Alabama Medicaid Dossier Submission Form/Packet

Instructions for Dossier Submission

The **Dossier Process** provides a structured and uniform way for individuals to submit evidence related to the effectiveness and safety of a service under review for coverage. All dossier submissions must use the *Dossier Submission Form.* Evidence dossiers submitted in other formats will not be accepted. **Dossier Submission Requirements** include:

- Submission form with detailed information on who is requesting coverage—manufacturer/distributor, health care provider, patient, advocacy groups, etc.
- Peer Reviewed literature/list of publications (randomized controlled trials; observational studies—prospective, retrospective, case series; Expert Panel, etc.)
    - Ascribe which of the following categories of evidence applies to each publication submitted:
        - Meta-analysis, systematic review, or technology assessment
        - Randomized controlled trial(s)
        - Non-randomized studies –non-randomized controlled, pre/post, cohort, case-control, cross-sectional. Observational studies, case series, economic studies.
        - Expert Panel Opinion
        - Case Reports
        - Single Expert Opinion
        - Other
- Product Information Sheet
- Supplemental Data for published studies (subgroup analysis, additional outcomes, methods details)
- Unpublished studies

Individuals submitting evidence dossiers should understand that submission of information in the format recommended herein does not mean a service will be covered or approved for payment. Individuals submitting evidence dossiers must answer a series of questions related to the service and submitted evidence and comment on the net health impact of the service based on the evidence submitted. All dossier submissions must use the *Dossier Submission Form*. Evidence dossiers submitted in other formats will not be accepted. A dossier submission that is incomplete or fails to follow this protocol will not be considered. All costs of dossier submission must be borne by the submitter.

Once a dossier submission is received, the Alabama Medicaid Agency will evaluate the submitted evidence, staff will make recommendations, and coverage will be determined by an assessment of the net health impact of the service as demonstrated by the available research evidence. Alabama Medicaid shall have no obligation to return submitted dossiers irrespective of any markings or statements of confidentiality contained in or on the dossier.

Dossier Submission Form Checklist
The following information should be included in the dossier submission:

- ✓ Overview, Contact Information, and Executive Summary
- ✓ Service Rationale
- ✓ References—full PDF copies of all references and articles cited
- ✓ Supporting Documents (e.g., FDA approval letter, IRB protocol, trial registration—if applicable)

All forms should be completed with one-inch margins using 10 pt Arial font. Please do not exceed 6,000 words on the Service Rationale (excluding PDF copies of references). Failure to follow these submission requirements may result in the entire dossier submission not being reviewed.

Overview and Contact Information

Contact Information

Name of Individual Submitting Dossier _____

Company/Organization _____

Address _____

Phone _____

Email address _____

Technology Information

Service Under Review _____

Manufacturer(s) _____

Description of Service _____

Applicable Codes

What HCPCS or CPT codes can be used to bill for this service? *Please list all applicable codes.*

Executive Summary

Please provide an overview of the service in 250 to 750 words. Additional pages may be attached if needed. The summary should include a short description of the service, included evidence, and any related harms. The executive summary may be used on the Department's website and should be written at a reading level for general public consumption.

Service Rationale

The following questions inquire about the safety and efficacy of the service under review and its applicability to the Alabama Medicaid population. The use of the term "service" refers to medical or surgical treatment procedures, devices, pharmaceuticals, and diagnostics. Please cite your responses and list all references. Please answer the questions below using 10 pt Arial font with one inch margins. Additional pages may be attached if needed. DO NOT EXCEED 6,000 words in total in answering the questions below.

1. **The service must have final approval from the appropriate US governmental regulatory bodies (e.g., FDA), if applicable.**
   a. What is/are the licensed use(s) of this service?

   b. Does the service have FDA or other regulatory agency approval and for what use(s)?

      What approval process was employed (e.g., 510(k), Premarket Approval, Investigational Device Exemption)?

   c. Please submit approval letter from the FDA or other regulatory agency, if applicable.

2. **The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.**
   a. Please specify how the submitted references demonstrate the efficacy and/or effectiveness of this service.

   b. Please disclose all potential harms or other safety concerns regarding this service (e.g., side effects, adverse events).

3. **The service must improve the net health outcome of a population.**
   a. How would this service increase the health of Alabama Medicaid patients?

4. **The service must be at least as beneficial as any established alternatives.**
    a. How is this service (1) different from, AND (2) more effective than services that currently address the medical condition for which this service is intended for use?

    b. How does the safety of this service compare with other services that are currently used to treat the medical conditions in question?

    c. If this is a diagnostic service, what is the current best diagnostic strategy (i.e., diagnostic gold standard), and how does this service compare with it?

5. **The improvement must be attainable outside of the investigational settings.**
    a. Please specify which submitted references discuss the clinical effectiveness of the service and its effect on health outcomes outside the investigational setting (e.g., in general community medical practice, among populations with known co-morbidities).

6. **The service must be cost-effective or cost neutral outside the investigational setting.**
    a. What is the total cost for the service (e.g., costs of related physician services or outpatient hospital charges or other services that patients using the service will need)? Please include both the initial costs and estimated lifetime costs.

    b. Please compare the total cost of the service with the cost of established services that currently address the medical conditions for which this service is intended for use. Please include both the initial costs and estimated lifetime costs.

7. **Other payer coverage of the service.**
    a. Which State Workers' Compensation programs and private Health Plans nationwide cover the use of this service, and have there been any Centers for Medicare and Medicaid Services (CMS) national or local coverage determinations?

    b. Are there any restrictions of this coverage? If yes, please list restrictions below.