



"People  
helping people  
help  
themselves"

Mitchell E. Daniels, Jr., Governor  
State of Indiana

**Office of Medicaid Policy and Planning**  
402 W. WASHINGTON STREET, ROOM W382  
INDIANAPOLIS, IN 46204-2739

## Manufacturer Preferred Drug List Submission Application

Dear Manufacturer,

Please provide the following information in order to be considered for the preferred drug list:

- Part 1: Product Information
  - Product Description
  - Place in Therapy
- Part 2: Disease(s) State Overview
- Part 3: Supporting Clinical and Economic Data
  - Clinical Study Results
  - Clinical and Disease Management Strategies
  - Economic Evaluation
- Part 4: Impact Model Report
  - Model Overview
  - Safety and Efficacy based on Clinical Trials
  - Incidence and Prevalence Impact Assessments
  - Optimizing Patient Care
  - Presentation of Model Results
  - Exceptions
- Part 5: Clinical Value and Overall Cost
- Part 6: Bias Disclosure
- Part 7: Supporting Information: Bibliography, Checklist and Appendices
  - References

It is important that all information be fully completed. Not providing complete information or including all required parts will delay your submission request.

Please identify the author(s) of the submission document as well as a contact person who can answer questions or provide additional information regarding the submission materials. An electronic copy must be submitted to the following address: [PDL@fssa.in.gov](mailto:PDL@fssa.in.gov).

*Note: Information/materials submitted are subject to the Indiana Public Records Act (Ind. Code 5-14-3) and may be viewed and copied by any member of the public, including news agencies and competitors. A manufacturer claiming a statutory exception to disclosure under the Indiana Public Records Act must designate on a cover sheet or on each page of the document such exemption from disclosure and specify the applicable statutory exception to disclosability. The State and its contractors shall exercise their best efforts to maintain the designation and shall refrain from removing it, as well as making an unauthorized disclosure of the document(s). Documents without any designation shall be considered fully disclosable.*

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## Preferred Drug List Submission Checklist

Please complete the submission checklist below to the email address provided.

<b>PRODUCT INFORMATION</b>	<b>YES</b>	<b>NO</b>
Has a product description been provided?		
Has a list of approved indications been provided?		
Have you included a summary of the product's "place in therapy" for each indication?		
Have copies of treatment guidelines been provided?		
Have the intermediate and final outcomes of therapy been listed?		
Have you listed any co-prescribed drugs by indication?		
Have you identified the comparator drugs by indication?		
<b>SUPPORTING CLINICAL INFORMATION</b>	<b>YES</b>	<b>NO</b>
Have you identified all relevant clinical and other experimental studies for the product?		
Have you identified all relevant clinical and other experimental studies for comparator products?		
Have you summarized the experimental studies?		
Are copies of all studies identified included in the submission package?		
Have you included all relevant non-experimental studies for the product?		
Have you included all relevant non-experimental studies for the comparator products?		
Have you summarized the non-experimental studies?		
<b>SUPPORTING ECONOMIC INFORMATION</b>	<b>YES</b>	<b>NO</b>
Have you identified all relevant pharmacoeconomic (PE) studies?		
Have you justified the relevance of these PE studies for Indiana Medicaid population?		
Have you provided a summary of the PE studies?		
Have you identified the characteristics of patients who may potentially be switched to this product?		
Have you identified the characteristics that would exclude patients from using the product?		
<b>COST IMPACT ASSESSMENT</b>	<b>YES</b>	<b>NO</b>
Is a baseline prevalence analysis of resource utilization and costs included?		
Have you detailed the scenarios for cost impact assessments?		
Have you considered and listed the assumptions made for projecting patient switching behavior?		

Adopted from: Sullivan SD, Lyles A, Luce B, Grigar J. AMCP Guidance for Submission of Clinical and Economic Evaluation Data to Support Formulary Listing in U.S. Health Plans and Pharmacy Benefits Management Organizations. J Managed Care Pharm 2001; 7: 272-282.





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Have you justified the scenarios and assumptions for Indiana Medicaid patient population?		
Have you provided estimated total cost impact assessments for the next three years?		
Have you provided a breakdown of the costs by medical resource utilization and drug categories?		
Have you included a proposal on how these cost-impact projections might be monitored?		
Have you explained how differences between projections and actual costs might be resolved?		
<b>OUTCOMES IMPACT ASSESSMENT</b>	<b>YES</b>	<b>NO</b>
Is a baseline prevalence analysis of patient outcomes included?		
Have you provided details for the scenarios for outcome impact assessment?		
Have you provided details for the assumptions made for projecting patient switching behavior?		
Have you justified the scenarios and assumptions for Indiana Medicaid population?		
Have you provided estimated total patient-outcome impact assessments for the next three years?		
Have you provided a breakdown of the costs by medical-resource utilization and drug categories?		
Have you included a proposal on how patient outcomes might be monitored?		
Have you explained the differences between the projected and actual patient outcomes?		

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## Notice of Intention to Submit

1. Manufacturer: \_\_\_\_\_

2. Date of Request: \_\_\_\_\_

3. Contact person: \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Phone number \_\_\_\_\_

E-mail address \_\_\_\_\_

4. Drug Generic Name: \_\_\_\_\_

5. Drug Trade Name: \_\_\_\_\_

6. Approved Indication: \_\_\_\_\_

7. Dosage Forms: \_\_\_\_\_

8. Dosage Strengths: \_\_\_\_\_

9. References (attach monograph): \_\_\_\_\_

10. Submissions may be made via electronic mail to the following address:

[PDL@fssa.in.gov](mailto:PDL@fssa.in.gov)

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## Manufacturer Responsibilities for Submission

1. List of intended indications
2. Full physical reproductions and summaries of all studies to be included in the preferred drug list submission including:
  - a. Clinical Trials (experimental and non-experimental)
  - b. Meta-analyses
  - c. Prospective/Retrospective studies
  - d. Pharmacoeconomic models
3. A general description of how cost and outcomes impact assessments will be developed including:
  - a. List of data sources (studies, databases, etc)
  - b. Discussion of the conversion of efficacy to effectiveness for both drug and comparators
  - c. Approach to modeling the environment of the health plan
  - d. Assumptions
  - e. Suggested approach for determining patient characteristics for switching
4. Summary of studies expected to be completed within one to three years
5. A completed submission checklist

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## Preferred Drug List Submission Timeline

The purpose of this notice is to inform Indiana Medicaid's T-Committee of the manufacturer's intent to submit a product for preferred drug list consideration.

1. At least 48 hours prior to submission, a letter (*Notice of Intention to Submit*) must be received by Indiana Medicaid at: [PDL@fssa.in.gov](mailto:PDL@fssa.in.gov)
2. Once this packet of information has been received, it will be reviewed and you may be asked to submit additional information to complete the dossier.
3. Manufacturers may be asked to provide for review to the T-Committee copyrighted materials in accordance with copyright laws.

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