NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Medical Technologies Evaluation Programme

MTG update decision

MTG1: SeQuent Please balloon catheter for in-stent coronary restenosis

1. Background

This guidance was issued in December 2010. NICE published the guidance review decision to update MTG1 SeQuent Please in February 2017. The guidance update was started in August 2017 and so far has produced an updated scope, a guidance update assessment report prepared by the External Assessment Centre and a guidance update overview prepared by the MTEP team. The evidence was presented to MTAC at its December 2017 meeting. In January 2018, the Centre Director reviewed a report prepared by the MTEP team, with input from the committee chair and endorsed its conclusions, which formed the basis of a report to Guidance Executive which was considered and agreed.

2. Recommendations

Guidance Executive approved the following steps:

- The update of the MTG1 is discontinued and the update documents are published on the website including this paper which describes the outcome of the committee discussion.

- The guidance is instead updated within the most relevant clinical guideline: possibly in the update and merger of 3 relevant clinical guidelines: Unstable angina and NSTEMI: early management (CG94), myocardial infarction with ST-segment elevation: acute management (CG167) and management of hyperglycaemia in acute coronary syndromes (CG130) or in the update of the stable angina: management (CG126) guideline.

- The current MTG1should be moved to the static list, to be withdrawn when the updated guideline is published.

3. Current guidance

1.1 The case for adopting SeQuent Please balloon catheter in the NHS, when used as described in 1.2 and 1.3, is supported by the evidence. The need for subsequent

re-intervention for coronary stenosis is reduced as is the duration of clopidogrel therapy, compared with paclitaxel-eluting stent. SeQuent Please balloon catheter is associated with a cost saving of £467 per patient compared with paclitaxel-eluting stent.

1.2 SeQuent Please balloon catheter should be considered for use in patients with in-stent restenosis in bare metal coronary artery stents.

1.3 SeQuent Please balloon catheter can also be considered as an option for patients with in-stent restenosis in any type of coronary artery stent if:

- there are clinical reasons to minimise the duration of clopidogrel treatment (for example, there is concern about an increased risk of bleeding or there is the need for surgical intervention) or
- placement of further stents is not technically possible.

1.4 Further research is recommended in a UK setting to compare the outcomes of patients treated with SeQuent Please balloon catheter with the outcomes of patients treated with other types of drug-eluting balloon catheter and stent. This research should report long-term outcomes (for example, after 3 years), including clinical outcomes and details of further revascularisation required for subsequent restenosis. Research should investigate the use of SeQuent Please balloon catheter for restenosis in drug-eluting coronary artery stents and in de novo coronary stenosis where stenting is either technically difficult or is associated with an increased risk of complications. If research shows that SeQuent Please balloon catheter reduces the rate of restenosis in patients with drug-eluting stents or in native coronary arteries, compared with other technologies, then the number of patients for whom it might be suitable would increase significantly.

4. Rationale

The outcome of the MTAC review of the evidence and discussion at the December 2017 meeting was to ask NICE to consider including this technology in the update of the relevant clinical guidelines. The committee did not consider it was appropriate to continue to update within the remit of medical technologies guidance.

4.1 Evidence base changes

The committee accepted that SeQuent Please Neo was the new version of this technology. It considered that the evidence base had developed significantly since the original evaluation, including studies addressing the research recommendation in section 1.4 of MTG1. It also heard from clinical expert advisers that clinical practice has also developed significantly since MTG1 was published. The experts explained that the mechanistic diagnosis of restenosis is now much better

understood and is guided by intra-coronary imaging as well as angiography. The treatment pathway is now also more complex, comprising a more targeted approach that reflects the likely pathophysiology. While the use of drug-coated balloons such as SeQuent Please Neo have become one of the standard treatment options, there are now a wider range of comparators that have also become part of the treatment pathway. These comparators, particularly '-limus' drug eluting stents have a substantial evidence base themselves.

The EAC's conclusions on the updated evidence, in its Guidance Update Report, were that:

Clinical evidence	SeQuent Please Neo reduced revascularisation and restenosis versus balloon angioplasty, atherectomy and bare metal stent, with similar outcomes to everolimus, paclitaxel or sirolimus-eluting stents. Paclitaxel-eluting cutting balloon, everolimus-eluting stent and SeQuent Please Neo were the most effective 3 treatments, with no significant difference between them, although data for paclitaxel-eluting balloons were from a single small (n = 33) study. Their relative efficacy needs to be tested in future trials. The 3 most recent randomised controlled trials reported that an everolimus-eluting stent was superior to SeQuent Please Neo for achieving a higher minimal lumen diameter at follow-up. The largest trial also reported that this stent significantly reduced revascularisation and the composite major adverse cardiac event outcome measure compared with SeQuest Please Neo. Two studies, with 3 year follow-up, comparing Sequent Please Neo with paclitaxel eluting stents found no statistically significant differences. The EAC noted that the breadth of comparators has expanded to reflect the evolution of available treatments. Most of the new studies focus on angiographic outcomes and the EAC noted uncertainties associated with generalising clinical data from studies not powered for these events and set outside the UK to the NHS setting.
Economic evidence	New evidence and updated economic modelling calls into question whether SeQuent Please Neo is cost saving compared with the first generation drug eluting stents and suggests it is cost incurring compared with second generation stents because of their improved efficacy and safety.

The committee concluded that it does not seem appropriate to update or retain medical technologies guidance on this technology because:

- it is no longer new or novel;

- has become incorporated into standard clinical practice since the original guidance was published;

- is a treatment strategy that is appropriate for only a proportion of patients with in-stent restenosis, as determined by the more contemporary methods of intravascular diagnosis.. Risks associated with retaining the MTG without update include the promotion of a technology that is no longer novel and is only one component in the complex standard care pathway for restenosis as well as the promotion of a treatment strategy that, based on current knowledge, may not be appropriate for some patient with restenosis.

The final reflections of the committee were that the dilemmas associated with the update of MTG1 are an indication of the success and impact of the original medical technologies guidance after its publication in 2010. The committee considered that this 'success story' should be shared as widely as possible to illustrate the potential impact of NICE medical technologies guidance in positively influencing clinical practice and promoting valuable research.

4.2 Planned guideline updates

The committee noted an update and merger is planned of 3 relevant clinical guidelines: Unstable angina and NSTEMI: early management (CG94), myocardial infarction with ST-segment elevation: acute management (CG167) and management of hyperglycaemia in acute coronary syndromes (CG130) which is at an early stage of development There is also the intention to update the technology appraisal on drug-eluting stents (TA152) within this guideline update. The committee therefore considered that the inclusion of suitable review questions during these updates about the clinical and cost-effectiveness of drug-eluting balloons for in-stent restenosis would be the most appropriate way for the SeQuent please medical technologies guidance to be updated. The Centre for Guidelines Director has been briefed about this option and judges that the topic will be included in either this guideline update or in the next update of the stable angina: management (CG126) guideline.

5. Proposed implementation

The MTEP Process Guide (Appendix E) contains provision for suspending or cancelling an evaluation as follows. Although this option was designed for topics being presented for the first time for guidance development, the principle would seem to apply equally to guidance updates.

Criterion	Detail

Technology not appropriate for the production of medical technologies guidance	The evidence presented to the committee indicates that, contrary to expectation at the routing stage, the technology is not appropriate for medical technologies guidance. NICE may suspend the development of guidance and refer the technology to another programme for evaluation.

If the current update is suspended, and the topic routed to the guideline development, there is no standard process option for deciding what to do with existing MTG1. The proposed implementation is that:

- The Guidance Update report and overview (as presented to the committee) should be published alongside this paper which describes the outcome of the committee discussions;

- The current guidance should be moved to the static list with a plan to withdraw it on publication of the updated guideline. This is consistent with the approach being taken for the technology appraisal TA159 on drug-eluting stents which is the original comparator technology and for the update to medical technologies guidance MTG3 Cardio-Q which is also being considered in a clinical guideline;

6. Equality issues

None identified.

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