

From: Trish Snegirev <[redacted]>
Sent: Tuesday, 15 October 2019 12:52 pm
To: Elena Saunders <[redacted]>
Cc: Janet Mackay <[redacted]>
Subject: PHARMAC proposal Tandem Basal IQ
Attachments: Habif_RealWorld_dia.2019.0190.pdf, Forlenza etl al_Results of the PROLOG Trial_Diabetes Care 2018.pdf, PHARMAC proposal Tandem Basal IQ.pdf

Hi Elena

As mentioned previously we would like to start supplying an updated Tandem pump model (Brand name is Basal IQ) directly to patients next year under our existing reimbursement arrangements. The technology will already be available to patients who eligible to upgrade from March 2020 and our proposal is seeking to supply the new model directly to patients who are able to access funding for a new pump from 1st May 2020.

I have attached our proposal and two recent published articles supporting the use of Basal IQ.

Please let me know if you need any more information. Also can you please confirm that you have received this application.

Regards
Trish Snegirev
Division Manager



P 09 259 4062 | M [redacted] | F 09 259 4067
Web: www.nzmsdiabetes.co.nz



24hr Technical Support **0508 634 103**

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2a Fisher Crescent, Mt Wellington, Auckland 1060
PO Box 132400, Sylvia Park, Auckland 1644, New Zealand

Proposal to List Tandem Basal IQ™ Insulin Pump



Background

NZMS is seeking to supply the alternative product as per Clause 5 in Annex Four of our Agreement with PHARMAC for the supply of insulin pump and consumables.

NZMS has recently successfully completed the transition of over [redacted] from the Animas Vibe to the Tandem t:slim X2 insulin pump. The t:slim X2 can be used as a stand alone insulin pump or run with the Dexcom G5 continuous glucose monitor as an optional accessory so that the sensor glucose values are displayed directly on the pump. Dexcom G5 is not currently funded in NZ.

One of the benefits of the t:slim X2 technology is that the pump has the ability to receive remote upgrades as new technology becomes available on the platform. This means the user can take advantage of having the most up to date pump and not be locked into older technology for the remainder of a four year warranty period.

The first technology upgrade to be released on the t:slim X2 platform is Basal IQ™. Basal IQ™ features Predictive Low Glucose Suspend (PLGS), which when used with Dexcom G6, will automatically suspend basal insulin delivery if a hypoglycaemic event occurs or is predicted within the next 30 minutes. Due to the nature of Type 1 Diabetes and insulin, hypoglycaemia can still occur when using PLGS technology, however studies have shown that the number of hypoglycaemic events and time spent in hypoglycaemia is significantly reduced and the overall time in range is increased when using Basal IQ™^{1, 2}. The PROLOG study published in 2018 demonstrated a 31% reduction in time spent <3.9mmol/l in participants using Basal IQ™². The study also found that 97% of participants felt very confident using the system².

As more and more users are moving to Basal IQ™, Tandem Diabetes Care have advised that they will move their manufacturing line to Basal IQ™ and plan to cease manufacturing the t:slim X2 in its current format by the end of 2020. The Basal IQ™ pump can be operated as a stand alone insulin pump without the use of CGM and the differences between the t:slim X2™ and Basal IQ™ pump interface are only minor. These differences are detailed later in the proposal.

Basal IQ is currently available in the USA, UK, South Africa, Italy, Spain and the Czech Republic. Approximately 15,000 users have already updated their t:slim X2™ to Basal IQ™ remotely with each one taking an average of just 6 minutes.

NZMS Diabetes is proposing to PHARMAC that it move to reimbursement of Basal IQ to ensure that the latest technology is available to patients eligible for insulin pump funding. NZMS Diabetes is not seeking any increase to the reimbursement price of the Tandem pump or consumables. NZMS is seeking to supply the alternative product under the provisions of Clause 5 in Annex Four of our Agreement with PHARMAC for the supply of insulin pump and consumables and that we would like to begin supplying the new product from 1st May 2020.

This proposal does not extend to a reimbursement application for Dexcom G6. Dexcom G6 is subject to a separate proposal. Users will be able to purchase Dexcom G6 sensors and

transmitters from NZMS Diabetes to enable use of Predictive Low Glucose Suspend until any funding arrangement is agreed to by PHARMAC.

How Basal IQ™ Technology Works

Basal IQ™ is compatible with Dexcom G6™ continuous glucose monitor system. When Basal IQ™ is used with G6, glucose values are transmitted to the pump every five minutes. Based on these readings and an algorithm in the pump, the pump will suspend basal insulin delivery if the sensor glucose reading is <3.9mmol/l or is predicted to be <4.4mmol/l within 30 minutes. Basal delivery will resume when:

- Sensor glucose value increases by one point
- Glucose is no longer predicted to drop <4.4mmol/l
- 10 mins of CGM data missing
- The suspension criteria is no longer true
- User chooses to override the suspension

There is a maximum suspension time of 2 hours every 2½ hours on a continuously sliding time line. An additional safety feature is that the Bolus Menu is not available during auto suspend.

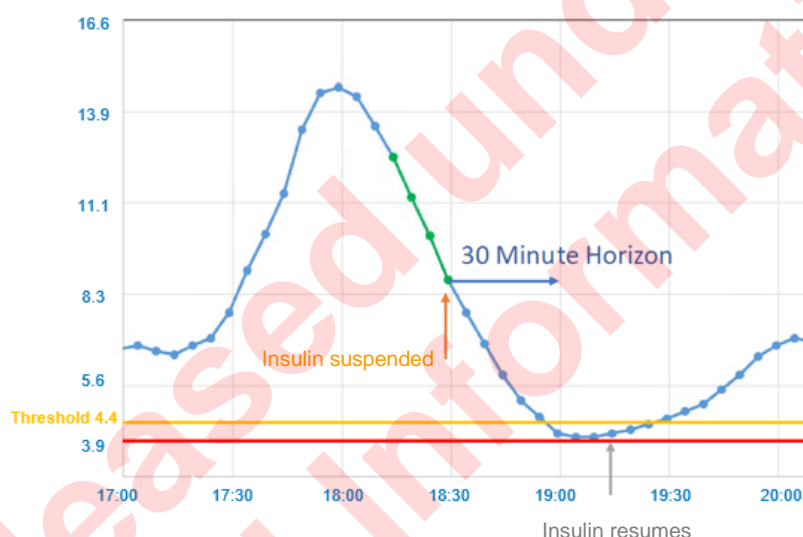


Illustration of Basal IQ Predictive Low Glucose Suspend and Resumption

In the illustration above, it can be seen that at 1830hrs, the algorithm has detected that the glucose value will be <4.4mmol/l at 1900hrs. Basal insulin delivery is stopped thereby preventing a hypoglycaemic event. Insulin delivery is automatically resumed when the sensor value increases by one point.



Illustration of Insulin Suspension Display on Pump

When basal insulin has been suspended, the user will see red bands on the home screen indicating the time and duration of each suspend. Note in the illustration above, that there are four suspensions in the previous three hours and that the glucose level has stayed within range during this time without the patient needing to do anything.

Functional Changes to Basal IQ Pump

There are a few minor screen changes that will be apparent to current users.

- Two new icons are available on the home screen to indicate when PLGS is active
- Red bands are displayed to indicate when LGS has been active
- A new history menu has been added relative to Basal IQ
- The glucose value will be auto-populated in the bolus calculator when using CGM
- A 4-6 user defined security pin code replaces the current feature lock



Funded Pump Comparison

Feature	Tandem t:slim X2™	Tandem® Basal IQ™	Medtronic® 640G
Physical			
Model	t:slim X2™ ³	t:slim X2™ ⁴	1712 ⁵
Colour choice	Black	Black	Black
Dimensions	7 95 x 5 08 x 1 52cm	7 95 x 5 08 x 1 52cm	5 3 x 9 6 x 2 44cm
Weight	112g with full cartridge	112g with full cartridge	95.7g w/out cartridge
Power Source	Rechargeable via µUSB cable	Rechargeable via µUSB cable	1 x AA battery
Battery life	7 days	7 days	7 – 14 days
Water tight	Yes IPX7 0 9 metres up to 30 minutes	Yes IPX7 0 9 metres up to 30 minutes	Yes
Cartridge size	300u	300u	180 and 300 unit
Feature block	Yes	Yes	
CGM enabled	Yes Dexcom G5	Yes Dexcom G6	Yes Medtronic Enlite II
Communication Protocol	Bluetooth	Bluetooth	Radio Frequency
Basal			
Number of segments	16 per program	16 per program	48 per program
Number of programs	6 custom labelled	6 custom labelled	8 pre labelled
Range	0 1 to 15u/hr	0 1 to 15u/hr	0 025 to 35u/hr
Increments	0 001u/hr	0 001u/hr	Varies depending on basal rate
Delivery frequency	5 mins regardless of basal rate	5 mins regardless of basal rate	Varies depending on basal rate
Temp basal range	100% to 250%	100% to 250%	0 to 200%
Temp basal increment	1%	1%	Varies depending on basal rate
Temp basal duration	15 minutes to 72 hours	15 minutes to 72 hours	30 minutes to 24 hrs
Bolus			
On board calculator	Yes	Yes	Yes
Bolus range	0 05 to 25u	0 05 to 25u	0 1 to 75 0u
Increments	0 01u	0 01u	Varies depending on bolus size
Extended/Combo bolus increments	1 min	1 min	30 min
Extended bolus duration	15 minutes to 8 hours	15 minutes to 8 hours	30 mins to 8 hours
Insulin on Board	2 to 8 hours	2 to 8 hours	2 to 8 hours
Exposure hazard to x-rays	Yes	Yes	Yes
Warranty	Four years	Four years	Four years
Software	Diasend	Diasend	Medtronic Link
Delivery accuracy	+/- 5%	+/- 5%	+/- 5%
Other			
Age Indication (Pump Use Only)	6 years and over	6 years and over	2 years and over
Insulin Indication	NovoRapid U100 Humalog U100	NovoRapid U100 Humalog U100	NovoRapid U100 Humalog U100

	Tandem® Basal IQ™	Medtronic® 640G
	Predictive Low Glucose Suspend	
Rules for Suspension	Sensor Glucose <3.9mmol/l OR Predicted to be <4.4mmol/l within 30 minutes	Sensor Glucose within 3.9mmol above user selected low limit AND SG predicted to reach or fall below a level that is 1.1mmol/l above user set low limit within 30 minutes
Minimum Suspension Time	5 minutes	30 minutes if alert confirmed unless overridden by user 2 hours if alert not confirmed by user
Maximum Suspension Time	2 hours every 2½ hours (continually sliding)	2 hours
Refractory Period (time PLGS unavailable)	Always available unless maximum suspension threshold met	30 minutes up to 4 hours
Fingerprick Calibration Requirement	None	Twice daily but 4 recommended.
Interference from Acetaminophen	No	Yes

Consumables for Basal IQ™

There is no change to the insulin pump consumable range required to operate the Basal IQ™ pump

Pricing Model

The pricing of hardware and consumables offered in this proposal is the same as our existing agreement.

Product Code	Pharmacode	Description	Price ex gst
TBA	TBA	Tandem Basal IQ™ insulin pump	\$4,500
1000727-PMAC	2556790	t:slim 300u cartridge	\$50
1000273-PMAC	2556804	AutoSoft™ 90 6mm 60cm	\$140
1000274-PMAC	2556812	AutoSoft™ 90 6mm 110cm	\$140
1000275-PMAC	2556820	AutoSoft™ 90 9mm 60cm	\$140
1000276-PMAC	2556839	AutoSoft™ 90 9mm 110cm	\$140
1000200-PMAC	2556847	AutoSoft™30 13mm 60cm	\$140
1000202-PMAC	2556855	AutoSoft™30 13mm 110cm	\$140
1000289-PMAC	2556863	TruSteel™ 6mm 60cm	\$130
1000290-PMAC	2556871	TruSteel™ 6mm 81cm	\$130
1000293-PMAC	2556898	TruSteel™ 8mm 60cm	\$130
1000294-PMAC	2556901	TruSteel™ 8mm 81cm	\$130

Regulatory Information

Tandem Basal IQ Insulin Pump

191014 WAND 6TERYI

SUPPLEMENTARY INFORMATION

Eligibility for Existing Users to Upgrade to Basal IQ™

NZMS is launching Basal IQ™ Device Updater in NZ in late March 2020. Basal IQ™ uses the same platform as the t:slim X2™ and patients can use the Device Updater to upgrade to the new technology at home. The Device Updater and Basal IQ™ are FDA approved and subject to the highest levels of data encryption.

Customers who are within their four-year warranty period and are purchasing Dexcom from NZMS Diabetes will be eligible for a free upgrade to their t:slim X2™ if they want to take advantage of the benefits that Basal-IQ brings.

Users will need to purchase and use Dexcom G6 sensors and transmitters in order for PLGS to work. Patients not using Dexcom G6 can continue to use their t:slim X2 as a stand-alone insulin pump.

Training of HCPs and Patients Prior to Upgrades

Although not part of this proposal, we would like to advise PHARMAC that upskilling of HCPs and patients will be undertaken prior to anyone being able to upgrade their current pump.

Training existing t:slim X2™ patients to use Basal IQ™ takes approximately 30-40 minutes. On-line training modules are being made available to assist patients before they upgrade and one on one training will be provided to anyone who requests this

HCPs will be provided full training before any of their patients are upgraded to Basal IQ.

References

- 1 Muller L, Habib S, Leas S, Aronoff-Spencer E: Reducing Hypoglycemia in the Real World: A Retrospective Analysis of Predictive Low Glucose Suspend Technology in an Ambulatory Insulin Dependent Cohort Diabetes Technology & Therapeutics 2019;21:10
- 2 Forlenza G, Li Z, Buckingham B et al: Predictive Low-Glucose Suspend Reduces Hypoglycemia in Adults, Adolescents, and Children With Type 1 Diabetes in an At Home Randomized Crossover Study: Results of the PROLOG Trial
- 3 t:slim X2™ User Guide.
- 4 Basal IQ™ User Guide
- 5 Medtronic® 640G Insulin Pump User Guide.

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2020 01 23 File note of call with NZMS pump transition, consumables limits and Basal IQ/Control IQ submission

File note – call with NZMS
23 Jan 2020
9:30am

Attendees:
Trish Snegirev(NZMS)
Hugh Plowright (NZMS)
Elena Saunders (PHARMAC)

Out of scope

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Basal IQ submission

Looking at being able to upgrade to next pump

Control IQ – would be launched, and patient **Withheld under section 9(2)(b)(ii), 9(2)(ba)(i),**

This is software for pump and would be optional

ES to ensure NZMS know when date of SC will be and when to submit any additional information

Elena Saunders | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington

Cell: **Withheld under** | DDI: **Withheld under** | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz
[SEEMail]

Keep in touch! If you would like to receive consults and communications from PHARMAC please sign up [here](#).

From: Joanne McFadyen

Sent: Wednesday, 5 August 2020 3:52 pm

To: Kirstin Brown <[Redacted]>

Cc: Elena Saunders <[Redacted]>

Subject: Amendment to the Agreement to list the Tandem Basal IQ Insulin Pump

Attachments: 2020-08-05 NZMS Amendment for listing Tandem Basal IQ Insulin Pump.pdf

Dear Kirstin

Please find attached an amendment to the agreement to list the Tandem Basal IQ Insulin Pump and delist the Tandem T: Slim X2 assuming there is no change to the consumables. We would really appreciate your help in getting a signed copy back to us as quickly as possible or no later than midday Monday 10 August 2020 for a 1 September listing

Please could you also complete an NOPC form <https://www.pharmac.govt.nz/assets/2019-new-Notification-of-product-changes-form-V2.pdf> no later than midday Monday 10 August for our internal processes.

Acceptance only requires your signatory(s) to sign page 3, no other initialling is required. Also, this is your copy for your records – we do not send hard copies following approval. Please can you scan a complete (all pages) signed copy and return to me via email. Please note that this amendment to the agreement is subject to approval by the Board (or its delegate under delegated authority).

Kind regards
Joanne

Joanne McFadyen | Contracts Administrator

PHARMAC Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [Redacted] | P: +64 4 460 4990 | M: [Redacted] | www.pharmac.govt.nz

5 August 2020

Kirstin Brown
Division Manager
New Zealand Medical and Scientific Limited
2a Fisher Crescent
Mt Wellington
AUCKLAND

By email to: [Withheld under section 9(2)]

Dear Kirstin

AMENDMENT TO TERMS OF LISTING OF INSULIN PUMPS AND CONSUMABLES

We refer to the agreement between PHARMAC and New Zealand Medical and Scientific Limited (**NZMS**) dated 15 February 2012, as amended on 26 July 2012, 16 October 2012 and 2 October 2018, relating to the terms of listing of insulin pumps and consumables in Section B of the Pharmaceutical Schedule ("the **Agreement**").

Background

NZMS wishes to exercise its option to supply an Alternative Brand of insulin pump in accordance with clause 5, Annex Four of the Agreement.

NZMS has notified PHARMAC that the Alternative Brand of insulin pump shall be the Tandem Basal IQ brand, which shall be supplied instead of the Tandem T: Slim X2 insulin pump.

The Alternative Brand Start Date shall be 1 September 2020.

In addition, NZMS and PHARMAC have agreed to delist the Tandem T: Slim X2 insulin pump and the Tandem T: Slim X2 insulin pump will be removed from the Agreement on 1 December 2020.

Amendments to the Agreement

PHARMAC and NZMS agree to amend the Agreement as follows:

- (a) Table One of Appendix One, states the Alternative Brand of insulin pump to be listed in Section B of the Pharmaceutical Schedule, with effect from 1 September 2020 as supplied by you in the form and strength set out in Table One ("New Listing").
- (b) The New Listing shall be available for supply by you at the relevant price ex-manufacturer (exclusive of GST) specified in Table One of Appendix One and is to be subsidised by the Funder at that price from 1 September 2020 ("New Price").

For the avoidance of doubt the New Listing and New Price in Table One will be added to Annex One and Annex Two of the Agreement with effect from 1 September 2020.

- (c) Table Two of Appendix One, states the pharmaceutical to be delisted from the Pharmaceutical Schedule with effect from 1 December 2020 ("Delisted Product").

For the avoidance of doubt the Delisted Product in Table Two will be removed from Annex One and Annex Two of the Agreement with effect from 1 December 2020.

Specific Conditions

This letter of amendment shall be conditional on the following conditions being met:

- i. The transition from the Tandem T:Slm X2 insulin pump to the Tandem Basal IQ insulin pump will be in accordance with the transition plan agreed between PHARMAC and NZMS, including but not limited to communications, contacts, training material and sequencing.
- ii. NZMS shall provide communications to clinicians prior to the Alternative Brand Start Date in respect of the Alternative Brand, and in addition following the Alternative Brand Start Date notify clinicians of any communications between NZMS and patients regarding insulin pumps on an ongoing basis, in order that clinicians have the information they need to manage the full clinical picture for each patient including safety.

General Terms

In accordance with clause 5(b)(i), Annex Four of the Agreement, the terms and conditions of the Agreement will apply to the Alternative Brand of insulin pump as stated in Table One of Appendix One.

For the avoidance of doubt, the terms and conditions of the Agreement, which specifically relate to the Tandem T:Slm X2 insulin pump listed in the Agreement shall apply to the Tandem Basal IQ insulin pump to be listed in the Agreement, unless the context otherwise requires.

All terms defined in the Agreement shall have the same meaning in this letter of amendment, unless otherwise stated.

In the event of any conflict between the terms of the Agreement and the terms stated in this letter of amendment, this letter of amendment shall prevail.

This letter of amendment is conditional on approval of its terms by PHARMAC's Board (or by its delegate acting under delegated authority pursuant to section 73 of the Crown Entities Act 2004, where applicable).


Acceptance

Please confirm that the Agreement is to be amended in the manner set out in this letter of amendment by signing and returning the attached copy of this letter to PHARMAC by 12.00pm on 10 August 2020.

Yours faithfully

Signed and agreed by New Zealand Medical
and Scientific Limited by:

Craig Butler
Manager Procurement and Contracts
PHARMAC


Name: KIRSTIN BROWN
Position: Division Manager
Date: 7 August 2020

APPENDIX ONE

Table One

New Listing to be added to Annex One of the Agreement

<i>Pharmaceutical</i>	<i>Brand</i>	<i>Description</i>	<i>Pack Size</i>
Insulin Pump	Tandem Basal IQ	Min Basal rate 0.1U/h	1

For the purpose of this Agreement:

“**Tandem Basal IQ**” applies to each form and description of Tandem Basal IQ insulin pump referred to in Table One above.

New Price to be added to Annex Two of the Agreement

<i>Presentation of Pharmaceutical</i>	<i>Price (Exclusive of GST) (\$NZ)</i>
Tandem Basal IQ	\$ 4,500.00

Table Two

Delisted Product to be removed from Annex One of the Agreement from 1 December 2020

<i>Pharmaceutical</i>	<i>Brand</i>	<i>Description</i>	<i>Pack Size</i>
Insulin Pump	Tandem t:Slm X2	Min Basal rate 0.1U/h	1

For the purposes of this Agreement:

“**Tandem t:slim X2**” applies to each form and description of Tandem t:slim X2 insulin pump referred to in Table Two above.

From: Kirstin Brown <[redacted]>
Sent: Thursday, 13 August 2020 5:30 pm
To: Schedule <Schedule@Pharmac.govt.nz>; Pharmacode Info <info@pharmacode.co.nz>;
nopc@nzuim.org.nz
Cc: Joanne McFadyen <[redacted]>; Elena Saunders
<[redacted]>; Kaye Wilson <[redacted]>; Doris Chong
<[redacted]>
Subject: FW: Amendment_ Tandem T: Slim Insulin Pump to Tandem T: Slim with Basal IQ Insulin Pump
Attachments: Basal IQ_September 1 2020.pdf

Dear Pharmac Team,

Please see below your Pharmacode for this application:

Pharmacode	Brand Name	Description	Pack Size	Pack UOM	Strength	GS1
2598345	TANDEM	t:slim X2 with Basal IQ Insulin Pump	1.0000	device		

Many Thanks &
Kind Regards,

Kirstin Brown

Division Manager

P +64 (9) 259 4062 | M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Kirstin Brown
Sent: Thursday, 13 August 2020 10:25 a.m.
To: 'schedule@pharmac.govt.nz' <schedule@pharmac.govt.nz>; 'info@pharmacode.co.nz' <info@pharmacode.co.nz>; 'nopc@nzuim.org.nz' <nopc@nzuim.org.nz>
Cc: 'Joanne McFadyen' <[redacted]>; Elena Saunders
<[redacted]>
Subject: FW: Amendment_ Tandem T: Slim Insulin Pump to Tandem T: Slim with Basal IQ Insulin Pump

Dear Pharmac Team,

Regarding the attached submission – confirming that this is a **New Product for the Schedule** (medical device).

NZMS is seeking a Pharmacode for our product; Tandem t:slim x2 with Basal IQ, for a 1 September listing date.

Product Code	Description
PMAC-1006419	Tandem: t:slim x2 with Basal IQ Insulin Pump

Please find attached “Notification of Product Changes Form”

Please let me know if any further information is required

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

P +64 (9) 259 4062 | M [redacted] Withheld under section 9(2)(a)
2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Kirstin Brown
Sent: Wednesday, 12 August 2020 4:06 PM
To: schedule@pharmac.govt.nz; info@pharmacode.co.nz; nopc@nzuim.org.nz
Cc: Elena Saunders <[redacted] Withheld under section 9(2)(a)>; Joanne McFadyen <[redacted] Withheld under section 9(2)(a)>
Subject: RE: Amendment_ Tandem T: Slim Insulin Pump to Tandem T: Slim with Basal IQ Insulin Pump

[Resending attachment](#)

From: Kirstin Brown
Sent: Wednesday, 12 August 2020 3:57 PM
To: schedule@pharmac.govt.nz; info@pharmacode.co.nz; nopc@nzuim.org.nz
Cc: Elena Saunders <[redacted] Withheld under section 9(2)(a)>; Joanne McFadyen <[redacted] Withheld under section 9(2)(a)>
Subject: Amendment_ Tandem T: Slim Insulin Pump to Tandem T: Slim with Basal IQ Insulin Pump

Dear Pharmac Team,

Please accept my apologies for this late submission for the September 1 Schedule.

Many Thanks &
Kind Regards,

Kirstin Brown

Division Manager

P +64 (9) 259 4062 | M [Redacted] Withheld under

2a Fisher Crescent, Mt Wellington, Auckland 1060



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NOTIFICATION OF PRODUCT CHANGES

PHARMAC
TE PĀTAKA WHAIORANGA

GENERAL INFORMATION: COMPLETE ALL FIELDS

PRODUCT DETAILS

Brand name:	Tandem t:slim X2 with Basal IQ Insulin Pump	
Generic name:		
Formulation:		
Pack size:	Each	
Packaging type:	Box	
Pharmacode:		
Unapproved medicine: <small>Please tick</small>	<input type="checkbox"/> s26 medicine	<input type="checkbox"/> s29 medicine

SUPPLIER DETAILS

Company:	New Zealand Medical & Scientific
Contact person:	Kirstin Brown
Phone:	Withheld under section 9(2)(a)
Email:	Withheld under section 9(2)(a)
Today's date:	12 August 2020

ADDITIONAL COMMENTS

CHANGE INFORMATION: COMPLETE ONE SECTION ONLY

NEW PRODUCT

NZMT CTPP:	
GTIN:	None
Supplier item code:	PMAC 1006419
Price ex supplier (excl GST):	\$4500
Effective date:	1 September, 2020

PRICE CHANGE

Current price ex supplier (excl GST):	
New price ex supplier (excl GST):	
Effective date:	

DISCONTINUATION

Effective date:	
-----------------	--

OTHER CHANGE

Details:	
Effective date:	

NOTIFICATION OF PRODUCT CHANGES: THE PROCESS

Complete this form for all **new products** or **changes to products** listed in the Schedule. This includes both contracted and non-contracted products.

- For changes to contracted listings, this form should only be completed after any price change or discontinuation has been agreed with PHARMAC.
- For changes that have not been previously agreed with PHARMAC, suppliers should discuss the change with their Contract Manager before submitting this form.

For new listings in the Pharmaceutical Schedule

For products listed through the **Invitation to Tender**, this information is required by the earlier of:

- 10 business days after Market Notification Date, or
- the 5th day of the month prior to the product being listed in the Schedule.

For **other contracted listings**, this information is required within 10 business days following a provisional listing agreement.

In **all other cases**, such as the listing of an Alternative Pharmaceutical, this information should be provided as soon as possible, and by the earlier of:

- 2 business days after a request for this form by PHARMAC or
- the 12th day of the month prior to the product being listed in the Schedule.

For other changes

This information is required no later than the earlier of:

- 2 business days after a request for this form by PHARMAC, or
- the 12th day of the month prior to the change being effective in the Schedule.

Please note that for changes that require a change in Pharmacode, such as a pack size or brand change, suppliers should submit 2 NOPC forms:

1. delisting the old product, and
2. listing the replacement product.

How to use this form

- Use one form per pharmaceutical product, completing all fields that are applicable.
- Email this form to (as soon as possible, but no later than the dates outlined above) :
 1. PHARMAC (schedule@pharmac.govt.nz)
 2. the Pharmacy Guild (info@pharmacode.co.nz), **and**
 3. the New Zealand Universal List of Medicines (nopc@nzulm.org.nz)
- Suppliers may provide this information in spreadsheet format where a large number of products are changing, as long as all of the required information is provided.

The Pharmacy Guild of New Zealand Inc
PO Box 27 139 Wellington 6141
Phone (04) 802 8200, Fax (04) 384 8085
Email: info@pharmacode.co.nz

PHARMAC
TE PĀTAKA WHAIORANGA

PHARMAC
PO Box 10 254 Wellington 6143
Phone (04) 460 4990, Fax (04) 460 4995
Email: schedule@pharmac.govt.nz

NEW ZEALAND UNIVERSAL
LIST OF MEDICINES
Phone (04) 567 8570
Email: nopc@nzulm.org.nz

MEMORANDUM FOR CONSIDERATION UNDER DELEGATED AUTHORITY

To: Director of Operations
From: Manager, Procurement and Contracts
Date: August 2020

MINOR SCHEDULE CHANGES

Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposals using the Factors for Consideration in the [Operating Policies and Procedures](#). Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The decision maker is not bound to accept PHARMAC staff's assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.



Footnotes

¹ The person receiving the medicine or medical device must be an eligible person, as set out in the [Health and Disability Services Eligibility Direction 2011](#) under Section 32 of the [New Zealand Public Health and Disability Services Act 2000](#).

² The current Māori health areas of focus are set out in PHARMAC's [Te Whaioranga Strategy](#)

³ Government health priorities are currently communicated to PHARMAC by the Minister of Health's [Letter of Expectations](#).

⁴ Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

⁵ Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this factor should be considered alongside those depicted in the schematic.

Consultation

Section 49(a) of the NZPHD Act requires PHARMAC to consult, when it considers it appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that, in the view of PHARMAC, may be affected by decisions on those matters

PHARMAC staff do not consider that sections of the public, groups or individuals would be significantly affected by decisions on the proposals relating to the items listed as numbers 1 – 7, in the document and do not consider that consultation is necessary or appropriate on those items, because:

- adequate funded alternatives would remain listed on the Pharmaceutical Schedule;
- the proposals in this paper seek to ensure the Pharmaceutical Schedule listings reflect the intent of previous decisions (for which consultation occurred);
- the proposals do not result in any additional financial expenditure
- the proposals would result only in improvements to procurement, dispensing, subsidy and claiming mechanisms; and/or
- The proposals are a necessary response to circumstances beyond PHARMAC's control, or are consequential to a decision already taken.

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•Advisor Conflicts of Interest

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•The recommendations in this paper do not rely on PTAC or Subcommittee advice.

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Glossary of terms and abbreviations

The terms and abbreviations used in this paper are set out in the attached/linked document below.



Glossary of Terms.obr

Recommendations

It is recommended that having regard to the decision criteria set out in Section 2.2 of PHARMAC's Operating Policies and Procedures you exercise your delegated authority and

resolve to amend Section B and/or Part D and/or Part II of Section H of the Pharmaceutical Schedule from the dates in this proposal and in the manner summarised in this document; and

resolve that consultation on the proposals in this paper was not necessary or appropriate.

6. Tandem Basal IQ Insulin Pump listing in Section B of the Pharmaceutical Schedule and the Tandem T: Slim X2 Insulin Pump delisting – amendment

resolve to list New Zealand Medical and Scientific Limited's brand of Tandem Basal IQ insulin pump in the Alimentary Tract and Metabolism therapeutic group in Section B of the Pharmaceutical Schedule from 1 September 2020 as follows:

Chemical and presentation	Brand	Pack Size	Subsidy and price (ex-man., ex GST)
Insulin pump Min basal rate 0.1U/h	Tandem Basal IQ	1	\$4,500 00

resolve to delist the following product from Section B of the Pharmaceutical Schedule on 1 December 2020:

Chemical and presentation	Supplier	Brand
Insulin pump Min basal rate 0 1U/h	New Zealand Medical and Scientific Limited	Tandem t: Slim X2

resolve to approve the Amendment to terms of listing of insulin pumps dated 5 August 2020 in Section B of the Pharmaceutical Schedule

Background and analysis

NZMS wishes to exercise its option to supply an alternative brand of insulin pump in accordance with clause 5, Annex Four of the agreement dated 15 February 2012 as amended 2 October 2018.

NZMS's proposal is to list the Tandem Basal IQ insulin pump from 1 September 2020 and delist the currently supplied brand Tandem T: Slim X2 from 1 December 2020.

The Tandem hardware, consumables and price remains the same, NZMS have requested a software upgrade advancing to the Basal IQ product features.

The implementation and comms would be managed by the supplier.

Summary of Financial Impact

[illegible]

Description	Financial impact 5 year NPV @ 8% discount		
	CPB		Other financial impacts
	Community	DHB Hospital	
Withheld under section 9(2)(b)(ii)			
Withheld under section 9(2)(b)(ii)			
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Withheld under section 9(2)(b)(ii)			
TOTAL	Withheld under section 9(2)(b)(ii)		

DELEGATED AUTHORITY

August 2020

The Director of Operations, exercising the authority delegated by the Chief Executive under the Financial Delegations Policy has made the following decision to:

resolve to amend Section B and/or Part D and/or Part II of Section H of the Pharmaceutical Schedule from the dates in this proposal and in the manner summarised in this document; and

resolve that consultation on the proposals in this paper was not necessary or appropriate.

[illegible]

[illegible]

6. Tandem Basal IQ Insulin Pump listing in Section B of the Pharmaceutical Schedule and the Tandem T: Slim X2 Insulin Pump delisting – amendment

resolve to list New Zealand Medical and Scientific Limited's brand of Tandem Basal IQ insulin pump in the Alimentary Tract and Metabolism therapeutic group in Section B of the Pharmaceutical Schedule from 1 September 2020 as follows:

Chemical and presentation	Brand	Pack Size	Subsidy and price (ex-man., ex. GST)
Insulin pump Min basal rate 0.1U/h	Tandem Basal IQ	1	\$4,500.00

resolve to delist the following product from Section B of the Pharmaceutical Schedule on 1 December 2020:

Chemical and presentation	Supplier	Brand
Insulin pump Min basal rate 0 1U/h	New Zealand Medical and Scientific Limited	Tandem t: Slim X2

resolve to approve the Amendment to terms of listing of insulin pumps dated 5 August 2020 in Section B of the Pharmaceutical Schedule

New Listings

Effective 1 September 2020

14 INSULIN PUMP – Special Authority see SA1603 – Retail pharmacy

a) Maximum of 1 dev per prescription

b) Only on a prescription

c) Maximum of 1 insulin pump per patient each four year period

Min basal rate 0.1 U/h

4,500.00

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✓ Tandem Basal IQ

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14	INSULIN PUMP Special Authority see SA1603 Retail pharmacy				
	a) Maximum of 1 dev per prescription				
	b) Only on a prescription				
	c) Maximum of 1 insulin pump per patient each four year period				
	Min basal rate 0.1 U/h	4,500.00	1		✓ Tandem t:slim X2

Out of scope

From: Gillian Anderson <[Redacted] Withheld under section 9(2)(a) [Redacted]>
Sent: Thursday, 26 November 2020 12:47 pm
To: Alishba Ali <[Redacted] Withheld under section 9(2)(a) [Redacted]>
Subject: NZMS - Tandem pumps notes

NZMS

[Redacted] Out of scope

[Redacted] Out of scope

- The 6.4 and 6.4.1 (Basal IQ software) G6 – next advancement in software, automated process. This has been
- Control IQ – different model which offers hypo and hyperglycaemic events
- [Redacted] Withh [Redacted] patients upgraded to the 6 4 1 is there a plan to upgrade patients?
 - This is a possibility and could be rolled out – possibly take 8 months for the [Redacted] Withh [Redacted] fleet
 - NZMS think it would be low that Medsafe ask them to do this – could be done though
 - [Redacted] Out of scope
- New model likely in February 2021

Ngā mihi

Gillian Anderson | Contract Manager/Team Leader | Procurement & Contracts

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [Redacted] Withheld under [Redacted] | P: +64 4 460 4990 | M: [Redacted] Withheld under [Redacted] | www.pharmac.govt.nz

[SEEMail]

From: Alishba Ali [mailto: [redacted]]
Sent: Wednesday, 25 November 2020 4:47 PM
To: Kirstin Brown < [redacted] >
Subject: RE: [redacted] - Tandem T: Slim X2 Insulin Pump

Hi Kirstin,

I trust that my email finds you well. Thank you for providing the information.

I am just touching base to ask if there has been an update on the Tandem pump. I understand that there is an update expected this week and would appreciate information that you can share. I am happy to discuss this over the phone – my contact details are in my signature below.

Ngā mihi,

Alishba Ali | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
P: +64 4 460 4990 M: [redacted] | www.pharmac.govt.nz

From: Kirstin Brown < [redacted] >
Sent: Wednesday, 18 November 2020 7:13 am
To: Alishba Ali < [redacted] >
Cc: Gillian Anderson < [redacted] >
Subject: RE: [redacted] - Tandem T: Slim X2 Insulin Pump

Hi Alishba,

Thank you very much for reaching out – lovely to meet you.

[redacted] Out of scope
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[redacted] Out of scope

Regarding your questions:

- The total number of NZ patients using a Tandem t:slim X2 pump is around [redacted]
- Around [redacted] of these have not yet upgraded to the BIQ Pump and are on the Tandem t:slim X2 (G5) with version 5.2.2 software. [redacted] Out of scope
[redacted] Out of scope
- The alternative to the Tandem t:slim X2 with version 5.2.2 software is the Tandem t:slim X2 BIQ with version 6.4.1 software and the Tandem t:slim X2 CIQ version software. [redacted] Out of scope
[redacted] Out of scope
[redacted] Out of scope

Alishba, I will be in touch early next week or as soon as I have any updated information to share on this.

Many Thanks &

Kind Regards,

Kirstin Brown

Division Manager

P +64 (0)9 259 4062 | M [Redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Alishba Ali [mailto:[Redacted]]
Sent: Tuesday, 17 November 2020 1:24 PM
To: Kirstin Brown <[Redacted]>
Cc: Gillian Anderson <[Redacted]>
Subject: RE: [Redacted] Out of scope Tandem T: Slim X2 Insulin Pump

Dear Kirstin,

Thank you for your advisement dated 6 November 2020 in relation to the Tandem T: Slim X2 Insulin Pump. I would like to also take this opportunity to introduce myself as your current Contract Manager.

I am contacting you to seek further information, particularly in relation to the items below:

- What is the total number of patients on the Tandem T: Slim X2 (I note that you have advised an install fleet of [Redacted] pumps, please confirm if this is equivalent to the number of patients currently using the pump)?
- How many of the above have not already been upgraded to the new Basal IQ software?
- Are there any alternative products that can be used in place of the Tandem T: Slim X2?

In addition, we are also interested to find out more about the proposal that you have indicated. I am contactable via email, or you can call Gillian Anderson on [Redacted] for further discussion.

I look forward to your response.

Kind regards,

Alishba Ali | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

Subject: Out of scope - Tandem T: Slim X2 Insulin Pump

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As you are aware NZMS launched the Tandem T: Slim X2 with Basal IQ Insulin Pump (WAND Ref: 191014 WAND 6TERYI) to pair with Dexcom G6 CGM device on the Pharmac Listing Schedule 1 October 2020 at this time we also removed the Tandem T: Slim X2 version 5.2.2 software Insulin Pump (WAND Ref: 180418 WAND 6Q679H) from the listing. This and the Dexcom G5 are no longer sold in the NZ market. NZMS is currently trialling in market the latest Basal IQ software version 6.4.1, Out of scope
Out of scope. We propose an option of an upgrade project of our full NZ fleet to this software version, as part of a managed compliance plan.

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Elena, if you have any questions or concerns, then please do not hesitate to contact me. I am more than happy to meet to discuss this afternoon or next week.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

P +64 (0)9 259 4062 | M Withheld under
2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Kirstin Brown <[Redacted]>
Sent: Thursday, 3 December 2020 6:34 pm
To: Alishba Ali <[Redacted]>
Subject: Weekly update (3 Dec 2020)

Hi Alishba,

I hope this finds you well.

[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

As discussed last week NZMS are planning software upgrade activities for next year which include, amongst others ...the launch of the Tandem t:slim x2 with a “Control IQ Software” – available in NZ from April 2021. Alishba, I have a couple of contract / operational questions relating to this (below) which I would appreciate your direction on...

What is Control IQ

The Tandem t:slim x2 with Control IQ in partnership with Dexcom G6 Continuous Glucose Monitoring (CGM) acts as an artificial pancreas for patients with Type 1 Diabetes and automates insulin delivery; addressing both hypoglycaemia and hyperglycaemia. Also called an advanced hybrid closed loop system, it consists of a Tandem t:slim x2 Insulin Pump, a Dexcom G6 glucose sensor, and the Control IQ software algorithm that continuously modifies the rate of insulin infusion on the basis of input from the sensor. Control IQ advanced hybrid closed loop technology makes it easier, by using Dexcom G6 CGM values to predict glucose levels 30 minutes ahead – the algorithm automatically adjusts insulin delivery to help increase the patients time in range. The system offers automatic correction boluses for added protection and includes Sleep and Exercise Activity settings for more personalised and targeted control. As well as the improved clinical outcomes from extended time in range the system offers patients automated control and consistency and gives them back time and lifestyle freedoms.

NZMS's Questions for Pharmac

1. Alishba, previously (I believe in late 2019) NZMS made a submission for reimbursement of the Dexcom G6 CGM. That submission did not include pricing at the time. Can you please let me know Pharmac's current position on CGM Reimbursement and what the next steps might be for discussing this further, to progress our submission.
2. NZMS has been able to provide the Basal IQ upgrade without additional cost to the NZ Market,
[Redacted]
[Redacted]
○ [Redacted]
[Redacted]
[Redacted]

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i)

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i)

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i)

Look forward to discussing this further with you tomorrow at 10am. Speak soon.

Many Thanks &
Kind Regards,

Kirstin Brown

Division Manager

P +64 (9) 259 4062 | M Withheld under
2a Fisher Crescent, Mt Wellington, Auckland 1060



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FILE NOTE

Subject:	Tandem pump Out of scope
Event Type:	Phone Call
Author:	Alishba Ali
Attendees:	Alishba Ali (AA) PHARMAC Kirstin Brown (KB) – NZMS
Location:	Phone call
Date event took place:	11 December 2020

Update:

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- KB also advised that the new software is all ready to go in NZ in January to ensure that all pumps in NZ are upgraded to version 6.

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From: Alishba Ali [mailto: [redacted]]

Sent: Friday, 18 December 2020 9:44 AM

To: Kirstin Brown < [redacted] >

Subject: RE: Weekly update (17 Dec 2020)

Hi Kirstin,

Thank you for the update. As there have been no new developments this week, may I suggest that we reschedule this to Friday, 8 January 2021 or Friday, 15 January 2021 (depending on your best availability)?

Wishing you a very joyful festive season. Happy holidays!

Ngā mihi,

Alishba Ali | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington

DDI: [redacted] | P: +64 4 460 4990 | M: [redacted] | www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2020 to 4 January 2021 inclusive.

PHARMAC
TE PĀTAKA WHAIORANGA

From: Kirstin Brown < [redacted] >

Sent: Thursday, 17 December 2020 6:01 pm

To: Alishba Ali < [redacted] >

Subject: Weekly update (17 Dec 2020)

Hi Alishba,

I hope this finds you well.

[redacted]
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NZMS is well into preparations for launching a full market upgrade to the latest software version in early January 2021. This will ensure NZ customers are getting access to the most up to-date advances in the technology.

Look forward to speaking with you tomorrow.

Many Thanks &
Kind Regards,

Kirstin Brown

Division Manager

P +64 (9) 259 4062 | M [REDACTED]
2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Kirstin Brown <[Redacted]>
Sent: Thursday, 14 January 2021 9:29 pm
To: Alishba Ali <[Redacted]>
Subject: Weekly Update (15 January 2021)

Hi Alishba,

I hope this finds you well.

[Redacted] Out of scope
[Redacted] Out of scope
[Redacted] Out of scope
[Redacted] Out of scope

- **Basal IQ Features will be available for all Tandem Pumpers, via a firmware upgrade as of January 25th, 2021.**

Like any modern device such as smartphones, keeping the Tandem pump updated with the latest software is important to ensure that our Patients have access to all the latest enhancements, so that they can get the most out of their pumping experience. Later this month NZMS will offer all New Zealand Tandem customers, with in-warranty pumps, the opportunity to upgrade their Pump to the latest Basal IQ version.

- **Launch plans are in place for Control IQ software in NZ.**

NZMS will trial 5 patients on Control IQ from January 27th with a trial review set for the 8th of March. All going well from the 15th of March we will run a pre launch to a select group of patients by the HCP's with a plan for a broader market launch May 3rd.

- **Questions for Pharmac**

Wondering if you have had any responses from your colleagues around the questions I asked late last year... 1) NZMS's next steps for our submission for reimbursement of the Dexcom G6 CGM and also, Wi

[Redacted] Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i)
[Redacted] Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i)
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[Redacted] Withheld under section 9(2)(b)(ii)
[Redacted] Withheld under section 9(2)(b)(ii)

Look forward to discussing these things with you next week Alishba Keep well!

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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2a Fisher Crescent, Mt Wellington, Auckland 1060



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Official Information Act