

It is the policy of the US Department of Veterans Affairs (VA) policy to offer anti-viral treatment chronic hepatitis C virus infection (HCV) based solely on clinical benefit, without consideration of cost. VA does not restrict anti-viral treatment based on stage of liver disease.

As of December 31, 2013:

- There were an estimated 233,000 Veterans with HCV in VA care (both diagnosed and undiagnosed).
- Approximately 180,000 of these had been diagnosed and are known to have chronic hepatitis C, meaning that VA has diagnosed 77% of those with HCV. By comparison, 57% of HCV patients in the general US population have been diagnosed.
- Over 90% of Veterans in VA care with a positive HCV test have had follow-up testing to confirm the diagnosis of HCV, compared to less than 50% for the general US HCV population.
- Approximately 39,000 Veterans with HCV in VA care had been started on anti-viral treatment, representing 17% of the VA HCV population, compared to 16% of the general US HCV population.
- If the denominator used to calculate treatment rates is the number of diagnosed patients, rather than all patients (diagnosed and undiagnosed), the VA treatment rate would be 22%, not the 12% reported for data through 2005 in the 2012 *Journal of Hepatology* study.
- Approximately 15,000 of these treated patients had been cured, representing 7% of the VA HCV population, compared to 9% of the general US population.

As of February 28, 2015:

- More than 14,000 patients had been started on treatment with one of four new treatment regimens (Sovaldi, Sovaldi + Olysio, Harvoni, Viekira).
- Over 8,000 of these patients had been treated an interferon—free regimen.
- About 51% of the 14,000 patients treated with one of the new regimens do not have advanced liver disease (ALD), defined as a FIB-4 score >3.25, roughly equivalent to stage F3 or F4 fibrosis).
- Cure rates for the new interferon-free regimens in VA are estimated to be about 85% for patients who do not have liver disease and who have never been treated before.

With regard to funding:

- In FY 2015, VA has allocated \$696M dollars for purchase of HCV drugs, out of a total outpatient pharmacy budget of \$4.3B.

- As of February 28, 2015, VA had spent more than \$300M on HCV drug purchases, about as much as it spent in all of FY 14.
- VA pharmacy managers have been able to negotiate discounts for HCV drugs that are significantly lower than the usual 24% discount.

With regard to the time needed to treat the VA patient population:

- As of June 2014, approximately 108,810 patients were treatment candidates (i.e., had been diagnosed with HCV, have not been cured by previous treatment, and have had their genotype, or strain, of HCV determined)
- Roughly 27,000 of these have ALD – we are focusing on treating those patients as quickly as we can. Some of these patients have other medical conditions (particularly alcohol and substance use disorders) that may affect their ability to adhere to treatment – in these cases we are working to address those treatment limiting conditions.
- We're now starting treatment on 733 patients per week.
- For patients who do not have ALD
 - Treatment is available, but these patients do not need to be treated right away
 - About 17% of patients have HCV due to strains that aren't susceptible to the new drugs (e.g., genotype 2) – interferon-based regimens are still used for these patients. Better drugs are expected in the next few years that will get rid of the need for interferon-based regimens.
- Although we feel reasonably confident that no new serious side-effects will emerge from use of these new drugs, it is still possible that we could see some unanticipated rare but serious toxicities (this has certainly happened with HIV drugs). For this reason, it would be prudent not to rush treatment for patients who do not have advanced liver disease.