The Pharmacy Guild of Australia Submission to the Post Market Review of Authority Required PBS Listings

About The Pharmacy Guild of Australia

The Pharmacy Guild of Australia (the Guild) was established in 1928, and is registered under the federal Workplace Relations Act 1996 as an employers' organisation. The Guild's members are the owners of approximately 80% of the 5,450 community pharmacies in Australia which dispense around 290 million prescriptions annually, the vast majority of which are dispensed under the Pharmaceutical Benefits Scheme (PBS).

The Guild aims to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

In the previous submission to the Post Market review the Guild proposed the following criteria for PBS restrictions:

A medicine or medicinal form is considered for **Restricted Benefit** for the following reasons:

- To limit PBS usage so that it is used in accordance with the approval and registration granted by the TGA.
- For items previously listed as STREAMLINED where there is only one indication and/or where usage data is considered unnecessary or not useful.

A medicine or medicinal form is considered for **Authority Required** listing for the following reasons:

- Instances where the prescriber is seeking an increase above the maximum quantity, and/or an increased number of repeats.
- To allow the controlled introduction of a medicine in a new therapeutic class if there is a need to limit PBS usage to those patient groups where it is found to be cost-effective.
- To allow for the listing of medicines where a prior written approval for authority to prescribe is required e.g. S100 HSD Complex Authority Required items.
- To limit PBS usage so that this is in accordance with the approval and registration granted by the TGA e.g. quinine for use in malaria as opposed to nocturnal leg cramps.
- To alleviate concerns about adverse reactions, possible misuse, overuse or abuse e.g. temazepam capsules where there was a risk of injection.

A medicine or medicinal form is considered for **Authority Required (STREAMLINED)** for the following reasons:

- After the controlled introduction of a medicine in a new therapeutic class and/or there is no longer a need to limit PBS usage and there are multiple restrictions for which usage data is considered necessary.
- To allow for treatment in patients groups of a drug in a Therapeutic Group with a Therapeutic Group Premium (TGP) where adverse effects occurring with all of the base-priced drugs, drug interactions occur or are expected to occur with all the base-priced drugs or transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.
- To allow for differential increased maximum quantities or increased repeats for special patient groups (e.g. oxazepam for use in patients who are receiving long-term nursing care on account of age, infirmity …)

The Guild previously made a submission to the November 2011 PBAC meeting requesting the PBAC consider a list of Authority Required (STREAMLINED) items we considered could be changed to Restricted Benefit. It addition to this suggested list of changes the Guild provides the following advice on the three tranches of Authority Required items for consideration by the Post Market Review.

On account of the page limit for submissions of 15 pages the Guild has tabulated its recommendations using the following coding system to explain its recommendations:

A. Product has no other indication (either TGA approved or 'off-label') that would lead to 'leakage' of use outside the PBS restriction. Therefore restriction could be relaxed without risk of an increase in usage.

B. Product has been listed for some time and its controlled introduction could now be considered over. Usage would be unlikely to increase if restriction relaxed.

C. Product has a niche market and/or prescriber base such that it is unnecessary to restrict its usage. Usage would be unlikely to increase if restriction relaxed.

D. Antimicrobial product – usage should be restricted as suggested by such learned bodies as the Antimicrobial Resistance Standing Committee (AMRSC) and NPS Medicineswise to ensure responsible stewardship of antimicrobial products to promote rational use and prevent antimicrobial resistance.

E. Product has the potential to be abused and/or misused outside of its indication and/or restriction eg opiates, anabolic steroids, CNS stimulants for ADHD narcolepsy etc

F. Section 100 HSD/Chemotherapy Items for Public Hospital Use and Section 100HSD/Chemotherapy Items for Private Hospital/Private Clinic – restriction should be made consistent between Public/Private

G. Product has multiple brands and/or undergone significant price reductions since patent expiry

General points worth noting

Effectiveness of PBS restrictions

The Pharmaceutical Benefits Scheme (PBS) began as a limited scheme in 1948, with free medicines for pensioners and a list of 139 'life-saving and disease preventing' medicines free of charge for others in the community. Today the PBS provides timely, reliable and affordable access to necessary medicines for Australians. The PBS is part of the Australian Government's broader National Medicines Policy. Under the PBS, the government subsidises the cost of medicine for most medical conditions. Most of the listed medicines are dispensed by pharmacists, and used by patients at home.

Since the advent of Price Disclosure and successive increases in the patient co-payments for both pensioners and general patients the effectiveness of any restriction placed on PBS listed medicines is less as the prescriber and patient may opt to have the prescription written and dispensed as a non-PBS item ie a "private item". This is of concern for such medicines as antibiotics, drugs of addiction, drugs that could be misused and/or abused and/or diverted. Prior to Price Disclose and relatively low patient co-payments the PBS-restriction had some influence as the cost of having a medicine dispensed "privately" was prohibitive for most patient groups.

As noted by the Hon. Member for Boothby Andrew Southcott MP on 15 July 2014:

There are a number of medicines that are already less than the current general co-payment and they account for more than 40 per cent of PBS listings and more than 70 per cent of general patient prescriptions.

What that means is that for these patients and for these scripts, the increase in the co-payment will have no effect. Take, for example, Amoxicillin, a common antibiotic currently costs $13.85 and is well below the PBS co-payment. After increases in the general co-payment, there will be no impact on the price of Amoxicillin. By the time the co-payment changes come into effect on 1 January next year, more than 55 per cent of listings will be below the general co-payment amount.[1]

The Guild would suggest that in the case of Controlled Drugs (or Schedule 8/Dangerous Drugs) the Electronic Recording and Reporting of Controlled Drugs (ERRCD) is the most effective mechanism to ensure appropriate use of these medicines to prevent overuse, misuse/abuse or diversion as the cost many these medicines is lower than the general patient co-payment. The Guild believes that many Authority Required restrictions could be made Authority Required (Streamlined) or Restricted Benefit when the States and Territories have implemented ERRCD.

[1] http://www.andrewsouthcott.com.au/Media/Videos/tabid/90/articleType/ArticleView/articleId/1167/Making-the-PBS-sustainable.aspx

With respect to the important concerns of antibiotic resistance the Guild notes the World Health Organisation Fact Sheet states that: [2]

"Policymakers can help tackle resistance by:

- *strengthening resistance tracking and laboratory capacity;*
- *strengthening infection control and prevention;*
- *regulating and promoting appropriate use of medicines;*
- *promoting cooperation and information sharing among all stakeholders.*

Policymakers, scientists and industry can help tackle resistance by:

- *fostering innovation and research and development of new vaccines, diagnostics, infection treatment options and other tools."*

The Guild would caution against the reliance on PBS-restrictions in isolation to help in the prevention of antibiotic resistance and notes with interest that Dr Southcott used amoxicillin as an example in his speech to parliament. It would appear that this product has gained such a reputation over the years that it is often used as an example when explaining aspects of the PBS. The Guild would suggest additional measures are put in place to ensure the continued effectiveness of antibiotics in the face of increasing antibiotic resistance caused by inappropriate antibiotic use. Educational activities for patients and health professionals such as that carried out by NPS Medicinewise[3] are valuable additional measures that would assist in proper antibiotic prescribing where PBS restrictions are losing their effectiveness due to the decrease in the price of many medicines with the corresponding increase in patient co-payments.

Further consideration could be given to inclusion of reminders or pop-ups in prescribing software to remind prescribers of the dangers of antibiotic overuse. In addition, having prescribing software automatically default to zero repeats on antibiotic prescriptions rather than the current situation where all antibiotic prescriptions default to the maximum number of repeats would go some way in preventing unnecessary and inappropriate antibiotic use.

Lifetime limits

Some PBS restrictions include a maximum number of treatments eg teriparatide, nafarelin in a lifetime or over a specified time period and the Guild questions how the compliance of these medicines could be monitored under a Streamlined restriction.

Authority Required (Streamlined) administrative requirements

The Guild questions why Authority Required (Streamlined) items need to be written on a special form which includes an 8-digit Authority Required Form Number. The important number is the 4-digit Streamlined Authority Code i.e. the number that identifies the indication for which the medicine is being prescribed. The Authority Required Form number

[2] http://www.who.int/mediacentre/factsheets/fs194/en/

[3] http://www.nps.org.au/medicines/infections-and-infestations/antibiotics

is an artefact of the Authority Required system where the form number was recorded by the Medicare operator when the prescriber telephoned for permission to write a PBS-subsidised prescription. This form number is not required for Streamlined prescriptions and should not have to be recorded by the dispenser.

The Guild would suggest that all Streamlined PBS listings could be written on regular PBS prescription stationery with the Streamlined Authority Code. This would also mean that multiple strengths of a medicine could be included on the same prescription form, for example; if a prescriber wished to order mycophenolate 750 mg bd a single form could be used to order mycophenolate 500 mg and mycophenolate 250 mg. As the majority of prescribers use computers to write prescriptions this should not be an onerous change to process and would in fact be a more efficient use of PBS stationery.

Online Prior Written Authority Required Portal for Prescribers

The Guild believes that given the delays with the postal system an online Authority Required application portal would be the most appropriate way to address this problem. However, given the time and cost to develop such a system the Guild questions why DHS-Medicare cannot accept applications via email from prescribers which would increase the efficiency and effectiveness of the approval system.

Section 100 Highly Specialised Drugs

The Highly Specialised Drugs Program provides for funding of specialised medications for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through hospitals having access to appropriate specialist facilities.

The Guild notes that many S100 HSD listings also have been subsequently listed in the Section 85 general schedule for 'maintenance' therapy eg mycophenolate, tacrolimus, cyclosporin, sirolimus and cinacalcet, presumably to address patient access problems. The original listing in the HSD program may no longer be appropriate for many of the listings.

With the recently announced policy initiative to allow patients to access HIV medicines and clozapine from July 2015 the Guild questions if there are not more medicines that could be available from a pharmacy of a patient's choice. Multiple listing also causes unnecessary confusion amongst prescribers, pharmacist and patients. The Guild suggests the listing of items could be simplified by having one HSD streamlined listing to cover prescribing from any setting along with a requirement in the restriction that initiation take place by a suitable specialist in a hospital environment and maintenance treatment could be managed by other prescribers in consultation with the specialist unit.

Authority Required "Life-time Approval"

The Guild questions why a prescriber has to phone for an Authority Required approval when the patient has a life time condition. For medicines a patient must remain on for the term of their natural life e.g. following a transplant, the Guild would suggest that only the initial

treatment needs a phone approval and the patient could then be continued on treatment by receiving a "Life-time Approval" which the prescriber access by writing a Restricted Benefit or Streamlined Authority.

Interferons

The Guild notes that there are many interferons listed on the PBS with some in Section 100 HSD program and some in Section 85. Many have different indications and levels of restrictions and the Guild questions whether consideration could be given to more consistency within this class of drugs.

The Guild also notes a recent recommendation made by the Pharmaceutical Benefits Advisory Committee at its meeting held in March 2014 where the Committee was asked to consider a change to the restriction for interferon beta-1a[4]. Whilst the Committee considered that it would be appropriate for the current Authority Required listing be amended to Authority Required (STREAMLINED) it also recommended "*that the Department review the administrative requirements for all PBS listed treatments for relapsing-remitting multiple sclerosis (RRMS) in a consolidated fashion, rather than considering the individual listings in a piecemeal approach*". Once again this highlights the Guild's suggestion that the PBAC should regularly review the PBS listings to ensure they remain appropriate.

bDMARDs

The Guild notes that most of the bDMARDs and similar medicines have very long restrictions the length and complexity of which may have the opposite of the intended effect of restricting use to certain patient groups in which they have been found to be cost-effective. The length and complexity may disengage the stakeholders and the Guild would suggest that it may be worthwhile considering a "General Statement" or flow chart that prescribers could more easily follow.

Bisphosphonates

The Guild notes that this class of drugs has a number of examples which are listed in both Section 100 HSD program and Section 85 with a number of indications and forms/presentations all with a variety of different restriction levels. The Guild questions whether there could be consideration given to more consistency in this class of drugs.

Tenofovir disoproxil fumarate 300 mg tablet

The Guild notes this item is listed in Section 100 HSD for chronic hepatitis B and for HIV.[5]

The Guild also notes the announcement by the Minister for Health, the Hon. Mr Peter Dutton MP, made on 7 July 2014 that from 1 July 2015 amendments will be made to the prescribing and dispensing arrangements for PBS subsidised HIV antiretroviral therapies so that these

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[4] http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/pbac-recommendations-march-2014

[5] http://www.pbs.gov.au/medicine/item/6358P-9563H

medicines can now be dispensed through a pharmacy of the patient's choice regardless of where they were prescribed.[6] Tenofovir highlights the inconsistency of making one group of HSD drugs for one disease available at a pharmacy of a patient's choice but not for other diseases as this drug can be used to treat both HIV and chronic hepatitis B. This decision is clearly inequitable and if one group of drugs can be made available at a pharmacy of a patient's choice for one patient group then all drugs should be available at a pharmacy of a patient's choice irrespective of what disease they are living with.

PBS listing "NOTES"

A number of PBS listings include a "NOTE" which excludes the use of a PBS-listed medicine with other medicines eg for rosiglitazone+metformin *"This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor."*

The Guild questions whether such notes are enforceable unless the restriction is Authority Required as the Medicare operator would be in a position to verify the patient was not on any PBS-listed medicine included in the NOTE.

General Nutrients

The Guild notes that there are a number of foods for special medical purposes listed on the PBS and many are listed for the management of inborn errors of metabolism which are diagnosed and treated by specialists. Whilst it could be argued that the red tape burden for these sometimes small patient groups may not be considered onerous it should be remembered that the red tape burden may be large for the limited number of specialists treating these patients. Given these considerations the Guild asks whether many of these items could not be listed as Restricted Benefits. It is unlikely that they would be used unless the patient had an inborn error of metabolism and are unlikely to be misused, abused or diverted.

[6] http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2013-dutton049.htm?OpenDocument&yr=2014&mth=07

Post-market Review of Authority Required PBS Listings Tranche 1 Medicine List

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
temozolomide	Glioblastoma multiforme anaplastic astrocytoma	Authority Required	Streamlined	A, B, C , G	Interestingly carmustine 7.7 mg implant with a DPMQ of $17,539.66 is Restricted Benefit
pemetrexed (as disodium heptahydrate)	Non-small cell lung cancer Mesothelioma in combo with cisplatin	Chemotherapy Item Streamlined And Authority Required	Streamlined	F	Chemotherapy Public and Private
fludarabine phosphate injection	B-cell chronic lymphocytic leukaemia	Chemotherapy Item Streamlined And Authority Required	Streamlined	F, G	Chemotherapy Public and Private
fludarabine phosphate 10 mg tablet, 20	B-cell chronic lymphocytic leukaemia in	Authority Required	Streamlined	F	The injection is listed as Section 100 HSD and has multiple brands whereas the tablet is listed in Section 85 with only one brand
capecitabine	Advanced breast cancer Colorectal cancer Oesophago-gastric cancer	Authority Required	Streamlined	B, G	In the adjuvant setting, the recommended treatment duration is 24 weeks.
azacitidine	Myelodysplastic syndrome Chronic Myelomonocytic Leukaemia Acute Myeloid Leukaemia	Prior Written Authority Required CAR	Streamlined	F	Section 100 HSD Private and Private Why is this not included in Efficient Funding of Chemotherapy?
vinorelbine	non-small cell lung cancer Advanced breast cancer	Streamlined and Authority Required	Streamlined	B, F, G,	Chemotherapy Items for Public Hospital use and Private Hospital Use
cabazitaxil	Carcinoma of the prostate	Streamlined and Authority Required	Streamlined	F	Chemotherapy Items for Public Hospital use and Private Hospital Use should be consistent

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
doxorubicin hydrochloride-pegylated liposomal	Ovarian cancer Breast cancer Kaposis's sarcoma	Streamlined and Authority Required	Streamlined	F, G	Chemotherapy Items for Public Hospital use and Private Hospital Use should be consistent
trastuzumab	Locally advance HER2 + breast cancer	Prior Written Authority Required	Phone Authority	B	Is a Written authority necessary to control prescribing to a max. of 52 weeks? Would a phone prevent usage past this point?
cetuximab	Cancer of the larynx	Streamlined and Authority Required	Streamlined	F	Chemotherapy Items for Public Hospital use and Private Hospital Use should be consistent
bevacizumab	Ovarian, fallopian tube peritoneal cancer Metastatic colorectal cancer	Streamlined and Authority Required	Streamlined	F	Chemotherapy Items for Public Hospital use and Private Hospital Use should be consistent
panitumumab	Metastatic colorectal cancer	Streamlined and Authority Required	Streamlined	F	Chemotherapy Items for Public Hospital use and Private Hospital Use should be consistent
ipilimumab	Malignant melanoma	Streamlined and Authority Required	Streamlined	F	Chemotherapy Items for Public Hospital use and Private Hospital Use should be consistent
dabrafenib	Malignant melanoma	Authority Required	Streamlined	C	
imatinib	Gastrointestinal stromal tumour chronic myeloid leukaemia	Prior Written Authority Required then phone for continuing tx	Phone Authority	A	There are 18 listing for imatinib. Is this complexity useful? Could the restrictions be simplified with a General Statement?
Gefitinib	Non-small cell lung cancer	Authority Required	As above	A	
erlotinib	Non-small cell lung cancer	Authority required	As above	B	There are 9 listings for erlotinib Is this complexity useful?
sunitinib	Pancreatic neuroendocrine tumour Stage IV clear cell variant renal cell carcinoma (RCC) gastrointestinal stromal tumour	Prior Written Authority Required Continuing treatment by phone	Streamlined	B	There are 15 listings for sunitinib Is this complexity useful?

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
dasatinib	Myeloid leukaemia acute lymphoblastic leukaemia	Prior Written Authority Required Continuing treatment by phone	Streamlined	B	There are 12 listings for dasatinib Is this complexity useful
lapatinib	HER2+ metastatic breast cancer	Prior Written Authority Required and for continuing	Phone Authority	B	Must have failed trastuzumab
nilotinib	Chronic myeloid leukaemia	Prior Written Authority Required and for continuing	Phone Authority	B	
everolimus	Stage IV clear cell variant renal cell carcinoma (RCC) Tuberous sclerosis complex Maintenance – renal transplant Maintenance – cardiac transplant	Section 85 Authority Required	Streamlined	B	Included in Section 100 HSD and Section 85 – is this necessary?
everolimus	Management of rejection – renal transplant Management of rejection – cardiac transplant	Section 100 HSD Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public – should be consistent
pazopanib	Advanced soft tissue sarcoma Stage IV clear cell variant renal cell carcinoma (RCC)	Authority Required	Streamlined	C	
arsenic trioxide	Acute promyleocytic leukaemia	Streamlined and Authority Required	Streamlined	F	Chemotherapy Items for Public Hospital use and Private Hospital Use should be consistent
bortezomib	Symptomatic multiple myeloma Multiple myeloma	Prior Written Authority Required	Streamlined or Phone Authority		There are 14 listings for bortezomib – is this complexity useful?
goserelin 3.6 mg implant, 1	Prostate cancer Breast cancer Endometriosis	Authority Required	Streamlined	F	The 3.6 mg implant is Authority Required yet the 10.8 mg implant is Streamlined – they should be consistent
goserelin 10 mg implant, 1	Prostate cancer	Streamlined	Streamlined	F	See above

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
abiraterone acetate	Prostate cancer	Authority Required	Authority Required	How to enforce the NOTE if it's not Authority Required?	Patients who have received PBS-subsidised abiraterone or cabazitaxel are not eligible for PBS-subsidised docetaxel.
filgrastim	22 different Authority Required restrictions	Section 100 HSD Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
lenograstim	14 different Authority Required restrictions	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
pegfilgrastim	15 different Authority Required restrictions	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
Interferons – some are Section 100 HSD Private and Public, whilst others are Section 85 Authority Required. Could consideration be given to more consistency for this class of medicines?					
interferon alfa-2a	Leukaemia Hepatitis B	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
interferon alfa-2b	Malignant melanoma Leukaemia Hepatitis B	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
interferon gamma-1b	Granulomatous disease	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
Interferon alfa-2a	Hairy cell leukaemia Myeloproliferative disease	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
Interferon alfa-2a	Hairy Cell leukaemia Myeloproliferative disease Non-Hodgkin's lymphoma	Authority Required	Streamlined	F	Section 100 HSD Private and Public
Interferon-alfa-2b	Multiple myeloma me Non-Hodgkins lymphoma Hairy Cell leukaemia	Authority Required	Streamlined	A, B	Section 85
Interferon beta-1a	Multiple sclerosis	Authority Required	Streamlined	A, B	Section 85

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
Interferon beta-1b	Multiple sclerosis	Authority Required	Streamlined	A, B	Section 85
peginterferon alfa-2a	Hepatitis B and C	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
Peginterferon alfa-2a and ribavirin	Hepatitis C	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
peginterferon alfa-2b and ribavirin	Hepatitis C	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
glatiramer acetate	Multiple sclerosis	Authority Required	Streamlined	C	Could original be AR and continuing treatment be STREAMLINED ?
plerixafor	Mobilisation of heamotopoietic stem cells	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
teriflunomide	Multiple sclerosis	Authority Required	Streamlined	B	Patient must have been receiving treatment with this drug prior to 1 December 2013. Can this be monitored with a Streamlined authority required?
Mycophenolate is an example of a medicine that is listed in Section 100 HSD Private (Authority Required), Section 100 HSD Public (Streamlined) and also Section 85 Authority Required for either maintenance therapy of treatment commenced in a hospital and/or another indication. The Guild questions if this level of complexity is necessary and whether this arrangement was initiated because the Section 100 HSD created barriers to patient access because the patient has to attend a hospital when they would prefer to attend a pharmacy of their choice.					
mycophenolate	Lupus nephritis	Authority Required	Streamlined	B	Section 85
mycophenolate	Maintenance of renal trans' patients following initiation and stabilisation and of cardiac trans' patients following initiation and stabilisation	Authority Required	Streamlined	B	Section 85
mycophenolate	Renal allograft Cardiac allograft Lupus nephritis	Streamlined And Authority Required	Streamlined	B, F	Section 100 HSD Private and Public

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
sirolimus	Maintenance of renal trans' patients following initiation and stabilisation	Authority Required	Streamlined	C	Section 85
sirolimus	Renal allograft	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public
everolimus	Maintenance of renal trans' patients following initiation and stabilisation and of cardiac trans' patients following initiation and stabilisation	Authority Required	Streamlined	C	Section 85
everolimus	Renal allograft Cardiac allograft	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public
natalizumab	Multiple sclerosis	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public
abatacept	Rheumatoid arthritis	Prior Written Authority Required	Phone Authority	B	Section 85
	Rheumatoid arthritis	Prior Written Authority Required	Phone Authority	B	Section 100 HSD Private and Public – Abatacept is in section 85 and Section 100 – why is this necessary? Could it just be in Section 85
fingolimod	Multiple sclerosis	Authority Required	Streamlined	C	Section 85
The Guild notes the PBS restrictions for most of the biological disease modifying anti-rheumatic drugs (bDMARDs) are notable for their length and complexity. For example, in the August 2014 edition of the printed Schedule of Pharmaceutical Benefits the etanercept listings and their restrictions extend from page 346 to 394 ie almost 50 pages. The Guild would suggest that such complex and lengthy restrictions may actually be counterproductive to the goal Authority Required restrictions as it may disengage stakeholders. Making the restrictions shorter and clearer may improve comprehension and therefore compliance to the restriction.					
Etanercept	Plaque psoriasis Active juvenile idiopathic arthritis Ankylosing spondylitis	Prior Written Authority Required	Phone Authority	B	Section 85

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
	Psoriatic arthritis Severe Active Rheumatoid Arthritis				
Etanercept	Severe active juvenile idiopathic arthritis	Prior Written Authority Required	Phone Authority	B	
infliximab	Ulcerative colitis Rheumatoid arthritis Psoriatic arthritis Crohn disease Plaque psoriasis	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public - should be consistent
adalimumab	Severe active juvenile idiopathic arthritis	Prior Written Authority Required	Streamlined	F	Section 100 HSD Private and Public –
adalimumab	Severe active juvenile idiopathic arthritis rheumatoid arthritis Crohn disease psoriatic arthritis ankylosing spondylitis rheumatoid arthritis plaque psoriasis	Prior Written Authority Required	Streamlined		Section 85
certolizumab pegol	rheumatoid arthritis	Prior Written Authority Required	Phone Authority	C	Section 85
golimumab	rheumatoid arthritis psoriatic arthritis ankylosing spondylitis	Prior Written Authority Required	Phone Authority	C	Section 85
ustekinumab	plaque psoriasis	Prior Written Authority Required	Phone Authority	C	Section 85
tocilizumab		Prior Written Authority Required	Phone Authority	C	Section 100
cyclosporin	Transplant Atopic dermatitis Severe psoriasis Nephrotic syndrome Rheumatoid arthritis	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public As with mycophenolate – listed in 3 sections

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
cyclosporin	Maintenance of pts with: Transplant Atopic dermatitis Severe psoriasis Nephrotic syndrome Rheumatoid arthritis Also management of patient with Atopic dermatitis Severe psoriasis Rhuematoid arthritis	Section 85	Streamlined	F	As above
tacrolimus	Management of rejection of transplant	Streamlined And Authority Required	Streamlined	F	As with mycophenolate – listed in 3 sections
tacrolimus	Maintenance therapy for Transplant	Authority Required	Streamlined		
rituximab	non-Hodgkin's lymphoma chronic lymphocytic leukaemia Rheumatoid arthritis	Chemo – Streamlined and Authority Required Prior Written Authority Required	Streamlined	F	Chemotherapy Items for Private/Public Section 100 HSD Private and Public
thalidomide	Multiple myeloma	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program. Authority Required may not be necessary. Does Medicare check that the prescriber has enrolled patient?
lenalidomide	Myelodsyplastic syndrome Multiple myeloma	Prior Written Authority Required	Streamlined	F	The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone. Clinical issues managed by the i–access risk management arrangements.
baclofen	Severe chronic spasticity	Streamlined And	Streamlined	F	Section 100 HSD Private and Public

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
		Authority Required			
pamidronate disodium	Hypercalcaemia of malignancy Multiple myeloma Bone mestastases due to breast cancer	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public
Pamidronate disodium	Symptomatic Paget disease of bone	Streamlined	Restricted Benefit	B	Section 85 Streamlined Authority with only one indication so it could be a Restricted Benefit
ibandronic acid 6 mg/6mL injection	Bone metastases from breast cancer	Streamlined and Authority Required	Streamlined	F	Section 100 HSD Private and Public
Ibandroic acid 50 mg tablet	Bone metastases from breast cancer	Restricted benefit	Restricted benefit		The tablet listed in Section 85 is Restricted benefit but the injection in Section 100 is Authority Required for the same indication.
zoledronic acid 5 mg/100 mL injection	Corticosteroid-induced osteoporosis Osteoporosis Established osteoporosis	Streamlined	Streamlined		Section 85 There appears to be an inconsistency in listings for Paget disease of the bone; some are Restricted benefit some are Streamlined whilst others are Authority Required. Is this complexity necessary?
zoledronic acid 5 mg/100 mL injection	Symptomatic Paget disease of bone	Authority Required	Authority Required		Section 85 – only 1 treatment each year per patient will be PBS-subsidised. Could this be monitored with Streamlined authority?
Zoledronic acid mg/5mL injection	Multiple myeloma Bone metastases from breast cancer Prostate Cancer Hypercalcaemia of malignancy	Streamlined And Authority Required	Streamlined	F	Section 100 HSD Private and Public
alendronate 70 mg + colecalciferol 70 microgram tablet, 4 alendronate 70 mg + colecalciferol 140 microgram	Corticosteroid-induced osteoporosis Osteoporosis Established osteoporosis	Streamlined	Restricted Benefit	G, B	This listing could be Restricted Benefit. The usage data has been collected and is unlikely to change.

Drug name	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containi	Corticosteroid-induced osteoporosis Osteoporosis Established osteoporosis	Streamlined	Restriction Benefit	B	This listing could be Restricted Benefit. The usage data has been collected and is unlikely to change.
teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge	Severe established osteoporosis	Authority Required	Authority Required	The treatment must not exceed a lifetime maximum of 18 months therapy.	Where a PBS listing has maximum lifetime treatment can it be monitored with a STREAMLINED authority? This listing is duplicated under two ATC codes – it this necessary?

Post-market Review of Authority Required PBS Listings Tranche 2 Medicine List

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
esomeprazole 40 mg tablet: enteric, 30 tablets	Hyersecretory conditions Zollinger-Ellison Idiopathic hyersecretion Scleroderma oesophagus	Authority Required	Streamlined	B, G	Esomeprazole patent has expired and is now subject to Price Disclosure.
vancomycin 125 mg capsule, 20	Pseudomembranous colitis due to Clostridium difficile	Authority Required	Authority Required	D	
rifaximin 550 mg tablet, 56	hepatic encephalopathy	Authority Required	Authority Required	D	
insulin neutral bovine and isophane	Diabetes mellitus patients intolerant to human insulin	Authority Required	Authority Required	Cost of bovine is > human	Accommodates a special patient group stabilised on a particular product. Prevents initiation.
Rosiglitazone [7]	Diabetes mellitus type 2	Authority Required	Authority Required	Boxed Warning	Note that pioglitazone is Streamlined but does not have Boxed Warning.
rosiglitazone + metformin hydrochloride	Diabetes mellitus type 2	Authority Required	Authority Required	This fixed dose combination is not PBS-subsidised for use with a sulfonylurea (triple oral therapy), or with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.	Is it possible to monitor the NOTE without Authority Required?
canagliflozin 100 mg tablet, 30	Diabetes mellitus type 2	Authority Required	Authority Required	New listing of a new class of drug	

[7] http://www.tga.gov.au/safety/alerts-medicine-rosiglitazone-100924.htm#.U_Qw8enlrcs

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
dapagliflozin 10 mg tablet, 28	Diabetes mellitus type 2	Authority Required	Authority Required	New listing of a new class of drug	
magnesium aspartate dihydrate 500	Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person	Authority Required	Restricted Benefit	C	There is only one indication – Restricted Benefit is sufficient
nandrolone decanoate 50 mg/mL injection	Monotherapy for osteoporosis long-term treatment with corticosteroids	Authority Required	Authority Required	E	
sapropterin dihydrochloride	Hyperphenylalaninaemia	Prior Written Authority Required	Phone Authority	C	How many patients? What is the risk of misuse?
romiplostim 250 microgram injection	chronic immune (idiopathic) thrombocytopenic purpura (ITP)	Prior Written Authority Required Subsequent tx by telephone	Phone Authority	What is the burden of red tape for very rare diseases? Compared to the cost of the treatment and the cost of maintaining a phone/written approval process?	If the disease is very rare, is a written authority needed? What is the risk? What's the Red Tape Burden? It may be large for the specialists treating this patient group.
eltrombopag 25 mg tablet, 28	chronic immune (idiopathic) thrombocytopenic purpura (ITP)	Prior Written Authority Required Subsequent tx by telephone	Phone Authority	As	As above
epoetin alfa	Anaemia due to renal disease	Streamlined and Authority Required	Streamlined	F What is the risk of abuse and misuse?	Section 100 HSD Private and Public
epoetin beta	Anaemia due to renal disease	Streamlined and Authority Required	Streamlined	F What is the risk of abuse and misuse?	Section 100 HSD Private and Public
epoetin lambda	Anaemia due to renal disease	Streamlined and Authority Required	Streamlined	F What is the risk of abuse and misuse?	Section 100 HSD Private and Public
darbepoetin alfa	Anaemia due to renal disease	Streamlined and Authority Required	Streamlined	F What is the risk of abuse and misuse?	Section 100 HSD Private and Public

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
methoxy polyethylene glycol-epoetin beta	Anaemia due to renal disease	Streamlined and Authority Required	Streamlined	F What is the risk of abuse and misuse?	Section 100 HSD Private and Public
Icatibant Injection	hereditary angioedema	Authority Required	Authority Required		
adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe	Anaphylaxis	Authority Required	Authority Required		Is this an expensive first aid kit DPMQ is $106.34 cf DMPQ of $20.68 for adrenalin ampoules
ivabradine 7.5 mg tablet, 56	Heart Failure	Authority Required	Authority Required		New drug in a new class
tadalafil 20 mg tablet, 56	pulmonary hypertension	Prior Written Authority	Written followed by Streamlined	F	Section 100 HSD Private and Public
Epoprostenol	Pulmonary hypertension	Prior Written Authority	Written followed by Streamlined	F	Section 100 HSD Private and Public
iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules	Pulmonary hypertension	Prior Written Authority	Written followed by Streamlined	F	Section 100 HSD Private and Public
sildenafil 20 mg tablet, 90	Pulmonary hypertension	Prior Written Authority	Written followed by Streamlined	F	Section 100 HSD Private and Public
bosentan 62.5 mg tablet, 60	Pulmonary hypertension	Prior Written Authority	Written followed by Streamlined	F	Section 100 HSD Private and Public
ambrisentan 5 mg tablet, 30	Pulmonary hypertension	Prior Written Authority	Written followed by Streamlined	F	Section 100 HSD Private and Public
eprosartan	Drug interactions, adverse effects, occurring with all of the base-priced drugs	Authority Required	Streamlined		Is this an Authority Required review question or a policy question as to why this mechanism exists?
olmesartan medoxomil	Drug interactions, adverse effects, occurring with all of the base-priced drugs	Authority Required	Streamlined		As above
terbinafine 250 mg tablet, 42	dermatophyte infection in an Aboriginal or a Torres Strait Islander person or patient aged up to 18 years	Authority Required	Streamlined	G	Multibrand product subject to Price Disclosure – it's the restriction clinical or economic?

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
	onychomycosis				
betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g	Chronic stable plaque type psoriasis vulgaris	Authority Required	Restricted Benefit		Is the restriction to prevent wastage ie prevent larger tube being prescribed
clobetasol propionate 0.05% shampoo, 125 mL	Moderate to severe scalp psoriasis	Authority Required	Streamlined		A 'very potent' corticosteroid. Could this be confused with a 'regular" shampoo and used inappropriately? Is the AR a safety issues?
pimecrolimus cream	atopic dermatitis	Authority Required	Streamlined		Is the restriction for safety or economic reasons?
imiquimod	Superficial basal cell carcinoma	Authority Required	Streamlined		Is the restriction for clinical or economic reasons?
misoprostol	Termination of an intra-uterine pregnancy	Authority Required	Authority Required	See mifepristone	
testosterone	Androgen deficiency Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age	Authority Required	Authority Required	E	Abuse, misuse and diversion
mifepristone 200 mg tablet, 1	Termination of an intra-uterine pregnancy	Authority Required	Authority Required		An authority prescription for misoprostol 200 microgram tablets must be sought at the time of authority application – can this be monitored by anything but Authority Required?

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
					Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.
nafarelin nasal spray	visually proven endometriosis	Authority Required	Authority Required		2 years must have elapsed b/t tx – could only be verified by phone authority
octreotide 50 microgram/mL injection, 5 x 1 mL ampoules	Acromegaly carcinoid tumour or vasoactive intestinal peptide secreting tumour	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack	As above	Streamlined and Authority Required	Streamlined	F	Must be controlled with immediate first
lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack	As above	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
lanreotide 60 mg injection, 1 syringe	As above	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
teriparatide 20 microgram/dose injection	Severe established osteoporosis	Authority Required	Authority Required	Can an item with a lifetime maximum be monitored without Authority Required?	Up to a maximum of 18 pens will be reimbursed through the PBS.
cinacalcet	chronic kidney disease	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
cinacalcet	Maintenance therapy	Streamlined	Streamlined	Can Medicare monitor the 'maintenance' is not 'initiation'?	Section 85 and Section 100 HSD; as with cyclosporin?
amoxycillin 100 mg/mL oral liquid: powder for, 20 mL	Infection	Authority Required	Streamlined		Is the AR to avoid the $0.61 extra Special Patient Contribution or for clinical reasons?
Cefepime	Febrile neutropenia	Authority Required	Authority Required	D	

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
clarithromycin 250 mg tablet, 100	Mycobacterium avium complex infections	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
azithromycin 600 mg tablet, 8	Mycobacterium avium complex infections in HIV-positive patients	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
ciprofloxacin 250 mg tablet, 14	Various	Authority Required	Authority Required	D	
norfloxacin 400 mg tablet, 14	Acute bacterial enterocolitis Complicated urinary tract infection	Authority Required	Authority Required	D	
fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL	Various fungal infections	Streamlined	Authority Required		Why is this item Streamlined and not AR as for antibiotics?
voriconazole	Various fungal infections	Authority Required	Authority Required	D	Why AR and fluconazole is Streamlined?
posaconazole 40 mg/mL oral liquid, 105 mL	Various fungal infections	Authority Required	Authority Required	D	Why is fluconazole streamlined and this item is not?
rifabutin 150 mg capsule, 30	Mycobacterium avium complex infections in HIV-positive patients	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
rifampicin 150 mg capsule, 100	Leprosy	Authority Required	Authority Required	D	The small qty for prophylactic treatment of contacts of patients with Haemophilus influenzae type B is Restricted Benefit which is inconsistent
ganciclovir 500 mg injection	Cytomegalovirus	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
valaciclovir 500 mg tablet, 100	Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease	Streamlined and Authority Required	Streamlined	F A variety of other Section 85 listings are Streamlined – multiple brands	Section 100 Private and Public

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
cidofovir 375 mg/5 mL injection	cytomegalovirus retinitis in patients with AIDS	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
valganciclovir 450 mg tablet, 60	Cytomegalovirus retinitis	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
Foscarnet sodium I.V. infusion	cytomegalovirus retinitis in patients with AIDS aciclovir-resistant herpes simplex virus	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
saquinavir 500 mg tablet, 120	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
indinavir 400 mg capsule, 180	HIV infection	Streamlined and Authority Required	Streamlined	As above	Section 100 Private and Public
ritonavir	HIV infection	Streamlined and Authority Required	Streamlined	As above	Section 100 Private and Public
fosamprenavir 700 mg tablet, 60	HIV infection	Streamlined and Authority Required	Streamlined	As above	Section 100 Private and Public
atazanavir 150 mg capsule, 60	HIV infection	Streamlined and Authority Required	Streamlined	As above	Section 100 Private and Public
tipranavir 250 mg capsule, 120	HIV infection	Streamlined and Authority Required	Streamlined	As above	Section 100 Private and Public
darunavir 600 mg tablet, 60	HIV infection	Streamlined and Authority Required	Streamlined	As above	Section 100 Private and Public
telaprevir 375 mg tablet, 42	Chronic genotype 1 hepatitis C infection	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
Boceprevir 200 mg capsule, 336 capsules	Chronic genotype 1 hepatitis C infection	Streamlined and Authority Required	Streamlined	F Should be available at a pharmacy of the patient's choice	Section 100 Private and Public
zidovudine 100 mg capsule, 100	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
didanosine 125 mg capsule: enteric, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
stavudine 20 mg capsule, 60	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
lamivudine	hepatitis B HIV infection	Streamlined and Authority Required	Streamlined	**For HIV patients this will be available at a pharmacy of the patient's choice but for Hep B patients it should also be available**	Section 100 Private and Public
abacavir 300 mg tablet, 60	HIV infection	Streamlined and Authority Required	Streamlined	As above	Section 100 Private and Public
tenofovir disoproxil fumarate 300 mg tablet, 30	HIV infection Chronic hepatitis B	Streamlined and Authority Required	Streamlined for all patients irrespective of their condition	**For HIV patients this will be available at a pharmacy of the patient's choice but for Hep B patients it should also be available**	Section 100 Private and Public
adefovir dipivoxil 10 mg tablet, 30	Chronic hepatitis B	Streamlined and Authority Required	Streamlined	F Should be available at a pharmacy of the patient's choice	Section 100 Private and Public
emtricitabine 200 mg capsule, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
entecavir monohydrate 500 microgram tablet, 30	Chronic hepatitis B	Streamlined and Authority Required	Streamlined	F Should be available at a pharmacy of the patient's choice	Section 100 Private and Public
telbivudine 600 mg tablet, 28	chronic hepatitis B	Streamlined and Authority Required	Streamlined	F Should be available at a pharmacy of the patient's choice	Section 100 Private and Public
nevirapine 400 mg tablet: modified release, 30 tablets	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the	Section 100 Private and Public

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
				patients choice in July 2015	
efavirenz 600 mg tablet, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
rilpivirine 25 mg tablet, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
lamivudine 150 mg + zidovudine 300 mg tablet, 60	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
abacavir 600 mg + lamivudine 300 mg tablet, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
lopinavir + ritonavir	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
dolutegravir	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
enfuvirtide	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
raltegravir 25 mg tablet	HIV infection	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
maraviroc 150 mg tablet, 60	CCR5-tropic HIV-1	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public
morphine sulfate 200 mg tablet: modified release, 28 tablets	Chronic severe disabling pain due to cancer	Authority Required	Authority Required	E	
codeine phosphate with paracetamol tablet 30 mg-500 mg, 20	Severe disabling pain not responding to non-narcotic analgesics	Authority Required	Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.	E	DPMQ is only $9.52 so only effective for Concessional Patients. General Patients could get a Private prescription.
naratriptan 2.5 mg tablet, 2	Migraine attack	Authority Required	Restricted Benefit	The condition must have **usually** failed to respond to analgesics in the past.	Sumatriptan is Streamlined; could all triptans be Restricted Benefits?
zolmitriptan 2.5 mg tablet, 2	Migraine attack	Streamlined	Restricted Benefit	As above – what does 'usually" mean	As above
nitrazepam 5 mg tablet, 25 in a max qty of 50	Myoclonic epilepsy Malignant neoplasia (late stage) RACF patients dependent	Authority Required	Restricted Benefit	RACF patients can be monitored under the PBS Dispensing and Claiming from a	Given that the cost difference between the 25 and the 50 is negligible what is the

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
				Medication Chart in RACF	point in the restriction?
clonazepam 500 microgram tablet, 100	Neurologically proven epilepsy	Authority Required	Authority Required	DPMQ $19.84 E	PBS NOTE: Abuse of clonazepam has been reported. Refer to the current product information.
clonazepam 2 mg tablet, 100	Neurologically proven epilepsy	Authority Required	Streamlined	E	Recommend Streamlined when ERRCD implemented
Clonazepam 1 mg/ml injection	Epilepsy	Restricted Benefit	Restricted Benefit		Why is the injection not Authority Required as with other forms?
clonazepam 2.5 mg/mL oral liquid, 10 mL	Neurologically proven epilepsy	Authority Required	Streamlined	E	Recommend Streamlined when ERRCD implemented. Should all clonazepam restrictions be consistent?
levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags	Advanced Parkinson disease	Authority Required Streamlined and Authority Required	Streamlined	Items listed in Section 100 and Section 85 cause confusion amongst prescribers, dispensers and patients.	Section 85 Section 100 Private and Public
apomorphine hydrochloride injection	Parkinson's disease in patients severely disabled	Streamlined and Authority Required	Streamlined	F	Section 100 Private and Public
clozapine 25 mg tablet, 100	Schizophrenia	Streamlined and Authority Required	Streamlined	This will be available at a pharmacy of the patients choice in July 2015	Section 100 Private and Public Patients must be registered in a clozapine monitoring program
diazepam 1 mg/mL oral liquid, 100 mL	Chronic spasticity	Authority Required	Restricted benefit	Under 18 yrs old	What is the risk of leakage and to who?

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
oxazepam 15 mg tablet, 25 , 50's and 2 repeats	Malignant neoplasia (late stage) RACF patients dependent	Authority Required	Restricted Benefit	E DPMQ is $9.24	RACF patients could be audited because the script will be dispensed from Medication Chart
alprazolam various strengths, tablet, 50	Panic disorder where other treatments have failed or are inappropriate	Authority Required	Authority Required	E DPMQ is $15.52 for 1 mg	The Therapeutic Goods Administration (TGA) has rescheduled alprazolam to a Schedule 8 drug, effective 1 February 2014.
nitrazepam 5 mg tablet, 25	Myoclonic epilepsy Malignant neoplasia (late stage) RACF patients dependent	Authority Required	Restricted Benefit	B DPMQ is $10.46	RACF patients could be audited because the script will be dispensed from Medication Chart
temazepam 10 mg tablet, 25, (50) and 2 repeats	Malignant neoplasia (late stage) RACF patients dependent	Authority Required	Restricted Benefit	B	RACF patients could be audited because the script will be dispensed from Medication Chart
dexamphetamine sulfate 5 mg tablet, 100	attention deficit hyperactivity disorder narcolepsy	Authority Required	Streamlined	E	Recommend Streamlined when ERRCD implemented
methylphenidate hydrochloride	attention deficit hyperactivity disorder	Authority Required	Streamlined	E	Recommend Streamlined when ERRCD implemented
modafinil 100 mg tablet, 60	narcolepsy	Prior Written Authority Required	Streamlined	E	Recommend Streamlined when ERRCD implemented
atomoxetine 10 mg capsule, 28	Attention deficit hyperactivity disorder	Streamlined	Streamlined		Inconsistent with other ADHD PBS listings
donepezil hydrochloride 5 mg tablet, 28	Mild to moderately severe Alzheimer disease	Authority Required and Streamlined for continuation	Streamlined	B	Could a prescriber initiate with a Streamlined? How

Drug, strength and form	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
					could Medicare monitor?
rivastigmine 1.5 mg capsule, 56	Mild to moderately severe Alzheimer disease	Authority Required and Streamlined for continuation	As above	B	As above
galantamine 8 mg capsule: modified release, 28 capsules	Mild to moderately severe Alzheimer disease	Authority Required and Streamlined for continuation	As above	B	As above
memantine hydrochloride 10 mg tablet, 56	Moderately severe Alzheimer disease	Authority Required and Streamlined for continuation	As above	B	As above

Post-market Review of Authority Required PBS Listings Tranche 3 Medicine List

Palliative Care Schedule

Many of the medicines in the Palliative Care section are already listed in the General section and this duplication is unnecessary as the prescriber could access treatment for the patient without recourse to the Palliative Care section. Duplicated listings should be removed as they only complicate the Schedule of Pharmaceutical Benefits.

In addition the Palliative Care section lists items as Initial Supply and Continuing Supply which is unnecessarily duplicative and a single restriction would be sufficient. The definition of 'palliative' used in the Schedule is "*A patient with an active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is the quality of life.* Therefore the listings could be assumed to be self-limiting and if a patient was on any of these restrictions for more than 4 months then it could questioned if the patient was palliative.

The Guild notes the following data of interest regarding the Palliative Care listings based on 12/2012-11/2013 from Department of Human Services[8]:

- The cost was $3.797 million a year over 46,708 prescriptions
- There were twice as many initial scripts as continuing: 31,294 vs 15,414
- Despite this $2.723 is on continuing vs $1.073 on initial despite continuing accounting for half the number of prescriptions scripts
- Of funding for continuing palliative care patients 86% was spent on fentanyl $2.342 million. This equates to 62% of all funds spent on palliative care going to the subset that is continuing purely for the use of fentanyl.
- Continuing palliative care fentanyl makes up only 15.6% of continuing palliative care scripts and only 5.1% of total palliative care scripts.
- Fentanyl prescriptions for continuing patients are for a quantity of 60 units, whereas for initial treatment they are for only 9 units, raising the question if all medication is being used by the patient and if these quantities are appropriate given the cost.

Given the above data the Guild suggests that this might be an area the Drug Utilisation Sub-Committee of the PBAC might investigate further if it has not already done so.

[8] http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp

Drug name	Current Indications	Current Restriction	Suggested Restriction	Justification	Comments
methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial	Initial palliative care patient with opioid-induced constipation	Authority Required	Authority Required		
Methylnaltrexone solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7	Continuing for palliative care pt with opioid induced constipation	Authority Required	Authority Required		The initial and continuing restrictions could be combined.
indomethacin 100 mg suppository, 20	palliative care patient where severe pain is a problem	Streamlined	Restricted Benefit in General Schedule		Available as a Restricted benefit for bone pain due to malignant disease Is an extra listing in Palliative Care necessary?
indomethacin 100 mg suppository, 20					Having initial and continuing restrictions is unnecessary.
diclofenac sodium 100 mg suppository, 20	Palliative Care where severe pain is a problem	Streamlined	Restricted		There is only one choice ie 3645 a Streamlined is unnecessary.
diclofenac sodium 100 mg suppository, 20	Palliative Care where severe pain is a problem				Having initiation and continuation rules is overly complex. The DPMQ is $11.10 – what is the risk?
ibuprofen 400 mg tablet, 30	Palliative Care where severe pain is a problem				Having initiation and continuation rules is overly complex. The DPMQ of $15.07 what is the risk being mitigated? -
ibuprofen 400 mg tablet, 30	Palliative Care where severe pain is a problem				
morphine sulfate 200 mg tablet: modified release, 28 tablets	Palliative Care severe disabling pain not responding to non-narcotic analgesics	Authority Required			Patients can already access these under general schedule. Is there a need to duplicate in a Palliative Care section? General section could include larger quantities for palliative care patients.
morphine sulfate 200 mg tablet: modified release, 28 tablets	As above	Authority Required			As above
morphine sulfate 10 mg tablet, 20	As above	Authority Required			As above
morphine sulfate 20 mg tablet, 20	As above	Authority Required			As above
morphine sulfate 10 mg tablet, 20	As above	Authority Required			As above
morphine sulfate 20 mg tablet, 20	As above	Authority Required			As above

Drug name	Current Indications	Current Restriction	Suggested Restriction	Justification	Comments
FENTANYL Lozenge 200 micrograms (as citrate), 9	Breakthrough pain for cancer pts on opioids for pain	Authority Required	Authority Required		Lozenge is not available on the General Schedule
methadone hydrochloride 5 mg/mL oral liquid, 200 mL	Severe disabling pain	Authority Required	Authority Required		
clonazepam 500 microgram tablet, 100	Prevention of epilepsy	Authority Required			Could patients access on the general schedule?
diazepam 2 mg tablet, 50	Anxiety	Authority Required			Could patients access on the general schedule?
oxazepam 15 mg tablet, 25	Anxiety	Authority Required			As above
nitrazepam 5 mg tablet, 25	Anxiety	Authority Required			As above
temazepam 10 mg tablet, 25	Anxiety	Authority Required			As above

Eye and Ear products

The Guild suggests that for antibacterial preparations that Expert Advisory Group on Antibacterials should provide advice on what is the most appropriate level of restriction to prevent the increase in bacterial resistance

The Guild notes that optometrists must write all prescriptions as Authority Required whereas a Nurse Practitioner can write as Streamlined. Could this not be consistent with all items listed as Streamlined? The distinction makes the Schedule of Pharmaceutical Benefit unnecessarily complex and longer than is necessary.

Eye drops available as single use for patients with "Severe dry eye syndrome who are sensitive to preservatives in multi-dose eye drops" are listed as Authority Required but a Restricted Benefit listing would be appropriate.

Drug	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	Bacterial keratitis ophthalmologist or in consultation with an ophthalmologist.	Authority Required	Authority Required	D	
ciprofloxacin 0.3% eye drops, 5 mL	As above	Authority Required	Authority Required	D	

Drug	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
verteporfin 15 mg injection, 1 x 15 mg vial	age-related macular degeneration (AMD	Prior Written Authority Required	Phone or Streamlined	C	Are these restrictions unnecessarily restrictive given that only ophthalmologists use these medicines? Would anyone want an eye injection unless they really needed one?
ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial	Subfoveal choroidal neovascularisation (CNV) age-related macular degeneration (AMD),	Authority Required (in writing or by telephone)	Phone or Streamlined	C	As above
aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial	As above	As above	Phone or Streamlined	C	As above
carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops	Streamlined and Authority Required	Restricted benefit	A	There is only one streamlined authority code 1359. Could this be Restricted Benefit? There are two listings one for NP and another for OP, is this duplication necessary?
sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL	Severe dry eye syndrome	Streamlined and Authority Required	Restricted Benefit	A	There are two listing to accommodate different prescribers, is this necessary?
sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL	Severe dry eye syndrome	Streamlined and Authority Required	Restricted Benefit	A	As above
carbomer-974 0.3% eye gel, 30 x 500 mg unit doses	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops	Streamlined and Authority Required	Restricted Benefit	A	As above
carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops	Authority Required	Restricted Benefit	A	As above
carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	As above	As above	Restricted Benefit	A	As above
carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	As above	As above	Restricted Benefit	A	As above

Drug	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses	As above	As above	Restricted Benefit	A	As above
carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses	As above	As above	Restricted Benefit	A	As above
dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses	As above	As above	Restricted Benefit	A	As above
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	As above	As above	Restricted Benefit	A	As above
soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations	As above	Streamlined and Authority Required	Restricted Benefit	A	As above
polyethylene glycol-400 0.25% (1 mg/0.4 mL) eye drops, 20 x 0.4 mL unit doses	As above	Streamlined and Authority Required	Restricted Benefit	A	As above
carmellose sodium 0.5% (2 mg/0.4 mL) + glycerol 0.9% (3.6 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	As above	Streamlined and Authority Required	Restricted Benefit	A	As above
ciprofloxacin 0.3% ear drops, 5 mL	Bacterial keratitis	Authority Required	Authority Required	D	Antibacterial

Miscellaneous including specialised medical foods

Drug	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
triglycerides medium chain oil: oral, 500 mL	Chylous ascites Chylothorax Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders Hyperlipoproteinaemia type 1 Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet Long chain fatty acid oxidation disorders	Authority Required	Restricted Benefit	C	What is the risk of misuse? Specialised dietary nutrients are used only in a small group of patients and are unlikely to be subject to misuse, abuse or diversion. The Nutritional Products Working Group of the PBAC could provide advice on this matter. Given the limited use of these products what is the Red Tape Burden? It could be large for the specialists who treat a number of these patients.
triglycerides medium chain oral liquid, 1 x 250 mL bottle	As above	Authority Required	Restricted Benefit	C	As above

Drug	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
triglycerides medium chain oral liquid, 18 x 250 mL cartons		Authority Required	Restricted Benefit	C	As above
amino acid synthetic formula oral liquid: powder for, 400 g	Various cow's milk allergies	Authority Required	Streamlined		The condition must not be isolated infant colic or reflux. What is the risk of inappropriate use?
amino acid synthetic formula oral liquid: powder for, 400 g	As above	Authority Required	Streamlined	C	As above
amino acid synthetic formula oral liquid: powder for, 400 g	As above	Authority Required	Streamlined	C	As above
amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	Various cow's milk allergies	Authority Required	Streamlined	C	As above
amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	Various cow's milk allergies	Authority Required	Streamlined	C	As above
protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g	Various cow's milk allergies and other conditions	Authority Required	Streamlined	C	As above
amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	Various cow's milk allergies and other conditions	Authority Required	Streamlined	C	As above
milk powder lactose modified predigested oral liquid: powder for, 900 g	Proven chronic lactose intolerance in children aged 1 year and over	Authority Required	Streamlined	C	What is the use of these products and what is the risk of misuse?
milk powder synthetic low calcium oral liquid: powder for, 400 g	Hypercalcaemia in children under the age of 4 years	Authority Required	Streamlined	C	There is only one indication – how many children have hypercalcaemia and are under 4 years of age, what is the risk of misuse?
milk powder lactose free formula oral liquid: powder for, 900 g	Acute lactose intolerance in infants up to the age of 12 months. Chronic lactose intolerance	Authority Required	Streamlined	C	What is the use of these products and what is the risk of misuse?
whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose	Chronic renal failure	Authority Required	Streamlined	C	How many children have Chronic Renal Failure and what is the risk of inappropriate use?
whey protein formula supplemented with amino acids, vitamins and minerals, and low in	Chronic renal failure	Authority Required	Streamlined	C	How many children have Chronic Renal Failure and what is the risk of inappropriate use?

Drug	Current Indication	Current Restriction	Suggested Restriction	Justification	Comments
protein, phosphate, potassium and lactose oral liquid: powder fo					
vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g	Infants and children whose vitamin and mineral intake is insufficient due to a specific diagnosis requiring a highly restrictive therapeutic diet	Authority Required	Streamlined	C	What is the risk of inappropriate use?
whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium	Chronic renal failure	Authority Required	Streamlined	C	What is the risk of inappropriate use? What is the incidence of chronic renal failure in children?
triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets	Chylous ascites Chylothorax Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders Hyperlipoproteinaemia type 1 Long chain fatty acid oxidation disorders	Authority Required	Streamlined	C	What is the risk of inappropriate use? Very specialised product for rare patient group?
arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for	Peroxisomal biogenesis disorders	Authority Required	Streamlined	C	What is the risk of inappropriate use? Very specialised product for rare patient group
docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets	Peroxisomal biogenesis disorders	Authority Required	Streamlined	C	What is the risk of inappropriate use? Very specialised product for rare patient group