

NAMCP Medical Diagnostics Dossier Template[©]

PURPOSE: The purpose is to provide medical directors and molecular, genetic and other appropriate diagnostic test laboratories with a dossier format that accounts for evidence development approaches and unique aspects of these technology types (versus simply following drug-based formats that may not be ideal for other types of health technologies).

This format has been developed with Medical Directors and test providers working collaboratively to ensure that the format is the most useful, practical, and succinct for US payer decision making.

Executive Summary (1-2 pages total)

Disease Clinical and Economic Burden Overview – half a page

Core Value and Evidence Supporting DIAGNOSTIC TEST (including key value messages/themes) 1-2 pages

List of Tables

List of Figures

List of Abbreviations

1 Burden of Illness (section to be succinct)

1.1 Clinical Characteristics and Presentation of Medical Condition

1.2 Epidemiology

1.2.1 Incidence of Medical Condition

1.2.2 Prevalence of Medical Condition

1.2.3 Risk Factors for Medical Condition

1.3 Clinical

1.3.1 Major Adverse Health Outcomes Associated with Medical Condition

1.3.2 Key Comorbidities and Increased Risk for Adverse Health Outcomes

1.4 Unmet Need

1.4.1 Description of Unmet Need

- Listing of Alternative Tests/Treatments including pharmacological, and their outcomes, adverse effects, in market place currently etc.
- Description and characteristics of the diagnostic test

1.4.2 How the New Test Will Address Unmet Need

- Indicated Patients
- Fit in Clinical Pathway

2 Diagnostics Test Information

2.1 Description and Characteristics

2.2 Test Classification and Approval Status

2.3 Test Components and Specifications

3 Value Evidence Supporting DIAGNOSTIC TEST

3.1 Analytical Validity

3.1.1 Core Value Drivers - (i.e. Value Messages) with supporting information/references including description of associated clinical (pre-clinical, feasibility, pivotal studies) registry and post market data

3.1.2 Role of DIAGNOSTIC TEST in Improving Patient Management and Health Outcomes

3.2 Clinical Validity

3.2.1 Core Value Drivers - (i.e., Value Messages) with supporting information/references

3.2.2 Role of DIAGNOSTIC TEST in Improving Patient Health Outcomes

3.2.3 Specificity and Sensitivity of Test

3.3 Clinical Utility

3.3.1 Core Value Drivers - (i.e. Value Messages) with supporting information/references including description of associated clinical, registry and post-market data and models

3.3.2 Role of DIAGNOSTIC TEST in Improving Economic Outcomes/Cost Offsets

3.4 Economic Utility

3.4.1 Direct Costs

3.4.2 Indirect Costs

4 Current Payer Coverage

4.1 Describe current coverage status among payers.

5 Future Directions and Applications

5.1 Emerging Clinical Applications – limit to 1 page if applicable

Appendix A: Literature Search Methodology

- Provide a list of publications on the product for committee review

Appendix B: References

Appendix C: Additional Information (e.g., evidence tables)