



Strategy and Sustainability Division
MINISTRY FOR HEALTH, THE ELDERLY AND COMMUNITY CARE

DH CIRCULAR No.111/2011

DH 2262/2011

17th May, 2011

Attention all Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: HMG CoA Reductase Inhibitors (Statins) protocol and Request form

The statins protocol (No.181) has been updated to include both first and second line statins to mirror international guidelines. Thus, atorvastatin protocol (No.12) will be deleted. Nephrotic Syndrome and Chronic Renal Failure, both current Schedule V conditions, have been added to the existing conditions for entitlement in the protocol (attached).

Patients will be entitled to first line statins under one of the following conditions that fall under the second part of the Fifth Schedule of the Social Security Act (2007)

- (i) Ischaemic Heart Disease
- (ii) Nephrotic Syndrome
- (iii) Chronic Renal Failure
- (iv) Hypertension: For hypertension patients should have a HEARTSCORE total CVD risk of $\geq 5\%$ (High Risk Quick calculator accessed from <http://www.heartscore.org/Pages/welcome.aspx>) - in this case HEARTSCORE documentation should be attached.
- (v) Diabetes Mellitus: Schedule II entitlement and SLH 145 should be presented for dispensing purposes.

Patients are entitled to second line statins when despite use of first line statins, respective target 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.

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Subsequently the statins request form (attached) has been amended accordingly to reflect the above-mentioned changes.

The old statins request form (carbonized in triplicate) will not be accepted any longer.

Thank you

For your attention, please

Dr Natasha Azzopardi Muscat

Director General

HMG CoA Reductase Inhibitors (Statins)

Prescriber Criteria: Consultant

Clinical Indications:

Hypercholesterolaemia

Conditions qualifying patients for drug:

Treatment with statins is provided to *all patients irrespective of their age*, when any of the following criteria are met with:

1. *Irrespective of the LDL cholesterol level with:*

- a) documented ischaemic heart disease following -
 - i) an acute myocardial infarction, OR
 - ii) a percutaneous coronary intervention, OR
 - iii) a coronary artery bypass

- b) familial (type 2) hypercholesterolaemia

2. *LDL cholesterol \geq 4.1mmol/L with either:*

- a) documented ischaemic heart disease, other than the conditions listed in point 1a above, OR
- b) diabetes mellitus

3. *LDL cholesterol \geq 4.1mmol/L, without ischaemic heart disease but with 2 or more of the following risk factors:*

- a) hypertension (blood pressure persistently above 160/95mmHg)
- b) family history for IHD (first degree relatives aged \leq 50)
- c) cerebral/peripheral vascular disease
- d) obesity (BMI $>$ 35%)

Investigations prior to starting treatment:

- Fasting lipid profile
- Liver function tests
- Creatine kinase estimation
- Thyroid function tests
- Fasting blood glucose

Objective indicators of efficacy:

Blood cholesterol levels

Patient Consent form:

No need for patient consent form or other declaration. However, all patients have to be informed of potential side-effects by the responsible physician

Duration of Approval:

10 years

Specific request form available (carbonized in triplicate).



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"/>
Schedule V Condition:		
<input type="checkbox"/> Ischaemic Heart Disease <input type="checkbox"/> Nephrotic Syndrome <input type="checkbox"/> Chronic Renal Failure <input type="checkbox"/> Hypertension - with a HEARTSCORE total CVD risk of $\geq 5\%$ * (http://www.heartscore.org/eu/high/Pages/Welcome.aspx)		
*HEARTSCORE® documentation MUST be attached with application for request to be processed		
Schedule II (+SLH 145):		
<input type="checkbox"/> Diabetes Mellitus		
Criteria for Eligibility for Second Line Statin:		
<i>Failure to achieve target LDL level</i>		
<input type="checkbox"/> High risk LDL* <2	<input type="checkbox"/> Low risk LDL* <3	
Ischaemic Heart Disease	Hypertension	
Nephrotic Syndrome		
Chronic Renal Failure		
Diabetes Mellitus		
*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:		
Hypertension: HEARTSCORE® documentation attached		<input type="checkbox"/>
Second line Statin: Lipid profile attached		<input type="checkbox"/>
Approved <input type="checkbox"/>	Not Approved	<input type="checkbox"/>
_____ Pharmacist's Signature	_____ Name in Block Letters	_____ Date

This form will be returned to the Consultant if any section is not completed.

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.