

# MENTAL HEALTH SUMMIT

## Invest in Mental Health. Treatment Works.

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October 17, 2014

Arvind K. Goyal, MD, MPH, MBA  
Medical Director  
Department of Healthcare and Family Services  
401 South Clinton—4th Floor  
Chicago, IL 60606

Re: DHFS Criteria for Prior Approval of Sovaldi

Dear Dr. Goyal:

It is my understanding that the Department of Healthcare and Family Services, in cooperation with the Hepatitis C Taskforce, has adopted criteria to be used for “prior approval” of Sovaldi. (See enclosure dated August 12, 2014) . I write on behalf of the Mental Health Summit (a list of our members is enclosed.) to ask you to reconsider two of those criteria—Numbers 6 and 16.

*6. The patient is mentally competent, able to make appropriate decisions about this treatment, comply with dosing and other instructions, and is capable of completing therapy.*

We are concerned because this criteria is vaguely written, may deny treatment to persons with a diagnosis of mental illness who are perfectly capable of benefitting from this medication and the criteria may be impossible to administer in any consistent and coherent manner.

Of course, any physician who is prescribing any medication should exercise her or his judgment in determining whether the patient, with or without help from family, friends or medical personnel, will take the medication in a manner which is safe and effective and consistent with the physician’s directions. But this clinical reality does not suggest that there is any clinical basis for having these judgments reviewed by DHFS as a condition for the prior authorization of Sovaldi (or any other medication). We are skeptical that there is evidence that Sovaldi is being inappropriately prescribed for people who do not meet Criteria Number 6.

Among our concerns is the reference to the patient being “mentally competent.” Illinois has specific statutory criteria for a judicial determination of competence in Section 11a-2 of the Probate Act. 755 ILCS 5/11a-2. To be found incompetent under the Probate Act requires a

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judicial hearing and other procedural protections. Moreover, this determination is generally utilized to help **provide** health care not to **deny** it. That is, the court appoints a guardian to provide informed consent for medications and other healthcare needs if it finds someone to be unable to do so her/himself. There is no reason to deny a medication even to someone found to be incompetent by a court unless arrangements cannot be made to assist an incompetent patient with the treatment. We are also concerned that Criteria Number 6 does not specify either the standards or procedures DHFS would utilize to determine whether someone is “mentally competent”.

The remainder of Criteria Number 6 is similarly problematic. If, and only if, DHFS has evidence to demonstrate that the ability to comply with dosing and instructions is a particular problem with Sovaldi, then any consideration of the patient’s ability to comply with dosing and other instructions should include a consideration of whether there are family, friends or medical personnel who are willing and able to assist the patient. Additionally, the criteria should explain how DHFS intends to determine whether a patient meet these criteria.

The Mental Health Summit urges DHFS to delete this criteria as an unnecessary roadblock to an FDA-approved medication. In the alternative, we urge that the criteria be more carefully defined. We would be happy to assist DHFS with re-drafting the criteria.

*#16 The patient does not have evidence of substance abuse diagnosis or treatment (alcohol, illicit drugs or prescription opioids and other drugs listed on the schedule of controlled drug maintained by the Drug Enforcement Administration) in the past 12 months based on department claims, records, prescriber’s knowledge, medical records entry, state’s narcotic prescription registry database, reports from a hospital, an Emergency Department visit, an urgent care clinic, a physician’s office or practice or another setting.*

Criteria #16 is problematic because it is unrelated to the patient’s **current** ability to benefit from Sovaldi. Current, untreated substance abuse may very well prevent a patient from adhering to the Sovaldi treatment regime and may be a clinically appropriate basis for denying approval for Sovaldi. However, a history of substance abuse would not. For example, a patient could have begun an intensive and successful substance abuse treatment program six months ago and be

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perfectly capable of benefitting from Sovaldi and greatly in need of this treatment. Like Criteria #6, this criteria should be either deleted or substantially modified to focus on the patient's current condition and ability to benefit from Sovaldi.

Criteria #16 also discriminates against individuals who are in Opioid Treatment Programs. In clinical trials Sovaldi has been shown to be just as effective when given in conjunction with Methadone. Indeed, the close supervision of medical care in Opioid Treatment Programs makes participants in these program **more** apt to successfully complete a course of treatment with Sovaldi than persons not in such programs.

In short, the Mental Health Summit urges that Criteria #6 and 16 be reconsidered and either eliminated or re-written.

Sincerely,

Mark J. Heyrman  
Summit Facilitator

cc: The Honorable Michael McAuliffe

enclosures.

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### Summit Members

Alexian Brothers Center for Mental Health/Behavioral Health Hospital  
Anixter  
Catholic Archdiocese of Chicago, Commission on Mental Illness  
Chasing Hope  
Chicago Institute for Psychoanalysis  
Child and Adolescent Bipolar Foundation  
Community Behavioral Healthcare Association of Illinois  
Community Counseling Centers of Chicago  
Community Mental Health Board of Chicago  
Cure-IL  
Depression and BiPolar Support Alliance  
Domestic Violence and Mental Health Policy Initiative  
Ecker Center for Mental Health  
Equip for Equality, Inc.  
GROW in Illinois  
Health and Disabilities Advocates  
Healthcare Alternative Systems  
Heartland Alliance  
Human Service Center  
Illinois Association of Community Mental Health Authorities  
Illinois Association of Rehabilitation Facilities  
Illinois Childhood Trauma Coalition  
Illinois Children's Mental Health Partnership  
Illinois Council on Problem Gambling  
Illinois Counseling Association  
Illinois Hospital Association  
Illinois Mental Health Counselor's Association  
Illinois Mental Health Planning and Advisory Council  
Illinois Rural Health Association  
Illinois Psychiatric Society  
Illinois Psychological Association  
Illinois Society for Clinical Social Work  
John Howard Association  
Kendall County Health Department  
Latino/a Mental Health Providers Network  
League of Women Voters of Illinois  
Lutheran Social Services of Illinois  
Mental Health America of Illinois  
Mental Health Consumer Education Consortium  
Mental Health Services–DuPage County Health Department  
Midwest Asian Health Association  
National Alliance on Mental Illness Cook County North Suburban  
National Alliance on Mental Illness DuPage County  
National Alliance on Mental Illness Greater Chicago  
National Alliance on Mental Illness Illinois  
National Alliance on Mental Illness Metro Suburban  
National Alliance on Mental Illness Will County  
National Alliance on Mental Illness South Suburbs of Chicago  
National Alliance on Mental Illness Southwestern Illinois  
National Association of Anorexia Nervosa and Associated Disorders  
National Association of Social Workers Illinois Chapter  
New Foundation Center  
Next Steps  
OCD--Chicago  
Recovery, Inc.  
Sankofa Organization of Illinois, Inc.  
Service Employees International Union Local 73  
Sonia Shankman Orthogenic School of the University of Chicago  
Suicide Prevention Association  
Supportive Housing Providers Association  
Thresholds, Inc.  
Trilogy  
University of Chicago Foundation for Emotionally Disordered Children  
Will County Health Department

201 South Grand Avenue East  
Springfield, Illinois 62763-0002

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**Sovaldi (Sofosbuvir) - HFS Criteria for Prior Approval  
August 12, 2014**

1. Patient is 18 years of age or over and enrolled in HFS Medical Programs.
2. Patient must have diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, or 4 confirmed by HCV RNA level and a metavir score  $\geq 4$  or equivalent.
3. The patient has not been denied Sovaldi from another insurance carrier for an acceptable cause. If approved for coverage by another carrier, HFS will only pay as a secondary payer after the primary payer has paid.
4. If patient is female, she must not currently be pregnant and may not become pregnant while taking Sovaldi. A negative pregnancy test must be obtained within the previous 30 days, and monthly thereafter during treatment with Sovaldi.
5. If patient is male, patient must not have a female partner who is currently pregnant, and agrees to use adequate contraception to avoid pregnancy during treatment.
6. The patient is mentally competent, able to make appropriate decisions about this treatment, comply with dosing and other instructions, and is capable of completing therapy.
7. The patient does not have end stage renal disease requiring dialysis.
8. The patient does not have glomerular filtration rate  $< 30$  mL/minute/1.73m<sup>2</sup>.
9. The patient, if Genotype 1, is not considered interferon-ineligible.
10. The patient does not have evidence or known diagnosis of malignancy of any body organ diagnosed within the last 12 months, or currently receiving or planning to receive chemotherapy or radiation therapy.
11. Exceptions will be made for hepatocellular carcinoma if patient has been cleared by HFS for liver transplant.
12. The patient does not have evidence of known terminal disease, with life expectancy  $< 12$  months.
13. The patient is not currently enrolled in hospice.
14. The patient is not taking rifampin, anticonvulsants, St. John's Wort or other prescribed or over-the-counter products known to be harmful while taking Sovaldi.

15. The treatment with Sovaldi is NOT for an indication outside of the FDA approved labeling and is prescribed with FDA-approved combination therapy. Further, no contraindications for use of Sovaldi exist as specified in the product labeling.
16. The patient does not have evidence of substance abuse diagnosis or treatment (alcohol, illicit drugs or prescription opioids and other drugs listed on the schedule of controlled drugs maintained by the Drug Enforcement Administration) in the past 12 months based on department claims records, prescriber's knowledge, medical record entry, state's narcotic prescription registry database, reports from a hospital, an Emergency Department visit, an urgent care clinic, a physician's office or practice or another setting.
17. The patient has a documented negative standard urine drug screen report within 15 days prior to submission of prior approval request.
18. The patient has no history of a full or incomplete course of Sovaldi treatment ("Once in a lifetime" treatment policy).
19. A full course of Sovaldi will usually consist of 12 weeks of therapy. The prescriber will submit additional information to justify a request for more than 12 weeks of therapy.
20. Sovaldi will be dispensed for 2 weeks at a time with further refills being available every 2 weeks for a total of 12 weeks (or longer if indicated).\*
21. Non-compliance with the regimen or patient's failure to obtain refills every 2 weeks will result in discontinuation of previous prior approval, and no further therapy with Sovaldi will be approved by the department.
22. Lost or misplaced Sovaldi will not be replaced, and further treatment with Sovaldi will not be approved. Exceptions will be made only in cases of an extreme hardship such as a house fire.
23. The prescriber can be any physician who holds a current unrestricted license to practice medicine and is currently enrolled as an Illinois Medicaid Provider. If the prescriber is NOT a board-certified gastroenterologist, transplant hepatologist or infectious disease specialist, a one-time written consultation report from a board-certified gastroenterologist, transplant hepatologist or infectious disease specialist will be required within the past 3 months. This consulting specialist must have recommended Sovaldi therapy prior to approval. Requests will not be accepted from mid-level practitioners and pharmacies.
24. The prescriber agrees to obtain all FDA recommended tests and to monitor therapy with Sovaldi for the entire duration of therapy.
25. The prescriber agrees to submit progress notes and HCV RNA level to HFS on patients prescribed Sovaldi within the first 8 weeks of treatment, upon completion of therapy, and at 12 months post-treatment.

\* Product stability testing suggests the medication is stable for 45 days and should be protected from light