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2/4/2025 13:02	2025-PHARM-22 POS Dermatology	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
12/20/2024 18:15	2024-PHARM-110 Spinal Muscular Atrophy	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. 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. 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: - 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 months at first dose of Nusinersen (n=12). - No emerging safety concerns have been identified at the time of the data cut in enrolled participants who received Nusinersen after Zolgensma. Thank you for your consideration in allowing access to Spinraza for patients with Spinal Muscular Atrophy.

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		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.
12/19/2024 9:38	2024-PHARM-107 Skyclarys	To the Louisiana Medicaid Drug Utilization Review Board: Thank you for your continued revision of the prior authorization criteria for Skyclarys. On behalf of the Louisiana Friedreich's ataxia (FA) community, we at the Friedreichâ€™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 Skyclarys. 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. The Food and Drug Administration (FDA) approved Skyclarys 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 Skyclarys with natural history controls showed that Skyclarys slows the progression of neurological symptoms of FA. Skyclarys 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. 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: -Replace baseline measurement of symptoms and disease state by the modified Friedreichâ€™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 individualâ€™s functional status and FA symptoms. Additionally, requiring patients to fall within a given range on the mFARS score restricts the usage of Skyclarys to a subset of FA patients, when it was approved for broader use. -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

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		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. -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. -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 patientâ€™s quality of life. -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. 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. Sincerely, Kellyn Madden, MS CGC Patient Engagement Manager Friedreich's Ataxia Research Alliance
9/25/2024 16:00	2024-PHARM-80 Rezdiffra	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.
9/16/2024 13:28	2024-PHARM-60 Wegovy	September 15, 2024 Kimberly Sullivan Medicaid Executive Director Louisiana Department of Health P.O. Box 629

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		Baton Rouge, LA 70821-0629 RE: The Louisiana Uniform Prescription Drug Prior Authorization Form to request clinical authorization for WEGOVY (2024-PHARM-60) The Obesity Action Coalition (OAC) appreciates the opportunity to comment on the Louisiana Department of Healthâ€™s Managed Care Pharmacy and Medical Drug Policies regarding the prior authorization criteria for Medicaid coverage of semaglutide (WEGOVY) â€“ 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. 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. *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. *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 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. 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, thatâ€™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

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		death and a variety of health problems, including heart attack and stroke. 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. 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. 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. Sincerely, Joe Nadglowski, President, Obesity Action Coalition
9/15/2024 20:33	2024-PHARM-60 Wegovy	September 15, 2024 Kimberly Sullivan Medicaid Executive Director Louisiana Department of Health PO Box 629 Baton Rouge, LA 70821 RE: The Louisiana Uniform Prescription Drug Prior Authorization Form to request authorization for WEGOVY (2024-PHARM-60) 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 Healthâ€™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.

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		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: 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 canâ€™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. 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. 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 donâ€™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. 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. 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

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		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. Sincerely, Catherine T. Hudson, MD, MPH, D-ABOM President of the Louisiana Obesity Society
9/13/2024 12:07	2024-PHARM-60 Wegovy	September 15, 2024 Kimberly Sullivan Medicaid Executive Director Louisiana Department of Health P.O. Box 629 Baton Rouge, LA 70821-0629 RE: The Louisiana Uniform Prescription Drug Prior Authorization Form to request clinical authorization for WEGOVY (2024-PHARM-60) 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 Healthâ€™s Managed Care Pharmacy and Medical Drug Policies regarding the prior authorization criteria for Medicaid coverage of semaglutide (WEGOVY) â€“ 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. 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: 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

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		meeting the FDA criteria, regardless of age. 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 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. 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. 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. Sincerely, Shauna Levy MD, MS, FACS, FASMBS, DABOM President of LA-ASMBS Slevy10@tulane.edu 832-816-4001
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.
9/5/2024 8:34	2024-PHARM-80 Rezdiffra	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,

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		including Metabolic Associated Steatohepatitis (MASH). 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. 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. 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.
9/4/2024 17:59	2024-PHARM-80 Rezdiffra	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
9/4/2024 17:14	2024-PHARM-80 Rezdiffra	Liver biopsy should not be required to stage a patientâ€™s liver disease prior to initiation of treatment, as there are now non-invasive procedures that can be used to adequately stage liver disease.
9/4/2024 16:06	2024-PHARM-80 Rezdiffra	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). 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. 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.

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		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.
9/4/2024 12:22	2024-PHARM-80 Rezdiffra	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-invading 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.
9/4/2024 12:09	2024-PHARM-80 Rezdiffra	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. 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: 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. 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 diagnostic methods would align with best practices in patient-centered care and promote better health outcomes.

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		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.
9/3/2024 19:53	2024-PHARM-80 Rezdiffra	The policy regarding qualifications for treatment with Rezdiffra should not be based on a need for a liver biopsy. Liver biopsy is not now routinely used to diagnose MASH or stating 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. 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. 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. Thanks for your attention to this matter and hope to modify this policy I will be more than happy to assist with this matter. Brian Borg
9/3/2024 17:28	2024-PHARM-80 Rezdiffra	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. George Catinis, MD
8/29/2024 22:28	2024-PHARM-80 Rezdiffra	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.
8/29/2024 22:04	2024-PHARM-80 Rezdiffra	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.
8/22/2024 14:02	2024-PHARM-80 Rezdiffra	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). 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

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		contexts, carry significant risks, including bleeding, infection, and patient discomfort, and are not without considerable financial burden. 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. 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.
8/20/2024 14:56	2024-PHARM-80 Rezdiffra	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 consquence 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.
8/2/2024 8:02	2024-PHARM-60 Wegovy	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. References:

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		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, Cercato C, Dicker D, Horn DB, Hovingh GK, Jeppesen OK, Kokkinos A, Lincoff AM, MeyhÃ¶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. Donna H. Ryan, MD Professor Emerita Pennington Biomedical Research Center
8/2/2024 6:28	2024-PHARM-58 Wegovy	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 thatn 5% at 20 weeks. Therefore it is not justifyiable and is dangerous to a patient's health to stop Wegovy for lack of 5% weight

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7/31/2024 6:41	2024-PHARM-60 Wegovy	In regard to the approval criteria for initiation of therapy: "The recipient has a documented BMI â‰¥ 35 kg/m2, and documentation of evaluation for bariatric surgery is provided with the request ; AND" 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. 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. Thank you for your consideration, and a special thank you for addressing this great need.
6/24/2024 11:05	2024-PHARM-58 Wegovy	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?
6/6/2024 16:22	2024-LHCC-MED-456 Allogenic Processed Thymus Tissue-agdc (Rethymic)	Hi- Where can I get a copy of this policy 2024-LHCC-MED-456 that is open for public comment?
6/5/2024 10:30	2024-PHARM-20 Casgevy	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 Casgey 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

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		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.
3/15/2024 15:22	2024-PHARM-16 Zurzuvae	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.
3/15/2024 13:22	2024-PHARM-16 Zurzuvae	Medication is working wonders! I feel better from what I was. I am more productive and the medication process is fast and easy!
3/4/2024 15:03	2024-PHARM-16 Zurzuvae	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. 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. 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 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. References 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.
2/26/2024 15:48	2024-PHARM-16 Zurzuvae	Issues that should be considered with the proposed draft policy: 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

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		Depression Inventory (BDI), Hamilton Depression Rating Scale (HAM-D)]; AND" 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 â€œsevereâ€. 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" 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. 3) "The recipient is < 6 months postpartum on the date of the request (state date of delivery on the request); AND" 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? 4) "The requested medication is being prescribed by a psychiatrist OR an obstetrician-gynecologist; AND" 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? 5) If request is for a non-preferred agent - ONE of the following is required: (See Depression â€“ Antidepressants, Other on the PDL/NPDL for list of preferred agents) 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. 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.

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11/28/2023 15:01	2023-PHARM-109 Vyjuvek	Due to the fragile nature of these patientsâ€™ 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 â€“ strike out â€˜BOTH of the followingâ€™, and 1) remove first bullet on skin biopsy, and require only genetic testing for confirmation of DEB, or 2) adding in â€˜AND/ORâ€™ after the first sub-bullet: The recipient has a diagnosis of dystrophic epidermolysis bullosa confirmed by : ï‚§ Skin biopsy of an induced blister with immunofluorescence mapping (IFM) and/or transmission electron microscopy (TEM); AND/OR ï‚§ Genetic test results showing mutations in the collagen type VII alpha 1 chain (COL7A1) gene; AND Thank you for your consideration.
6/17/2022 14:36	2022-PHARM-40 Sickle Cell Anemia	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. 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: o The recipient continues to meet initial approval criteria; AND o The recipientâ€™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.) 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. Thank you again for your time and consideration.
5/3/2022 13:54		Global Blood Therapeutics would like to thank you for the opportunity to provide written comment on the current Oxbryta criteria. 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. â€¢ Current criteria require documentation of ONE or more vaso-occlusive crises within the previous 12 months. â€¢ The HOPE-Kids 1 trial did not require children to have a VOC in the previous 12

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		months to enroll in the study. - 21 patients (46.7%) in the HOPE-Kids 1 trial did not have a VOC in the past year. 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. - The HOPE study was not enriched nor powered to evaluate VOCs as an efficacy endpoint. 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. â€¢ The FDA labeled indication does not include a requirement for a specific number of VOCs prior to initiating treatment with Oxbryta. - 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. 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. Thank you for your time and consideration.
2/11/2021 14:02	2021-PHARM-10 Sickle Cell Anemia	I'm a nurse practitioner at OLOL adult sickle cell clinic. I've reviewed the updated criteria for approval of Oxbryta. I noticed that the requirement for documented vaso-occlusive crises was changed from two to one, however episodes of vaso-occlusive crises should not be included in the criteria as Oxbryta is not indicated to treat pain crises. It's indication is to improve anemia in sickle cell disease by increasing hemoglobin and reduce red blood cell sickling. We have several patients that are currently on Oxbryta who would not meet this criteria because they haven't experienced a vaso-occlusive crises in over a year. Since Oxbryta is a first in class drug indicated specifically to treat anemia in sickle cell disease in individuals with a hemoglobin level of 5.5 g/dl or less to 10.5 g/dl, the approval criteria should be specific to that need. Requiring documentation of pain crises could limit availability to patients who would benefit from therapy due to a history of complications related to chronic anemia such as strokes, retinopathy, priapisms, leg ulcers, iron overload, kidney injury, and pulmonary hypertension. Please consider removing the criteria for pain crisis.
12/29/2020 17:11	2020-PHARM-240 PDL 1.1.21	I am writing today on behalf of the Tulane University Louisiana Center for Bleeding & Clotting Disorders, one of the only two federally designated hemophilia treatment centers (HTC) in the state of Louisiana, and the only HTC in the state that serves both pediatric and adult patients, in regards to the State's implementation plan for the recent Pharmaceutical & Therapeutics (P&T) Committee's recommendations regarding products

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		to treat bleeding disorders. The two federally recognized HTC's in Louisiana located at Tulane University School of Medicine and Children's Hospital are part of a national network of federally designated HTCs. Studies from the CDC have shown that mortality and hospitalization rates are 40% lower for people who receive care at an HTC than in those who do not, despite the fact that more severely affected patients are more likely to be seen in HTCs. HTCs provide integrated, multi-disciplinary, patient-centered care for bleeding disorders and their long-term complications, including inhibitors, liver disease, and HIV/AIDS. Our HTC understands that clotting factor products were re-visited at a recent P&T Committee meeting. The recommendations posted November 16, 2020 indicated that the hemophilia product Hemlibra will be preferred, while several other effective treatments widely used (Advate, Alphanine, Hemofil M, Idelvion, Alprolix, Kogenate, Kovaltry, Adynovate, Eloctate, Koate, Recombinate) will be non-preferred. We understand this will be effective January 1, 2021. While we recognize that hemophilia therapies are costly, excluding specific drugs and requiring a fail-first methodology for covering treatments will jeopardize the health of bleeding disorder patients. We are very concerned that the changes proposed will impact the health and care for patients, their adherence to taking their medications as directed, lead to fragmented care, and over time will drive-up the cost of care for patients in the state. This therapeutic class has previously been excluded from strategies typically employed to control costs, such as establishing a Preferred Drug List (PDL) and step therapy edits. We recognize that the complexities involved in treating hemophilia and related bleeding disorders can result in high medical expenses for patients and their health insurance plans. While we appreciate the need to identify cost containment strategies, it is critical that such strategies not compromise continuity of care for those with complex medical conditions. The establishment of a PDL directly contradicts the National Hemophilia Foundation's (NHF) Medical and Scientific Advisory Council (MASAC) recommended treatment of bleeding disorders.(1) Hemophilia and related bleeding disorders are rare, complex genetic conditions for which there are no known cures. Individuals often experience spontaneous and prolonged internal bleeding into the joints and soft tissues. To effectively manage these disorders, patients often depend on ongoing therapy with prescription medications (clotting factor and/or novel, non-factor treatments) to treat or avoid debilitating and life-threatening internal bleeding episodes that can lead to advanced medical issues. While today's therapies are safer and more effective than ever, they are also undeniably costly. Clotting factor and non-factor replacement therapies are biological products derived from human blood plasma or else produced by using recombinant technology; there are no generic equivalents. Differences among these therapies (e.g., recombinant or plasma-derived; variations in half-life; etc.) mean that these therapies are neither pharmacologically nor therapeutically equivalent. Collectively these characteristics make an individual's response and tolerability for a specific product unique. Because hemophilia treatments are not all created equal with the utilization of pharmacokinetics HTCs have been able to more directly match the most appropriate therapy to the individual patient. By placing a subset of therapies on the non-preferred drug list, some patients will be forced to change their treatment, which may not be as effective in controlling their bleeds. The proposed PDL excludes extended half-life (EHL) products for Hemophilia A and B, and while making Hemlibra a preferred drug. The PDL also does not recognize that

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		patients on Hemlibra will still require another therapy for bleeding episodes. Over the years, EHL products have become a valuable solution for patients to encourage and promote adherence to a prophylactic regimen to prevent bleeds from occurring. The reduction in infusion intervals and IV needle sticks appeal to patients who have struggled in the past, who have missed school and work in order to treat their disease. These products provide a very successful treatment option for many of our patients. The goal of hemophilia management is prevention of bleeds and preservation of joints. EHL products are a valuable tool in the toolbox to reach this goal and should not be on the non-preferred drug list. Instituting a trial and failure requirement for approval of extended-half life products or the product deemed most appropriate by the treating provider for the individual patient's needs, could result in bleeding, potentially damaging joints, requiring additional doses of factor, missing work or school, and possibly seeking care in an emergency department or inpatient setting. All of these scenarios of the potential to drive up costs of care and drive down the quality of life for these patients. For these reasons, MASAC, the National Hemophilia Foundation (NHF), the Hemophilia Federation of America (HFA), the Louisiana Hemophilia Foundation (LHF), the Hemophilia Alliance, and the federally recognized national network of hemophilia treatment centers all recommend that individuals retain access to the full range of FDA-approved bleeding disorder products. Limiting access through the use of restrictive drug formularies such as those requiring prior authorization, PDLs, and fail first/step therapy, negatively impacts patient care and ultimately results in higher drug spends. Therefore, dug benefit designs employing these methods should be avoided. At a minimum, timelines and processes for obtaining prior authorizations should be clear, standardized, and streamlined, since delays in treatment are tantamount to denial of treatment. Finally, patients who are clinically stable on an existing drug therapy should be allowed to continue on that product without having to go through the prior authorization process. On behalf of individuals in the State of Louisiana affected by bleeding disorders, we urge you to reconsider this decision and reject, or, at a minimum, delay for 180 days implementation of the P&T committee's recommendation. We further request that you permanently grandfather patients who are stable on their existing drug regimens. Thank you for your time and consideration. (1) MASAC Document #166 (2005) MASAC Resolution Regarding Preferred Drug Lists. Available at www.hemophilia.org
12/21/2020 7:30	2020-PHARM-240 PDL 1.1.21	I am writing today on behalf of the Louisiana Hemophilia Foundation (LHF), the National Hemophilia Foundation (NHF), and the Hemophilia Federation of America (HFA) to inquire about the Stateâ€™s implementation plan for the recent Pharmaceutical & Therapeutics (P&T) Committeeâ€™s recommendations regarding products to treat bleeding disorders. We understand that clotting factor products were re-visited at a recent P&T Committee meeting. The recommendations posted November 16, 2020, indicated that the hemophilia product Hemlibra will be preferred while other products (Advate, Mononine, Profilnine, and Recombinate) will be non-preferred. We understand this will be effective on January 1, 2021. This therapeutic class has previously been excluded from strategies typically employed to

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