Overview of a Hepatitis C Medication Monitoring Program in a State Medicaid Program

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Learning Assessment Question

Which of the following interventions have been successfully used by a state Medicaid program to optimize the use of Hepatitis C medications?

a. Extending duration of prior authorization for members with delayed start
b. Closing active prior authorizations for members who have discontinued therapy
c. Prescriber outreach to promote medication adherence and suggest alternative, cost-effective regimens
d. All of the above

Background

- HCV infection is the most common chronic bloodborne infection in the United States.[1]
- Two novel direct-acting antivirals — sofosbuvir and simeprevir — were approved by the FDA in late 2013.[2,3]
- AASLD/IDSA/IAS-USA recommend sofosbuvir-based combination therapy for most patients with chronic HCV genotypes 1 through 6 infection.[4]

AASLD=American Association for the Study of Liver Diseases, HCV=hepatitis C virus, IAS-USA=International Antiviral Society-USA, IDSA=Infectious Diseases Society of America

1. Workowski KA, Berman S; Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines, 2010. MMWR Recomm Rep. 2010 Dec 17;59(RR-12):1-110.
2. Sovaldi® [package insert]. Foster City (CA): Gilead Sciences, Inc.; 2013 Dec.
3. Olysio® [package insert]. Titusville (NJ): Janssen Therapeutics; 2013 Nov.
4. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. Available at http://www.hcvguidelines.org. Accessed on 8/31/14.

Background

- High cost and potential for off-label use have necessitated insurers to evaluate approach to access these medications.[5]
- Suboptimal medication adherence is associated with treatment failure and the emergence of drug resistance.[6]
- Selecting a regimen with the best chance of virologic cure, while monitoring medication adherence, may promote cost-effective care.

5. U.S. Senate Committee on Finance [letter]. Available at: http://www.finance.senate.gov/imo/media/doc/Wyden-Grassley%20Document%20Request%20to%20Gilead%207-11-141.pdf. Accessed on 8/31/14.
6. EASL. Treatment of Hepatitis. Available from: http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C.pdf. Accessed on 8/31/14.

Medication Monitoring Program Objectives

- Promote cost-effective regimen use through telephonic prescriber outreach on prior authorization (PA) requests
- Promote medication adherence through refill reminders using pharmacy claims data
- Identify members with undetectable HCV viral load 12 weeks post-therapy completion (SVR12) by conducting prescriber outreach

Methods: Tracking Log

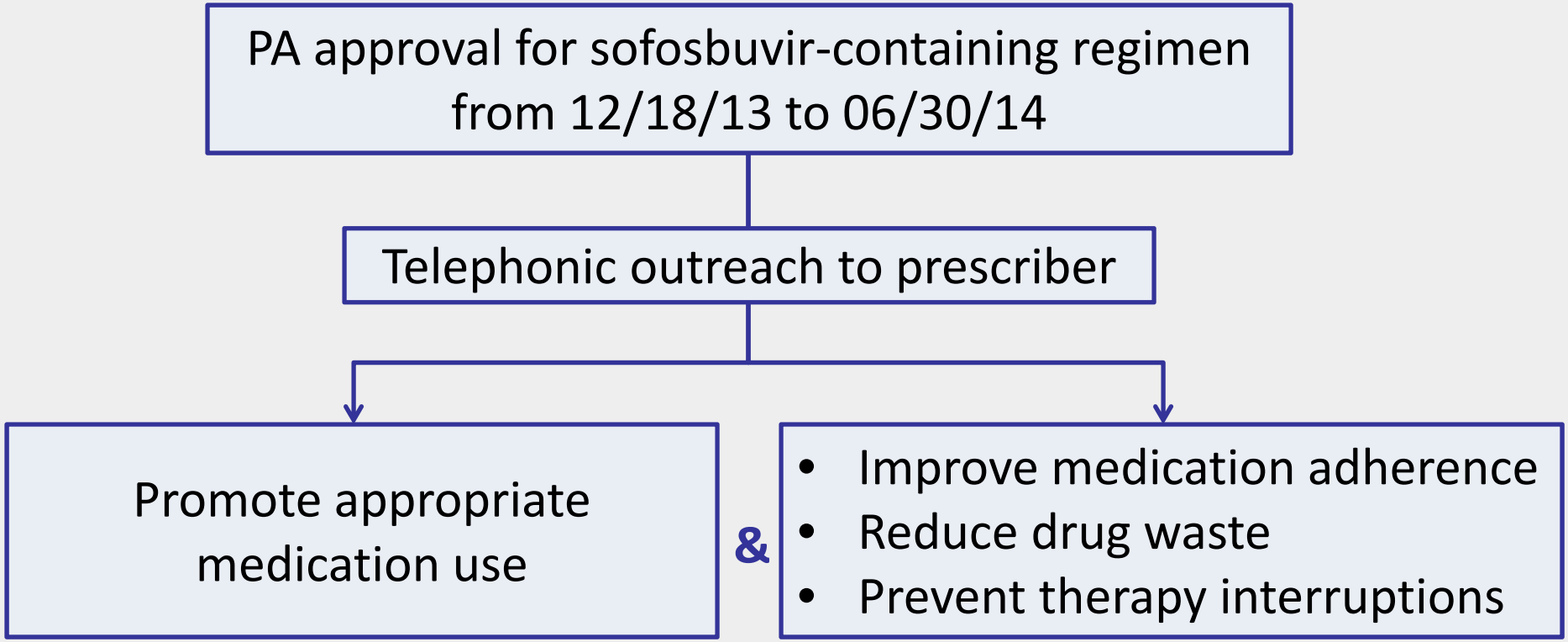
The tracking log began in December 2013.

- Member and prescriber demographics
- Disease-specific parameters, such as:
  - Baseline HCV viral load
  - HCV genotype
  - Liver disease stage
  - Prior therapy with response
- Medication fill dates
- Viral load 12 weeks after treatment completion

Methods: Interventions

- Clinical pharmacists contact prescriber
  - Discuss use of alternative regimens
  - Discuss appropriateness of therapy deferral
  - Close or extend PAs, if clinically appropriate
- Pharmacy associates contact prescriber
  - Inform of refill being due
  - Inquire if virological cure has been achieved
- Approved members with substance use disorders are referred to case management

Results: Study Population (N=396)



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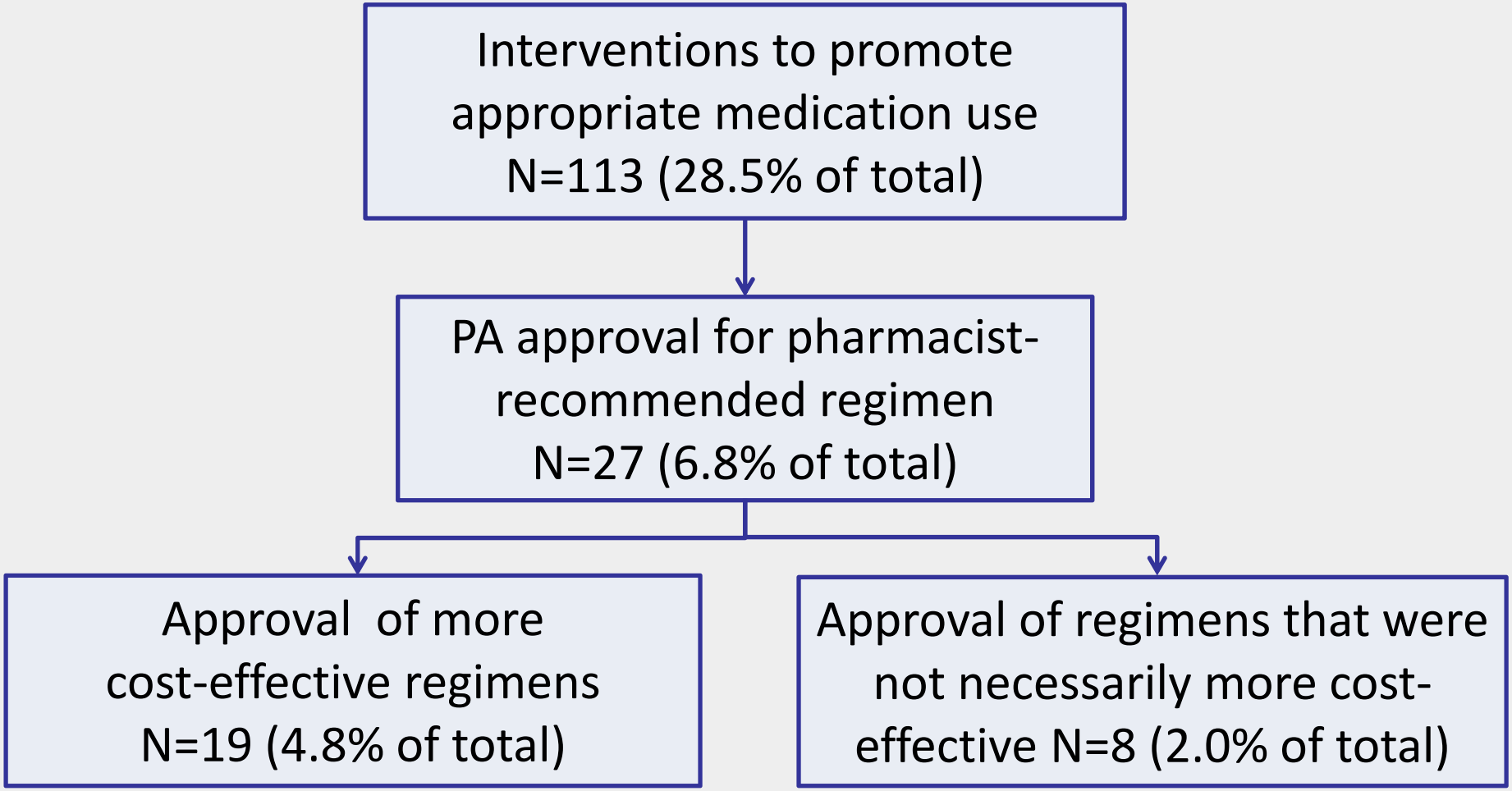


Interventions Resulting in Regimen Change

HCV Genotype 1 Infection PA Approvals			
Requested Regimen	**Recommended Regimen**	**# of Members**	**Member Characteristics**
SOF/RBV	SOF/SMV	12*	PEG ineligible
SOF+PEG/RBV	SOF/SMV	5	PEG/RBV nonresponder
SOF/SMV	SOF+PEG/RBV	4*	Treatment-naïve
SOF/SMV	SOF+PEG/RBV	1	Prior PI exposure
SOF/SMV	SOF+RBV	1	Liver decompensation
SOF/SMV	SOF+RBV	1	Prior PI exposure and PEG ineligibility

PEG=peginterferon alfa, PI=protease inhibitor, RBV=ribavirin, SMV=simeprevir, SOF=sofosbuvir

*A total of 10 members who completed treatment with the more cost-effective regimen were included in the cost-avoidance analysis.

Interventions Resulting in Regimen Change

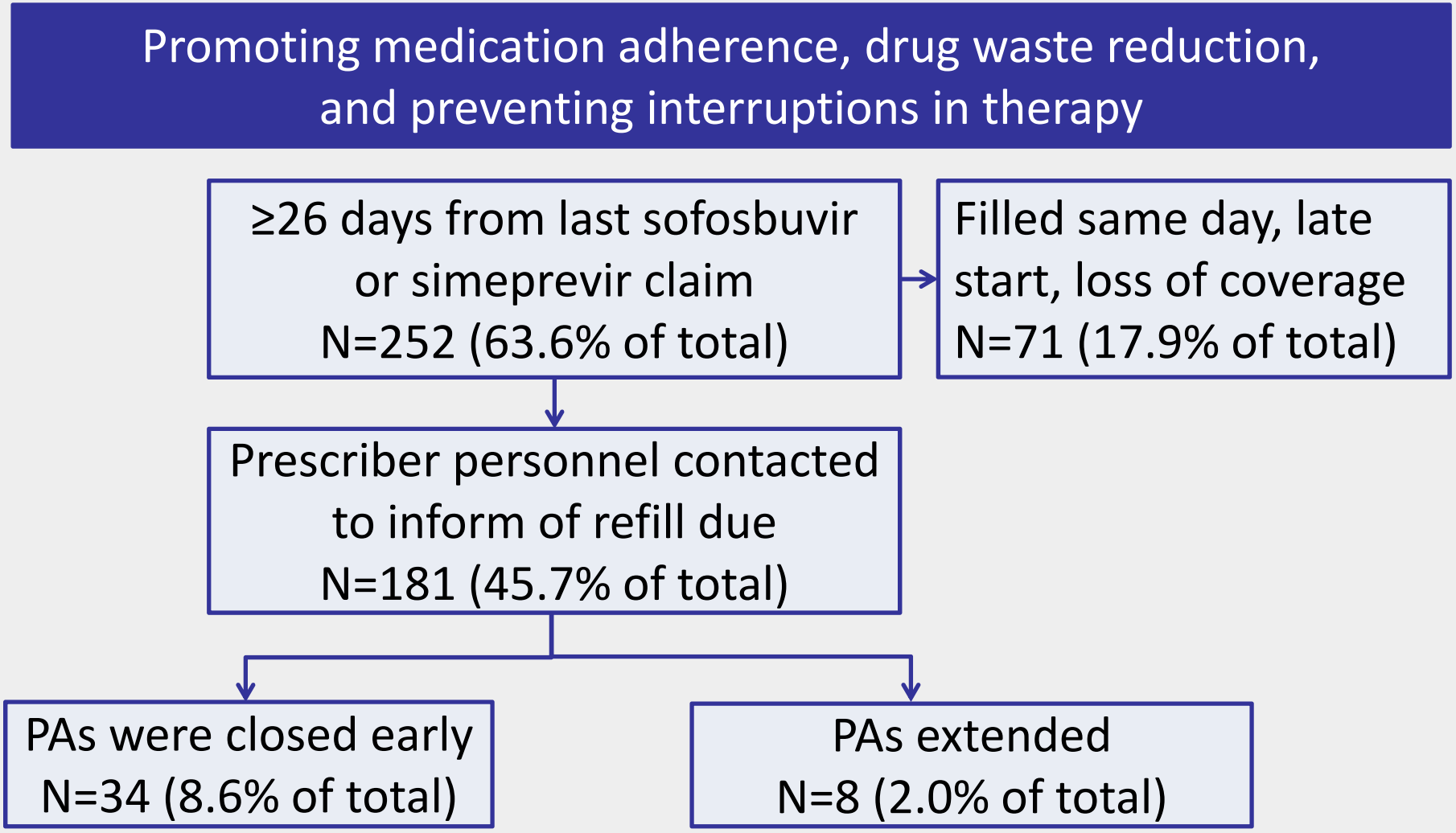
HCV Genotype 3 Infection PA Approvals			
Requested Regimen	**Recommended Regimen**	**# of Members**	**Member Characteristics**
SOF+RBV	SOF+PEG/RBV	1*	Treatment-naïve, no cirrhosis
SOF+RBV	SOF+PEG/RBV	1*	Treatment-naïve, cirrhosis
SOF+RBV	SOF+PEG/RBV	1*	Treatment-experienced, cirrhosis

PEG=peginterferon alfa, RBV=ribavirin, SOF=sofosbuvir

*A total of 10 members who completed treatment with the more cost-effective regimen were included in the cost-avoidance analysis.

- **Viral load screening conducted for one of eight members, at least 12 weeks post-therapy completion, showed virologic cure.**

Results: Study Population (N=396)



Interventions to Improve Medication Adherence

Clinical Pharmacist Interventions Resulting in PA Closure

Rationale for Intervention	Number of Members			
	SOF/RBV	SOF+PEG/RBV	SOF/SMV±RBV	Total
Nonadherence	3	0	1	**4**
Loss to follow-up	3	0	4	**7**
Adverse event	4	4	1	**9**
Therapy deferral	4	3	3	**10**
Loss of coverage	2	0	0	**2**
Change in treatment plan	0	0	2	**2**
Total	**16**	**7**	**11**	**34**

PA=prior authorization, PEG=peginterferon alfa, RBV=ribavirin, SMV=simeprevir, SOF=sofosbuvir

Interventions to Improve Medication Adherence

Clinical Pharmacist Interventions Resulting in PA Extension				
Rationale for Intervention	**Number of Members**			
	SOF/RBV	**SOF+PEG/RBV**	**SOF/SMV±RBV**	**Total**
Late start	2	3	3	**8**
Total (closed or extended PAs)	**18**	**10**	**14**	**42**

PA=prior authorization, PEG=peginterferon alfa, RBV=ribavirin, SMV=simeprevir, SOF=sofosbuvir

- **A total of 13 members with comorbid substance use disorders have been referred for enrollment into a case management program.**

Summary of Cost-Avoidance Estimates

Interventions to Promote Cost-Effective Medication Use

- 10 members completed therapy with more cost-effective, pharmacist-recommended regimen
    - Estimated cost avoidance: **$569K to $1.2M***

Intervention to Promote Medication Adherence, Reduce Drug Waste, and Prevent Therapy Interruptions

- A pharmacy for one of 34 members, for whom PAs have already been closed early, has attempted to submit a claim, which was rejected at the point-of-sale
    - Estimated drug waste cost-avoidance: **$29K**

*Cost-avoidance was calculated as the difference in cost (or cost/cure) between the pharmacist-recommended regimen and the regimen originally requested by the prescriber.

Limitations

- Lack of direct contact with the member
- Lack of directly observed therapy to ensure medication adherence
- Member loss to follow-up
- Medication adherence monitoring varies by practice site
- Insufficient time to determine if members achieved virologic cure

Learning Assessment Question #1

Which of the following interventions have been successfully used by a state Medicaid program to optimize the use of Hepatitis C medications?

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Learning Assessment Question #1

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Summary

- A Hepatitis C monitoring program has proven to be successful in this Medicaid program
  - Opportunity for optimal, cost-effective regimen selection
  - Refill reminders and member referral to case management may promote medication adherence
  - Potential for drug waste reduction from identifying members who discontinue therapy
  - Ability to identify members who achieve virologic cure
- High cost of therapy, high prevalence of chronic infections, and availability of several regimens support an ongoing monitoring program

Thank you!

Comments/Questions?

References

1. Workowski KA, Berman S; Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines, 2010. MMWR Recomm Rep. 2010 Dec 17;59(RR-12):1-110.
2. Sovaldi® [package insert]. Foster City (CA): Gilead Sciences, Inc.; 2013 Dec.
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4. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. Available at http://www.hcvguidelines.org. Accessed on 8/31/14.
5. U.S. Senate Committee on Finance [letter]. Available at: http://www.finance.senate.gov/imo/media/doc/Wyden-Grassley%20Document%20Request%20to%20Gilead%207-11-141.pdf. Accessed on 8/31/14.
6. EASL. Treatment of Hepatitis. Available from: http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C.pdf. Accessed on 8/31/14.