New York Department of Health Evidence-based Review Process for Coverage Determinations

Dossier Instructions

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Introduction

Background

Historically, Medicaid benefits and covered services have rarely been examined on a systematic basis. As an essential part of the New York Medicaid Redesign Team (MRT), New York State is committed to structuring the Medicaid benefit to ensure that all beneficiaries have access to the clinically effective, efficiently delivered services they require. To that end, the New York Department of Health (DOH) has established a new, systematic process for making decisions about Medicaid benefits using the best available research evidence. The Dossier Process is designed to support transparent and consistent coverage and payment decisions that align with the Centers for Medicare and Medicaid Services' Triple Aim vision for health care of achieving better health, better quality, and lower costs.

Through the Dossier Process, the Department evaluates available evidence to determine coverage of health care services, procedures and devices (hereafter referred to as services). Covered services must be FDA approved when required and supported by evidence of safety and effectiveness. Services of uncertain value (e.g., high cost with lower cost alterative; high risk) will be selected to go through the Dossier Process. Individuals or entities may an evidence dossier. Dossiers should be comprehensive and include the most current research available. This dossier submission process will help the State better understand the body of clinical research evidence (hereafter referred to as evidence) related to the service under review, what limitations on use may be appropriate, and whether coverage of the service represents significant value to the people of the State of New York. Figure 1 (below) summarizes the DOH Dossier Process and highlights where individuals or entites may submit an evidence dossier on a service under review.

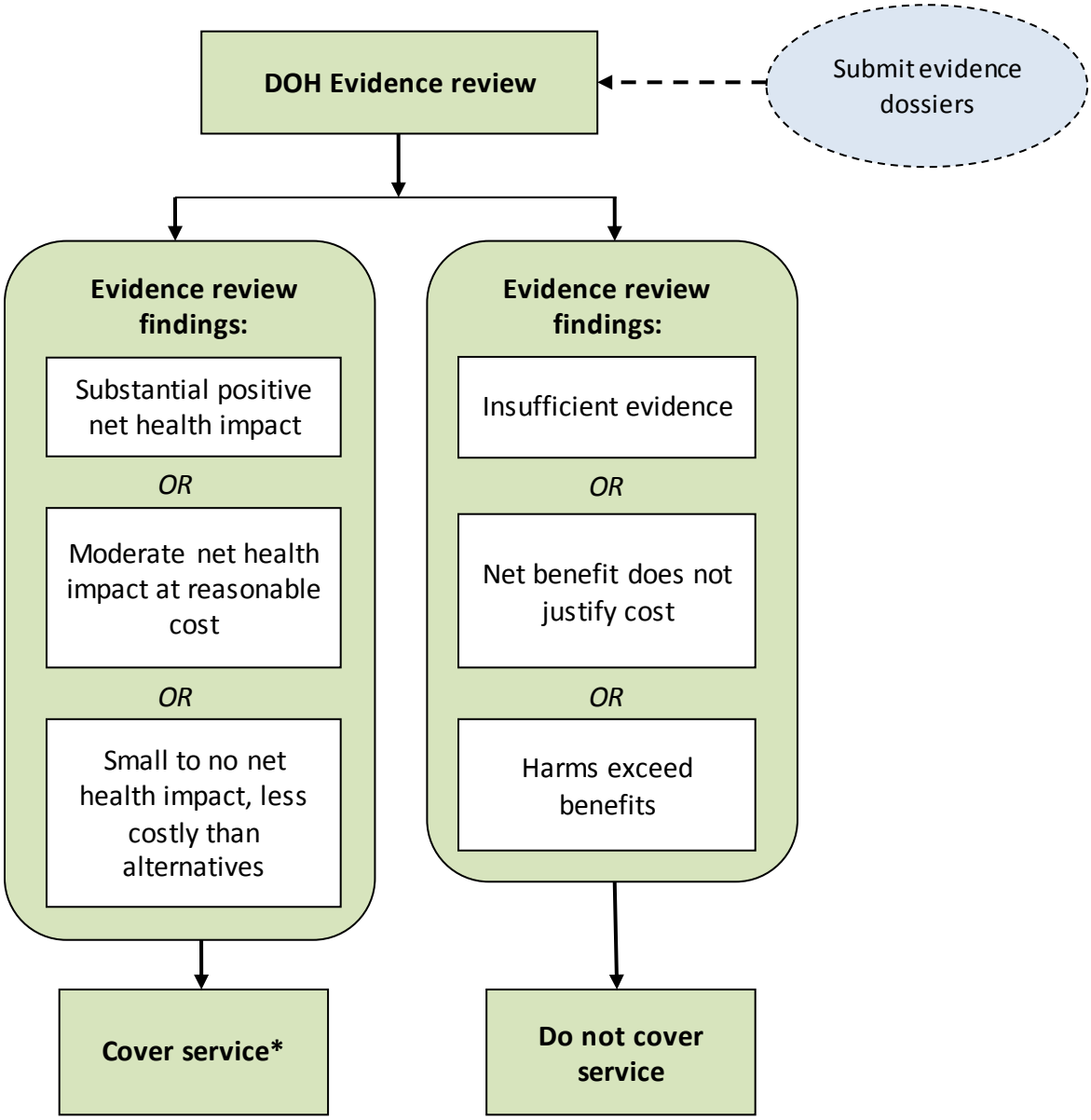
Dossier Submission Process

The dossier submission process provides a structured and uniform way for individuals or entities to submit evidence related to the effectiveness and safety of a service under review. Individuals or entities submitting evidence dossiers must answer a series of questions related to the service and submitted evidence, assess the methodological quality of the submitted evidence, and calculate 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. Incomplete dossier submissions will not be reviewed, and the submitter will be notified. The *Dossier Submission Form* includes quality appraisal checklists necessary to assess the methodology quality of the evidence submitted. Please refer to the accompanying *Dossier Methods Guidance* document for a more detailed discussion of assessing

the methodological quality of a study, determining the overall strength of a body of evidence, and assessing the net health impact of a product.

Figure 1. Evidence-based Review Process for Coverage Determinations



Once a dossier submission is received, DOH will evaluate the submitted evidence, the appraised methodological quality of the evidence, and the calculations of net benefit. Coverage will be determined by an assessment of the net health impact of the service as demonstrated by the

available research evidence. DOH reserves the right to consult additional sources of evidence and consult with external reviewers to assist in evaluating dossier submissions for making coverage determinations.

General Information for Submissions

Individuals or entities 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. This *Dossier Instructions* document describes the minimum information requirements necessary to support a comprehensive assessment of the service in relation to other similar services.

All costs for suggesting a service for review or submitting an evidence dossier must be borne by the submitter. A dossier submission that is incomplete or fails to follow this protocol will not be considered. All information submitted to DOH through an evidence dossier submission may become available to the public. It is the submitter's responsibility to limit information (including, but not limited to clinical, price, financial and all other data and information) submitted under this process to data and information that may be publicly disclosed.

Regardless of any markings or statements of confidentiality contained in the dossier and supporting documents submitted to DOH, the submitter authorizes the DOH to:

- Use any or all materials in the dossier submission in their evaluation of a service; and
- Make any and all information available to the public, including but not limited to Freedom of Information Law requests.

The New York DOH shall accept all dossier submissions and shall have no obligation to return submitted dossiers irrespective of any markings or statements of confidentiality contained in or on the dossier.

Dossier Submission Instructions

New York DOH coverage decisions are based on whether a service has a positive net impact on improving the health and improving the quality of care for recipients, and containing costs for the New York Medicaid program. Patient important health outcomes such as mortality, morbidity, and quality of life are of primary interest to DOH and surrogate outcomes such as test results or physiologic measurements are of little or no importance unless such surrogate measures have a strong and established link to key patient-oriented outcomes. Submitting available evidence on a service and using internationally recognized methods for appraising the quality and strength of the research submitted through this process will create an unbiased, transparent, and consistent foundation for making a coverage determination.

The following instructions address each section of the *Dossier Submission Form*. Evaluating the methodological quality of evidence and determining an overall strength of the evidence are sequential actions; the instructions provide a suggested order for completing the *Dossier Submission Form* to aid in these tasks.

Step 1 – Overview, Contact Information, PICO and Executive Summary

Please provide contact information for the individual submitting the evidence dossier, a description of the service, and all relevant HCPCS and CPT codes. The PICO (Population, Intervention, Comparator, Outcome) framework should be included, along with specific references to all potential harms. The executive summary should include a short description of the service, included evidence body, 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.

Step 2 – Identification of Studies

Identify individual references on the service that relate to the specified applicable population(s), intervention(s), comparator(s), and patient important outcomes (PICO) of the service. A full citation and a PDF copy of the article must be provided for each study included in the dossier submission. Submitters should include all applicable evidence on the effectiveness and safety of a selected service (including unpublished studies). Please list all study citations in alphabetical order (by last name of first author) in the *Reference & Quality Appraisal Ratings* section of the *Dossier Submission Form*.

Note: While clinical practice guidelines may be pertinent to the service under review, DOH does not consider them an acceptable evidence source for this process. However, all good quality guidelines are supported by a systematic review of the evidence (Institute of Medicine 2011), and these systematic reviews can be included in the dossier submission.

Step 3 – Service Rationale

The Service Rationale includes seven multiple part questions. The questions relate to the efficacy and safety of the service under review, and the applicability of the service to the New York Medicaid population. Each question should be answered in entirety. Please cite the references listed on the *Reference & Quality Appraisal Ratings* section as part of the response to each question. The total response length must be limited to 6,000 words. All references cited in this section should be listed in the *References & Quality Appraisal Ratings* section (Step 2), and every study must be assessed for methodological quality (Step 4).

New York DOH will prioritize patient important outcomes in its review of the evidence. If an individual or entity would like to submit evidence on surrogate outcomes, they must provide the references to support how the surrogate outcomes are directly linked to patient important outcomes. In addition, a time frame for each outcome discussed (e.g., cardiac events – per year; chronic migraines – per month) must be provided.

Step 4 – Assess Methodological Quality of Each Study

New York DOH uses a hierarchy of evidence to determine the weight given to available evidence on a given service. Please see the *Dossier Methods Guidance* document for further discussion of the hierarchy of evidence and the integral components that factor into assessing the methodological quality of a study. The tools used by DOH to quality assess individual studies are listed in Figure 2 and are included in the *Dossier Submission Form* document. The tools, otherwise known as checklists, are modeled after nationally and internationally recognized processes (Grading of Recommendations Assessment, Development and Evaluation (GRADE) (Guyatt 2008)[1] in order to satisfy the requirements for scientific validity in the ethical conduct of clinical research. The Quality Appraisal Checklists and the *Dossier Methods Guidance* document provide step-by-step guidance on how to critically appraise the studies included in the dossier submission. A completed Quality Appraisal Checklist must be submitted for each study included in the dossier submission.

Figure 2. Quality Appraisal Tools

Study Description	Study Type	Quality Appraisal Checklist
Meta-analysis, systematic review, or technology assessment	Type I	Quality Appraisal Checklist: Systematic Reviews and Meta-analyses
Randomized controlled trial(s)	Type II	Quality Appraisal Checklist: Randomized Controlled Trials

[1] Guyatt, G.H., Oxman, A.D., Vist, G.E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., et al. (2008). GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. *British Medical Journal, 336*(7650), 924-926.

Study Description	Study Type	Quality Appraisal Checklist
Non-randomized studies (e.g., nonrandomized controlled, pre-post, cohort, case-control, cross-sectional, observational studies, economic studies)	Type III	Quality Appraisal Checklist: Cohort Studies Quality Appraisal Checklist: Cross Over Studies Quality Appraisal Checklist: Diagnostic Test Accuracy Quality Appraisal Checklist: Case Series Quality Appraisal Checklist: Economic Evaluation

Each Quality Appraisal Checklist includes questions pertaining to the internal validity of a study. Internal validity refers to how well a study was conducted to minimize bias, or in other words, how likely the findings of the study are to be true. Every question should be answered with Yes, No, Unclear, or N/A as appropriate. Detailed guidance on filling out the Quality Appraisal Checklist(s) is provided in the *Dossier Methods Guidance* document. Each Quality Appraisal Checklist assesses the overall methodological quality of an individual study through a series of questions. For every study included in the dossier submission, please list the overall quality rating with the corresponding full citation in the *References & Quality Appraisal Ratings* section of the *Dossier Submission Form*.

Step 5 – Assess the Overall Body of Evidence

To evaluate the strength of the overall body of evidence submitted, the body of evidence for each outcome is synthesized. Several factors are considered when determining the overall strength of a body of evidence. In order to accurately assess the strength of a body of evidence, it is essential to include all available evidence that meets the specified inclusion criteria (see topic PICO and Key Questions). Please refer to the *Dossier Methods Guidance* document for a detailed discussion of determining the overall strength of a body of evidence for a service.

Descriptions of the four overall ratings for strength of evidence based on the GRADE system are provided below to assist with your appraisal of the evidence.

- **High** (Highly confident that the true effect lies close to that of the estimate of the effect)
    - Evidence typically consists of systematic reviews, meta-analyses, and randomized controlled trials without important limitations
- **Moderate** (Moderately confident in the estimate of of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is different)
    - Evidence typically consists of systematic reviews, meta-analyses and/or randomized controlled trials with some limitations; or

    - Well designed large observational studies with additional strengths that guard against potential bias and have large estimates of effects.

- **Low** (Limited confidence in the estimate of the effect: The true effect may be substantially different from the estimate of the effect)
    - Evidence typically consists of systematic reviews, meta-analyses, and randomized controlled trials with a number of significant limitations; or
    - Observational studies without special strengths.

- **Very Low** (Very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect)
    - Evidence typically consists of observational studies with serious limitation and outcomes for which there is very little evidence, or studies with conflicting outcomes.

- **None** (no evidence is available).

Step 6 – Assess Impact

Determining the net health impact of a service is a necessary piece of DOH's evaluation process. Assessing harm versus benefits of a service compares the magnitude of benefit and harms within a population. There are a number of measures that can help calculate the net impact of a service. Some services can be used for multiple outcomes; when that is the case, it is necessary to assess the net impact for each outcome. The net impact of a service may be different for individual outcomes. Refer to the *Dossier Methods Guidance* document for a detailed discussion of outcome measures.

Step 7 – Dossier Submission

Upon receipt of an evidence dossier, the Department medical team will evaluate the entire dossier submission for completeness and accuracy. This will include independent quality appraisal of submitted studies and an independent literature search. The Department will determine an independent overall strength of evidence for each outcome based on its review of the evidence and determine the net impact for each outcome.

Please mail six hard copies and four electronic copies (on USB devices) of your dossier submission and all supporting documents to:

New York Department of Health
Office of Health Insurance Programs
99 Washington Ave.
One Commerce Plaza - 720

Albany, NY 12210
ATTN: Dossier Review Unit

Contact phone number: (518) 473-2160
Contact email: dossier@health.ny.gov

References

Institute of Medicine. (2011). *Clinical practice guidelines we can trust*. Washington, D.C.: The National Academies Press. Retrieved December 17, from http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx