ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

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Dear AMCP:

ISPOR – the professional society for health economics and outcomes research - is pleased to respond on behalf of its membership to your consultation entitled "AMCP Format for Formulary Submissions — Guidance on Submission of Pre-Approval and Post-Approval Clinical and Economic Information and Evidence, Version 4.1 – Revision."

ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, and other interventions. We have a large membership living and working in 110 countries globally, across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government, and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

The response to this consultation was led by the Policy Outlook Committee of our most senior advisory body, the Health Science Policy Council. To engage our membership, we consulted with interested members of Institutional Council (ie, industry and consulting), our Digital Health and Health Equity in Research Special Interest Groups, as well as soliciting our general membership for comments. The attached document provides both summary and line-by-line responses based on their comments. We hope they prove useful.

ISPOR would be happy to answer any questions about our response, and to participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Robert Abbott
CEO & Executive Director
ISPOR

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"AMCP Format for Formulary Submissions — Guidance on Submission of Pre-Approval and Post-Approval Clinical and Economic Information and Evidence, Version 4.1 – Revision"

ISPOR would like to thank AMCP for facilitating value communications with managed care stakeholders via the AMCP Format for Formulary Submissions and for engaging broader stakeholders in healthcare access for feedback on the proposed updates to version 5.0. Generally speaking, our members welcome the consideration of digital therapeutics, health disparities, and overall efforts to encourage brevity.

Question 1: Digital Therapeutics: Does this section properly convey information incorporating digital therapeutics into the AMCP Format?

Yes

ISPOR appreciates that the revision specifies that the AMCP Format is intended for prescription digital therapeutics while providing a framework more broadly for digital health products. The table 'Definitions Related to DTx' is very well done and particularly helpful. With respect to digital health start-ups and small digital therapeutics companies, the Format may be overwhelming, and additional guidance regarding which sections are most important for digital health products with minimal clinical trial data is suggested. Guidance regarding the optimal placement of optional appendices (data privacy, engagement, screenshots) within the document is also welcome.

Question 2: Digital Therapeutics: Does the following table encompass all the important/unique product information considerations for formulary evaluation of digital therapeutics? Is the layout conducive to efficient review?

Yes

The proposed table 2.1.2B provides critical information for stakeholders regarding digital therapeutics products. Our members suggest amending 'Technical Requirements' to also include network requirements (along with hardware and software required) and providing space for details regarding product updates and general product maintenance (bug fixes, etc). Additionally, space within Table 2.1.2B to discuss integration with existing systems is also welcome (EHRs, interoperability, etc).

Question 3: Health Disparities: What is the feasibility of manufacturers to provide this information? What is the demand for this information among payers?

Regarding the diversity of study participants within clinical trials and tables depicting trial representativeness: Much of this information is consistently collected and shared within current AMCP Format for Formulary submissions (ie, baseline characteristics/demographics). As a cautionary note, according to Vance et al, "the use of race as a biologic variable to study health disparities may inadvertently promote a notion of biologic inferiority between races." AMCP should consider guidance to clarify the intent of inclusion of this information within the updated Format for Formulary Submissions 4.1.

REFERENCE: Vince RA Jr, Eyrich NW, Mahal BA, Stensland K, Schaeffer EM, Spratt DE. Reporting of Racial Health Disparities Research: Are We Making Progress? J Clin Oncol. 2022 Jan 1;40(1):8-11. doi: 10.1200/JCO.21.01780. Epub 2021 Oct 25. PMID: 34694897; PMCID: PMC8683227.

Regarding the disclosure of retrospective studies that include subgroups disproportionately affected by the health condition, and data limitations that erode generalizability: While race/ethnicity/socio-demographics are highly valued in retrospective studies, data fields necessary for evaluation are often limited if available at all.

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Further, HIPAA privacy parameters frequently prevent inclusion of zip code in a retrospective dataset. Without zip code, it is extremely difficult or impossible to connect to other data sources that might contain socio-demographic determinants. We suggest modification of the language in this section to address these potential limitations.

Question 4: Health Disparities: The intent is that the dossier explains if/how patient cost sharing was captured in the pharmacoeconomic model. Does this come across in the new language?

Yes

This revision is welcomed by the ISPOR community, and we encourage the inclusion of economic data, whenever possible, that specifically represent patient and caregiver perspectives.

Question 5: Health Disparities: What is the manufacturers' ability to address these concerns, particularly at launch? To what extent do payers and manufacturers consider these aspects to be in scope for a new product assessment?

ISPOR shares the vision of AMCP to promote equitable access to healthcare and encourage manufacturers to develop evidence on the same; however, manufacturers alone have a limited ability to address the systemic challenges and barriers that have perpetuated inequitable healthcare and poor health outcomes for many Americans in historically underserved and marginalized communities. The concerns described in this section should be addressed through broad industry partnerships, where healthcare ecosystem stakeholders establish common expectations and collective accountability while implementing key health equity initiatives.

Question 6: Format of the Format: The goal was to balance brevity without sacrificing clarity. Does this meet the objective?

Yes

Question 7: Format of the Format: We are proposing from an efficiency standpoint to use external hyperlinks for product information, websites, and guidelines. How would this affect your resources?

ISPOR supports this change, and our members do not believe this will impact resources adversely; however, our members suggest that manufacturers and authors make every effort to ensure the current version of their dossier has no broken or inactive hyperlinks.

Question 8: Format of the Format: Information regarding digital therapeutics was added to the dossier. Are there any other categories of products for which specific guidance would be helpful?

ISPOR members would like to see specific guidance developed for diagnostics, particularly genetic and epigenetic tests, as the field of precision therapeutics and pharmacogenomics grows.

Question 9: PIE Deck Guidance: Does this section accurately represent key considerations for pre-approval information exchange (PIE) decks? What other aspects of PIE decks would you like to see AMCP address in this proposed guidance?

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Yes

This section accurately represents key considerations for pre-approval information exchange (PIE) decks. In addition, ISPOR members suggest and encourage the inclusion of pipeline information in PIE decks keeping with trends in horizon scanning and payer appetites for information that is helpful in long-term planning.

We would like to acknowledge ISPOR members Anthony Hasan and Erin Zagadailov for their assistance in assembling these comments, as well as ISPOR staff Richard Willke and Kelly Lenahan.