

Procedure for *BPaL(M)* regimen and *Delamanid* request

The pulmonologist/infectious disease specialist requests reimbursement for the medications **Sirturo (Bedaquiline)** and/or **Dovprela (Pretomanid)** or **Deltyba (Delamanid)** from BELTA-TBnet.

Prior authorization for the purchase of these medications is granted by BELTA-TBnet.

In general, authorization is granted for:

- **1 box of Sirturo** (188 tablets)
- **7 boxes of Dovprela** (26 tablets each) to treat the patient.

Ordering Information:

- **Sirturo (Bedaquiline)**
Can be ordered directly by your hospital from **Janssen Belgium**.
The BELTA-TBnet authorization (Bedaquiline – BDQ) must be included with your purchase order.
Each box of Sirturo contains **188 tablets**.
Price: **€24.758,11 VAT included**
- **Delamanid**
Can also be ordered directly by your hospital.
You must attach the BELTA-TBnet authorization (Delamanid – DLM) to your order, along with the **order form** (see attachment).
Price: **€22.330,00 VAT included**
- **Dovprela (Pretomanid)**
Must be ordered directly from **Tanner Pharma (Switzerland)** by your hospital.
Price: **€22.423,69 VAT included**

Contact details are provided below.

150-8-1-1: Signalétique Fournisseurs		VERELLEN,HERMAN
Données SBIM		
Code : 1700200	Nom : TANNER PHARMA CH GMBH	
Actif : [*]	CptB : CH490027327314633360V	
N° TVA : DE 345884940	BIC : UBSWCHZH80A	
Classe TVA : IC-Intra-Com.	Devise : EURO	
Données Roméo — Vous éditez le Siège Central de ce fournisseur		
Succursale :	Nom : TANNER PHARMA CH GMBH *	
Actif : [*]	Synonyme 1 :	
S.Compta : []	2 :	
Réf.Cli. :	3 :	
Escompte : []	Adr.1 : ALte Steinhauserstrasse 21	
Tél :	2 :	
Fax :	CP : CH-6330	
Comment. : []	Ville : CHAM	
Commandes		
Langue : Français		
Secteur(s) :		
Montant Min :	Dest. : pretomanidaccess@tannerpharma.com	
Frais sinon :	Copie :	
Type d'Envoi: Email PDF	Conf. :	

One box of Dovprela contains 26 tablets. The unit price per tablet is €116.2331 excluding VAT and €123.2071 including VAT.

Code: S12027	Actif : 01/04/2023-31/12/9999
Libellé: DOVPRELA 200 mg TABS	
Code ATC: J04AK08 - Pretomanid	
Code Wish: 17930	Prix Rev.: 123.2071
Cat: D	Prix *: 123.2071
Inami/APB: 7799984	Prix **: 123.2071
Réf.Fab.:	Unité Dél.Pat: COMP
Fournis.: 1700200-TANNER PHARMA CH	
Réf.Fou.:	Cond.Fourn: BOITE = 26xCOMP
Code Cpt: 600000	type(s) Factu: Patient et Interne
Groupe: 5531	Info:
Famille: 999 PRODUIT IM	
Au Form.: Non	
Créé: 12/04/2023 - 09:27 par VERELLEN,HERMAN	
Mod.: 31/08/2023 - 14:40 par NAVARRE,ALICE	

⚠ Important Notice

These medications **must not be charged to the patient or to the RIZIV.**

Please invoice **BELTA-TBnet directly** (info@belta.be) for the full amount, and attach a copy of:

- Your **purchase invoice**
- The **authorization letter** from BELTA-TBnet

If the patient is discharged from the hospital

Any remaining medication must be made available to the patient through the FARES-VRGT service. This service should oversee the continuation of treatment.

Urgent Start of Treatment

To enable early treatment initiation, **CHU Saint-Pierre Brussels** can lend you **1 box of Dovprela (26 tablets)**.

This box must be **returned once your order from Tanner Pharma arrives**.

Same-Day Supply of Sirturo

If urgently needed, **Sirturo ordered from Janssen** can be **delivered the same day**, provided this is mentioned on your purchase order.


Contact Details – CHU Saint-Pierre Pharmacy

 **CHU Saint-Pierre – Pharmacy**

Rue Haute 322

1000 Brussels

 **pharmaciens@stpierre-bru.be**

 **+32 2 535 44 61**

Procedure for BPaL(M) regimen and Delamanid request

PTM 22.000€
BDQ: 25.000€



The physician diagnoses RR/MDR-TB in the patient.

The physician sends the *MDR-TB standard form* to the BELTA-TBnet coordinator at info@belta.be

The BELTA-TBnet coordinator shares the *MDR-TB standard form* with the Expert Group.

Adverse event

Case discussion by Expert Group

Treatment Prolongation

Change of treatment

**BPaL(M)-treatment:
agreed**
Consensus within 48h by the experts group

BELTA-TBnet coordinator provides *BDQ-PTM-DLM guarantee letters* to the physician

The physician is required to fill out, sign, and return *BDQ-PTM-DLM guarantee letters* to the BELTA-TBnet coordinator

The physician provides the hospital pharmacy with the signed *guarantee letter(s)* for order

- The hospital pharmacy includes
- the signed *PTM guarantee letter* for order to Tanner Pharma: PDWet@tannerpharma.com, JWieland@tannerpharma.com, pretomanidaccess@tannerpharma.com
 - the signed *BDQ guarantee letter* to Johnson & Johnson (former Janssen) for order: slavenne@its.jnj.com & salesdesk@jacbe.jnj.com
 - if applicable, the signed *DLM guarantee letter* and *order form* for order to Otsuka (see attachment)

The hospital pharmacy sends the BPaL(M)/Delamanid-treatment to the beneficiary hospital service and prepares the invoice at cost price for BELTA-TBnet: info@belta.be

Order Form

Shipping Address:

Billing Address (if different):

Organisation Name:
 Street Address:
 Street Address:
 City, Post code:
 VAT Reg. No.:
 Contact Person:
 Phone/Fax:
 E-mail:

Please return the completed Order Form via fax or e-mail to order@otsuka-onpg.com

Quantity	Article No.	Article Description	Unit Price	Total
		Delyba™ 50 mg, 40 film-coated tablets		

- This order is an initial supply for a hospitalised patient.
- This order is an initial supply for an out-patient.
- This order is a re-supply for an out-patient. Remaining duration of treatment is days.
- This order is for stock.

I herewith confirm the following:

- My/the treatment facility's experience in the management of multidrug-resistant tuberculosis
- That appropriate infection control measures are in place at the treatment facility
- That the treatment facility has access to drug susceptibility testing
- That the treatment facility has access to quality assured drug supply for the appropriate combination treatment regimen throughout the planned treatment
- That the treatment facility has access to ECG (electrocardiogram) testing and interpretation
- That pharmacovigilance reporting guidelines will be followed
- That the risk minimisation information supplied will be provided to the treating physician
- That appropriate education will be provided to patients on the risk of use during pregnancy and breast-feeding

Name: Name of treating physician:
 Date: E-mail:
 Signature: Telephone: