

Medicare Australia

PBS Reforms
Streamlining of the Authority
Approval Process
Guidance
for
Software Vendors
2 March 2007



Australian Government
Medicare Australia

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1. Introduction

In November 2006 a package of reforms to the Pharmaceutical Benefits Scheme (PBS) was announced by the Australian Government.

Among other impacts, the PBS Reforms will mean changes to the current PBS authority process. Under the new arrangements, PBS-listed medicines that require a prescriber to obtain approval prior to prescribing will be split into two categories:

- A. PBS items that continue to require approval under the current process, i.e. the prescriber will need to obtain approval by contacting Medicare Australia.
 - This category will include short term use medicines, Section 100 medicines, requests for increased quantities and/or repeats and those medicines with an increased potential for misuse, abuse or adverse effects, such as narcotic medicines.
- B. Medicines where the prescriber will no longer need to obtain approval directly from Medicare Australia.
 - This category will include medicines for the treatment of chronic and stable long term conditions (such as diabetes and osteoporosis) where the patient and doctor are both very familiar with the condition and medication.

Where the prescriber wishes to increase quantities and/or repeats, the medicine must be treated as a category A medicine, meaning contact with Medicare Australia will be required.

These changes to the authority process will come into force on 1 July 2007. This list of PBS Items to be affected by this new process can be found at Annex A.

1.1 Document Purpose

Information relating to these reforms was provided at a meeting of the Department of Health and Ageing's PharmBiz Software Vendors Forum on 26 February 2007. At this meeting, it was requested that the Government make documentary guidance relating to these reforms available to prescription writing software vendors.

This document forms this guidance. It identifies the key points of change from the existing process and highlights the requirements of prescribers under the new process.

This guidance does not extend to the level of providing advice to software vendors regarding how their system might be modified to assist prescribers in meeting their obligations.

1.2 Intended Audience

This document is directed toward all prescription writing software vendors affected by the changes to the authority process under the PBS Reforms. It will be distributed to all parties registered with Medicare Australia's Software Vendor Liaison Team as being interested in this issue.

It may also be further distributed by other parties as they see fit.

2. Process Changes

A diagrammatic representation of the changes to the authority process is provided in Annex B.

2.1 Current Process

Under the existing process, the PBS Schedule identifies those items that are subject to the authority process by indicating that they are "*Authority Required*" in the item description. Further information relating to the indications for which the item can be prescribed under the PBS is also provided in the Schedule.

The key implication of an item falling under the authority process is that:

- a) They must be prescribed on an authority script; and
- b) A valid authority approval number must appear on the script.

Pharmacists have been instructed not to dispense authority required items under the PBS if they do not meet these criteria.

Prescribers have routine access to the authority script but there are currently a number of avenues through which they can receive the authority approval number. Depending on the status of the patient, they may contact either Medicare Australia or the Department of Veteran's Affairs (DVA).

Prescribers may make this contact via telephone, in writing or, where they have access, via certain electronic means (eg. eAuthority or ANS).

Currently, software vendors receive data feeds from the Government that reflect this information and enable their software to assist prescribers through this process.

2.2 The Streamlined Authority Process

The PBS Reforms will introduce a new avenue through which prescribers may obtain the authority approval number.

Under the new process, the PBS Schedule and the associated data feeds will continue to indicate that these items are authority required. For the items listed at Annex A, however, the PBS Schedule will further indicate that the prescriber does not need to contact Medicare Australia or DVA to obtain an authority approval number.

In these cases, the authority approval number will be published in the PBS Schedule.

For these items, the authority approval number will be composed of the current PBS item number and the 'restriction code' related to the indication. For example:

- Dr wishes to prescribe Adrenaline – initial supply for emergency treatment of acute allergic reactions with anaphylaxis injection 150 micrograms in 0.3ml single dose syringe.

Authority number is 8697R1808

- Dr wishes to prescribe adrenaline – continuing supply (for condition as per above) where patient has previously been issued with an authority prescription for this drug.

Authority number is 8697R1810

Consistent with the existing process, the prescriber will be required to place the authority approval number on the script to indicate that the prescription meets the prescribing

requirements of the PBS Schedule. The requirements regarding the placement of this number or any other information on the script have not altered.

Similarly, the new authority process applies equally for both DVA and Medicare Australia patients. That is, if the item is listed as being subject to the new process, no contact is required even if the patient has a DVA gold or white card.

As indicated above, increased quantities and/or repeats beyond the specifications in the PBS Schedule will require the prescriber to follow the existing authority process and contact either Medicare Australia or DVA.

2.3 Data Source Changes

Precisely how and in what format the PBS Schedule data will be made available to assist software vendors in implementing this new process has been discussed at the PharmBiz Software Vendor Forum. A schema for the data that will be provided can be found at <http://xml.pbs.gov.au>. Further information can be obtained by contacting Judith Forster within the Department of Health and Ageing at:

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Annex A: PBS Items Affected by the Streamlined Process

Drug Name	Item code	Drug Name	Item code
ABCIXIMAB	8048N	CABERGOLINE	8114C
ACAMPROSATE CALCIUM	8357W	CALCITRIOL	2502Q
ACITRETIN	2019G	CALCIUM	8560M
ACITRETIN	2020H	CALCIUM	3116B
ADRENALINE	8697R	CALCIUM	3117C
ADRENALINE	8698T	CARBOMER 974	8514D
ALBENDAZOLE	8503M	CARBOMER 980	8578L
ALBENDAZOLE	8459F	CARMELLOSE SODIUM	8823J
ALENDRONATE SODIUM	8511Y	CARMELLOSE SODIUM	2338C
ALENDRONATE SODIUM	8090T	CARMELLOSE SODIUM	2324H
ALENDRONATE SODIUM with COLECALCIFEROL	9012H	CARMELLOSE SODIUM	8824K
AMISULPRIDE	8594H	CARVEDILOL	8742D
AMISULPRIDE	8595J	CARVEDILOL	8255L
AMISULPRIDE	8596K	CARVEDILOL	8256M
AMISULPRIDE	8736T	CARVEDILOL	8257N
ARIPIRAZOLE	8717T	CARVEDILOL	8258P
ARIPIRAZOLE	8718W	CLOPIDOGREL HYDROGEN SULFATE	8358X
ARIPIRAZOLE	8719X	CLOTRIMAZOLE	1027C
ARIPIRAZOLE	8720Y	DANAZOL	1285P
ATOVAQUONE	8300W	DANAZOL	1287R
BALSALAZIDE SODIUM	8845M	DESMOPRESSIN ACETATE	8662X
BIFONAZOLE	8066M	DESMOPRESSIN ACETATE	2129C
BISOPROLOL FUMARATE	8604W	DESMOPRESSIN ACETATE	8711L
BISOPROLOL FUMARATE	8605X	DISODIUM ETIDRONATE	2920Q
BISOPROLOL FUMARATE	8606Y	DISODIUM ETIDRONATE and CALCIUM	8056B

		CARBONATE	
BIVALIRUDIN TRIFLUOROACETATE	8844L	DISODIUM PAMIDRONATE	8461H
BUDESONIDE	2065Q	DISODIUM PAMIDRONATE	8208B
BUDESONIDE	2066R	DISODIUM PAMIDRONATE	8462J
Drug Name	Item code	Drug Name	Item code
DISODIUM PAMIDRONATE	8209C	LAMOTRIGINE	8063J
DISODIUM PAMIDRONATE	8463K	LAMOTRIGINE	2848X
ENTACAPONE	8367J	LAMOTRIGINE	2849Y
EPLERENONE	8879H	LAMOTRIGINE	2850B
EPLERENONE	8880J	LAMOTRIGINE	2851C
EPTIFIBATIDE ACETATE	8683B	LEFLUNOMIDE	8373Q
EPTIFIBATIDE ACETATE	8684C	LEFLUNOMIDE	8374R
EZETIMIBE	8757X	LEFLUNOMIDE	8375T
EZETIMIBE	8757X	LEVODOPA with CARBIDOPA	1255C
EZETIMIBE with SIMVASTATIN	8881K	LEVODOPA with CARBIDOPA and ENTACAPONE	8797B
EZETIMIBE with SIMVASTATIN	8882L	LEVODOPA with CARBIDOPA and ENTACAPONE	8798C
FONDAPARINUX SODIUM	8775W	LEVODOPA with CARBIDOPA and ENTACAPONE	8799D
GABAPENTIN	8505P	LIOTHYRONINE SODIUM	2318B
GABAPENTIN	1834M	MESALAZINE	1611T
GABAPENTIN	1835N	MESALAZINE	8731M
GABAPENTIN	8559L	MESALAZINE	8598M
GABAPENTIN	8389M	MESALAZINE	8599N
GLUCOSE INDICATOR—BLOOD	8634K	MESALAZINE	8753Q
GLUCOSE INDICATOR—BLOOD	2926B	MESALAZINE	8616L
HYPROMELLOSE with DEXTRAN	8299T	MESALAZINE	8617M

IRON SUCROSE	8807M	MESALAZINE	8768L
ISOTRETINOIN	2591J	METOPROLOL SUCCINATE	8818D
ISOTRETINOIN	2592K	METOPROLOL SUCCINATE	8732N
IVERMECTIN	8359Y	METOPROLOL SUCCINATE	8733P
KETOCONAZOLE	9024Y	METOPROLOL SUCCINATE	8734Q
KETOCONAZOLE	9025B	METOPROLOL SUCCINATE	8735R
KETOCONAZOLE	1574W	MICONAZOLE	9031H

Drug Name	Item code	Drug Name	Item code
MICONAZOLE NITRATE	9026C	PIOGLITAZONE HYDROCHLORIDE	8696Q
MICONAZOLE NITRATE	9027D	QUETIAPINE FUMARATE	8456C
MICONAZOLE NITRATE	9028E	QUETIAPINE FUMARATE	8457D
MICONAZOLE NITRATE	9029F	QUETIAPINE FUMARATE	8458E
MICONAZOLE NITRATE	9030G	QUETIAPINE FUMARATE	8580N
MINOXIDIL	2313R	QUINAGOLIDE HYDROCHLORIDE	8860H
MONTELUKAST SODIUM	8627C	QUINAGOLIDE HYDROCHLORIDE	8822H
MONTELUKAST SODIUM	8628D	QUININE BISULFATE	1972T
NALTREXONE HCL	8370M	QUININE SULFATE	1975Y
NAPROXEN	1658G	RALOXIFENE HYDROCHLORIDE	8363E
NARATRIPTAN HYDROCHLORIDE	8298R	RISEDRONATE SODIUM	8481J
NYSTATIN	1698J	RISEDRONATE SODIUM	8621R
OLANZAPINE	8170B	RISEDRONATE SODIUM	8482K
OLANZAPINE	8185T	RISEDRONATE SODIUM and CALCIUM CARBONATE	8899J
OLANZAPINE	8186W	RISPERIDONE	8787L
OLANZAPINE	8187X	RISPERIDONE	8788M
OLANZAPINE	8433W	RISPERIDONE	8789N

OLANZAPINE	8434X	RISPERIDONE	8790P
OLSALAZINE SODIUM	1728Y	RISPERIDONE	8791Q
OLSALAZINE SODIUM	8086N	RISPERIDONE	8869T
OXCARBAZEPINE	8584T	RISPERIDONE	8870W
OXCARBAZEPINE	8585W	RISPERIDONE	3169T
OXCARBAZEPINE	8586X	RISPERIDONE	8792R
OXCARBAZEPINE	8588B	RISPERIDONE	3170W
PERHEXILINE MALEATE	1822X	RISPERIDONE	8794W
PIOGLITAZONE HYDROCHLORIDE	8694N	RISPERIDONE	3171X
PIOGLITAZONE HYDROCHLORIDE	8695P	RISPERIDONE	3172Y

Drug Name	Item code	Drug Name	Item code
RISPERIDONE	8100H		
RISPERIDONE	8780D	TIAGABINE HYDROCHLORIDE	8221Q
RISPERIDONE	8781E	TIAGABINE HYDROCHLORIDE	8222R
RISPERIDONE	8782F	TIAGABINE HYDROCHLORIDE	8223T
ROSIGLITAZONE MALEATE	8690J	TICLOPIDINE HYDROCHLORIDE	2095G
ROSIGLITAZONE MALEATE	8689H	TILUDRONATE DISODIUM	8267D
ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE	9060W	TIROFIBAN HYDROCHLORIDE	8350L
ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE	9059T	URSODEOXYCHOLIC ACID	8448P
ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE	9062Y	VIGABATRIN	2667J
ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE	9061X	VIGABATRIN	2668K
SALCATONIN	2995P	ZOLMITRIPTAN	8266C

SALCATONIN	2997R		
SODIUM ACID PHOSPHATE	2946C		
SUMATRIPTAN	8341B		
SUMATRIPTAN SUCCINATE	8144P		
SUMATRIPTAN SUCCINATE	8885P		
TETRABENAZINE	1330B		
THIAMINE HYDROCHLORIDE	1070H		
THIORIDAZINE HYDROCHLORIDE	2163W		
THIORIDAZINE HYDROCHLORIDE	2359E		
THIORIDAZINE HYDROCHLORIDE	2164X		
THIORIDAZINE HYDROCHLORIDE	2165Y		

Annex B: Authority Process Changes

