

TO: PMSCO

We appreciate the opportunity to review and comment on the IBC policy concerning Implantable Loop Recorders (ILR). Our reviewers found the document to be acceptable with the exception of one issue needing further clarification:

1. In reference to an "appropriate diagnostic workup (e.g. ambulatory monitoring....)" Is ambulatory monitoring mandatory or optional (left up to the discretion of the physician)? It's not entirely clear from the wording. Since the indication for ILR implantation states that syncopal episodes must be "infrequent (less than monthly)" it makes little sense to mandate monitoring for a shorter duration. Indeed, one of the purposes of the ILR is to identify the cause of symptoms that are so infrequent that the yield of ambulatory monitoring is likely to be low. It is the recommendation of the PaACC that ambulatory monitoring before ILR implantation should be optional.

(See Ref: Randomized Assessment Syncope Trial: conventional diagnostic testing versus a prolonged monitoring strategy (Circulation 2001; 104:46-51).

Again, we appreciate the opportunity to provide comments concerning this policy. Please do not hesitate to contact me if any further questions arise.

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