

Tips on Claims Relating to Patient Assistance Programs

The following document was created in response to requests for guidance relating to “acceptability of claims based on data from patient assistance programs”.

The “acceptability of claims” depends on the type of claim the sponsor would like to make. Please note that data from a support program is insufficient evidentiary support for claims relating to effectiveness and/or safety. Refer to the documents “Guidance on Observational Studies” and “Marketing benefit claims: What are they and what level of support do they require?” on the PAAB website for further information.

Observational data on retention could be considered if the program has a valid and reliable mechanism to monitor when prescriptions are filled. Sufficient information about the program must be provided to enable PAAB to make this assessment. The APS claim/data from a manufacturer’s patient support programs should be non-comparative (as it relates to the manufacturer’s product), it should reflect past study findings (i.e. formatted in the past-tense), and it should be structured so as to limit the findings to the support program. Study parameters such as the time period pertaining to the claim/data could be relegated to a footnote. Note that retention data will be required to be updated every 6 months as changes in the market place can impact retention.

Non-comparative claims relating to adherence/compliance would require that the program have a valid and reliable mechanism to monitor when/how the product is administered in addition to degree of alignment with the prescriber’s directions. Sufficient information about the program must be provided to enable PAAB to make this assessment. Rx claim data would not suffice. The additional provisions stated above would apply here as well.

Non-comparative claims relating to patient attitudes toward the services provided in the program could be considered (e.g. satisfaction level with the provided reimbursement assistance). It is advisable to submit the proposed rating items and/or survey questions along with a detailed description of the proposed methodology in a PAAB opinion before conducting this research. See the PAAB fee schedule on our website for more information.