Agenda item 14.06

Continued Dispensing Arrangements

1. Purpose of Item
	1. To request that the PBAC:

• NOTE that the Continued Dispensing Emergency Measures are due to cease on 30 June 2022;

• CONSIDER the stakeholder feedback on the proposed changes to ongoing Continued Dispensing arrangements recommended by PBAC in May 2020;

• CONSIDER making changes to the May 2020 recommendations, including the list of medicines and principles, to ongoing Continued Dispensing arrangements, in response to stakeholder feedback.

1. Context

*Revised PBS Medicines under ongoing Continued Dispensing Arrangements*

* 1. In March 2020, the PBAC considered a proposal from the Pharmacy Guild of Australia (Guild) to expand Continued Dispensing arrangements to all PBS medicines, with particular exclusions.
	2. The PBAC did not support this approach, and instead requested that the Department develop a list of medicines that would be appropriate for a Continued Dispensing supply on the basis that they would be safe and well-tolerated for the treatment of chronic and stable disease.
	3. A list of medicines was endorsed by the PBAC in May 2020. The PBAC also endorsed a set of principles for consideration of new medicines for inclusion in Continued Dispensing arrangements.
	4. The medicines recommended by the PBAC are predominantly chronic disease medicines (such as those used to treat asthma, lung disease, diabetes, heart disease) and supplied under the PBS General Schedule (s85). However, the PBAC also endorsed the inclusion of medicines for human immunodeficiency virus (HIV), which are available under the s100 Highly Specialised Drugs (HSD) Program.
	5. The PBAC also supported a proposal that the Closing the Gap PBS Copayment Program (the CTG Program), which reduces or removes the PBS copayment for eligible Aboriginal and Torres Strait Islander people, should apply to medicines supplied under Continued Dispensing.

*Stakeholder Consultations*

* 1. On 1 February 2021, the Department wrote to the following stakeholders to seek comments about the proposed changes to Continued Dispensing as recommended by the PBAC:
* Guild;
* Pharmaceutical Society of Australia (PSA);
* Australian Medical Association (AMA);
* Royal Australian College of General Practitioners (RACGP);
* Consumer Health Forum (CHF); and
* Australian Federation of AIDS Organisations (AFAO).
	1. The feedback received from stakeholder groups was varied, with medical groups generally expressing concerns with the proposal. Key feedback from medical, pharmacy and consumer groups was considered by the PBAC.
	2. As part of the consultation process, the Department offered stakeholders the opportunity to meet with the Chair of the PBAC.
	3. The PBAC noted that, since its recommendations in May 2020, there have been significant changes in the health sector in response to the COVID-19 pandemic, including a range of new measures which can support patients to continue receiving their PBS medicines.
1. Background

*Continued Dispensing Arrangements*

* 1. The Continued Dispensing Initiative commenced in 2013, as part of the Fifth Community Pharmacy Agreement. It enables an approved pharmacist to supply a PBS quantity of an eligible medicine to a person when there is an immediate need for that medicine but it is not practicable to obtain a prescription. In this context, practicable is where “it is not possible to contact a prescriber to obtain a prescription (hard or electronic copy) or a telephone order to supply the medicine”.
	2. In conducting a continued dispensing supply, pharmacists are required to consider the Pharmaceutical Society of Australia’s Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists. Pharmacists must be satisfied that the patient has previously been prescribed the medicine, therapy is stable, and the medicine is safe and appropriate for the consumer. A person may only receive one continued dispensing supply per eligible medicine within a twelve-month period. When first established, Continued Dispensing arrangements only applied to certain oral contraceptives and lipid-lowering medicines (statins). These (ongoing) arrangements are legally underpinned by the *National Health (Continued Dispensing) Determination 2012.*

*Continued Dispensing Emergency Measures*

* 1. In response to the bushfire crisis in January 2020, the range of PBS-subsidised medicines that could be supplied without a prescription under continued dispensing arrangements was temporarily expanded until 31 March 2020 through the *National Health (Continued Dispensing – Emergency Measures) Determination 2020*. Due to the ongoing impact of the COVID-19 pandemic, the Government extended these arrangements on several occasions, most recently until 30 June 2022.
	2. From 13 January 2020 to 30 June 2021, over 360,000 people received at least one supply of medicine under the Emergency Measures, with 75% receiving one supply, and the remainder receiving two or more supplies for different medicines. In addition, more than 3,800 community pharmacies supplied a PBS medicine under these arrangements during that time. These numbers exclude supplies of oral contraceptives and lipid-lowering medicines (statins).
1. PBAC Outcome
	1. The PBAC noted the Continued Dispensing Emergency Measures were to cease on 31 December 2021, but on 5 November 2021 it was announced that the Continuing Dispensing Emergency Measures were extended until 30 June 2022.
	2. The PBAC reviewed and acknowledged the concerns raised by stakeholder groups. The PBAC noted the general support for the proposed changes to ongoing Continued Dispensing arrangements endorsed by PBAC in May 2020.
	3. The PBAC reviewed the list of medicines for inclusion out of the May 2020 recommendations and did not propose changes to the list. However, the PBAC recommended the following changes to the Continued Dispensing principles:

|  |  |
| --- | --- |
| **Original wording of general principles from May 2020** | **Revised wording** |
| It is not practicable for the person to obtain a valid prescription from an authorised prescriber (including via a telehealth consultation) | The usual prescriber must be unable to be contacted and/or is unable to provide an e-prescription or owing prescription |
| The medicine has been supplied to the person in the last six (6) months and their condition is stable | The medicine has been supplied to the person in the last three (3) months and their condition is stable |
| The pharmacists must consider all other options prior to utilising Continued Dispensing. | Nil (Removed) |

1. Recommended Listing

*List of medicines endorsed by the PBAC for continued dispensing*

| **ATC** | **DRUG CLASS** | **ACTIVE INGREDIENT**  | **FORM** | **RESTRICTIONS** | **COMMENTS** |
| --- | --- | --- | --- | --- | --- |
| A10AB | Insulins and Analogues for injection, fast acting | Insulin aspart | Injection | Unrestricted |   |
|   |   | Insulin glulisine | Injection | Unrestricted |   |
|   |   | Insulin lispro | Injection | Unrestricted |   |
|   |   | Insulin neutral human | Injection | Unrestricted |   |
| A10AC | Insulins and Analogues for injection, intermediate acting | Insulin isophane human | Injection | Unrestricted |   |
| A10AD | Insulins and Analogues for injection, intermediate or long acting combined with fast acting | Insulin aspart + insulin aspart protamine | Injection | Unrestricted |   |
|   |   | Insulin degludec + insulin aspart | Injection | Unrestricted |   |
|   |   | Insulin isophane human + insulin neutral human | Injection | Unrestricted |   |
|   |   | Insulin lispro + insulin lispro protamine | Injection | Unrestricted |   |
| A10AE | Insulins and Analogues for injection, long acting | Insulin detemir | Injection | Restricted |   |
|   |   | Insulin glargine | Injection | Unrestricted |   |
| A10BA | Biguanides | Metformin | Tablet | Unrestricted |   |
| A10BB | Sulfonylureas | Glibenclamide | Tablet | Unrestricted |   |
|   |   | Gliclazide | Modified release | Unrestricted |   |
|   |   | Glimepiride | Tablet | Unrestricted |   |
|   |   | Glipizide | Tablet | Unrestricted |   |
| A10BC | Combinations of oral blood glucose lowering drugs | Alogliptin + metformin | Tablet | Streamlined |   |
|   |   | Dapagliflozin + metformin | Tablet | Streamlined |   |
|   |   | Empagliflozin + linagliptin | Tablet | Streamlined |   |
|   |   | Empagliflozin + metformin | Tablet | Streamlined |   |
|   |   | Ertugliflozin + metformin | Tablet | Streamlined |   |
|   |   | Ertugliflozin + sitagliptin | Tablet | Streamlined |   |
|   |   | Linagliptin + metformin | Tablet | Streamlined |   |
|   |   | Metformin + glibenclamide | Tablet | Unrestricted |   |
|   |   | Saxagliptin + dapagliflozin | Tablet | Streamlined |   |
|   |   | Saxagliptin + metformin | Tablet | Streamlined |   |
|   |   | Sitagliptin + metformin | Tablet | Streamlined |   |
|   |   | Vildagliptin + metformin | Tablet | Streamlined |   |
| A10BF | Alpha glucosidase inhibitors | Acarbose | Tablet  | Unrestricted |   |
| A10BG | Thiazolidinediones  | Pioglitazone | Tablet | Streamlined |   |
| A10BH | Dipeptidyl peptidase 4 (DPP-4) inhibitors | Alogliptin | Tablet  | Streamlined |   |
|   |   | Linagliptin | Tablet | Streamlined |   |
|   |   | Saxagliptin | Tablet | Streamlined |   |
|   |   | Sitagliptin | Tablet | Streamlined |   |
|   |   | Vildagliptin | Tablet | Streamlined |   |
| A10BJ | Glucagon-like peptide-1 (GLP-1) analogues | Dulaglutide | Injection | Streamlined |   |
|   |   | Exenatide | Injection | Streamlined |   |
|   |   | Semaglutide | Injection | Streamlined |   |
| A10BK | Sodium-glucose co-transporter 2 (SGLT2) inhibitors | Dapagliflozin | Tablet | Streamlined |   |
|   |   | Empagliflozin | Tablet | Streamlined |   |
|   |   | Ertugliflozin | Tablet | Streamlined |   |
| C03AA | Low-ceiling diuretics - thiazides, plain | Hydrochlorothiazide | Tablet | Unrestricted |   |
| C03BA | Low-ceiling diuretics - sulfonamides, plain | Chlortalidone | Tablet | Unrestricted |   |
|   |   | Indapamide | Tablet | Unrestricted |   |
| C03CA | High-ceiling diuretics - sulfonamides, plain | Furosemide (frusemide)  | Tablet | Unrestricted |   |
| C03CC | High-ceiling diuretics - aryloxyacetic acid derivatives | Etacrynic acid | Tablet | Restricted |   |
| C03DA | Potassium-sparing agents - aldosterone antagonists | Eplerenone | Tablet | Streamlined |   |
|   |   | Spironolactone | Tablet | Unrestricted |   |
| C03EA | Diuretics and potassium-sparing agents in combination | Amiloride +hydrochlorothiazide | Tablet  | Unrestricted |   |
| C07AA | Beta blocking agents, non-selective | Oxprenolol | Tablet | Unrestricted |   |
|   |   | Pindolol | Tablet | Unrestricted |   |
|   |   | Propranolol | Tablet  | Unrestricted |   |
| C07AB | Beta blocking agents, selective | Atenolol | Tablet | Unrestricted |   |
|   |   | Bisoprolol | Tablet  | Restricted |   |
|   |   | Metoprolol succinate | Tablet  | Restricted |   |
|   |   | Metoprolol tartrate | Tablet | Unrestricted |   |
|   |   | Nebivolol | Tablet  | Restricted |   |
| C07AG | Alpha and beta blocking agents | Carvedilol | Tablet  | Restricted |   |
|   |   | Labetalol | Tablet | Unrestricted |   |
| C08CA | Selective calcium channel blockers with mainly vascular effects - dihydropyridine derivatives | Amlodipine | Tablet | Unrestricted |   |
|   |   | Felodipine | Tablet | Unrestricted |   |
|   |   | Lercanidipine | Tablet | Unrestricted |   |
|   |   | Nifedipine | Tablet | Unrestricted |   |
| C08DA | Selective calcium channel blockers with direct cardiac effects vascular - phenylalkylamine derivatives | Verapamil | Tablet | Unrestricted |   |
| C08DB | Selective calcium channel blockers with direct cardiac effects vascular - benzothiazepine derivatives | Diltiazem | Tablet, capsule | Unrestricted |   |
| C09AA | ACE inhibitors, plain | Captopril | Tablet | Unrestricted |   |
|   |   | Enalapril | Tablet | Unrestricted |   |
|   |   | Fosinopril | Tablet | Unrestricted |   |
|  |   | Lisinopril | Tablet | Unrestricted |   |
|   |   | Perindopril | Tablet | Unrestricted |   |
|   |   | Quinapril | Tablet | Unrestricted |   |
|  |   | Ramipril | Tablet | Unrestricted |   |
|   |   | Trandolapril | Capsule | Unrestricted  |   |
| C09BA | ACE inhibitors + diuretics | Enalapril + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Fosinopril + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Perindopril + indapamide | Tablet | Restricted |   |
|   |   | Quinapril + hydrochlorothiazide | Tablet | Restricted |   |
| C09BB | ACE inhibitors + calcium channel blockers | Lercanidipine + enalapril | Tablet | Restricted |   |
|   |   | Perindopril + amlodipine | Tablet | Restricted |   |
|   |   | Ramipril + felodipine | Tablet | Restricted |   |
|   |   | Trandolapril + verapamil | Tablet | Restricted |   |
| C09CA | Angiotensin II receptor blockers (ARBS), plain | Candesartan | Tablet | Unrestricted |   |
|   |   | Eprosartan | Tablet | UNCLEAR |   |
|   |   | Irbesartan | Tablet | Unrestricted |   |
|   |   | Losartan | Tablet | Unrestricted |   |
|   |   | Olmesartan | Tablet | Unrestricted |   |
|   |   | Telmisartan | Tablet | Unrestricted |   |
|   |   | Valsartan | Tablet | Unrestricted |   |
| C09DA | Angiotensin II receptor blockers (ARBS) and diuretics | Candesartan + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Eprosartan + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Irbesartan + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Olmesartan + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Telmisartan + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Valsartan + hydrochlorothiazide | Tablet | Restricted |   |
| C09DB | Angiotensin II receptor blockers (ARBS) and calcium channel blockers | Amlodipine + valsartan | Tablet | Restricted |   |
|   |   | Olmesartan medoxomil + amlodipine | Tablet | Restricted |   |
|   |   | Telmisartan + amlodipine | Tablet | Restricted |   |
| C09DX | Angiotensin II receptor blockers (ARBS), other combinations | Amlodipine + valsartan + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Olmesartan + amlodipine + hydrochlorothiazide | Tablet | Restricted |   |
|   |   | Sacubitril + valsartan | Tablet | Restricted |   |
| C10BA | HMG CoA reductase inhibitors in combination with other lipid modifying agents | Ezetimibe + rosuvastatin | Tablet | Streamlined |   |
|   |   | Ezetimibe + atorvastatin | Tablet | Streamlined |   |
|   |   | Ezetimibe + simvastatin | Tablet | Streamlined |   |
| C10BX | HMG CoA reductase inhibitors, other combinations | Amlodipine + atorvastatin | Tablet | Unrestricted |   |
| J05AE | Protease inhibitors  | Atazanavir | Capsule | Streamlined | S100 HSD Community Access |
|   |   | Atazanavir + cobicistat | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Darunavir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Fosamprenavir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Ritonavir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Saquinavir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Tipranavir | Capsule | Streamlined | S100 HSD Community Access |
| J05AF | Nucleoside and nucleotide reverse transcriptase inhibitors | Abacavir | Tablet and liquid | Streamlined | S100 HSD Community Access |
|   |   | Adefovir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Entecavir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Lamivudine | Tablet | Streamlined | S100 HSD Community Access  |
|   |   | Tenofovir disoproxil | Tablet | Streamlined | S100 HSD Community Access  |
|   |   | Zidovudine | Capsule and liquid | Streamlined | S100 HSD Community Access |
| J05AG | Non-nucleoside reverse transcriptase inhibitors | Efavirenz | Tablet and liquid | Streamlined | S100 HSD Community Access |
|   |   | Etravirine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Nevirapine | Tablet and liquid | Streamlined | S100 HSD Community Access |
|   |   | Rilpivirine | Tablet | Streamlined | S100 HSD Community Access |
| J05AJ | Integrase inhibitors | Dolutegravir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Raltegravir | Tablet | Streamlined | S100 HSD Community Access |
| J05AR | Antivirals for treatment of HIV infections, combinations | Abacavir + lamivudine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Abacavir + lamivudine + zidovudine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Bictegravir + emtricitabine + tenofovir alafenamide | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Darunavir + cobicistat | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Darunavir + cobicistat + emtricitabine + tenofovir alafenamide | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Dolutegravir + abacavir + lamivudine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Dolutegravir + lamivudine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Dolutegravir + rilpivirine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Emtricitabine + rilpivirine + tenofovir alafenamide | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Emtricitabine + tenofovir alafenamide | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Lamivudine + zidovudine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Lopinavir + ritronavir | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Tenofovir + emtricitabine | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Tenofovir + emtricitabine + efavirenz | Tablet | Streamlined | S100 HSD Community Access |
|   |   | Tenofovir alafenamide + emtricitabine + elvitegravir + cobicistat | Tablet | Streamlined | S100 HSD Community Access |
| J05AX | Other antivirals | Enfuvirtide | Injection | Streamlined | S100 HSD Community Access |
|   |   | Maraviroc | Tablet | Streamlined | S100 HSD Community Access |
| R03AC | Selective beta-2-adrenoreceptor agonists | Formoterol (eformoterol) | Inhalation | Restricted |   |
|   |   | Indacaterol | Inhalation | Restricted |   |
|   |   | Salbutamol | Inhalation | Restricted |   |
|   |   | Salmeterol | Inhalation | Restricted |   |
|   |   | Terbutaline | Inhalation | Streamlined |   |
| R03AK | Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics | Beclometasone + Formoterol (eformoterol) | Inhalation | Streamlined |   |
|   |   | Budesonide + Formoterol (eformoterol) | Several | Streamlined  |   |
|   |   | Fluticasone furoate + Vilanterol | Inhalation | Streamlined |   |
|   |   | Fluticasone propionate + Formoterol (eformoterol) | Inhalation | Streamlined |   |
|   |   | Fluticasone propionate + Salmeterol | Inhalation | Streamlined |   |
|   |   | Indacaterol + Mometasone | Inhalation | Streamlined |   |
| R03BA | Glucocorticoids | Beclometasone | Inhalation | Unrestricted |   |
|   |   |   | Activated inhalation | Restricted |   |
|  |   | Budesonide | Inhalation Powder | Unrestricted |   |
|  |   |   | Inhalation Solution | Streamlined |   |
|   |   | Ciclesonide | Inhalation | Unrestricted |   |
|   |   | Fluticasone furoate | Inhalation | Unrestricted |   |
|   |   | Fluticasone propionate | Inhalation | Unrestricted |   |
| R03BC | Antiallergic agents, excl. corticosteroids | Cromoglycate | Inhalation | Unrestricted |   |
|   |   | Nedocromil | Inhalation | Unrestricted |   |