FORMAT for Formulary Submission – Version 4.0 Release

AMCP Managed Care & Specialty Pharmacy Annual Meeting

April 21, 2016

AMCP Academy of Managed Care Pharmacy®

Speakers

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Format Executive Committee Chair

Iris Tam
General Information Work Group Chair

Pete Penna
Clinical Evidence Work Group Chair

Kim Saverno
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Why Version 4.0?

- Address contemporary issues in health care related to formulary management and evidence assessment
- Address feedback from users related to the *Format*
- Refresh *Format* alignment with external best practices in clinical and economic evidence development and communication
- Provide updated guidance to enhance the clarity, transparency, and usability of the *Format*

Clinical Evidence

- Overall increased and improved guidance
- Focus on drugs, biosimliars, CDTs, CER, and devices
- Comprehensive guidance added for specialty pharmaceuticals: handling & distribution requirements & restrictions; appropriate settings; supportive care services; medical benefit considerations e.g. coding
- New section specifying comparative information parameters for biosimilars relative to respective reference products (demonstrating "biosimilarity," interchangeability and dosing equivalency)
- Companion diagnostic testing information updated to reflect the technical and economic considerations for CDTs, and when such information should be supplied
- Improved definition of and guidance for submitting "Supporting Clinical Evidence" and "All relevant clinical studies"

Clinical Evidence

- Restructured Section 3 (Clinical Evidence) and Section 5 (Additional Supporting Evidence) to provide additional clarity and guidance regarding recommended evidence components for each section
- Additional guidance provided for inclusion of other supporting evidence including Clinical Practice Guidelines, Health Technology Assessments and Systematic Reviews, Compendia, and additional economic evidence not provided in Section 4
- Refined guidance on page "limits" for various sections
- Review of evidence dealing with heterogeneity of effect
- Describe post-marketing surveillance requirements
- Other data elements added to summaries in sections 3 and 5, e.g. NNT, author-described limitations, etc.
- Treatment Guidelines moved from Section 2 to Section 5, with more detail to be provided

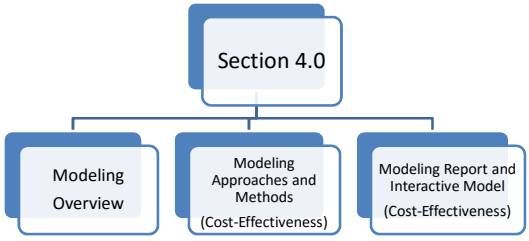
Economic Evidence

- Provides more guidance on budget impact models to highlight the importance of this type of model in the decision-making process.
- Section was revised, as appropriate, to align with updated best practices published by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and Society for Medical Decision Making (SMDM) Modeling Good Research Practices Task Force for economic models.[1]
- Provides guidance on modeling considerations for biosimilars and specialty products.
- Offers more specific guidance for presenting the results of economic analyses, including both cost effectiveness and budget impact models, reflecting updated reporting standards for economic evaluations (Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement).[2]

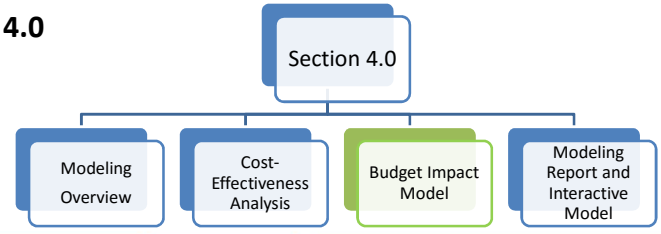
1. Caro JJ, et al. *ViH*. 2012;15(6):796-803.
2. Husereau D, et al. *ViH*. 2013;16(2):231-250.

Economic Value and Modeling Report

Version 3.1



Version 4.0



General Information

General Logistical Considerations

- Defines Health Care Decision Makers (HCDMs) and Manufacturers (drugs, tests, devices)
- Reiterates importance of communications between HCDMs and manufacturers
  - Incorporates FDA's draft guidance for manufacturers on unsolicited requests
  - Acknowledges FDAMA Section 114
  - Encourages feedback from HCDMs
- Clarifies guidance on updating dossiers, page limits, and dossiers before FDA approval
- Recognizes electronic formats rather than print
- Implementation of Version 4.0 – adopt when developing new or updating existing dossier

Special Content Considerations

- Comparative effectiveness research (CER) – based on V3.1 CER Addendum; suggests CER Collaborative
- Dossier for drugs, tests, and devices – intent to broad scope of Format to include tests and devices relevant to formulary & policy decisions
- Companion diagnostic tests (CDT) – based on V3.1 CDT Addendum; specifics in new Section 2.3
- Biosimilars – requires evidence similar to innovator product; transparency about source of evidence (directly from biosimilar or extrapolated)
- Heterogeneity – substantiate statements about variability in treatment effects with evidence

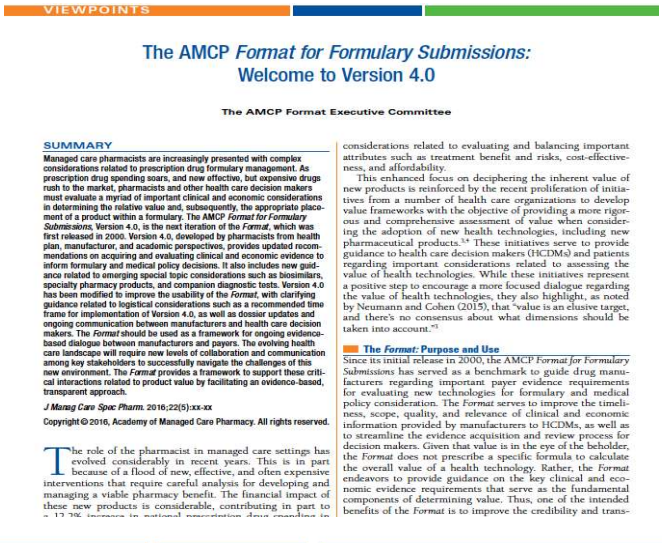
General Information (cont.)

- **Section 1 Executive Summary – Clinical and Economic Value of the Product**
  – Increase page allowance, from 2 pages to recommended 5 pages (max 8)
- **Section 2 Product Information and Disease Description**
  – New fields: CPT and ICD-10 (ICD-9), special populations, implication for quality measures
  – Clarify handling of clinical practice guidelines (briefly in Sec 2.2; fully summarized in Sec 5)
  – Replaced Sec 2.3 Pharmacogenomic Tests with Evidence for CDTs (adapted from "The Guidance" for medical tests by U of WA)
- **Section 6 Dossier Appendices**
  – References, Models, Product PI, Patient Information; Material Safety Data Sheet (MSDS)
- **Terms and Definitions**
  – Updated
- **Appendices**
  – Sample Unsolicited Request Letter; Formulary Monograph Template
- **Citations**
  – Include updated and new sources of background information with links where available
- Removed draft recommendation for manufacturers to rate quality of studies/evidence

Link to *Format* 4.0

www.amcp.org/FormatV4

Available online today



VIEWPOINTS

The AMCP *Format for Formulary Submissions:* Welcome to Version 4.0

The AMCP Format Executive Committee

SUMMARY

Managed care pharmacists are increasingly presented with complex considerations related to prescription drug formulary management. As prescription drug spending soars, and new effective, but expensive drugs rush to the market, pharmacists and other health care decision makers must evaluate a myriad of important clinical and economic considerations in determining the relative value and, subsequently, the appropriate placement of a product within a formulary. The AMCP *Format for Formulary Submissions*, Version 4.0, is the next iteration of the *Format*, which was first released in 2000. Version 4.0, developed by pharmacists from health plan, manufacturer, and academic perspectives, provides updated recommendations on acquiring and evaluating clinical and economic evidence to inform formulary and medical policy decisions. It also includes new guidance related to emerging special topic considerations such as biosimilars, specialty pharmacy products, and companion diagnostic tests. Version 4.0 has been modified to improve the usability of the *Format*, with clarifying guidance related to logistical considerations such as a recommended time frame for implementation of Version 4.0, as well as dossier updates and ongoing communication between manufacturers and health care decision makers. The *Format* should be used as a framework for ongoing evidence-based dialogue between manufacturers and payers. The evolving health care landscape will require new levels of collaboration and communication among key stakeholders to successfully navigate the challenges of this new environment. The *Format* provides a framework to support these critical interactions related to product value by facilitating an evidence-based, transparent approach.

J Manag Care Spec Pharm. 2016;22(5):xx-xx

The role of the pharmacist in managed care settings has evolved considerably in recent years. This is in part because of a flood of new, effective, and often expensive interventions that require careful analysis for developing and managing a viable pharmacy benefit. The financial impact of these new products is considerable, contributing in part to

considerations related to evaluating and balancing important attributes such as treatment benefit and risks, cost-effectiveness, and affordability.

This enhanced focus on deciphering the inherent value of new products is reinforced by the recent proliferation of initiatives from a number of health care organizations to develop value frameworks with the objective of providing a more rigorous and comprehensive assessment of value when considering the adoption of new health technologies, including new pharmaceutical products.[1-4] These initiatives serve to provide guidance to health care decision makers (HCDMs) and patients regarding important considerations related to assessing the value of health technologies. While these initiatives represent a positive step to encourage a more focused dialogue regarding the value of health technologies, they also highlight, as noted by Neumann and Cohen (2015), that "value is an elusive target, and there's no consensus about what dimensions should be taken into account."[3]

The *Format*: Purpose and Use

Since its initial release in 2000, the AMCP *Format for Formulary Submissions* has served as a benchmark to guide drug manufacturers regarding important payer evidence requirements for evaluating new technologies for formulary and medical policy consideration. The *Format* serves to improve the timeliness, scope, quality, and relevance of clinical and economic information provided by manufacturers to HCDMs, as well as to streamline the evidence acquisition and review process for decision makers. Given that value is in the eye of the beholder, the *Format* does not prescribe a specific formula to calculate the overall value of a health technology. Rather, the *Format* endeavors to provide guidance on the key clinical and economic evidence requirements that serve as the fundamental components of determining value. Thus, one of the intended benefits of the *Format* is to improve the credibility and trans-

AMCP Webinar

AMCP Format for Formulary Submissions, Version 4.0: A Guided Tour of Key Changes and Enhancements

Wednesday, May 4, 2016

2:00 – 3:00 pm, ET

http://www.amcp.org/Newsletter.aspx?id=20856

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