



Next Steps for *Payers and Policymakers*: An Action Guide on the Newest Treatments for Chronic Hepatitis C Infection

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Completed by:

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Introduction

About This Guide

Evidence from clinical research, which informs effectiveness reviews, provides a critical foundation for judgments that patients, clinicians, and health insurers must make about treatment choices and coverage policies. Yet that evidence is often not translated in a way that is helpful to inform health care decisions. This document is a companion action guide designed to help payers and policymakers make use of the results of a recent technology assessment entitled “[*The Comparative Clinical Effectiveness and Value of Novel Combination Therapies for the Treatment of Patients with Genotype 1 Chronic Hepatitis C Infection*](#)” developed by the Institute for Clinical and Economic Review (ICER) and faculty/researchers at University of California, San Francisco. This report formed the basis for the deliberations and votes of the California Technology Assessment Forum (CTAF) Panel – an independent committee of medical evidence experts from across California, with a mix of practicing clinicians, methodologists, and leaders in patient engagement and advocacy, who evaluate evidence and vote on the comparative clinical effectiveness and value of medical interventions. All CTAF Panel members meet strict conflict of interest policies.

CTAF held its public meeting on the newest treatments for hepatitis C on December 18, 2014 in Oakland, California. A full report summarizing the discussion and votes taken is available on the [CTAF website](#). We have developed this Action Guide to provide a list of specific action steps that payers and policymakers can take to improve patient outcomes and the overall value of treating patients with hepatitis C, genotype 1. This guide serves as a companion to the evidence review and meeting results. The content provided here is for informational purposes only, and it is not designed to replace professional medical advice.

A Note on CTAF Evidence Voting

Each public meeting of CTAF involves deliberation and voting on key questions on the comparative clinical effectiveness and value of the various diagnosis and treatment options discussed. When voting, CTAF Panel members are asked to assume the perspective of a state Medicaid program making resource allocation decisions within a relatively fixed budget.

Action Steps for Payers and Policymakers

The following action steps are designed to help payers and policymakers develop policies that encourage the appropriate use of treatments for patients with hepatitis C, genotype 1. Some recommendations are also relevant to other highly effective but very expensive new therapies. These action steps reflect 1) the CTAF Panel's judgment of published evidence as of December 2014, and 2) best practices discussed by subject matter experts during a policy roundtable discussion at the CTAF meeting.

- 1. Given that new oral drug regimens for hepatitis C all provide viral clearance above 90% with very low side effect rates, payers can leverage the availability of multiple comparable treatment options to negotiate vigorously for lower prices.**

Research evidence shows that several treatment regimens for patients with hepatitis C, genotype 1 are equivalent in terms of clinical effectiveness – the newest combination direct-acting antiviral agents (DAAs)¹ eliminate the virus from the bloodstream for at least 12 weeks following the end of treatment in up to 95-100% of participants enrolled in clinical trials. The new combination DAA therapies have fewer side effects than older regimens containing interferon. Recently, payers have begun to negotiate considerable discounts from manufacturers, and several health plans and pharmacy benefit managers (PBMs) have selected one drug regimen as the preferred therapy among the various FDA-approved treatments.

More information on public and private payer discounts for the combination DAAs is available here:

- http://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html?_r=0
- http://www.stltoday.com/news/special-reports/mohealth/missouri-to-drop-expensive-hepatitis-c-drug-sovaldi-use-alternative/article_0f2a8964-d4bc-5362-8d41-b10e65d13408.html

- 2. If lower prices are obtained, consider expanding coverage by reducing or eliminating requirements for documented liver fibrosis and by beginning to allow primary care clinicians to prescribe the new all-oral DAA regimens.**

Ideally, all patients who seek and would benefit from treatment would be able to obtain the newest therapies. Our analyses showed that a strategy of treating patients at all fibrosis stages rather than

¹ FDA-approved combination DAAs for the treatment of hepatitis C genotype 1, as of December 19, 2014, were ledipasvir/sofosbuvir, simeprevir + sofosbuvir, and paritaprevir/ritonavir/ ombitasvir + dasabuvir (3D) with or without ribavirin.

waiting to treat patients until they reached fibrosis levels F3 or F4 provided a net clinical benefit for the population and met commonly accepted cost-effectiveness thresholds. Given treatment capacity constraints and limits on financial resources, priority for treatment has been targeted through coverage policies and clinical guidelines to patients with advanced liver disease and to those who are at high risk of infecting others with hepatitis C. For many payers these restrictions will remain necessary, but if payers are able to improve affordability by negotiating lower prices from manufacturers, receiving external funding assistance, or negotiating extended payment terms, they should consider expanding coverage by reducing or eliminating requirements for documented liver fibrosis and by beginning to allow primary care clinicians who have been educated and trained in hepatitis C treatment to prescribe the new all-oral DAA regimens. If health plan policies allow prescribing by primary care clinicians, it is important that these clinicians be able to readily access experts in treating hepatitis C for guidance on questions that arise during treatment.

More information on a national PBM that recently changed its coverage policies to allow all patients with hepatitis C to receive treatment and to expand prescribing privileges to primary care physicians is available here:

- http://www.nytimes.com/2014/12/22/business/pharmacy-deal-heralds-changed-landscape-for-hepatitis-drugs.html?_r=0

The VA's February 2015 hepatitis C treatment considerations document indicates that, in addition to specialists, treatment can be provided by non-specialists, including general internist or family medicine physicians, who have been educated and trained in hepatitis C therapy and have access to specialists for support. See page 7 for more information:

- <http://www.hepatitis.va.gov/pdf/treatment-considerations-2015-02.pdf>

Another way to expand treatment capacity involves additional investment in training programs and new models of care so that more patients can be treated. Efforts are underway to increase education and training in hepatitis C among non-specialist physicians and providers. One example of a program that helps build treatment capacity is Project ECHO® (Extension for Community Healthcare Outcomes), which is a collaborative model of medical education and care management using telemedicine. Its long-standing program based in New Mexico increases access to specialty treatment in *rural*, underserved areas by providing front-line clinicians with the knowledge and support they need to manage patients with complex conditions such as hepatitis C. This model has been shown to be extremely effective in terms of patient outcomes and is very popular with primary care physicians. More information may be found at these links:

- <http://echo.unm.edu/>
- <http://echo.unm.edu/nm-teleecho-clinics/hepatitis-c-community-clinic/>

In 2014, The University of Chicago Medicine received a grant from the Centers for Disease Control and Prevention (CDC) to lead a public health collaboration aimed at reducing hepatitis C infections

in Chicago through education, testing, and treatment. The ECHO-Chicago program seeks to significantly increase the number of community-based primary care providers trained to diagnose and treat HCV, particularly in *urban*, underserved communities. More information is available here:

- <http://www.uchospitals.edu/news/2014/20141009-hepcatt.html>
- <http://www.echo-chicago.org/>

To maximize the clinical benefit of all-oral hepatitis C therapies, payers may wish to implement programs, or partner with provider groups to implement programs, that involve patient outreach to improve adherence; these may involve phone calls from members of the patient's care team, text messages, support groups, etc.

Some examples of patient support tools to enhance adherence to hepatitis C treatment regimens may be found at these links:

- AbbVie (for patients with a prescription for Viekira only, designed to provide personalized treatment support): <https://www.viekira.com/proceed-program>
- Accredo Plus C (free iPhone application designed to help hepatitis C patients manage treatment): <https://itunes.apple.com/us/app/accredo-plus-c/id885883930?ls=1&mt=8>

3. Develop transparent approaches for identifying pragmatic thresholds for incremental cost-effectiveness and budget impact that represent both reasonable care value and health system value.² Efforts to establish and justify price points for new therapies will require dialogue among payers, providers, manufacturers, and other stakeholders.

Health economists and public policy experts have long debated thresholds for incremental cost-effectiveness, but budget impact thresholds are less well rooted in the health policy arena. Further work will be needed to document the validity and utility of these thresholds across settings, and all stakeholders will need to contribute to identifying both thresholds and suitable payment and policy options to collectively promote high value in the US health care system.

A robust discussion of incremental cost-effectiveness and budget impact thresholds is included in the full ICER report available here:

- <http://www.ctaf.org/reports/newest-treatments-hepatitis-c-genotype-1>

² “Care value” is a judgment comparing the clinical outcomes, average per-patient costs, and broader health effects of two alternative interventions or approaches to care. “Health system value” is a judgment of the affordability of the short-term budget impact that would occur with a change to a new care option for all eligible patients, assuming the current price and payment structure.

4. Partner with other stakeholders to develop new mechanisms that can support the sustainable adoption of expensive treatments for hepatitis C and other treatments of high care value that could breach acceptable budget impact thresholds.

The newest treatments for hepatitis C – highly effective yet expensive – represent a high care value at the individual patient level. However, when large numbers of patients are eligible for treatment, the potential budget impact raises stark financial challenges for health systems. Policy action is needed to design mechanisms that can achieve lower drug prices and/or create new payment models to moderate short-term budget impacts. Examples of innovative mechanisms discussed at the CTAF meeting are shown below. The overall goals of these various policy and payment mechanisms include sustaining innovation, linking prices to the underlying degree of benefit (care value), and helping to identify budget impact problems ahead of time so collaborative solutions can be implemented.

Drug Development/Policy

- Guide the FDA to provide accelerated approval pathways for competing drugs in order to maximize market forces that can stimulate price competition
- Establish a prize or award fund for a cure that provides a financial reward for innovation and allows treatments to be spread widely and quickly (e.g., the government could buy the patent for a cure and make the product available to everyone at very low cost)
- Develop a mechanism that would allow more anticipatory, collaborative policymaking between manufacturers, payers, and other stakeholders so that preventive policy actions can be taken when drugs that will have large budget impacts are on the horizon

Pricing and Payment

- Engage other stakeholders including the public in a broad discussion of manufacturer pricing and encourage advocacy for more affordable prices
- Pay for outcomes rather than for the treatment (e.g., if a patient doesn't achieve the desired clinical benefit, the manufacturer refunds the payment; alternatively, the manufacturer receives payment only when a patient achieves the desired clinical outcome)
- Negotiate price volume agreements with manufacturers so that prices continue to decrease with increasing volume. When alternatives exist in the marketplace, consider making one of them the preferred treatment in order to move market share and lower price.
- Use mechanisms such as reinsurance or risk corridors to help manage unexpectedly high costs
- Target federal funding to provide access to care for those who need it but do not have health insurance coverage or other financial resources to obtain care (akin to Ryan White Act for HIV/AIDS)

- Use data to identify opportunities to disinvest from low value care and eliminate waste in the health care system, so that the savings can be redirected to higher value options now and in the future
- Mandate at the federal level that important drugs not priced reasonably be placed in the public domain so other manufacturers can make generics, as is done in India

More information on cost issues and potential solutions for Medicaid programs (specific to hepatitis C treatments, but applicable to specialty drugs in general) are available through the following links:

National Association of Medicaid Directors letter to Congressional leaders on policy options:

- http://medicaiddirectors.org/sites/medicaiddirectors.org/files/public/namd_sovaldi_letter_to_congress_10-28-14.pdf

American Academy of Actuaries letter to the Centers for Medicare & Medicaid Services (CMS) on challenges related to cost uncertainties for breakthrough therapies:

- http://actuary.org/files/Medicaid_capitation_rates_and_BT_D_medications_Letter_to_CMS_Nov%2011.pdf

More information on *drug development and other policy* mechanisms may be found at these links:

FDA accelerated approval program:

- <http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm313768.htm>
- <http://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm>

Medical prize fund to reward those who discover cures and vaccines:

- Article in the New Scientist:
https://www0.gsb.columbia.edu/faculty/jstiglitz/download/2006_New_Scientist.pdf
- Proposed federal legislation (not enacted):
<https://www.govtrack.us/congress/bills/113/s627/summary>

More information on innovative *pricing and payment* mechanisms may be found at these links:

Initiative to make drugs more affordable:

- National Coalition on Health Care (NCHC): <http://www.nchcbeta.org/>
- NCHC Campaign for Sustainable Drug Pricing: <http://www.csrxp.org/>

Risk-sharing arrangements, in the US and other countries:

- Health Affairs article: <http://content.healthaffairs.org/content/30/12/2329.abstract>
- International Society For Pharmacoeconomics and Outcomes Research conference presentation: <http://www.ispor.org/meetings/montreal0614/presentations/IP9-AllSpeakers.pdf>
- VA presentation: http://www.amsus.org/wp-content/uploads/2014/05/RxRiskSharingAgreements_Good1.pdf

Ryan White HIV/AIDS program: <http://hab.hrsa.gov/abouthab/aboutprogram.html>

Disinvestment in health care services (in the UK and Australia):

- Journal of Health Organization and Management article on efforts in the UK: <http://www.ncbi.nlm.nih.gov/pubmed/24422258>
- Implementation Science article on efforts in Australia: <http://www.implementationscience.com/content/7/1/101>

5. Support provider groups as they work to build a system to screen and identify patients with hepatitis C, track them over time, and provide treatment as needed.

To better understand and address the needs of patients with hepatitis C, provider groups should consider developing a comprehensive system to identify these patients; assess their need for treatment, including tracking them to see how those needs evolve over time; and treat patients to the extent possible given system resources, with a priority given to patients with advanced liver fibrosis or who are at high risk of infecting others. Payers and policymakers can support these efforts by providing financial, technological, analytic, or other resources.

Kaiser Permanente Northern California has a viral hepatitis registry that includes administrative and clinical data for all patients with chronic hepatitis C. More information may be found at these links:

- <http://share.kaiserpermanente.org/article/successful-hepatitis-c-treatment-lowers-subsequent-medical-costs/>
- <http://amcp.org/WorkArea/DownloadAsset.aspx?id=16750>

Eleven health plans have partnered to develop the largest diabetes disease registry in the US. More information is available here:

- <http://share.kaiserpermanente.org/article/eleven-integrated-health-systems-form-largest-private-sector-diabetes-registry-in-united-states/>

HealthPartners HMO in Minnesota supplies chronic disease registry data to its contracted medical groups. More information is available here:

- <http://www.whynotthebest.org/uploads/download/79>

Hudson Health Plan, a not-for-profit Medicaid managed care plan in New York, developed a registry for diabetic patients that affiliated providers can access. More information is available here:

- http://www.hudsonhealthplan.org/gedownload!/Reprint014_Health%20Plan%20Technology%20Improves%20Diabetes.pdf?item_id=159009&version_id=159010

6. Closely monitor evolving evidence and clinical guidelines to ensure that prior authorization criteria and other coverage policies for hepatitis C therapies remain up-to-date with the most recent evidence.

Payers and policymakers must ensure that systems are in place to keep all coverage policies up to date with new evidence as current clinical trials are reported and new therapies come to market. Many organizations in the United States and internationally will continue to perform periodic evidence reviews on the newest hepatitis C treatments, and payers and policymakers can gain important insights into the strength of evidence by examining the findings of these reviews. Similarly, payers should seek to use only high-quality evidence-based clinical guidelines as input into coverage determinations.

Organizations that have produced clinical guidelines on hepatitis C treatment and may produce updated ones in the future include:

- American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA)/International Antiviral Society – USA (IAS USA):
<http://www.hcvguidelines.org>
- European Association for the Study of the Liver (EASL):
<http://www.easl.eu/clinical-practice-guideline>
- National Institute for Health and Care Excellence (NICE):
<http://cks.nice.org.uk/hepatitis-c>
<http://www.nice.org.uk/guidance/conditions-and-diseases/liver-conditions/hepatitis>
- US Department of Veterans Affairs (VA), updated February 2015:
<http://www.hepatitis.va.gov/pdf/treatment-considerations-2015-02.pdf>