

Requester: Industry

Reason for request: The purpose of the data is to support a submission to the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC) requesting the extension of the PBS restriction of a currently listed antiretroviral to include earlier treatment stages of HIV-1 , and funding of a corresponding genetic test.

Inclusion criteria: People receiving ART at or after 1 January 2006

Report definitions:

Treatment cycle: ART of more than 14 days duration. Periods off treatment of less than 14 days are considered to be continued treatment using intention to treat principles.

Background:

This report is based on all patients in AHOD having received ART between 1 January 2006 and 31 March 2011. At the time of this report 3,378 patients had been recruited to AHOD ever and 2076 patients were under active follow up.

This report describes:

1. The distribution of patient CD4 count by ART treatment cycle number for patients receiving ART at or after 1 January 2006 (Table 1).
2. The 10 most frequently used regimens between 1 January 2006 and 31 March 2011 listed for each of treatment cycles 1 – 12 (Table a – Table l). Counts of 5 or less are listed as “≤5”.

Results in this report are based on and subject to the limitations of AHOD data. AHOD data reflects the experience of patients receiving routine care. Although more recent recruitment targets HIV positive patients who are treatment naive or recently treated, AHOD remains a highly treatment experienced cohort. Standard quality assurance procedures are implemented across all participating AHOD sites.

**Table 1 ART cycle number and CD4 count for AHOD patients receiving ART at or after 1 January 2006 until 31 March 2011**

Cycle <sup>1</sup>	Time of test <sup>2</sup>	CD4 category (cells/ $\mu$ L)						Total n (%)	mean (sd) (cells/ $\mu$ L)
		<50	51-200	201-350	351-500	500+	Missing		
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
1	Start of regimen	47 (6)	143 (19)	215 (28)	106 (14)	69 (9)	183 (24)	763 (100)	322 (223)
	365 days later	3 (0)	39 (5)	94 (12)	129 (17)	182 (24)	316 (41)		456 (261)
2	Start of regimen	10 (2)	62 (10)	134 (22)	123 (20)	185 (30)	102 (17)	616 (100)	404 (276)
	365 days later	1 (0)	24 (4)	48 (8)	92 (15)	199 (32)	252 (41)		480 (293)
3	Start of regimen	9 (2)	46 (9)	102 (19)	103 (19)	191 (35)	88 (16)	539 (100)	419 (302)
	365 days later	2 (0)	11 (2)	44 (8)	71 (13)	195 (36)	216 (40)		475 (296)
4	Start of regimen	3 (1)	51 (10)	88 (17)	85 (17)	195 (38)	89 (17)	511 (100)	415 (299)
	365 days later	1 (0)	15 (3)	37 (7)	79 (15)	188 (37)	191 (37)		462 (291)
5	Start of regimen	5 (1)	35 (8)	66 (15)	67 (16)	178 (41)	79 (18)	430 (100)	408 (294)
	365 days later	2 (0)	6 (1)	50 (12)	65 (15)	151 (35)	156 (36)		454 (284)
6	Start of regimen	5 (1)	36 (10)	59 (17)	55 (16)	142 (40)	54 (15)	351 (100)	394 (280)
	365 days later	0 (0)	16 (5)	31 (9)	50 (14)	130 (37)	124 (35)		445 (283)
7	Start of regimen	3 (1)	32 (10)	51 (16)	59 (19)	114 (36)	57 (18)	316 (100)	389 (277)
	365 days later	2 (1)	15 (5)	35 (11)	37 (12)	107 (34)	120 (38)		428 (281)
8	Start of regimen	6 (2)	35 (13)	34 (13)	44 (16)	104 (38)	49 (18)	272 (100)	387 (286)
	365 days later	2 (1)	14 (5)	28 (10)	39 (14)	87 (32)	102 (38)		422 (292)
9	Start of regimen	6 (2)	38 (14)	52 (20)	42 (16)	82 (31)	43 (16)	263 (100)	364 (282)
	365 days later	2 (1)	19 (7)	29 (11)	38 (14)	82 (31)	93 (35)		397 (266)
10	Start of regimen	5 (2)	23 (11)	41 (19)	36 (17)	61 (29)	45 (21)	211 (100)	342 (270)
	365 days later	0 (0)	16 (8)	26 (12)	32 (15)	48 (23)	89 (42)		381 (259)
11	Start of regimen	8 (5)	23 (13)	37 (21)	25 (14)	45 (26)	38 (22)	176 (100)	326 (257)
	365 days later	1 (1)	15 (9)	30 (17)	28 (16)	40 (23)	62 (35)		363 (274)
12	Start of regimen	7 (5)	21 (14)	28 (19)	26 (17)	48 (32)	19 (13)	149 (100)	351 (282)
	365 days later	2 (1)	13 (9)	22 (15)	18 (12)	38 (26)	56 (38)		368 (277)
13	Start of regimen	5 (4)	27 (20)	26 (19)	23 (17)	32 (24)	22 (16)	135 (100)	322 (247)
	365 days later	2 (1)	15 (11)	21 (16)	29 (21)	30 (22)	38 (28)		359 (253)
14	Start of regimen	5 (5)	17 (18)	17 (18)	21 (23)	23 (25)	10 (11)	93 (100)	317 (241)
	365 days later	2 (2)	6 (6)	15 (16)	14 (15)	16 (17)	40 (43)		338 (262)
15	Start of regimen	7 (9)	14 (18)	12 (16)	17 (22)	16 (21)	11 (14)	77 (100)	283 (229)
	365 days later	4 (5)	8 (10)	13 (17)	13 (17)	14 (18)	25 (32)		323 (288)
16+	Start of regimen	27 (9)	62 (20)	55 (18)	39 (13)	63 (21)	58 (19)	304 (100)	272 (244)
	365 days later	8 (3)	33 (11)	51 (17)	40 (13)	68 (22)	104 (34)		332 (257)
Total	Start of regimen	158 (3)	665 (13)	1017 (20)	871 (17)	1548 (30)	947 (18)	5206 (100)	377 (278)
	365 days later	34 (1)	265 (5)	574 (11)	774 (15)	1575 (30)	1984 (38)		440 (284)

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Excludes off treatment (not receiving ART for more than 14 days).
2. CD4 at start of regimen taken as closest test date within 90 days prior to commencement. CD4 365 days later taken as closest test date within 45 days before or after test date +365 days.

Treatment numbers by cycle number for all treatment cycles from 1 January 2006 until 31 March 2011

**Table a: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 1<sup>1</sup>**

Regimen	Number
truvada-efavirenz	108
combivir-nevirapine	49
truvada-nevirapine	47
emtricitabine-efavirenz-tenofovir	43
atrima	39
combivir-efavirenz	34
kivexa-efavirenz	27
kivexa-nevirapine	27
truvada-atazanavir-ritonavir	23
truvada-kaletra	23
all others	343
<b>Total</b>	<b>763</b>
<b>Off treatment</b>	<b>102</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table b: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 2<sup>1</sup>**

Regimen	Number
truvada-efavirenz	55
atrima	50
kivexa-nevirapine	36
truvada-nevirapine	32
abacavir-lamivudine-nevirapine	27
combivir-efavirenz	27
combivir-nevirapine	23
truvada-atazanavir-ritonavir	23
kivexa-efavirenz	21
lamivudine-nevirapine-tenofovir	14
all others	308
<b>Total</b>	<b>616</b>
<b>Off treatment</b>	<b>71</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table c: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 3<sup>1</sup>**

Regimen	Number
truvada-nevirapine	34
atrima	30
truvada-efavirenz	22
abacavir-lamivudine-nevirapine	21
trizivir	21
kivexa-nevirapine	19
lamivudine-efavirenz-tenofovir	18
combivir-nevirapine	16
truvada-atazanavir-ritonavir	14
lamivudine-nevirapine-tenofovir	14
all others	330
<b>Total</b>	<b>539</b>
<b>Off treatment</b>	<b>65</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table d: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 4<sup>1</sup>**

<b>Regimen</b>	<b>Number</b>
kivexa-nevirapine	27
abacavir-lamivudine-nevirapine	27
truvada-nevirapine	23
truvada-atazanavir-ritonavir	21
truvada-efavirenz	21
kivexa-efavirenz	17
lamivudine-nevirapine-tenofovir	15
atripla	14
combivir-nevirapine	14
kivexa-atazanavir-ritonavir	9
all others	323
<b>Total</b>	<b>511</b>
<b>Off treatment</b>	<b>38</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table e: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 5<sup>1</sup>**

<b>Regimen</b>	<b>Number</b>
truvada-nevirapine	21
kivexa-nevirapine	17
abacavir-lamivudine-nevirapine	14
truvada-atazanavir-ritonavir	13
combivir-nevirapine	13
lamivudine-nevirapine-tenofovir	11
truvada-efavirenz	10
truvada-kaletra	8
kivexa-atazanavir-ritonavir	8
atripla	7
all others	308
<b>Total</b>	<b>430</b>
<b>Off treatment</b>	<b>33</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table f: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 6<sup>1</sup>**

<b>Regimen</b>	<b>Number</b>
truvada-atazanavir-ritonavir	17
kivexa-nevirapine	16
truvada-nevirapine	16
abacavir-lamivudine-nevirapine	11
emtricitabine-atazanavir-ritonavir-tenofovir	8
abacavir-lamivudine-efavirenz	7
truvada-efavirenz	6
truvada-kaletra	6
lamivudine-atazanavir-ritonavir-tenofovir	≤5
lamivudine-efavirenz-tenofovir	≤5
all others	254
<b>Total</b>	<b>351</b>
<b>Off treatment</b>	<b>38</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table g: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 7<sup>1</sup>**

Regimen	Number
truvada-nevirapine	12
truvada-atazanavir-ritonavir	11
abacavir-lamivudine-nevirapine	10
lamivudine-nevirapine-tenofovir	10
kivexa-atazanavir-ritonavir	9
abacavir-atazanavir-ritonavir-tenofovir	8
truvada-kaletra	7
kivexa-efavirenz	6
abacavir-lamivudine-ritonavir	6
emtricitabine-atazanavir-ritonavir-tenofovir	6
all others	231
<b>Total</b>	<b>316</b>
<b>Off treatment</b>	<b>28</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table h: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 8<sup>1</sup>**

Regimen	Number
truvada-nevirapine	13
abacavir-lamivudine-nevirapine	10
truvada-atazanavir-ritonavir	10
kivexa-atazanavir-ritonavir	8
truvada-efavirenz	8
kivexa-nevirapine	7
truvada-kaletra	≤5
lamivudine-atazanavir-ritonavir-tenofovir	≤5
efavirenz-atazanavir-ritonavir	≤5
lamivudine-efavirenz-tenofovir	≤5
all others	200
<b>Total</b>	<b>272</b>
<b>Off treatment</b>	<b>25</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table i: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 9<sup>1</sup>**

Regimen	Number
truvada-atazanavir-ritonavir	15
abacavir-lamivudine-nevirapine	9
truvada-nevirapine	7
lamivudine-nevirapine-tenofovir	6
lamivudine-kaletra-tenofovir	6
abacavir-lamivudine-efavirenz	≤5
atrima	≤5
kivexa-atazanavir-ritonavir	≤5
kivexa-efavirenz	≤5
truvada-efavirenz	≤5
all others	197
<b>Total</b>	<b>263</b>
<b>Off treatment</b>	<b>26</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table j: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 10<sup>1</sup>**

Regimen	Number
lamivudine-atazanavir-ritonavir-tenofovir	6
truvada-nevirapine	6
truvada-atazanavir-ritonavir	6
kivexa-nevirapine	≤5
abacavir-lamivudine-nevirapine	≤5
emtricitabine-kaletra-tenofovir	≤5
atazanavir-raltegravir	≤5
trizivir-nevirapine	≤5
emtricitabine-nevirapine-tenofovir	≤5
kivexa-kaletra	≤5
all others	168
<b>Total</b>	<b>211</b>
<b>Off treatment</b>	<b>24</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table k: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 11<sup>1</sup>**

Regimen	Number
truvada-atazanavir-ritonavir	6
kivexa-atazanavir-ritonavir	6
emtricitabine-atazanavir-ritonavir-tenofovir	≤5
truvada-nevirapine	≤5
truvada-kaletra	≤5
lamivudine-etravirine-ritonavir-darunavir-raltegravir	≤5
abacavir-kaletra-tenofovir	≤5
abacavir-lamivudine-kaletra	≤5
atazanavir-raltegravir	≤5
kaletra-tenofovir	≤5
all others	137
<b>Total</b>	<b>176</b>
<b>Off treatment</b>	<b>17</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.

**Table l: Most used drug combinations for people receiving ART at or after 1 January 2006 - CYCLE 12<sup>1</sup>**

Regimen	Number
truvada-atazanavir-ritonavir	8
lamivudine-kaletra-tenofovir	≤5
kivexa-nevirapine	≤5
stavudine-truvada-kaletra	≤5
emtricitabine-ritonavir-darunavir-tenofovir-raltegravir	≤5
abacavir-lamivudine-atazanavir-ritonavir	≤5
combivir-atazanavir-ritonavir-tenofovir	≤5
emtricitabine-kaletra-tenofovir	≤5
combivir-tenofovir	≤5
nevirapine-atazanavir-ritonavir-tenofovir	≤5
all others	120
<b>Total</b>	<b>149</b>
<b>Off treatment</b>	<b>19</b>

1. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens commencement dates are the later of commencement date and 1 Jan 2006. Off treatment is not receiving ART for more than 14 days.