Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 OCTOBER 2007

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 October 2007. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 October 2007 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.44
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.48
Additional Fees (for safety net prices):	Ready-prepared	$1.01
	Extemporaneously-prepared	$1.40
Patient Co-payments:	General	$30.70
	Concessional	$4.90
Safety Net Thresholds:	General	$1059.00
	Concessional	$274.40
Safety Net Card Issue Fee:		$7.72

SUMMARY OF CHANGES

ADDITIONS

Additions - Items

(see under 'RESTRICTIONS' below for more details)

2136K **Irbesartan with hydrochlorothiazide**, Tablet 300 mg-25 mg (*Avapro HCT 300/25, Karvezide 300/25*)

2310N **Oxaliplatin**, Solution concentrate for I.V. infusion 200 mg in 40 mL (*Eloxatin*)

The entries for Doxycycline and Omeprazole have been amended to reflect the different salts of the active ingredient in various products. This has resulted in the following new item codes and the addition of notes relating to bioequivalence.

9106G **Doxycycline**, Tablet 50 mg (as monohydrate) (*Chem mart Doxycycline, Doxyhexal, Frakas, GenRx Doxycycline, Terry White Chemists Doxycycline*)

9108J **Doxycycline**, Tablet 100 mg (as monohydrate) (*Chem mart Doxycycline, Doxyhexal, Terry White Chemists Doxycycline, GenRx Doxycycline*)

9105F **Doxycycline**, Tablet 100 mg (as monohydrate) (*Chem mart Doxycycline, Doxyhexal, GenRx Doxycycline, Terry White Chemists Doxycycline*) **(Diff. Max. Qty and Rpts)**

9107H **Doxycycline**, Tablet 100 mg (as monohydrate) (*Chem mart Doxycycline, Doxyhexal, GenRx Doxycycline, Terry White Chemists Doxycycline*) **(Diff. Max. Qty and Rpts)**

5082L **Doxycycline**, Tablet 100 mg (as monohydrate) (*Chem mart Doxycycline, Doxyhexal, GenRx Doxycycline, Terry White Chemists Doxycycline*) **(Dental)**

9109K **Omeprazole**, Tablet 20 mg (as magnesium) (*Acimax Tablets, Omepral, Losec Tablets*)

9110L **Omeprazole**, Tablet 20 mg (as magnesium) (*Acimax Tablets, Omepral, Losec Tablets*) **(Diff. Max. Rpts)**

Additions - Brands

8594H *Amisulpride Sandoz, AV* — **Amisulpride**, Tablet 100 mg

8595J *Amisulpride Sandoz, AV* — **Amisulpride**, Tablet 200 mg

8596K *Amisulpride Sandoz, AV* — **Amisulpride**, Tablet 400 mg

1472L *Fluconazole Winthrop, BG* — **Fluconazole**, Capsule 100 mg

1475P *Fluconazole Winthrop, BG* — **Fluconazole**, Capsule 200 mg

1921D *Apidra SoloStar, SW* — **Insulin glulisine**, Injections (human analogue) 100 units per mL, 3 mL, 5

8470T *Tryzan 10, AF* — **Ramipril**, Capsule 10 mg

DELETIONS

Deletions - Items

8557J **Glucose indicator—blood**, Electrode strips, 50 (*GlucoMen Sensor*)

1425B **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (50 units-50 units) per mL, 10 mL (*Mixtard 50/50*)

8006J **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injections (human) 100 units (20 units-80 units) per mL, 3 mL, 5 (*Mixtard 20/80 Penfill 3 mL*)

2261B **Lumiracoxib**, Tablet 100 mg (*Prexige*)

Deletions - Brands

The entries for Doxycycline and Omeprazole have been amended to reflect the different salts of the active ingredient in various products. This has resulted in new item codes and the addition of notes relating to bioequivalence.

2709N *Chem mart Doxycycline, CH; Doxyhexal, SZ; GenRx Doxycycline, GX; Terry White Chemists Doxycycline, TW* — **Doxycycline**, Tablet 100 mg (as hydrochloride) (**Note:** These brands are now listed under item 9105F **Doxycycline**, Tablet 100 mg (as monohydrate).)

2711Q *Chem mart Doxycycline, CH; Doxyhexal, SZ; Frakas, AW; GenRx Doxycycline, GX; Terry White Chemists Doxycycline, TW* — **Doxycycline**, Tablet 50 mg (as hydrochloride) (**Note:** These brands are now listed under item 9106G **Doxycycline**, Tablet 50 mg (as monohydrate).)

2702F *Chem mart Doxycycline, CH; Doxyhexal, SZ; GenRx Doxycycline, GX; Terry White Chemists Doxycycline, TW* — **Doxycycline**, Tablet 100 mg (as hydrochloride) **(Diff. Max. Qty and Rpts)** (**Note:** These brands are now listed under item 9107H **Doxycycline**, Tablet 100 mg (as monohydrate).)

2714W *Chem mart Doxycycline, CH; Doxyhexal, SZ; GenRx Doxycycline, GX; Terry White Chemists Doxycycline, TW* — **Doxycycline**, Tablet 100 mg (as hydrochloride) **(Diff. Max. Qty)** (**Note:** These brands are now listed under item 9108J **Doxycycline**, Tablet 100 mg (as monohydrate).)

3321T *Chem mart Doxycycline, CH; Doxyhexal, SZ; GenRx Doxycycline, GX; Terry White Chemists Doxycycline, TW* — **Doxycycline**, Tablet 100 mg (as hydrochloride) **(Dental)** (**Note:** These brands are now listed under item 5082L **Doxycycline**, Tablet 100 mg (as monohydrate).)

1921D *Apidra, AV* — **Insulin glulisine**, Injections (human analogue) 100 units per mL, 3 mL, 5

1426C *Mixtard 30/70, NO* — **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (30 units-70 units) per mL, 10 mL

8331L *Acimax Tablets, AL; Omepral, PM; Losec Tablets, AP* — **Omeprazole**, Tablet 20 mg (**Note:** These brands are now listed under item 9109K **Omeprazole**, Tablet 20 mg (as magnesium).)

8333N *Acimax Tablets, AL; Omepral, PM; Losec Tablets, AP* — **Omeprazole**, Tablet 20 mg **(Diff. Max. Rpts)** (**Note:** These brands are now listed under item 9110L **Omeprazole**, Tablet 20 mg (as magnesium).)

2013Y *Lipex 5, FR* — **Simvastatin**, Tablet 5 mg

ALTERATIONS

Alterations - Items

The entries for Doxycycline, Omeprazole, Potassium Chloride and Prochlorperazine have been amended to reflect the different salts of the active ingredient in various products.

From:
2711Q **Doxycycline**, Tablet 50 mg (*Chem mart Doxycycline, Doxy-50, Doxyhexal, Doxylin 50, Frakas, GenRx Doxycycline, Terry White Chemists Doxycycline, Vibra-Tabs*)
To:
2711Q **Doxycycline**, Tablet 50 mg (as hydrochloride) (*Doxy-50, Doxylin 50, Vibra-Tabs*)

From:
2709N **Doxycycline**, Tablet 100 mg (*Chem mart Doxycycline, Doxsig, Doxy-100, Doxyhexal, Doxylin 100, GenRx Doxycycline, Terry White Chemists Doxycycline, Vibramycin*)
To:
2709N **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*)

From:
2702F **Doxycycline**, Tablet 100 mg (*Chem mart Doxycycline, Doxsig, Doxy-100, Doxyhexal, Doxylin 100, GenRx Doxycycline, Terry White Chemists Doxycycline, Vibramycin*)
To:
2702F **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*) **(Diff. Max. Qty and Rpts)**

From:
2714W **Doxycycline**, Tablet 100 mg (*Chem mart Doxycycline, Doxsig, Doxy-100, Doxyhexal, Doxylin 100, Terry White Chemists Doxycycline, GenRx Doxycycline, Vibramycin*)
To:
2714W **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*) **(Diff. Max. Qty)**

From:
3321T **Doxycycline**, Tablet 100 mg (*Chem mart Doxycycline, Doxsig, Doxy-100, Doxyhexal, Doxylin 100, GenRx Doxycycline, Terry White Chemists Doxycycline, Vibramycin*) **(Dental)**
To:
3321T **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*) **(Dental)**

From:
2707L **Doxycycline**, Capsule 50 mg (*DBL Doxycycline, Doryx*)
To:
2707L **Doxycycline**, Capsule 50 mg (as hydrochloride) (*DBL Doxycycline, Doryx*)

From:
2708M **Doxycycline**, Capsule 100 mg (*DBL Doxycycline, Doryx*)
To:
2708M **Doxycycline**, Capsule 100 mg (as hydrochloride) (*DBL Doxycycline, Doryx*)

From:
2703G **Doxycycline**, *Capsule 100 mg (DBL Doxycycline, Doryx)*
To:
2703G **Doxycycline**, Capsule 100 mg (as hydrochloride) (*DBL Doxycycline, Doryx*) **(Diff. Max. Qty and Rpts)**

From:
2715X **Doxycycline**, Capsule 100 mg (*DBL Doxycycline, Doryx*)
To:
2715X **Doxycycline**, Capsule 100 mg (as hydrochloride) (*DBL Doxycycline, Doryx*) **(Diff. Max. Qty)**

From:
3322W **Doxycycline**, Capsule 100 mg (*DBL Doxycycline, Doryx*) **(Dental)**
To:
3322W **Doxycycline**, Capsule 100 mg (as hydrochloride) (*DBL Doxycycline, Doryx*) **(Dental)**

From:
3012M **Potassium chloride**, Effervescent tablet 14 mmol K+ and 8 mmol Cl- (*K-Sol, Chlorvescent*)
To:
3012M **Potassium chloride with potassium bicarbonate**, Effervescent tablet 14 mmol potassium and 8 mmol chloride (*K-Sol, Chlorvescent*)

From:
2893G **Prochlorperazine**, Tablet 5 mg (*Stemzine, Stemetil*)
To:
2893G **Prochlorperazine**, Tablet containing prochlorperazine maleate 5 mg (*Stemzine, Stemetil*)

From:
5205Y **Prochlorperazine**, Tablet 5 mg (*Stemzine, Stemetil*) **(Dental)**
To:
5205Y **Prochlorperazine**, Tablet containing prochlorperazine maleate 5 mg (*Stemzine, Stemetil*) **(Dental)**

From:
2369Q **Prochlorperazine**, Injection 12.5 mg in 1 mL (*Stemetil*)
To:
2369Q **Prochlorperazine**, Injection containing prochlorperazine mesylate 12.5 mg in 1 mL (*Stemetil*)

From:
5206B **Prochlorperazine**, Injection 12.5 mg in 1 mL (*Stemetil*) **(Dental)**
To:
5206B **Prochlorperazine**, Injection containing prochlorperazine mesylate 12.5 mg in 1 mL (*Stemetil*) **(Dental)**

From:
3477B **Prochlorperazine**, Injection 12.5 mg in 1 mL (*Stemetil*) **(Doctor's Bag)**
To:
3477B **Prochlorperazine**, Injection containing prochlorperazine mesylate 12.5 mg in 1 mL (*Stemetil*) **(Doctor's Bag)**

From:
2894H **Prochlorperazine**, Suppositories 5 mg, 5 (*Stemetil*)
To:
2894H **Prochlorperazine**, Suppositories containing prochlorperazine equivalent to 5 mg prochlorperazine maleate, 5 (*Stemetil*)

From:

5207C **Prochlorperazine**, Suppositories 5 mg, 5 (*Stemetil*) **(Dental)**

To:

5207C **Prochlorperazine**, Suppositories containing prochlorperazine equivalent to 5 mg prochlorperazine maleate, 5 (*Stemetil*) **(Dental)**

From:

2895J **Prochlorperazine**, Suppositories 25 mg, 5 (*Stemetil*)

To:

2895J **Prochlorperazine**, Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5 (*Stemetil*)

From:

5208D **Prochlorperazine**, Suppositories 25 mg, 5 (*Stemetil*) **(Dental)**

To:

5208D **Prochlorperazine**, Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5 (*Stemetil*) **(Dental)**

Alterations - Restrictions

(see under 'RESTRICTIONS' below for more details)

8664B **Riluzole**, Tablet 50 mg (*Rilutek*)

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)

8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

Alterations - Manufacturer's Codes

		From	*To*
8406K	**Beclomethasone dipropionate**, Oral pressurised inhalation 50 micrograms per dose (200 doses), CFC-free formulation (*Qvar 50*)	MM	IA
8407L	**Beclomethasone dipropionate**, Oral pressurised inhalation 100 micrograms per dose (200 doses), CFC-free formulation (*Qvar 100*)	MM	IA
8408M	**Beclomethasone dipropionate**, Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation (*Qvar 50 Autohaler*)	MM	IA
8409N	**Beclomethasone dipropionate**, Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation (*Qvar 100 Autohaler*)	MM	IA
3038X	**Benztropine mesylate**, Injection 2 mg in 2 mL (*Cogentin*)	MK	FK
5031T	**Benztropine mesylate**, Injection 2 mg in 2 mL (*Cogentin*) **(Dental)**	MK	FK
3457Y	**Benztropine mesylate**, Injection 2 mg in 2 mL (*Cogentin*) **(Doctor's Bag)**	MK	FK
1121B	**Benzydamine hydrochloride**, Mouth and throat rinse 22.5 mg per 15 mL, 500 mL (*Difflam*)	MM	IA
5032W	**Benzydamine hydrochloride**, Mouth and throat rinse 22.5 mg per 15 mL, 500 mL (*Difflam*) **(Dental)**	MM	IA
5385K	**Benzydamine hydrochloride**, Mouth and throat rinse 22.5 mg per 15 mL, 500 mL (*Difflam*) **(Palliative Care)**	MM	IA
5386L	**Benzydamine hydrochloride**, Mouth and throat rinse 22.5 mg per 15 mL, 500 mL (*Difflam*) **(Palliative Care) (Diff. Max. Rpts)**	MM	IA

3116B	**Calcium**, Tablet (chewable) 500 mg (as carbonate) (*Cal-Sup*)	MM	IA
8853Y	**Ciclesonide**, Oral pressurised inhalation 80 micrograms per dose (120 doses), CFC-free formulation (*Alvesco 80*)	AH	NQ
8854B	**Ciclesonide**, Oral pressurised inhalation 160 micrograms per dose (120 doses), CFC-free formulation (*Alvesco 160*)	AH	NQ
1088G	**Flecainide acetate**, Tablet 50 mg (*Tambocor*)	MM	IA
1090J	**Flecainide acetate**, Tablet 100 mg (*Tambocor*)	MM	IA
8027L	**Glyceryl trinitrate**, Transdermal patch releasing approximately 5 mg per 24 hours (*Minitran 5*)	MM	IA
8028M	**Glyceryl trinitrate**, Transdermal patch releasing approximately 10 mg per 24 hours (*Minitran 10*)	MM	IA
8119H	**Glyceryl trinitrate**, Transdermal patch releasing approximately 15 mg per 24 hours (*Minitran 15*)	MM	IA
3124K	**Hexamine hippurate**, Tablet 1 g (*Hiprex*)	MM	IA
2546B	**Imiquimod**, Cream 50 mg per g (5%), 250 mg single use sachets, 12 (*Aldara*)	MM	IA
8485N	**Oestradiol**, Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 4 (*Femtran 25*)	MM	IA
8125P	**Oestradiol**, Transdermal patches 3.8 mg (releasing approximately 50 micrograms per 24 hours), 4 (*Femtran 50*)	MM	IA
8126Q	**Oestradiol**, Transdermal patches 7.6 mg (releasing approximately 100 micrograms per 24 hours), 4 (*Femtran 100*)	MM	IA
8399C	**Pantoprazole sodium sesquihydrate**, Tablet (enteric coated), equivalent to 20 mg pantoprazole (*Somac*)	AH	NQ
8007K	**Pantoprazole sodium sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole (*Somac*)	AH	NQ
8008L	**Pantoprazole sodium sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole (*Somac*) **(Diff. Max. Rpts)**	AH	NQ
3495Y	**Salbutamol sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation (*Airomir*) **(Doctor's Bag)**	MM	IA
8288F	**Salbutamol sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation (*Airomir*)	MM	IA
8354Q	**Salbutamol sulfate**, Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation (*Airomir Autohaler*)	MM	IA
2634P	**Theophylline**, Tablet 250 mg (sustained release) (*Nuelin-SR 250*)	MM	IA
8230E	**Theophylline**, Tablet 200 mg (sustained release) (*Nuelin-SR 200*)	MM	IA
8231F	**Theophylline**, Tablet 300 mg (sustained release) (*Nuelin-SR 300*)	MM	IA
2614N	**Theophylline**, Syrup 133.3 mg per 25 mL, 500 mL (*Nuelin*)	MM	IA

NOTES

Additions - Notes

Notes have been **added** in respect of the following **:**

2711Q **Doxycycline**, Tablet 50 mg (as hydrochloride) (*Doxy-50, Doxylin 50, Vibra-Tabs*)

2709N **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*)

2702F **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*) **(Diff. Max. Qty and Rpts)**

2714W **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*) **(Diff. Max. Qty)**

3321T **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig, Doxy-100, Doxylin 100, Vibramycin*) **(Dental)**

8331L **Omeprazole**, Tablet 20 mg (*Meprazol, Omeprazole-GA, Omeprazole Winthrop*)

8333N **Omeprazole**, Tablet 20 mg (*Meprazol, Omeprazole-GA, Omeprazole Winthrop*) **(Diff. Max. Rpts)**

Deletion - Note

The note has been **deleted** in respect of the following **:**

1326T **Omeprazole**, Capsule 20 mg (*Probitor*)

SECTION 100 - HIGHLY SPECIALISED DRUGS PROGRAM
ADDITIONS

Additions - Items

(see under 'RESTRICTIONS' below for more details)

9613Y **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

9612X **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) **(Diff. Restriction)**

DELETIONS

Deletions - Brands

6101D *CloSyn, ZT* — **Clozapine**, Tablet 25 mg

6102E *CloSyn, ZT* — **Clozapine**, Tablet 100 mg

SECTION 100 - HUMAN GROWTH HORMONE
DELETION

Deletion - Item

6266T **Somatropin (recombinant human growth hormone)**, Injection 4 mg (12 i.u.) vial with 3.5 mL diluent (with preservative) (*SciTropin*)

ADVANCE NOTICES

Advance Notices - Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **January** 2008:

Items discontinued by the manufacturer -

8012Q	**Oestradiol**, Transdermal patches 3.28 mg (releasing approximately 37.5 micrograms per 24 hours), 8 (*Menorest 37.5*)
8013R	**Oestradiol**, Transdermal patches 4.33 mg (releasing approximately 50 micrograms per 24 hours), 8 (*Menorest 50*)
8014T	**Oestradiol**, Transdermal patches 6.57 mg (releasing approximately 75 micrograms per 24 hours), 8 (*Menorest 75*)
8041F	**Oestradiol**, Transdermal patches 8.66 mg (releasing approximately 100 micrograms per 24 hours), 8 (*Menorest 100*)
2163W	**Thioridazine hydrochloride**, Tablet 10 mg (*Aldazine 10*)
2359E	**Thioridazine hydrochloride**, Tablet 25 mg (*Aldazine 25*)
2164X	**Thioridazine hydrochloride**, Tablet 50 mg (*Aldazine 50*)
2165Y	**Thioridazine hydrochloride**, Tablet 100 mg (*Aldazine 100*)

RESTRICTIONS

The text of restrictions mentioned above:

Infliximab

Note:

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

9613Y **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Public and private hospital authority required

Initial treatment of Crohn's disease in a patient with severe disease as assessed by CDAI

Initial PBS-subsidised treatment by a gastroenterologist of a patient with severe refractory Crohn's disease who satisfies the following criteria:
(a) has confirmed Crohn's disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

If treatment with any of the above-mentioned 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, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn's Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn's Disease Activity Index (CDAI) 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]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Continuing treatment of Crohn's disease in a patient with severe disease as assessed by CDAI

Continuing PBS-subsidised treatment by a gastroenterologist, or consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn's disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as a reduction in Crohn's Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn's Disease Activity Index (CDAI) Score calculation sheet along with the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn's disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

Initial treatment of Crohn's disease in a patient with short gut syndrome or an ostomy patient

Initial PBS-subsidised treatment by a gastroenterologist of a patient with severe refractory Crohn's disease who satisfies the following criteria:
(a) has confirmed Crohn's disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

If treatment with any of the above-mentioned 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, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have evidence of intestinal inflammation, including:
(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; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/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;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Continuing treatment of Crohn's disease in a patient with short gut syndrome or an ostomy patient

Continuing PBS-subsidised treatment by a gastroenterologist, or consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn's disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn's disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

Initial treatment of Crohn's disease in a patient with extensive small intestine disease

Initial PBS-subsidised treatment by a gastroenterologist of a patient with severe refractory Crohn's disease who satisfies the following criteria:
(a) has confirmed Crohn's disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

If treatment with any of the above-mentioned 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, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have severity of disease activity which results in a Crohn's Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(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; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/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;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn's Disease Activity Index (CDAI) calculation sheets including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Continuing treatment of Crohn's disease in a patient with extensive small intestine disease

Continuing PBS-subsidised treatment by a gastroenterologist, or consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn's disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn's Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn's Disease Activity Index (CDAI) Score calculation sheet along with the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

The CDAI assessment, where relevant, must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn's disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

Initial PBS-subsidised treatment of Crohn's disease in a patient with severe disease as assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab

Initial PBS-subsidised supply for continuing treatment by a gastroenterologist, or consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn's disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) had a Crohn's Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An adequate response to infliximab treatment is defined as a reduction in Crohn's Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn's Disease Activity Index (CDAI) Score calculation sheet along with the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgment.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn's disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Public and private hospital authority required

Initial PBS-subsidised treatment of Crohn's disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab

Initial PBS-subsidised supply for continuing treatment by a gastroenterologist, or consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn's disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn's Disease Activity Index (CDAI) Score to no greater then 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn's Disease Activity Index (CDAI) Score calculation sheet, where relevant, along with the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment, where applicable, must be from immediately prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn's disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

9612X **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Public and private hospital authority required

Initial treatment of Crohn's disease in a paediatric patient

Initial PBS-subsidised treatment by a gastroenterologist or paediatrician of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn's disease who satisfies the following criteria:
(a) has confirmed Crohn's disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist; and
(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period;
(ii) an 8 week course of enteral nutrition;
(iii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

If treatment with any of the above-mentioned 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, please provide details of the degree of this toxicity at the time of

application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) severity of disease activity which results in a Paediatric Crohn's Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn's Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Continuing treatment of Crohn's disease in a patient initiated on PBS-subsidised treatment as a paediatric patient

Continuing PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of moderate to severe refractory Crohn's disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn's Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and

(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Paediatric Crohn's Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn's disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

Initial PBS-subsidised treatment of Crohn's disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab

Initial PBS-subsidised supply for continuing treatment by a gastroenterologist, paediatrician or consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:
(a) has a documented history of moderate to severe refractory Crohn's disease and was receiving treatment with infliximab prior to 4 July 2007; and
(b) had a Paediatric Crohn's Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn's Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and

(b) a completed Crohn's Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Paediatric Crohn's Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn's disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

2136K **Irbesartan with hydrochlorothiazide**, Tablet 300 mg-25 mg (*Avapro HCT 300/25*, *Karvezide 300/25*)

Restricted benefit

Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or irbesartan monotherapy

2310N **Oxaliplatin**, Solution concentrate for I.V. infusion 200 mg in 40 mL (*Eloxatin*)

Authority required

Metastatic colorectal cancer in patients with a WHO performance status of 2 or less, to be used in combination with 5-fluorouracil and folinic acid.

Authority required

Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with 5-fluorouracil and folinic acid, following complete resection of the primary tumour.

Note:

Oxaliplatin is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.

Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

8664B **Riluzole**, Tablet 50 mg (*Rilutek*)

Authority required

Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who:

(1) are ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure; OR

(2) are not ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure, and

(c) are either able to use upper limbs or able to swallow.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

Authority required

Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who:

(1) are ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure; OR

(2) are not ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure, and

(c) are either able to use upper limbs or able to swallow.

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)

8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

Authority required (STREAMLINED)

2635

Dual oral combination therapy with metformin or a sulfonylurea.

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Rosiglitazone maleate is not PBS-subsidised as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority required (STREAMLINED)

2648

Triple oral combination therapy with metformin and a sulfonylurea.

Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Rosiglitazone maleate is not PBS-subsidised as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority required (STREAMLINED)

2730

Combination therapy with insulin.

Type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of insulin despite treatment with rosiglitazone maleate and at least 1 other oral anti-diabetic agent.

The date and level of the HbA1c must be documented in the patient's medical records at the time insulin therapy is initiated. The HbA1c must be no more than 4 months old at the time insulin therapy is initiated.

Note:

Rosiglitazone maleate should not be initiated in patients who already receive insulin.

Rosiglitazone maleate is not PBS-subsidised as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority required (STREAMLINED)

2731

Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of anti-diabetic medicines which includes both rosiglitazone maleate and insulin.

NOTES

The text of notes mentioned above:

2711Q **Doxycycline**, Tablet 50 mg (as hydrochloride) (*Doxy-50*, *Doxylin 50*, *Vibra-Tabs*)

Note:

Bioequivalence has been demonstrated between doxycycline tablet 50 mg (as hydrochloride) and doxycycline tablet 50 mg (as monohydrate).

2709N **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig*, *Doxy-100*, *Doxylin 100*, *Vibramycin*)

2702F **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig*, *Doxy-100*, *Doxylin 100*, *Vibramycin*) **(Diff. Max. Qty and Rpts)**

2714W **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig*, *Doxy-100*, *Doxylin 100*, *Vibramycin*) **(Diff. Max. Qty)**

3321T **Doxycycline**, Tablet 100 mg (as hydrochloride) (*Doxsig*, *Doxy-100*, *Doxylin 100*, *Vibramycin*) **(Dental)**

Note:

Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).

8331L **Omeprazole**, Tablet 20 mg (*Meprazol*, *Omeprazole-GA*, *Omeprazole Winthrop*)

8333N **Omeprazole**, Tablet 20 mg (*Meprazol*, *Omeprazole-GA*, *Omeprazole Winthrop*) **(Diff. Max. Rpts)**

Note:

Bioequivalence has been demonstrated between omeprazole tablet 20 mg and omeprazole tablet 20 mg (as magnesium).

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 October 2007 and all previous issues are cancelled.

New Schedules take effect on the first day of each month.

SUMMARY OF CHANGES

ALTERATIONS

Alterations - Manufacturer's Codes

		From	*To*
4333C	**Calcium**, Tablet (chewable) 500 mg (as carbonate) (*Cal-Sup*)	MM	IA
4559Y	**Imiquimod**, Cream 50 mg per g (5%), 250 mg single use sachets, 12 (*Aldara*)	MM	IA
4071G	**Pholcodine**, Linctus 1 mg per mL (0.1%), 100 mL (*Duro-Tuss*)	MM	IA