and data included in this submission regarding lurbinectedin are based solely on publicly available information. For further information specifically on the use of lurbinectedin, please contact the U.S. distributor, which is Jazz Pharmaceuticals, Inc. Medical Information at (800) 520-5568.</p> <p>-----</p> <p>Section, Page, Text/Criteria:</p> <ul style="list-style-type: none"> - FDA Approved Indication(s): alveolar soft part sarcoma (ASPS), Page 2 - Initial Approval Criteria: Section I.E.4.b (Alveolar Soft Part Sarcoma), Page 4 <p>Request #2:</p> <ul style="list-style-type: none"> - Please update the text in the above ASPS sections to reflect the recent Tecentriq Hybreza label update to include use in pediatric patients 12 years of age and older who meet the approved 40 kg weight threshold.[2] (Centene Clinical Policy # CP.PHAR.235)

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		<p>Scientific Evidence and FDA Clearance:</p> <ul style="list-style-type: none"> - In November 2025, the Tecentriq Hybreza indication for ASPS was expanded to include both adult and pediatric patients (12 years of age and older who weigh 40 kg or greater) with unresectable or metastatic ASPS.[2] - Updating this criterion ensures Medicaid beneficiaries have access to the newly approved maintenance combination regimen. - Tecentriq IV is currently FDA-approved for the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS.[1] <p>Please refer to the product prescribing information for the full FDA-approved indications and safety information, available below:</p> <p>https://www.gene.com/download/pdf/tecentriq_prescribing.pdf</p> <p>https://www.gene.com/download/pdf/tecentriq_hybreza_prescribing.pdf</p> <p>-----</p> <p>Section, Page, Text/Criteria:</p> <ul style="list-style-type: none"> - Clinical Criteria B. Adjuvant treatment of hepatocellular carcinoma (HCC) at high risk of recurrence. Page 3 <p>Request #3:</p> <ul style="list-style-type: none"> - Remove the recommendation for the adjuvant treatment of hepatocellular carcinoma. (Centene Clinical Policy # CP.PHAR.235) <p>Scientific Evidence:</p> <ul style="list-style-type: none"> - IMbrave050 was a Phase 3, multicenter, randomized, open-label study evaluating atezolizumab plus bevacizumab versus active surveillance as adjuvant therapy in patients with hepatocellular carcinoma (HCC) at high risk of recurrence following surgical resection or ablation.Â³ The primary endpoint was independent review facility (IRF)â€ assessed recurrence-free survival (RFS). Select secondary endpoints

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		<p>included overall survival (OS), investigator-assessed RFS, and safety.</p> <ul style="list-style-type: none"> - Results from the first interim analysis demonstrated an improvement in IRF-assessed RFS among patients treated with atezolizumab plus bevacizumab.³ However, updated findings from the second interim analysis indicated that the RFS benefit observed at the initial analysis was not maintained with longer follow-up.⁴ Overall survival data remain immature and continue to show no demonstrated benefit. The safety profile was consistent with that reported at the first interim analysis. - Based on the totality of available data, the benefit/risk profile does not support the use of atezolizumab plus bevacizumab as adjuvant therapy for HCC.⁴ A Direct Healthcare Professional Communication (DHPC) was issued to inform physicians and advise against off-label use of atezolizumab plus bevacizumab in this setting. <p>FDA Clearance:</p> <p>Tecentriq and Tecentriq Hybreza are FDA approved in combination with bevacizumab for first-line treatment of unresectable or metastatic HCC; they are not approved for adjuvant use with bevacizumab following resection or ablation.</p> <p>Please refer to the product prescribing information for the full FDA-approved indications and safety information, available below:</p> <p>https://www.gene.com/download/pdf/tecentriq_prescribing.pdf</p> <p>https://www.gene.com/download/pdf/tecentriq_hybreza_prescribing.pdf</p> <p>Any references supplied to you are protected under U.S. Copyright Law (Title 17, U.S. Code). No further reproduction or distribution is permitted.</p> <p>Thank you for your consideration of these requests. If you have any questions, please contact me at the email provided above.</p> <p>References</p> <p>1. TECENTRIQ (atezolizumab) Prescribing Information. South San Francisco, CA: Genentech, Inc.; October 2025</p>

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		<p>2. TECENTRIQ HYBREZA (atezolizumab and hyaluronidase-tqjs) Prescribing Information. South San Francisco, CA: Genentech, Inc.; November 2025.</p> <p>3. Qin S, Chen M, Cheng AL, et al. Atezolizumab plus bevacizumab versus active surveillance in patients with resected or ablated high-risk hepatocellular carcinoma (IMbrave050): a randomised, open-label, multicentre, phase 3 trial. Lancet 2023;402:1835-1847. https://pubmed.ncbi.nlm.nih.gov/37871608/</p> <p>4. Direct Healthcare Professional Communication (DHPC): Genentech INC. (August 2024). Tecentriq +Avastin not recommended for use in adjuvant HCC setting. Available at: https://www.gene.com/download/pdf/Tecentriq_DHCP_Important_Drug_Warning_08-2024.pdf</p>

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3/10/2026 12:45	2026-LHCC-MED-912 Obinutuzumab (Gazyva)	<p>Dear Louisiana Healthcare Connections Clinical Policy Review Team:</p> <p>This evidence submission pertains to the Louisiana Department of Health (LDH) pharmacy and medical drug policy open comment process for new or updated data relevant to the recently posted “Obinutuzumab (Gazyva)” clinical policy. Please consider the enclosed information on the use of Gazyva in patients with Lupus Nephritis for your policy updating needs.</p> <p>Specific Change Request(s) & Supporting Scientific Evidence:</p> <p>Section, Page, Text/Criteria:</p> <ul style="list-style-type: none"> - FDA Approved Indication - Policy/Criteria <p>Request:</p> <ul style="list-style-type: none"> - Please update the obinutuzumab policy to reflect the FDA-approval in active lupus nephritis (CP.PHAR.305) <p>Scientific Evidence and FDA Clearance:</p> <ul style="list-style-type: none"> - On October 17, 2025, the Food and Drug Administration (FDA) approved Gazyva® (obinutuzumab) for the treatment of adult patients with active lupus nephritis who are receiving standard therapy.[1] - Please refer to the product prescribing information for the full FDA-approved indications and safety information, available below: <p>https://www.gene.com/download/pdf/gazyva_prescribing.pdf</p> <p>Pivotal Study for Obinutuzumab in Active Lupus Nephritis:</p>

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		<p>Study Design</p> <ul style="list-style-type: none"> - The safety and efficacy of obinutuzumab plus standard therapy was evaluated in the Phase 3, randomized, double-blind, placebo-controlled, multicenter REGENCY study in patients with International Society of Nephrology (ISN)/Renal Pathology Society (RPS) 2003 Class III or IV LN with or without concomitant Class V LN, based on a renal biopsy within 6 months.[2] - Patients were randomized 1:1 to receive obinutuzumab or placebo intravenously, in combination with mycophenolate mofetil (MMF) and a tapering course of corticosteroids.[2] <p>Study Results</p> <ul style="list-style-type: none"> - Treatment with obinutuzumab in combination with standard therapy met its primary endpoint by demonstrating a statistically significant improvement in complete renal response (CRR) at Week 76 compared with placebo plus standard therapy (46.4% vs 33.1%; p=0.0232).[2] - For key secondary endpoints, a significantly higher proportion of patients in the obinutuzumab arm achieved CRR with successful prednisone taper to a dose of ≤ 7.5 mg per day at Week 76 (42.7% vs 30.9%; p=0.0421), as well as a significant reduction in proteinuria, a surrogate for enhanced long-term kidney survival, at Week 76 (55.5% vs 41.9%; p=0.0227).[2] - Patients who received obinutuzumab were less likely to experience renal-related events (treatment failure, worsening proteinuria [i.e., a confirmed $\geq 50\%$ increase in the urine protein creatinine ratio ≥ 3 from the previous visit], or worsening estimated glomerular filtration rate [eGFR] [i.e., a confirmed $\geq 30\%$ decrease in the eGFR to < 60 mL/min/1.73 m² of body-surface area]) or death compared with placebo (17.8% obinutuzumab arm vs 33.8% placebo arm; HR=0.5; 95% CI, 0.3-0.8). Fewer patients also experienced worsening of kidney function or doubling of serum creatine (3% obinutuzumab arm vs 5.9% placebo arm).[1] - The most common adverse reactions of any grade (occurring in $\leq 5\%$ of patients) in patients receiving obinutuzumab were upper respiratory tract infection, COVID-19, urinary tract infections, bronchitis, pneumonia, infusion-related reactions, and neutropenia.[2] <p>Guideline Considerations:</p>

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		<p>- Major medical society guidelines are aligned in recommending early, intensive combination therapy as the standard of care for active Class III or IV LN, with or without concomitant Class V LN.[3-5] This uniformity across the American College of Rheumatology (ACR), Kidney Disease - Improving Global Outcomes (KDIGO), and European Alliance of Associations for Rheumatology (EULAR) guidelines reflects a clear clinical consensus: early combination therapy is critical to preventing irreversible kidney damage and improving long-term renal outcomes.</p> <p>- The 2024 ACR guidelines conditionally recommend first-line triple therapy“glucocorticoids plus two additional immunosuppressive agents”for new-onset or flare of active Class III/IV LN. This recommendation explicitly supports initiating combination therapy at diagnosis rather than escalating stepwise, due to the high risk of rapid progression.[3]</p> <p>- Similarly, the KDIGO 2024 clinical practice guideline advises dual or triple therapy as initial treatment for active Class III or IV LN. KDIGO emphasizes the importance of early, effective disease control to prevent chronic kidney damage and reduce the likelihood of progression to kidney failure.[4]</p> <p>The 2025 EULAR update further reinforces this direction, now specifically recommending early combination treatment with a glucocorticoid, an immunosuppressant, and either a calcineurin inhibitor or a biologic agent such as obinutuzumab for proliferative LN.[5] This reflects growing recognition that early use of targeted biologic therapy may improve the depth and durability of renal response.</p> <p>- Collectively, these guidelines demonstrate a strong, evidence-based shift toward aggressive first-line combination therapy to maximize renal protection.</p> <p>Any references supplied to you are protected under U.S. Copyright Law (Title 17, U.S. Code). No further reproduction or distribution is permitted.</p> <p>Thank you for your consideration of these requests. If you have any questions, please contact me at the email provided above.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Gazyva® [Package Insert]. Genentech, Inc.; South San Francisco, CA. 2025 2. Furie RA, Rovin BH, Garg JP, et al. Efficacy and Safety of Obinutuzumab in Active

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		<p>Lupus Nephritis. N Engl J Med. 2025;392(15):1471-1483. doi:10.1056/NEJMoa2410965.</p> <p>3. Sammaritano LR, Askanase A, Bermas BL, et al. 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and Management of Lupus Nephritis. Arthritis Care & Research. 2025; Accessed Online October 13, 2025. DOI 10.1002/acr.25528.</p> <p>4. Kidney Disease Improving Global Outcomes. KDIGO 2024 Clinical Practice Guideline for the Management of Lupus Nephritis. Kidney International (2024) 105 (Suppl 1S), S1â€“S69. Accessed online October 13, 2025.</p> <p>5. Fanouriakis A, Kostopoulou M, Anders HJ, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. Ann Rheum Dis. Published online October 16, 2025. doi:10.1016/j.ard.2025.09.007</p>
11/10/2025 16:29	2025-PHARM-158 Zepbound	<p>I am requesting that the coverage criteria for Zepbound (tirzepatide) in moderate-to-severe Obstructive Sleep Apnea (OSA) be revised to better reflect real-world clinical practice and study findings. Evidence from the SURMOUNT-OSA trial (NCT05412004) shows significant improvement in AHI among patients treated with Zepbound, including those not using CPAP therapy (mean AHI reduction of -25.25 events/hour in non-CPAP users). I also encourage acceptance of Home Sleep Apnea Tests (HSATs) as appropriate diagnostic and reassessment tools, and recognition of previously established OSA diagnoses (AHI >15) beyond 12 months. Adopting these updates would help ensure timely access to effective therapy and reduce unnecessary obstacles to care.</p>
11/10/2025 16:28	2025-PHARM-158 Zepbound	<p>I am requesting that the coverage policy for Zepbound (tirzepatide) in moderate-to-severe Obstructive Sleep Apnea (OSA) be updated to align with current clinical evidence. The SURMOUNT-OSA trial (NCT05412004) demonstrated substantial AHI improvement in patients both using and not using CPAP therapy (mean AHI reduction of -25.25 events/hour in non-CPAP users). I also recommend acceptance of Home Sleep Apnea Tests (HSATs) as valid for diagnosis and follow-up, and recognition of established OSA diagnoses (AHI >15) beyond 12 months to avoid redundant</p>

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		testing. These changes would improve patient access to effective treatment while reducing unnecessary barriers to care.
11/10/2025 16:27	2025-PHARM-158 Zepbound	I am requesting an update to the coverage criteria for Zepbound (tirzepatide) in the treatment of moderate-to-severe Obstructive Sleep Apnea (OSA) to better reflect the evidence supporting its use. Clinical data from the SURMOUNT-OSA trial (NCT05412004) demonstrated meaningful improvement in AHI both in patients using CPAP and in those who were unable or unwilling to use it (mean AHI reduction of -25.25 events/hour in non-CPAP users). I also ask that Home Sleep Apnea Tests (HSATs) be accepted as equivalent to Polysomnography (PSG) for diagnosis and reassessment, and that documentation of previous OSA diagnoses (AHI >15) beyond 12 months be permitted. These revisions would expand access to a proven therapy and reduce unnecessary delays in care.
11/10/2025 16:25	2025-PHARM-158 Zepbound	I am requesting broader coverage criteria for Zepbound (tirzepatide) for patients with moderate-to-severe Obstructive Sleep Apnea (OSA) to better reflect clinical evidence and FDA labeling. Zepbound has shown significant efficacy both with and without CPAP therapy (mean AHI reduction of -25.25 events/hour in non-CPAP users per the SURMOUNT-OSA trial, NCT05412004). Please consider accepting Home Sleep Apnea Tests (HSATs) as valid for diagnosis and reassessment, and allow use of previously established OSA diagnoses (AHI >15) beyond 12 months to avoid unnecessary repeat testing. These updates would reduce barriers and ensure timely access to effective therapy for eligible patients.
11/8/2025 9:26	2025-PHARM-158 Zepbound	<p>I have many patients that would benefit from coverage of this drug for moderate-to-severe Obstructive Sleep Apnea. I prefer to use this treatment concurrently with CPAP therapy, but I also prescribe this medication without CPAP therapy. That said, the current coverage criteria is more restrictive than the product label. Kindly consider using less restrictive verbiage to allow Zepbound Coverage for patients not using CPAP therapy. As referenced in the current coverage criteria, Zepbound was studied in patients on CPAP therapy as well as patients who were "unable or unwilling to use Positive Airway Pressure (PAP) therapy" where patients not on CPAP therapy had a mean change in AHI of -25.25 events/hour.</p> <p style="text-align: center;">- ClinicalTrials.gov. Obstructive Sleep Apnea Master Protocol GPIF: A Study of Tirzepatide (LY3298176) in Participants With Obstructive Sleep Apnea (SURMOUNT-OSA). https://clinicaltrials.gov/study/NCT05412004</p> <p>Please accept Home Sleep Apnea Tests (HSATs) as well as Polysomnography (PSG). HSAT is my preferred method of diagnosis for most patients suspected of having OSA. Many patients prefer HSAT over PSG, and patients may be subject extended wait times due to limited appointment availability at local sleep labs, which leads to delayed diagnosis and treatment.</p>

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		<p>Please consider accepting documentation of established diagnosis of moderate-to-severe OSA (AHI > 15) beyond that of the previous 12 months. At the very least, please accept HSAT for reassessment/re-testing of OSA in patients with previously established diagnosis. Many patients with established diagnosis beyond the previous 12 months can benefit from this drug coverage; especially, those who have a history of non-adherence or non-compliance with CPAP Therapy. Requiring another Sleep Study (HSAT or PSG) can be a barrier between the patients and a treatment that can help them.</p>
11/5/2025 11:21	2025-PHARM-158 Zepbound	The approval criteria CPAP therapy should be removed
11/1/2025 10:41	2025-PHARM-158 Zepbound	<p>After reading the proposed Zepbound policy I had a few questions</p> <p>1. In order to qualify it states "has an apnea hypopnea index of greater than or equal to 15 on polysomnography"</p> <p>Does that include home sleep testing?</p> <p>It would be very cost prohibitive and disruptive to sleep labs to try to accommodate getting in-lab studies for all these patients</p> <p>2. States study must have been done "within the previous 12 months"</p> <p>It seems this will also cause increased cost and inconvenience</p> <p>If they are the same weight as a previous study the severity of OSA should be comparable</p> <p>Maybe use 2 or 3 years if weight unchanged or increased?</p> <p>Feel this medication will be extremely efficacious in treating this high risk population</p>

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10/31/2025 11:10	2025-PHARM-158 Zepbound	<p>I have many patients that would benefit from coverage of this drug for moderate-to-severe Obstructive Sleep Apnea. I prefer to use this treatment concurrently with CPAP therapy, but I also prescribe this medication without CPAP therapy when appropriate.</p> <p>Please accept Home Sleep Apnea Tests (HSATs) as well as Polysomnography (PSG). HSAT is my preferred method of diagnosis for most patients suspected of having OSA. Many patients prefer HSAT over PSG, and patients may be subject extended wait times due to limited appointment availability at local sleep labs, which leads to delayed diagnosis and treatment.</p> <p>Please consider accepting documentation of established diagnosis of moderate-to-severe OSA (AHI > 15) beyond that of the previous 12 months. At the very least, please accept HSAT for reassessment/re-testing of OSA in patients with previously established diagnosis. Many patients with established diagnosis beyond the previous 12 months can benefit from this drug coverage; especially, those who have a history of non-adherence or non-compliance with CPAP Therapy. Requiring another Sleep Study (HSAT or PSG) can be a barrier between the patients and a treatment that can help them.</p>
10/29/2025 8:21	2025-PHARM-158 Zepbound	<p>I very much look forward to being able to treat my patients with obstructive sleep apnea according to the newest available data and person experience in prescribing the drug (zepbound). Increasing access to treatment of this disease will make for a significantly healthier Louisiana.</p> <p>There are a large number of patients who benefit from the 12.5mg dose as a maintenance therapy who see significantly better results than with 10mg but do not tolerate 15mg. To not include it as an option is going to lead to suboptimal care of a fair number of patients. Similarly, it does not appear that you have the other doses (7.5, 5, 2.5) listed as maintenance doses. I have seen patients lose >15% of their body weight at the lowest dose without symptoms. When this happens, increasing the dose while they are achieving significant weight loss has no real clinical benefit but introduces the risk of side effects. Please consider making all doses available as maintenance doses.</p> <p>Otherwise, I am excited that LDH is considering adopting a great medication for an FDA improved indication, and many of our patients/citizens will benefit from the addition.</p>

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10/20/2025 17:21	2025-PHARM-158 Zepbound	<p>I am very pleased that Zepbound is being considered for treatment of OSA. It is a very effective treatment. I am also pleased that PAP therapy usage is not an absolute requirement. I agree it should be attempted initially.</p> <p>My opinion is the policy should be approved as is.</p> <p>Great job whoever wrote it!</p> <p>I'd be happy to help in any way I can.</p> <p>David Ware, MD</p> <p>Family Medicine</p> <p>Sleep Medicine</p> <p>281 Moosa Blvd.</p> <p>Eunice, LA</p> <p>337-457-2200</p>
10/20/2025 14:02	2025-PHARM-154 POS Zepbound	<p>Servicing in a rural community where Obstructive Sleep Apnea and Morbid obesity is pandemic, this drug will definitely help my patients. I also serve two Nursing Homes and have seen morbid obese patients without proper medicine that will cover for OSA and morbid obesity. Some of my patients have severe osteoarthritis and the orthopedics will not do surgery since they weight is more than BMI of 40. And most of them cannot lose weight.</p> <p>I feel that most patient are just lying in bed without a future to help with their disease process.</p> <p>Getting this medicine approve would change the lives of our patients.</p> <p>Thank you</p>
10/20/2025 11:49	2025-PHARM-154 POS Zepbound	<p>I feel this drug should be covered and be more cost effective for medicaid in the long run. Treating obesity in a person now is more effective than treating the comorbidities that put the patient at risk for in later years such as OSA and diabetes and subsequent dialysis.</p>

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10/14/2025 12:53	2025-PHARM-159 Zepbound Patient Agreement	I am in favor of the proposed patient agreement for use of Zepbound and other weight loss GLP-1. It ensures proper education is being done.
10/14/2025 12:52	2025-PHARM-158 Zepbound	As an internal medicine physician, I am trained in taking care of Diabetes and nutritional aspects for patients. I often have to account for comorbidities when making medical decisions. I do not think that it would be wise to require physicians who specialize in medications (but with less training in CPAP) to manage a CPAP in addition to weight loss medications. Additionally, sleep medicine / OSA physicians are not going to prescribe GLP-1 medications. This example is similar to asking a primary care physician to write chemotherapy for cancer while they write for nausea medication. It's like asking me to do a heart catheterization because I write for hypertension medications. Just because there's an association doesn't mean the physician should manage both aspects.
10/14/2025 12:47	2025-PHARM-154 POS Zepbound	I have many patients that need access to this medication. Weight loss would improve their health and return some patients to the active work force.
10/8/2025 13:26	2025-PHARM-158 Zepbound	Request and support wholeheartedly for the addition of coverage for use of Zepbound in our obese moderate to severe OSA population. This is an extremely viable option especially in our patients who are unable to use PAP therapy consistently as an alternative way to treat them and help to prevent further worsening of cardiopulmonary complications.
10/6/2025 13:47	2025-PHARM-154 POS Zepbound	I would support the addition of Zepbound for treatment of moderate to severe OSA in use in obese patients. I would support with the least restrictions as possible. I have had very good results with this drug in use of Medicare and commercial patients

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10/6/2025 13:16	2025-PHARM-158 Zepbound	<p>As a licensed Nurse Practitioner providing care for patients with obesity and obstructive sleep apnea, I am writing to strongly advocate for Medicaid coverage and approval of Zepbound (tirzepatide) for the treatment of OSA in appropriate adult patients.</p> <p>OSA is a chronic, progressive disorder characterized by upper airway collapse during sleep, resulting in intermittent hypoxia, elevated sympathetic activity, and significant cardiovascular and metabolic burden. Despite standard therapies such as CPAP and lifestyle modification, many patients continue to experience residual symptoms and elevated morbidity risk due to underlying obesity and metabolic dysfunction.</p> <p>OSA contributes to high healthcare utilization through recurrent cardiovascular admissions, poor glycemic control, and reduced medication adherence secondary to fatigue and depression. Studies have shown that OSA increases all-cause mortality by up to 46%, and patients with both obesity and OSA face a twofold higher risk of cardiovascular events.</p> <p>By addressing the root pathophysiology—obesity and insulin resistance—Zepbound offers a mechanism-based approach that complements existing OSA therapies rather than replacing them. Significant weight loss and reduction in AHI directly translate to:</p> <p>Lower cardiovascular morbidity and mortality, Reduced CPAP pressures and improved adherence, Improved functional capacity and employment productivity, Reduced emergency and hospital utilization, leading to cost savings for Medicaid programs</p> <p>For Medicaid beneficiaries, many of whom face barriers to weight loss interventions and CPAP adherence, coverage of Zepbound is both clinically necessary and economically justified.</p> <p>I respectfully request that Medicaid approve Zepbound (tirzepatide) for OSA treatment under medical necessity criteria to improve outcomes, reduce disease burden, and enhance quality of life for patients in our care.</p>

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		<p>Thank you for your time and consideration.</p> <p>Kayla Gearen MSN, APRN, FNP-C</p>
9/29/2025 13:22	2025-PHARM-154 POS Zepbound	yes we want Zepbound to be available with patient that has OSA
2/4/2025 13:02	2025-PHARM-22 POS Dermatology - Atopic Dermatitis, Immunomodulators	I would request to have quantity limits applied for other drugs in this market basket for Dupixent for its various indication - Atopics Dermatitis, Asthma, Nasal Polyps, EOE, Prurigo Nodularis

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12/20/2024 18:15	2024-PHARM-110 Spinal Muscular Atrophy	<p data-bbox="493 243 1479 380">Thank you for the opportunity to provide public comment on the Nusinersen (Spinraza) Approval Criteria for Initiation of Therapy. We respectfully request that this therapy be made available for patients who have previously been treated with Zolgensma.</p> <p data-bbox="493 493 1503 737">Studies have demonstrated that Zolgensma transduces only a subpopulation of motor neurons. Preclinical animal models and limited post-mortem human evaluations suggest that the AAV9 vector transduces approximately 40% of motor neurons (1-3). Nusinersen has the potential to increase survival motor neuron (SMN) protein in untransduced motor neurons via SMN2 modulation. Thus, treatment with Nusinersen after Zolgensma has potential to spare additional motor neurons and provide clinical benefit to the patient.</p> <p data-bbox="493 850 1487 1056">There is currently a Phase 4 Study of Nusinersen (BIIB058) (RESPOND) Among Patients With Spinal Muscular Atrophy Who Received Zolgensma (4). The primary objective of this study is to evaluate clinical outcomes following treatment with Nusinersen in participants with spinal muscular atrophy (SMA) who previously received Zolgensma. Enrollment for RESPOND began in 2021 and currently includes 46 participants. Interim data from this study has shown:</p> <ul data-bbox="493 1169 1515 1940" style="list-style-type: none"> - Baseline characteristics of children enrolled in RESPOND as of 18 October 2023 showed suboptimal clinical status in multiple domains as determined by the investigator, including motor, respiratory, and swallowing/ feeding functions, after receiving treatment with Zolgensma. At Day 302: Mean total HINE-1 and CHOP INTEND scores increased across age groups. HINE-1 scores improved by an average of 8.7 points in children 9 months or younger at first dose of Nusinersen (n=21). HINE-1 scores improved by an average of 6.9 in children older than 9 months at first dose of Nusinersen (n=13). CHOP INTEND scores improved by an average of 9.3 points in children 9 months or younger at first dose of Nusinersen (n=21). CHOP INTEND scores improved by an average of 5.4 in children older than 9 months at first dose of Nusinersen (n=11). - Of 27 participants unable to sit at baseline, 14 (52%) achieved sitting by day 302. - Elevated neurofilament levels at baseline suggest active neurodegeneration at study entry, and reductions to Day 302 suggest a slowing of this axonal injury. At Day 302 NfL decreased by 102.7 pg/mL in children 9 months or younger at first dose of Nusinersen (n=12). At Day 302 NfL decreased by 110.3 pg/mL in children older than 9

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		<p>months at first dose of Nusinersen (n=12).</p> <p>- No emerging safety concerns have been identified at the time of the data cut in enrolled participants who received Nusinersen after Zolgensma.</p> <p>Thank you for your consideration in allowing access to Spinraza for patients with Spinal Muscular Atrophy.</p> <ol style="list-style-type: none">1. Foust KD, et al. Nat Biotechnol. 2009;27(1):59-65. 5.2. Thomsen G, et al. Nat Med. 2021;27(10):1701-1711.3. Meyer K, et al. Mol Ther. 2015;23(3):477-487.4. https://clinicaltrials.gov/ct2/show/NCT04488133. Accessed December 18, 2024.

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12/19/2024 9:38	2024-PHARM-107 Skyclarlys	<p>To the Louisiana Medicaid Drug Utilization Review Board:</p> <p>Thank you for your continued revision of the prior authorization criteria for Skyclarlys. On behalf of the Louisiana Friedreich's ataxia (FA) community, we at the Friedreich's Ataxia Research Alliance ask the Drug Utilization Review Board to consider the following points regarding the latest version of the proposed PA criteria for Skyclarlys.</p> <p>FA is a progressive, neurodegenerative disease that affects about 5,000 individuals in the US. The disease occurs at higher rates in people with Acadian ancestry, leading to a substantial population of individuals with FA in Louisiana. All individuals with FA suffer neurological symptoms that are progressive and lead to loss of ambulation and independence with all activities of daily living over two to three decades. The neurological symptoms together with cardiac dysfunction lead to early mortality, with an average life expectancy of 35 years.</p> <p>The Food and Drug Administration (FDA) approved Skyclarlys in 2023 for all individuals with genetically confirmed FA over the age of 16, regardless of stage of progression or presence of specific disease states such as cardiomyopathy or pes cavus. Clinical trials and a propensity matched analysis comparing individuals taking Skyclarlys with natural history controls showed that Skyclarlys slows the progression of neurological symptoms of FA. Skyclarlys is the only approved treatment for FA and a huge step forward for the patient community. Slowing of neurological progression may mean extending the time period where a patient can ambulate independently or communicate clearly with their loved ones.</p> <p>To ensure all individuals with FA insured through Louisiana Medicaid have access to this treatment, we ask the board to consider the following revisions to the PA criteria:</p> <p>-Replace baseline measurement of symptoms and disease state by the modified Friedreich's Ataxia Rating Scale (mFARS) with measurement of symptoms and disease state by a clinical neurology exam. The mFARS was developed as a specialized research tool and is not regularly used in clinical practice. We suggest clinical notes from a neurologist as a more appropriate measure of an individual's functional status and FA symptoms. Additionally, requiring patients to fall within a given range on the mFARS score restricts the usage of Skyclarlys to a subset of FA patients, when it was approved for broader use.</p>

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		<p>-Remove restrictions based on ejection fraction and presence of cardiac disease. FDA did not include restrictions based on heart function in its label for Skyclarys. A LVEF >40% was required for clinical trial participation because individuals with low EF are at higher risk for medical complications which could impact safety and efficacy data. This was not intended to be carried over to clinical care. Individuals affected by cardiomyopathy would still greatly benefit from the slowing of progression of neurological symptoms provided by Skyclarys.</p> <p>-Remove restriction based on presence of pes cavus. While pes cavus was considered a possible confounding variable during clinical trials, it was ultimately found that this variable did little to affect results, as patients with pes cavus still showed slowed progression of neurological symptoms when compared to control subjects.</p> <p>-Remove restriction based on upper limb function, as individuals with advanced disease may no longer retain significant upper limb function. However, Skyclarys may still benefit these patients by slowing progression of bulbar symptoms that affect speech and swallowing, functions that greatly impact a patient’s quality of life.</p> <p>-Extend duration of approval for initiation of therapy to one year. In Skyclarys clinical trials, the treatment group did not diverge from the placebo group until 12 months. Six months may not allow enough time for the patient or provider to notice a clinical benefit.</p> <p>We strongly encourage revision of your PA criteria to reflect the FDA label, ensuring that all eligible individuals with FA have access to the first and only approved treatment for this relentlessly progressive disease. Thank you for providing this opportunity to comment on this topic.</p> <p>Sincerely,</p>

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		<p>Kellyn Madden, MS CGC</p> <p>Patient Engagement Manager</p> <p>Friedreich’s Ataxia Research Alliance</p>
<p>9/25/2024 16:00</p>	<p>2024-PHARM-80 Rezdifra</p>	<p>The requirement for a liver biopsy for all patients with Medicaid can potentially cause a barrier to treatment for MASH with liver fibrosis. According to the American Association for the Study of Liver Disease, liver biopsies for grading and staging of MASH are not consistently performed in clinical practice and should be reserved for specific clinical scenarios. Therefore, most patients are not biopsied and instead are evaluated using non-invasive staging modalities such as fibroscan, MRI elastography or various non-invasive test calculations. If a liver biopsy was required for all Medicaid patients, it has the potential to create a barrier to patient care, increase risk given potential biopsy complications, and can prevent patients from accessing a medication that may potentially improve MASH and liver fibrosis.</p>
<p>9/23/2024 12:25</p>	<p>2024-LHCC-MED-604 Ferric Derisomaltose (Monoferric)</p>	<p>LDH Pharmacy Team test</p>

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9/16/2024 13:28	2024-PHARM-60 Wegovy	<p>September 15, 2024</p> <p>Kimberly Sullivan Medicaid Executive Director Louisiana Department of Health P.O. Box 629 Baton Rouge, LA 70821-0629</p> <p>RE: The Louisiana Uniform Prescription Drug Prior Authorization Form to request clinical authorization for WEGOVY (2024-PHARM-60)</p> <p>The Obesity Action Coalition (OAC) appreciates the opportunity to comment on the Louisiana Department of Health’s Managed Care Pharmacy and Medical Drug Policies regarding the prior authorization criteria for Medicaid coverage of semaglutide (WEGOVY) specifically in patients with cardiovascular (CV) disease who are affected by obesity. The OAC is a national non-profit organization dedicated to giving a voice to individuals affected by the disease of obesity.</p> <p>We are pleased that the Louisiana Medicaid program has developed prior authorization (PA) criteria to allow coverage of semaglutide (WEGOVY) for secondary prevention of major CV events. This is a significant step forward in updating state policies into alignment with advances in science and clinical standards. It provides opportunities to reduce the risk of heart attack and stroke in those living with obesity who also have a history of heart disease. However, we respectfully ask you to reconsider two provisions in the proposed criteria that exacerbate health inequities, perpetuate bias and could delay critical treatment. These include the age limit of 45 years old for coverage and the requirement that patients lose 5% of weight within 6-months of initiating treatment to continue on semaglutide.</p> <p>*Remove the age limit of 45 years old for coverage. There are some patients who are experiencing cardiovascular disease younger than 45 years old that could also benefit if the minimum age was reduced to include all adults. Additionally, this criteria does not align with the FDA indication for use and would penalize those Louisianans unfortunate enough to have developed cardiovascular disease before the age of 45, but also could create confusion among healthcare providers and patients about coverage criteria.</p> <p>*Remove the requirement that patients must lose 5% of weight within six-months of initiating treatment to continue use of semaglutide. The SELECT trial was designed as a cardiovascular outcomes trial and was not formally designed as a weight loss trial. This is important because there was no goal for weight loss in the trial nor required as an inclusion criteria for patients entering the study. Therefore, the</p>

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		<p>medicine should not be withdrawn for lack of "sufficient" weight loss as it is not necessary to lose weight to have reduction in MACE (major adverse cardiovascular events). This was demonstrated in an analysis of SELECT presented at the European Congress on Obesity in 2024. That analysis showed that for those who lost 5% or more at 20 weeks, the MACE reduction was the same as those who lost less than 5% at 20 weeks. Therefore, it is both unjustifiable and dangerous to a patient's health to stop WEGOVY for lack of 5% weight loss if they are taking it to prevent a secondary cardiovascular event.</p> <p>The OAC proudly serves 2,870 members living in Louisiana and is backed by more than 85,000 members across the United States. Louisiana currently has the second highest obesity rate in the country with more than 40% of the population living with the disease and another 31% with overweight. Altogether, that's more than 71% of people living in Louisiana who experience overweight or obesity. Approximately 42% of American adults are affected by obesity, a chronic disease that increases the risk for premature death and a variety of health problems, including heart attack and stroke.</p> <p>Obesity is a complex chronic disease that extends beyond individual lifestyle choices to encompass a broader landscape of social determinants and systemic factors, contributing significantly to health inequities. Disparities in obesity rates are often closely intertwined with socioeconomic status, geographic location, and access to resources. Individuals in marginalized communities may face barriers to affordable and nutritious food options, safe spaces for physical activity, and unequal access to qualified providers of quality healthcare. These structural inequities exacerbate the prevalence of obesity among vulnerable populations, leading to a cycle of poor health outcomes. Tackling obesity requires a comprehensive approach.</p> <p>Our country must acknowledge obesity for the chronic disease that it is and take steps to treat it in the same serious fashion as other chronic disease states such as diabetes and hypertension. We respectfully request that the Louisiana State Medicaid program consider adding coverage of all obesity medications which would reduce other Medicaid costs associated with the disease and ensure that state policies do not discriminate against individuals with obesity as compared to other highly prevalent health conditions.</p> <p>Thank you for your consideration of our comments regarding the proposed prior authorization criteria. OAC urges the State Medicaid program to remove the age limitation and the 5% weight-loss requirement for continuing coverage of WEGOVY. We would be happy to meet and share further information and perspectives of people living with obesity. Should you have questions, please contact our Policy Advisor, Chris Gallagher at chris@potomaccurrents.com.</p> <p>Sincerely,</p> <p>Joe Nadglowski, President, Obesity Action Coalition</p>

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9/15/2024 4 20:33	2024-PHARM-60 Wegovy	<p>September 15, 2024</p> <p>Kimberly Sullivan Medicaid Executive Director Louisiana Department of Health PO Box 629 Baton Rouge, LA 70821</p> <p>RE: The Louisiana Uniform Prescription Drug Prior Authorization Form to request authorization for WEGOVY (2024-PHARM-60)</p> <p>The Louisiana Obesity Society (LOS) is a non-profit organization that serves the patients and providers in Louisiana as it relates to obesity care and the treatment of the disease of obesity. We submit this letter as a comment on the Louisiana Department of Health’s Managed Care Pharmacy and Medical Drug Policies regarding the prior authorization criteria for Medicaid coverage of semaglutide (WEGOVY) for the indication of cardiovascular disease in patient with obesity.</p> <p>Louisiana Medicaid coverage for semaglutide (WEGOVY) for the indication of secondary prevention of cardiovascular disease in patients with obesity is a monumental step forward. However, some of the criteria suggested are not evidence-based and will further create bias and limit access to care. We ask that you reconsider the following criteria:</p> <p>AGE RESTRICTION >45 YEARS OLD. Remove the age restriction. The FDA indication is for 18 years and above. Because Louisiana ranks so poorly in health statistics including obesity and cardiovascular disease, we have patients with disease at younger ages (18-45 years old) who can’t afford to wait for treatment based on arbitrary criteria. One could argue these patients are the sickest and need care the soonest. Anyone who meets the FDA indication regardless of age should receive treatment.</p>

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		<p>WEIGHT LOSS REQUIREMENT TO CONTINUE THERAPY. Eliminate the weight loss requirement to continue therapy. The SELECT trial was not a weight loss trial and no lifestyle modification was offered or required. This was intentional in its design to show that the benefit of secondary cardiovascular prevention was not the result of weight loss. The evidence shows that the cardiovascular benefit is INDEPENDENT of weight loss. Nonetheless, patients lost a very small amount of weight over several months regardless. Asking patients to lose more weight in a very short period of time relative to the evidence is not only unreasonable, but it is setting these patients up for failure. It is an arbitrary criterion that will limit access without any evidentiary justification. It furthers the bias that exists against those struggling with the disease of obesity.</p> <p>BARIATRIC SURGERY EVALUATION/REFERRAL. Change this language to say that patients with obesity should be made aware of treatments for obesity including lifestyle modification, anti-obesity medications, bariatric endoscopy, and bariatric surgery and that referrals will be made as appropriate and available. Many patients in remote areas may not have access to bariatric surgery evaluations so requiring patients on Louisiana Medicaid to wait months or years to have a bariatric surgery evaluation to qualify for semaglutide (WEGOVY) for the FDA approved indication of cardiovascular disease will further limit access and delay appropriate care. Not only would this harm those with obesity waiting for semaglutide (WEGOVY) for the treatment of cardiovascular disease but it would also harm those patients with obesity who don't have cardiovascular disease that are waiting for bariatric surgery by delaying their care as well. Additionally, semaglutide is just one of a number of GLP1 receptor agonist drugs in a class of medications called incretin mimetics. Essentially, incretin mimetics mimic gut hormones that are pleiotropic meaning that they work on many organ systems in the body. Therefore, it is disingenuous to assign weight loss criteria to the use of semaglutide (WEGOVY) for the FDA indication of cardiovascular disease.</p> <p>We acknowledge that there are limited resources available to provide care to recipients of Louisiana Medicaid. However, creating arbitrary barriers to care that are not evidence-based does not benefit patients and in this case is likely to create further harm. Please also consider the unintentional harm of perpetuating the bias and stigma associated with obesity as a disease.</p> <p>We appreciate your hard work and dedication to provide the best access possible to our Louisiana Medicaid population. We are working right alongside you in the trenches. We understand the challenges we all face in Louisiana. So, we want to make sure that each step forward is thoughtful and meaningful without causing unintended harm. Please let me know if we can provide any further information or support for your efforts. And thank you for accepting this feedback.</p>

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		<p>Sincerely,</p> <p>Catherine T. Hudson, MD, MPH, D-ABOM</p> <p>President of the Louisiana Obesity Society</p>

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9/13/2024 12:07	2024-PHARM-60 Wegovy	<p>September 15, 2024</p> <p>Kimberly Sullivan</p> <p>Medicaid Executive Director</p> <p>Louisiana Department of Health</p> <p>P.O. Box 629</p> <p>Baton Rouge, LA 70821-0629</p> <p>RE: The Louisiana Uniform Prescription Drug Prior Authorization Form to request clinical authorization for WEGOVY (2024-PHARM-60)</p> <p>I am writing you today on behalf of the Louisiana chapter of the American Society for Metabolic and Bariatric Surgery (LA-ASMBS) regarding the Louisiana Department of Health’s Managed Care Pharmacy and Medical Drug Policies regarding the prior authorization criteria for Medicaid coverage of semaglutide (WEGOVY) – specifically in patients with cardiovascular (CV) disease who are affected by obesity. The LA-ASMBS is a non-profit organization that represents the bariatric surgeons in the state of Louisiana. We work closely with the Louisiana Obesity Society to advocate for the rights of citizens with overweight and obesity in our state.</p> <p>Louisiana Medicaid’s decision to cover semaglutide (WEGOVY) for secondary prevention of cardiovascular disease in patients with obesity is a significant advancement. However, some proposed criteria restrict access to necessary care, and we urge a reconsideration of the following restrictions:</p> <p>AGE RESTRICTION >45 YEARS OLD: Remove the age limitation. The FDA approval is for individuals aged 18 and older. Louisiana’s poor health statistics, including high rates of obesity and cardiovascular disease, mean that younger patients (18-45 years old) may urgently need treatment. Delaying treatment based on arbitrary age restrictions is unjust, as these patients could be among the most in need. We know that patients are more successful with treatment the earlier we intervene, and waiting for patients to have more progressed disease is inappropriate. Treatment should be available to anyone meeting the FDA criteria, regardless of age.</p> <p>WEIGHT LOSS REQUIREMENT TO CONTINUE THERAPY: Eliminate the weight loss requirement for continuing therapy. While there is a lot of overlap between patients with obesity and those with cardiac disease, it is important to note that the cardiovascular indication for semaglutide is unrelated to the obesity indication. The SELECT trial, which supported the use of semaglutide, was not designed as a weight loss trial and did not include lifestyle modifications. Its purpose was to demonstrate that cardiovascular benefits were independent of weight loss. While some weight loss was observed, it was minimal and not the focus of the study. Requiring</p>

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		<p>significant weight loss in a short period, contrary to the evidence, is unreasonable, unethical and sets patients up for failure. This criterion lacks justification and perpetuates bias against those with obesity.</p> <p>BARIATRIC SURGERY EVALUATION/REFERRAL: Revise this requirement to ensure patients with obesity are informed about all treatment options, including lifestyle changes, anti-obesity medications, bariatric endoscopy, and surgery. Referrals should be made as appropriate and feasible. Many patients in remote areas may not have immediate access to bariatric surgery evaluations and requiring such evaluations to qualify for semaglutide (WEGOVY) could delay access to necessary care. This not only affects those needing semaglutide for cardiovascular disease but also delays care for patients awaiting bariatric surgery.</p> <p>We appreciate your hard work to expand coverage for the citizens of Louisiana, but we implore you to do this in a way that is safe and ethical. Please consider that no other cardiac medications have a weight component to the prior authorization requirement. We hope these concerns will be addressed to ensure equitable and timely access to care for all eligible patients.</p> <p>Sincerely,</p> <p>Shauna Levy MD, MS, FACS, FASMBS, DABOM</p> <p>President of LA-ASMBS</p> <p>Slevy10@tulane.edu</p> <p>832-816-4001</p>
9/10/2024 21:42	2024-PHARM-4 Growth Factors	xlpharmacy review viagra: toronto pharmacy viagra - xl pharmacy generic viagra
9/5/2024 14:57	2024-PHARM-80 Rezdiffra	This is an exciting new product that is the first medication approved for Metabolic associated steatotic liver disease (MASLD). The standard of care for the evaluation of these patients is a non-invasive fibrosis assessment. A liver biopsy is no longer necessary for the vast majority of these patients and therefore, I believe that access to this drug should not require a liver biopsy assessment.

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9/5/2024 8:34	2024-PHARM-80 Rezdiffra	<p>As a clinical pharmacist, I am deeply concerned about the current Prior Authorization requirements for Rezdiffra, particularly the stipulation mandating a liver biopsy for approval. This requirement is not aligned with the latest guidelines from the American Association for the Study of Liver Diseases (AASLD), which strongly recommend the use of non-invasive testing (NIT) for the assessment and management of liver conditions, including Metabolic Associated Steatohepatitis (MASH).</p> <p>The AASLD's guidance, as outlined in a recent publication (https://pubmed.ncbi.nlm.nih.gov/36727674/), emphasizes that non-invasive methods, such as elastography and serum biomarkers, provide a safer, more cost-effective, and equally reliable alternative to liver biopsy. Liver biopsies, while valuable in certain contexts, carry significant risks, including bleeding, infection, and patient discomfort, and are not without considerable financial burden.</p> <p>Given that Rezdiffra is the only FDA-approved medication for the treatment of MASH, it is imperative that access to this treatment is not unduly restricted by outdated or overly burdensome diagnostic requirements. The necessity of a liver biopsy as a prerequisite for therapy not only contravenes current best practices but also imposes unnecessary barriers to patient care.</p> <p>I strongly urge the Louisiana Medicaid program to revise the Prior Authorization criteria for Rezdiffra, allowing for the use of non-invasive diagnostic tests in accordance with contemporary clinical guidelines. This change would better serve patients, align with evidence-based practices, and reduce the risks and costs associated with invasive procedures.</p>
9/4/2024 17:59	2024-PHARM-80 Rezdiffra	<p>We have significant population of fatty liver disease in need to treatment to prevent progression to cirrhosis and Transplant. Diagnosis and management MASLD mainly uses non invasive tests of fibrosis and liver biopsy is getting obsolete due it risk. Also Theses non invasive tests show good correlation with degree of fibrosis in multiple studies. Resmetron is new drug approved and clinical study has shown the benefit with using Noninvasive markers. As a hepatologist, getting liver biopsy for every patient to decide the candidacy is increasing the risk of bleeding and other complications related to liver biopsy. In my opinion liver biopsy should not be required before prescribing effective medications for fatty liver</p>
9/4/2024 17:14	2024-PHARM-80 Rezdiffra	<p>Liver biopsy should not be required to stage a patient's liver disease prior to initiation of treatment, as there are now non-invasive procedures that can be used to adequately stage liver disease.</p>

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9/4/2024 16:06	2024-PHARM-80 Rezdiffra	<p>As a clinical pharmacist specializing in hepatology, I am very concerned about the current Prior Authorization requirements for Rezdiffra, specifically the mandate for a liver biopsy to secure approval. This requirement does not align with the latest recommendations from the American Association for the Study of Liver Diseases (AASLD), which advocate for non-invasive testing (NIT) for assessing and managing liver conditions like Metabolic Associated Steatohepatitis (MASH).</p> <p>According to recent AASLD guidelines (https://pubmed.ncbi.nlm.nih.gov/36727674/), non-invasive methods such as elastography and serum biomarkers are considered safer, more cost-effective, and just as reliable as liver biopsies. While liver biopsies have their place, they come with significant risks, including bleeding, infection, and patient discomfort, as well as considerable financial costs.</p> <p>Given that Rezdiffra is the sole FDA-approved medication for MASH, it is crucial that access to this treatment is not hindered by outdated or excessive diagnostic requirements. Requiring a liver biopsy for therapy approval not only contradicts current best practices but also creates unnecessary obstacles to patient care.</p> <p>I strongly recommend that the Louisiana Medicaid program update the Prior Authorization criteria for Rezdiffra to permit the use of non-invasive diagnostic tests, in line with contemporary clinical guidelines. This adjustment would better serve patients, align with evidence-based practices, and minimize the risks and costs associated with invasive procedures.</p>
9/4/2024 12:22	2024-PHARM-80 Rezdiffra	<p>This medication has been proven to RESOLVE hepatic steatosis and REDUCE fibrosis, both of which lead to cirrhosis. This is the ONLY medicine available and needs to be readily available to all patients. Insurance restrictions are limiting treatment which in turn, creates more serious illness. Please consider making this drug accessible. Currently, non-invasive testing qualifies patients for this drug. And basic testing, like a biopsy, is much more expensive, and unlikely the patient will follow through. Elf and Fibroscan are justification for diagnosis. we should not have to perform in basic testing for patient to receive life-saving medication.</p>

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9/4/2024 12:09	2024-PHARM-80 Rezdiffra	<p>I am writing to express my concerns about the current Louisiana Medicaid policy requiring liver biopsies for the treatment of Non-Alcoholic Steatohepatitis (NASH). While I understand the intent behind such policies is to ensure appropriate and effective treatment, I believe that this requirement may not be in the best interest of the patients affected by this condition.</p> <p>Non-Alcoholic Steatohepatitis is a progressive liver disease that often requires careful management and treatment. Liver biopsy has traditionally been used to assess the degree of liver damage, but there are several compelling reasons why this policy may be problematic:</p> <ol style="list-style-type: none"> 1. Invasiveness and Risk: Liver biopsy is an invasive procedure that carries potential risks, including bleeding, infection, and discomfort. For patients with NASH, who may already be at risk due to their liver condition, the procedure can present unnecessary risks. 2. Alternative Diagnostic Methods: Advances in medical technology have provided less invasive and effective alternatives for assessing liver fibrosis and disease progression. Techniques such as FibroScan, magnetic resonance elastography (MRE), and non-invasive blood tests have demonstrated comparable accuracy in evaluating liver health without the associated risks of biopsy. These methods can provide essential information while minimizing patient discomfort and risk. 3. Patient Experience and Compliance: The requirement for a liver biopsy can be a significant barrier for patients seeking timely treatment. The procedure can cause anxiety and reluctance, potentially leading to delays in diagnosis and management. By adopting less invasive diagnostic methods, patients may be more likely to engage in and adhere to their treatment plans. 4. Cost-Effectiveness: Non-invasive tests are often more cost-effective compared to liver biopsies, considering the direct and indirect costs associated with the biopsy procedure. Reducing reliance on invasive methods could lead to overall cost savings for the Medicaid program while maintaining high standards of patient care. <p>In light of these considerations, I respectfully urge Medicaid to reevaluate the current policy requiring liver biopsies for the treatment of NASH. Embracing non-invasive</p>

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		<p>diagnostic methods would align with best practices in patient-centered care and promote better health outcomes.</p> <p>Thank you for your attention to this matter. I am hopeful that Medicaid will consider these points and make necessary adjustments to ensure that patients receive the most appropriate and compassionate care possible.</p>
<p>9/3/2024 19:53</p>	<p>2024-PHARM-80 Rezdiffra</p>	<p>The policy regarding qualifications for treatment with Rezdiffra should not be based on a need for a liver biopsy.</p> <p>Liver biopsy is not now routinely used to diagnose MASH or staging of the disease. Although it was a requirement for all clinical trials to assess the efficacy of treatment, non invasive tests are more and more used on a daily basis in the clinical setting.</p> <p>implementation of such policy will impose a significant cost and risk of an invasive procedure for the patient not to mention that most of the pathologist are not adept to read liver biopsies and can not assess the extent of disease in MASH. The assessment of the efficacy of treatment will also be dependent on a repeat liver biopsy based on the current policy, adding more to the risk and cost burden.</p> <p>This policy is written based on the inclusion and exclusion criteria of the clinical trials (I have been part of those trials as an investigator) however, in clinical practice we do not need and should not follow them for multiple reason as mentioned before.</p> <p>Thanks for your attention to this matter and hope to modify this policy</p> <p>I will be more than happy to assist with this matter.</p>

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		<p>Brian Borg</p>
<p>9/3/2024 17:28</p>	<p>2024-PHARM-80 Rezdiffra</p>	<p>Routinely performing a liver biopsy to assess level of fibrosis is no longer considered the standard of care. We benefit from the age of significant advances in healthcare, and two of those advances are the use of a fibroscan to assess the CAP and kPa score for steatosis and fibrosis, in conjunction with "ELF" score. Requiring an invasive liver biopsy on millions of Americans, where a reasonable non-invasive alternative is available, in order to provide a therapy that can be lifesaving is a policy that needs to be reevaluated.</p> <p>George Catinis, MD</p>
<p>8/29/2024 22:28</p>	<p>2024-PHARM-80 Rezdiffra</p>	<p>Liver biopsy must not be made mandatory to select people with MASH who will benefit from treatment. It is not the standard of care since noninvasive tests became available.</p>
<p>8/29/2024 22:04</p>	<p>2024-PHARM-80 Rezdiffra</p>	<p>Liver biopsy is not needed to determine stage of hepatic fibrosis. It can be determined with fair accuracy using easily available noninvasive tests, and avoid procedure-related risks, patient discomfort and time lost on recovery from a procedure, and high cost.</p>
<p>8/22/2024 14:02</p>	<p>2024-PHARM-80 Rezdiffra</p>	<p>As a hepatology clinical pharmacist, I am deeply concerned about the current Prior Authorization requirements for Rezdiffra, particularly the stipulation mandating a liver biopsy for approval. This requirement is not aligned with the latest guidelines from the American Association for the Study of Liver Diseases (AASLD), which strongly recommend the use of non-invasive testing (NIT) for the assessment and management of liver conditions, including Metabolic Associated Steatohepatitis (MASH).</p> <p>The AASLD's guidance, as outlined in a recent publication (https://pubmed.ncbi.nlm.nih.gov/36727674/), emphasizes that non-invasive methods, such as elastography and serum biomarkers, provide a safer, more cost-effective, and equally reliable alternative to liver biopsy. Liver biopsies, while valuable in certain contexts, carry significant risks, including bleeding, infection, and patient discomfort, and are not without considerable financial burden.</p> <p>Given that Rezdiffra is the only FDA-approved medication for the treatment of MASH,</p>

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		<p>it is imperative that access to this treatment is not unduly restricted by outdated or overly burdensome diagnostic requirements. The necessity of a liver biopsy as a prerequisite for therapy not only contravenes current best practices but also imposes unnecessary barriers to patient care.</p> <p>I strongly urge the Louisiana Medicaid program to revise the Prior Authorization criteria for Rezdiffra, allowing for the use of non-invasive diagnostic tests in accordance with contemporary clinical guidelines. This change would better serve patients, align with evidence-based practices, and reduce the risks and costs associated with invasive procedures.</p>
8/20/2024 14:56	2024-PHARM-80 Rezdiffra	<p>This policy for resmetirom approval appears to mirror the inclusion criteria in the clinical trial, which creates an increased cost and risk to patients because of the liver biopsy. The liver biopsy is very helpful in following a patient's objective response, but in clinical practice, MASH is diagnosed clinically and there is good correlation between noninvasive testing such as fibroscan with liver fibrosis. The unintended consequence of this policy disproportionately selects for patients who have time to come to ever more office visits and take days off for procedures such as liver biopsy, and leaves patients with lower socioeconomic status (Medicaid insurance) with disparate healthcare.</p>

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8/2/2024 8:02	2024-PHARM-60 Wegovy	<p>I was the co-Chair of the Steering Committee that designed and executed the SELECT Trial, a cardiovascular outcome trial (CVOT) which forms the basis for the FDA approval of Wegovy for secondary prevention of cardiovascular disease. This trial has excellent evidence to support the use of Wegovy in individuals with established cardiovascular disease and I attach those references at the end of this statement. It is important that the nature of Wegovy be recognized for this statute to be relevant. Wegovy is the trade name for semaglutide, a GLP-1 receptor analog that has 94% homology with native GLP-1 and has modifications to make it long acting. This is a powerful medication. It has multiple effects. It improves glycemia and the molecule is approved for diabetes treatment as Ozempic. It does indeed affect appetite and produces weight loss, with an indication for weight management. But the molecule also has effects beyond glycemia and weight loss - it has effects on the kidneys to improve diuresis and naturiesis, on blood vessels to reduce blood pressure, on the stomach to delay gastric emptying, on improving platelet coagulation and it has powerful effects on inflammation. It is a mistake to withdraw this medication when it is being given for secondary prevention of cardiovascular events - heart attack, stroke or sudden cardiac death. The medicine should not be withdrawn for lack of "sufficient" weight loss. The effects of semaglutide on heart disease prevention and weight loss are independent. It is not necessary to lose weight to have reduction in MACE (major adverse cardiovascular events. This was demonstrated in an analysis of SELECT presented at the European Congress on Obesity in 2024. That analysis showed that for those who lost 5% or more at 20 weeks, the MACE reduction was the same as those who lost less than 5% at 20 weeks. Therefore it is not justifiable and is dangerous to a patient's health to stop Wegovy for lack of 5% weight loss if they are taking it to prevent a secondary cardiovascular event. Please revise this statute.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Ryan DH, Lingvay I, Colhoun HM, Deanfield J, Emerson SS, Kahn SE, Kushner RF, Marso S, Plutzky J, Brown-Frandsen K, Gronning MOL, Hovingh GK, Holst AG, Ravn H, Lincoff AM. Semaglutide Effects on Cardiovascular Outcomes in People With Overweight or Obesity (SELECT) rationale and design. Am Heart J. 2020 Nov;229:61-69. doi: 10.1016/j.ahj.2020.07.008. Epub 2020 Jul 17. PMID: 32916609. 2. Lincoff AM, Brown-Frandsen K, Colhoun HM, Deanfield J, Emerson SS, Esbjerg S, Hardt-Lindberg S, Hovingh GK, Kahn SE, Kushner RF, Lingvay I, Oral TK, Michelsen MM, Plutzky J, TornÃ_e CW, Ryan DH; SELECT Trial Investigators. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med. 2023 Dec 14;389(24):2221-2232. 3. Lingvay I, Brown-Frandsen K, Colhoun HM, Deanfield J, Emerson SS, Esbjerg S, Hardt-Lindberg S, Hovingh GK, Kahn SE, Kushner RF, Lincoff AM, Marso SP, Fries TM, Plutzky J, Ryan DH; SELECT Study Group. Semaglutide for cardiovascular event reduction in people with overweight or obesity: SELECT study baseline characteristics. Obesity (Silver Spring). 2023 Jan;31(1):111-122. doi: 10.1002/oby.23621. Epub 2022 Dec 10. PMID: 36502289. 4. Ryan DH, Lingvay I, Deanfield J, Kahn SE, Barros E, Burguera B, Colhoun HM,

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		<p>Cercato C, Dicker D, Horn DB, Hovingh GK, Jeppesen OK, Kokkinos A, Lincoff AM, MeyhÄ¶fer SM, Oral TK, Plutzky J, van Beek AP, Wilding JPH, Kushner RF. Long-term weight loss effects of semaglutide in obesity without diabetes in the SELECT trial. Nat Med. 2024 May 13. doi: 10.1038/s41591-024-02996-7. Epub ahead of print. PMID: 38740993.</p> <p>Donna H. Ryan, MD</p> <p>Professor Emerita</p> <p>Pennington Biomedical Research Center</p>

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8/2/2024 6:28	2024-PHARM-58 Wegovy	<p>I was the co-Chair of the Steering Committee that designed and executed the SELECT Trial, a cardiovascular outcome trial (CVOT) which forms the basis for the FDA approval of Wegovy for secondary prevention of cardiovascular disease. This trial has excellent evidence to support the use of Wegovy in individuals with established cardiovascular disease and I attach those references at the end of this statement. It is important that the nature of Wegovy be recognized for this statute to be relevant. Wegovy is the trade name for semaglutide, a GLP-1 receptor analog that has 94% homology with native GLP-1 and has modifications to make it long acting. This is a powerful medication. It has multiple effects. It improves glycemia and the molecule is approved for diabetes treatment as Ozempic. It does indeed affect appetite and produces weight loss, with an indication for weight management. But the molecule also has effects beyond glycemia and weight loss - it has effects on the kidneys to improve diuresis and naturiesis, on blood vessels to reduce blood pressure, on the stomach to delay gastric emptying, on improving platelet coagulation and it has powerful effects on inflammation. It is a mistake to withdraw this medication when it is being given for secondary prevention of cardiovascular events - heart attack, stroke or sudden cardiac death. The medicine should not be withdrawn for lack of "sufficient" weight loss. The effects of semaglutide on heart disease prevention and weight loss are independent. It is not necessary to lose weight to have reduction in MACE (major adverse cardiovascular events. This was demonstrated in an analysis of SELECT presented at the European Congress on Obesity in 2024. That analysis showed that for those who lost 5% or more at 20 weeks, the MACE reduction was the same as those who lost less than 5% at 20 weeks. Therefore it is not justifiable and is dangerous to a patient's health to stop Wegovy for lack of 5% weight loss if they are taking it to prevent a secondary cardiovascular event. Please revise this statute.</p> <p>References: 1. Ryan DH, Lingvay I, Colhoun HM, Deanfield J, Emerson SS, Kahn SE, Kushner RF, Marso S, Plutzky J, Brown-Frandsen K, Gronning MOL, Hovingh GK, Holst AG, Ravn H, Lincoff AM. Semaglutide Effects on Cardiovascular Outcomes in People With Overweight or Obesity (SELECT) rationale and design. Am Heart J. 2020 Nov;229:61-69. doi: 10.1016/j.ahj.2020.07.008. Epub 2020 Jul 17. PMID: 32916609. 2. Lincoff AM, Brown-Frandsen K, Colhoun HM, Deanfield J, Emerson SS, Esbjerg S, Hardt-Lindberg S, Hovingh GK, Kahn SE, Kushner RF, Lingvay I, Oral TK, Michelsen MM, Plutzky J, Torn�e CW, Ryan DH; SELECT Trial Investigators. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med. 2023 Dec 14;389(24):2221-2232. 3. Lingvay I, Brown-Frandsen K, Colhoun HM, Deanfield J, Emerson SS, Esbjerg S, Hardt-Lindberg S, Hovingh GK, Kahn SE, Kushner RF, Lincoff AM, Marso SP, Fries TM, Plutzky J, Ryan DH; SELECT Study Group. Semaglutide for cardiovascular event reduction in people with overweight or obesity: SELECT study baseline characteristics. Obesity (Silver Spring). 2023 Jan;31(1):111-122. doi: 10.1002/oby.23621. Epub 2022 Dec 10. PMID: 36502289. 4. Ryan DH, Lingvay I, Deanfield J, Kahn SE, Barros E, Burguera B, Colhoun HM, Cercato C, Dicker D, Horn DB, Hovingh GK, Jeppesen OK, Kokkinos A, Lincoff AM, Meyh�fer SM, Oral TK, Plutzky J, van Beek AP, Wilding JPH, Kushner RF. Long-term weight loss effects of semaglutide in obesity without diabetes in the SELECT trial. Nat Med. 2024 May 13. doi: 10.1038/s41591-024-02996-7. Epub ahead of print. PMID: 38740993.</p>

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7/31/2024 6:41	2024-PHARM-60 Wegovy	<p>In regard to the approval criteria for initiation of therapy:</p> <p>"The recipient has a documented BMI \geq 35 kg/m², and documentation of evaluation for bariatric surgery is provided with the request ; AND"</p> <p>I would favor language that states that: the patient was informed that they are a candidate for, and given information about bariatric surgical procedures. In addition, documentation that the patient was offered a referral for evaluation for bariatric surgery.</p> <p>I feel that if evaluation by bariatric surgery is mandatory for this very large group of patients, this may lead to a delay in care.</p> <p>Thank you for your consideration, and a special thank you for addressing this great need.</p>
6/24/2024 11:05	2024-PHARM-58 Wegovy	<p>Since the studies do not indicate an end point, is there a duration of use or BMI endpoint, since it is anticipated that BMI will drop on the medication?</p>
6/6/2024 16:22	2024-LHCC-MED-456 Allogenic Processed Thymus Tissue-agdc (Rethymic)	<p>Hi- Where can I get a copy of this policy 2024-LHCC-MED-456 that is open for public comment?</p>
6/5/2024 10:30	2024-PHARM-20 Casgevy	<p>Thank you for the opportunity to provide public comment. We would like to ask the board to consider expanding access to Casgevy for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs) as stated by the Casgevy FDA package insert. The current draft policy restricts access to only patients aged 12 -35 years of age. We would like to ask the board to consider including patients that are aged over 35 who are fit for treatment per providers judgement and/or request a case by case access for patients outside of the 12-35 restrictions.</p>
3/15/2024 15:22	2024-PHARM-16 Zurzuvae	<p>Please do not limit use of Zurzuvae to "severe" depression. Postpartum depression can arise anytime during the first year after childbirth. Please allow treatment anytime during the first year postpartum. Please know that Zurzuvae is the only approved oral therapy specifically for use in postpartum depression. Please add Zurzuvae to the PDL without restrictions. Please do not designate Zurzuvae as non-preferred.</p>
3/15/2024 13:22	2024-PHARM-16 Zurzuvae	<p>Medication is working wonders! I feel better from what I was. I am more productive and the medication process is fast and easy!</p>

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3/4/2024 15:03	2024-PHARM-16 Zurzuvae	<p>It is well established in medical literature that depression severity may not fully reflect the level of functional impairment or suicide risk.^{1,2} Additionally, the FDA granted a broad postpartum depression (PPD) indication for Zurzuvae in adults and did not establish a severity requirement. Hence, the request is to consider removing the severe PPD requirement or allow moderate-severe patients access to this therapy.</p> <p>The ACOG guidelines state PPD can occur up to 1 year after having a baby. Hence the request is to consider changing the time period of the onset of postpartum depression symptoms out to 1 year postpartum.</p> <p>Per a KFF 2019 report, potentially 1/3 of people living in Louisiana were affected by a mental illness. Given that Louisiana has anywhere from 75 - 150 psychiatrists in the entire state, access could take 3 - 4 months. Hence, the request is please consider allowing other prescribers such as primary care or neurologist since access to a Psych or OBGYN may not be possible especially in rural areas and due to scheduling issues with specialists.³</p> <p>Zurzuvae is a first in class oral agent and is the only approved oral therapy for PPD, hence the request is please consider adding Zurzuvae to the PDL without restrictions.</p> <p>References</p> <ol style="list-style-type: none"> 1. Silverman JJ, Galanter M, Jackson-Triche M, et al. The American Psychiatric Association Practice Guidelines for the Psychiatric Evaluation of Adults. Am J Psychiatry. 2015;172:798-802. 2. Gelenberg AJ, Freeman MP, et al. The American Psychiatric Association Practice Guidelines for the Treatment of Patients with Major Depressive Disorder. Am J Psychiatry. 2010;167:15-31.American Psychiatric Association. Depressive disorders. In: Diagnostic and Statistical Manual of Mental Disorders. 5th ed., text rev. American Psychiatric Publishing Inc. 2022. 3. https://www.kff.org/statedata/mental-health-and-substance-use-state-fact-sheets/louisiana/#:~:text=As%20shown%20in%20the%20figure,of%20adults%20in%20the%20U.S.

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2/26/2024 15:48	2024-PHARM-16 Zurzuvae	<p>Issues that should be considered with the proposed draft policy:</p> <p>1) "The recipient has a diagnosis of severe postpartum depression determined by a standardized screening tool for depression [such as, but not limited to, Edinburgh Postnatal Depression Scale (EPDS), Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI), Hamilton Depression Rating Scale (HAM-D)]; AND"</p> <p>When looking at number 1 above, according to the PI, Zurzuvae is indicated for the treatment of postpartum depression (PPD) in adults. The FDA did not limit its use to "severe".</p> <p>2) "The time period of the onset of postpartum depression symptoms is stated on the request, and onset of symptoms occurred during the third trimester of pregnancy up to four weeks after delivery (the third trimester is from the beginning of pregnancy week 27 to the end of the pregnancy); AND"</p> <p>When looking at number 2, Louisiana extended postpartum care out to 12 months in 2022. Women may experience symptoms of PPD at different times and some experience those symptoms past this 4-week time frame. In fact, data from HCUP shows that black women and Asian and Pacific Islander women had a higher risk of being diagnosed with PPD later in the postpartum period (> 8 weeks after delivery) compared to white women. So, this 4-week limit in the draft policy may affect a large portion of your membership with PPD who seek treatment.</p> <p>3) "The recipient is < 6 months postpartum on the date of the request (state date of delivery on the request); AND"</p> <p>When looking at number 3, this seems to contradict state recommendations on postpartum care. As stated above, Louisiana extended postpartum care out to 12 months back in 2022. Could these 6 months be extended to 12 months?</p> <p>4) "The requested medication is being prescribed by a psychiatrist OR an obstetrician-gynecologist; AND"</p>

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		<p>When looking at number 4, we are finding that some women, especially in rural areas may not be followed by either a psych or OBGYN. They may be followed through their pregnancy by a GP, FP, or even a NP. Trying to even get an appointment with a Pych or OBGYN may take weeks or months, which can delay care. Any thoughts on expanding access to other prescribers?</p> <p>5) If request is for a non-preferred agent - ONE of the following is required: (See Depression “ Antidepressants, Other on the PDL/NPDL for list of preferred agents)</p> <p>Lastly, since the proposed policy does not state whether or not Zurzuvae will be classified as non-preferred, a step therapy in this case could delay possible remission for a patient. Where traditional (non-FDA approved therapies) may take 2-6 weeks for a patient to see an effect, Zurzuvae was shown to have an effect as early as 3 days in clinical trials. Hopefully with it being the only FDA approved therapy for PPD and its three-day efficacy data will allow it to be listed as a preferred product.</p> <p>We have requested dates since last September to review the above information with LA Medicaid. But due to Medicaid staff time, this is the only opportunity.</p>
11/28/2023 15:01	2023-PHARM-109 Vyjuvek	<p>Due to the fragile nature of these patients’ skin, there may be providers who would prefer to only do genetic testing to confirm the diagnosis of DEB, rather than do a skin biopsy. We would like to make the following suggestion “ strike out “BOTH of the following”, and 1) remove first bullet on skin biopsy, and require only genetic testing for confirmation of DEB, or 2) adding in “AND/OR” after the first sub-bullet:</p> <p>The recipient has a diagnosis of dystrophic epidermolysis bullosa confirmed by :</p> <p>ï,§ Skin biopsy of an induced blister with immunofluorescence mapping (IFM) and/or transmission electron microscopy (TEM); AND/OR</p> <p>ï,§ Genetic test results showing mutations in the collagen type VII alpha 1 chain (COL7A1) gene; AND</p>

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		<p>Thank you for your consideration.</p>
<p>6/17/2022 2 14:36</p>	<p>2022-PHARM-40 Sickle Cell Anemia</p>	<p>Global Blood Therapeutics would like to thank you for the opportunity to provide comment on the policy for the sickle cell anemia drug class. We appreciate your willingness to work with us on access to these therapies and would like to highlight a couple of minor points that may help with access.</p> <p>1. Current reauthorization criteria for voxelotor (Oxbryta) require the most recent hemoglobin level to show a >1 g/dL increase from baseline. Since there can be variability in hemoglobin levels from day to day, we would like the committee to consider giving providers the option to also attest to improvements in hemolysis during the renewal process. We would like to suggest the following wording:</p> <ul style="list-style-type: none"> o The recipient continues to meet initial approval criteria; AND o The recipient's most current hemoglobin level is stated on the request and shows an increase of >1 g/dL from baseline; OR o The recipient demonstrates positive hemolytic clinical response through reduction in laboratory markers of hemolysis or improvement in clinical symptoms and complications of hemolysis (i.e. leg ulcers, jaundice, etc.) <p>2. We would also like the committee to consider extending the duration of the initial approval for all sickle cell anemia agents to 12 months to align with other agents in the class.</p> <p>Thank you again for your time and consideration.</p>

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5/3/2022 13:54		<p>Global Blood Therapeutics would like to thank you for the opportunity to provide written comment on the current Oxbryta criteria.</p> <p>We would like the committee to consider removing the pain crisis/vaso-occlusive crisis (VOC) requirement from the policy to align with our most recent clinical trial data.</p> <p>â€¢ Current criteria require documentation of ONE or more vaso-occlusive crises within the previous 12 months.</p> <p>â€¢ The HOPE-Kids 1 trial did not require children to have a VOC in the previous 12 months to enroll in the study.</p> <ul style="list-style-type: none"> - 21 patients (46.7%) in the HOPE-Kids 1 trial did not have a VOC in the past year. <p>â€¢ The annualized incidence of VOCs was evaluated as a secondary endpoint in the Phase 3 HOPE trial. The results of this analysis provided reassurance that voxelotor treatment could safely raise hemoglobin without causing a viscosity-related increase in the risk of VOCs.</p> <ul style="list-style-type: none"> - The HOPE study was not enriched nor powered to evaluate VOCs as an efficacy endpoint. <p>â€¢ Although VOCs are a common complication of sickle cell disease (SCD), one retrospective study of patients with SCD showed that 52.3% did not have any VOC episodes over a 12-month period.</p> <p>â€¢ The FDA labeled indication does not include a requirement for a specific number of VOCs prior to initiating treatment with Oxbryta.</p> <ul style="list-style-type: none"> - Oxbryta inhibits hemoglobin S polymerization, the root cause of sickle cell disease pathology. - Patients who suffer from anemia and hemolysis can still potentially benefit from Oxbryta regardless of the number of baseline VOCs. <p>We would also like to request an extension of the initial approval to 12 months to align with some of the other products in the category and the long-term data from the HOPE pivotal trial.</p> <p>Thank you for your time and consideration.</p>

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