

UNIQUE HEPATITIS C TREATMENT REGIMENS USED SINCE 2015 IN MISSISSIPPI MEDICAID

BACKGROUND

Eight new drugs have been approved for the treatment of hepatitis C since November 2013 (Table 1). These new drugs have provided significant improvement in the cure rate of the disease. Nationally, Medicaid programs and other payers have expressed concerns that a large number of patients had been “warehoused” while waiting for the introduction of new “improved” treatment options and the potential financial impact. Many state Medicaid programs restricted access to the new drugs by requiring documentation of existing hepatic fibrosis with varying levels being required by states. The Mississippi Division of Medicaid (DOM) established and has maintained prior authorization (PA) guidelines based on the American Association For The Study Of Liver Diseases (AASLD) / Infectious Diseases Society of America (ISDA) Recommendations for Testing, Managing, and Treating Hepatitis C.¹ The treatment recommendations in these guidelines do not include clinical criteria based on hepatic fibrosis level.

TABLE 1: New Drugs Approved for Hepatitis C Treatment

Hepatitis C drug	FDA Approval Date
Olysio	November 2013
Sovaldi	December 2013
Harvoni	October 2014
Viekira Pak	December 2014
Technivie	July 2015
Daklinza	July 2015
Zepatier	January 2016
Epclusa	June 2016

During the February 2017 DUR Board Meeting a board member requested an update on the treatment trend for hepatitis C in Medicaid. In response to this inquiry, MS-DUR conducted an analysis to examine the number of beneficiaries treated and the specific regimens used for treatment of hepatitis C during the last two years.

METHODS

MS-DUR conducted a retrospective analysis using Division of Medicaid (DOM) pharmacy claims from all the pharmacy programs including fee-for-service (FFS) and coordinated care organizations (CCOs) for the period July 1, 2014 – February 28, 2017. Data from 2014 was used as a “wash out” period so that new treatment starts could be identified in January of 2015.

Identifying treatment regimens: Recommended regimens consist of using one, and sometimes two, of the new medications listed in Table 1. Some recommended regimens include the addition of pegylated interferon and/or ribavirin. MS-DUR used refill patterns for each medication option to determine regimens used to treat beneficiaries. Regimens were identified as the combination of drugs used concomitantly. The length of treatment was determined by the total days supply of the major drug used in the regimen. Refill gaps resulting in lack of possession of the major drug in the regimen for 30 days or more were classified as breaks in therapy with the next prescription fill considered to be a restart of therapy.

¹ American Association for The Study of Liver Diseases (AASLD) / Infectious Diseases Society of America (ISDA) Recommendations for Testing, Managing, and Treating Hepatitis C. <http://www.hcvguidelines.org/full-report-view>

RESULTS

Table 2 shows the number of beneficiaries starting hepatitis C treatment regimens during each quarter since January 2015. There was a sharp increase in the number of beneficiaries starting treatment during the first quarter of 2015. Since that time, there has been a slow decline in the number of beneficiaries starting treatment with approximately 50-60 currently initiating treatment each quarter. Harvoni monotherapy has been the dominant treatment regimen since it was introduced to the market. Recently there has been an increase in Eplusa use.

**TABLE 2: Number of Beneficiaries Starting Hepatitis C Treatment Regimens
by Quarter Started**

Regimen	Quarter When Regimen Started*									Total
	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2016	
ALL PHARMACY PROGRAMS										
Epclusa							3	17	5	25
Harvoni	33	86	69	49	53	45	39	35	21	430
Harvoni / Viekira Pak	0	0	0	1	0	0	0	0	0	1
Harvoni / ribavirin	0	0	0	0	0	3	0	2	1	6
Sovaldi	0	0	0	0	1	1	0	0	0	2
Sovaldi / Daklinza			0	1	3	3	2	0	0	9
Sovaldi / Daklinza / ribavirin			0	0	0	1	0	0	0	1
Sovaldi / peg-interferon / ribavirin	0	0	0	0	0	0	1	0	0	1
Sovaldi / ribavirin	7	13	15	8	5	19	3	2	0	72
Viekira Pak / ribavirin	0	6	2	0	1	0	2	0	1	12
Zepatier					0	0	1	3	3	7
TOTAL STARTS	40	105	86	59	63	72	51	59	31	566
FFS										
Epclusa							2	3	0	5
Harvoni	10	7	10	11	11	8	7	9	4	77
Harvoni / ribavirin	0	0	0	0	0	1	0	2	1	4
Sovaldi / Daklinza			0	0	1	1	2	0	0	4
Sovaldi / ribavirin	2	1	1	3	1	0	0	0	0	8
Viekira Pak / ribavirin	0	1	0	0	0	0	0	0	0	1
Zepatier					0	0	0	0	1	1
TOTAL STARTS	12	9	11	14	13	10	11	14	6	100
UHC										
Epclusa							0	6	4	10
Harvoni	10	24	25	18	18	20	16	10	5	146
Sovaldi	0	0	0	0	1	0	0	0	0	1
Sovaldi / peg-interferon / ribavirin	0	0	0	0	0	0	1	0	0	1
Sovaldi / ribavirin	1	3	7	2	0	2	1	2	0	18
Viekira Pak / ribavirin	0	3	0	0	0	0	0	0	0	3
Zepatier					0	0	1	1	0	2
TOTAL STARTS	11	30	32	20	19	22	19	19	9	181
MAG										
Epclusa							1	8	1	10
Harvoni	13	55	34	20	24	17	16	16	12	207
Harvoni / Viekira Pak	0	0	0	1	0	0	0	0	0	1
Harvoni / ribavirin	0	0	0	0	0	2	0	0	0	2
Sovaldi	0	0	0	0	0	1	0	0	0	1
Sovaldi / Daklinza			0	1	2	2	0	0	0	5
Sovaldi / Daklinza / ribavirin			0	0	0	1	0	0	0	1
Sovaldi / ribavirin	4	9	7	3	4	17	2	0	0	46
Viekira Pak / ribavirin	0	2	2	0	1	0	2	0	1	8
Zepatier					0	0	0	2	2	4
TOTAL STARTS	17	66	43	25	31	40	21	26	16	285

* Data for 2017 Q1 are not complete.

Beneficiaries receiving more than one treatment regimen were identified in order to evaluate effectiveness of the new treatment regimens. Only seven (7) beneficiaries were identified as having two treatment regimens. In each of these cases, the beneficiary initiated treatment with Harvoni monotherapy and had a more than 30-day lapse in therapy before filling a second prescription for Harvoni. All of these cases occurred in 2015. These cases could indicate poor compliance and a decision to not approve continued treatment after the second prescription fill. However, these cases could also have been 8-week treatment regimens where the patients did not start the medication until several weeks after the first prescription fills.

CONCLUSIONS

The number of beneficiaries being treated for hepatitis C spiked in early 2015 and has declined to around 50-60 beneficiaries per quarter at this time. Some problems have occurred with beneficiaries not completing their regimens. Hepatitis C regimens are expensive. When patients do not complete their regimens, a successful outcome (cure) is highly unlikely. Hepatitis C is one of the initial disease categories being addressed by DOM's new Complex Pharmacy Care program.