NewTherapiesSubgroup

GMMMG Greater Manchester Medicines Management Group

NHS

May 2016

Ticagrelor for the long term prevention of atherothrombotic events in adult patients with a history of MI.

The New Therapies Subgroup discussed the above at its meeting on 17th May 2016. The recommendation of this subgroup is as follows:*

Drug/Indication	Ticagrelor the long term prevention of atherothrombotic events in adult patients with a history of MI and a high risk of developing an atherothrombotic event. The dose for this indication is 60 mg twice daily; a new 60 mg tablet has been licensed to allow this.
Recommendation	**The group does not recommend the use of ticagrelor for the above indication.** The group agreed that the harms (risk of bleeding) from use of ticagrelor for the above indication outweighed any benefits gained from extra treatment so could not recommend use. ***According to set criteria ticagrelor for the above indication was deemed to be a low priority for funding.***
Clinical Trial Data – Efficacy	The pivotal trial enrolled patients with a spontaneous myocardial infarction in the previous 1-3 years, plus an additional risk factor for cardiovascular disease. Exclusions included: patients taking other drugs that may alter bleeding risk and those with bleeding disorders or recent surgery, recent GI bleeding and those with a history of ischaemic stroke or intracranial vascular abnormalities. Ticagrelor at a dose of 60 mg or 90 mg twice daily reduced the risk of the composite outcome of cardiovascular death, MI or stroke compared to placebo. The reductions were small but statistically significant.
Clinical Trial Data – Safety	Both doses of ticagrelor significantly increased the risk of major and minor bleeding. Ticagrelor was also associated with increased rates of dyspnoea and gout. The results of the pivotal trial suggest that for every cardiovascular death, MI or stroke prevented, ticagrelor 60 mg twice daily is likely to cause one major bleed, one bleed requiring a blood transfusion, three to four bleeds leading to discontinuation and seven new cases of dyspnoea.
Cost Effectiveness/ Affordability	The NHS list price for ticagrelor is £54.60 for 56 tablets of either strength, equating to £710 per person per year. There were 147,000 acute myocardial infarctions recorded in England in 2013/14, equating to approximately 270 per 100,000 population. With a population of roughly 2.6 million Greater Manchester would expect to treat approximately 7,000 people with an incident of MI each year. Treatment is licensed for up to an additional three years so treating

	all eligible patients would cost approximately £5 million in year one, £10 million in year two and £15 million in year three. As this is currently a negative recommendation, there are no additional commissioning or financial implications. However, NICE Guidance for this indication is expected to be issued in December 2016 and the Appraisal Consultation Document is positive. Therefore **costs above will be additional** to the £2M per annum already spent on this drug in GM in accordance with NICE TA236.
Patient perspective	Patients will be concerned about the adverse effects associated with use of ticagrelor for this indication.

** This recommendation is valid unless it is has been superseded by a NICE TA or national guidance. The recommendation will only be reviewed when there is substantial new data that may change the initial recommendation. For recommendations that are >24 months old please note that there may be new data available and this should be checked prior to prescribing.*

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

References available on request.