Monitoring hepatitis C treatment uptake in Australia

Issue #3 July 2016[1]

Reimbursements for new treatment for chronic hepatitis C during March to May 2016

A total of 11,216 patient PBS initial prescriptions for hepatitis C direct acting antiviral (DAA) were processed for reimbursement during March to May 2016. Based on extrapolation of wholesale data to PBS reimbursement data, to account for the time lag in reporting, an estimated 17,870 (range: 15,100 – 20,700) individuals initiated DAA treatment during March to May 2016, equating 8% (range: 7 – 9%) of total individuals living with chronic hepatitis C in Australia. Most individuals (79%) were prescribed under the General Schedule (S85). The most commonly prescribed regimen was sofosbuvir/ledipasvir for 58%, followed by sofosbuvir/daclatasvir for 38%. Based on PBS reimbursement data in March, 63% of prescriptions were for men and 37% for women. Almost half (48%) of prescriptions were among individuals 51-60 years.

New treatments for chronic hepatitis C virus (HCV) infection, named direct acting antiviral (DAA) therapy, were recently listed on the Pharmaceutical Benefits Scheme (PBS): sofosbuvir/ledipasvir (Harvoni®), sofosbuvir/daclatasvir (Sovaldi®/Daklinza®), sofosbuvir/ribavirin (Sovaldi®/Ibavyr®), and sofosbuvir/pegylated interferon-alfa-2a/ribavirin (Sovaldi®/Pegysus®/ribavirin) in March 2016, and ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira PAK®) in May 2016.[2]

1. The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 3). The Kirby Institute, UNSW Australia, Sydney, Australia, July 2016 (available online at: http://kirby.unsw.edu.au/research-programs/vhcrp-newsletters)
2. Given the listing of Viekira PAK®, in May 2016 and time lag for PBS reimbursement data, the number of individuals initiating on Viekira PAK® were not included in this issue. Data will be included in subsequent issues.

Issue #3 newsletter provides data on:

- Estimated total number of individuals initiating HCV DAA treatment during March to May 2016
- Estimated proportion of individuals living with chronic HCV who initiated DAA treatment during March to May 2016, by jurisdiction
- The number of PBS reimbursement-based DAA prescriptions during March to May 2016, by month, jurisdiction, regimen, and PBS schedule.
- The number of individuals initiating HCV DAA treatment in March 2016, by gender and age.

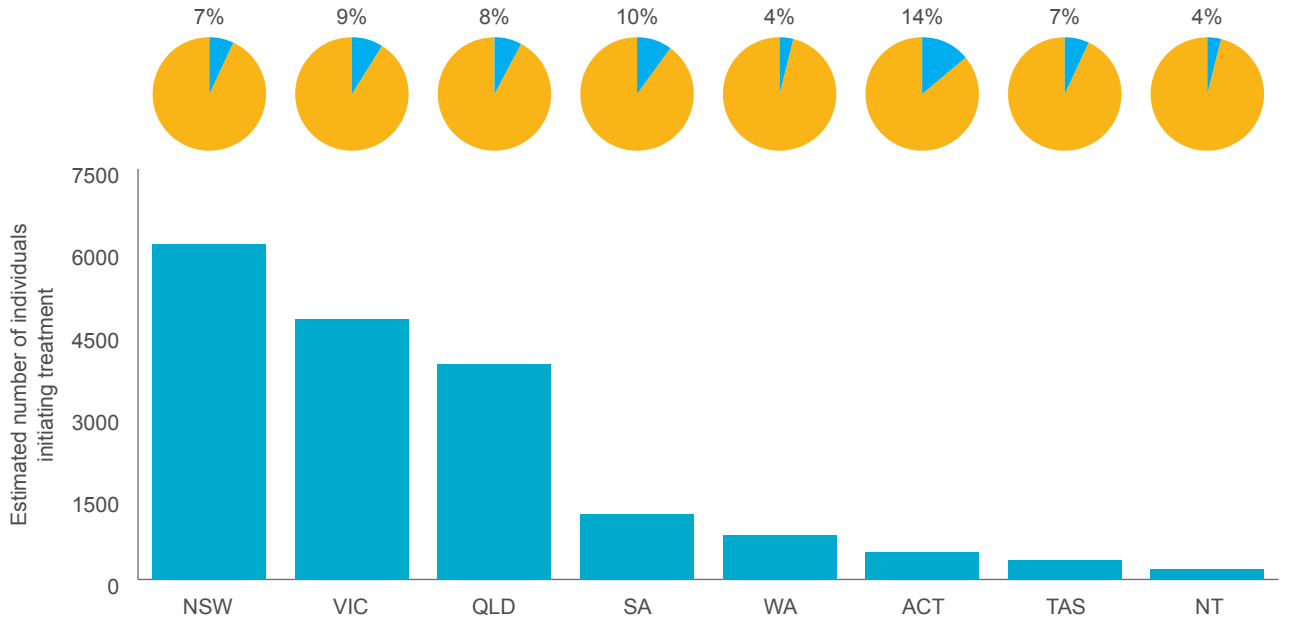
Estimated hepatitis C DAA treatment initiations

Based on extrapolation of wholesale data to PBS reimbursement data, to account for the time lag in reporting, an estimated 17,870 (range: 15,100 – 20,700) individuals initiated chronic HCV DAA treatment during March to May 2016 in Australia, including 6,120 in New South Wales, 4,760 in Victoria, 3,930 in Queensland, 1,200 in South Australia, 820 in Western Australia, 510 in Australian Capital Territory, 350 in Tasmania, and 190 in Northern Territory (Figure 1).

Estimated proportion of individuals living with chronic HCV who initiated DAA treatment

In 2014, an estimated 230,470 individuals were living with chronic HCV in Australia, including, 81,940 individuals in New South Wales, 55,760 individuals in Victoria, 47,950 individuals in Queensland, 11,850 in South Australia, 20,510 in Western Australia, 3,650 in Australian Capital Territory, 5,130 in Tasmania, and 3,690 in Northern Territory.[3] Therefore it is estimated that 8% (range 7 - 9%) of total individuals living with chronic HCV in Australia have initiated DAA treatment during March to May 2016, including 7% in New South Wales, 9% in Victoria, 8% in Queensland, 10% in South Australia, 4% in Western Australia, 14% in Australian Capital Territory, 7% in Tasmania, and 5% in Northern Territory (Figure 1).

Figure 1: The estimated number of individuals initiating HCV DAA treatment (bar charts) and the proportion of individuals living with chronic HCV who initiated DAA treatment (pie charts) during March to May 2016, by jurisdiction



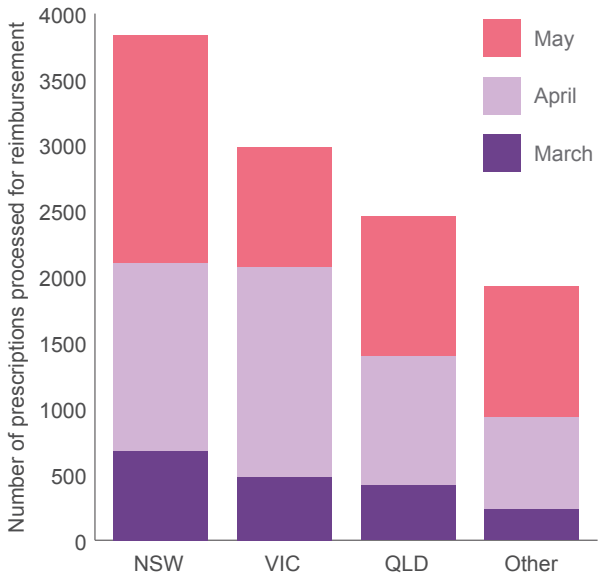
NSW: New South Wales; VIC: Victoria; QLD: Queensland; SA: South Australia; WA: Western Australia; ATC: Australian Capital Territory; TAS: Tasmania; NT: Northern Territory

3. The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia. Annual Surveillance Report 2015. The Kirby Institute, UNSW Australia, Sydney NSW 2052

Hepatitis C DAA prescriptions processed by the PBS by month, jurisdiction, PBS scheme, and regimen

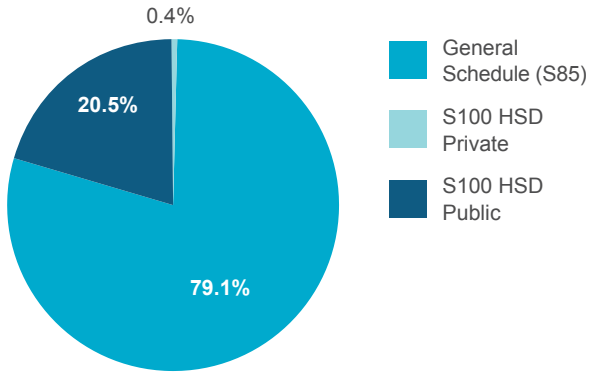
A total of 11,216 individuals had chronic HCV DAA initial prescriptions processed by the PBS during March to May 2016, including 34% (n=3,838) in New South Wales, 27% (n=2,985) in Victoria, 22% (n=2,464) in Queensland, and 17% (n=1,929) in the other jurisdictions (Figure 2). Further information for individual jurisdictions is provided in Table 1. The monthly numbers do not represent the monthly treatment initiations, but PBS reimbursement-based reporting. Due to the time lag, it is likely that a large proportion of April PBS reimbursements and even some of May PBS reimbursements are for individuals initiating in March. Similarly a large proportion of May treatment initiations will not be included in these figures (more details are provided in the Methodology section).

Figure 2: Number of chronic HCV DAA initial prescriptions processed for reimbursement by the PBS during March to May 2016 in Australia, by month and jurisdiction



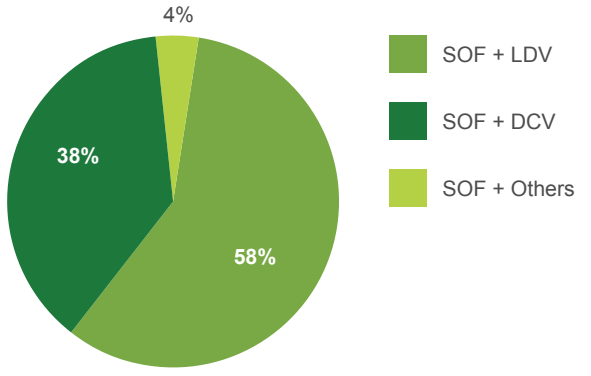
Most individuals (79%) were prescribed under the General Schedule (S85), 20% under S100 HSD Public and <1% under S100 HSD Private (Figure 3). The 20% for S100 is an increase from the 9% in Issue #1 (March PBS data), which may indicate a longer lag for S100 versus S85 scheme reimbursement reporting, rather than an actual increase in S100 prescribing.

Figure 3: Distribution of PBS schedule of chronic HCV DAA prescriptions during March to May 2016 in Australia



The most commonly prescribed regimen was sofosbuvir/ledipasvir, for 58% (n=6,508), followed by sofosbuvir/daclatasvir for 38% (n=4,294), and sofosbuvir/other agents for 4% (n=414; Figure 4). Other agents would include ribavirin, or pegylated interferon-alfa-2a/ribavirin.

Figure 4: Distribution of chronic HCV DAA regimens prescribed during March to May 2016 in Australia



*SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir ; NSW: New South Wales; VIC: Victoria; QLD: Queensland

Of individuals initiated on sofosbuvir/ledipasvir (n=6,508), 9% (n=570) were prescribed an 8-week course, 73% (n=4,722) a 12-week course, and 19% (n=1,216) a 24-week course.

Of individuals initiated on sofosbuvir/daclatasvir (n=4,294), 55% (n=2,360) were prescribed a 12-week course, and 45% (n=1,934) a 24-week course.

Of individuals initiated on sofosbuvir/other agents (n=414), 95% (n=392) were prescribed a 12-week course, and 4% (n=22) a 24-week course (Figure 5 and Figure 6).

The vast majority of individuals prescribed sofosbuvir/daclatasvir for 24 weeks (n=1,934; 45% of total sofosbuvir/daclatasvir) will be individuals with genotype 3 and cirrhosis. Those prescribed sofosbuvir/ledipasvir for 24 weeks (n=1,216; 19% of total sofosbuvir/ledipasvir) should represent individuals with genotype 1, prior treatment and cirrhosis.

Figure 5: Distribution of chronic HCV DAA prescriptions during March to May 2016 in Australia, by treatment regimen and treatment course duration

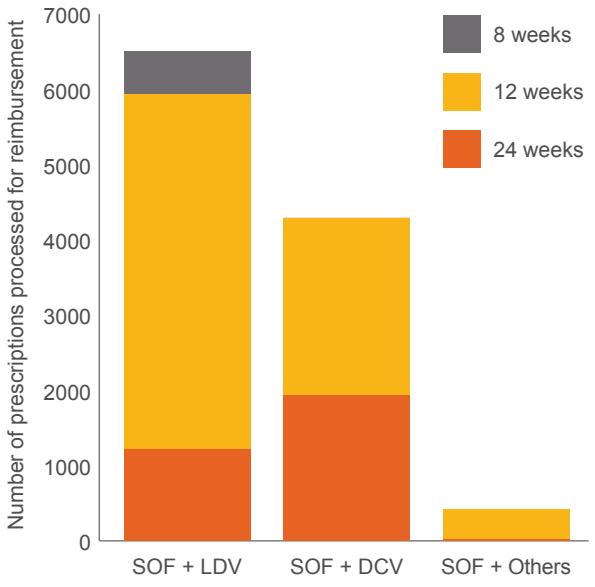


Figure 6: Distribution of chronic HCV DAA prescriptions during March to May 2016 in Australia, by treatment regimen, treatment course duration and jurisdiction

*SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir ; NSW: New South Wales; VIC: Victoria; QLD: Queensland

Table 1: Distribution of chronic HCV DAA prescriptions during March to May 2016 in Australia, by regimen, jurisdiction and PBS schedule (based on the number of prescriptions processed for reimbursement by PBS)

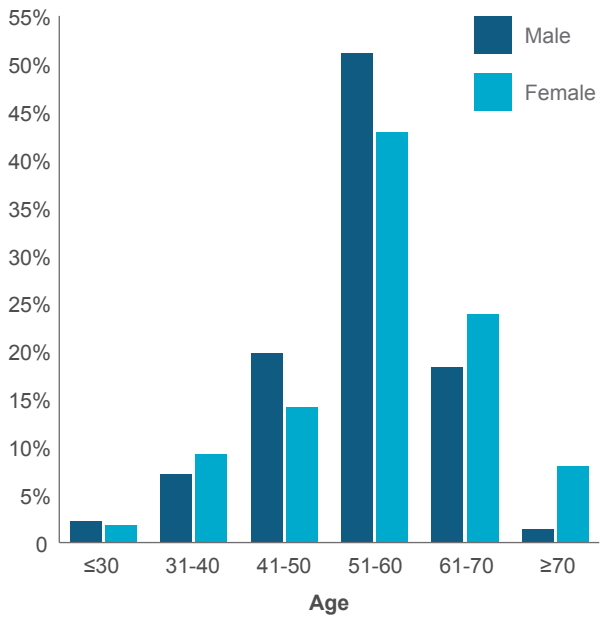
			NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Total
SOFOSBUVIR + LEDIPASVIR	General Schedule	24 weeks	257	299	240	62	56	15	1	2	**932**
SOFOSBUVIR + LEDIPASVIR	S100 HSD Private	24 weeks	2	0	2	0	0	0	0	0	**4**
SOFOSBUVIR + LEDIPASVIR	S100 HSD Public	24 weeks	152	30	36	7	30	1	15	9	**280**
SOFOSBUVIR + LEDIPASVIR	General Schedule	12 weeks	1210	1189	893	277	132	82	44	14	**3841**
SOFOSBUVIR + LEDIPASVIR	S100 HSD Private	12 weeks	7	3	0	0	0	0	0	0	**10**
SOFOSBUVIR + LEDIPASVIR	S100 HSD Public	12 weeks	407	121	86	30	71	5	114	37	**871**
SOFOSBUVIR + LEDIPASVIR	General Schedule	8 weeks	221	84	131	29	3	11	6	1	**486**
SOFOSBUVIR + LEDIPASVIR	S100 HSD Private	8 weeks	2	0	0	0	0	0	0	0	**2**
SOFOSBUVIR + LEDIPASVIR	S100 HSD Public	8 weeks	26	12	11	20	1	0	6	6	**82**
SOFOSBUVIR + DACLATASVIR	General Schedule	24 weeks	392	470	358	115	56	29	12	1	**1433**
SOFOSBUVIR + DACLATASVIR	S100 HSD Private	24 weeks	7	3	2	0	0	0	1	0	**13**
SOFOSBUVIR + DACLATASVIR	S100 HSD Public	24 weeks	229	60	68	16	48	0	39	28	**488**
SOFOSBUVIR + DACLATASVIR	General Schedule	12 weeks	561	591	468	141	49	63	23	5	**1901**
SOFOSBUVIR + DACLATASVIR	S100 HSD Private	12 weeks	4	4	0	3	0	0	0	0	**11**
SOFOSBUVIR + DACLATASVIR	S100 HSD Public	12 weeks	221	50	53	21	48	2	51	2	**448**
SOFOSBUVIR + Others	General Schedule	24 weeks	0	2	8	0	4	3	0	0	**17**
SOFOSBUVIR + Others	S100 HSD Private	24 weeks	2	0	0	0	0	0	0	0	**2**
SOFOSBUVIR + Others	S100 HSD Public	24 weeks	3	0	0	0	0	0	0	0	**3**
SOFOSBUVIR + Others	General Schedule	12 weeks	74	50	90	30	5	8	3	0	**260**
SOFOSBUVIR + Others	S100 HSD Private	12 weeks	0	0	1	0	0	0	0	0	**1**
SOFOSBUVIR + Others	S100 HSD Public	12 weeks	61	17	17	5	12	0	3	16	**131**
		Total	**3838**	**2985**	**2464**	**756**	**515**	**219**	**318**	**121**	**11216**

*NSW: New South Wales; VIC: Victoria; QLD: Queensland; SA: South Australia; WA: Western Australia; TAS: Tasmania; ACT: Australian Capital Territory; NT: Northern Territory

Hepatitis C DAA treatment initiation in March 2016, by patient gender and age

Based on PBS reimbursement data in March 2016, which now has available gender and age information, 63% of prescriptions were for men and 37% for women. Almost half (48%) of prescriptions were among individuals 51-60 years (Figure 7).

Figure 7: Age distribution of individuals with chronic HCV, initiating DAA treatment in March 2016, by gender



Methodology

Two data sources were used for analysing DAA uptake during March to May 2016: PBS monthly reports of prescriptions processed for reimbursement; and wholesale expenditure data. For gender- and age-specific analysis of DAA treatment initiation in March 2016, data on a 10% random sample of PBS reimbursements was available.

PBS reports the number of prescriptions processed for reimbursement on a monthly basis. Pharmacies submit prescriptions for reimbursement 2-12 weeks (generally 2-4 weeks) after dispensing. Therefore, PBS reports of the number of prescriptions are subject to a time lag between drug dispensing and reimbursement submissions. This lag may also vary by pharmacy type, with potentially longer lags for public hospital-based pharmacies (S100 scheme) compared to community-based pharmacies (S85 scheme).

The wholesale price expenditure on chronic HCV DAA drugs during March to May has been estimated at 1.59 times wholesale price equivalent for PBS reimbursements reported for the same period.[4] For the estimate of the number of individuals initiated on HCV treatment during March to May 2016, we have used 1.59 as the adjustment factor with a range of 1.34-1.84 given inherent uncertainties within this methodology. Similar adjustments were applied to jurisdiction-specific data assuming a consistent time lag over jurisdictions.

PBS provided aggregated monthly data, rather than individual patient data. Then three assumptions have been made in reporting of the PBS reimbursement data, and in extrapolation:

1. All individuals who initiated a 12-week or a 24-week DAA treatment course in March have continued treatment in April and May.
2. All individuals who initiated any DAA treatment in April (8-week, 12-week or 24-week) have continued treatment in May.
3. The time lag is similar for individuals initiated in March, April and May.

Therefore, the aggregated numbers reported for the month of May for each regimen, duration, and scheme (except for March initiations on an 8-week treatment course) will represent all individuals initiated in March, April and May. The number of prescriptions for the 8-week treatment courses initiated in March have not been included in May report, given that the prescriptions were dispensed in March and April. Then the number of 8-week treatment courses initiated in March was added to the total number reported in May.

Data on dispensed DAA prescriptions for a longitudinal cohort of individuals representing a 10% random sample of the PBS database were used for more detailed analysis of DAA treatment initiation in March 2016. These data provide more details, including the patients' age and gender.

4. Have HCV therapies already topped $1 billion? PharmaDispatch, 29 June 2016