With pan-genotypic regimens at the helm of hepatitis C treatment, genotype testing is more hindrance than help to patients.

Hepatitis C genotype testing is a blood test that determines the genotype or "strain" of hepatitis C virus. There are six major HCV genotypes in the world. Genotypes 1, 2, and 3 are most common in the United States. [1]

Prior to the advent of pan-genotypic regimens in 2016 and 2017, it was important for providers to check what strain of hepatitis C virus was present in a patient's body because this could determine what course of treatment would be most effective. Now, genotype testing usually isn't medically necessary because the recommended first-line regimens are pan-genotypic and appropriate for any patient who qualifies for simplified treatment.

While genotype testing may be situationally useful on a case-by-case basis (for example, when retreating patients to distinguish between treatment failure and reinfection), many providers believe genotype testing should no longer be a one-size-fits-all prerequisite to accessing treatment. Instead, providers should be free to consider whether cost and delays in care situationally outweigh the benefit of ordering a genotype test.

KEY TERMS

Genotype:
in the context of HCV, genotypes are particular strains of the virus.

Simplified Treatment:
a streamlined model for initial treatment for people who don't have liver cirrhosis or significant coinfections, with reduced need for on-treatment monitoring and appropriate for prescribing and managing by a broad range of non-specialist health care providers.

Pan-Genotypic:
in the context of HCV treatment, pan-genotypic means effective in treating all HCV genotypes.

Direct-Acting Antivirals (DAAs):
available since 2013, these medications reliably treat and cure HCV in 8 to 12 weeks with little to no side effects. First-line DAA treatment regimens are now pan-genotypic, effective for all major HCV genotypes.

AASLD/IDSA guidelines don't require pre-treatment genotype testing for simplified treatment.

According to the AASLD/IDSA guidelines, genotype testing is not required for patients who qualify for simplified treatment, which is most patients.[2] The recommended first-line regimens glecaprevir/pibrentasvir (Mavyret) and sofosbuvir/velpatasvir (Epclusa) are effective to treat infections of any genotype in adults without cirrhosis. They only recommend genotype testing for some patients who have compensated cirrhosis,[3] patients who were previously unsuccessful with HCV treatment,[4] and patients with certain coinfections.[5] These guidelines are also borne out by research: in a recent study, researchers found that eliminating pre-treatment genotype testing was safe and achieved sustained viral response comparable to standard monitoring.[6]

The collection and documentation of genotype delay treatment initiation and increase cost of care.

As of May 2023, more than a third of state Medicaid programs and many commercial and Medicare plans require documentation of genotype as part of their prior authorization (PA) processes for treatment-naïve patients. Many even require a genotype to be collected within a certain timeframe. These PA requirements and the administrative burdens they entail lead to delays and stoppages in care that disproportionately impact communities of color, people who use drugs, and people experiencing homelessness or incarceration.

Genotype testing increases the amount of blood needed for pre-treatment lab tests[7] and adds unnecessary strain for patients who have difficult venous access.[8] Such patients may not be able to provide enough blood in one sitting, forcing them to return for multiple visits to complete blood draws for pre-treatment labs. After the blood draw is complete, genotype tests have a long turnaround time, with providers reporting that it can take up to 10 days to get results. This unnecessarily lengthens the pre-treatment timeline and makes it more likely that patients will be lost to follow-up, thereby increasing the risk of transmission and worsening health outcomes.

Genotype testing also adds unnecessary costs to the healthcare system. A recent study found that a minimal monitoring approach, which omits pre-treatment genotype testing, was safe and effective compared to standard monitoring that includes genotype testing. The authors noted that skipping genotype testing is critical for HCV elimination, given its high cost.[9] It's easy to see how the cost of genotype testing can add up. The National Academies of Sciences, Engineering, and Medicine estimate that at least 260,000 people need to be treated annually to eliminate hepatitis C by 2030.[10] At an average of $500 per test,[11] hitting that target number of genotype tests would cost $130 million per year.

When asked about HCV treatment access challenges, providers noted genotype testing as a barrier to access:

"Genotype results have a long turnaround time, sometimes creating delays. We sometimes can't get a genotype for folks who have a low [viral load], which has also been a barrier as there is value in treating someone quickly rather than waiting to see if low [viral load] results in spontaneous clearance."

"I don't understand [the] need for genotype since meds are [pan-genotypic]. This seems like [a] waste of resources."

"The time it takes to get the labs done, especially in our offices that don't draw labs, often results in significant delays, if not losing the patient to follow up entirely."

"[Insurance plans] often have archaic PA criteria requiring genotypes for uncomplicated patients [when] a genotype will have no bearing on medication selection."

"Genotypes require a lot of blood volume at the point of phlebotomy. It is often difficult enough to get the minimum necessary sample for basic labs such as a complete metabolic panel or HCV RNA; adding a genotype to this often leads to insufficient draws and delays in care, especially among people who inject drugs."

Evidence points toward moving from blanket requirements to case-by-case decision-making.

Requiring providers to submit genotype documentation is no longer a sensible guardrail to ensure good treatment decisions—it's a needless barrier to HCV care initiation that rarely guides medication selection for initial treatment. And while there are specific cases where providers may deem genotype testing medically necessary—like needing to differentiate reinfection from treatment failure prior to retreatment—those decisions should be made by providers, not insurers.

State Medicaid programs that currently impose genotype testing requirements should reconsider whether the high cost of these policies, and the resulting delays in care, outweigh the benefit. We can achieve hepatitis C elimination, but only if people living with HCV have timely access to treatment in a manner that is consistent with established treatment guidelines and best practices. Ultimately, the decision to order (or not order) a genotype test should be left in the hands of the provider, who has the medical expertise needed to make those calls.

About This Fact Sheet

This resource has been brought to you by the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) as part of the *Hepatitis C: State of Medicaid Access* project. For more information about hepatitis C treatment access barriers, please visit www.stateofhepc.org.

Sources

[1] Michael P. Manns et al., Hepatitis C Virus Infection, Nature Reviews Disease Primers, March 2, 2017, at 1–19, https://pubmed.ncbi.nlm.nih.gov/28252637.

[2] See American Association For The Study Of Liver Diseases ("AASLD") & Infectious Diseases Society Of America ("IDSA"), HCV Guidance: Recommendations For Testing, Managing, And Treating Hepatitis C, hcvguidelines.org.

[3] AASLD & IDSA, Simplified HCV Treatment for Treatment-Naïve Adults Without Cirrhosis (last updated October 24, 2022), https://www.hcvguidelines.org/treatment-naive/simplified-treatment.

[4] AASLD &IDSA, Initial Treatment of Adults with HCV Infection (last updated October 24, 2022), https://www.hcvguidelines.org/treatment-naive.

[5] AASLD & IDSA, Management of Unique & Key Populations With HCV Infection (last updated August 27, 2020), https://www.hcvguidelines.org/unique-populations.

[6] Sunil S. Solomon et al., A Minimal Monitoring Approach for the Treatment of Hepatitis C Virus Infection (ACTG A5360 [MINMON]): A Phase 4, Open-Label, Single-Arm Trial, 7 Lancet: Gastroenterology & Hepatology 307–17 (2022), https://pubmed.ncbi.nlm.nih.gov/35026142.

[7] See Labcorp, HCV Specimen Collection Guide (last updated 2016), https://www.labcorp.com/tests/related-documents/L12160.

[8] See, e.g., Sinead Sheils et al., Acceptability of External Jugular Venepuncture for Patients With Liver Disease and Difficult Venous Access, 29 British J. Nursing S27–S34 (2020), https://www.magonlinelibrary.com/doi/abs/10.12968/bjon.2020.29.2.S27 (discussing difficulties faced by patients with difficult venous access, including physical pain, feelings of shame, stigmatizing behavior from providers, and delays in care).

[9] Sunil Majethia et al., Economic Impact of Applying the AASLD-IDSA Simplified Treatment Algorithm on the Real-World Management of Hepatitis C, 28 J. Managed Care & Speciality Pharmacy 48–57 (2022), https://pubmed.ncbi.nlm.nih.gov/34677088.

[10] National Academies Of Sciences, Engineering, And Medicine, A National Strategy For The Elimination Of Hepatitis B And Phase Two Report (2017), https://doi.org/10.17226/24731.

[11] See, e.g., RequestATest: Hepatitis C (HCV) Genotype Test, requestatest.com (last accessed May 22, 2023) (showing the Labcorp price as $449.00 and the Quest price as $599.00).