Optum

InterQual®

Clinical Development Process 2024

InterQual Integrity Charter

Thousands of people in hospitals, health plans, and government agencies trust InterQual® evidence-based clinical decision support content to provide recommendations about the appropriateness and management of care and resource use including helping to facilitate equitable access to care. During the last four decades, InterQual has helped define and advance the disciplines of utilization and care management, providing medical directors, utilization management leaders, and other hospital and health plan professionals support in making the type of objective, evidence-based decisions that define top-quality, safe, equitable, and efficient care. This leads to greater transparency and collaboration between payers and providers.

The InterQual suite has expanded to 30 modules providing industry-leading objective clinical evidence and expert technology to help payers and providers collaborate for better healthcare outcomes at lower cost. While individual solutions meet key needs in a time of rapid industry change, the breadth of our portfolio allows healthcare organizations to combine our solutions in innovative ways to turn challenge into opportunity.

Our history of growth and innovation highlights our commitment to enhance InterQual through unbiased clinical content development and technology solutions. As our team is a part of Optum, we have access to a wealth of data and technologists. Aggregated data and literature search technologies are instrumental to the future of content curation. Our data can help us understand current practices and provide benchmarks, which are not intended to serve as treatment limits or substitute for clinical judgment, but can help medical directors, utilization leaders, and other hospital and health plan professionals understand normal ranges for current practice.

With over 4,000 InterQual customers relying on the guidance that InterQual provides, we take our responsibility to provide accurate, objective, evidence-based content very seriously. For over 40 years, our commitment is reflected in our rigorous evidence-based development process, designed to protect against bias.

InterQual development process

InterQual is produced using a rigorous development process based on the principles of evidence-based medicine (EBM). InterQual clinical content is created by the Optum research and content development staff of over 55 research and clinical decision support specialists including physicians, registered nurses, physician assistant, nurse practitioners, social workers, physical and occupational therapists, and other healthcare professionals, including a medical librarian. The physicians' backgrounds include experience or specialization in internal medicine, neurology, psychiatry, substance use disorders, hospital medicine, pulmonary medicine, and critical care medicine. Most of the clinical staff hold advanced degrees (e.g., MD, DO, Masters, Ph.D.), certifications (e.g., nurse practitioner, physician assistant), and/or case management certification. All InterQual research and content development staff receive comprehensive,

ongoing training at least quarterly in the concepts and methods of EBM and value-based clinical improvement to ensure that InterQual uses the best available evidence to support improved clinical decision-making, outcomes, quality, and value. New content staff receive comprehensive training in the principles of evidence-based medicine including the completion of 9 modules. Additionally, all staff participate in annual refresher training regarding mental health parity to reinforce that the processes, strategies, factors, and evidentiary standards are applied consistently and no more stringently between the development of our medical/surgical content and behavioral health content. The InterQual clinical content development process relies on, and is generally consistent with, the following:

- AHRQ Methods Guides, the Cochrane Handbook, and the NICE guideline development manual for literature searching, critical appraisal, and combining results of studies
- GRADE methodology for compiling evidence and determining recommendations

Although InterQual Criteria are not clinical practice guidelines, their development process is closely aligned with the AGREE-II and National Academy of Medicine (formerly IOM) standards for high-quality, trustworthy clinical practice guidelines.

Optum uses a multi-step standardized development process across our medical/surgical (physical medicine), care management, and mental health/substance use disorders content that synthesizes the best quality relevant scientific evidence and standards of care to ensure that the content reflects unmatched clinical rigor and integrity. The process is the same across all areas of medical and behavioral health literature. (Figure 1.)

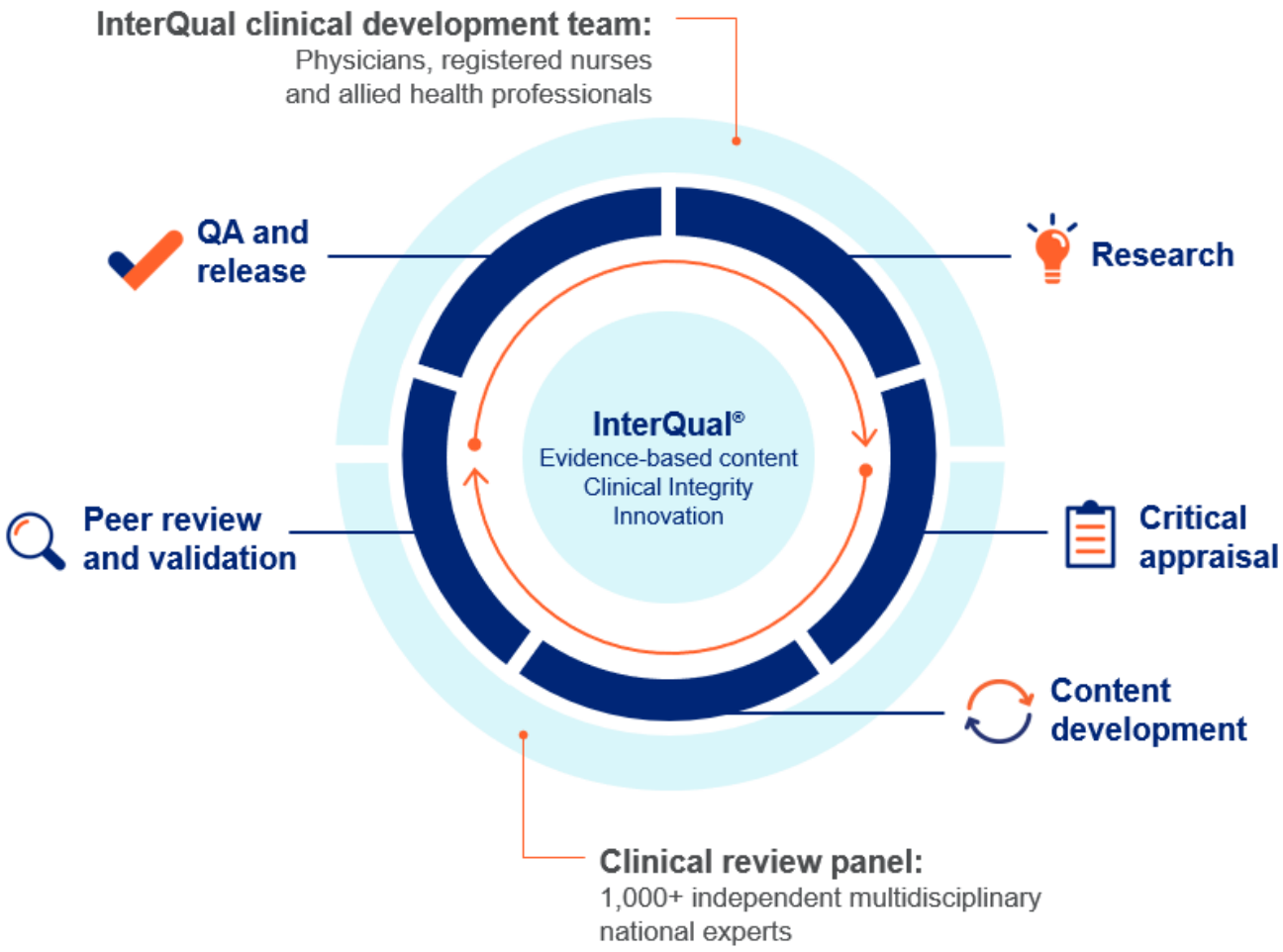

Figure 1. InterQual evidence-based content is reviewed at least annually and updated as necessary through a rigorous and comprehensive development cycle.

Step 1: Research

Optum observes a planned schedule for reviewing and updating every InterQual subset and module it produces. Our automated literature surveillance processes ensure that, when a critical publication emerges that may necessitate an interim update, our staff are immediately alerted.

The InterQual research and content development team uses a systematic and continuous review of the published medical and behavioral health literature, combined with customer and external peer review panel feedback, to identify content that needs revision and additional content that must be developed as both physical and behavioral health medicine advances. These teams are physician-led and the mix of internal staff and external peer review panel members include those who have licensure and expertise specific to the specialty area of the services being reviewed. In addition to their professional and academic experiences, all research and content development staff undergo extensive training in the principles and application of evidence-based medicine and critical appraisal upon hire and year-round education sessions led by members of our Evidence Based Medicine Committee. Content is reviewed and updated as needed, at least annually, with the capability to release updates as frequently as every month for critical and regulatory updates in the evidence base. Peer-reviewed journals are monitored, and our proprietary automated surveillance system monitors thousands of key sites and topical areas for newly published literature and guidelines. Additionally, we review customer feedback received through our toll-free number (800-CRITERIA), email (mailto:interqualsupport@changehealthcare.com), and our customer website (https://customercare.changehealthcare.com), Additionally, there is proactive outreach for voice of the customer sessions, and at least annual customer surveys. Additionally, we monitor state and federal regulation and legislation that can impact our content. Our internal staff annually reviews thousands of articles across the InterQual suite of products. We also subscribe to a proprietary, web-based medical literature service (Clinical Key) and the Cochrane Library.

Content research and development staff formulate key research questions. This helps focus the literature search on information that is needed to determine appropriate care, such as clinical effectiveness, potential harms, or diagnostic accuracy. Scoping reviews of the literature and healthcare-related news sites, customer feedback, input from internal medical directors and other clinical staff, and guidance from our medical librarian help the developer to create and refine the key research questions. Searches are designed based on the population and interventions to be included, critical and important clinical outcomes, and relevant comparators; key concepts and terminology are noted in related content. A search is initiated using a combination of search engines that are public (e.g., PubMed,) and proprietary (e.g., Cochrane Library). For specific topics, focused databases such as the Physiotherapy Evidence Database (PEDro) and PsycNet may be used. Developers also review the bibliographies of relevant articles and consult with practicing experts about any soon-to-be published research. The search looks for recent systematic reviews and meta-analyses, randomized controlled trials, society guidelines, and additional publication types as needed. For example, RCTs are not the most appropriate study design for certain types of questions. For questions of risk factors and prognosis, prospective cohort studies are best. For questions of diagnostic test accuracy, cohort or cross-sectional studies are used. Epidemiologic studies may also be important for addressing clinical utility (e.g., screening for a rare disease).

InterQual is supported by tens of thousands of citations; sources include but are not limited to:

- **General databases:** PubMed
- **Specialty guidelines:** American Academy of Family Physicians, American Academy of Orthopedic Surgeons, American College of Cardiology, American Academy of Pediatrics, Society of Critical Care Medicine, American College of Medical Genetics and Genomics, American College of Obstetrics and Gynecology, American College of Radiology, American Society of Addiction Medicine, American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Psychological Association, American Association of Community Psychiatrists, Association For Ambulatory Behavioral Healthcare, American Thoracic Society, National Comprehensive Cancer Network, Infectious Diseases Society of America, Surviving Sepsis Campaign
- AHRQ-contracted Evidence-based Practice Centers (EPCs) and Cochrane Review Groups

- **Accreditation organizations' standards:** URAC, NCQA, The Joint Commission, and CARF
- **National guidelines:** Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), U.K.'s National Institute for Health and Care Excellence (NICE), Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Medicare and Medicaid Services (CMS) Coverage Determinations, U.S. Food and Drug Administration

Step 2: Critical appraisal

The research and content development team conducts a critical appraisal of the search results to identify studies that include best available, peer reviewed evidence. The certainty of each primary research study is assessed using critical appraisal from tools such as the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews, the Cochrane Handbook for Systematic Reviews Chapter 8, the AHRQ Methods Guide for Medical Test Reviews, the Cochrane Handbook for DTA Reviews Chapter 9, NICE Methodology Checklists, and QUADAS-2. Principles found in the Cochrane Handbook for Systematic Reviews and methods promoted by the GRADE Working Group are used to combine findings from multiple primary studies so that the overall certainty of evidence is evident for each clinically relevant outcome. Landmark studies are acknowledged when applicable. The quality of each systematic review and health technology assessment, including those embedded in clinical practice guidelines, is assessed using tools such as the Cochrane Handbook for Systematic Reviews, AHRQ Methods Guide, and AMSTAR.

Evidence is classified to help user understanding. The classifications, which are not intended to be hierarchical, are as follows:

Classification	Type of Evidence
Class I	Meta-analysis, technology assessment, or systematic review
Class II	Randomized controlled clinical trial
Class III	Observational or epidemiologic study
Class IV	Evidence-based guideline
Class V	Expert opinion, panel consensus, literature review, text or reference book, descriptive study, case report, or case series

Assessing the certainty of the evidence

Utilizing an extensive library of critical appraisal tools and guided by the InterQual policies and procedures and training, staff apply their expertise to complete their assessment of the current body of knowledge. When developing clinical recommendations, InterQual staff and external expert peer review panelists consider the likely effectiveness of each intervention, based on a synthesis of the best available evidence. The certainty of that evidence is used to determine whether we can have sufficient confidence in our estimate of the intervention's effectiveness to support a particular recommendation. In determining the certainty of the evidence, sourced through the critically appraised research described in Step 1, the following key factors are taken into consideration across the body of evidence as a whole:

- Supporting research studies
- Study designs and sample sizes
- Risk of bias across the best available studies
- Consistency of findings between different studies

- Directness
- Precision of the estimated effect after combining all studies
- Size of the effect
- Whether there appears to be a dose-response relationship
- Potential impact of plausible confounders
- Likelihood of publication bias

To summarize the certainty of evidence, Optum adopted the following categories:

Category	Definition
High	Additional research is considered very unlikely to change our confidence in the estimate of effect
Medium	Further research is likely to have an important impact on the estimate of effect
Low	Further research is very likely to change the estimate of effect
Very Low	Our estimate of effect is very uncertain

Step 3: Content development

Based on the outcome of the critical appraisal phase, content drafts are updated accordingly, noting the evidence base. Each multidisciplinary content development team is physician-led and includes members with licensure and expertise specific to the services being reviewed. Initial drafts of the InterQual content are created by Optum's clinical staff, based on the exhaustive review and critical appraisal of external guidelines, medical and behavioral literature, and extensive internal peer review.

The following factors are considered:

- Clinically relevant benefits (e.g., related to disease progression, mortality, and quality of life)
- Risk of harms (e.g., serious adverse events)
- Certainty of the research evidence
- Relative resource utilization between comparably effective interventions
- Potential impact of patient preferences on compliance
- Whether the optimal intervention or treatment setting is widely available

Recommendations from key medical specialty societies, FDA approval status (when applicable), government regulations, accreditation standards, and standards of care are also taken into consideration. Clinical utility (i.e., whether the result of the service(s) will impact patient management and improve outcomes) and, when appropriate, diagnostic accuracy are also taken into consideration. The drafts reflect the analysis and synthesis of all information collected.

Recommendations are intended to optimize clinical outcomes while avoiding invasive, costly, or potentially harmful interventions that are not necessary or appropriate. When an intervention or treatment setting is fully recommended, that should be considered a "strong" recommendation; the intervention should be applied in most cases.

When a recommendation is designated as "Limited Evidence (secondary review required)," this indicates a weak recommendation. Recommendations are designated as "Limited Evidence" based on one or more of the following:

- Research to date has not demonstrated this intervention's equivalence or superiority to the current standard of care
- The balance of benefits and harms does not clearly favor this intervention
- The clinical utility of this intervention has not been clearly established
- The evidence is mixed, unclear, or of low quality
- This intervention is not standard of care
- New technology is still being investigated

Notes attached to these recommendations indicate whether it is a weak recommendation in favor of the intervention or against it. "Limited Evidence" is used when the intervention may be appropriate for many individuals, but reviewers should consider each situation individually.

When an intervention (or treatment setting) is not included in the recommendations or "Evidence does not support [the intervention]" appears, that can be considered a strong recommendation against that intervention in the given situation. In these cases, most patients should not receive the intervention under that set of circumstances.

Table 6.1. Implications of strong and weak recommendations for different users of guidelines[1]

	Strong Recommendation	Weak Recommendation
For patients	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For clinicians	Most individuals should receive the recommended course of action. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for different patients, and that you must help each patient arrive at a management decision consistent with her or his values and preferences. Decision aids may well be useful helping individuals making decisions consistent with their values and preferences. Clinicians should expect to spend more time with patients when working towards a decision.
For policy makers	The recommendation can be adapted as policy in most situations including for the use as performance indicators.	Policy making will require substantial debates and involvement of many stakeholders. Policies are also more likely to vary between regions. Performance indicators would have to focus on the fact that adequate deliberation about the management options has taken place.

[1] Schünemann H et al., Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. Updated October 2013. Available from: https://gdt.gradepro.org/app/handbook/handbook.html. Accessed Jan 22, 2024.

Detailed notes and literature references provide the clinical basis for decisions. Less commonly, there are key clinical questions where evidence is limited or lacks consensus and may reflect topics which are not conducive to formal study. In these situations, standards of care are used to support the development of criteria which reflect the highest quality available literature and best practice. Identification and validation of standards of care is the product of an external peer review process involving multiple practicing clinicians with diverse expertise in varied relevant practice and geographic settings who assist with the translation of current standards of care.

Step 4: External peer review

Once a subset or module is created or updated, it is sent for external peer review by a group of independent experts drawn from the Optum external clinical review panel. This multidisciplinary panel is comprised of over 1,100 board-certified, practicing clinicians (two thirds of whom are MDs or DOs), all of whom have been screened for conflicts of interest and are credentialed every two years. Clinicians are widely dispersed geographically and practice in various settings, including academic and community-based practices. These experts serve two purposes: first, to ensure that the interpretation of the literature is correct and that they are not aware of any other practice-changing new literature about to be published, and to validate the application of evidence underpinning the standard of care into best practice medical appropriateness criteria. The number of external clinicians assembled is in inverse correlation to the strength of the evidence for the topic. For cases that do not lend themselves to formalized study, larger geographically dispersed groups of clinical experts are used to better establish the standard of care. When clinically meaningful changes are made during the external review process and/or there is a lack of consensus among the panel members, the content is vetted again, and additional external peer reviewers are added when necessary to ensure accuracy.

Step 5: Quality assurance and release

Quality is central throughout the development process to help ensure effectiveness and the correct interpretation and application of the evidence. Prior to release, certified medical coders work with the team to help ensure appropriate codes are applied to the relevant areas of content and the team conducts a final quality assurance check. The content is reviewed for clinical accuracy, consistency and completeness across products and approved content is prepared for distribution. A physician medical director provides oversight throughout the development process and helps to ensure clinical accuracy of the content. Extensive clinical revision documents accompany each release outlining the changes made and their rationale along with extensive bibliographies. Releases occur at least annually in the spring for all content modules and as often as monthly to reflect key changes in the literature or regulatory content for any module affected.

Summary

We are proud of our objective process, our large external expert peer review panel, and the quality that we incorporate into every InterQual clinical content set we develop. These processes, based on the principles of evidence-based medicine (EBM), continue to drive value and confidence for our customers, as they have for over 40 years.