Reviewer’s report

Title: Cost-effectiveness of insulin degludec versus insulin glargine U100 in adults with type 1 and type 2 diabetes mellitus in Bulgaria

Version: 0 Date: 06 Oct 2019

Reviewer: Yasutaka Maeda

Reviewer's report:

This nation-wide investigation in Bulgaria compared the cost-effectiveness of basal insulin using a preestablished national database. The study design was well conducted to elucidate whether insulin degludec or insulin glargine-U100 was superior in the reduction of hypoglycemia-related economic burden. It is the important suggestion that the cheaper insulin is not always the better choice in a broad aspect. However, the author should describe the manuscript in compliance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement. It would be appreciated if the CHEERS check list is provided in the Supplementary Materials. Therefore, the work will be suitable for publication in "BMC Endocrine Disorders" if the authors properly address the following concerns.

Major concern:
1) Although an approval by the ethical committee is not necessary, the study reporting about healthcare economy is still required to be fair enough to avoid any misguided conclusion. The authors should observe the CHEERS statement and fill up the check list given at the following URL (http://www.ispor.org/taskforces/EconomicPubGuidelines.asp). Then, the list should be included in the Supplementary Materials.
2) The economic burden related to the insulin treatment is not dependent only on hyperglycemia. Unfortunately, it remains controversial whether the difference of insulin analogues affects the incidence of cancers, cardiovascular diseases and other complications. At least, it would be better to mention it in the limitation.

Minor concern:
1) The authors assumed that the biosimilar glargine U100 has the same efficacy to Lantus. I agree that it is true as far as in bioactivity, but they are actually not completely equal in clinical use because of the difference of device or vender supports. Please just mention it in the limitation.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes
Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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