#### Statin monotherapy for the treatment of hypercholesterolaemia & prevention of cardiovascular events in adults



The MMP recommends ATORVASTATIN as the preferred statin for the treatment of hypercholesterolaemia & prevention of cardiovascular events

- > This recommendation is based on a number of factors including cost, prescribing frequency, patient factors, contraindications and cautions
- > A full evaluation report is available at <a href="http://www.hse.ie/yourmedicines">www.hse.ie/yourmedicines</a>

# Prior to initiation of statin therapy<sup>1</sup>

- 1. Check baseline lipid levels (TC, LDL-C, HDL-C, TG)
- 2. Address lifestyle issues including advice on healthy eating, smoking cessation, alcohol consumption, weight reduction (where appropriate) and physical activity
- 3. Consider:
  - Thyroid function- treat uncontrolled hypothyroidism prior to starting statin therapy
  - Liver function- check prior to commencing treatment; if transaminases are >3x ULN, do NOT start statin therapy
  - Renal function- check individual SmPCs. Dose adjustment may be necessary in renal impairment\*
  - History of **unexplained muscle pain-** check CK levels. If elevated, re-measure after 5-7 days. If still >5x ULN, do NOT start statin therapy.

## Prescribing statin therapy

- 1. Consider prescribing the MMP-preferred statin, atorvastatin
- 2. Consider drug interactions with concomitant medications & adjust dose accordingly\*
- 3. Advise patients to report any unexplained muscle pain, tenderness or weakness
- 4. Arrange a follow-up appointment for 1-3 months

## Review and follow up<sup>2-6</sup>

- 1. Measure liver transaminase enzymes after three months and 12 months of treatment, but not again unless clinically indicated
- 2. Review patients after three months of treatment and at least annually thereafter, to discuss medication adherence, dose response, lifestyle modifications, drug interactions and tolerability
- **3. Monitor** for clinically significant adverse events including severe myalgia, myositis or unexplained, persistent elevations of serum transaminases (>3x ULN)
- 4. Monitor for undesirable effects including elevated blood glucose levels, interstitial lung disease and renal effects e.g. proteinuria and haematuria\*
- 5. Adjust the dose or medication as required

Atorvastatin dosing information <sup>2</sup>		
Indication	Starting Dose	Note
Hypercholesterolaemia	10 mg daily	Adjustment of dose should be made at intervals of 4 weeks or more. The maximum dose is 80 mg once a day.
Homozygous familial hypercholesterolaemia	10-80 mg daily	Used as an adjunct to other lipid-lowering treatments
Prevention of cardiovascular events	10 mg daily	Higher doses may be necessary in order to attain LDL-C levels according to current guidelines

#### Managing statin intolerance<sup>2-7</sup>

- 1. Patients intolerant to high-intensity statins (atorvastatin ≥ 40 mg, rosuvastatin ≥ 20 mg) should use the maximum tolerated dose
- 2. Address adverse effects of statins which relate to muscle pain or weakness by\*:
  - Checking CK levels <u>AND</u>
  - If CK ≤ ULN: Stop the statin and restart treatment when symptoms have resolved, to determine if symptoms were statin-related. Reassess CK and symptoms in 6-12 weeks <u>OR</u>
  - If CK ≤ 5 x ULN and muscle symptoms are severe: Stop the statin, eliminate any predisposing factors. Consider reintroducing treatment (same statin at lower dose or different statin at low dose) once CK ≤ ULN and patient is asymptomatic. Monitor regularly <u>OR</u>
  - If CK ≥ 5 x ULN: Stop the statin, eliminate any predisposing factors and consider specialist advice
- 3. Reduce the dose or change to a different statin if intolerance is non-muscle related and CK is normal
- 4. Seek specialist advice for patients at high risk of CVD who are intolerant to at least two statins

CK: creatine kinase; CVD: cardiovascular disease; HDL-C: high density lipoprotein cholesterol; LDL-C: low density lipoprotein cholesterol; SmPC: summary of product characteristics; TC: total cholesterol; TG: triglycerides; ULN: Upper limit of normal

References:1. National Institute for Health and Care Excellence (NICE) Guidance CG181: Cardiovascular disease: risk assessment and reduction, including lipid modification (2016)2. SmPCs atorvastatin (Lipitor®) 10 mg, 20 mg & 40 mg3. SmPCs fluvastatin (Lescol®) XL 80 mg4. SmPCs pravastatin (Lipostat®) 10 mg, 20 mg & 40 mg40 mg5. SmPCs rosuvastatin (Crestor®) 5 mg, 10 mg, 20 mg & 40 mg6. SmPCs sinvastatin (Zocor®) 10 mg, 20 mg & 40 mg7. Guidance on prescribing statins. NHS South East London Area Prescribing Committee, 2016\* See individual SmPCs for further informationVERSION 1.0 MMP July 2020