Guidelines for Utilization Management Policy Development & Revision

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Related Policies

Utilization Management Overview

Policy Number	**429**
Original Effective Date:	3/2003
Current Approval Date:	4/23/20
Next Review:	4/2021
Category:	Compliance

Policy Statement

The application of utilization management (UM) policies is embedded within the structure of benefit coverage documents (certificates of coverage or summary plan descriptions), which represent the contractual arrangement between health plan members and purchasers. UM policies are subordinate to member benefit coverage documents.

Optum* by OptumHealth Care Solutions, LLC develops and implements UM policies to:

- Serve as the clinical criteria for utilization review (UR) determinations;
- Describe administrative processes and requirements associated with UM programs; and
- Function as a resource for peer-to-peer outreach.

The basis for UM policy statements should be explicitly derived from information obtained using transparent and evidence-informed processes including descriptions of the methods used to identify evidence, critical appraisal of research evidence, considered judgments and contextual factors. The findings should be translated into terminology that is consistent with member benefit documents.

Purpose

This guideline describes the framework for the development and revision of Optum UM policies.

Scope

This guideline is applicable to all UM policies.

Overview

Optum* by OptumHealth Care Solutions, LLC develops and implements UM policies to: 1) serve as the clinical criteria for utilization review (UR) determinations; 2) describe administrative processes and requirements associated with UM programs; and 3) function as a resource for peer-to-peer outreach. The application of UM policies is embedded within the structure of benefit coverage documents (certificates of coverage or summary plan descriptions), which represent the contractual arrangement between health plan members and purchasers.

Optum recognizes the need to use rigorous processes that ensure healthcare policies and guidelines are *informed* by the best available evidence. Systematic and explicit methods of making judgments can reduce errors and improve communication.[1] Further, Optum recognizes that transparency in the development and implementation of clinical policies will help to assure an explicit and supportable process. Most importantly, the provision of evidence-informed healthcare has been shown to result in more equitable care[2] and improved patient outcomes, when compared with non-evidence-based strategies.[2-4] "Evidence-informed health policy-making is an approach to policy decisions that aims to ensure that decision making is well-informed by the best available research evidence. It is characterised by the systematic and transparent access to, and appraisal of, evidence as an input into the policy-making process."[5] The World Health Organization[6] has described the following stages in the process of evidence-informed policy making:

- DEFINE: Clearly define the health problem or issue
- SEARCH: Efficiently search for research evidence
- APPRAISE: Critically and efficiently appraise the research sources
- SYNTHESIZE: Interpret/ form options or recommendations for practice or policy based on the literature found
- ADAPT: Adapt the information to a local context
- IMPLEMENT: Decide whether to implement the adapted evidence into practice or policy
- EVALUATE: Evaluate the effectiveness of implementation efforts

Figure 1 outlines the framework for evidence-informed UM policy development and revision. This process maintains fidelity to the stages listed above. Optum follows guidance provided by the Agency for Healthcare Research and Quality (AHRQ) for ongoing horizon scanning[7] to identify emerging technologies that may require new policies, and literature surveillance to detect signals for policy revision.[8] The need for a new policy or a revision of an existing policy can also be identified by a range of stakeholders including but not limited to individual health care providers, professional organizations, client health plans, regulators, Optum personnel, and researchers.

The crafting of questions central to the policy topic helps to more clearly define the issue. Well-formatted key questions facilitate the next stage of EIP – conducting a search of the literature for relevant evidence.

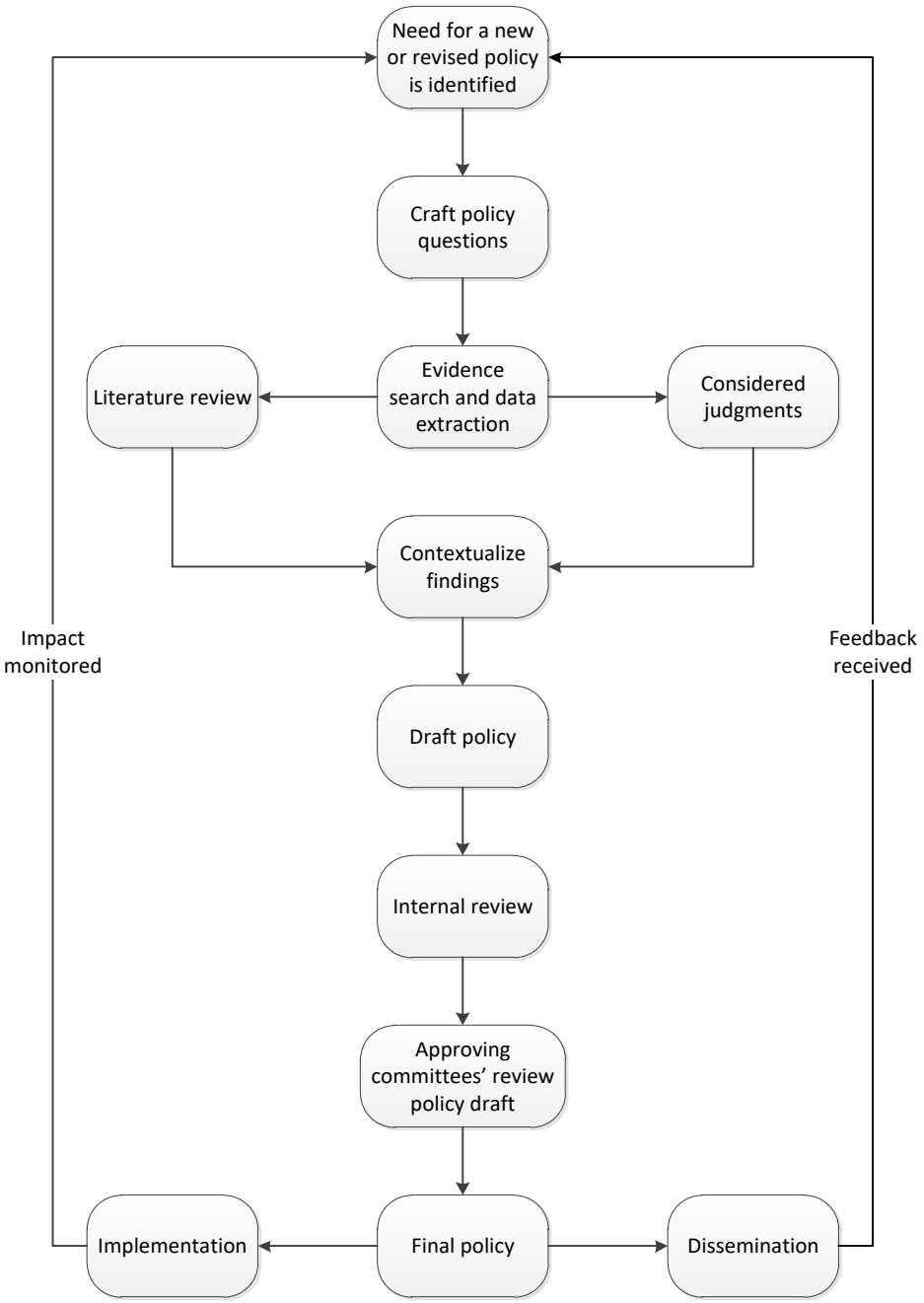
A thoughtfully constructed search strategy enables the efficient identification and extraction of the body of evidence for completing a literature review on a policy topic. The review is conducted using critical appraisal tools to assess for evidence quality and strength of recommendations. The results are then translated into analogous terminology consistent with the language found in benefit coverage documents. The interpretation of the evidence is complemented by considered judgments, which help to bridge gaps in empirical knowledge. The synthesis of evidence and considered judgments is then contextualized by considering system-level impacts and adaptability to local conditions.

Once these core stages are completed, a policy draft can be developed for internal (Optum) review. Internal review aims to: 1) assure the policy is compliant with applicable regulations; 2) justify concordance with client health plan policies and benefit documents; and 3) confirm the policy can be implemented. Following internal review, a series of committees consider the policy for approval. Once approved, a policy is then

scheduled for implementation. UM policies are disseminated using a variety of strategies including presentations, webinars, posting to a web portal, newsletters, and provider outreach. Feedback can be provided through a designated email address provided with each policy. The impact of a policy is monitored though standardized audit procedures.

Figure 1:

UM Policy Development & Revision Framework



Policy Development & Revision Framework

Policy Questions:
Once the need for a new or revised policy has been identified, it is essential to determine the central issue to be covered by the policy. Typically, this can be accomplished by considering and prioritizing topic-specific issues. A scoping literature search and/or assessment of administrative data can help to further specify and refine the scope and purpose of the policy.

Well-built clinical policy questions should then be crafted so they are directly relevant to the issue at hand. Questions should be phrased to facilitate searching for precise answers. To achieve these aims, each question must be focused and well-articulated using the PICO methodology.[9,10]

- P: Population and/or problem;
- I: Intervention (or exposure, diagnostic test, prognostic factor, etc.);
- C: Comparison Intervention (if relevant);
- O: Outcome

Additional components of a policy question may relate to the setting (eg, outpatient care) and timing (eg, post-surgical rehabilitation).

Evidence Search:
An evidence search is a systematic and explicit approach to the identification, retrieval, and bibliographic management of all types of published literature; as well as unpublished and reasonably available information relevant to a specific topic. The goal of an evidence search is to conduct an efficient yet comprehensive retrieval of the salient information on a topic.

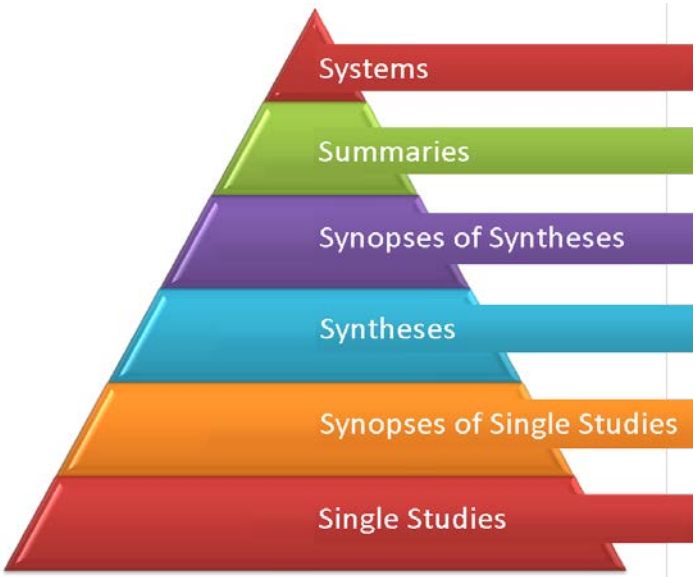
Guidance describing the methods and resources for identifying the current best evidence on a policy topic is found in authoritative texts.[11,12] Additional recommendations for specific topics have also been published.[13]

Three classification systems have been recommended to guide evidence searches.[11] The first classification refers to the hierarchy of evidence at the level of primary (experimental and observational) studies. Here the goal is to prioritize research designs that minimize the risk of bias for a particular topic. For example, well-conducted randomized clinical trials (RCTs) are superior to observational studies for questions about a therapy or harm.

The next classification relates to the level of processing the evidence. Ideally, primary studies can be processed into systematic reviews, which can then be translated into guideline recommendations for clinical practice.

The third classification is the pyramid of evidence-based medicine (EBM) resources. (Figure 2) The different layers show the different types of evidence and how to structure a search for the highest quality information. EBM resources can be broadly categorized as; 1) summaries and guidelines; 2) pre-appraised research; and 3) non-pre-appraised research. Detailed guidance on choosing EBM resources and using the EBM pyramid to answer policy questions is provided in the *Users' Guide to the Medical Literature*.[14]

Figure 2: EBM Resources (6S Pyramid)



Adapted from DiCenso, Bayley and Haynes (2009). Accessing pre-appraised evidence: Fine-tuning the 5S model into a 6S model. Annals of Internal Medicine, 151(6):JC3-2, JC3-3 OR Evidence-Based Nursing, 12,99-101

Literature Review:
A literature review is a systematic means of evaluating and interpreting all available research evidence relevant to a particular policy question or topic area of interest.

In the context of policy making, the literature review is essential to: 1) summarize the existing research evidence concerning a treatment, test or technology; 2) identify any knowledge gaps; and 3) provide a framework/background for evidence-informed policy.

Measuring the methodological quality of research evidence is a core process of the literature review. The quality of available research directly affects the recommendations of UM policies. There are a variety of quality appraisal tools available to policy makers (Table 1).

The appraisal of guidelines, research and evaluation (AGREE II) tool is commonly used for the appraisal of clinical practice guidelines. In contrast to other evidence appraisal tools, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology represents a systematic approach towards assessing and communicating the overall quality of evidence for each patient-important outcome and the strength of recommendations. It has been developed to address the weaknesses of other grading systems and is now widely used internationally. GRADE is the preferred approach for Optum policy-related literature reviews.

There are at least four instruments (AMSTAR, CASP, SIGN, and ROBIS) used to assess the quality of systematic literature reviews and/or meta-analyses. The risk of bias in systematic reviews (ROBIS) tool is designed specifically to assess the risk of bias in systematic reviews within health care settings for interventions, diagnosis, prognosis, and etiology. The questions incorporated in ROBIS flag aspects of review design related to the potential for bias and aim to help assessors judge risk of bias in the review process, results, and conclusions.

A number of critical appraisal instruments have been developed for single studies. Many of the checklists are designed to assess for risk of bias (internal validity or confidence in the estimate of effect). They are tailored to evaluate the components of different types of study designs (RCTs, cohort, case-control, etc.) for different types of questions (therapy, harm, diagnosis, and prognosis). The Cochrane risk of bias tool is the preferred appraisal tool for Optum policy-related systematic reviews of RCTs for therapies. The ROBINS-I tool (Risk Of Bias In Non-randomized Studies - of Interventions) tool, also developed by a Cochrane methods group, is the preferred assessment tool for observational study designs eg, cohort.[15]

Table 1: Quality Appraisal Tools for Different Types of EBM Resources

Type of EBM Resource	Tool (*Owner*)	Website
Clinical practice guidelines	AGREE II (*AGREE Enterprise*)	www.agreetrust.org
Evidence syntheses	GRADE (*GRADE Working Group*)	http://www.gradeworkinggroup.org/
Systematic reviews	AMSTAR 2	https://amstar.ca/Amstar-2.php
	CASP	www.casp-uk.net/
	SIGN	http://www.sign.ac.uk
	ROBIS (*University of Bristol*)	http://www.bristol.ac.uk/social-community-medicine/projects/robis/
Single studies	SIGN	http://www.sign.ac.uk
	PEDro (*CEBP*)	http://www.pedro.org.au/
	CASP	www.casp-uk.net/
	Cochrane Back and Neck Group (*Cochrane Collaboration*)	http://back.cochrane.org/forms
	QUADAS-2 (*University of Bristol*)	http://www.bris.ac.uk/quadas/
	ROBINS-I	http://methods.cochrane.org/news/robins-i-tool

AGREE – The Appraisal of Guidelines, Research and Evaluation; GRADE – The Grading of Recommendations Assessment, Development and Evaluation ; AMSTAR – Assessment of Multiple Systematic Reviews; CASP – Critical Appraisal Skills Programme; SIGN – Scottish Intercollegiate Guidelines Network; ROBIS – Risk of Bias in Systematic Reviews; CEBP – The Centre of Evidence-Based Physiotherapy; QUADAS – Quality Assessment of Diagnostic Accuracy Studies; ROBINS-I – Risk of Bias in Non-randomized Studies –of Interventions

Considered Judgments:

Research evidence is only one factor that can influence the policy making process.[16] "Policymakers often have insufficient evidence to know with certainty what the impacts of a health policy or programme option will be, but they must still make decisions."[17] There are methods that may increase confidence about policy development when there is a lack of research evidence. The application of a structured decision making framework, when experimental clinical research evidence is insufficient for making confident judgments, has been promoted to support policy making.[18,19]

The following series of questions comprises a recommended qualitative assessment that relies on pragmatic reasoning:[19]

- Does the service in question address a significant patient or plan need?
- Is insufficient evidence likely to continue?
- Is the service already used or will it soon be in widespread use?
- Do the potential benefits for the patient outweigh the risks?
- From the plan perspective, are the coverage risks less than the non-coverage risks?

The Scottish Intercollegiate Guidelines Network (SIGN) has also made available a checklist of considered judgments.[20] While a number of items are already integrated within the GRADE system, there are additional judgments relating to the feasibility of implementation.

A promising option to facilitate considered judgments about policy is the availability of interactive evidence-to decision (EtD) tools from the Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence (DECIDE) Consortium.[21,22] The EtD tool inventory includes a template for policy makers, who make coverage decisions about clinical interventions.

Context:
Developing a clinical policy is a complex process by which the characteristics of the topic, options for addressing it and implementation considerations are contextual factors that need to be addressed by policy makers. The following steps should be considered when developing evidence-informed policy:

1. Clarify and refine what is known about the topic
2. Frame the options
3. Identify implementation considerations
4. Consider the broader health system (including the policies and positions of other organizations)
5. Consider the impact on key stakeholders
6. Anticipate monitoring and evaluation needs
7. Make fully informed policy recommendations

Local Context:
The development and implementation of the UM program and policies takes into consideration the implications of local context including but not limited to: 1) regional regulations and requirements; 2) local market structures and dynamics; 3) geographic access standards; 4) the local population and provider characteristics; 5) and professional/social networks [e.g., a set of norms, or standards of care] that can potentially influence health care delivery in a particular region or for a specific population.

Internal Review:
The process of internal (Optum) review provides assurance the policy conforms to all regulatory, contractual, operational, and clinical program requirements prior to submission to the approving committees. A critical function of internal review is assuring that evidence ratings are translated into terminology that is consistent with member benefit documents.

Policy Approval Process:
New and recently revised UM policies are submitted to standing committees for approval. The Utilization Management Committee (UMC) is responsible to assure proposed policies conform to the standards described in the UM Program document. The Quality Improvement Committee (QIC) determines whether or not a draft policy meets all organizational standards for quality assurance. Thereafter, all UM policies undergo annual review and consideration for approval by the same two committees.

Both the UMC and the QIC include external members with diverse backgrounds eg, researchers, educators and health care providers (chiropractors and physical therapists).

Policy Implementation and Dissemination:
Following the approval of the final policy, implementation is the next phase of the cycle in which adopted policies are put into effect. Effective policy implementation involves three key elements broadly categorized as organization, interpretation, and application. Effective organization entails that policies are

implemented by Optum using a standardized process, which is coordinated by the Clinical-Operations Department. Interpretation means that the policy's intent is translated into operating rules and guidelines eg, for UR decision-making. Application describes the process of coordinating new or revised policy with ongoing operations and programs.

Dissemination means the targeted distribution of policy to a specific audience. The intent is to spread awareness and knowledge of the policy content in useful formats. Optum uses a multi-faceted approach to disseminate UM policies among health care providers. Approved policies are posted to an open-access web portal. Newsletters provide a medium for announcements and summaries of new and revised policies. Optum support clinicians supply one-to-one detailing of policies with health care providers. Policies are also disseminated via presentations to relevant professional organizations. Individual health plan members can access plain language summaries through the Optum web portal.

Feedback and Monitoring:
The framework for policy development and revision is an ongoing process that is activated when new evidence or information suggests the need for a policy revision.

Optum actively seeks feedback from professional groups at conferences and through web-enabled meetings. Optum also promotes feedback from a broad range of stakeholders (eg, individual providers, members) concerning UM policies. A dedicated email address is provided with each policy: policy.inquiry@optumhealth.com.

The monitoring of policies for accuracy and completeness is conducted using ongoing literature surveillance and other horizon scanning methods. The impact of UM policy is also regularly assessed through internal and external audits.

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Policy History/Revision Information

Date	Action/Description
11/11/2003	Original effective date
11/18/2004	Policy updated and Annual review completed
2/14/2006	Annual review completed
12/04/2006	Annual review completed
4/10/2008	Annual review completed
11/11/2008	Policy header rebranded, "OptumHealth Care Solutions – Physical Health
1/15/2009	Policy placed into new format
4/30/2009	Annual review completed
4/08/2010	Quality Improvement Committee review and approval. Policy revised: re-titled to reflect an expanded scope; the definition of evidence has been broadened; the policy statement completely revised - allows for externally sourced literature reviews to be used in lieu of internally derived systematic reviews under specific circumstances; decision guidance is provided that describes a hierarchy of evidence for policy making; The *Strength of Recommendation* scale has been replaced by an *Evidence Rating* scheme, which correlates with benefits terminology; Appraisal tools for systematic reviews and guidelines have been added
10/26/2010	Policy rebranded to "OptumHealth Care Solutions, Inc. (OptumHealth)"
4/07/2011	Annual review completed
7/21/2011	GRADE, AMSTAR, and AGREE appraisal schemes revised to reflect recently published interpretative guidance. Literature search methodology revised to be consistent with recommendations of the Cochrane Back Review Group.
4/19/2012	Annual review completed
4/18/2013	Annual review completed
4/17/2014	Annual review completed; Policy rebranded "Optum* by OptumHealth Care Solutions, Inc."
4/16/2015	Annual review and approval completed
4/21/2016	Policy title revised to reflect a change in purpose and content. Previously, the policy focused on evidence appraisal and ratings. This revision describes the framework for policy development and revision. Changes made to the policy include a broader set of external resources for application in UM policy making.
4/20/2017	Annual review and approval completed; Policy updated to include the ROBIS and ROBINS-I quality assessment tools for systematic reviews and nonrandomized intervention studies respectively. Legal entity name changed from "OptumHealth Care Solutions, Inc." to "OptumHealth Care Solutions, LLC."
4/26/2018	Annual review and approval completed; Policy updated to include the consideration of local context; The annual policy approval process was clarified.
4/25/2019	Annual review and approval completed; Updated Table 1 (replaced AMSTAR with AMSTAR 2)
4/23/2020	Annual review and approval completed

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: policy.inquiry@optumhealth.com with the word "Policy" in the subject line.

The services described in Optum* by OptumHealth Care Solutions, LLC policies are subject to the terms, conditions and limitations of the Member's contract or certificate. Optum reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Optum's administrative procedures.

Certain internal policies may not be applicable to self-funded members and certain insured products. Refer to the member's Summary Plan Description (SPD) or Certificate of Coverage (COC) to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the member's SPD or COC, the member's SPD or COC will govern.