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.

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. 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.

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.

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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.