

Monitoring hepatitis C treatment uptake in Australia

Issue #4 August 2016¹

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

An estimated 15,493 patient PBS initial prescriptions for hepatitis C direct acting antiviral (DAA) were processed for reimbursement during March to June 2016. Based on extrapolation of wholesale data to PBS reimbursement data, to account for the time lag in reporting, an estimated 22,470 individuals initiated DAA treatment during March to June 2016, including 7,240 individuals in March, 7,390 individuals in April, 3,250 individuals in May, and 4,590 individuals in June. It is estimated that 10% of total individuals living with chronic hepatitis C in Australia have initiated DAA treatment during March to June 2016. 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 37%.

New treatments for chronic hepatitis C virus (HCV) infection, named direct acting antiviral (DAA) therapy, were 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 paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira PAK®) in May 2016.

1. The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 4). The Kirby Institute, UNSW Australia, Sydney, Australia, August 2016 (available online at: <http://kirby.unsw.edu.au/research-programs/vhcrp-newsletters>).

Issue #4 newsletter provides data on:

- Estimated number of individuals initiating HCV DAA treatment during March to June 2016, by month and jurisdiction
- Estimated proportion of individuals living with chronic HCV who initiated DAA treatment during March to June 2016, by jurisdiction
- Number of PBS reimbursement-based DAA prescriptions during March to June 2016, by jurisdiction, regimen, and PBS schedule.

Estimated hepatitis C DAA treatment initiations

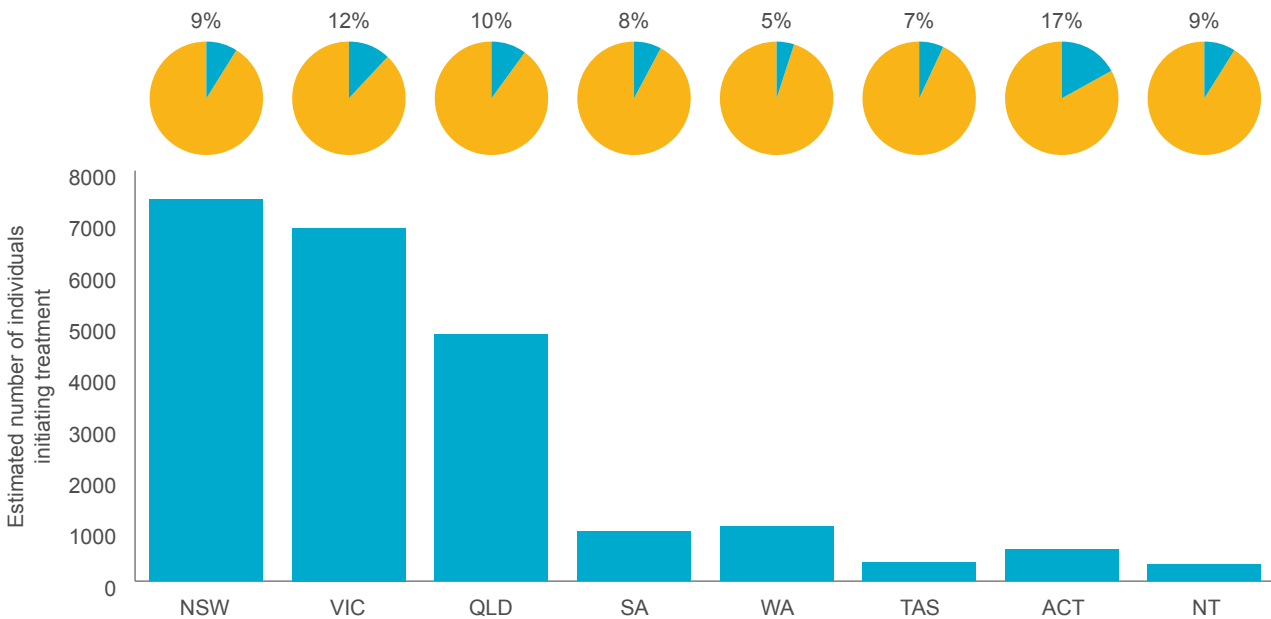
Based on extrapolation of wholesale data to PBS reimbursement data to account for the time lag in reporting and other adjustments (details provided in the Methodology section), an estimated 22,470 (range: 19,080 – 25,850) individuals initiated chronic HCV DAA treatment during March to June 2016 in Australia, including 7,430 in New South Wales, 6,880 in Victoria, 4,810 in Queensland, 970 in South Australia², 1,060 in Western Australia, 370 in Tasmania, 620 in Australian Capital Territory, and 320 in Northern Territory (Figure 1).

Estimated monthly numbers of individuals initiating DAA treatment was 7,240 in March, 7,390 in April, 3,250 in May, and 4,590 in June (Figure 2).

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, 5,130 in Tasmania, 3,650 in Australian Capital Territory, and 3,690 in Northern Territory.³ Therefore it is estimated that 10% (range 8 - 11%) of total individuals living with chronic HCV in Australia have initiated DAA treatment during March to June 2016, including 9% in New South Wales, 12% in Victoria, 10% in Queensland, 8% in South Australia, 5% in Western Australia, 7% in Tasmania, 17% in Australian Capital Territory, and 9% in Northern Territory (Figure 1).

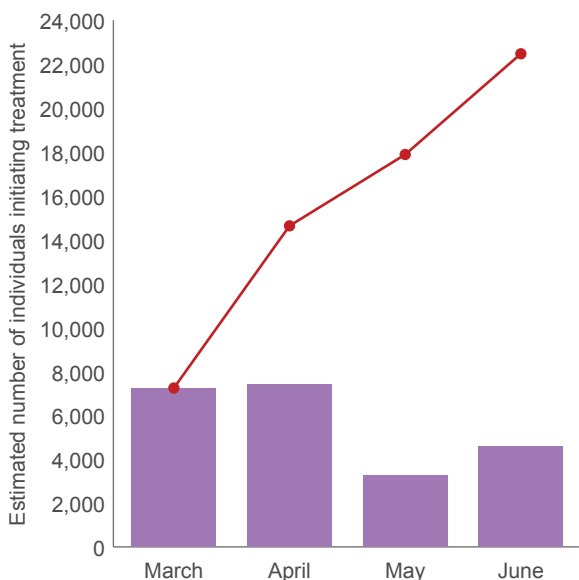
Figure 1: The estimated number of individuals initiating HCV DAA treatment (bar charts) and the proportion of individuals living with chronic HCV who initiated DAA treatment (pie charts) during March to June 2016, by jurisdiction²



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

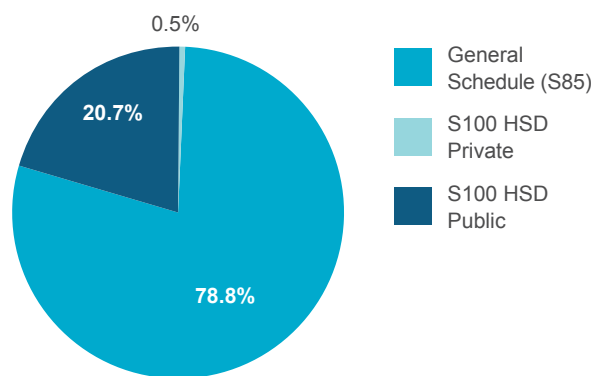
2. The data of South Australia should be interpreted conservatively. The number of prescriptions in June reported by PBS was substantially lower than that in the previous month (more details in the methodology section).
 3. The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia. Annual Surveillance Report 2015. The Kirby Institute, UNSW Australia, Sydney NSW 2052

Figure 2: The estimated number of individuals initiating HCV DAA treatment in each month (bars) during March to June 2016. The red line represents the cumulative treatment initiation numbers.



Most individuals (79%) were prescribed under the General Schedule (S85), 21% under S100 HSD Public and <1% under S100 HSD Private (Figure 3). The proportion of S100 HSD Public scheme in PBS data is highly variable across jurisdictions: New South Wales (30%), Victoria (13%), Queensland (7%), South Australia (1%), Western Australia (38%), Tasmania (8%), Australian Capital Territory (68%), and Northern Territory (83%). The S100 percent in PBS data has been gradually increased from 9% in March to 17% in April and 21% in May and June. It may represent 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 June 2016 in Australia



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

A total of 15,493 individuals had chronic HCV DAA initial prescriptions processed by the PBS during March to June 2016, including 33% (n=5,046) in New South Wales, 33% (n=5,100) in Victoria, 21% (n=3,265) in Queensland, and 13% (n=2,082) in the other jurisdictions. Further information for individual jurisdictions is provided in Table 1.

Table 1

	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Total
General Schedule	3,503	4,421	3,008	441	434	227	127	48	12,209
S100 HSD Private	32	13	22	6	0	0	0	0	73
S100 HSD Public	1,511	666	235	3	267	20	274	235	3,211
Total	5,046	5,100	3,265	450	701	247	401	283	15,493

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

The most commonly prescribed regimen was sofosbuvir/ledipasvir, for 58% (n=8,994), followed by sofosbuvir/daclatasvir for 37% (n=5,809), and sofosbuvir/other agents for 4% (n=576) and paritaprevir/ritonavir/ombitasvir/dasabuvir for 1% (n=114; Figure 4). Other agents used in combination with sofosbuvir include ribavirin, or pegylated interferon-alfa-2a/ribavirin.

Of individuals initiated on sofosbuvir/ledipasvir (n=8,994), 10% (n=867) were prescribed an 8-week course, 72% (n=6,520) a 12-week course, and 18% (n=1,607) a 24-week course.

Of individuals initiated on sofosbuvir/daclatasvir (n=5,809), 56% (n=3,279) were prescribed a 12-week course, and 44% (n=2,530) a 24-week course.

Of individuals initiated on sofosbuvir/other agents (n=414), 96% (n=551) were prescribed a 12-week course, and 4% (n=25) a 24-week course.

Of individuals initiated on paritaprevir/ritonavir/ombitasvir/dasabuvir ± ribavirin (n=114), 92% (n=105) were prescribed a 12-week course, and 8% (n=9) a 24-week course (Figure 5 and Figure 6). Forty-three individuals were prescribed paritaprevir/ritonavir/ombitasvir/dasabuvir + ribavirin for 12 weeks (n=34) or 24 weeks (n=9).

The vast majority of 2,530 individuals prescribed sofosbuvir/daclatasvir for 24 weeks will be individuals with genotype 3 and cirrhosis. Those prescribed sofosbuvir/ledipasvir for 24 weeks (n=1,607) or paritaprevir/ritonavir/ombitasvir/dasabuvir + ribavirin for 12 weeks (n=9) should represent individuals with genotype 1, prior treatment and cirrhosis.

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

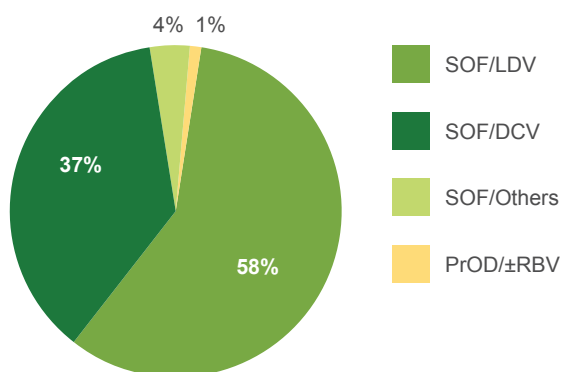
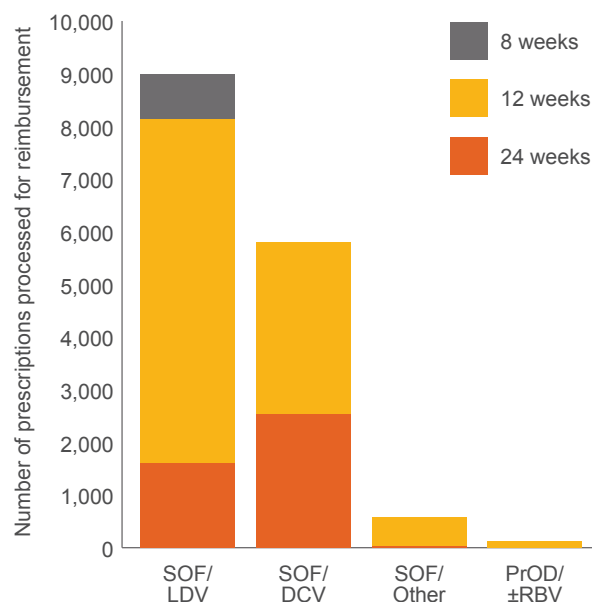
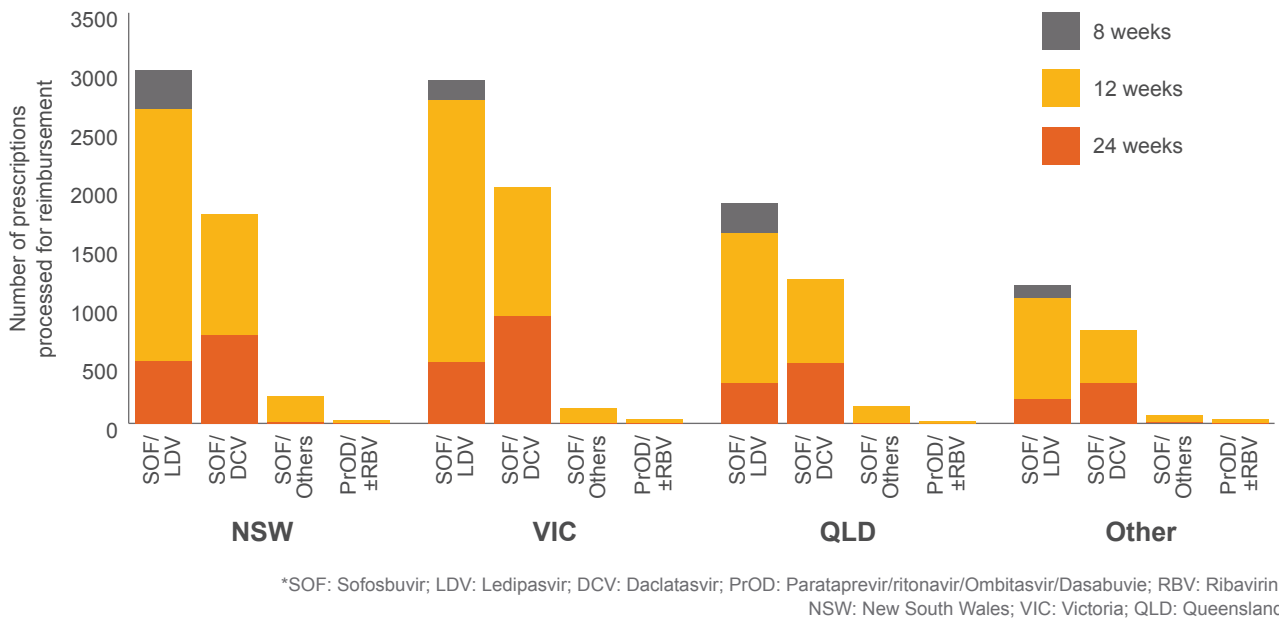


Figure 5: Distribution of chronic HCV DAA prescriptions during March to June 2016 in Australia, by treatment regimen and treatment course duration



*SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir; PrOD: Parataprevir/ritonavir/Ombitasvir/Dasabuvie; RBV: Ribavirin

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




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.

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 June has been estimated at 1.33 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 June 2016, we have used 1.33 as the adjustment factor with a range of 1.13-1.53 given inherent uncertainties within this methodology. In the jurisdiction level, the proportion of cumulative PBS prescription number from March to June in each jurisdiction to the total was applied to the total estimated number of individuals initiating HCV treatment. Cumulative PBS prescription number (instead of June number) was used given that the June reported number was lower than the previous months in some jurisdictions. This difference was substantial, particularly for South Australia where the June number was about 50% less than May number. Therefore, the estimated number for South Australia should be considered conservatively until the accuracy of reported PBS data is confirmed.

4. Official PBS data catching up. PharmaDispatch, 26 July 2016



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

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

Therefore, the aggregated numbers reported for the month of June for each regimen, duration, and scheme will represent all individuals initiated in March, April, May, and June, except for March initiations on an 8-week or 12-week treatment course and April initiations on an 8-week treatment course given that these treatment courses have been completed before June. Then the numbers of 8-week treatment courses initiated in March and April and 12-week treatment courses initiated in March were added to the total number reported in June.

It is also assumed that 5% of patients who were initially authorised for 12 weeks treatment with sofosbuvir/ledipasvir, stopped treatment after 8 weeks due to the clinician's decision after re-evaluating the patient's situation. Then a 5% drop-out was added to the number of individuals initiated on a 12-week sofosbuvir/ledipasvir course.

Treatment courses in the prescriptions are by week while PBS reports are monthly. Then a 4-week prescription (28 days) is reported in monthly PBS reports (30 days). For the time period of four months (March to June), it causes a discrepancy between 112 days prescription versus 120 days PBS reports. Then the PBS reported prescription number was adjusted by adding 7% as a conversion of 28 days prescription to 30 days of a month.