[redacted]

Thank you for taking the time to discuss this with us.

Our thoughts regarding this matter are as follows:

The comparison of ND to surrounding states may not be the best stance, as many of their requirements are not based on current medical evidence.

Appeal for Fibrosis Score

According to the American Association for the Study for Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) recommendations, a higher fibrosis score should not dictate treatment initiation for hepatitis c (HepC). Studies have shown that starting treatment in patients with a lower fibrosis score augments the benefits of Sustained Virologic response (SVR) or "cure". In a study with 820 participants with Metavir stage F0 or F1, they found statistical significance at 15-year survival rates for patients who achieved SVR versus patients that were left untreated.[1] In summary, there is a higher benefit for overall cure rates when treatment is initiated at a lower fibrosis score.

What if we wait until F3 or F4?

Additionally, a different study demonstrated that waiting to treat FlepC until patients "get sicker" at Metavir stage F3 or F4 resulted in 2 to 5-fold higher rates of liver-related mortality compared with treating at an earlier stage.[2] Medical guidelines in the past supported restricting access to HEPC medications to sicker patients. However, just last year medical experts in the areas of liver and infectious disease recommended treatment for nearly all patients with chronic HEPC.[3] By amending our state Medicaid rules, we will be keeping up with current medically based evidence, thus allowing healthcare providers to dispense care more successfully.

Just keep up with current medical practice →

With regards to abstinence requirements, we are starting to see a push towards easing restrictions to allow "access-for-all" for HepC treatment, including patients with recent use of injectable drugs. Injection drug use is certainly the driving force in perpetuating the hepatitis c virus (HCV) epidemic; however, with the availability of interferon-free regimens, we have been enabled to dramatically decrease HCV incidence and prevalence. Studies done in populations during the interferon era demonstrate comparable adherence and efficacy rates. The newer, shorter, well-tolerated regimens currently available in the market are expected to improve these rates.[4] The rate of re-infection in patients actively injecting drugs is 6.44/100 person-year, although we do acknowledge more studies are needed since new drugs have been introduced into the market. This is due to health models showing that even modest increases in treatment of this patient population can decrease the prevalence and incidence of HCV, thereby reducing the overall cost of treatment for the population of the state.[5, 6]

IVDU & re-infection rates

What was your state Medicaid data based on? or what are their reservations?

A study conducted in San Francisco initially reported a high incidence of re-infection rates up to 25% and revised their results to go down to 5.4/100 person-years, due to lack of viral sequencing and other reasons. Risk of reinfection in active drug users (after being cured) is 3.2 cases per 100 person-years versus risk of first HCV infection in the same populations studied in Vancouver being 7.3 cases per 100 person-years. This makes the case that benefits in treating drug users outweighs the risks of spreading the infection to others.

Per recommendations from experts, these requirements should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy.[7]

Homerun!

Comparing us to one of the states that integrates the most current medical practices into their policymaking puts us ahead of the game in tackling the HepC epidemic. Last year a Federal judge in Washington State ordered their Medicaid program to end their stance at limiting HepC treatment to patients with higher liver fibrosis stage. The injunction ordered the Health Care Authority (HCA) to cover Harvoni® "without regards to fibrosis score".[8]

Help them understand we will be spending more if we do not do this now.

Class action law suits were also filed in Indiana, Massachusetts, Minnesota, Oregon and Pennsylvania to mention a few. This highlights the fact that it is a matter of when and not if we would have to make these changes down the line.[9] States like Oregon that were treating based on severity of disease are currently spending a lot of taxpayer money to go back and track these patients that were initially denied, redo all necessary labs and provide compensation for time lost. We need be proactive rather than reactive and get our communities treated now instead of waiting years until they get sicker. One possible benefit would be the potential reduction in overall cost of caring for patients who may further develop complications stemming from delay in treatment or being lost to follow up care.

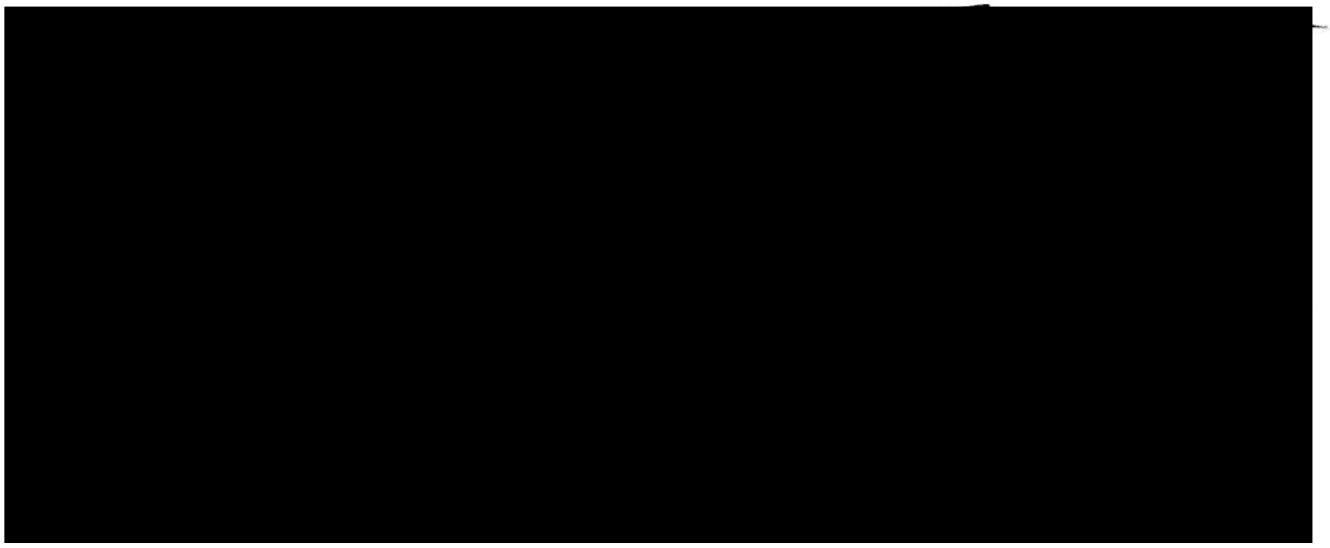
We here in North Dakota, have a great opportunity to serve as an example to surrounding states in following current medical practices, like they do in Washington, Oregon, New Mexico and California, and not ration care to only sicker patients.

NS5A testing in all GT 1 patients?

With regards to NS5A resistance testing for patients with Genotype 1 (GT 1), current recommendations include testing for resistance if patient is receiving Elbasvir/Grazoprevir (Zepatier)® as treatment. Although Harvoni® and Epclusa® each have drug components that target NS5A replication complex; we see differences in SVR rates only for patients that are treatment-experienced GT 1a or 1b, and treatment-naïve cirrhotic. In patients that are treatment-naive GT 1a or 1b, this expensive resistance test is unnecessary. Studies have shown that NS5A polymorphisms are not a class-effect in developing resistance to these drugs in the treatment-naive GT 1a/1b population. It would be our recommendation to decrease the burden on the health care system by eliminating this test for GT 1 patients while recognizing this test should only be mandated for patients whom are treatment-experienced or treatment-naive with cirrhosis.[10]

In conclusion, we believe the North Dakota is in a great position to serve as an example to surrounding states in treating hepatitis c by integrating current medical evidence into its policies and improving quality of care for our state. Thus, we propose that North Dakota Medicaid lower minimum Fibrosis Score to initiate treatment to F0, remove the requirement for NS5A resistance testing for GT 1 patients unless they are treatment-experienced or treatment-naive with cirrhosis, and ease restrictions with regards to abstinence. We look forward to working with you and your team.

Very Sincerely,



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