



L-Uffiċċju tal-Uffiċjal Mediku Ewlieni

Office of the Chief Medical Officer

DH CIRCULAR No. 105/2012
DH 1555/2012

29th March 2012

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: HMG CoA Reductase Inhibitors (Statins)

It is being brought to your attention that protocol 181 for HMG CoA Reductase Inhibitors (Statins) has been deleted and replaced by protocols (attached):

- 12 - Atorvastatin
- 71 - Fluvastatin

Patients will be entitled to statins under one of the following conditions that fall under the Fifth Schedule of the Social Security (Amendment) Act, 2012:

1. Cerebrovascular Disease
2. Chronic Kidney Disease
3. Diabetes Mellitus
4. Genetic Dyslipidaemia
5. Hypertension
6. Ischaemic Heart Disease
7. Peripheral Vascular Disease

Simvastatin will no longer be protocol regulated.

Fluvastatin should be used in patients with Chronic Kidney Disease and patients intolerant to simvastatin. It will be regulated by protocol 71.

Atorvastatin should be used when the target LDL is not achieved with another statin. It will be regulated by protocol 12.

Patients are entitled to Atorvastatin when despite the use of another statin, the respective target LDL levels (as per attached protocol) are not achieved. In this case, the lipid profile (laboratory test) must be attached with the request form in order to be processed. The application will not be processed if the lipid profile is not attached.

DIPARTIMENT TAS-SAĦĦA



DEPARTMENT OF HEALTH

MALTA

L-Uffiċċju tal-Uffiċjal Mediku Ewlieni

Office of the Chief Medical Officer

Applicants are being requested to specify the medical substance when prescribing a particular statin through the Schedule V and permit applications (including renewals) e.g. 'Fluvastatin' instead of 'Statins'.

The old statins request form will no longer be accepted.

For your attention, please

Dr. Natasha Azzopardi Muscat
Chief Medical Officer

"PALAZZO CASTELLANIA" 15, MERCHANTS STREET, VALLETTA, VLT 03

Tel. Nos. +00356 21224071/ 2299 2232

Fax no. +00356 2299 2663

e-mail: dgss.mhec@gov.mt

Version 01

Sept 11

Atorvastatin Tablets

Prescriber Criteria: Consultant

Out-patient and In-patient use:

1. Cerebrovascular Disease
2. Chronic Kidney Disease
3. Diabetes Mellitus
4. Genetic Dyslipidaemia
5. Hypertension
6. Ischaemic Heart Disease
7. Peripheral Vascular Disease

To be used when the target level is not achieved with simvastatin/fluvastatin:

- Low risk level: LDL[#] >3
 1. Hypertension
 2. Genetic Dyslipidaemia
- High risk level: LDL[#] >2
 1. Cerebrovascular Disease
 2. Chronic Kidney Disease
 3. Diabetes Mellitus
 4. Ischaemic Heart Disease
 5. Peripheral Vascular Disease

[#]Lipid profile MUST be attached with application for request to be processed

Duration of Approval:

10 years

Fluvastatin Capsules and Prolonged Release Tablets

Prescriber Criteria: Consultant

Out-patient and In-patient use:

1. Chronic Kidney Disease

Fluvastatin should be used in patients intolerant to simvastatin with the following Schedule V conditions:

2. Cerebrovascular Disease
3. Diabetes Mellitus
4. Genetic Dyslipidaemia
5. Hypertension
6. Ischaemic Heart Disease
7. Peripheral Vascular Disease

Duration of Approval:

10 years

STATINS REQUEST FORM

Patient's Name and Surname: _____	
Date of Birth: _____	I.D. Card No: _____
Address: _____	
Age: _____ Tel/Mob No: _____ Date of application: _____	
First Application <input type="checkbox"/>	Renewal <input type="checkbox"/>
FLUVASTATIN	
Schedule V Condition:	
<input type="checkbox"/> Chronic Kidney Disease	
Schedule V Condition:	
<input type="checkbox"/> Cerebrovascular Disease	<input type="checkbox"/> Hypertension
<input type="checkbox"/> Diabetes Mellitus	<input type="checkbox"/> Ischaemic Heart Disease
<input type="checkbox"/> Genetic Dyslipidaemia	<input type="checkbox"/> Peripheral Vascular Disease
Reason why fluvastatin is requested: _____	
ATORVASTATIN (to be used when target LDL level is not achieved with fluvastatin/simvastatin)	
High Risk: LDL* > 2	Low Risk : LDL* >3
Schedule V Condition:	Schedule V Condition:
<input type="checkbox"/> Cerebrovascular Disease	<input type="checkbox"/> Hypertension
<input type="checkbox"/> Chronic Kidney Disease	<input type="checkbox"/> Genetic Dyslipidaemia
<input type="checkbox"/> Diabetes Mellitus	
<input type="checkbox"/> Ischaemic Heart Disease	
<input type="checkbox"/> Peripheral Vascular Disease	
*Lipid profile MUST be attached with application for request to be processed	
_____ Signature of Consultant	_____ Name in Block Letters and Medical Council Reg. Number
Date _____	
For office use only:	
Atorvastatin: Lipid profile attached <input type="checkbox"/>	Approved <input type="checkbox"/>
	Not Approved <input type="checkbox"/>
_____ Pharmacist's Signature	_____ Name in Block Letters
	_____ Date

Kindly fill ALL required sections

Data Protection Statement

All personal data is required to provide you with health care services as necessary, and is processed in accordance with the Data Protection Act, and as permitted by law. Further information about your data can be obtained on request.