EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MAXIMUM DISPENSED QUANTITIES SEPTEMBER UPDATE) INSTRUMENT 2024

PB 85 of 2024

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* (the Act), is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) to make changes to the pharmaceutical benefits listed for the purposes of the Pharmaceutical Benefits Scheme (PBS), and related matters. This legislative instrument includes changes to increase the maximum dispensed quantity (MDQ) for certain pharmaceutical benefits, in certain circumstances, from one to two months' supply, as the third of three stages of implementation of the MDQ measure. As a result of the changes, an eligible patient can be prescribed two months' supply of a pharmaceutical benefit to be dispensed on the one occasion under the PBS.

The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing Instrument) determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) through declarations of drugs and medicinal preparations, and for ready-prepared benefits: determinations of forms, manners of administration and brands. It also provides for related matters (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

These changes will commence on 1 September 2024.

Stage 3 of the MDQ measure includes some medicines for chronic medical conditions such as acne, anxiety disorders, asthma, chronic obstructive pulmonary disease (COPD), constipation, depression, dry eyes, gastro-oesophageal reflux disease (GORD), glaucoma and Parkinson disease.

This instrument applies increased maximum dispensed quantities to 302 PBS items to implement Stage 3 of medicines approved for listing with an increased MDQ.

Authority

This Instrument exercises various powers in Part VII of the Act, as set out below:

Pharmaceutical benefits listed on the PBS

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug' (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

Prescribing pharmaceutical benefits

Paragraph 85A(2)(a) allows the Minister to determine the maximum quantity or number of units of the pharmaceutical item in a pharmaceutical benefit (or of the pharmaceutical benefit where there is no pharmaceutical item) that may, in one prescription, be directed to be supplied on one occasion. Paragraph 85A(2)(b) also allows the Minister to determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated. The maximum quantities and repeats may be determined for all purposes or for particular purposes.

Subsection 85(7) provides that the Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit.

Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)), participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

Paragraph 88(1EB) provides that the Minister can list pharmaceutical benefits without determining any authorised prescribers for the benefit allowing the benefit to be supplied only.

This legislative instrument is made pursuant to section 88 and subsection 100(2) of the Act.

Supplying pharmaceutical benefits

Subsection 85(2A) provides that the Minister must declare that a particular listed drug can only be provided under a special arrangement under section 100 if the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

Subsection 85(2AA) provides that the Minister must declare that a particular listed drug can only be provided under one or more of the prescriber bag provisions if the PBAC has recommended under subsection 101(4AACA) that the drug be made available only under one or more of the prescriber bag provisions.

Subsection 85(6A) provides that the Minister may also determine for the purposes of paragraph 103(2A)(b) that a brand of a pharmaceutical item determined under subsection 85(6) is to be treated as equivalent to one or more other brands of pharmaceutical items.

Paragraph 85(7A) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under one or more of the prescriber bag provisions.

Paragraph 85(8)(a) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100.

Paragraph 85(8)(b) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100 for one or more of the circumstances determined for that pharmaceutical benefit under subsection 85(7).

Variation and revocation

Unless there is an express power to revoke or vary PB 26 of 2024 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 26 of 2024.

Subsection 101(4AAA) allows the Minister to, by legislative instrument, revoke or vary a subsection 85(2) declaration in relation to a drug or medicinal preparation. Advice from the PBAC is required if the effect of the legislative instrument would be that a drug or medicinal preparation would cease to be a listed drug (subsection 101(4AAB)).

Background – Maximum Dispensed Quantity

The MDQ is the maximum number or quantity of units of a pharmaceutical benefit that can be prescribed for a particular purpose for supply to a patient on the one occasion under the PBS. Currently, the MDQ for many PBS medicines used in the treatment of chronic medical conditions equates to one month's supply.

In December 2022, the PBAC considered and provided advice to the Minister for Health and Aged Care on a proposal that would improve access to PBS medicines for patients with stable, chronic medical conditions by providing prescribers the choice to prescribe an increased quantity for selected PBS medicines - two months' or three months' supply instead of the current one month's supply at each dispensing.

The PBAC considered a list of medicines from the General Schedule (section 85) of the PBS listed for use in treatment of chronic conditions for suitability for the proposal. Based on an assessment of clinical

safety and ongoing cost-effectiveness, the PBAC recommended that over 300 medicines were acceptable for listing with increased MDQ. The PBAC also agreed on standard restriction wording for all medicines included in this proposal, to ensure the higher MDQ items are only prescribed to patients whose condition is stable.

The Minister for Health and Aged Care announced the Government's intention to implement the two month MDQ proposal on 26 April 2023 as part of the 2023-24 Budget. Stage 1 of the MDQ measure was implemented 1 September 2023, Stage 2 was implemented on 1 March 2024 and Stage 3 will be implemented 1 September 2024.

Schedule 1 to the *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024* amends the listings of 302 PBS items to implement Stage 3 of MDQ. New PBS items with the increased MDQ will be included in the Schedule of Pharmaceutical Benefits in addition to the medicine's current PBS items that provide for one month's supply and five repeats (in general). This will facilitate prescribing of smaller quantities than the new MDQ for patients as clinically appropriate, to avoid medicine wastage and support closer clinical monitoring of patients where required.

An increase in the MDQ for certain medicines used in treating chronic conditions will improve access to and affordability of PBS medicines. It will also mean that patients with chronic, stable medical conditions will need to make less visits to a pharmacy and their prescriber for some common PBS medicines. It will result in reduced 'out of pocket costs' for both concessional and general patients and provide added convenience for many people. Public representations and discussion have indicated broad support from prescribers and consumers for the policy.

Evaluation of MDQ and stakeholder impacts

The Department has committed to developing a comprehensive evaluation framework that will monitor risks and provide mitigation strategies over the course of implementation. This will utilise existing data sources (including PBS claims data) to analyse uptake rates of increased MDQ items, medicine shortages, pharmacovigilance and medicine wastage.

Lower health care costs for patients and Government and maintenance of patient safety will be evaluated by reviewing the PBS statistics for MDQ PBS items once sufficient data is available.

The Department's evaluation framework will utilise existing well-developed processes within the Therapeutic Goods Administration (TGA) and the PBS program to assess outcomes of the implementation of MDQ on patient safety, optimal use of medicines and to identify/evaluate any previously unreported adverse reactions to MDQ medicines (pharmacovigilance).

The impact on the community pharmacy sector remuneration and continued participation in community pharmacy programs will be monitored through the Eighth Community Pharmacy Agreement (8CPA). The Department will monitor the number and distribution of pharmacies across Australia. The ongoing impact on wholesalers will be monitored through the 8CPA. The Department will continue to monitor impacts arising from implementation on software vendors through routine software vendor forums.

Changes to PB 26 of 2024 made by this Instrument

Schedule 1 to this Instrument provides for the addition to the PBS Schedule of the drug migalastat, and forms of the listed drugs amoxicillin with clavulanic acid, azithromycin, budesonide, and tiotropium. It also provides for deletion of the listed drug fosinopril with hydrochlorothiazid, and the form of the listed drug methylprednisolone, and the the alteration of circumstances in which prescriptions may be written for the supply of 118 listed drugs.

Schedule 1 to this Instrument also provides for the following changes:

- the addition of 264 pharmaceutical items for the maximum dispensed quantity (MDQ) measure
- the addition of 223 brands of existing pharmaceutical items
- the deletion of 42 brands of existing pharmaceutical items
- the deletion of a maximum quantity and number of repeats for an existing pharmaceutical item

- the alteration of responsible person codes for 3 brands of existing pharmaceutical items
- the addition of 2 responsible persons for the list of responsible persons
- the deletion of 2 responsible persons for the list of responsible persons
- the addition of 2 pharmaceutical items covered under Supply Only arrangements
- the deletion of 2 pharmaceutical items covered under Supply Only arrangements

These changes are summarised, by subject matter, in the Attachment.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

Consistent with the approach taken for implementation of Stages 1 and 2 of the increased MDQ measure, the government has considered current shortages in determining the medicines included in Stage 3. Medicines have been considered suitable for implementation of the increased MDQ measure on 1 September 2024 if they have premium-free alternative brands of the same form that are substitutable by the pharmacist (based on the shortages reported to TGA in one, or more, brands, of one, or more, forms at 1 July 2024).

A minor adjustment has been made to this implementation approach for Stage 3. The PBAC recommended 60-day prescription option for PBS items that are in shortage in the lead up to 1 September 2024, have also been considered suitable for implementation where other PBS items of the same drug:

- have been listed in Stages One or Two; or,
- will be listed in Stage Three of 60-day prescriptions on 1 September 2024.

This is intended to eliminate confusion for prescribers where certain forms (e.g some strengths) of a medicine are available for 60-day prescriptions and others are not.

A full list of the medicines, including forms and PBS item codes, for which an increased MDQ will be implemented on 1 September 2024 for all brands listed on the PBS, is provided at Attachment A. The medicines and PBS item codes included in Attachment A have all been recommended by the PBAC for inclusion in the increased MDQ measure.

The PBS Schedule is part of the wider PBS managed by the Department and administered by Services Australia. As part of the consultation process the Department and Services Australia have collaborated on required information technology system changes, including to ensure that software vendors receive data outputs with sufficient time to ensure prescribing and dispensing software can be updated for the 1 September 2024 commencement of Stage 3 of the increased MDQ measure.

General

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 September 2024.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MAXIMUM DISPENSED QUANTITIES SEPTEMBER UPDATE) INSTRUMENT 2024*

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024* and may also be cited as PB 85 of 2024.

Section 2 Commencement

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, Schedule 1 to the Instrument commences on 1 September 2024.

Section 3 Authority

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

Section 4 Schedules

This section provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

Schedule 1 of the Instrument amends Schedules 1 and 4 of the 2024 Listing Instrument to increase the maximum dispensed quantity (MDQ) for 302 PBS items. Schedule 1 will take effect on 1 September 2024. These items include some medicines for chronic conditions such as acne, anxiety disorders, asthma, chronic obstructive pulmonary disease (COPD), constipation, depression, dry eyes, gastro-oesophageal reflux disease (GORD), glaucoma and Parkinson disease

The MDQ is the maximum quantity or number of units of a pharmaceutical benefit that a PBS prescriber can direct to be supplied to a patient on the one occasion. The MDQ for the relevant items is currently an amount sufficient to one month's supply. Schedule 1 will amend the entries for the relevant items in Schedule 1 of the 2024 Listing Instrument to include a new MDQ, sufficient for two months' supply, along with the applicable new 'purposes codes' and 'circumstances codes'.

Schedule 1 of the Instrument will also amend Schedule 4 of the 2024 Listing Instrument to detail, for the new purposes and circumstances codes, the purposes for which, and circumstances in which, the new MDQ amounts can be prescribed. These relevantly will include that the patient's condition must be stable for the prescriber to consider the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Current listings enabling the prescription of one month's supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

The amendments in Schedule 1 also involve the addition and deletion of listed drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the deletion of a maximum quantity and number of repeats for a form of a listed drug, the addition and deletion of responsible persons for the list of responsible persons, the alteration of the responsible persons for existing brands, the addition and deletion of pharmaceutical benefits covered under Supply Only arrangements, and the alteration of circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme. These changes are summarised below.

SUMMARY OF CHANGES
TO THE PHARMACEUTICAL BENEFITS SCHEME
MADE BY SCHEDULE 1 OF THIS INSTRUMENT

Addition of Increased Maximum Dispensed Quantity

Drug	***Form (strength and presentation)***	***30-day Item Code***	***60-day Item Code***
Aclidinium	Powder for oral inhalation in breath actuated device 322 micrograms (as bromide) per dose, 60 doses	10124W	14539F
Aclidinium with formoterol	Powder for oral inhalation in breath actuated device containing aclidinium 340 micrograms (as bromide) with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	10565C	14410K
Amantadine	Capsule containing amantadine hydrochloride 100 mg	03016R	14486K
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	12142C	14375N
	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	12133N	14309D
	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	12137T	14485J
	Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe	12319J	14377Q
	Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL	12306Q	14407G
Beclometasone with formoterol and glycopyrronium	Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses	12468F	14310E
Beclometasone with formoterol	Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose,120 dose	12183F	14376P
	Pressurised inhalation containing beclometasone dipropionate 200 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	13205B	14538E
Beclometasone	Pressurised inhalation in breath actuated device containing beclometasone dipropionate 100 micrograms per dose, 200 doses (CFC-free formulation)	08409N	14514X
	Pressurised inhalation containing beclometasone dipropionate 100 micrograms per dose, 200 doses (CFC-free formulation)	08407L	14541H
	Pressurised inhalation in breath actuated device containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation)	08408M	14378R
	Pressurised inhalation containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation)	08406K	14540G

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
Betaxolol	Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL	02825Q	14425F
	Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL	05544T	
Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL	05558M	14317M
	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL	09464D	
	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30	10107Y	14351H
	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30	10108B	
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	05551E	14315K
	Eye drops 300 micrograms per mL, 3 mL	08620Q	
	Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30	10046R	14422C
	Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30	10053D	
Bisacodyl	Suppositories 10 mg, 10	01260H	14447J
	Suppositories 10 mg, 12	01258F	14305X
	Tablet 5 mg	01259G	14446H
Brimonidine	Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL	05298W	14496Y
	Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL	05563T	
	Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL	05534G	14497B
	Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL	08351M	
Brimonidine with timolol	Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL	05535H	14491Q
	Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL	08826M	
Brinzolamide with brimonidine	Eye drops 10 mg brinzolamide with 2 mg brimonidine tartrate per mL, 5 mL	10536M	14423D
	Eye drops 10 mg brinzolamide with 2 mg brimonidine tartrate per mL, 5 mL	10547D	
Brinzolamide with timolol	Eye drops 10 mg brinzolamide with timolol 5 mg (as maleate) per mL, 5 mL	03438Y	14495X
	Eye drops 10 mg brinzolamide with timolol 5 mg (as maleate) per mL, 5 mL	05562R	
Brinzolamide	Eye drops 10 mg per mL, 5 mL	05540N	14321R
	Eye drops 10 mg per mL, 5 mL	08483L	

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
Budesonide	Nebuliser suspension 500 micrograms in 2 mL single dose units, 30	02065Q	14438X
	Nebuliser suspension 1 mg in 2 mL single dose units, 30	02066R	14469M
	Powder for oral inhalation in breath actuated device 100 micrograms per dose, 200 doses	02070Y	14331G
	Powder for oral inhalation in breath actuated device 200 micrograms per dose, 200 doses	02071B	14503H
	Powder for oral inhalation in breath actuated device 400 micrograms per dose, 200 doses	02072C	14470N
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	10015D	14467K
	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	12089G	14535B
	Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	08796Y	14440B
	Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	12101X	14437W
	Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	10018G	14468L
	Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	12082X	14436T
	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	08625Y	14439Y
	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	11273H	14434Q
	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	12093L	14365C
	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	11301T	14435R
	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	13258T	14398T

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
Budesonide with glycopyrronium and formoterol	Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses	12672Y	14536C
Cabergoline	Tablet 1 mg	08393R	14516B
	Tablet 2 mg	08394T	14543K
Carbamazepine	Tablet 100 mg	02422L	14509P
	Tablet 200 mg	01706T	14338P
Carbomer-980	Eye gel 2 mg per g, single dose units 0.6 mL, 30	05504Q	14420Y
	Eye gel 2 mg per g, single dose units 0.6 mL, 30	08578L	
	Eye gel 2 mg per g, 10 g	05503P	14385D
	Eye gel 2 mg per g, 10 g	08384G	
Carmellose sodium	Eye drops containing carmellose sodium 5 mg per mL, 10 mL	11852T	14319P
	Eye drops containing carmellose sodium 5 mg per mL, 10 mL	11853W	
	Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30	02338C	14522H
	Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30	05506T	
	Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30	02324H	14452P
	Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30	05505R	
Ciclesonide	Pressurised inhalation 160 micrograms per dose, 120 doses (CFC-free formulation)	08854B	14348E
	Pressurised inhalation 80 micrograms per dose, 120 doses (CFC-free formulation)	08853Y	14312G
Citalopram	Tablet 10 mg (as hydrobromide)	08702B	14313H
	Tablet 20 mg (as hydrobromide)	08220P	14490P
	Tablet 40 mg (as hydrobromide)	08703C	14518D
Colestyramine	Sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50	02967E	14477Y
Desvenlafaxine	Tablet (extended release) 100 mg (as succinate)	09367B	14545M
	Tablet (modified release) 100 mg	10231L	14489N
	Tablet (modified release) 100 mg (as benzoate)	10245F	14384C
	Tablet (extended release) 50 mg (as succinate)	09366Y	14451N
	Tablet (modified release) 50 mg (as benzoate)	10234P	14418W
	Tablet (modified release) 50 mg	10241B	14383B

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
Dextran-70 with hypromellose	Eye drops containing 3 mg hypromellose 4500 with 1 mg dextran 70 per mL, 15 mL	05520M	14521G
	Eye drops containing 3 mg hypromellose 4500 with 1 mg dextran 70 per mL, 15 mL	01509K	
Diltiazem	Capsule (controlled delivery) containing diltiazem hydrochloride 180 mg	01312C	14564M
	Capsule (controlled delivery) containing diltiazem hydrochloride 240 mg	01313D	14508N
	Capsule (controlled delivery) containing diltiazem hydrochloride 360 mg	08480H	14565N
	Tablet containing diltiazem hydrochloride 60 mg	01335G	14479C
Dorzolamide with timolol	Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL	05542Q	14386E
	Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL	08567X	
Dorzolamide	Eye drops 20 mg (as hydrochloride) per mL, 5 mL	05541P	14524K
	Eye drops 20 mg (as hydrochloride) per mL, 5 mL	08488R	
Doxycycline	Capsule 100 mg (as hyclate) (containing enteric coated pellets)	10777F	14443E
	Tablet 100 mg (as hyclate)	10779H	14480D
	Tablet 100 mg (as monohydrate)	10781K	14511R
	Capsule 50 mg (as hyclate) (containing enteric coated pellets)	02707L	14484H
	Tablet 50 mg (as hyclate)	02711Q	14307B
	Tablet 50 mg (as monohydrate)	09106G	14513W
Entacapone	Tablet 200 mg	08367J	14542J
Eprosartan with hctz	Tablet 600 mg eprosartan (as mesilate) with 12.5 mg hydrochlorothiazide	08624X	14337N
Erythromycin	Capsule 250 mg (containing enteric coated pellets)	10780J	14409J
Escitalopram	Tablet 10 mg (as oxalate)	08700X	14349F
	Tablet 10 mg (as oxalate)	09432K	14519E
	Tablet 20 mg (as oxalate)	08701Y	14415Q
	Tablet 20 mg (as oxalate)	09433L	14416R
	Oral solution 20 mg (as oxalate) per mL, 15 mL	10181W	14546N
Esomeprazole	Capsule (enteric) 20 mg (as magnesium)	10343J	14510Q
	Capsule (enteric) 20 mg (as magnesium)	11687D	14303T
	Capsule (enteric) 20 mg (as magnesium)	12275C	14537D
	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	11692J	14444F
	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	12287Q	14481E

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
	Capsule (enteric) 40 mg (as magnesium)	10331R	14405E
	Capsule (enteric) 40 mg (as magnesium)	12290W	14445G
	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	12283L	14512T
	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	03401B	14373L
	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	08600P	14308C
Estradiol with noresthisterone	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8	08428N	14336M
Fluoxetine	Capsule 20 mg (as hydrochloride)	01434L	14548Q
Fluticasone furoate with umeclidinium and vilanterol	Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses	11379X	14346C
	Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses	12917W	14382Y
Fluticasone furoate with vilanterol	Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses	11124L	14379T
	Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses	11129R	14345B
Fluticasone furoate	Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms per dose, 30 doses	11719T	14515Y
	Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms per dose, 30 doses	11729H	14380W
Fluticasone propionate with salmeterol	Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses	08430Q	14413N
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses	08431R	14449L
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses	08432T	14450M
	Pressurised inhalation containing fluticasone propionate 50 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)	08517G	14414P
	Pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)	08518H	14544L

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
	Pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)	08519J	14311F
Fluticasone propionate	Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation)	08516F	14487L
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms per dose, 60 doses	08147T	14412M
	Pressurised inhalation containing fluticasone propionate 125 micrograms per dose, 120 doses (CFC-free formulation)	08345F	14347D
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms per dose, 60 doses	08148W	14381X
Fluticasone propionate with formoterol	fluticasone propionate 125 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations	10007Q	14343X
	fluticasone propionate 250 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations	10008R	14344Y
	fluticasone propionate 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations	02827T	14411L
Fluvoxamine	Tablet containing fluvoxamine maleate 50 mg	08512B	14488M
	Tablet containing fluvoxamine maleate 100 mg	08174F	14314J
Formoterol	Powder for oral inhalation in breath actuated device containing formoterol fumarate dihydrate 6 micrograms per dose, 60 doses	08239P	14547P
	Powder for oral inhalation in breath actuated device containing formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	08240Q	14517C
	Capsule containing powder for oral inhalation containing formoterol fumarate dihydrate 12 micrograms (for use in Foradile Aerolizer)	08136F	14419X
Glyceryl trinitrate	Transdermal patch 36 mg	08028M	14478B
	Transdermal patch 54 mg	08119H	14335L
	Transdermal patch 18 mg	08027L	14371J
Glycopyrronium	Capsule containing powder for oral inhalation 50 micrograms (as bromide) (for use in Breezhaler)	10059K	14417T
Hyaluronate sodium	Eye drops containing sodium hyaluronate 1 mg per mL, 10 mL	02181T	14354L
	Eye drops containing sodium hyaluronate 1 mg per mL, 10 mL	02184Y	

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
	Eye drops containing sodium hyaluronate 2 mg per mL, 10 mL	02171G	14494W
	Eye drops containing sodium hyaluronate 2 mg per mL, 10 mL	02253N	
Hydrocortisone	Tablet 20 mg	01500Y	14476X
Hypromellose	0.3% w/v eye drops, 10 mL (preservative free)	11842G	14492R
	0.3% w/v eye drops, 10 mL (preservative free)	11849P	
	Eye drops 3 mg per mL, 10 mL	11625W	14318N
	Eye drops 3 mg per mL, 10 mL	11634H	
	Eye drops 5 mg per mL, 15 mL	05517J	14320Q
	Eye drops 5 mg per mL, 15 mL	02956N	
Indacaterol with glycopyrronium	Capsule containing powder for oral inhalation indacaterol 110 micrograms (as maleate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler)	10156M	14504J
Indacaterol with glycopyrronium with mometasone	Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 136 micrograms (for use in Breezhaler)	12295D	14399W
	Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 68 micrograms (for use in Breezhaler)	12298G	14471P
Indacaterol with mometasone	Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 127.5 micrograms (for use in Breezhaler)	12289T	14333J
	Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 260 micrograms (for use in Breezhaler)	12279G	14441C
	Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 62.5 micrograms (for use in Breezhaler)	12269R	14332H
Indacaterol	Capsule containing powder for oral inhalation 150 micrograms (as maleate) (for use in Breezhaler)	05134F	14334K
	Capsule containing powder for oral inhalation 300 micrograms (as maleate) (for use in Breezhaler)	05137J	14368F
Lansoprazole	Capsule 15 mg	08198L	14448K
	Tablet 15 mg (orally disintegrating)	09331D	14374M
	Capsule 30 mg	02241Y	14340R
	Capsule 30 mg	11669E	14302R
	Capsule 30 mg	12284M	14304W
	Tablet 30 mg (orally disintegrating)	09478W	14342W

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
	Tablet 30 mg (orally disintegrating)	11697P	14406F
	Tablet 30 mg (orally disintegrating)	12276D	14339Q
Latanoprost with timolol	Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL	05553G	14350G
	Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL	08895E	
Latanoprost	Eye drops 50 micrograms per mL, 2.5 mL	05552F	14453Q
	Eye drops 50 micrograms per mL, 2.5 mL	08243W	
Levodopa with benserazide	Capsule containing levodopa 50 mg with 12.5 mg benserazide (as hydrochloride)	02227F	14388G
	Capsule containing levodopa 100 mg with 25 mg benserazide (as hydrochloride)	02225D	14387F
	Capsule containing levodopa 200 mg with 50 mg benserazide (as hydrochloride)	02226E	14551W
	Tablet containing levodopa 100 mg with 25 mg benserazide (as hydrochloride)	02229H	14455T
	Tablet containing levodopa 200 mg with 50 mg benserazide (as hydrochloride)	02228G	14428J
	Dispersible tablet containing levodopa 50 mg with 12.5 mg benserazide (as hydrochloride)	08218M	14356N
	Dispersible tablet containing levodopa 100 mg with 25 mg benserazide (as hydrochloride)	08219N	14552X
	Capsule containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) (sustained release)	02231K	14525L
Levodopa with carbidopa and entacapone	Tablet 50 mg-12.5 mg (as monohydrate)-200 mg	08797B	14456W
	Tablet 100 mg-25 mg (as monohydrate)-200 mg	08798C	14554B
	Tablet 150 mg-37.5 mg (as monohydrate)-200 mg	08799D	14357P
	Tablet 200 mg-50 mg (as monohydrate)-200 mg	09292C	14457X
	Tablet 75 mg-18.75 mg (as monohydrate)-200 mg	09344T	14498C
	Tablet 125 mg-31.25 mg (as monohydrate)-200 mg	09345W	14527N
Levodopa with carbidopa	Tablet 100 mg-25 mg (as monohydrate)	01242J	14427H
	Tablet 250 mg-25 mg (as monohydrate)	01245M	14454R
	Tablet (modified release) 200 mg-50 mg (as monohydrate)	01255C	14322T
Macrogol 3350	Powder for oral solution 510 g	03416T	14341T
Macrogol 3350	Sachets containing powder for oral solution 13.125 g with electrolytes, 30	08612G	14408H
Mianserin	Tablet containing mianserin hydrochloride 10 mg	01627P	14366D

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
	Tablet containing mianserin hydrochloride 20 mg	01628Q	14505K
Minocycline	Tablet 50 mg (as hydrochloride)	01616C	14483G
Mirtazapine	Tablet 15 mg (orally disintegrating)	08855C	14369G
	Tablet 15 mg	09365X	14507M
	Tablet 30 mg (orally disintegrating)	08856D	14370H
	Tablet 30 mg	08513C	14473R
	Tablet 45 mg (orally disintegrating)	08857E	14475W
	Tablet 45 mg	08883M	14561J
Moclobemide	Tablet 150 mg	01900B	14560H
	Tablet 300 mg	08003F	14442D
Montelukast	Tablet, chewable, 4 mg (as sodium)	08627C	14526M
	Tablet, chewable, 5 mg (as sodium)	08628D	14553Y
Nizatidine	Capsule 150 mg	01505F	14306Y
	Capsule 300 mg	01504E	14372K
Omeprazole	Tablet 10 mg (as magnesium)	08332M	14432N
	Capsule 20 mg	01327W	14559G
	Capsule 20 mg	11682W	14464G
	Capsule 20 mg	12281J	14465H
	Tablet 20 mg	08333N	14364B
	Tablet 20 mg (as magnesium)	09110L	14397R
	Tablet 20 mg (as magnesium)	11677N	14557E
	Tablet 20 mg	11683X	14533X
	Tablet 20 mg (as magnesium)	12270T	14363Y
	Tablet 20 mg	12272X	14558F
Oxcarbazepine	Tablet 150 mg	08584T	14562K
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	08399C	14501F
	Sachet containing granules 40 mg (as sodium sesquihydrate)	09424B	14466J
	Sachet containing granules 40 mg (as sodium sesquihydrate)	11678P	14500E
	Sachet containing granules 40 mg (as sodium sesquihydrate)	12282K	14395P
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	08008L	14330F
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	11681T	14362X
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	12277E	14394N
Paraffin	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	05522P	14493T
	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	1750D	

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
	Eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	05523Q	14353K
	Eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	1754H	
	Eye drops containing liquid paraffin, glycerol, tyloxapol, poloxamer-188, trometamol hydrochloride, trometamol, cetalkonium chloride, 10 mL (preservative free)	12612T	14352J
Paroxetine	Tablet 20 mg (as hydrochloride)	02242B	14367E
Perfluorohexyloctane	Eye drops, 3 mL	11439C	14424E
	Eye drops, 3 mL	11446K	
Pilocarpine	Eye drops containing pilocarpine hydrochloride 10 mg per mL, 15 mL	02595N	14355M
	Eye drops containing pilocarpine hydrochloride 10 mg per mL, 15 mL	05536J	
	Eye drops containing pilocarpine hydrochloride 20 mg per mL, 15 mL	02596P	14523J
	Eye drops containing pilocarpine hydrochloride 20 mg per mL, 15 mL	05537K	
	Eye drops containing pilocarpine hydrochloride 40 mg per mL, 15 mL	02598R	14550T
	Eye drops containing pilocarpine hydrochloride 40 mg per mL, 15 mL	05538L	
Polyethylene glycol 400 with propylene glycol	Eye drops 4 mg-3 mg per mL, 15 mL	05524R	14421B
	Eye drops 4 mg-3 mg per mL, 15 mL	8676P	
	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30	13100L	14520F
	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30	13113E	
Pramipexole	Tablet containing pramipexole dihydrochloride monohydrate 1 mg	09153R	14532W
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg	03420B	14360T
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg	05143Q	14556D
	Tablet containing pramipexole dihydrochloride monohydrate 250 micrograms	09152Q	14329E
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg	03421C	14460C
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg	05145T	14461D

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms	03418X	14324X
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg	03422D	14325Y
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 750 micrograms	03419Y	14459B
Pyridostigmine	Tablet containing pyridostigmine bromide 10 mg	02724J	14392L
	Tablet containing pyridostigmine bromide 180 mg (modified release)	02608G	14462E
	Tablet containing pyridostigmine bromide 60 mg	01959D	14529Q
Rabeprazole	Tablet containing rabeprazole sodium 10 mg (enteric coated)	08507R	14502G
	Tablet containing rabeprazole sodium 20 mg (enteric coated)	08508T	14433P
	Tablet containing rabeprazole sodium 20 mg (enteric coated)	11670F	14463F
	Tablet containing rabeprazole sodium 20 mg (enteric coated)	12286P	14396Q
Rasagiline	Tablet 1 mg (as mesilate)	01952R	14458Y
Reboxetine	Tablet 4 mg (as mesilate)	08583R	14474T
Riluzole	Tablet 50 mg	08664B	14393M
	Oral suspension 50 mg per 10 mL, 300 mL	11662T	14429K
Rotigotine	Transdermal patch 4.5 mg	02385M	14327C
	Transdermal patch 9 mg	02384L	14326B
	Transdermal patch 13.5 mg	02410W	14431M
	Transdermal patch 18 mg	11140H	14359R
Safinamide	Tablet 100 mg	11666B	14528P
	Tablet 50 mg	11656L	14391K
Salmeterol	Powder for oral inhalation in breath actuated device 50 micrograms (as xinafoate) per dose, 60 doses	08141L	14328D
Selegiline	Tablet containing selegiline hydrochloride 5 mg	01973W	14430L
Sertraline	Tablet 100 mg (as hydrochloride)	02237R	14506L
	Tablet 100 mg (as hydrochloride)	08837D	14404D
	Tablet 50 mg (as hydrochloride)	02236Q	14400X
	Tablet 50 mg (as hydrochloride)	08836C	14403C
Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	02091C	14534Y
Soy lecithin	Eye spray 10 mg per mL, 10 mL	05545W	14426G
	Eye spray 10 mg per mL, 10 mL	09448G	

Drug	*Form (strength and presentation)*	*30-day Item Code*	*60-day Item Code*
Teriparatide	Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen	14093R	14482F
Testosterone	Transdermal cream 50 mg per mL, 50 mL	10378F	14563L
Tetrabenazine	Tablet 25 mg	01330B	14390J
Tiotropium	Capsule containing powder for oral inhalation 13 micrograms (as bromide) (for use in Zonda device)	11892X	14555C
	Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in HandiHaler)	08626B	14361W
	Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in LupinHaler)	14576E	14574C
	Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)	10509D	14499D
	Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)	11043F	14323W
	Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)	11629C	14531T
Tiotropium with olodaterol	Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses	10557P	14530R
Tranylcypromine	Tablet 10 mg (as sulfate)	02444P	14401Y
Travoprost with timolol	Eye drops 40 micrograms travoprost with timolol 5 mg (as maleate) per mL, 2.5 mL	05555J	14316L
	Eye drops 40 micrograms travoprost with timolol 5 mg (as maleate) per mL, 2.5 mL	09057Q	
Travoprost	Eye drops 40 micrograms per mL, 2.5 mL	05554H	14549R
	Eye drops 40 micrograms per mL, 2.5 mL	08597L	
Umeclidinium	Powder for oral inhalation in breath actuated device 62.5 micrograms (as bromide) per dose, 30 doses	10187E	14389H
Umeclidinium with vilanterol	Powder for oral inhalation in breath actuated device containing umeclidinium 62.5 micrograms (as bromide) with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses	10188F	14358Q
Venlafaxine	Capsule (modified release) 150 mg (as hydrochloride)	08302Y	14402B
	Capsule (modified release) 75 mg (as hydrochloride)	08301X	14472Q

Drug Added

Listed Drug

Migalastat

Drug Deleted

Listed Drug

Fosinopril with hydrochlorothiazid

Form Added

Listed Drug	*Form*
Amoxicillin with clavulanic acid	Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A)
Azithromycin	Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL (S19A)
Budesonide	Capsule (enteric) 3 mg
Tiotropium	Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in LupinHaler)

Form Deleted

Listed Drug	*Form*
Methylprednisolone	Powder for injection 40 mg (as sodium succinate) (S19A)

Brand Added

Listed Drug	*Form and Brand*
Acamprosate	Tablet (enteric coated) containing acamprosate calcium 333 mg *(ACAMPROSATE-WGR)*
Aciclovir	Tablet 200 mg *(ACICLOVIR-WGR)*
	Tablet 800 mg *(ACICLOVIR-WGR)*
Alendronic acid	Tablet 70 mg (as alendronate sodium) *(ALENDRONATE-WGR)*
Allopurinol	Tablet 100 mg *(ALLOPURINOL-WGR)*
	Tablet 300 mg *(ALLOPURINOL-WGR; APO-ALLOPURINOL)*
Amisulpride	Tablet 100 mg *(AMISULPRIDE-WGR)*
	Tablet 200 mg *(AMISULPRIDE-WGR)*
	Tablet 400 mg *(AMISULPRIDE-WGR)*
Amitriptyline	Tablet containing amitriptyline hydrochloride 10 mg *(AMITRIPTYLINE-WGR)*
	Tablet containing amitriptyline hydrochloride 25 mg *(AMITRIPTYLINE-WGR)*
Amlodipine	Tablet 5 mg (as besilate) *(AMLODIPINE-WGR)*
	Tablet 10 mg (as besilate) *(AMLODIPINE-WGR)*
Amoxicillin	Capsule 500 mg (as trihydrate) (AMOXICILLIN-WGR)
	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL *(AMOXICILLIN-WGR)*
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(AMOXICILLIN/CLAVULANIC ACID-WGR 500/125)*

	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(AMOXICILLIN/CLAVULANIC ACID-WGR 875/125)*
Anastrozole	Tablet 1 mg *(ANASTROZOLE-WGR)*
Aripiprazole	Tablet 10 mg *(ARIPIPRAZOLE-WGR)*
	Tablet 15 mg *(ARIPIPRAZOLE-WGR)*
	Tablet 20 mg *(ARIPIPRAZOLE-WGR)*
	Tablet 30 mg *(ARIPIPRAZOLE-WGR)*
Atenolol	Tablet 50 mg *(ATENOLOL-WGR)*
Atorvastatin	Tablet 10 mg (as calcium) *(ATORVASTATIN-WGR)*
	Tablet 20 mg (as calcium) *(ATORVASTATIN-WGR)*
	Tablet 40 mg (as calcium) *(ATORVASTATIN-WGR)*
	Tablet 80 mg (as calcium) *(ATORVASTATIN-WGR)*
Azathioprine	Tablet 25 mg *(AZATHIOPRINE-WGR)*
	Tablet 50 mg *(AZATHIOPRINE-WGR)*
Azithromycin	Tablet 500 mg (as dihydrate) *(AZITHROMYCIN-WGR)*
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL *(BIMATOPROST-WGR)*
Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg *(BISOPROLOL-WGR)*
	Tablet containing bisoprolol fumarate 5 mg *(BISOPROLOL-WGR)*
	Tablet containing bisoprolol fumarate 10 mg *(BISOPROLOL-WGR)*
Candesartan	Tablet containing candesartan cilexetil 4 mg *(CANDESARTAN-WGR)*
	Tablet containing candesartan cilexetil 8 mg *(CANDESARTAN-WGR)*
	Tablet containing candesartan cilexetil 16 mg *(CANDESARTAN-WGR)*
	Tablet containing candesartan cilexetil 32 mg *(CANDESARTAN-WGR)*
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg *(CANDESARTAN HCTZ-WGR 16/12.5)*
	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg *(CANDESARTAN HCTZ-WGR 32/12.5)*
	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg *(CANDESARTAN HCTZ-WGR 32/25)*
Carvedilol	Tablet 6.25 mg *(CARVEDILOL-WGR)*
	Tablet 12.5 mg *(CARVEDILOL-WGR)*
	Tablet 25 mg *(CARVEDILOL-WGR)*
Cefalexin	Capsule 500 mg (as monohydrate) *(CEPHALEXIN-WGR)*
Celecoxib	Capsule 100 mg *(CELECOXIB-WGR)*
	Capsule 200 mg *(CELECOXIB-WGR)*
Ciclosporin	Capsule 25 mg *(CICLOSPORIN-WGR)*
	Capsule 50 mg *(CICLOSPORIN-WGR)*
	Capsule 100 mg *(CICLOSPORIN-WGR)*

Ciprofloxacin	Tablet 250 mg (as hydrochloride) *(CIPROFLOXACIN-WGR)*
	Tablet 500 mg (as hydrochloride) *(CIPROFLOXACIN-WGR)*
	Tablet 750 mg (as hydrochloride) *(CIPROFLOXACIN-WGR)*
Clindamycin	Capsule 150 mg (as hydrochloride) *(CLINDAMYCIN-WGR)*
Clomipramine	Tablet containing clomipramine hydrochloride 25 mg *(CLOMIPRAMINE-WGR)*
Clopidogrel	Tablet 75 mg (as besilate) *(CLOPIDOGREL-WGR)*
Desvenlafaxine	Tablet (modified release) 50 mg *(DESVENLAFAXINE-WGR XR)*
	Tablet (modified release) 100 mg *(DESVENLAFAXINE-WGR XR)*
Diazepam	Tablet 2 mg *(DIAZEPAM-WGR)*
	Tablet 5 mg *(DIAZEPAM-WGR)*
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg *(DICLOFENAC-WGR)*
	Tablet (enteric coated) containing diclofenac sodium 50 mg *(DICLOFENAC-WGR)*
Donepezil	Tablet containing donepezil hydrochloride 5 mg *(DONEPEZIL-WGR)*
	Tablet containing donepezil hydrochloride 10 mg *(DONEPEZIL-WGR)*
Doxycycline	Tablet 50 mg (as hyclate) *(DOXYCYCLINE-WGR)*
	Tablet 100 mg (as hyclate) *(DOXYCYCLINE-WGR)*
Enalapril	Tablet containing enalapril maleate 5 mg *(ENALAPRIL-WGR)*
	Tablet containing enalapril maleate 10 mg *(ENALAPRIL-WGR)*
	Tablet containing enalapril maleate 20 mg *(ENALAPRIL-WGR)*
Entecavir	Tablet 0.5 mg (as monohydrate) *(ENTECAVIR-WGR)*
	Tablet 1 mg (as monohydrate) *(ENTECAVIR-WGR)*
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate) *(ESOMEPRAZOLE-WGR)*
	Tablet (enteric coated) 40 mg (as magnesium trihydrate) *(ESOMEPRAZOLE-WGR)*
Exemestane	Tablet 25 mg *(EXEMESTANE-WGR)*
Ezetimibe	Tablet 10 mg *(EZETIMIBE-WGR)*
Ezetimibe with simvastatin	Tablet 10 mg-10 mg (EZETIMIBE/SIMVASTATIN-WGR 10/10)
	Tablet 10 mg-20 mg (EZETIMIBE/SIMVASTATIN-WGR 10/20)
	Tablet 10 mg-40 mg (EZETIMIBE/SIMVASTATIN-WGR 10/40)
	Tablet 10 mg-80 mg (EZETIMIBE/SIMVASTATIN-WGR 10/80)
Famciclovir	Tablet 250 mg *(FAMCICLOVIR-WGR)*
	Tablet 500 mg *(FAMCICLOVIR-WGR)*
Fenofibrate	Tablet 48 mg *(FENOFIBRATE-WGR)*
	Tablet 145 mg *(FENOFIBRATE-WGR)*
Fluvoxamine	Tablet containing fluvoxamine maleate 50 mg *(FLUVOXAMINE-WGR)*

	Tablet containing fluvoxamine maleate 100 mg *(FLUVOXAMINE-WGR)*
Furosemide	Tablet 20 mg *(FUROSEMIDE-WGR)*
	Tablet 40 mg *(FUROSEMIDE-WGR)*
Gabapentin	Capsule 300 mg *(GABAPENTIN-WGR)*
	Capsule 400 mg *(GABAPENTIN-WGR)*
Glimepiride	Tablet 1 mg *(GLIMEPIRIDE-WGR)*
	Tablet 2 mg *(GLIMEPIRIDE-WGR)*
	Tablet 3 mg *(GLIMEPIRIDE-WGR)*
	Tablet 4 mg *(GLIMEPIRIDE-WGR)*
Imatinib	Capsule 100 mg (as mesilate) *(ARX-IMATINIB)*
Irbesartan	Tablet 75 mg *(IRBESARTAN-WGR)*
	Tablet 150 mg *(IRBESARTAN-WGR)*
	Tablet 300 mg *(IRBESARTAN-WGR)*
Irbesartan with hydrochlorothiazide	Tablet 150 mg-12.5 mg *(IRBESARTAN HCTZ-WGR 150/12.5)*
	Tablet 300 mg-12.5 mg *(IRBESARTAN HCTZ-WGR 300/12.5)*
	Tablet 300 mg-25 mg *(IRBESARTAN HCTZ-WGR 300/25)*
Isosorbide mononitrate	Tablet 60 mg (sustained release) *(ISOSORBIDE MR-WGR)*
Isotretinoin	Capsule 10 mg *(ISOTRETINOIN-WGR)*
	Capsule 20 mg *(ISOTRETINOIN-WGR)*
Ivabradine	Tablet 5 mg (as hydrochloride) *(IVABRADINE-WGR)*
Lamotrigine	Tablet 25 mg *(LAMOTRIGINE-WGR)*
	Tablet 50 mg *(LAMOTRIGINE-WGR)*
	Tablet 100 mg *(LAMOTRIGINE-WGR)*
	Tablet 200 mg *(LAMOTRIGINE-WGR)*
Latanoprost	Eye drops 50 micrograms per mL, 2.5 mL *(LATANOPROST-WGR)*
Leflunomide	Tablet 10 mg *(LEFLUNOMIDE-WGR)*
	Tablet 20 mg *(LEFLUNOMIDE-WGR)*
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg *(LERCANIDIPINE-WGR)*
	Tablet containing lercanidipine hydrochloride 20 mg *(LERCANIDIPINE-WGR)*
Letrozole	Tablet 2.5 mg *(LETROZOLE-WGR)*
Levetiracetam	Tablet 250 mg *(LEVETIRACETAM-WGR)*
	Tablet 500 mg *(LEVETIRACETAM-WGR)*
	Tablet 1 g *(LEVETIRACETAM-WGR)*
Levonorgestrel with ethinylestradiol	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets *(LEVETH 150/30 ED)*

Lisinopril	Tablet 5 mg *(LISINOPRIL-WGR)*
	Tablet 10 mg *(LISINOPRIL-WGR)*
	Tablet 20 mg *(LISINOPRIL-WGR)*
Lurasidone	Tablet containing lurasidone hydrochloride 40 mg *(LURASIDONE-WGR)*
	Tablet containing lurasidone hydrochloride 80 mg *(LURASIDONE-WGR)*
Meloxicam	Capsule 7.5 mg *(MELOXICAM-WGR)*
	Capsule 15 mg *(MELOXICAM-WGR)*
	Tablet 7.5 mg *(MELOXICAM-WGR)*
	Tablet 15 mg *(MELOXICAM-WGR)*
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg *(METFORMIN-WGR XR)*
	Tablet (extended release) containing metformin hydrochloride 1 g *(METFORMIN-WGR XR)*
	Tablet containing metformin hydrochloride 500 mg *(METFORMIN-WGR)*
	Tablet containing metformin hydrochloride 850 mg *(Diaformin Viatris; METFORMIN-WGR)*
	Tablet containing metformin hydrochloride 1 g *(Diaformin Viatris)*
Metoclopramide	Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) *(METOCLOPRAMIDE-WGR)*
Metoprolol	Tablet containing metoprolol tartrate 50 mg *(METOPROLOL-WGR)*
	Tablet containing metoprolol tartrate 100 mg *(METOPROLOL-WGR)*
Mirtazapine	Tablet 15 mg *(MIRTAZAPINE-WGR)*
	Tablet 30 mg *(MIRTAZAPINE-WGR)*
	Tablet 45 mg *(MIRTAZAPINE-WGR)*
Moclobemide	Tablet 150 mg *(MOCLOBEMIDE-WGR)*
	Tablet 300 mg *(MOCLOBEMIDE-WGR)*
Modafinil	Tablet 100 mg *(MODAFINIL-WGR)*
Montelukast	Tablet, chewable, 5 mg (as sodium) *(Montelukast Viatris)*
Moxonidine	Tablet 200 micrograms *(MOXONIDINE-WGR)*
	Tablet 400 micrograms *(MOXONIDINE-WGR)*
Olanzapine	Tablet 5 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)*
	Tablet 10 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)*
	Tablet 15 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)*
	Tablet 20 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)*
Olmesartan	Tablet containing olmesartan medoxomil 20 mg *(OLMESARTAN-WGR)*
	Tablet containing olmesartan medoxomil 40 mg *(OLMESARTAN-WGR)*
Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) *(APO-OLMESARTAN/AMLODIPINE 20/5; OLMESARTAN AMLODIPINE-WGR 20/5)*

	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) *(OLMESARTAN AMLODIPINE-WGR 40/10)*
	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) *(OLMESARTAN AMLODIPINE-WGR 40/5)*
Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg *(OLMESARTAN HCTZ-WGR 20/12.5)*
	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg *(OLMESARTAN HCTZ-WGR 40/12.5)*
	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg *(OLMESARTAN HCTZ-WGR 40/25)*
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate) *(ONDANSETRON-WGR)*
	Tablet 8 mg (as hydrochloride dihydrate) *(ONDANSETRON-WGR)*
	Tablet (orally disintegrating) 4 mg *(ONDANSETRON ODT-WGR)*
	Tablet (orally disintegrating) 8 mg *(ONDANSETRON ODT-WGR)*
Oxazepam	Tablet 30 mg *(OXAZEPAM-WGR)*
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate) *(PANTOPRAZOLE-WGR)*
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *(PANTOPRAZOLE-WGR)*
Paroxetine	Tablet 20 mg (as hydrochloride) *(PAROXETINE-WGR)*
Perindopril	Tablet containing perindopril arginine 2.5 mg *(Perindopril Arginine-WGR)*
	Tablet containing perindopril arginine 5 mg *(Perindopril Arginine-WGR)*
	Tablet containing perindopril arginine 10 mg *(Perindopril Arginine-WGR)*
	Tablet containing perindopril erbumine 2 mg *(PERINDOPRIL-WGR)*
	Tablet containing perindopril erbumine 4 mg *(PERINDOPRIL-WGR)*
	Tablet containing perindopril erbumine 8 mg *(PERINDOPRIL-WGR)*
Perindopril with indapamide	Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg *(PERINDOPRIL/INDAPAMIDE-WGR 4/1.25)*
Pioglitazone	Tablet 15 mg (as hydrochloride) *(ARX-PIOGLITAZONE)*
Posaconazole	Tablet (modified release) 100 mg *(POSACONAZOLE-WGR)*
Pravastatin	Tablet containing pravastatin sodium 10 mg *(PRAVASTATIN-WGR)*
	Tablet containing pravastatin sodium 20 mg *(PRAVASTATIN-WGR)*
	Tablet containing pravastatin sodium 40 mg *(PRAVASTATIN-WGR)*
Pregabalin	Capsule 25 mg *(PREGABALIN-WGR)*
	Capsule 75 mg *(PREGABALIN-WGR)*
	Capsule 150 mg *(PREGABALIN-WGR)*
	Capsule 300 mg *(PREGABALIN-WGR)*
Prochlorperazine	Tablet containing prochlorperazine maleate 5 mg *(PROCHLORPERAZINE-WGR)*
Propranolol	Tablet containing propranolol hydrochloride 10 mg *(PROPRANOLOL-WGR)*

	Tablet containing propranolol hydrochloride 40 mg *(PROPRANOLOL-WGR)*
Rabeprazole	Tablet containing rabeprazole sodium 10 mg (enteric coated) *(RABEPRAZOLE-WGR)*
	Tablet containing rabeprazole sodium 20 mg (enteric coated) *(RABEPRAZOLE-WGR)*
Ramipril	Capsule 10 mg *(RAMIPRIL-WGR)*
	Tablet 1.25 mg *(RAMIPRIL-WGR)*
	Tablet 2.5 mg *(RAMIPRIL-WGR)*
	Tablet 5 mg *(Ramipril Viatris; RAMIPRIL-WGR)*
	Tablet 10 mg *(RAMIPRIL TABS-WGR)*
Rasagiline	Tablet 1 mg (as mesilate) *(RASAGILINE-WGR)*
Risedronic acid	Tablet containing risedronate sodium 35 mg *(RISEDRONATE-WGR)*
Risperidone	Oral solution 1 mg per mL, 100 mL *(Risperidone Lupin)*
Rizatriptan	Tablet (orally disintegrating) 10 mg (as benzoate) *(RIZATRIPTAN ODT-WGR)*
Rosuvastatin	Tablet 5 mg (as calcium) *(APO-ROSUVASTATIN; ROSUVASTATIN-WGR)*
	Tablet 10 mg (as calcium) *(ROSUVASTATIN-WGR)*
	Tablet 20 mg (as calcium) *(ROSUVASTATIN-WGR)*
	Tablet 40 mg (as calcium) *(ROSUVASTATIN-WGR)*
Roxithromycin	Tablet 150 mg *(ROXITHROMYCIN-WGR)*
	Tablet 300 mg *(ROXITHROMYCIN-WGR)*
Sertraline	Tablet 50 mg (as hydrochloride) *(SERTRALINE-WGR)*
	Tablet 100 mg (as hydrochloride) *(SERTRALINE-WGR)*
Sotalol	Tablet containing sotalol hydrochloride 80 mg *(SOTALOL-WGR)*
	Tablet containing sotalol hydrochloride 160 mg *(SOTALOL-WGR)*
Sumatriptan	Tablet 50 mg (as succinate) *(SUMATRIPTAN-WGR)*
Telmisartan	Tablet 40 mg *(TELMISARTAN-WGR)*
	Tablet 80 mg *(TELMISARTAN-WGR)*
Telmisartan with hydrochlorothiazide	Tablet 40 mg-12.5 mg *(TELMISARTAN HCTZ-WGR 40/12.5)*
	Tablet 80 mg-12.5 mg *(TELMISARTAN HCTZ-WGR 80/12.5)*
	Tablet 80 mg-25 mg *(TELMISARTAN HCTZ-WGR 80/25)*
Temazepam	Tablet 10 mg *(TEMAZEPAM-WGR)*
Terbinafine	Tablet 250 mg (as hydrochloride) *(TERBINAFINE-WGR)*
Topiramate	Tablet 25 mg *(TOPIRAMATE-WGR)*
	Tablet 50 mg *(TOPIRAMATE-WGR)*
	Tablet 100 mg *(TOPIRAMATE-WGR)*
	Tablet 200 mg *(TOPIRAMATE-WGR)*

Tramadol	Capsule containing tramadol hydrochloride 50 mg *(TRAMADOL-WGR)*
	Tablet (sustained release) containing tramadol hydrochloride 100 mg *(TRAMADOL-WGR SR)*
	Tablet (sustained release) containing tramadol hydrochloride 150 mg *(TRAMADOL-WGR SR)*
	Tablet (sustained release) containing tramadol hydrochloride 200 mg *(TRAMADOL-WGR SR)*
Trimethoprim	Tablet 300 mg *(TRIMETHOPRIM-WGR)*
Valaciclovir	Tablet 500 mg (as hydrochloride) *(VALACICLOVIR-WGR)*
Venlafaxine	Capsule (modified release) 37.5 mg (as hydrochloride) *(VENLAFAXINE XR-WGR)*
	Capsule (modified release) 75 mg (as hydrochloride) *(VENLAFAXINE XR-WGR)*
	Capsule (modified release) 150 mg (as hydrochloride) *(VENLAFAXINE XR-WGR)*

Brands Deleted

Listed Drug	***Form and Brand***
Amlodipine	Tablet 5 mg (as besilate) *(BTC Amlodipine)*
Amoxicillin with clavulanic acid	Tablet 10 mg (as besilate) *(BTC Amlodipine)*
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(AlphaClav Duo Forte)*
Atorvastatin	Tablet 10 mg (as calcium) *(Blooms the Chemist Atorvastatin)*
	Tablet 20 mg (as calcium) *(Blooms the Chemist Atorvastatin)*
	Tablet 40 mg (as calcium) *(Blooms the Chemist Atorvastatin)*
Candesartan	Tablet 80 mg (as calcium) *(Blooms the Chemist Atorvastatin)*
Candesartan	Tablet containing candesartan cilexetil 4 mg *(Blooms the Chemist Candesartan)*
	Tablet containing candesartan cilexetil 8 mg *(Blooms the Chemist Candesartan)*
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg *(Blooms the Chemist Candesartan)*
	Tablet containing candesartan cilexetil 32 mg *(Blooms the Chemist Candesartan)*
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg *(Blooms the Chemist Candesartan HCTZ 32/12.5)*
	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg *(Blooms the Chemist Candesartan HCTZ 32/25)*
Capecitabine	Tablet 500 mg *(Capecitabine-DRLA)*
Clopidogrel	Tablet 75 mg (as besilate) *(BTC Clopidogrel)*
Escitalopram	Tablet 10 mg (as oxalate) *(Blooms the Chemist Escitalopram)*
Fenofibrate	Tablet 20 mg (as oxalate) *(Blooms the Chemist Escitalopram)*
Fenofibrate	Tablet 145 mg *(Blooms the Chemist Fenofibrate)*
Fluoxetine	Capsule 20 mg (as hydrochloride) *(BTC Fluoxetine)*
Glimepiride	Tablet 1 mg *(Amaryl)*

Granisetron	Concentrated injection 3 mg (as hydrochloride) in 3 mL *(Granisetron Kabi)*
Irbesartan	Tablet 75 mg *(Avapro; Blooms the Chemist Irbesartan)*
	Tablet 150 mg *(Blooms the Chemist Irbesartan)*
Leflunomide	Tablet 10 mg *(Arabloc)*
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg *(BTC Lercanidipine)*
	Tablet containing lercanidipine hydrochloride 20 mg *(BTC Lercanidipine)*
Olanzapine	Tablet 2.5 mg *(NOUMED OLANZAPINE)*
	Tablet 5 mg *(NOUMED OLANZAPINE)*
	Tablet 7.5 mg *(NOUMED OLANZAPINE)*
	Tablet 10 mg *(NOUMED OLANZAPINE)*
Perindopril	Tablet containing perindopril erbumine 2 mg *(BTC Perindopril)*
	Tablet containing perindopril erbumine 4 mg *(BTC Perindopril)*
	Tablet containing perindopril erbumine 8 mg *(BTC Perindopril)*
Pregabalin	Capsule 75 mg *(Blooms The Chemist Pregabalin)*
Rosuvastatin	Tablet 5 mg (as calcium) *(Blooms the Chemist Rosuvastatin)*
	Tablet 10 mg (as calcium) *(Blooms the Chemist Rosuvastatin)*
	Tablet 20 mg (as calcium) *(Blooms the Chemist Rosuvastatin)*
	Tablet 40 mg (as calcium) *(Blooms the Chemist Rosuvastatin)*
Venlafaxine	Capsule (modified release) 75 mg (as hydrochloride) *(Blooms the Chemist Venlafaxine XR)*
	Capsule (modified release) 150 mg (as hydrochloride) *(Blooms the Chemist Venlafaxine XR)*

Deletion of Maximum Quantity and Number of Repeats

Listed Drug	*Form*	*Maximum Quantity*	*Number of Repeats*
Colestyramine	Sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50	2	11

Alteration of Responsible Person Code

Listed Drug	*Form*	*Brand Name*	*Responsible Person*	
Haloperidol decanoate	I.M. injection equivalent to 50 mg haloperidol in 1 mL ampoule	Haldol decanoate	From: JC	To: IX
	I.M. injection equivalent to 150 mg haloperidol in 3 mL ampoule	Haldol decanoate	From: JC	To: IX
Oxycodone	Tablet containing oxycodone hydrochloride 5 mg	Mayne Pharma Oxycodone IR	From: YN	To: SZ

Addition of Responsible Person

Responsible Person and Code

AMICUS THERAPEUTICS PTY LTD *(FT)*

WAGNER PHARMACEUTICALS PTY LTD *(WG)*

Deletion of Responsible Person

Responsible Person and Code

Medis Pharma Pty Ltd *(ZP)*

Apotex Pty Ltd *(JB)*

Supply Only – Additions

Listed Drug	***Form***
Budesonide with formoterol	Pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses
Triglycerides, long chain with glucose polymer	Oral liquid 250 mL, 18 (ProZero)

Supply Only – Deletions

Listed Drug	***Form***
Bisacodyl	Enemas 10 mg in 5 mL, 25
Ketoconazole	Cream 20 mg per g, 30 g

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Adalimumab	Hypromellose with dextran
Alectinib	Indacaterol
Amantadine	Indacaterol with glycopyrronium
Beclometasone	Indacaterol with glycopyrronium and mometasone
Beclometasone with formoterol	Indacaterol with mometasone
Beclometasone with formoterol and glycopyrronium	Lansoprazole
Betaxolol	Larotrectinib
Bimatoprost	Latanoprost
Bimatoprost with timolol	Latanoprost with timolol
Bisacodyl	Levodopa with benserazide
Brigatinib	Levodopa with carbidopa

Brimonidine

Brimonidine with timolol

Brinzolamide

Brinzolamide with brimonidine

Brinzolamide with timololDorzolamide with timolol

Budesonide

Budesonide with formoterol

Budesonide with glycopyrronium and formoterol

Cabergoline

Cabozantinib

Carbomer

Carmellose

Carmellose with glycerin

Ceritinib

Ciclesonide

Citalopram

Colestyramine

Crizotinib

Desvenlafaxine

Diltiazem

Dorzolamide

Doxycycline

Entacapone

Entrectinib

Eprosartan with hydrochlorothiazide

Erythromycin

Escitalopram

Ganciclovir

Gemfibrozil

Esomeprazole

Esomeprazole and clarithromycin and amoxicillin

Fluoxetine

Levodopa with carbidopa and entacapone

Lorlatinib

Macrogol 3350

Mianserin

Migalastat

Minocycline

Pyridostigmine

Rabeprazole

Rasagiline

Reboxetine

Mirtazapine

Moclobemide

Montelukast

Nizatidine

Omeprazole

Pantoprazole

Paraffin

Paroxetine

Perfluorohexyloctane

Pilocarpine

Polyethylene glycol 400 with propylene glycol

Pramipexole

Riluzole

Rotigotine

Safinamide

Salmeterol

Secukinumab

Selegiline

Sertraline

Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate

Soy lecithin

Sulfasalazine

Fluticasone furoate	Teriparatide
Fluticasone furoate with umeclidinium and vilanterol	Testosterone
Fluticasone furoate with vilanterol	Tetrabenazine
Fluticasone propionate	Tiotropium
Fluticasone propionate with formoterol	Tiotropium with olodaterol
Fluticasone propionate with salmeterol	Trabectedin
Fluvoxamine	Tranylcypromine
Formoterol	Trastuzumab
Fosinopril with hydrochlorothiazide	Trastuzumab deruxtecan
Glycopyrronium	Trastuzumab deruxtecan
Hyaluronic acid	Trastuzumab emtansine
Hypromellose	Travoprost
Hypromellose	Travoprost with timolol
Hypromellose with carbomer 980	Umeclidinium
Hypromellose with carbomer 980	Valganciclovir
Hypromellose with dextran	Venlafaxine

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Cabozantinib	**International Metastatic RCC Database Consortium (IMDC) Risk Model for Metastatic Renal Cell Carcinoma** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)b of the *Legislation Act 2003.* The International Metastatic RCC Database Consortium (IMDC) Risk Model for Metastatic Renal Cell Carcinoma is a tool used to predict survival in patients with metastatic renal cell carcinoma who are treated with systemic therapy.	The IMDC Risk Model is available for download for free from the MDCalc website: www.mdcalc.com/calc/3008/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma
Cabozantinib	**Response Evaluation Criteria in Solid Tumours (RECIST) guidelines** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The RECIST guidelines are a tool used widely for defining when tumours in cancer patients respond, stabilise and/or progress during treatment.	The RECIST guidelines are available for download for free from the RECIST Working Group website: https://recist.eortc.org/

Alectinib Brigatinib Cabozantinib Ceritinib Crizotinib Entrectinib Lorlatinib	**World Health Organisation (WHO) / Eastern Cooperative Oncology Group (ECOG) Performance Status Grading system** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. Performance status quantifies the general well-being and ability to perform activities of daily life of a patient affected by cancer. The grading runs in whole numbers from 0 to 5, with grade 0 representing perfect health and 5 representin g death. It is also known as the Eastern Cooperative Oncology Group (ECOG) score, or as the Zubrod score.	Medical text books and literature. Scientific journals that reference: Oken MM et al. 1982. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol* 5:649-655 The ECOG-ACRIN Cancer Research Group publishes the scale on the following website: https://ecog-acrin.org/resources/ecog-performance-status/

Diagnostic tools referenced in the Instrument

The following standard medical diagnostic tools are referenced in the Instrument but are not intended to incorporate a document by reference.

Listed Drug	***Diagnostic tool***	***Purpose and use in the Instrument***	***Reason this reference does not serve to incorporate a document***
Cardiac MRI	Migalastat	It is a magnetic resonance imaging technology used for non-invasive assessment of the function and structure of the cardiovascular system.	Cardiac MRI is used to diagnose a wide range of heart conditions. These include Left ventricular hypertrophy shown in cardiac related Fabry disease.
Echocardiogram	Migalastat	It is an ultrasound test that checks the structure and function of your heart. An echocardiogram uses sound waves to create pictures of the heart. This common test can show blood flow through the heart and heart valves.	The test can help a health care provider diagnose heart conditions such as Left ventricular hypertrophy shown in cardiac related Fabry disease.
Hidradenitis Suppurativa Clinical Response (HiSCR)	Adalimumab Secukinumab	The HiSCR is used to assess/determine an adequate response to a particular biological medicine for the treatment of Hidradenitis Suppurativa. HiSCR is defined as a ≥ 50% reduction in inflammatory lesion count (abscesses + inflammatory nodules), and no increase in abscesses or draining fistulas when compared with baseline.	Assessing the validity, responsiveness and meaningfulness of the Hidradenitis Suppurativa Clinical Response (HiSCR) as the clinical endpoint for hidradenitis suppurativa treatment.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024
(PB 85 of 2024)

This Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Instrument

The *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

On 1 September 2024 the Principal Instrument will be amended by Schedule 1 to this Instrument to implement Stage 3 of the maximum dispensed quantity (MDQ) measure. The MDQ measure increases the maximum quantity that may be prescribed to be dispensed on one occasion for certain pharmaceutical benefits, in certain circumstances, from one to two months' supply. As a result of the changes, an eligible patient can be prescribed two months' supply of a pharmaceutical benefit to be dispensed on the one occasion under the PBS. The amendments made by the Instrument are the third of three stages of implementation of the MDQ measure. Stage 3 includes some medicines for chronic conditions such asacne, anxiety disorders,asthma, chronic obstructive pulmonary disease (COPD), constipation, depression, dry eyes, gastro-oesophageal reflux disease (GORD), glaucoma and Parkinson disease

Patients will only be eligible to receive an increased supply where their chronic condition is stable. Current listings enabling the prescription of one month's supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

Human rights implications

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

The Instrument advances the right to health and the right to social security by providing new drugs, forms and brands of existing listed drugs, and ensuring the deletion of drugs, forms and brands of listed drugs does not affect access to subsidised medicines. The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the Schedule are evidence-based. The Instrument includes the addition of a new drug, the addition of 4 new forms of existing drugs, and the addition of 223 new brands across existing forms, which allows for greater patient access to these drugs.

Stage 3 of the MDQ measure will be implemented on 1 September 2024 by amendments to the Principal Instrument made by the *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024.* A detailed analysis of the human rights implications of the MDQ measure is included in the Statement of Compatibility with Human Rights in the Explanatory Statement for the instrument which implemented Stage 1 of the MDQ measures on 1 September 2023, which can be found on the Federal Register of Legislation at *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*. However, the overall policy behind the MDQ measure is to address the affordability of medicines and the cost-of-living pressures many Australians are currently facing. The MDQ increases the amount of drugs that eligible patients can receive for a single co-payment, which allows for greater patient access to these drugs, convenience and financial savings. The lowering of costs to patients is likely to have a positive impact on patient medication compliance and associated health outcomes.

Addition of new purposes and circumstances codes does not affect human rights. The new purposes and circumstances codes detail the purposes for which, and circumstances in which, the new MDQ amounts can be prescribed. These relevantly will include that the patient's condition must be stable for the prescriber to consider the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Implementation of the MDQ measure does not risk exacerbating any shortages of these medicines in the community as a whole. It should be noted that before making the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023,* the Minister sought advice from the PBAC who noted that the number of patients and volume of medicines prescribed will not change significantly as a result of the MDQ measure and that any medicine shortages were likely to be short-term as the system adjusts to a new phased model of supply.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. The PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with the monthly amendments to the Principal Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of drugs and forms of drugs in the abovementioned instruments, would not

result in an unmet clinical need, except where indicated for a particular drug or form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period has been/will be instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these amounts are $31.60 for general patients and $7.70 for concession card holders.

Where there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The delisting of brands in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings.

The drug bisacodyl in the form enemas 10 mg in 5 mL, 25 (Bisalax) was requested to be delisted from the PBS by the sponsor. The PBAC noted that there are alternative products available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug budesonide with formoterol in the form pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses (Symbicort Rapihaler 50/3) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug fosinopril with hydrochlorothiazide (Fosetic 20/12.5) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug ketoconazole (Nizoral 2% Cream) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the sponsor's plans to discontinue manufacture of Nizoral 2% cream and that there are alternative products available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug methylprednisolone in the form powder for injection 40 mg (as sodium succinate) (S19A) (Solu-Medrone) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of methylprednisolone in the form powder for injection 40 mg (as sodium succinate) with diluent. The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 March 2024. Patient access has not been affected by this delisting, as the approved form of the drug is now available and remains PBS-subsidised and accessible for patients.

The drug triglycerides, long chain with glucose polymer in the form oral liquid 250 mL, 18 (ProZero) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are alternatives on the PBS, however the alternatives may not be suitable for all patients. The PBAC advised the delisting of these products may result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

Nikolai Tsyganov
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health and Aged Care