Section One - Differences

Unapproved Product Dossier / Unapproved Use Dossier

- Section 1.0A or 1.0C Highlights and Overview
- Section contains 1 at-a-glance table
- Recommended Length: 2 pages (max 4 pages)

Approved Product Dossier

- Section 1.0B Executive Summary — Clinical And Economic Value Of The Product
  - Section 1.1B Clinical Benefits
  - Section 1.2B Economic Benefits
  - Section 1.3B Conclusions
- Recommended Length: 5 pages (max 8 pages)

Reference: AMCP Format Executive Committee. *AMCP Format for Formulary Submissions: Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence.* Accessed January 29, 2020. https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1

Section Two - Differences

Unapproved Product Dossier / Unapproved Use Dossier

- Section 2.0A or 2.0C Product Information and Disease Description
  - Section 2.1A or 2.1C Product Description
  - Section 2.2A or 2.1C Disease Description
- Recommended Length: 5 pages (max 10 pages)

Approved Product Dossier

- Section 2.0B Product Information and Disease Description
  - Section 2.1B Product Description
    - Section 2.1.1B Product Comparison
  - Section 2.2B Place of Product in Therapy
    - Section 2.2.1B Disease Description
    - Section 2.2.2B Approaches to Treatment
  - Section 2.3B Evidence for Companion Diagnostic Tests
- Recommended Length: 5 pages (max 10 pages)

Reference: AMCP Format Executive Committee. *AMCP Format for Formulary Submissions: Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence.* Accessed January 29, 2020. https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1

Section Three - Similarities

Unapproved Product Dossier / Unapproved Use Dossier

- Section 3.0A or 3.0C Clinical Evidence
  - Section 3.1A or 3.1C Study Summaries
  - Section 3.2A or 3.1C Evidence Tables

- Recommended Length for each Study Summary: 2 pages (max 5 pages)
- Recommended Length for each Evidence Table: <1 page (max 2 pages)

Approved Product Dossier

- Section 3.0B Clinical Evidence
  - Section 3.1B Study Summaries
  - Section 3.2B Evidence Tables

- Recommended Length for each Study Summary: 2 pages (max 5 pages)
- Recommended Length for each Evidence Table: <1 page (max 2 pages)

Reference: AMCP Format Executive Committee. *AMCP Format for Formulary Submissions: Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence.* Accessed January 29, 2020. https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1

Section Four - Differences

Unapproved Product Dossier / Unapproved Use Dossier

- Section 4.0A and 4.0C Economic Information

Approved Product Dossier

- Section 4.0B Economic Value and Modeling Report
  - Section 4.1B Modeling Overview
    - Section 4.1.1B Use of Modeling for Decision-Making
    - Section 4.1.2B Types of Models
    - Section 4.1.3B Other Considerations
  - Section 4.2B Cost-Effectiveness Analysis
    - Section 4.2.1B Approach and Framework
    - Section 4.2.2B Data Sources
    - Section 4.2.3B Conduct
  - Section 4.3B Budget Impact Model
    - Section 4.3.1B Approach and Framework
    - Section 4.3.2B Data Sources
    - Section 4.3.3B Conduct
  - Section 4.4B Budget Impact Model
    - Section 4.4.1B Transparency
    - Section 4.4.2B Modeling Report Format
    - Section 4.4.3B Interactive Model

Reference: AMCP Format Executive Committee. *AMCP Format for Formulary Submissions: Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence.* Accessed January 29, 2020. https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1

Section Five - Differences

Unapproved Product Dossier / Unapproved Use Dossier

- Not included

Approved Product Dossier

- Section 5.0B Additional Supporting Evidence
  - Section 5.1B Clinical Practice Guidelines
  - Section 5.2B HTAs and Systematic Reviews
  - Section 5.3B Compedia
  - Section 5.4B Other Economic or Outcomes Evidence
  - Section 5.5B Effect on Quality
  - Section 5.6B Other Evidence or Information

Reference: AMCP Format Executive Committee. *AMCP Format for Formulary Submissions: Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence.* Accessed January 29, 2020. https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1

Section Six - Differences

Unapproved Product Dossier / Unapproved Use Dossier

- Not included

Approved Product Dossier

- Section 6.0B Dossier Appendices
  - Section 6.1B References Contained in Dossiers
  - Section 6.2B Economic Models
  - Section 6.3B Product Prescribing Information
  - Section 6.4B Patient Information
  - Section 6.5B Material Safety Data Sheet

Reference: AMCP Format Executive Committee. *AMCP Format for Formulary Submissions: Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence.* Accessed January 29, 2020. https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1