Conveying Product Value with the AMCP *Format* Version 4.0

Identifying and communicating the value story of a product is integral for strategic planning, market access, and reimbursement. Evidera can help you plan appropriately, identify evidence needs, generate studies to capture evidence, and prepare Academy of Managed Care Pharmacy (AMCP) dossiers to communicate your product's value to U.S. managed care payers.

An effective AMCP dossier communicates the value of the product in a manner that:

- Is consistent with the global value story
- Resonates with the specific needs of U.S. payers
- Focuses on the U.S. market
- Presents the information in a user-friendly, accessible format
- Complies with AMCP *Format* Version 4.0
- Adheres to FDA requirements regarding fair balance and product claims

Evidera's AMCP Dossier Development Process

Evidera will work with you to design a customized approach to developing or updating an AMCP dossier. As we devise the optimal approach and timeline, we consider your objectives in initiating an AMCP dossier project.

- **Stage in the product's lifecycle:** Is this a new product launch? Is the indication being expanded? Is there a label update expected?
- **Market developments in the indication:** Are new product approvals expected? Are there new clinical and economic data for competitors? Have treatment guidelines been updated, or have there been shifts in treatment patterns?
- **General updating needs:** Does the dossier need to undergo an update before its approved usage time (based on your company's review process) expires? Do you need to conduct a general sweep of the literature to ensure that the dossier is current? Do price adjustments necessitate changes in the modeling report?
- **AMCP Format alignment:** Do you need to update the dossier to align with AMCP *Format* Version 4.0? Note that a format update is only required if the dossier is undergoing a content update.

Why Evidera?

- Experienced, specialized market access writers exclusively focused on developing evidence-based value stories and dossiers that demonstrate product value
- Highly experienced in developing content that minimizes internal review timelines; we provide carefully annotated references and use of fair-balanced language when discussing a drug and its comparators
- Developed over 150 global value dossiers and approximately 60 AMCP dossiers, each based around a compelling value story for payers
- 1,000+ market access / pricing and reimbursement projects with more than 70 client organizations (pharma, biotech, device, diagnostics, health services)
- 25,000+ payer interviews conducted entirely in-house

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AMCP *Format* Version 4.0: What Has Changed?

In April 2016, the AMCP released *Format* Version 4.0, with the following key differences versus Version 3.1. The complete updated *Format* can be seen on their website (www.amcp.org/FormatV4).

Section	Key Changes / Comments
General / overall	Includes a focus on not only drugs but also biosimilars, companion diagnostic tests, comparative effectiveness research, and medical devices Restructured Section 3 (Clinical evidence) and Section 5 (Additional supporting evidence) to provide additional clarity and guidance regarding recommended evidence components for each section
1. Executive summary	Recommended length is now 5 to 8 pages
2. Product information and disease description	New items to be included: • CPT and ICD-10/ICD-9 codes • Information on use in special populations • Post-marketing surveillance requirements • Information on how the product may impact quality measures, e.g., HEDIS scores, 30-day readmissions, CMS Star rating • Statement about how comparator products were selected For specialty pharmaceuticals, there should be information on handling and distribution requirements and restrictions; appropriate settings; supportive care services; medical benefit considerations, e.g., coding Treatment guidelines should only be briefly discussed in Section 2.2.2, with more detail in Section 5 Section 2.3 (formerly Pharmacogenomics) is now "Evidence for companion diagnostics" and includes: • 2.3.1 - Product information for CDT • 2.3.2 - Place of CDT in clinical practice • 2.3.3 - Supporting clinical data for CDT
3. Clinical evidence	Improved guidance for selecting studies for inclusion; suggestions for stratifying studies according to whether they should be fully summarized, only included in an evidence table, or only listed in a bibliography Recommended length of study summaries is now 2 to 5 pages
4. Economic value and modeling report	To highlight the importance of budget impact models in the decision-making process, more guidance has been incorporated, including guidance on modeling considerations for biosimilars and specialty products Section was revised to align with updated best practices for economic models published by ISPOR and the Society for Medical Decision Making (SMDM) Modeling Good Research Practices Task Force There is more specific guidance for presenting the results of both cost effectiveness and budget impact models, reflecting updated reporting standards for economic evaluations (Consolidated Health Economic Evaluation Reporting Standards [CHEERS] Statement)
5. Additional supporting evidence	Additional guidance provided for inclusion of other supporting evidence, including: • Clinical practice guidelines (which are now only introduced in Section 2) • Health technology assessments • Systematic reviews • Compendia • Additional economic / outcomes evidence not provided in Section 4 • Impact of the product on quality measures Recommended length of study summaries is now 2 to 5 pages
6. Dossier appendices	Should include references, prescribing information, materials safety data sheet, patient information, and economic models