List of Section 100 drugs with special arrangements including Complex Authority Required (CAR) drugs – current at August 2016

HSD Complex Authority Required (CAR) Items

s94 Public Hospital Item Code	Private Hospital and s90 Item Code	Generic Name / Brand Name®
05605B	09621J	ABATACEPT / Orencia®
09661L	09678J	ADALIMUMAB / Humira®
09662M	09679K	ADALIMUMAB / Humira®
09663N	09680L	ADALIMUMAB / Humira®
05607D	09648T	AMBRISENTAN / Volibris®
05608E	09649W	AMBRISENTAN / Volibris®
09597D	06100C	AZACTIDINE / Vidaza® Azadine® Celazadine®
09598E	06138C	AZACTIDINE / Vidaza® Azadine® Celazadine®
05618Q	06429J	BOSENTAN / Tracleer®
05619R	06430K	BOSENTAN / Tracleer®
10183Y	10182X	ECULIZUMAB/Soliris®
10190H	10192K	ECULIZUMAB/Soliris®
10191J	10194M	ECULIZUMAB/Soliris®
10525Y	10521R	ECULIZUMAB/Soliris®
05826P	05828R	ELTROMBOPAG / Revolade®
05825N	05827Q	ELTROMBOPAG / Revolade®
05035B	05042J	EPOPROSTENOL / Flolan Kit®
05030R	05036C	EPOPROSTENOL / Flolan Kit®
10130E	10111E	EPOPROSTENOL / Veletri®
10117L	10129D	EPOPROSTENOL / Veletri®
05733R	09615C	ETANERCEPT / Enbrel®
05734T	06367D	ETANERCEPT / Enbrel®
05735W	09641K	ETANERCEPT / Enbrel®
05751Q	06456T	ILOPROST / Ventavis®
09654D	09674E	INFLIXIMAB / Remicade®, Inflectra®
05753T	06448J	INFLIXIMAB / Remicade®, Inflectra®
05754W	09613Y	INFLIXIMAB / Remicade®, Inflectra®
05755X	09612X	INFLIXIMAB / Remicade®, Inflectra®
05756Y	06496X	INFLIXIMAB / Remicade®, Inflectra®
05757B	06397Q	INFLIXIMAB / Remicade®, Inflectra®
05758C	09617E	INFLIXIMAB / Remicade®, Inflectra®
10196P	10184B	INFLIXIMAB / Remicade®, Inflectra®
10170G	10175M	IVACAFTOR/ Kalydeco®
02799H	02798G	LENALIDOMIDE / Revlimid®
02802L	02796E	LENALIDOMIDE / Revlimid®
05783J	09642L	LENALIDOMIDE / Revlimid®
05784K	09643M	LENALIDOMIDE / Revlimid®
05785L	09644N	LENALIDOMIDE / Revlimid®
05786M	09645P	LENALIDOMIDE / Revlimid®
10136L	10134J	MACITENTAN / Opsumit®
10118M	10110D	OMALIZUMAB / Xolair®
10109C	10122R	OMALIZUMAB / Xolair®

10406Q	10417G	POMALIDOMIDE / Pomalyst®
10387Q	10386P	POMALIDOMIDE / Pomalyst®
09544H	09611W	RITUXIMAB / Mabthera®
10591K	10583B	RITUXIMAB / Mabthera®
10593M	10576P	RITUXIMAB / Mabthera®
09696H	09697J	ROMIPLOSTIM / Nplate®
09698K	09699L	ROMIPLOSTIM / Nplate®
09547L	09605M	SILDENAFIL / Revatio®, APO-Sildenafil PHT®, SILDINAFIL-DRX®, Sildenafil AN PHT 20®, Sildenafil Sandoz PHT 20®
01308W	01304P	TADALAFIL / Adcirca®
01476Q	01419Q	TOCILIZUMAB / Actemra®
01481Y	01423X	TOCILIZUMAB / Actemra®
01482B	01464C	TOCILIZUMAB / Actemra®
09657G	09671B	TOCILIZUMAB / Actemra®
09658H	09672C	TOCILIZUMAB / Actemra®
09659J	09673D	TOCILIZUMAB / Actemra®
10056G	10071C	TOCILIZUMAB / Actemra®
10058J	10079L	TOCILIZUMAB / Actemra®
10064Q	10060L	TOCILIZUMAB / Actemra®
10072D	10078K	TOCILIZUMAB / Actemra®
10077J	10068X	TOCILIZUMAB / Actemra®
10081N	10073E	TOCILIZUMAB / Actemra®
10384M	10398G	VEDOLIZUMAB / Entyvio®
10390W	10415E	VEDOLIZUMAB / Entyvio®

Efficient Funding of Chemotherapy (EFC) items, administered by DHS the same as CARs

s94 Public Hospital Item Code	Private Hospital and s90 Item Code	Generic Name / Brand Name®
10166C	10172J	BRENTUXIMAB VEDOTIN/Adcetris®
10171H	10180T	BRENTUXIMAB VEDOTIN/Adcetris®
04706Q	07268M	BORTEZOMIB /Velcade®
04712B	07269N	BORTEZOMIB /Velcade®
04713C	07271Q	BORTEZOMIB /Velcade®
04725Q	07272R	BORTEZOMIB /Velcade®
04403R	07238Y	BORTEZOMIB /Velcade®
04429D	07274W	BORTEZOMIB /Velcade®
04732C	07275X	BORTEZOMIB /Velcade®
10407R	10418H	OBINUTUZUMAB / Gazyva®
10267J	10334X	PERTUZUMAB / Perjeta®
10309N	10268K	PERTUZUMAB / Perjeta®
10333W	10308M	PERTUZUMAB / Perjeta®
10575N	10595P	TRASTUZUMAB / Herceptin®
10589H	10581X	TRASTUZUMAB / Herceptin®
10597R	10588G	TRASTUZUMAB / Herceptin®
10391X	10381J	TRASTUZUMAB / Herceptin®
10401K	10383L	TRASTUZUMAB / Herceptin®
10423N	10402L	TRASTUZUMAB / Herceptin®
04632T	07264H	TRASTUZUMAB / Herceptin®
04639E	07265J	TRASTUZUMAB / Herceptin®
04650R	07266K	TRASTUZUMAB / Herceptin®
04703M	07267L	TRASTUZUMAB / Herceptin®
10282E	10281D	TRASTUZUMAB EMTANSINE/ Kadcyla®

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 August 2016 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$7.02
	Dangerous drug fee	$2.95
	Extemporaneously-prepared	$9.06
	Allowable additional patient charge*	$4.33
Additional Fees (for safety net prices):	Ready-prepared	$1.19
	Extemporaneously-prepared	$1.55
Patient Co-payments:	General	$38.30
	Concessional	$6.20
Safety Net Thresholds:	General	$1475.70
	Concessional	$372.00
Safety Net Card Issue Fee:		$9.61

* 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 August 2016. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

10862Q **MORPHINE**, morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

10868B **MORPHINE**, morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

General Pharmaceutical Benefits

Additions

Addition – Item

10865W **FOLLITROPIN ALFA**, follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices *(Bemfola)*

10877L **FOLLITROPIN ALFA**, follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices *(Bemfola)*

10876K **FOLLITROPIN ALFA**, follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices *(Bemfola)*

10863R **MORPHINE**, morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)* **(Dental)**

10864T **MORPHINE**, morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

10858L **MORPHINE**, morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)* **(Dental)**

10874H **MORPHINE**, morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

10869C **MORPHINE**, morphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules *(Morphine Juno)*

10878M **MORPHINE**, morphine hydrochloride 100 mg/5 mL injection, 5 x 5 mL ampoules *(Morphine Juno)*

10870D **TACROLIMUS**, tacrolimus 750 microgram capsule, 100 *(Tacrolimus Sandoz)*

10871E **TACROLIMUS**, tacrolimus 2 mg capsule, 100 *(Tacrolimus Sandoz)*

Addition – Brand

2417F *ENTRIP, RW* – **AMITRIPTYLINE**, amitriptyline hydrochloride 10 mg tablet, 50

2418G *ENTRIP, RW* – **AMITRIPTYLINE**, amitriptyline hydrochloride 25 mg tablet, 50

2429W *ENTRIP, RW* – **AMITRIPTYLINE**, amitriptyline hydrochloride 50 mg tablet, 50

9092M *Atomoxetine Amneal, EA* – **ATOMOXETINE**, atomoxetine 10 mg capsule, 28

9093N *Atomoxetine Amneal, EA* – **ATOMOXETINE**, atomoxetine 18 mg capsule, 28

9094P *Atomoxetine Amneal, EA* – **ATOMOXETINE**, atomoxetine 25 mg capsule, 28

9095Q *Atomoxetine Amneal, EA* – **ATOMOXETINE**, atomoxetine 40 mg capsule, 28

9096R *Atomoxetine Amneal, EA* – **ATOMOXETINE**, atomoxetine 60 mg capsule, 28

9289X *Atomoxetine Amneal, EA* – **ATOMOXETINE**, atomoxetine 80 mg capsule, 28

9290Y *Atomoxetine Amneal, EA* – **ATOMOXETINE**, atomoxetine 100 mg capsule, 28

8879H *ESPLER, RW* – **EPLERENONE**, eplerenone 25 mg tablet, 30

8880J *ESPLER, RW* – **EPLERENONE**, eplerenone 50 mg tablet, 30

9048F *Hydroxo-B12, AS* – **HYDROXOCOBALAMIN**, hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

9169N *APO-Levetiracetam, TX* – **LEVETIRACETAM**, levetiracetam 100 mg/mL oral liquid, 300 mL

9006B *Blooms the Chemist Perindopril Arginine, IB* – **PERINDOPRIL**, perindopril arginine 2.5 mg tablet, 30

9006B *IDAPREX ARG 2.5mg, TZ* – **PERINDOPRIL**, perindopril arginine 2.5 mg tablet, 30

9006B *PERINDO ARG 2.5mg, TR* – **PERINDOPRIL**, perindopril arginine 2.5 mg tablet, 30

9007C *Blooms the Chemist Perindopril Arginine, IB* – **PERINDOPRIL**, perindopril arginine 5 mg tablet, 30

9007C *IDAPREX ARG 5mg, TZ* – **PERINDOPRIL**, perindopril arginine 5 mg tablet, 30

9007C *PERINDO ARG 5mg, TR* – **PERINDOPRIL**, perindopril arginine 5 mg tablet, 30

9008D *Blooms the Chemist Perindopril Arginine, IB* – **PERINDOPRIL**, perindopril arginine 10 mg tablet, 30

9008D *IDAPREX ARG 10mg, TZ* – **PERINDOPRIL**, perindopril arginine 10 mg tablet, 30

9008D *PERINDO ARG 10mg, TR* – **PERINDOPRIL**, perindopril arginine 10 mg tablet, 30

9346X *Deflectum 5/5, TZ* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9346X *Dynoval 5/5, TR* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9347Y *Deflectum 5/10, TZ* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9347Y *Dynoval 5/10, TR* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9348B *Deflectum 10/5, TZ* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9348B *Dynoval 10/5, TR* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9349C *Deflectum 10/10, TZ* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

9349C *Dynoval 10/10, TR* – **PERINDOPRIL + AMLODIPINE**, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

2845R *Idaprex ARG Combi 5mg/1.25mg, TZ* – **PERINDOPRIL + INDAPAMIDE**, perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

2845R *Perindo ARG Combi 5mg/1.25mg, TR* – **PERINDOPRIL + INDAPAMIDE**, perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

9203J *APO-Quetiapine XR, TX* – **QUETIAPINE**, quetiapine 200 mg modified release tablet, 60

9204K *APO-Quetiapine XR, TX* – **QUETIAPINE**, quetiapine 300 mg modified release tablet, 60

9205L *APO-Quetiapine XR, TX* – **QUETIAPINE**, quetiapine 400 mg modified release tablet, 60

8470T *Ramipril AN, EA* – **RAMIPRIL**, ramipril 10 mg capsule, 30

5299X *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 500 microgram capsule: modified release, 30

5300Y *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 1 mg capsule: modified release, 60

5451X *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 5 mg capsule: modified release, 30

1356J *Tobramycin Mylan, AF* – **TOBRAMYCIN**, tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

5442K *Tobramycin AN, EA* – **TOBRAMYCIN**, tobramycin 300 mg/5 mL inhalation: solution, 56 x 5 mL ampoules

Addition – Equivalence Indicator

9092M *Strattera, LY* – **ATOMOXETINE**, atomoxetine 10 mg capsule, 28

9093N *Strattera, LY* – **ATOMOXETINE**, atomoxetine 18 mg capsule, 28

9094P *Strattera, LY* – **ATOMOXETINE**, atomoxetine 25 mg capsule, 28

9095Q *Strattera, LY* – **ATOMOXETINE**, atomoxetine 40 mg capsule, 28

9096R *Strattera, LY* – **ATOMOXETINE**, atomoxetine 60 mg capsule, 28

9289X *Strattera, LY* – **ATOMOXETINE**, atomoxetine 80 mg capsule, 28

9290Y *Strattera, LY* – **ATOMOXETINE**, atomoxetine 100 mg capsule, 28

1644M *Hospira Pty Limited, HH* – **MORPHINE**, morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules

5168B *Hospira Pty Limited, HH* – **MORPHINE**, morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules **(Dental)**

5299X *Prograf XL, LL* – **TACROLIMUS**, tacrolimus 500 microgram capsule: modified release, 30

5300Y *Prograf XL, LL* – **TACROLIMUS**, tacrolimus 1 mg capsule: modified release, 60

5451X *Prograf XL, LL* – **TACROLIMUS**, tacrolimus 5 mg capsule: modified release, 30

1356J *Hospira Pty Limited, HH* – **TOBRAMYCIN**, tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

5442K *Tobi, NV* – **TOBRAMYCIN**, tobramycin 300 mg/5 mL inhalation: solution, 56 x 5 mL ampoules

Deletions

Deletion – Item

3036T **STRONTIUM**, strontium ranelate 2 g granules, 28 sachets *(Protos 2 g)*

Deletion – Brand

1003T *Zovirax 200 mg, GK* – **ACICLOVIR**, aciclovir 200 mg tablet, 25

1052J *Zovirax 800 mg, GK* – **ACICLOVIR**, aciclovir 800 mg tablet, 35

2502Q *Calcitriol Sandoz, SZ* – **CALCITRIOL**, calcitriol 0.25 microgram capsule, 100

8220P *Ciazil, UA* – **CITALOPRAM**, citalopram 20 mg tablet, 28

8896F *Chem mart Famciclovir, CH* – **FAMCICLOVIR**, famciclovir 500 mg tablet, 56

8896F *Terry White Chemists Famciclovir, TW* – **FAMCICLOVIR**, famciclovir 500 mg tablet, 56

8897G *Chem mart Famciclovir, CH* – **FAMCICLOVIR**, famciclovir 500 mg tablet, 30

8897G *Terry White Chemists Famciclovir, TW* – **FAMCICLOVIR**, famciclovir 500 mg tablet, 30

2457H *Prinivil 10, MK* – **LISINOPRIL**, lisinopril 10 mg tablet, 30

2458J *Prinivil 20, MK* – **LISINOPRIL**, lisinopril 20 mg tablet, 30

1596B *Ondansetron Kabi, PK* – **ONDANSETRON**, ondansetron 4 mg/2 mL injection, 2 mL ampoule

8226Y *Ondansetron Kabi, PK* – **ONDANSETRON**, ondansetron 4 mg/2 mL injection, 2 mL ampoule

1597C *Ondansetron Kabi, PK* – **ONDANSETRON**, ondansetron 8 mg/4 mL injection, 4 mL ampoule

8227B *Ondansetron Kabi, PK* – **ONDANSETRON**, ondansetron 8 mg/4 mL injection, 4 mL ampoule

8507R *Chem mart Rabeprazole, CH* – **RABEPRAZOLE**, rabeprazole sodium 10 mg tablet: enteric, 28

8507R *Terry White Chemists Rabeprazole, TW* – **RABEPRAZOLE**, rabeprazole sodium 10 mg tablet: enteric, 28

8470T *Ramipril CH, EA* – **RAMIPRIL**, ramipril 10 mg capsule, 30

1978D *GenRx Ranitidine, GX* – **RANITIDINE**, ranitidine 150 mg tablet, 60

1978D *Ranoxyl, FM* – **RANITIDINE**, ranitidine 150 mg tablet, 60

1977C *GenRx Ranitidine, GX* – **RANITIDINE**, ranitidine 300 mg tablet, 30

1977C *Ranoxyl, FM* – **RANITIDINE**, ranitidine 300 mg tablet, 30

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

8511Y **ALENDRONATE**, alendronate 70 mg tablet, 4 *(APO-Alendronate, Alendro Once Weekly, Alendrobell 70mg, Alendronate AN, Alendronate Sandoz, Alendronate-GA, Densate 70, Fonat)*

9012H **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4 *(APO-Alendronate Plus D3 70 mg/70 mcg, Alendrobell plus D3, Alendronate D3 70 mg/70 microgram, Alendronate Plus D3 Sandoz, Alendronate plus D3-DRLA, Chem mart Alendronate Plus D3 70 mg/70 mcg, FonatPlus, Fosamax Plus, Terry White Chemists Alendronate Plus D3 70 mg/70 mcg)*

9183H **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram tablet, 4 *(APO-Alendronate Plus D3 70 mg/140 mcg, Alendrobell plus D3, Alendronate D3 70 mg/140 microgram, Alendronate Plus D3 Sandoz, Alendronate plus D3-DRLA, Chem mart Alendronate Plus D3 70 mg/140 mcg, Dronalen Plus, FonatPlus, Fosamax Plus 70 mg/140 mcg, Terry White Chemists Alendronate Plus D3 70 mg/140 mcg)*

9351E **ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack *(Alendronate Plus D3 Calcium Actavis, Alendronate Plus D3 and Calcium Sandoz, Dronalen Plus D-Cal, Fosamax Plus D-Cal, ReddyMax Plus D-Cal)*

5457F **DENOSUMAB**, denosumab 60 mg/mL injection, 1 mL syringe *(Prolia)*

8713N **FOLLITROPIN ALFA**, follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge *(Gonal-f Pen)*

8714P **FOLLITROPIN ALFA**, follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge *(Gonal-f Pen)*

8715Q **FOLLITROPIN ALFA**, follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge *(Gonal-f Pen)*

8565T **FOLLITROPIN BETA**, follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge *(Puregon 300 IU/0.36 mL)*

8566W **FOLLITROPIN BETA**, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge *(Puregon 600 IU/0.72 mL)*

8871X **FOLLITROPIN BETA**, follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge *(Puregon 900 IU/1.08 mL)*

1644M **MORPHINE**, morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

5168B **MORPHINE**, morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)***(Dental)**

8363E **RALOXIFENE**, raloxifene hydrochloride 60 mg tablet, 28 *(APO-Raloxifene, Chem mart Raloxifene, Evifyne, Evista, Fixta 60, Raloxifene AN, Terry White Chemists Raloxifene)*

8481J **RISEDRONATE**, risedronate sodium 5 mg tablet, 28 *(Actonel)*

8621R **RISEDRONATE**, risedronate sodium 35 mg tablet, 4 *(APO-Risedronate, Acris Once-a-Week, Risedro once a week, Risedronate AN, Risedronate Sandoz, Risedronate-GA)*

8972F **RISEDRONATE**, RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 *(Actonel EC)*

9391G **RISEDRONATE**, risedronate sodium 150 mg tablet, 1 *(APO-Risedronate, ATELVIA ONCE-A-MONTH, Acris Once-a-Month, Actonel Once-a-Month, Chem mart Risedronate, Terry White Chemists Risedronate)*

8899J **RISEDRONATE (&) CALCIUM CARBONATE**, risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28 *(Acris Combi)*

8973G **RISEDRONATE (&) CALCIUM CARBONATE**, RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1 *(Actonel EC Combi)*

8974H **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1 *(Actonel EC Combi D)*

10719E **RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*

9411H **TERIPARATIDE**, teriparatide 20 microgram injection, 2.4 mL cartridge *(Forteo)*

10378F **TESTOSTERONE**, testosterone 5% (50 mg/mL) cream, 50 mL *(AndroForte 5)*

10380H **TESTOSTERONE**, testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations *(Testogel)*

2341F **TESTOSTERONE**, testosterone 2% (30 mg/actuation) solution, 60 actuations *(Axiron)*

8460G **TESTOSTERONE**, testosterone 2.5 mg/24 hours patch, 60 *(Androderm)*

8619P **TESTOSTERONE**, testosterone 5 mg/24 hours patch, 30 *(Androderm)*

8830R **TESTOSTERONE**, testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets *(Testogel)*

2114G **TESTOSTERONE ENANTHATE**, testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes *(Primoteston Depot)*

10205D **TESTOSTERONE UNDECANOATE**, testosterone undecanoate 1 g/4 mL injection, 4 mL vial *(Reandron 1000)*

2115H **TESTOSTERONE UNDECANOATE**, testosterone undecanoate 40 mg capsule, 60 *(Andriol Testocaps)*

10555M **ZOLEDRONIC ACID**, zoledronic acid 5 mg/100 mL injection, 100 mL bag *(Ostira)*

9288W **ZOLEDRONIC ACID**, zoledronic acid 5 mg/100 mL injection, 100 mL vial *(Aclasta, Osteovan, Zoledasta)*

Alteration – Manufacturer Code

		From	*To*
8202Q	*Spren 100* – **ASPIRIN**, aspirin 100 mg tablet, 112	QA	OW
2591J	*Oratane* – **ISOTRETINOIN**, isotretinoin 10 mg capsule, 60	AG	RF
2592K	*Oratane* – **ISOTRETINOIN**, isotretinoin 20 mg capsule, 60	AG	RF
2549E	*Oratane* – **ISOTRETINOIN**, isotretinoin 40 mg capsule, 30	AG	RF
1746X	*Paralgin* – **PARACETAMOL**, paracetamol 500 mg tablet, 100	FM	OW
5196L	*Paralgin* – **PARACETAMOL**, paracetamol 500 mg tablet, 100 **(Dental)**	FM	OW

5224Y	*Paralgin* – **PARACETAMOL**, paracetamol 500 mg tablet, 100 **(Dental)**	FM	OW
8784H	*Paralgin* – **PARACETAMOL**, paracetamol 500 mg tablet, 100	FM	OW

Advance Notices

1 September 2016

Deletion – Brand

8297Q *Candesartan RBX, RA* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

8889W *Candesartan RBX, RA* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

8504N *Candesartan HCTZ RBX 16/12.5, RA* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

1211R *Serophene, SG* – **CLOMIPHENE**, clomiphene citrate 50 mg tablet, 10

8535F *Oziclide MR, RA* – **GLICLAZIDE**, gliclazide 30 mg modified release tablet, 100

10621B *Hymenoptera Honey Bee Venom, DE* – **HONEY BEE VENOM**, bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

8423H *Dilaudid-HP, MF* – **HYDROMORPHONE**, hydromorphone hydrochloride 500 mg/50 mL injection, 50 mL vial

2420J *Tolerade 10, PQ* – **IMIPRAMINE**, imipramine hydrochloride 10 mg tablet, 50

2421K *Tolerade 25, PQ* – **IMIPRAMINE**, imipramine hydrochloride 25 mg tablet, 50

1801T *Metformin Ranbaxy, RA* – **METFORMIN**, metformin hydrochloride 850 mg tablet, 60

1703P *Abbocillin-VK Filmtab, QA* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25

1787C *Abbocillin-VK Filmtab, QA* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25

3028J *Abbocillin-VK Filmtab, QA* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 500 mg tablet, 25

3360W *Abbocillin-VK Filmtab, QA* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25 **(Dental)**

3361X *Abbocillin-VK Filmtab, QA* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 500 mg tablet, 25 **(Dental)**

5012T *Abbocillin-V, QA* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL **(Dental)**

9143F *Abbocillin-V, QA* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

8695P *Pizaccord, RA* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

8355R *Telmisartan RBX, RA* – **TELMISARTAN**, telmisartan 40 mg tablet, 28

8356T *Telmisartan RBX, RA* – **TELMISARTAN**, telmisartan 80 mg tablet, 28

1070H *Betavit, PP* – **THIAMINE**, thiamine hydrochloride 100 mg tablet, 100

3130R *Vancocin CP, AS* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

3131T *Vancocin CP, AS* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

3323X *Vancocin CP, AS* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial **(Dental)**

8301X *Venla RBX, RA* – **VENLAFAXINE**, venlafaxine 75 mg capsule: modified release, 28

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

10875J **TACROLIMUS**, tacrolimus 750 microgram capsule, 100 *(Tacrolimus Sandoz)*

10879N **TACROLIMUS**, tacrolimus 2 mg capsule, 100 *(Tacrolimus Sandoz)*

Addition – Brand

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

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

9681M *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 500 microgram capsule: modified release, 30

9682N *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 1 mg capsule: modified release, 60

9683P *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 5 mg capsule: modified release, 30

Addition – Equivalence Indicator

9681M *Prograf XL, LL* – **TACROLIMUS**, tacrolimus 500 microgram capsule: modified release, 30

9682N *Prograf XL, LL* – **TACROLIMUS**, tacrolimus 1 mg capsule: modified release, 60

9683P *Prograf XL, LL* – **TACROLIMUS**, tacrolimus 5 mg capsule: modified release, 30

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Item

10372X **TELBIVUDINE**, telbivudine 600 mg tablet, 28 *(Sebivo)*

IVF Program

Additions

Addition – Item

10861P **FOLLITROPIN ALFA**, follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices *(Bemfola)*

10873G **FOLLITROPIN ALFA**, follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices *(Bemfola)*

10872F **FOLLITROPIN ALFA**, follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices *(Bemfola)*

10866X **FOLLITROPIN ALFA**, follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices *(Bemfola)*

10867Y **FOLLITROPIN ALFA**, follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices *(Bemfola)*

Alterations

Alteration – Maximum Quantity

		From	*To*
10491E	**FOLLITROPIN ALFA + LUTROPIN ALFA**, follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance diluent [1 vial], 1 pack *(Pergoveris)*	7	14
10465T	**LUTROPIN ALFA**, lutropin alfa 75 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack *(Luveris)*	7	14

Repatriation Pharmaceutical Benefits

Alterations

Alteration – Manufacturer Code

		From	*To*
10590J	*Spren 100* – **ASPIRIN**, aspirin 100 mg tablet, 112	QA	OW
10582Y	*Paralgin* – **PARACETAMOL**, paracetamol 500 mg tablet, 100	FM	OW
10585D	*Paralgin* – **PARACETAMOL**, paracetamol 500 mg tablet, 100	FM	OW

Prescriber Bag

- **MORPHINE**

morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

10862Q	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	19.83	Morphine Juno [JU]

OR

morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules

10868B	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	23.19	Morphine Juno [JU]

OR

morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules

3479D	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	21.23	Hospira Pty Limited [HH]

OR

morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules

3480E	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	23.33	Hospira Pty Limited [HH]

General Pharmaceutical Benefits

▪ ALENDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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alendronate 70 mg tablet, 4

8511Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	15.46	16.65	[a] Alendrobell 70mg [GQ]	[a] Alendronate AN [EA]
					[a] Alendronate-GA [ED]	[a] Alendronate Sandoz [SZ]
					[a] Alendro Once Weekly [RW]	[a] APO-Alendronate [TX]
					[a] Densate 70 [DO]	[a] Fonat [AL]

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6306

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6325

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

alendronate 70 mg + colecalciferol 140 microgram tablet, 4

9183H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	39.49	38.30	[a] Alendrobell plus D3 [GQ]	[a] Alendronate D3 70 mg/140 microgram [EA]
					[a] Alendronate plus D3-DRLA [RZ]	[a] Alendronate Plus D3 Sandoz [SZ]
					[a] APO-Alendronate Plus D3 70 mg/140 mcg [TX]	[a] Chem mart Alendronate Plus D3 70 mg/140 mcg [CH]
					[a] Dronalen Plus [AL]	[a] FonatPlus [AF]
					[a] Terry White Chemists Alendronate Plus D3 70 mg/140 mcg [TW]	
		[B]2.49	41.98	38.30	[a] Fosamax Plus 70 mg/140 mcg [MK]	

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

Authority required (STREAMLINED)

6307

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6320

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6315
Established osteoporosis
Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
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.

alendronate 70 mg + colecalciferol 70 microgram tablet, 4

9012H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	39.49	38.30	[a] Alendrobell plus D3 [GQ]	[a] Alendronate D3 70 mg/70 microgram [EA]
						[a] Alendronate plus D3-DRLA [RZ]	[a] Alendronate Plus D3 Sandoz [SZ]
						[a] APO-Alendronate Plus D3 70 mg/70 mcg [TX]	[a] Chem mart Alendronate Plus D3 70 mg/70 mcg [CH]
						[a] FonatPlus [AF]	[a] Terry White Chemists Alendronate Plus D3 70 mg/70 mcg [TW]
			[B]2.50	41.99	38.30	[a] Fosamax Plus [MK]	

▪ ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)
6306
Corticosteroid-induced osteoporosis
Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)
6325
Osteoporosis
Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)
6319
Established osteoporosis
Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
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.

alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

9351E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	40.13	38.30	[a] Alendronate Plus D3 and Calcium Sandoz [SZ]	[a] Alendronate Plus D3 Calcium Actavis [EA]
						[a] Dronalen Plus D-Cal [AF]	[a] ReddyMax Plus D-Cal [RZ]
			[B]2.50	42.63	38.30	[a] Fosamax Plus D-Cal [MK]	

▪ DENOSUMAB

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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.

Authority required (STREAMLINED)

6311

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6326

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

denosumab 60 mg/mL injection, 1 mL syringe

5457F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	270.96	38.30	Prolia [AN]

▪ FOLLITROPIN ALFA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices

10877L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	1	..	*963.39	38.30	Bemfola [FX]

follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices

10876K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	1	..	*1414.74	38.30	Bemfola [FX]

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge

8713N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*391.08	38.30	Gonal-f Pen [SG]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge

8714P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*584.49	38.30	Gonal-f Pen [SG]

follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10865W	3	1	..	*483.84	38.30	Bemfola [FX]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8715Q	2	5	..	*777.92	38.30	Gonal-f Pen [SG]

▪ FOLLITROPIN BETA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8565T	3	5	..	*480.00	38.30	Puregon 300 IU/0.36 mL [MK]

follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8566W	2	5	..	*623.16	38.30	Puregon 600 IU/0.72 mL [MK]

follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8871X	2	5	..	*924.34	38.30	Puregon 900 IU/1.08 mL [MK]

▪ MORPHINE

Caution The risk of drug dependence is high.

morphine hydrochloride 100 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10878M (NP)	1	..	..	40.39	38.30	Morphine Juno [JU]

morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10874H (NP)	1	..	..	23.19	24.38	Morphine Juno [JU]

morphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10869C (NP)	1	..	..	29.64	30.83	Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10858L (DP)	1	..	..	23.19	24.38	Morphine Juno [JU]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

10864T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP MW	1	..	..	19.83	21.02	[a] Morphine Juno [JU]

morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules

1644M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP MW	1	..	..	19.83	21.02	[a] Hospira Pty Limited [HH]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

10863R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	19.83	21.02	[a] Morphine Juno [JU]

morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules

5168B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	19.83	21.02	[a] Hospira Pty Limited [HH]

▪ RALOXIFENE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6314

Established post-menopausal osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

raloxifene hydrochloride 60 mg tablet, 28

8363E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.32	38.30	[a] APO-Raloxifene [TX] [a] Evifyne [EL] [a] Fixta 60 [DO] [a] Terry White Chemists Raloxifene [TW]	[a] Chem mart Raloxifene [CH] [a] Evista [LY] [a] Raloxifene AN [EA]

▪ RISEDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

8972F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.87	38.30	Actonel EC [UA]

risedronate sodium 150 mg tablet, 1

9391G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	40.16	38.30	[a] Acris Once-a-Month [AF]	[a] Actonel Once-a-Month [UA]
					[a] APO-Risedronate [TX]	[a] ATELVIA ONCE-A-MONTH [GN]
					[a] Chem mart Risedronate [CH]	[a] Terry White Chemists Risedronate [TW]

risedronate sodium 35 mg tablet, 4

8621R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	37.87	38.30	[a] Acris Once-a-Week [AF]	[a] APO-Risedronate [TX]
					[a] Risedronate AN [EA]	[a] Risedronate-GA [GN]
					[a] Risedronate Sandoz [SZ]	[a] Risedro once a week [RW]

risedronate sodium 5 mg tablet, 28

8481J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.87	38.30	Actonel [UA]

▪ RISEDRONATE (&) CALCIUM CARBONATE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6306

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6325

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8973G NP	‡1	5	..	45.03	38.30	Actonel EC Combi [UA]

risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8899J NP	‡1	5	..	45.03	38.30	Acris Combi [AF]

▪ RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6306

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6325

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8974H NP	‡1	5	..	45.03	38.30	Actonel EC Combi D [UA]

▪ RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

Authority required (STREAMLINED)

6309

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be for induction treatment purposes only, **AND**

- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

Authority required (STREAMLINED)

6162

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10719E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	6	..	2851.66	38.30	Mabthera SC [RO]

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

tacrolimus 2 mg capsule, 100

10871E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	560.68	38.30	Tacrolimus Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10870D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	212.92	38.30	Tacrolimus Sandoz [SZ]

▪ 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 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 agent, **AND**
- The treatment must not exceed a lifetime maximum of 18 months 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 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 provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Authority required

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.

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

teriparatide 20 microgram injection, 2.4 mL cartridge

9411H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	411.27	38.30	Forteo [LY]

▪ TESTOSTERONE

Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

10380H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	4	..	87.17	38.30	Testogel [HB]

testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

8830R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	87.17	38.30	Testogel [HB]

testosterone 2% (30 mg/actuation) solution, 60 actuations

2341F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	76.23	38.30	Axiron [LY]

testosterone 2.5 mg/24 hours patch, 60

8460G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	87.78	38.30	Androderm [AG]

testosterone 5 mg/24 hours patch, 30

8619P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	87.78	38.30	Androderm [AG]

testosterone 5% (50 mg/mL) cream, 50 mL

10378F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	6	..	73.42	38.30	AndroForte 5 [LX]

▪ TESTOSTERONE ENANTHATE

Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes

2114G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	32.91	34.10	Primoteston Depot [BN]

▪ TESTOSTERONE UNDECANOATE

Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone undecanoate 1 g/4 mL injection, 4 mL vial

10205D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	132.33	38.30	Reandron 1000 [BN]

testosterone undecanoate 40 mg capsule, 60

2115H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	36.26	37.45	Andriol Testocaps [MK]

▪ ZOLEDRONIC ACID

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6308

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6313

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6318

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

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.

zoledronic acid 5 mg/100 mL injection, 100 mL bag

10555M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	491.42	38.30	[a] Ostira [HH]

zoledronic acid 5 mg/100 mL injection, 100 mL vial

9288W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	491.42	38.30	[a] Aclasta [NV] [a] Zoledasta [TX]	[a] Osteovan [SZ]

Highly Specialised Drugs Program (Private Hospital)

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

tacrolimus 2 mg capsule, 100

10879N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1047.02	Tacrolimus Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10875J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*397.02	Tacrolimus Sandoz [SZ]

Highly Specialised Drugs Program (Public Hospital)

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5569

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

tacrolimus 2 mg capsule, 100

10860N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*1000.00	Tacrolimus Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10859M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*375.00	Tacrolimus Sandoz [SZ]

IVF Treatment Program

▪ FOLLITROPIN ALFA

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices

10873G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*903.39	38.30	Bemfola [FX]

follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices

10872F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*1339.86	38.30	Bemfola [FX]

follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices

10866X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*1770.81	38.30	Bemfola [FX]

follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices

10867Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*2632.71	38.30	Bemfola [FX]

follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices

10861P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*455.22	38.30	Bemfola [FX]