Department of Human Services – Office of Medical Assistance Programs
Prior Authorization Feedback on Public Input from May 25, 2023

Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
Clinical Prior Authorization of Non-PDL Drugs	We would like to acknowledge that The PA Department of Human Services has provided thoughtful and comprehensive guidelines for appropriate use of a multitude of products, including HEMGENIX. We would like to provide clarification for #7 requiring a "history of therapeutic failure or a contraindication or an intolerance to first-line therapy(ies) if applicable according to consensus treatment guidelines" Per the HEMGENIX FDA package label, HEMGENIX is indicated for use in adults with Hemophilia B who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. This indication does not necessitate a therapeutic failure, contraindication, or intolerance to first-line therapy, in this case, FIX concentrate. Additionally, due to the novel nature of HEMGENIX there are currently limited consensus treatment guidelines to reference. It is expected that patients being considered for HEMGENIX will have received IV FIX throughout their lifetime, and have a serious bleeding phenotype, such that gene therapy may offer discontinuation of FIX prophylaxis.	Vidhi Desai, MD, Senior Medical Director, Coagulation, & Debbie Bensen-Kennedy, MD, Vice President, Medical Affairs North America, CSL Behring	**X**			If there are no applicable first-line therapy(ies) the requirement does not apply.
	We are an advocacy organization that serves individuals and families affected by Duchenne Muscular Dystrophy. Duchenne Muscular Dystrophy (DMD) is a rare, progressive, muscle-wasting disease in which those diagnosed are unable to produce dystrophin, a protein essential for the repair and stability of muscle fibers. Without dystrophin, muscle	Amy Aikins, Director, Government and Social Programs, Little Hercules Foundation	**X**			

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	cells are damaged and replaced with connective tissue. It primarily affects boys. Muscle loss typically occurs first in the thighs and pelvis followed by the arms. Although there is some variability in disease progression, most individuals with DMD lose the ability to walk around 10-13. There continues to be the need for treatment at all stages of progression, including after loss of ambulation. There are currently five approved treatments for Duchenne. All are orphan drugs, and of the approved treatments, four of them were approved via the Accelerated Approval (AA) pathway. In addition, we have a potential for a gene therapy approval a short time from now. I am writing on behalf of our organization in support of the proposed prior authorization policy and applaud the Department for what we view as common sense policy. Specifically, we appreciate that the FDA label regarding treatment group, population age, dose and duration is recognized in the proposed policy. We also agree that these medications be prescribed by or in consultation with the appropriate specialists of the condition(s) in which the medication is approved to treat. We would also ask that the Department continue to seek the expert opinions of the providers who treat these patients in DUR and P&T processes. Further, we would like to ask that the Department engage with patients and/or patient advocacy groups of a specific condition when reviewing both new and existing treatments for said conditions.					

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
Hepatitis C Agents	My name is Sneha Thatipelli and I am an infectious disease provider in Philadelphia. I frequently diagnose and treat hepatitis C (HCV) patients in my practice. Often times, there is a significant delay in diagnosis to treatment due to the need for a prior authorization for HCV medications. As such, several patients have been lost of follow-up and have not returned to have their HCV treated. Requiring prior authorizations has also led to a significant back and forth with our support staff to ensure that we have all the appropriate information and paperwork needed for the process. This has added a significant administrative burden to our already busy clinic. Many patients also have barriers to coming in for clinic visits, so being able to identify and treat HCV in an expedited manner is crucial. For example, I had a patient who lives in an assisted living facility who has not been able to start treatment because he does not have a HCV genotype in the system which is required for the prior authorization. However, we know from previous studies that both Mavyret and Epclusa are pangenotypic agents and are highly active. Thus a genotype is not necessary for most patients. I strongly agree with the revised guidelines to remove prior authorizations for HCV agents on the preferred formulary list. This will only improve the care we are able to deliver patients and allow us to further the goal of hepatitis C elimination.	Sneha Thatipelli, MD	**X**			
	As a nurse practitioner at Central Outreach Wellness Center-Infectious Disease community based clinics, I am the director of our HCV, HIV, STI mobile testing and treatment program since 2017. It has been my great pleasure to have tested over 32,000 folks in the	Kathleen Scholz, RN, MSN, APRN, CRNP, FNP-BC, Central Outreach Wellness Centers	**X**			Prior authorization will be required only for non-preferred agents.

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	addiction recovery & incarceration communities of Pennsylvania to date. We have found an overall HCV positivity rate of 43% in this community. Most importantly, we have been able to cure almost 9,000 folks in Pennsylvania! We are passionate and dedicated to eradicating Pennsylvania of HCV & the way I read the new proposed changes to the MAAC Prior Auth requirements is going to be a game-changer in getting more folks cured of HCV! The way I read the new proposed changes, the MAAC Prior Authorization requirement will be eliminated as long as a preferred Hepatitis C Agent is prescribed in the appropriate quantity limits. Is this correct? 95% of these folks are young (average age 33 years old), treatment naive, non-cirrhotic, have minimal comorbidities outside of substance use and psychiatric disorders. With all the existing barriers to HCV treatment, for one example, treatment initiation following HCV diagnosis has been historically very low, with a number of studies indicating that less than a third of patients initiated HCV treatment. For a second example, patient attitudes towards the "stigmatizing" medical community and low trust & confidence in the effectiveness of treatment, not to mention folks who have Interferon PTSD & their fear of awful side effects. Beyond low treatment initiation rates, time to treatment initiation has been extremely too long. A recent study of over 8,000 HCV infected patients in					

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	the US, found that less than 10% initiated treatment with DAAs within the two year study period and the median time to treatment initiation was 300 days!!!!!!!!! Is a median time to treatment of 300 days really helping our Pennsylvania community stay safe from these folks who are out spreading HCV? THE ANSWER IS NO! The process of HCV treatment initiation involves a highly coordinated effort between our dedicated testing staff, our telehealth nurse practitioners, our prior authorization team, our nurse coordinators, our pharmacy staff and the insurance companies. Once all the requisite materials are ready, the nurse coordinator prepares an extensive pre-authorization packet which consists of all relevant paperwork including findings from the clinical evaluation, laboratory results, and administrative requirements necessary for insurance authorization. The pre-authorization packet is sent to a dedicated in-house pharmacist who serves as the pharmacy 'case manager' in order to usher the approval process through the system. The steps include verifying coverage, outreach to patient assistance programs to mitigate cost of treatment including those whose health insurance may not cover the entirety of the cost, (co-pay costs) as well as follow-up calls to ensure that the insurance has been able to connect with the patients (which is an insurance regulation which always delays the process), medications have been ordered. We estimate that each case requires several phone calls and can take several hours to manage these efforts. Once insurance coverage has been authorized which takes up to a full week in some cases, the nurse coordinates with the patient to ensure medication					

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	pick-up/delivery with additional calls to verify treatment start date. This in turn will allow the nurse coordinator to schedule a follow-up visit after four weeks of treatment for laboratory testing. Not surprisingly, this requires significant effort with multiple phone calls, multiple stakeholders, and much time in order to ensure successful treatment initiation and compliance. Given the workload, the nurse coordinator estimates a maximum possible patient load of fifteen patients at any given point in time. Our HCV mobile testing team all agree that the insurance authorization for treatment was the most resource-intensive step in HCV treatment delivery and served as the greatest barrier to initiating therapy in a timely manner, noting that the process takes at least four to eight weeks and even longer in cases where appeals need to be submitted. Overall, we find that the process of insurance authorization for HCV treatment—even in the context of a well-resourced health system—to be super labor-intensive and serves as the greatest obstacles to initiation of HCV treatment regimen. By allowing the Pennsylvania Medicare/Medicaid system to proceed to a "No Prior Authorization required" for the vast majority of folks in PA with HCV, you will exponentially increase access to a life saving medication needed by so many! Thank you so very much for taking comments on this extremely important issue!					

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	As a physician who has been actively treating patients living with hepatitis C for nearly 20 years, I am very pleased to be writing in support of The Drug Utilization Review (DUR) Board's recommendation to revise the prior authorization guidelines to apply only to non-preferred DAA HCV agents. The Hepatitis Care Center at LVHN grew out of a pilot program started by me and, at the time, other resident physicians with the primary purpose to expand access to treatment of hepatitis C in underserved individuals. People living with hepatitis C face numerous barriers to accessing curative antiviral therapy. These barriers are due to well-established racial, ethnic, socioeconomic disparities as well as stigma, both related to hepatitis C infection and substance use disorders (SUD), which are common in this population. Most concerning are the barriers created by the design of the healthcare system, particularly drug utilization strategies such as prior authorization. Prior authorization (PA) creates multiple intended and unintended barriers to the cure of hepatitis C infection, including preventing treatment of hepatitis C altogether, stifling innovative approaches to care, and can cause incomplete courses of treatment. Those not cured of HCV can continue to serve as a source of infection, increasing the number of people who ultimately will need to be treated for HCV, many of whom are also Medicaid eligible. PA directly contributes to treatment delays, gaps in therapy and treatment discontinuations. Patients with	Joseph Yozviak, DO, FACP, AAHIVS, Chief Medical Officer, Valley Health Partners Community Health Center, Medical Director, Comprehensive Health Services & Hepatitis Care Center	X			

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	HCV are frequently in early recovery from SUD. Their primary focus is to maintain recovery and this focus can delay a HCV treatment start. Because PAs are time-limited, an authorization can expire during antiviral therapy, resulting in gaps in treatment or an incomplete treatment course. If this leads to a treatment failure, costs related to re-treatment rise. Additionally, whereas common PA criteria such as requiring HAV/HBV immunity/vaccination status to be addressed are well-intentioned, they can inappropriately delay treatment when they can just be addressed clinically at a subsequent visit. PA stifles innovative approaches to care, particularly in those in early SUD recovery. Those in early recovery represent the best opportunity to cure HCV in a group that is the highest risk to resume substance use and possibly become the source of another HCV infection. Rapidly curing HCV in this population both cures the individual and can prevent a future transmission. Test and treat strategies have been highly successful in HIV management to improve rates of viral suppression, and pilot data shows similar promise for HCV treatment. Prior authorization can delay treatment by weeks, making test and treat approaches ineffective. PA also directly and indirectly adds cost to the health care system and the Medicaid program through the countless hours Medicaid and MCO staff devote to review prior authorizations for HCC antivirals. Similarly, substantial time is devoted to coordinating PAs by nurses and other clinical staff in our practices,					

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	who can be better utilized to educate patients and support adherence. We fully support the DUR Board's recommendation to revise the prior authorization guidelines to apply only to non-preferred DAA HCV agents as well as the July 10, 2023 effective date for these updated guidelines. This revised guidance will demonstrate Pennsylvania's commitment to the elimination of hepatitis C from our commonwealth and help ensure our most vulnerable communities benefit from these efforts.					
	The Center for Health Law and Policy Innovation at Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) appreciate the opportunity to submit comments on the proposed clinical criteria for the treatment of hepatitis C virus (HCV) for Pennsylvania Medicaid beneficiaries. CHLPI advocates for legal, regulatory, and policy reforms to improve the health of marginalized populations, with a focus on the needs of low-income people living with chronic illnesses and disabilities. NVHR is a national coalition of patients, health care providers, community-based organizations, and public health partners fighting for an equitable world free of viral hepatitis. CHLPI and NVHR collaboratively support the *Hepatitis C: State of Medicaid Access* project which tracks and documents HCV treatment access across the country. We commend the Drug Utilization Review Board's recommendation to remove the prior authorization requirement for preferred direct-acting antivirals, as well as the proposed changes for non-preferred agents,	Elizabeth Kaplan, JD, Director of Health Care Access, Center for Health Law & Policy Innovation, & Adrienne Simmons, PharmD, MS, BCPS, Director of Programs, National Viral Hepatitis Roundtable	**X**			

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	effective July 10, 2023. To date, 23 state Medicaid programs have removed prior authorization for most patients entirely, including Delaware, the District of Columbia, New York, and Virginia. We look forward to Pennsylvania joining this growing tide of jurisdictions who recognize the importance of streamlining access to hepatitis C treatment. In implementing these policy changes, we urge the Commonwealth to ensure that managed care organizations continue to follow the same requirements as set forth by the Fee-for-Service program. We also encourage Medicaid to collaborate with the Department of Health and the Hep Free PA Coalition to educate providers and the community about the policy changes by (a) sharing the updates via established communication channels (e.g., newsletters, social media), (b) reaching out to prescribers, medical and pharmacy societies, health systems and community clinics, and community-based organizations, and (c) leveraging administrative data to initiate lookback programs to notify diagnosed but uncured patients of their treatment eligibility. For additional examples of ways to communicate about these policy changes, visit NVHR's toolkit. We look forward to Pennsylvania's continued leadership in making significant progress towards viral hepatitis elimination and will monitor developments with great interest.					

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	The Philadelphia Department of Public Health (PDPH) applauds the decision made by the Pennsylvania Drug Utilization Review Board (DUR) on April 26, 2023, recommending revisions to the prior authorization guidelines for Direct Acting Antiviral Hepatitis C Virus (DAA HCV) agents to apply only to non-preferred drugs. PDPH works vigorously to ensure all communities in Philadelphia have equitable access to healthcare, and this adjustment aligns with that vision. Removing prior authorization for selected DAA HCV agents brings Philadelphia one step closer to eliminating Hepatitis C and aligns with local, statewide, national and international goals of HCV elimination by 2030. PDPH fully supports the DUR Board's recommendation to revise the prior authorization guidelines to apply only to non-preferred DAA HCV agents along with the effective date of July 10, 2023 for these updated guidelines. Pennsylvania now joins many states in effectively removing this barrier to residents receiving timely and equitable access to HCV treatment.	Cheryl Bettigole, MD MPH, Commissioner, Philadelphia Department of Public Health	**X**			
	On behalf of the Hep Free PA Coalition, it is with great pleasure we are writing to you to support the Drug Utilization Review (DUR) Board's recommendation to revise the prior authorization guidelines to apply only to non-preferred DAA HCV agents. The DUR Board recommended these revisions at their most recent meeting held on Wednesday, April 26, 2023.	Amy Jessop, PhD, MPH, Co-Chair, & Tuesdae Stainbrook, DO, MPH, Co-Chair, Hep Free PA Coalition	**X**			

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	Hep Free PA Coalition is a coalition of patients, providers and community members advocating for the elimination of viral hepatitis in the Commonwealth of Pennsylvania. You may recall, we wrote to you back in August 2021 acknowledging the Commonwealth had made great progress in increasing access to treatment for hepatitis C virus (HCV) by simplifying the prior authorization process, but we also recognized prior authorizations continued to be a significant barrier to accessing HCV treatment. Utilization management strategies, including prior authorization, are commonly used to facilitate guideline-adherent therapy of complex and costly therapies. However, as currently employed, they disproportionately restrict access to care for and unintentionally perpetuate stigma against the very communities who need treatment most. The World Health Organization (WHO) has committed to eliminating viral hepatitis globally by 2030. To meet this goal, every nation and every state must remove unnecessary barriers to treatment for an otherwise curable disease. We fully support the DUR Board's recommendation to revise the prior authorization guidelines to apply only to non-preferred DAA HCV agents and support the July 10, 2023, effective date for these updated guidelines. Pennsylvania can now proudly count itself as one of the many states that have taken this action to eliminate barriers to cure this disease.					

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Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	We are grateful for the opportunity to comment on the Drug Utilization Review (DUR) Board Recommendations: Pennsylvania Department of Human Services Medical Assistance Advisory Committee Briefing Document regarding Hepatitis C Agents. We are members of primary care teams - physicians, pharmacists, nurses and social workers - across several locations in Western PA. Our primary care settings range from large academic programs in urban centers to small community health centers and safety net practices in areas of highest hepatitis C impact. The DUR Board proposed changes will decrease barriers to care of Pennsylvanians with hepatitis C by **removing the prior authorization requirement for preferred hepatitis C antivirals**. We expect this change to significantly decrease hepatitis C treatment delays experienced by patients in primary care, decrease the administrative burden of providing hepatitis C treatment, and over time, increase the primary care locations able to offer hepatitis C treatment. **Timeliness** In a study in 4 of our family practice sites, we observed a large decrease in average time from medication order to authorization after 2018 changes, from an average of 42 days 2016-2017, down to 10 days in 2018-2020 (internal report, 2022). Ongoing delays typically include obtaining additional lab values beyond those required by national hepatitis C treatment guidelines, providing further documentation	Stephanie Ballard, PharmD, BCPS, BCACP, Clinical Pharmacist - Family Medicine, Pharmacy Ambulatory Services Director, PGY2 Ambulatory Care Pharmacy Residency Faculty, Family Medicine Residency UPMC Shadyside Family Health Center	X			The suggested revision will be made in the published guidelines.

Drug	Comment	Commenter	Agree	Agree In Part	Disagree	Response
	to insurers, as well as ongoing system inefficiencies for communication between providers, specialty pharmacies and payers. We further believe that removal of the prior authorization requirement for preferred hepatitis C antivirals will make completion of treatment more feasible for patients in transitional housing. The typical stay in transitional is approximately 6 months, and the current minimum time from medication start to assessment of HCV cure is currently 5 months, leaving little time for establishing care, initial assessment, obtaining labs, counseling for medication start, and mailing or delivering hepatitis C antivirals to patients from the limited pharmacy sites dispensing them. **Additional Requested Changes** For HCV antivirals requiring prior authorization after the DUR Board's recommended changes (i.e. non-preferred agents), **we recommend updating the list of acceptable cirrhosis assessments as follows:** e. Has a cirrhosis assessment documented by a recent noninvasive test (e.g.,bloodtest or imaging, a Fibroscan, **FIB-4 calculation,** or findings on physical examination) Including the Fibrosis-4 (FIB-4) calculation is consistent with national guidelines including the AASLD/IDSA Simplified HCV Treatment Algorithm for Treatment-Naive Adults (https://www.hcvguidelines.org/treatment-					

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	naive/simplified-treatment) and adding the specific name would help clarify and standardize acceptance of the FIB-4 assessment among insurers. We fully support the DUR Board's recommendation to revise the prior authorization guidelines to apply only to non-preferred DAA HCV agents and support the July 10, 2023, effective date for these updated guidelines. We request ongoing vigilance in streamlining and removing variability for remaining prior authorization for hepatitis C antivirals, starting with the addition of the FIB-4 calculation to the accepted cirrhosis assessments.					

- **No comments were received on the following guidelines:**
  - Amyloid-Targeted Monoclonal Antibodies (MABs)
  - Analgesics, Opioid Long-Acting
  - Analgesics, Opioid Short-Acting
  - Antiemetic/Antivertigo Agents
  - Antiparasitics, Topical
  - Compounded Prescriptions
  - Cough and Cold Medications
  - Opioid Use Disorder
  - Progestational Agents
  - Tepezza (teprotumumab-trbw)