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Testimony of Kevin Costello
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Pennsylvania Pharmacy & Therapeutics Committee
Mechanicsburg, Pennsylvania
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- My name is Kevin Costello. I am an attorney with the Center for Health Law and Policy Innovation at Harvard Law School.

- You already know that HCV is a serious disease. But HCV is more than that – it is the leading cause of death among infectious diseases – killing more Americans each year than the next **60** infectious diseases ***combined***.[i]

- You certainly know that treatment is costly. Advanced modeling in study after study, however, shows that coverage of this treatment in the Medicaid population is cost-effective.[ii] Unsurprisingly, these studies show that the earlier treatment is entered, the more cost-effective that treatment is.

- Early treatment does more than just prevent retransmission. The modeling shows that treatment upon diagnosis **saves public money** by preventing future spending to treat liver cancer, cirrhosis and liver transplant. Cure also avoids the cost of treating the extrahepatic effects of this chronic inflammatory condition.

- **This** is why treatment without regard to fibrosis score is the prevailing standard of care. And this is why no disease severity requirement is justified under the explicit definition of "medical necessity" in the Pennsylvania Code, which expressly requires treatment where it "is reasonably expected to prevent the onset of an illness condition, or disability."

- The CMS Guidance issued in Nov. 2015 recognizes this prevailing standard of care, while reminding states of their obligations under the federal Medicaid statute.

- New York State recognized this last month when it's P & T Committee decided to remove all fibrosis scoring restrictions.

- Medicare and the VA health system have done the same, along with

- Massachusetts, Connecticut, Georgia, Wyoming, Alabama and Maine have all recognized that Medicaid coverage for early treatment consistent with the standard of care is not only the right medical decision, it is the right legal decision and the right fiscal decision as well.[iii] [Cut off nose to spite face.]

- We have a long way to go to eradicate HCV. But the path is there. And proper treatment coverage for Pennsylvania's Medicaid enrollees is the right first step.

[i] Ly, et al., Rising Mortality Associated With Hepatitis C Virus in the United States, 2003–2013, Clin Infect Dis. (2016) 62 (10):1287-1288.

[ii] (1) Petta S, Cabibbo G, Enea M, et al. *Cost-effectiveness of sofosbuvir-based triple therapy for untreated patients with genotype 1 chronic hepatitis C.* HEPATOLOGY. May 2014;59(5):1692-1705. PMID 24691835; (2) Leleu H, Blachier M, Rosa I. *Cost-effectiveness of sofosbuvir in the treatment of patients with hepatitis C*. J VIRAL HEPAT. Sep 15 2014. PMID 25219291; (3) Saab S, Gordon SC, Park H, et al. *Cost-effectiveness analysis of sofosbuvir plus peginterferon/ribavirin in the treatment of chronic hepatitis C virus genotype 1 infection*. ALIMENT PHARMACOL THER. Sep 2014;40(6):657-675. PMID 25065960; (4) Tice JA, Ollendorf DA, Pearson SD. *The comparative clinical effectiveness and value of simeprevir and sofosbuvir in the treatment of chronic hepatitis C infection* 2014; (5) Chhatwal J, Kanwal F, Roberts MS, Dunn MA. *Cost-effectiveness and budget impact of hepatitis C virus treatment with sofosbuvir and ledipasvir in the United States*. ANNALS OF INTERNAL MEDICINE. 2015; 162(6):397-406; (6) Linas BP, Barter DM, Morgan JR, Pho MT, Leff JA, Schackman BR, et al. *The cost-effectiveness of sofosbuvir-based regimens for treatment of hepatitis C virus genotype 2 or 3 infection*. ANNALS OF INTERNAL MEDICINE. 2015;162(9):619-29; (7) Najafzadeh, Mehdi, *Cost-Effectiveness of Novel Regimens for the Treatment of Hepatitis C Virus*, ANNALS OF INTERNAL MED. 2015; 162:407-419; (8) Younossi ZM, Park H, Saab S, Ahmed A, Dieterich D, Gordon SC. *Cost-effectiveness of all-oral ledipasvir/sofosbuvir regimens in patients with chronic hepatitis C virus genotype 1 infection*. ALIMENTARY PHARMACOLOGY & THERAPEUTICS. 2015a;41(6):544-63**.**
[iii] Center for Evidence-based Policy. (2015b). State Medicaid Coverage Policies for Harvoni and Viekira Pak Treatment of Hepatitis C. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University
https://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/evidence/med/upload/02b-HCV-Medicaid-Policy-SenFin-2015.pdf

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The definition of medical necessity is spelled out in Pennsylvania regulations (55 Pa. Code §1101.21a), and see DPW "Clarification Regarding the Definition of 'Medical Necessity'" at 37 Pa.B. 1880 (April 27, 2007). and in the contracts between the Pennsylvania Department of Public Welfare and the HMOs.

To meet the Medicaid standard for Medical Necessity, **any one** of the three standards below can be met:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness condition, or disability
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition or disability.
- The service or benefit will assist the individual to achieve or maintain maximum functional capacity in performing daily activities taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age.

The determination can be made either by prior authorization, concurrent review, or post-utilization. For a service to be medically necessary, it must be compensable under the Medicaid program. Determinations of medical necessity and denials of medical necessity must be in writing.