PB 88 of 2025

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, PBS Listing, Pricing and Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 28 July 2025

REBECCA RICHARDSON
Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division

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1 Name

(1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2025*.

(2) This instrument may also be cited as PB 88 of 2025.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 August 2025	1 August 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)

[1] Part 1, Division 1, Section 6 (definition of *CAR drug*)

repeal the definition, substitute:

CAR drug (short for Complex Authority Required drug) means any of the following highly specialised drugs:

(a) abatacept;
(b) adalimumab;
(c) ambrisentan;
(d) anifrolumab;
(e) avatrombopag;
(f) azacitidine;
(g) benralizumab;
(h) bosentan;
(i) burosumab;
(j) difelikefalin;
(k) dupilumab;
(l) eculizumab;
(m) eflornithine;
(n) elexacaftor with tezacaftor and with ivacaftor, and ivacaftor;
(o) eltrombopag;
(p) epoprostenol;
(q) etanercept;
(r) iloprost;
(s) infliximab;
(t) ivacaftor;
(u) lenalidomide;

(v) lumacaftor with ivacaftor;
(w) macitentan;
(x) macitentan with tadalafil;
(y) mepolizumab;
(z) midostaurin;
(aa) nusinersen;
(bb) omalizumab;
(cc) onasemnogene abeparvovec;
(dd) pasireotide;
(ee) patisiran;
(ff) pegcetacoplan;
(gg) pegvisomant;
(hh) pomalidomide;
(ii) ravulizumab;
(jj) riociguat;
(kk) risdiplam;
(ll) romiplostim;
(mm) selexipag;
(nn) sildenafil;
(oo) tadalafil;
(pp) teduglutide;
(qq) tezacaftor with ivacaftor and ivacaftor;
(rr) tocilizumab;
(ss) ustekinumab;
(tt) vedolizumab;
(uu) vutrisiran.

[2] Schedule 1, after entry for Edaravone *[Maximum quantity: 28; Maximum repeats: 0]*

insert:

Eflornithine	Tablet 192 mg (as hydrochloride)	Oral	Ifinwil	C16839 C16841 C16959		See Schedule 2	See Schedule 2

[3] Schedule 1, after entry for Filgrastim in the form Injection 480 micrograms in 0.5 mL single-use pre-filled syringe *[Brand: Zarzio]*

insert:

Foslevodopa with foscarbidopa	Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL	Injection	Vyalev	C16812 C16853 C16883 C16972	P16812 P16883	28	5
				C16812 C16853 C16883 C16972	P16853 P16972	56	5

[4] Schedule 1, entry for Ivacaftor in each of the forms: Sachet containing granules 25 mg; Sachet containing granules 50 mg; Sachet containing granules 75 mg; and Tablet 150 mg

omit from the column headed "Circumstances": **C15251 C15252 C15253 C15255** *substitute:* **C16844 C16845 C16876 C16878**

[5] Schedule 1, entry for Omalizumab

substitute:

Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled pen	Injection	Xolair	C15347 C15376 C15846 C15870	See Schedule 2	See Schedule 2
	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Omlyclo	C15347 C15352 C15376 C15403 C15846 C15870 C16846 C16879 C16904 C16948 C16949	See Schedule 2	See Schedule 2
			Xolair	C15347 C15352 C15376 C15403 C15846 C15870 C16879	See Schedule 2	See Schedule 2
	Injection 150 mg in 1 mL single dose pre-filled pen	Injection	Xolair	C7046 C15347 C15376 C15846 C15870 C16906	See Schedule 2	See Schedule 2
	Injection 150 mg in 1 mL single dose pre-filled	Injection	Omlyclo	C7046 C15347	See Schedule 2	See Schedule 2

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	syringe			C15376 C15403 C15846 C15870 C16846 C16879 C16904 C16905 C16906 C16948 C16949 C16960			
	Injection 300 mg in 2 mL single dose pre-filled pen	Injection	Xolair	C7046 C15347 C15376 C15846 C15870 C16906		See Schedule 2	See Schedule 2

[6] Schedule 1, entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg

(a) *omit:*

		Tenofovir APOTEX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2

(b) *omit:*

		Tenofovir APOTEX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5

[7] Schedule 1, entry for Tenofovir with emtricitabine

omit:

	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)	C6985 C6986	60	5

[8] Schedule 1, entry for Ustekinumab

omit from the column headed "Circumstances": **C9655 C9656 C9710 C13975 C13976 C14010 C14758 C14787 C14801**

substitute: **C14801 C16824 C16829 C16863 C16866 C16890 C16939 C16944 C16958**

[9] Schedule 1, entry for Ustekinumab

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Steqeyma	C14801 C16824 C16829 C16863 C16866 C16890 C16939 C16944 C16958	See Schedule 2	See Schedule 2

[10] Schedule 2, after entry for Eculizumab *[Maximum quantity: 8; Maximum repeats: 0]*

insert:

Eflornithine	C16839 C16841 C16959	3 packs	2

[11] Schedule 2, entry for Ivacaftor

omit from the column headed "Circumstances": **C15251 C15252 C15253 C15255** *substitute:* **C16844 C16845 C16876 C16878**

[12] Schedule 2, entry for Omalizumab

substitute:

Omalizumab	C16906	Sufficient for 4 weeks of treatment	2
	C7046 C15347 C15352 C16846 C16904 C16905 C16948 C16949 C16960	Sufficient for 4 weeks of treatment	5
	C16879	Sufficient for 4 weeks of treatment	6
	C15846 C15870	Sufficient for 4 weeks of treatment	7
	C15403	Sufficient for up to 28 weeks of treatment	0
	C15376	Sufficient for up to 32 weeks of treatment	0

[13] Schedule 2, entry for Ustekinumab

omit from the column headed "Circumstances": **C9655 C9656 C9710 C13975 C13976 C14010 C14758 C14787 C14801**

substitute: **C14801 C16824 C16829 C16863 C16866 C16890 C16939 C16944 C16958**

[14] Schedule 3, after entry for Edaravone

insert:

Eflornithine	C16839		High-risk neuroblastoma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2025; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 27 cycles (based on 4 weeks per cycle) from the first dose of this drug, regardless of whether it was PBS/non-PBS-subsidised. Must be treated in a hospital/cancer centre by either a: (i) paediatric oncologist, (ii) haematologist; OR Must be treated by a medical practitioner under the direct supervision of either a: (i) paediatric oncologist, (ii) haematologist. At the time of the authority application, the prescriber should request an appropriate quantity and number of repeats based on the patient's Body Surface Area (BSA), according to the dosing schedule in the TGA approved Product Information. The following maximum quantity units and repeats may be authorised under this restriction (providing 3 months of therapy for each prescription). Up to a maximum quantity of 100 units and 1 repeat for a BSA 0.25 $m^2$to less than 0.5 m^2; Up to a maximum quantity of 200 units and 1 repeat for a BSA 0.5 $m^2$to less than 0.75 m^2; Up to a maximum quantity of 200 units and 2 repeats for a BSA 0.75 $m^2$to 1.5 m^2; Up to a maximum quantity of 300 units and 2 repeats for a BSA greater than 1.5 m^2.	Compliance with Authority Required procedures
	C16841		High-risk neuroblastoma Initial treatment Patient must have high-risk neuroblastoma according to a validated risk classification system; AND Patient must be in remission, with at least a partial response, at the end of multiagent, multimodality therapy for high-risk neuroblastoma; AND The treatment must be initiated after completing previous therapy; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Must be treated in a hospital/cancer centre by either a: (i) paediatric oncologist, (ii) haematologist. Prior to initiating treatment with this drug, a complete blood count, liver function tests and baseline hearing assessments should be performed and documented in the patient's medical records.	Compliance with Written Authority Required procedures

			At the time of the authority application, the prescriber should request an appropriate quantity and number of repeats based on the patient's Body Surface Area (BSA), according to the dosing schedule in the TGA approved Product Information. The following maximum quantity units and repeats may be authorised under this restriction (providing 3 months of therapy for each prescription). Up to a maximum quantity of 100 units and 1 repeat for a BSA 0.25 $m^2$to less than 0.5 m^2; Up to a maximum quantity of 200 units and 1 repeat for a BSA 0.5 $m^2$to less than 0.75 m^2; Up to a maximum quantity of 200 units and 2 repeats for a BSA 0.75 $m^2$to 1.5 m^2; Up to a maximum quantity of 300 units and 2 repeats for a BSA greater than 1.5 m^2. Authority applications for initial treatment must be made in writing and must include: (a) details of the proposed prescription; and (b) a completed PBS authority application form, relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) details of prior multiagent, multimodality therapy for high-risk neuroblastoma [date of commencement and duration of therapy]; and (ii) the patient's BSA measurement.	
	C16959		High-risk neuroblastoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 27 cycles (based on 4 weeks per cycle) from the first dose of this drug, regardless of whether it was PBS/non-PBS-subsidised. Must be treated in a hospital/cancer centre by either a: (i) paediatric oncologist, (ii) haematologist; OR Must be treated by a medical practitioner under the direct supervision of either a: (i) paediatric oncologist, (ii) haematologist. At the time of the authority application, the prescriber should request an appropriate quantity and number of repeats based on the patient's Body Surface Area (BSA), according to the dosing schedule in the TGA approved Product Information. The following maximum quantity units and repeats may be authorised under this restriction (providing 3 months of therapy for each prescription). Up to a maximum quantity of 100 units and 1 repeat for a BSA 0.25 $m^2$to less than 0.5 m^2; Up to a maximum quantity of 200 units and 1 repeat for a BSA 0.5 $m^2$to less than 0.75 m^2;	Compliance with Authority Required procedures

			Up to a maximum quantity of 200 units and 2 repeats for a BSA 0.75 $m^2$to 1.5 m^2; Up to a maximum quantity of 300 units and 2 repeats for a BSA greater than 1.5 m^2.	

[15] Schedule 3, after entry for Filgrastim

insert:

Foslevodopa with foscarbidopa	C16812	P16812	Advanced Parkinson disease Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 16812
	C16853	P16853	Advanced Parkinson disease Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND Patient must require continuous administration of foslevodopa without an overnight break; OR Patient must require a total daily dose of more than 2,400 mg of foslevodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 16853
	C16883	P16883	Advanced Parkinson disease Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 16883
	C16972	P16972	Advanced Parkinson disease Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND Patient must require continuous administration of foslevodopa without an overnight break; OR Patient must require a total daily dose of more than 2,400 mg of foslevodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 16972

[16] Schedule 3, entry for Infliximab

omit from the column headed "Authority Requirements—Part of Circumstances" for Circumstances Code "C13702": **Compliance with Written Authority Required procedures** *substitute:* **Compliance with Authority Required procedures**

[17] Schedule 3, entry for Ivacaftor

substitute:

Ivacaftor	C16844		Cystic fibrosis Initial treatment - New patient (non-gating mutations) Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data; AND Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged 4 months or older. For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort	Compliance with Written Authority Required procedures

			Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA-approved Product Information. Quote each of the: (a) the specific mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and (2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C16845		Cystic fibrosis Continuing treatment (non-gating mutations) Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction per authority application; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged 4 months or older. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy.	Compliance with Written Authority Required procedures

			Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C16876		Cystic fibrosis Continuing treatment (gating mutations) Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction per authority application; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged 4 months or older. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy.	Compliance with Written Authority Required procedures

			Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C16878		Cystic fibrosis Initial treatment - New patient (gating mutations) Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged 4 months or older. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy.	Compliance with Written Authority Required procedures

			Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (a) the specific CFTR mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and (2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	

[18] Schedule 3, entry for Omalizumab

(a) *omit:*

	C7055		Severe chronic spontaneous urticaria Initial treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria); AND Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines; AND Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy; AND Patient must not receive more than 12 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

			A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following: 1) a H2 receptor antagonist (150 mg twice per day); or 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or 3) doxepin (up to 25 mg three times a day) If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include: (i) demonstration of failure to achieve an adequate response to standard therapy; and (ii) drug names and doses of standard therapies that the patient has failed; and (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.	

(b) *omit:*

	C15350		Uncontrolled severe allergic asthma Initial treatment Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either: a (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more	Compliance with Written Authority Required procedures

			than 12 months prior to the time of application; AND Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 6 to less than 12 years. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be under the care of the same physician for at least 6 months. Optimised asthma therapy includes: (i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND (ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND (b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, should be	

			conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (c) the IgE result and date; and (d) Asthma Control Questionnaire (ACQ-5) score; or (e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.	

(c) *insert in numerical order after existing text:*

	C16846		Uncontrolled severe asthma Continuing treatment Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16846

			Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 12 years or older. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction). For second and subsequent continuing treatment with this drug, a measurement of response to the prior course of therapy must be documented in the patient's medical records. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated. The following information must be documented in the patient's medical records: (a) Asthma Control Questionnaire (ACQ-5) score; and (b) If applicable, maintenance oral corticosteroid dose; and (c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced. The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.	
	C16879		Uncontrolled severe allergic asthma Initial treatment Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either: a (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application; AND	Compliance with Written Authority Required procedures

			Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 6 to less than 12 years. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be under the care of the same physician for at least 6 months. Optimised asthma therapy includes: (i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND (ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND (b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment	

			is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (c) the IgE result and date; and (d) Asthma Control Questionnaire (ACQ-5) score; or (e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.	
	C16904		Uncontrolled severe allergic asthma Continuing treatment Patient must have a documented history of severe allergic asthma; AND Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR	Compliance with Authority Required procedures - Streamlined Authority Code 16904

			(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline. A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The following information must be provided at the time of application and must be documented in the patient's medical records: (a) If applicable, the baseline and maintenance oral corticosteroid dose; and (b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or (c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and (d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced. The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.	
	C16905		Severe chronic spontaneous urticaria Continuing treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16905

			Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.	
	C16906		Severe chronic spontaneous urticaria Initial treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria); AND Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines; AND Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy; AND Patient must not receive more than 12 weeks of treatment under this restriction. A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following: 1) a H2 receptor antagonist (150 mg twice per day); or 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or 3) doxepin (up to 25 mg three times a day) If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy. The authority application must be made in writing and must include: (a) details of the proposed prescription; and (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include: (i) demonstration of failure to achieve an adequate response to standard therapy; and (ii) drug names and doses of standard therapies that the patient has failed; and (iii) a signed patient acknowledgment that cessation of therapy should be considered after the	Compliance with Written Authority Required procedures

			patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.	
	C16948		Uncontrolled severe allergic asthma Continuing treatment Patient must have a documented history of severe allergic asthma; AND Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline. A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The following information must be provided at the time of application and must be documented in the patient's medical records:	Compliance with Authority Required procedures - Streamlined Authority Code 16948

			(a) If applicable, the baseline and maintenance oral corticosteroid dose; and (b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or (c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and (d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced. The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.	
	C16949		Uncontrolled severe asthma Continuing treatment Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 12 years or older. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction). For second and subsequent continuing treatment with this drug, a measurement of response to the prior course of therapy must be documented in the patient's medical records. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated. The following information must be documented in the patient's medical records:	Compliance with Authority Required procedures - Streamlined Authority Code 16949

			(a) Asthma Control Questionnaire (ACQ-5) score; and (b) If applicable, maintenance oral corticosteroid dose; and (c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced. The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.	
	C16960		Severe chronic spontaneous urticaria Continuing treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 16960

[19] Schedule 3, entry for Ustekinumab

substitute:

Ustekinumab	C14801		Complex refractory Fistulising Crohn disease Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR	Compliance with Authority Required procedures

			Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]	
	C16824		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the two proposed prescriptions; and	Compliance with Written Authority Required procedures

			(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse	

			reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C16829		Complex refractory Fistulising Crohn disease Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have an externally draining enterocutaneous or rectovaginal fistula. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (1) details of the two proposed prescriptions; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised	Compliance with Written Authority Required procedures

			Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.	
	C16863		Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index	Compliance with Written Authority Required procedures

			(CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the two proposed prescriptions; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment. Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.	

			Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C16866		Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND	Compliance with Written Authority Required procedures

			Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND The treatment must not exceed a single dose to be administered at week 0 under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second	

			prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	
	C16890		Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the two proposed prescriptions; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.	Compliance with Written Authority Required procedures

			A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to Services Australia no later than 4 weeks from the date of completion of treatment. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C16939		Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND	Compliance with Written Authority Required procedures

			Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a single dose to be administered at week 0 under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	

	C16944		Complex refractory Fistulising Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Applications for authorisation must be made in writing and must include: (1) details of the two proposed prescriptions; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats. The most recent fistula assessment must be no more than 4 weeks old at the time of application.	Compliance with Written Authority Required procedures

			A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.	
	C16958		Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND The treatment must not exceed a single dose to be administered at week 0 under this restriction. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) details of the proposed prescription; and	Compliance with Written Authority Required procedures

			(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy). All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.	