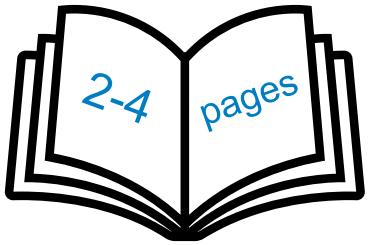
Unapproved Use Dossiers

What goes in each section?

Section 1.0C Highlights and Overview

Don't Include

- Executive Summary
- Claims
- Characterizations or conclusions

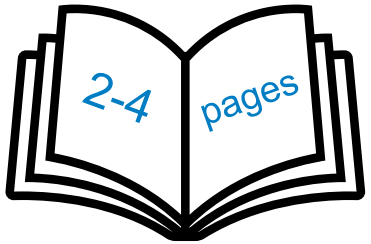


References: AMCP Format Executive Committee. *AMCP Format for Formulary Submissions: Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence.* Accessed January 29, 2020. https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1

Section 1.1C Table of Highlights

Include

- Brief and concise information
- Factual and objective data
- Citations and references



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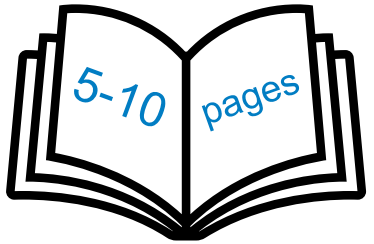
Section 2.1C Product Information

Include

Statements	"not FDA-approved" "safety and effectiveness have not been established"
Phase of product development	Provide FDA-approved prescribing information
Product information	
Information about the indications being sought	
Anticipated timeline for possible commercialization	
Patient utilization projections	
Product-related programs or services	



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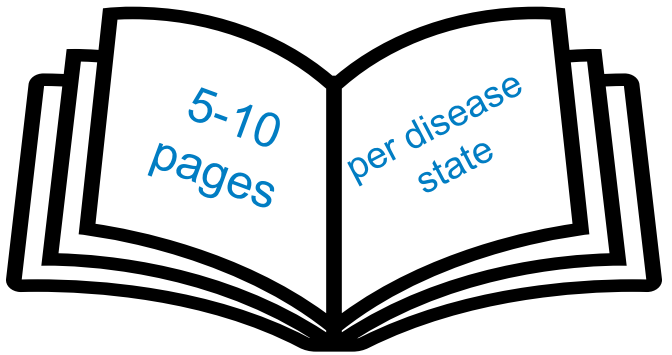
Section 2.2C Disease Description

Include

- "an overall sense of the disease."
- Epidemiology
- Risk factors
- Pathology
- Clinical presentation
- Burden of disease



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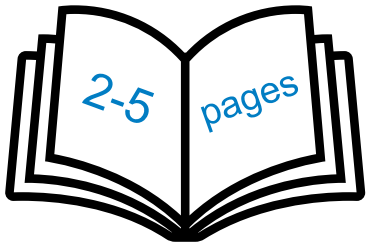
Section 3.1C Study Summaries

Include

Publication citations, study name, clinicaltrails.gov ID number, funding source
Objective, location, and study start and completion dates
Trial design, randomization, blinding procedures
Setting, inclusion and exclusion criteria
Baseline patient characteristics and demographics
Drop-out rates and procedures for handling
Treatments, interventions, dosage regimens, washout period, concomitant therapies
Clinical outcomes evaluated, measured, and collected; primary vs secondary endpoints; prespecified vs post hoc
Measures of effect, statistical significance, power calculations
Validation of outcomes instruments
Generalizability of population treated
Study limitations



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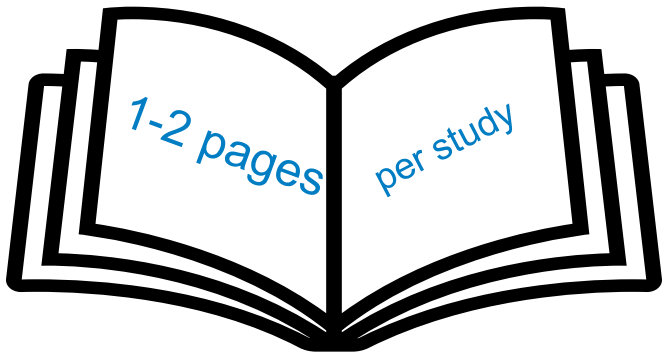
Section 3.2C Evidence Tables

Include	
	Citation, clinicaltrails.gov ID number
	Treatments, sample size, length of follow-up
	Study design, inclusion and exclusion criteria
	Primary and secondary endpoints, results



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Section 4.0C Economic Information

Include	Price of approved product
	Potential or anticipated changes in costs

References: 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 5.0C Dossier Appendices

Include

5.1.C References Contained in Dossier

Include citations and links to original sources if they are freely available.

5.2C Product Prescribing Information

Include label or PI.

Note: Section 5.0C is not included in the current version of the *AMCP Format for Formulary Submissions*, but Section 1.1C requires citations and references and Section 2.1C requires the full FDA-approved prescribing information, so we are assuming there should be a Section 5.0C with these included.

References: 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