COMMONWEALTH OF AUSTRALIA

Instrument number PB 98 of 2008

Amendment determinations under sections 85, 85A and 88 of the National Health Act 1953

I, DIANA MACDONELL, Acting Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing, delegate of the Minister for Health and Ageing, make this instrument under sections 85, 85A and 88 of the *National Health Act 1953*.

Dated 2nd OCTOBER 2008

DIANA MACDONELL
Acting Assistant Secretary
Pharmaceutical Evaluation Branch
Department of Health and Ageing

Amendment determination — pharmaceutical benefits

1 Commencement

This instrument commences on 1 November 2008.

2 Amendment of PB 75 of 2008

Schedule 1 amends PB 75 of 2008.

Schedule 1 Amendments

[1] Paragraph 3(b), immediately after the semi-colon

insert:

or

[2] Paragraph 3, after the entry "g" means gram;

insert:

"GP Management Plan" means a comprehensive written plan for the treatment of a patient, prepared by a medical practitioner, that includes a description of the patient's health care needs, management goals, actions to be taken by the patient and treatment and services the patient is likely to need;

[3] Paragraph 3, for the entry "Regulations" means the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act.

omit the "fullstop" and substitute with a "semi-colon"

[4] Paragraph 3, after the entry "Regulations" means the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act;

insert:

"Team Care Arrangements" means a document prepared by a medical practitioner, following consultation with collaborating providers, that includes a description of the treatment and service goals for the patient, the treatment and services that all collaborating providers will provide and the actions to be taken by the patient.

[5] Part 1 of Schedule 1, item dealing with Amisulpride in the form Tablet 400 mg

in the column headed "Brand" insert in alphabetical order:

Amipride 400

[6] Part 1 of Schedule 1, item dealing with Amlodipine in the form Tablet 5 mg (as besylate)

in the column headed "Brand" insert in alphabetical order:

Amlotrust 5

[7] Part 1 of Schedule 1, item dealing with Amlodipine in the form Tablet 10 mg (as besylate)

in the column headed "Brand" insert in alphabetical order:

Amlotrust 10

[8] Part 1 of Schedule 1, item dealing with Cabergoline

omit from the columns in the order indicated:

	Tablet 4 mg	Oral	30	5	Cabaser

[9] Part 1 of Schedule 1, item dealing with Carvedilol in the forms Tablet 3.125 mg, Tablet 6.25 mg, Tablet 12.5 mg and Tablet 25 mg

in the column headed "Brand" insert in alphabetical order:

GN-Carvedilol

[10] Part 1 of Schedule 1, item dealing with Epirubicin

omit from the columns in the order indicated:

	Powder for injection containing epirubicin hydrochloride 50 mg	Injection/intravesical	4	. .	Hospira Pty Limited

[11] Part 1 of Schedule 1, item dealing with Insulin Glulisine

insert as first entry in the columns in the order indicated:

	Injection (human analogue) 100 units per mL, 10 mL	Injection	5	2	Apidra

[12] Part 1 of Schedule 1, item dealing with Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL

in the column headed "Brand" insert in alphabetical order:

Irinotecan-GA

[13] Part 1 of Schedule 1, item dealing with Lamotrigine in the forms Tablet 25 mg, Tablet 50 mg, Tablet 100 mg and Tablet 200 mg

in the column headed "Brand" insert in alphabetical order:

Lamotrigine-GA

[14] Part 1 of Schedule 1, item dealing with Lisinopril in the form Tablet 5 mg

omit from the column headed "Brand":

Lisinotrust 5

[15] Part 1 of Schedule 1, item dealing with Lisinopril in the form Tablet 10 mg

omit from the column headed "Brand":

Lisinotrust 10

[16] Part 1 of Schedule 1, item dealing with Lisinopril in the form Tablet 20 mg

omit from the column headed "Brand":

Lisinotrust 20

[17] Part 1 of Schedule 1, after item dealing with Mesalazine in the form Sachet containing granules, 1 g per sachet

insert in the columns in the order indicated:

	Sachet containing granules, 1.5 g per sachet	Oral	60	5	Salofalk

[18] Part 1 of Schedule 1, item dealing with Nilotinib

omit from the column headed "Maximum number of repeats":

5

and substitute:

2

[19] Part 1 of Schedule 1, item dealing with Pancreatic Extract in the form Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity

omit from the column headed "Brand":

Creon

and substitute:

Creon 10,000

[20] Part 1 of Schedule 1, item dealing with Pancreatic Extract in the form Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity

omit from the column headed "Brand":

Creon Forte

and substitute:

Creon 25,000

[21] Part 1 of Schedule 1, after item dealing with Paroxetine in the form Tablet 20 mg (as hydrochloride)

insert in the columns in the order indicated:

	Tablet 20 mg (as mesilate)	Oral	30	5	Paroxetine generichealth

[22] Part 1 of Schedule 1, item dealing with Polyethylene Glycol 400 with Propylene Glycol

omit from the columns in the order indicated:

	Eye drops 4 mg-3 mg per mL, single dose units 0.7 mL, 28	Application to the eye	3	5	Systane

and substitute:

	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	Application to the eye	2	5	Systane

[23] Part 1 of Schedule 1, after item dealing with Quetiapine in the form Tablet 300 mg (as fumarate)

insert in the columns in the order indicated:

	Tablet (modified release) 50 mg (as fumarate)	Oral	60	5	Seroquel XR
	Tablet (modified release) 200 mg (as fumarate)	Oral	60	5	Seroquel XR
	Tablet (modified release) 300 mg (as fumarate)	Oral	60	5	Seroquel XR
	Tablet (modified release) 400 mg (as fumarate)	Oral	60	5	Seroquel XR

[24] Part 1 of Schedule 1, item dealing with Sertraline in the form Tablet 50 mg (as hydrochloride)

omit from the column headed "Brand":

Sertratrust 50

[25] Part 1 of Schedule 1, item dealing with Sertraline in the form Tablet 100 mg (as hydrochloride)

omit from the column headed "Brand":

Sertratrust 100

[26] Part 1 of Schedule 1, item dealing with Simvastatin in the form Tablet 10 mg

omit from the column headed "Brand":

Simvatrust 10

[27] Part 1 of Schedule 1, item dealing with Simvastatin in the form Tablet 20 mg

omit from the column headed "Brand":

Simvatrust 20

[28] Part 1 of Schedule 1, item dealing with Simvastatin in the form Tablet 40 mg

omit from the column headed "Brand":

Simvatrust 40

[29] Part 1 of Schedule 1, item dealing with Simvastatin in the form Tablet 80 mg

omit from the column headed "Brand":

Simvatrust 80

[30] Part 1 of Schedule 1, item dealing with Tramadol

(a) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 50 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 50 mg

(b) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 100 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 100 mg

[31] Part 1 of Schedule 1, after item dealing with Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 100 mg

insert in the columns in the order indicated:

	Tablet (extended release) containing tramadol hydrochloride 100 mg	Oral	10	. .	Durotram XR

[32] Part 1 of Schedule 1, item dealing with Tramadol

(a) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 150 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 150 mg

(b) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 200 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 200 mg

[33] Part 1 of Schedule 1, after item dealing with Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 200 mg

insert in the columns in the order indicated:

	Tablet (extended release) containing tramadol hydrochloride 200 mg	Oral	10	. .	Durotram XR
	Tablet (extended release) containing tramadol hydrochloride 300 mg	Oral	10	. .	Durotram XR

[34] Part 2 of Schedule 1, item dealing with Botezomib

(a) *omit from the column headed "Listed Drug":*

Botezomib

and substitute:

Bortezomib

(b) *omit from the column headed "Purposes":*

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid, of multiple myeloma in a patient with a World Health Organisation (WHO) performance status of 2 or less, who has progressive disease, who has received at least 1 prior therapy (other than thalidomide), who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least 4 weeks of thalidomide at a dose of at least 100 mg daily; and				

and substitute:

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient with a World Health Organisation (WHO) performance status of 2 or less, who has progressive disease, who has received at least 1 prior therapy (other than thalidomide), who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least 4 weeks of thalidomide at a dose of at least 100 mg daily; and				

(c) *omit from the column headed "Purposes":*

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid, of multiple myeloma in a patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib; and				

and substitute:

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib; and				

[35] Part 2 of Schedule 1, after item dealing with Cabergoline

insert in the columns in the order indicated:

Carbomer 980	Ocular lubricating gel 2 mg per g, 10 g		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	GelTears PAA Viscotears Liquid Gel
Carmellose	Eye drops containing carmellose sodium 5 mg per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Refresh Tears Plus

	Eye drops containing carmellose sodium 10 mg per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Refresh Liquigel

[36] Part 2 of Schedule 1, items dealing with Dasatinib

omit all text from the columns in the order indicated and substitute:

Dasatinib	Tablet 20 mg		**Chronic myeloid leukaemia** In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript BCR-ABL, and who: (a) has active leukaemia (as defined by the presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or fluorescence in situ hybridisation (FISH) analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale); and (b) has failed an adequate trial of imatinib, where failure of an adequate trial of imatinib is defined as: (i) lack of response to initial imatinib therapy, defined as either: — failure to achieve a haematological response after a minimum of 3 months of therapy with imatinib, for patients initially treated in chronic phase; or — failure to achieve any cytogenetic response after a minimum of 6 months of therapy with imatinib, for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or — failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months of therapy with imatinib; or	Oral	60	2	Sprycel

			(ii) loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Philadelphia positive cells on bone marrow biopsy), during ongoing imatinib therapy; or (iii) loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test); or (iv) development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia, where: (1) accelerated phase is defined by the presence of 1 or more of the following: — percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or — percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or — peripheral basophils greater than or equal to 20%; or — progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or — karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); and (2) blast crisis is defined as either: — percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or — extramedullary involvement other than spleen and liver; or (v) disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia; or (vi) grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib; and where the authority application includes: (a) a completed copy of the appropriate Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and				

			(b) a signed patient acknowledgement; and (c) a bone marrow biopsy pathology report demonstrating that the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale, and the date of the relevant pathology report; and (d)(1) where there has been a loss of response to imatinib, a copy of the current confirming pathology report, or reports, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement; or (2) details of Grade 3 or 4 non-haematological imatinib related toxicity; for patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated				
	Tablet 20 mg		**Chronic myeloid leukaemia** In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response to dasatinib, or less than 1% BCR-ABL level in the blood, within 18 months of the commencement of treatment and at 12 monthly intervals thereafter; and where the following conditions apply: a major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells; a bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) indicates a response, at least the biological equivalent of a major cytogenetic response; response to PBS-subsidised treatment with dasatinib is assessed by: (1) cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or, in the case where standard karyotyping is not informative for technical reasons, cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe; or	Oral	60	5	Sprycel	

			(2) quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale; the cytogenetic or peripheral blood quantitative PCR analyses demonstrating response are submitted as follows: (i) between 10 and 18 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated are eligible for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained; the authority application includes: (1) a completed copy of the appropriate Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and (2) demonstration of continued response to treatment as evidenced by: (a) a copy of the cytogenetic analysis showing a major cytogenetic response, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; or (b) a copy of the quantitative PCR analysis showing a peripheral blood level of BCR-ABL of less than 1% on the international scale, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; and (3) if the cytogenetic analysis submitted with the application was conducted using FISH with BCR-ABL specific probe because standard karyotyping was not informative, a copy of the non-informative standard karyotype analysis; a patient who has previously received PBS-subsidised treatment with dasatinib and has at any time failed to meet the criteria for continuing treatment, is not eligible for PBS-subsidised re-treatment				

	Tablet 50 mg		**Chronic myeloid leukaemia** In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript BCR-ABL, and who: (a) has active leukaemia (as defined by the presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or fluorescence in situ hybridisation (FISH) analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale); and (b) has failed an adequate trial of imatinib, where failure of an adequate trial of imatinib is defined as: (i) lack of response to initial imatinib therapy, defined as either: — failure to achieve a haematological response after a minimum of 3 months of therapy with imatinib, for patients initially treated in chronic phase; or — failure to achieve any cytogenetic response after a minimum of 6 months of therapy with imatinib, for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or — failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months of therapy with imatinib; or (ii) loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Philadelphia positive cells on bone marrow biopsy), during ongoing imatinib therapy; or (iii) loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test); or (iv) development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia, where: (1) accelerated phase is defined by the presence of 1 or more of the following:	Oral	60	2	Sprycel

			— percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or — percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or — peripheral basophils greater than or equal to 20%; or — progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or — karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); and (2) blast crisis is defined as either: — percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or — extramedullary involvement other than spleen and liver; or (v) disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia; or (vi) grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib; and where the authority application includes: (a) a completed copy of the appropriate Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and (b) a signed patient acknowledgement; and (c) a bone marrow biopsy pathology report demonstrating that the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale, and the date of the relevant pathology report; and (d)(1) where there has been a loss of response to imatinib, a copy of the current confirming pathology report, or reports, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement; or				

			(2) details of Grade 3 or 4 non-haematological imatinib related toxicity; for patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated				
	Tablet 50 mg		**Chronic myeloid leukaemia** In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response to dasatinib, or less than 1% BCR-ABL level in the blood, within 18 months of the commencement of treatment and at 12 monthly intervals thereafter; and where the following conditions apply: a major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells; a bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) indicates a response, at least the biological equivalent of a major cytogenetic response; response to PBS-subsidised treatment with dasatinib is assessed by: (1) cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or, in the case where standard karyotyping is not informative for technical reasons, cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe; or (2) quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale; the cytogenetic or peripheral blood quantitative PCR analyses demonstrating response are submitted as follows: (i) between 10 and 18 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated are eligible for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained;	Oral	60	5	Sprycel

			the authority application includes: (1) a completed copy of the appropriate Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and (2) demonstration of continued response to treatment as evidenced by: (a) a copy of the cytogenetic analysis showing a major cytogenetic response, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; or (b) a copy of the quantitative PCR analysis showing a peripheral blood level of BCR-ABL of less than 1% on the international scale, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; and (3) if the cytogenetic analysis submitted with the application was conducted using FISH with BCR-ABL specific probe because standard karyotyping was not informative, a copy of the non-informative standard karyotype analysis; a patient who has previously received PBS-subsidised treatment with dasatinib and has at any time failed to meet the criteria for continuing treatment, is not eligible for PBS-subsidised re-treatment					
	Tablet 70 mg		**Chronic myeloid leukaemia** In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript BCR-ABL, and who: (a) has active leukaemia (as defined by the presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or fluorescence in situ hybridisation (FISH) analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale); and (b) has failed an adequate trial of imatinib, where failure of an adequate trial of imatinib is defined as: (i) lack of response to initial imatinib therapy, defined as either:	Oral	60	2	Sprycel	

			— failure to achieve a haematological response after a minimum of 3 months of therapy with imatinib, for patients initially treated in chronic phase; or — failure to achieve any cytogenetic response after a minimum of 6 months of therapy with imatinib, for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or — failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months of therapy with imatinib; or (ii) loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Philadelphia positive cells on bone marrow biopsy), during ongoing imatinib therapy; or (iii) loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test); or (iv) development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia, where: (1) accelerated phase is defined by the presence of 1 or more of the following: — percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or — percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or — peripheral basophils greater than or equal to 20%; or — progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or — karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); and (2) blast crisis is defined as either: — percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or — extramedullary involvement other than spleen and liver; or				

			(v) disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia; or (vi) grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib; and where the authority application includes: (a) a completed copy of the appropriate Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and (b) a signed patient acknowledgement; and (c) a bone marrow biopsy pathology report demonstrating that the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale, and the date of the relevant pathology report; and (d)(1) where there has been a loss of response to imatinib, a copy of the current confirming pathology report, or reports, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement; or (2) details of Grade 3 or 4 non-haematological imatinib related toxicity; for patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated					
	Tablet 70 mg		**Chronic myeloid leukaemia** In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response to dasatinib, or less than 1% BCR-ABL level in the blood, within 18 months of the commencement of treatment and at 12 monthly intervals thereafter; and where the following conditions apply: a major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells;	Oral	60	5	Sprycel	

			a bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) indicates a response, at least the biological equivalent of a major cytogenetic response; response to PBS-subsidised treatment with dasatinib is assessed by: (1) cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or, in the case where standard karyotyping is not informative for technical reasons, cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe; or (2) quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale; the cytogenetic or peripheral blood quantitative PCR analyses demonstrating response are submitted as follows: (i) between 10 and 18 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated are eligible for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained; the authority application includes: (1) a completed copy of the appropriate Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and (2) demonstration of continued response to treatment as evidenced by: (a) a copy of the cytogenetic analysis showing a major cytogenetic response, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; or (b) a copy of the quantitative PCR analysis showing a peripheral blood level of BCR-ABL of less than 1% on the international scale, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; and				

			(3) if the cytogenetic analysis submitted with the application was conducted using FISH with BCR-ABL specific probe because standard karyotyping was not informative, a copy of the non-informative standard karyotype analysis; a patient who has previously received PBS-subsidised treatment with dasatinib and has at any time failed to meet the criteria for continuing treatment, is not eligible for PBS-subsidised re-treatment				

[37] Part 2 of Schedule 1, after item dealing with Hydromorphone

insert in the columns in the order indicated:

Hypromellose	Eye drops 3 mg per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Genteal In a Wink Moisturising
	Eye drops 5 mg per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Methopt
Hypromellose with Carbomer 980	Ocular lubricating gel 3 mg-2 mg per g, 10 g		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Genteal gel HPMC PAA
Hypromellose with Dextran	Eye drops containing 3 mg hypromellose 4500 with 1 mg dextran 70 per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Poly-Tears Tears Naturale

[38] Part 2 of Schedule 1, item dealing with Imatinib in the form Tablet 100 mg (as mesylate)

omit text from the column headed "Purposes" under the heading ***Myelodysplastic or myeloproliferative disorder*** *(second occurring only) and substitute:*

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing PBS-subsidised treatment (at a dose that does not exceed 400 mg per day) of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response, and where the application for authorisation includes: (a) a completed copy of the appropriate Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (b) a copy of the full blood examination report which demonstrates a complete haematological response; and (c) a statement that the disease has not progressed on imatinib therapy				

[39] Part 2 of Schedule 1, item dealing with Imatinib in the form Tablet 100 mg (as mesylate)

(a) *omit from the column headed "Purposes" the heading*

Mastocytosis with eosinophilia *(twice occurring)*

and substitute:

Systemic mastocytosis with eosinophilia

(b) *omit text from the column headed "Purposes" under the heading* ***Systemic mastocytosis with eosinophilia*** *(as amended — second occurring only) and substitute:*

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing PBS-subsidised treatment (at a dose that does not exceed 400 mg per day) of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response, and where the application for authorisation includes: (a) a completed copy of the appropriate Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (b) a copy of the full blood examination report which demonstrates a complete haematological response; and (c) a statement that the disease has not progressed on imatinib therapy				

[40] Part 2 of Schedule 1, item dealing with Imatinib in the form Tablet 400 mg (as mesylate)

(a) *omit from the column headed "Purposes" the heading*

Myelodysplastic or myeloproliferative *(twice occurring)*

and substitute:

Myelodysplastic or myeloproliferative disorder

(b) *omit text from the column headed "Purposes" under the heading* ***Myelodysplastic or myeloproliferative disorder*** *(as amended — second occurring) and substitute:*

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing PBS-subsidised treatment (at a dose that does not exceed 400 mg per day) of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response, and where the application for authorisation includes: (a) a completed copy of the appropriate Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (b) a copy of the full blood examination report which demonstrates a complete haematological response; and (c) a statement that the disease has not progressed on imatinib therapy				

[41] Part 2 of Schedule 1, item dealing with Imatinib in the form Tablet 400 mg (as mesylate)

(a) *omit from the column headed "Purposes" the heading*

Aggressive systemic mastocytosis with eosinophilia *(twice occurring)*

and substitute:

Systemic mastocytosis with eosinophilia

(b) *omit from the column headed "Purposes" under the heading* ***Systemic mastocytosis with eosinophilia*** *(as amended — second occurring) and substitute:*

			In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing PBS-subsidised treatment (at a dose that does not exceed 400 mg per day) of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response, and where the application for authorisation includes: (a) a completed copy of the appropriate Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (b) a copy of the full blood examination report which demonstrates a complete haematological response; and (c) a statement that the disease has not progressed on imatinib therapy				

[42] Part 2 of Schedule 1, after item dealing with Nifedipine

insert in the columns in the order indicated:

Nilotinib	Capsule 200 mg (as hydrochloride monohydrate)		In compliance with authority procedures set out in subsubparagraph 11 (d) (i): Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with nilotinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response to nilotinib, or less than 1% BCR-ABL level in the blood, within 18 months of the commencement of treatment and at 12 monthly intervals thereafter; and where the following conditions apply: a major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells; a bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) indicates a	Oral	112	5	Tasigna

response, at least the biological equivalent of a major cytogenetic response;

response to PBS-subsidised treatment with nilotinib is assessed by:

(1) cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or, in the case where standard karyotyping is not informative for technical reasons, cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe; or

(2) quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale;

the cytogenetic or peripheral blood quantitative PCR analyses demonstrating response are submitted as follows:

(i) between 10 and 18 months of the commencement of treatment with nilotinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated are eligible for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained;

the authority application includes:

(1) a completed copy of the appropriate Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and

(2) demonstration of continued response to treatment as evidenced by:

(a) a copy of the cytogenetic analysis showing a major cytogenetic response, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; or

(b) a copy of the quantitative PCR analysis showing a peripheral blood level of BCR-ABL of less than 1% on the international scale, unless the relevant pathology report has been supplied within the previous 12 months (or 18 months if the application is the first application for continuing treatment), in which case only the date of this report needs to be provided; and

(3) if the cytogenetic analysis submitted with the application was conducted using FISH with BCR-ABL specific probe because standard karyotyping was not informative, a copy of the non-

			informative standard karyotype analysis; a patient who has previously received PBS-subsidised treatment with nilotinib and has at any time failed to meet the criteria for continuing treatment, is not eligible for PBS-subsidised re-treatment				

[43] Part 2 of Schedule 1, after item dealing with Paracetamol

insert in the columns in the order indicated:

Paraffin	Eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	2	11	Duratears Poly Visc
	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Ircal Lacri-Lube Poly Visc

[44] Part 2 of Schedule 1, after item dealing with Phenoxymethylpenicillin

insert in the columns in the order indicated:

Polyethylene Glycol 400 with Propylene Glycol	Eye drops 4 mg-3 mg per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Systane
Polyvinyl Alcohol	Eye drops 14 mg per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Liquifilm Tears PVA Tears

	Eye drops 14 mg per mL, 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Vistil
	Eye drops 30 mg per mL, 15 mL		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Liquifilm Forte PVA Forte
	Eye drops 30 mg per mL, 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)		For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Application to the eye	1	11	Vistil Forte

[45] Part 2 of Schedule 1, after item dealing with Sertraline

insert in the columns in the order indicated:

Sulfasalazine	Tablet 500 mg		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Oral	200	11	Salazopyrin
	Tablet 500 mg (enteric coated)		For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements	Oral	200	11	Pyralin EN Salazopyrin-EN

[46] Part 2 of Schedule 1, item dealing with Tramadol

(a) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 50 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 50 mg

(b) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 100 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 100 mg

[47] Part 2 of Schedule 1, after item dealing with Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 100 mg

insert in the columns in the order indicated:

	Tablet (extended release) containing tramadol hydrochloride 100 mg		In compliance with authority procedures set out in subparagraph 11 (d): Severe disabling pain not responding to non-narcotic analgesics	Oral	20	..	Durotram XR

[48] Part 2 of Schedule 1, item dealing with Tramadol

(a) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 150 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 150 mg

(b) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 200 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 200 mg

[49] Part 2 of Schedule 1, after item dealing with Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 200 mg

insert in the columns in the order indicated:

	Tablet (extended release) containing tramadol hydrochloride 200 mg		In compliance with authority procedures set out in subparagraph 11 (d): Severe disabling pain not responding to non-narcotic analgesics	Oral	20	..	Durotram XR
	Tablet (extended release) containing tramadol hydrochloride 300 mg		In compliance with authority procedures set out in subparagraph 11 (d): Severe disabling pain not responding to non-narcotic analgesics	Oral	20	..	Durotram XR

[50] Part 1 of Schedule 3, item dealing with Tramadol

(a) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 50 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 50 mg

(b) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 100 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 100 mg

[51] Part 1 of Schedule 3, after item dealing with Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 100 mg

insert in the columns in the order indicated:

	Tablet (extended release) containing tramadol hydrochloride 100 mg	Oral	10	..	Durotram XR

[52] Part 1 of Schedule 3, item dealing with Tramadol

(a) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 150 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 150 mg

(b) *omit from the column headed "Form":*

Tablet containing tramadol hydrochloride 200 mg (sustained release)

and substitute:

Tablet (sustained release) containing tramadol hydrochloride 200 mg

[53] Part 1 of Schedule 3, after item dealing with Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 200 mg

insert in the columns in the order indicated:

	Tablet (extended release) containing tramadol hydrochloride 200 mg	Oral	10	..	Durotram XR
	Tablet (extended release) containing tramadol hydrochloride 300 mg	Oral	10	..	Durotram XR