This policy statement is approved by Halton, Knowsley, Liverpool, Southport and Formby, South Sefton, St Helens and Warrington CCGs

Halton | Knowsley | Liverpool | Southport and Formby | South Sefton | St Helens | Warrington

PAN MERSEY MEDICINES MANAGEMENT BOARD
PRESCRIBING POLICY STATEMENT
REF: PS43 FINAL
FIRST APC BOARD DATE: 12 FEB 2014
LAST APC BOARD DATE: 31 JAN 2018

NHS
Pan Mersey
Area Prescribing Committee

ROSUVASTATIN tablets

GREEN

The Pan Mersey Area Prescribing Committee recommends the prescribing of ROSUVASTATIN TABLETS tablets ONLY where no other statin is suitable.

The Pan Mersey Area Prescribing Committee does not recommend the routine prescribing of rosuvastatin tablets. It recommends that patients currently prescribed rosuvastatin should have their treatment reviewed and, where appropriate, be switched to a NICE approved statin or a statin with a lower acquisition cost.

> When the decision has been made to prescribe a statin, NICE recommend that therapy should be initiated with atorvastatin.[1]

> At the time of writing the acquisition costs for rosuvastatin are significantly more than that for generic atorvastatin and other generic statins.

> MHRA safety guidance[2], with regards to dose titration and maximum dosing, should be followed in patients prescribed rosuvastatin.

Note: Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. If appropriate, an exceptional funding request will be required following the usual locally defined process.

ROSUVASTATIN tablets (Crestor®)

Effectiveness

The Jupiter trial (2008)[3] showed rosuvastatin, compared to placebo, has benefit in risk reduction of major cardiovascular (CV) events, in patients without significantly raised cholesterol but with elevated high sensitivity C-reactive protein (marker of increased risk of CV disease).

The Saturn study (2011)[4] compared rosuvastatin 40mg /day with atorvastatin 80mg/day in high risk patients with pre-existing CVD. The trial found no statistically significant difference between the two groups in the primary outcome (a regression of coronary atherosclerosis from baseline). Reduction in athero-sclerotic plaque volume is a surrogate marker and it is unclear whether the reduction in plaque volume translates into reduction in the risk of CV events.

Safety

The adverse events seen with rosuvastatin are generally mild and transient, but are similar to those observed with other statins.[5]

Muscular side-effects, including myositis, which can lead to rhabdomyolysis, are rare but often significant. MHRA has issued prescribing advice following concerns of rhabdomylosis with rosuvastatin;

- All patients (including those who are switching from another statin) must start on 10mg dose (5mg in Asian patients and those with predisposing factors for myopathy) and should only be titrated to 20mg if considered necessary after a 4 week trial of 10mg.
- The 40mg dose should only be prescribed under specialist supervision as it is contraindicated in patients with predisposing risk factors for muscle toxicity. Patients who are currently taking 40mg and who have not already been seen by a specialist should have their treatment reviewed at their next routine appointment and appropriate down-titration of dose or specialist referral should be considered.

Refer to SPC[5] for up to date prescribing advice.

Cost

Rosuvastatin is now off-patent but at time of writing is significantly more expensive than atorvastatin and simvastatin.

Annual costs of treatment[7] are:
Simvastatin 40mg: £10.69
Atorvastatin 20mg £11.34; 40mg £13.69 & 80mg £21.37
Rosuvastatin 5mg £234.93; 10mg £234.93; 20mg £339.04 & 40mg £386.86.

Patient Factors

For important drug interactions, see MHRA Drug Safety Update.[6]

Rosuvastatin is contraindicated in the following patients; those with active liver disease, severe renal impairment (creatinine clearance <30ml/min), myo-pathy, and patients on ciclosporin. The 40mg dose is contraindicated in patients with pre-disposing factors for myopathy/ rhabdomyolysis.

Refer to SPC[5] for up to date prescribing advice.

PRESCRIBING INFORMATION

- Creatine kinase (CK) should not be routinely monitored in asymptomatic people who are being treated with a statin. Liver function should be measured within 3 months of starting treatment and at 12 months, but not again unless clinically indi-cated[1].

IMPLEMENTATION NOTES

- Prescribers should follow NICE guidelines[1] which recommends atorvastatin for people in whom statins are indicated.
- Rosuvastatin should only be considered where no other statin is suitable.

REFERENCES:

1. NICE Clinical Guideline No. 181 Cardiovascular disease: risk assessment and reduction, including lipid modification. July 2014.
2. MHRA. Current Problems in Pharmacovigilance. Volume 31, May 2006.
3. Ridker P et al. Rosuvastatin to prevent vascular events in men and women with elevated C-reactive protein. (JUPITER Study) N.Engl.J.Med. 2008;359:2195-2207.
4. Nicholls SJ et al. Effect of two intensive statin regimens on progression of coronary disease. N Engl J Med 2011:365:2078-87.
5. Summary of Product Characteristics. Crestor 5mg, 10mg, 20mg and 40mg film-coated tablets. Accessed 07/11/2017
6. MHRA. Drug Safety Update: Volume 1, Issue 6, January 2008.
7. NHSBA. Drug Tariff, Nov 2017. Accessed 07/11/2017