Australian Government
Department of Health

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 January 2022

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 January 2022 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$7.78
	Dangerous drug fee	$4.82
	Extemporaneously-prepared	$9.82
	Allowable additional patient charge*	$4.54
Additional Fees (for safety net prices):	Ready-prepared	$1.30
	Extemporaneously-prepared	$1.67
Patient Co-payments:	General	$42.50
	Concessional	$6.80
Safety Net Thresholds:	General	$1542.10
	Concessional	$326.40
Safety Net Card Issue Fee:		$10.65

* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 January 2022. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

12823X **DAPAGLIFLOZIN**, dapagliflozin 10 mg tablet, 28 *(Forxiga)*

12814K **ENCORAFENIB**, encorafenib 75 mg capsule, 42 *(Braftovi)*

12815L **ENCORAFENIB**, encorafenib 75 mg capsule, 42 *(Braftovi)*

12813J **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

12812H **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

12818P **PALBOCICLIB**, palbociclib 75 mg tablet, 21 *(Ibrance)*

12819Q **PALBOCICLIB**, palbociclib 100 mg tablet, 21 *(Ibrance)*

12822W **PALBOCICLIB**, palbociclib 125 mg tablet, 21 *(Ibrance)*

Addition – Brand

5470X *Ondansetron ODT Lupin, HQ* – **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 4

5472B *Ondansetron ODT Lupin, HQ* – **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 10

5471Y *Ondansetron ODT Lupin, HQ* – **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 4

5473C *Ondansetron ODT Lupin, HQ* – **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 10

8836C *APO-Sertraline, TX* – **SERTRALINE**, sertraline 50 mg tablet, 30

8836C *Sertra 50, RW* – **SERTRALINE**, sertraline 50 mg tablet, 30

8836C *Sertraline Sandoz, SZ* – **SERTRALINE**, sertraline 50 mg tablet, 30

8837D *APO-Sertraline, TX* – **SERTRALINE**, sertraline 100 mg tablet, 30

8837D *Sertra 100, RW* – **SERTRALINE**, sertraline 100 mg tablet, 30

8837D *Sertraline Sandoz, SZ* – **SERTRALINE**, sertraline 100 mg tablet, 30

Deletions

Deletion – Item

12581E **IMIPRAMINE**, imipramine hydrochloride 10 mg tablet, 100 *(Imipramine (Leading))*

Deletion – Brand

9092M *ATOMERRA, RW* – **ATOMOXETINE**, atomoxetine 10 mg capsule, 28

9093N *ATOMERRA, RW* – **ATOMOXETINE**, atomoxetine 18 mg capsule, 28

9094P *ATOMERRA, RW* – **ATOMOXETINE**, atomoxetine 25 mg capsule, 28

9095Q *ATOMERRA, RW* – **ATOMOXETINE**, atomoxetine 40 mg capsule, 28

9096R *ATOMERRA, RW* – **ATOMOXETINE**, atomoxetine 60 mg capsule, 28

9289X *ATOMERRA, RW* – **ATOMOXETINE**, atomoxetine 80 mg capsule, 28

9290Y *ATOMERRA, RW* – **ATOMOXETINE**, atomoxetine 100 mg capsule, 28

1169M *Cefaclor GH, GQ* – **CEFACLOR**, cefaclor 375 mg modified release tablet, 10

5045M *Cefaclor GH, GQ* – **CEFACLOR**, cefaclor 375 mg modified release tablet, 10

2834E *Pravastatin generichealth, GQ* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30

9238F *Pravastatin generichealth, GQ* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30

8456C *Quetiapine GH 25, GQ* – **QUETIAPINE**, quetiapine 25 mg tablet, 60

8457D *Quetiapine GH 100, GQ* – **QUETIAPINE**, quetiapine 100 mg tablet, 90

8580N *Quetiapine GH 300, GQ* – **QUETIAPINE**, quetiapine 300 mg tablet, 60

1968N *Acquin Aspen 5, RW* – **QUINAPRIL**, quinapril 5 mg tablet, 30

1969P *Acquin Aspen 10, RW* – **QUINAPRIL**, quinapril 10 mg tablet, 30

1970Q *Acquin Aspen 20, RW* – **QUINAPRIL**, quinapril 20 mg tablet, 30

2590H *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2606E *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2584B *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2628H *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2574L *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2609H *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2594M *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

2636R *Rosuvastatin generichealth, HQ* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

Deletion – Equivalence Indicator

2420J *Tofranil 10, GH* – **IMIPRAMINE**, imipramine hydrochloride 10 mg tablet, 50

Deletion – Note

2420J **IMIPRAMINE**, imipramine hydrochloride 10 mg tablet, 50 *(Tofranil 10)*

12670W **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge *(Terrosa)*

Alterations

Alteration – Note

11170X **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

11171Y **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

11162L **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

11165P **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

Alteration – Restriction

12117R **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 *(Calquence)*

11213E **IBRUTINIB**, ibrutinib 140 mg capsule, 90 *(Imbruvica)*

11170X **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

11171Y **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

11162L **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

11165P **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

12301K **ROMOSOZUMAB**, romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes *(Evenity)*

12670W **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge *(Terrosa)*

11630D **VENETOCLAX**, venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack *(Venclexta)*

Supply Only

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.

Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

11699R	**PALBOCICLIB**, palbociclib 75 mg capsule, 21 *(Ibrance)*
11700T	**PALBOCICLIB**, palbociclib 100 mg capsule, 21 *(Ibrance)*
11698Q	**PALBOCICLIB**, palbociclib 125 mg capsule, 21 *(Ibrance)*
9411H	**TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL pen device *(Forteo)*

Advance Notices

1 February 2022

Deletion – Brand

8358X	*Clopidogrel Sandoz, SZ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
9317J	*Clopidogrel Sandoz, SZ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
11815W	*Semglee, AF* – **INSULIN GLARGINE**, insulin glargine 100 units/mL injection, 5 x 3 mL pen devices
1558B	*Isomonit, SZ* – **ISOSORBIDE MONONITRATE**, isosorbide mononitrate 60 mg modified release tablet, 30
1906H	*Adefin XL 30, AF* – **NIFEDIPINE**, nifedipine 30 mg modified release tablet, 30
1907J	*Adefin XL 60, AF* – **NIFEDIPINE**, nifedipine 60 mg modified release tablet, 30
1898X	*Feldene, PF* – **PIROXICAM**, piroxicam 20 mg capsule, 25
5204X	*Feldene, PF* – **PIROXICAM**, piroxicam 20 mg capsule, 25
1977C	*Rani 2, AF* – **RANITIDINE**, ranitidine 300 mg tablet, 30
1978D	*Rani 2, AF* – **RANITIDINE**, ranitidine 150 mg tablet, 60
10647J	*Ibavyr, IX* – **RIBAVIRIN**, ribavirin 400 mg tablet, 28
10665H	*Ibavyr, IX* – **RIBAVIRIN**, ribavirin 600 mg tablet, 28
10666J	*Ibavyr, IX* – **RIBAVIRIN**, ribavirin 600 mg tablet, 28
10673R	*Ibavyr, IX* – **RIBAVIRIN**, ribavirin 400 mg tablet, 28

1 March 2022

Deletion – Brand

8295N	*Candesartan Aspen 4, RW* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30
8296P	*Candesartan Aspen 8, RW* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30
8297Q	*Candesartan Aspen 16, RW* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30
8889W	*Candesartan Aspen 32, RW* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30
8504N	*Candesartan Combi Aspen 16/12.5, RW* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F	*Candesartan Combi Aspen 32/12.5, RW* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9315G	*Candesartan Combi Aspen 32/25, RW* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
1834M	*Gabapentin Aspen 300, RW* – **GABAPENTIN**, gabapentin 300 mg capsule, 100
1835N	*Gabapentin Aspen 400, RW* – **GABAPENTIN**, gabapentin 400 mg capsule, 100
8389M	*Gabapentin Aspen 800, RW* – **GABAPENTIN**, gabapentin 800 mg tablet, 100
8505P	*Gabapentin Aspen 100, RW* – **GABAPENTIN**, gabapentin 100 mg capsule, 100
8559L	*Gabapentin Aspen 600, RW* – **GABAPENTIN**, gabapentin 600 mg tablet, 100
2848X	*Lamotrigine Aspen 25, RW* – **LAMOTRIGINE**, lamotrigine 25 mg tablet, 56
2849Y	*Lamotrigine Aspen 50, RW* – **LAMOTRIGINE**, lamotrigine 50 mg tablet, 56
2850B	*Lamotrigine Aspen 100, RW* – **LAMOTRIGINE**, lamotrigine 100 mg tablet, 56

2851C *Lamotrigine Aspen 200, RW* – **LAMOTRIGINE**, lamotrigine 200 mg tablet, 56

8063J *Lamotrigine Aspen 5, RW* – **LAMOTRIGINE**, lamotrigine 5 mg tablet, 56

5442K *TOBRAMYCIN WOCKHARDT, WC* – **TOBRAMYCIN**, tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

1 April 2022
Deletion – Brand

8748K *Edecrin, FK* – **ETACRYNIC ACID**, etacrynic acid 25 mg tablet, 100

8450R *Dimirel, AV* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30

1621H *Metronide 400, AV* – **METRONIDAZOLE**, metronidazole 400 mg tablet, 21

5155H *Metronide 400, AV* – **METRONIDAZOLE**, metronidazole 400 mg tablet, 21

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

11545P *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 90 mg tablet, 30

11548T *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 90 mg tablet, 30

11558H *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 90 mg tablet, 30

11510T *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11546Q *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11557G *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11496C *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11511W *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11547R *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

Advance Notices

1 February 2022
Deletion – Brand

12784W *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6100C *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6138C *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

12139X *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12143D *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12146G *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

12148J *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6429J *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6430K *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

6363X *Fulphila, AF* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10623D *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 400 mg tablet, 28

10635R *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 400 mg tablet, 28

10637W *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 600 mg tablet, 28

10675W *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 600 mg tablet, 28

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

11499F *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 90 mg tablet, 30

11519G *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 90 mg tablet, 30

11534C *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 90 mg tablet, 30

11500G *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11535D *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11556F *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11533B *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11536E *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11555E *Deferasirox Sandoz, SZ* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

Advance Notices

1 February 2022

Deletion – Brand

12771E *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9597D *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9598E *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

12134P *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12140Y *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12145F *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12149K *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

5618Q *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5619R *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

9514R *Fulphila, AF* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10638X *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 600 mg tablet, 28

10646H *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 400 mg tablet, 28

10663F *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 600 mg tablet, 28

10678B *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 400 mg tablet, 28

Highly Specialised Drugs Program (Community Access)

Supply Only

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.

Substitution of Supply Only items/brands with products flagged as "equivalent for substitution" still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

10344K **TIPRANAVIR**, tipranavir 250 mg capsule, 120 *(Aptivus)*

Advance Notices

1 February 2022

Deletion – Brand

10349Q *Atazanavir Mylan, AF* – **ATAZANAVIR**, atazanavir 200 mg capsule, 60

11657M *Atazanavir Mylan, AF* – **ATAZANAVIR**, atazanavir 300 mg capsule, 60

Repatriation Pharmaceutical Benefits

Alterations

Alteration – Item Description

From

12765W **DRESSING ALGINATE WITH SILVER CAVITY WOUND**, dressing alginate with silver cavity wound 3 cm x 44 cm medicated dressing, 10 *(Melgisorb Ag 256605)*

To

12765W **DRESSING ALGINATE WITH SILVER CAVITY WOUND**, dressing alginate with silver cavity wound 3 cm x 44 cm dressing, 10 *(Melgisorb Ag 256605)*

From

12772F **DRESSING ALGINATE WITH SILVER DEEP WOUND**, dressing alginate with silver deep wound 5 cm x 5 cm medicated dressing, 10 *(Melgisorb Ag 256055)*

To

12772F **DRESSING ALGINATE WITH SILVER DEEP WOUND**, dressing alginate with silver deep wound 5 cm x 5 cm dressing, 10 *(Melgisorb Ag 256055)*

From

12801R **DRESSING ALGINATE WITH SILVER DEEP WOUND**, dressing alginate with silver deep wound 10 cm x 10 cm medicated dressing, 10 *(Melgisorb Ag 256105)*

To

12801R **DRESSING ALGINATE WITH SILVER DEEP WOUND**, dressing alginate with silver deep wound 10 cm x 10 cm dressing, 10 *(Melgisorb Ag 256105)*

Advance Notices

1 March 2022

Deletion – Brand

4591P *Gabapentin Aspen 100, RW* – **GABAPENTIN**, gabapentin 100 mg capsule, 100

4592Q *Gabapentin Aspen 300, RW* – **GABAPENTIN**, gabapentin 300 mg capsule, 100

4593R *Gabapentin Aspen 400, RW* – **GABAPENTIN**, gabapentin 400 mg capsule, 100

4594T *Gabapentin Aspen 600, RW* – **GABAPENTIN**, gabapentin 600 mg tablet, 100

4595W *Gabapentin Aspen 800, RW* – **GABAPENTIN**, gabapentin 800 mg tablet, 100

General Pharmaceutical Benefits

▪ ACALABRUTINIB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue, **AND**
- Patient must not have received treatment with another Bruton's tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;

b) Age is 70 years or older;

c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;

d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;

e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test.

Authority required

Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment of relapsed or refractory CLL/SLL

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

acalabrutinib 100 mg capsule, 56

12117R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	8218.96	42.50	Calquence [AP]

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12477

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

dapagliflozin 10 mg tablet, 28

12823X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	56.91	42.50	Forxiga [AP]

▪ ENCORAFENIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12487

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have BRAF V600 variant positive metastatic colorectal cancer, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have received prior treatment with cetuximab for this condition; OR
- Patient must not have developed disease progression while receiving cetuximab for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have failed to respond to at least one other line of systemic therapy, **AND**
- Patient must have a WHO performance status of 2 or less.

encorafenib 75 mg capsule, 42

12814K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	3	..	*5302.09	42.50	Braftovi [FB]

▪ ENCORAFENIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12484

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

encorafenib 75 mg capsule, 42

12815L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*5302.09	42.50	Braftovi [FB]

▪ IBRUTINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received treatment with another Bruton's tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;

b) Age is 70 years or older;

c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;

d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;

e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

ibrutinib 140 mg capsule, 90

11213E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	8794.51	42.50	Imbruvica [JC]

▪ IDELALISIB

Note Special Pricing Arrangements apply.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12480

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

idelalisib 100 mg tablet, 60

12813J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5378.97	42.50	Zydelig [GI]

idelalisib 150 mg tablet, 60

12812H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5378.97	42.50	Zydelig [GI]

▪ IDELALISIB

Note Special Pricing Arrangements apply.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent within 6 months after completion of treatment with an alkylating agent, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The date of completion of prior therapies with rituximab and an alkylating agent must be documented in the patient's medical records.

idelalisib 100 mg tablet, 60

11171Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5378.97	42.50	Zydelig [GI]

idelalisib 150 mg tablet, 60

11165P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5378.97	42.50	Zydelig [GI]

▪ IDELALISIB

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; OR
- The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage), **AND**
- Patient must be inappropriate for chemo-immunotherapy.

The prescriber must provide the CIRS score at the time of application.

A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:

1. Severe neutropenia defined as absolute neutrophil count of less than or equal to 1.0 x 10^9/L; or
2. Severe thrombocytopenia defined as platelet count of less than or equal to 50 x 10^9/L; or
3. Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test.

A pathology report confirming the patient is inappropriate for chemo-immunotherapy must be documented in the patient's medical records and must be no more than 4 weeks old at the time of application.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; OR
- Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

idelalisib 100 mg tablet, 60

11170X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5378.97	42.50	Zydelig [GI]

idelalisib 150 mg tablet, 60

11162L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5378.97	42.50	Zydelig [GI]

▪ PALBOCICLIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the form 'tablet' and pharmaceutical benefits that have the form 'capsule' of this drug are equivalent for the purposes of substitution where the strength is the same.

Note Special Pricing Arrangements apply.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with abemaciclib or ribociclib; OR
- Patient must have developed an intolerance to abemaciclib or ribociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with abemaciclib or ribociclib.

Population criteria:

- Patient must not be premenopausal.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with abemaciclib or ribociclib.

Population criteria:

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

palbociclib 100 mg tablet, 21

12819Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.07	42.50	Ibrance [PF]

palbociclib 125 mg tablet, 21

12822W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.07	42.50	Ibrance [PF]

palbociclib 75 mg tablet, 21

12818P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.07	42.50	Ibrance [PF]

▪ ROMOSOZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe established osteoporosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised teriparatide; OR
- Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Authority required

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy.

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes

12301K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	628.87	42.50	Evenity [AN]

▪ TERIPARATIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL pen device and pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL cartridge are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

12492

Severe established osteoporosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised romosozumab; OR
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy**.** Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg

once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

Authority required (STREAMLINED)

12270

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

- Must be treated by a by a specialist; OR
- Must be treated by a consultant physician.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 250 microgram/mL injection, 2.4 mL cartridge

12670W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	175.92	42.50	Terrosa [FX]

▪ VENETOCLAX

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Initial treatment - Dose titration

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be used as monotherapy for this condition under this restriction.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;

b) Age is 70 years or older;

c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;

d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;

e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test.

venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack

11630D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1791.49	42.50	Venclexta [VE]