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# 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.<sup>1</sup>
- Two novel direct-acting antivirals — sofosbuvir and simeprevir — were approved by the FDA in late 2013.<sup>2,3</sup>
- AASLD/IDSA/IAS-USA recommend sofosbuvir-based combination therapy for most patients with chronic HCV genotypes 1 through 6 infection.<sup>4</sup>

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.<sup>5</sup>
- Suboptimal medication adherence is associated with treatment failure and the emergence of drug resistance.<sup>6</sup>
- 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)

PA approval for sofosbuvir-containing regimen  
from 12/18/13 to 06/30/14

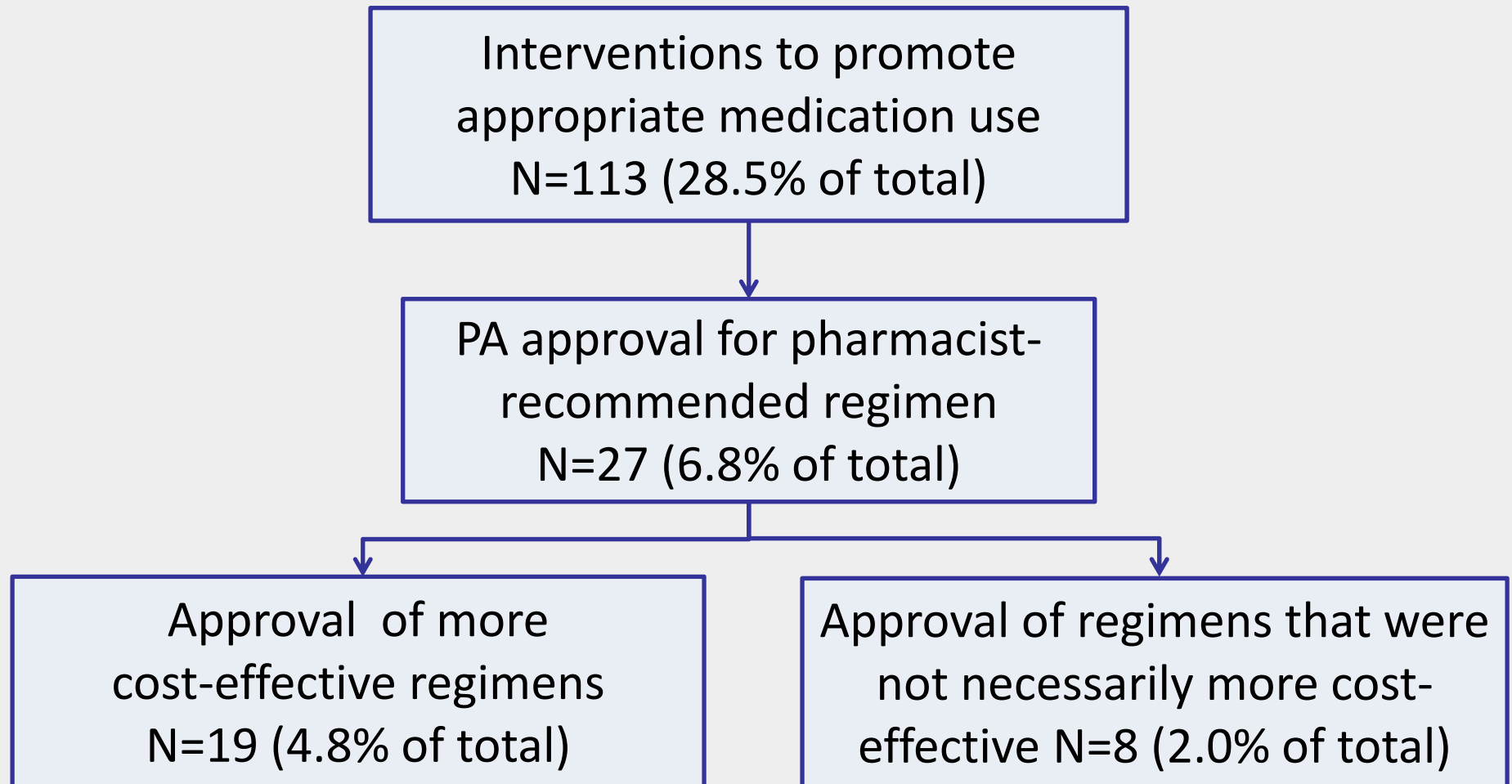
Telephonic outreach to prescriber

Promote appropriate  
medication use

&

- Improve medication adherence
- Reduce drug waste
- Prevent therapy interruptions

# Results: Study Population (N=396)



# 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

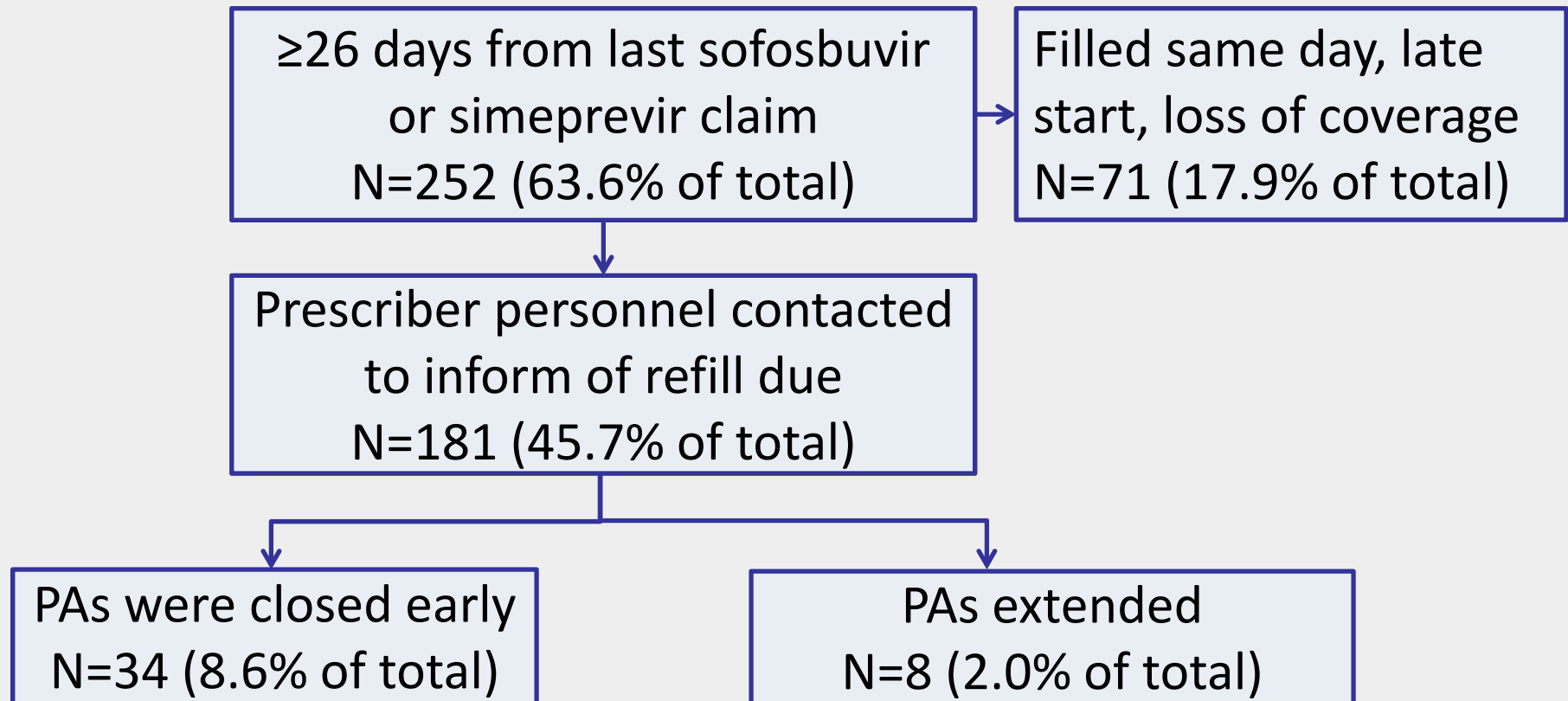
PEG=peginterferon alfa, RBV=ribavirin, SOF=sofosbuvir

\*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)

Promoting medication adherence, drug waste reduction,  
and preventing interruptions in therapy



# 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
<b>Total</b>	<b>16</b>	<b>7</b>	<b>11</b>	<b>34</b>

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
<b>Total (closed or extended PAs)</b>	<b>18</b>	<b>10</b>	<b>14</b>	<b>42</b>

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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- b. Closing active prior authorizations for members who have discontinued therapy
- c. Prescriber outreach to promote medication adherence and suggest alternative, cost-effective regimens
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# Learning Assessment Question #1

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- d. All of the above**

# 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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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.