

Monitoring hepatitis C treatment uptake in Australia

Issue #2 June 2016¹

Reimbursements for new treatment for chronic hepatitis C during March and April 2016

A total of 6,503 patient PBS initial prescriptions were processed for reimbursement in March-April 2016. Based on extrapolation of wholesale data to PBS reimbursement data, to account for the time lag in reporting, an estimated 13,000 – 16,250 patients initiated hepatitis C treatment in March-April 2016.

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. Issue #2 newsletter provides the estimated total number of patients with chronic HCV who initiated treatment during March and April 2016, and detailed data on the smaller sample of patients with PBS reimbursement-based prescriptions.

1. The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 2). The Kirby Institute, UNSW Australia, Sydney, Australia, June 2016

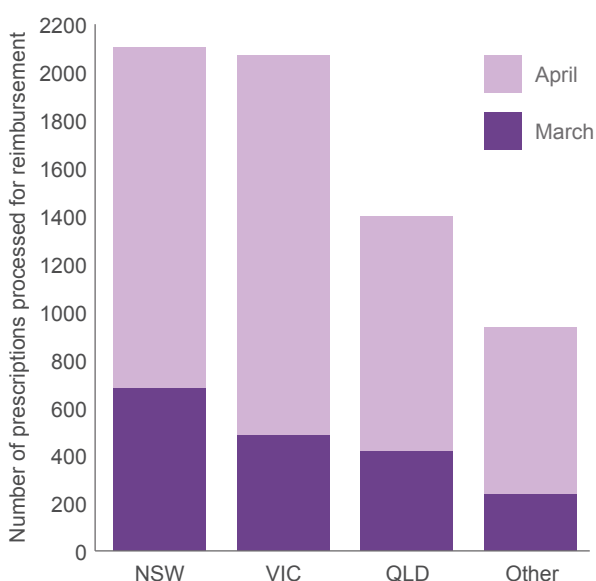
Estimated total hepatitis C treatment initiations

Based on extrapolation of wholesale data to PBS reimbursement data, to account for the time lag in reporting, an estimated 13,000 – 16,250 patients initiated chronic HCV treatment in March-April 2016.

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

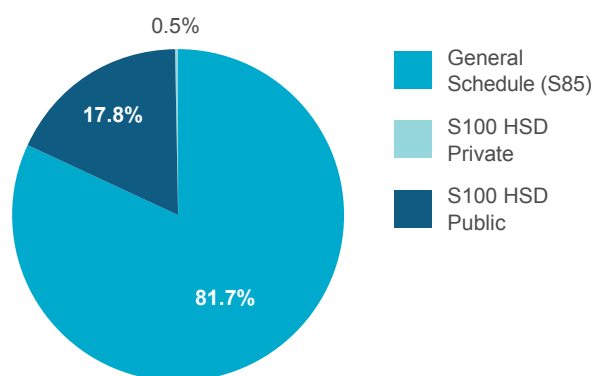
A total of 6,503 individuals had chronic HCV DAA initial prescriptions processed by the PBS during March and April 2016, including 32% (n=2,102) in New South Wales, 32% (n=2,071) in Victoria, 21% (n=1,397) in Queensland, and 14% (n=933) in the other jurisdictions (Figure 1). Further information for individual jurisdictions are provided in Table 1. The higher numbers for April compared to March in all jurisdictions does not represent an increase in treatment initiations, but relates to the time lag in PBS reimbursement-based reporting (it is likely that a majority of April PBS reimbursements are for patients initiated in March).

Figure 1: Number of chronic HCV DAA initial prescriptions processed for reimbursement by the PBS during March and April 2016 in Australia, by jurisdiction



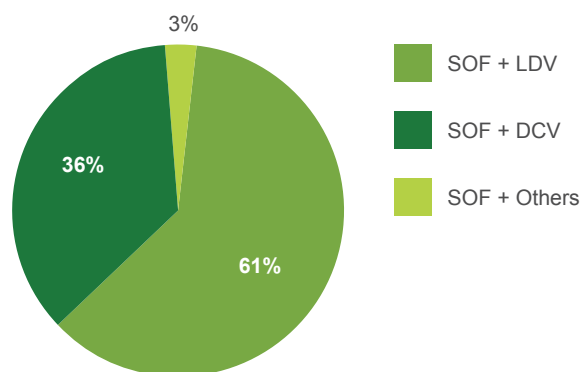
Most individuals (82%) were prescribed under the General Schedule (S85), 18% under S100 HSD Public and <1% under S100 HSD Private (Figure 2). The 18% for S100 is an increase from the 9% in Issue #1, which may indicate a longer lag for S100 versus S85 scheme reimbursement reporting, rather than an actual increase in S100 prescribing.

Figure 2: Distribution of PBS schedule of chronic HCV DAA prescriptions during March-April 2016 in Australia



The most commonly prescribed regimen was sofosbuvir/ledipasvir, for 61% (n=3,991), followed by sofosbuvir/daclatasvir for 35% (n=2,305), and sofosbuvir/other agents for 3% (n=207; Figure 3). Other agents would include ribavirin, or pegylated interferon-alfa-2a/ribavirin.

Figure 3: Distribution of chronic HCV DAA regimens prescribed during March-April 2016 in Australia



Of individuals initiated on sofosbuvir/ledipasvir (n=3,991), 7% (n=281) were prescribed an 8-week course, 72% (n=2,887) a 12-week course, and 21% (n=823) a 24-week course.

Of individuals initiated on sofosbuvir/daclatasvir (n=2,305), 56% (n=1,295) were prescribed a 12-week course, and 44% (n=1,010) a 24-week course.

Of individuals initiated on sofosbuvir/other agents (n=207), 98% (n=203) were prescribed a 12-week course, and 2% (n=4) a 24-week course (Figure 4 and Figure 5).

The vast majority of patients prescribed sofosbuvir/daclatasvir for 24 weeks (n=1,010; 44% of total sofosbuvir/daclatasvir) will be individuals with genotype 3 and cirrhosis. Those prescribed sofosbuvir/ledipasvir for 24 weeks (n=823; 21% of total sofosbuvir/ledipasvir) should represent individuals with genotype 1, prior treatment and cirrhosis.

Figure 4: Distribution of chronic HCV DAA prescriptions during March-April 2016 in Australia, by treatment regimen and treatment course duration

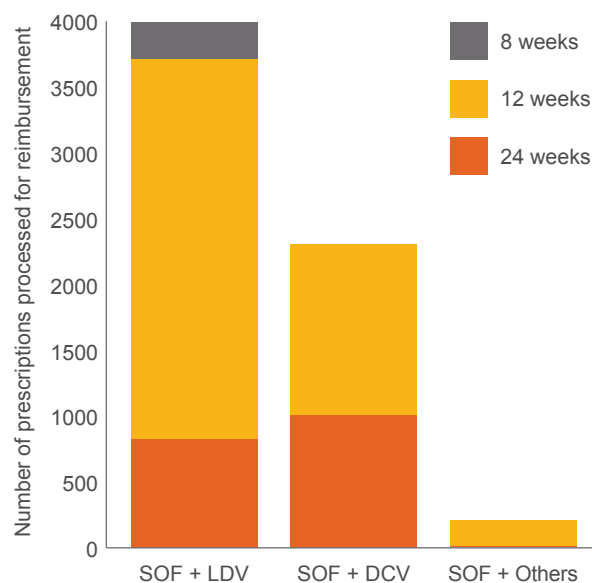
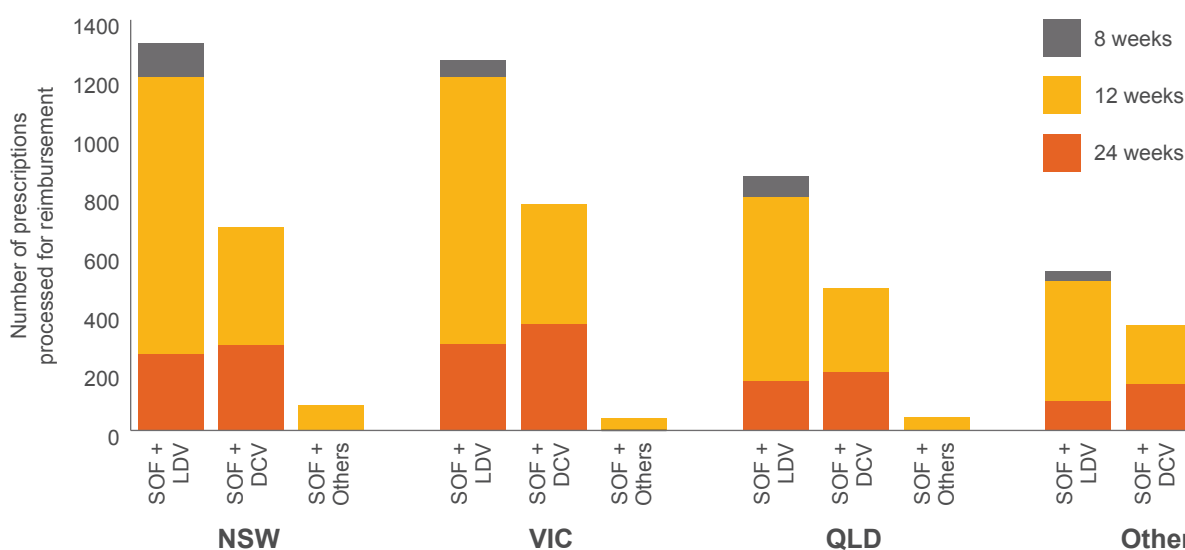


Figure 5: Distribution of chronic HCV DAA prescriptions during March-April 2016 in Australia, by treatment regimen, treatment course duration and jurisdiction



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

Table 1: Distribution of chronic HCV DAA prescriptions during March-April 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
LEDIPASVIR + SOFOSBUVIR	General Schedule	24 weeks	169	256	158	22	24	8	0	1	638
LEDIPASVIR + SOFOSBUVIR	S100 HSD Private	24 weeks	0	0	4	0	0	0	0	0	4
LEDIPASVIR + SOFOSBUVIR	S100 HSD Public	24 weeks	90	39	7	1	19	2	16	7	181
LEDIPASVIR + SOFOSBUVIR	General Schedule	12 weeks	742	816	606	97	125	33	9	9	2437
LEDIPASVIR + SOFOSBUVIR	S100 HSD Private	12 weeks	7	3	1	1	1	0	0	0	13
LEDIPASVIR + SOFOSBUVIR	S100 HSD Public	12 weeks	196	91	18	0	33	1	80	18	437
LEDIPASVIR + SOFOSBUVIR	General Schedule	8 weeks	105	49	74	6	4	7	4	0	249
LEDIPASVIR + SOFOSBUVIR	S100 HSD Private	8 weeks	0	0	0	0	0	0	0	0	0
LEDIPASVIR + SOFOSBUVIR	S100 HSD Public	8 weeks	11	6	0	1	0	0	14	0	32
SOFOSBUVIR + DACLATASVIR	General Schedule	24 weeks	180	314	186	37	38	15	6	0	776
SOFOSBUVIR + DACLATASVIR	S100 HSD Private	24 weeks	4	2	1	0	0	0	0	0	7
SOFOSBUVIR + DACLATASVIR	S100 HSD Public	24 weeks	106	47	11	0	19	0	26	18	227
SOFOSBUVIR + DACLATASVIR	General Schedule	12 weeks	317	353	276	50	47	14	9	1	1067
SOFOSBUVIR + DACLATASVIR	S100 HSD Private	12 weeks	6	2	0	0	0	0	0	0	8
SOFOSBUVIR + DACLATASVIR	S100 HSD Public	12 weeks	79	52	10	1	22	0	54	2	220
SOFOSBUVIR + Others	General Schedule	24 weeks	0	0	0	0	0	0	1	0	1
SOFOSBUVIR + Others	S100 HSD Private	24 weeks	1	0	0	0	0	0	0	0	1
SOFOSBUVIR + Others	S100 HSD Public	24 weeks	2	0	0	0	0	0	0	0	2
SOFOSBUVIR + Others	General Schedule	12 weeks	50	31	44	6	5	5	1	0	142
SOFOSBUVIR + Others	S100 HSD Private	12 weeks	2	0	0	0	0	0	0	0	2
SOFOSBUVIR + Others	S100 HSD Public	12 weeks	35	10	1	0	7	0	3	3	59
Total			2102	2071	1397	222	344	85	223	59	6503

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

Methodology

Two data sources were used: PBS 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. PBS reports of the number of prescriptions are therefore 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 and April has been estimated

at 2.25 times wholesale price equivalent for PBS reimbursements reported for the same period.^{2,3} For the estimate of the number of patients initiated on HCV treatment during March-April 2016, we have used a range of 2.00-2.50 (rather than 2.25) given inherent uncertainties within this methodology.

Two assumptions have been made in reporting of the PBS reimbursement data, and in extrapolation: 1) All patients who initiated treatment in March have continued treatment in April, given that the shortest duration therapy is 8 weeks (aggregated monthly data is provided by PBS, rather than individual patient data). The aggregated numbers reported for the month of April for each regimen, duration, and scheme will therefore represent all patients initiated in both March and April; 2) The time lag is similar for patients initiated in March and April.

2. Hep C sales hit half a billion in just nine weeks. PharmaDispatch, 13 May 2016
3. Medicare catching up on HCV therapies. PharmaDispatch, 26 May 2016