

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guidance review decision paper

Outcome of review of [MTG1: SeQuent Please balloon catheter for in-stent coronary restenosis](#)

1. Background

The guidance was published in December 2010. In October 2016 the NICE Guidance Executive approved the [review proposal to be published for](#) consultation. This paper confirms the review decision and includes comments from consultees.

2. Review proposal put to consultees

MTG1 should be updated because there is new information available on SeQuent Please for treatment of in-stent restenosis.

3. Rationale for the review proposal

The guidance review¹ found that there is new evidence (see section 5 of the review proposal) which addresses the research recommendations in section 1.4 of the guidance in relation to the use of SeQuent Please for in-stent restenosis. There is also new evidence (see section 5) and updated information relevant to the cost model inputs which are likely to change the recommendation in section 1.3 of the guidance.

The guidance will be updated using the abbreviated process described in [Section 8 of the MTEP Process Guide](#).

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees (see Annex 1).

Paper signed off by: **Mark Campbell, Associate Director** 27 January 2017

¹ The review proposal was informed by additional work undertaken by an External Assessment Centre which was published on the NICE website alongside the review proposal.

Annex 1. Consultation comments table

There were 7 consultation comments from 2 consultees (2 NHS professionals and 1 manufacturer). Because some comments relate to sections of the original guidance, rather than to the review proposal, NICE contacted consultees after public consultation had closed to clarify whether they agreed with the review proposal. All agreed that the guidance should be updated.

Comment number	Consultee	Section number	Comment	Response
1	Manufacturer	2.3	prices for SQ Please are lower than £800	Thank you for your comment. Section 5.1 of the review proposal reads: 'the manufacturer states the current UK price for SeQuent Please is £450 to £650 (based on volume)'.
2	Manufacturer	2.5	Dual antiplatelet therapy (DAPT), e.g. clopidogrel, prasugrel, ticagrelor are typically used for 6 to 12 months in case of DES, For SQ Please only 1 month of (DAPT) is prescribed.	Thank you for your comment. The use of DAPT will be updated in the guidance to reflect current practice.
3	Manufacturer	3.1-3.5	There is a vast body of new evidence with longer follow-ups by 1. Unverdorben et al 2015 Paclitaxel-coated balloon catheter versus paclitaxel-coated stent for the treatment of coronary in-stent restenosis: the three-year results of the PEPCAD II ISR study. Unverdorben M, Vallbracht C, Cremers B, Heuer H, Hengstenberg C, Maikowski C, Werner GS, Antoni D, Kleber FX, Bocksch W, Leschke M,	Thank you for your comment. The Unverdorben paper is described in section 5.3. The Pleva paper has not been included in this review as it was published after the guidance review literature search was done (January 2016).

Comment number	Consultee	Section number	Comment	Response
			<p>Ackermann H, Boxberger M, Speck U, Degenhardt R, Scheller B. EuroIntervention. 2015 Dec;11(8):926-34.</p> <p>2. Pleva et al 2016 (Comparison of the Efficacy of Paclitaxel-Eluting Balloon Catheters and Everolimus-Eluting Stents in the Treatment of Coronary In-Stent Restenosis: The Treatment of In-Stent Restenosis Study. Pleva L, Kukla P, Kusnierova P, Zapletalova J, Hlinomaz O. Circ Cardiovasc Interv. 2016 Apr;9(4):e003316.)</p> <p>3. Studies by Alfonso et al. are not meaningful in this regard since the SQ Please was not properly used in the Spanish studies</p>	
4	Manufacturer	5.3	new tariffs for EA 31Z	Thank you for your comment, this will be updated in the guidance.
5	Manufacturer	5.3	cost difference in the real UK market may be lower than £200	Thank you for your comment. The cost model has not been updated as a part of this review. Narrative descriptions of the changes will be included in the updated guidance.
6	Manufacturer	5.10	use longer time horizon (Unverdorben et al. 2015) for Markov model	Thank you for your comment. The cost model has not been updated as a part of this review.

Comment number	Consultee	Section number	Comment	Response
7	NHS professional	General	On behalf of BCIS myself and the clinical standards group have read and reviewed this Updated guidance and agree with it in its current form	Thank you for your comment.