InterQual® Criteria

Clinical Development Process 2017

InterQual Criteria Overview

Thousands of people in hospitals, health plans, and government agencies use InterQual® evidence-based clinical decision support criteria to answer critical questions about the appropriateness of care and resource use. During the last four decades, these criteria have helped define and legitimize the disciplines of utilization and care management, providing medical directors, utilization leaders, and other hospital and health plan professionals support in making the type of objective, evidence-based decisions that define top-quality, efficient care. This leads to greater transparency and collaboration between payers and providers.

The InterQual Criteria suite has expanded to over 20 modules providing industry-leading 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 the criteria through clinical content development and technology solutions. With over 4,000 InterQual licensees relying on the guidance that InterQual provides, we take our responsibility to provide accurate, evidence-based criteria very seriously. Our commitment is reflected in our rigorous evidence-based development process, refined and enhanced over the past 40 years.

InterQual Criteria Development Process

InterQual Criteria are produced using a rigorous development process based on the principles of evidence-based medicine (EBM). InterQual clinical content is created by McKesson’s clinical research staff of over 40 research and clinical decision support specialists including physicians, registered nurses, clinical psychologists, physical and occupational therapists, and other healthcare professionals, including medical librarians. The physicians’ backgrounds include experience or specialization in internal medicine, infectious disease, psychiatry, emergency medicine, hospital medicine, occupational medicine, public health, and surgery. Most of the clinical staff hold advanced degrees (e.g., Masters, Ph.D.), certifications (e.g., nurse practitioner), and/or case management certification. InterQual developers receive comprehensive training by the Delfini Group, experts in applying the concepts, methods, statistical analyses, processes, skills and tools of evidence, and value-based clinical improvement to make practice change and achieve improved medical decision-making, outcomes, and value.
McKesson uses a multi-step standardized development process across our medical/surgical (physical medicine) and mental health/substance use disorders criteria that synthesizes valid, relevant, scientific evidence and real-world best practices to ensure that the criteria reflect unmatched clinical rigor and integrity. The process is the same regardless of the topic area being researched. (See Figure 1.)

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

Step 1: Research

The InterQual clinical development team uses a systematic and continuous review of the medical and behavioral health literature, combined with client and clinical consultant feedback, to identify content that needs revision and new content that must be developed as medicine advances. Content is reviewed and updated as needed, at least annually, with the capability to release updates as frequently as quarterly for critical updates in the evidence base. Peer-reviewed journals are monitored and our proprietary automated surveillance system monitors 2000 key sites and topical areas for newly published literature.
and guidelines. In addition, we review client feedback received through our toll-free number (800-CRITERIA), Internet website (cesupport.mckesson.com), InterQual Criteria Customer Solution Council, and annual conference at which we host roundtable discussions, industry-leading speakers, and breakout sessions for medical and behavioral topics. 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.

Developers formulate 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, National Guideline Clearinghouse) and proprietary (e.g., Clinical Key). 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 ask 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.

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

- **General databases**: PubMed, National Guidelines Clearing House
- **AHRQ-contracted Evidence-based Practice Centers (EPCs) and Cochrane Review Groups**
- **Accreditation organizations' guidelines**: URAC, NCQA, and the Joint Commission
- **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)

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**Step 2: Critical Appraisal**

The team conducts a critical appraisal of the search results, using its Delfini training to identify studies that include valid evidence. The quality of each primary research study is assessed using critical appraisal criteria from tools such as The AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews, the Cochrane Handbook for Systematic Reviews Chapter 8, 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 quality 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 criteria from tools such as the Cochrane Handbook for Systematic Reviews, Agency for Healthcare Research and Quality (AHRQ) Methods Guides, and AMSTAR.

McKesson observes a strict schedule for review and updating every InterQual subset it produces. Our automated literature surveillance processes ensure that, when a critical publication emerges that may necessitate an interim update, clinical staff is immediately alerted.
Evidence is classified to help user understanding. The classifications, which are not intended to be hierarchical, are as follows:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Type of Evidence</th>
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<tbody>
<tr>
<td>Class I</td>
<td>Meta-analysis, technology assessment, or systematic review</td>
</tr>
<tr>
<td>Class II</td>
<td>Randomized controlled clinical trial</td>
</tr>
<tr>
<td>Class III</td>
<td>Observational or epidemiologic study</td>
</tr>
<tr>
<td>Class IV</td>
<td>Evidence-based guideline</td>
</tr>
<tr>
<td>Class V</td>
<td>Expert opinion, panel consensus, literature review, text or reference book, descriptive study, case report, or case series</td>
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Assessing the quality of the evidence

When developing clinical recommendations, InterQual staff and expert consultants must estimate the likely effectiveness of each intervention, based on a synthesis of the best available evidence. The quality 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 quality of the evidence, the following key factors are taken into consideration:

- The number of supporting research studies
- Study designs and sample sizes
- Risk of bias
- Consistency of findings
- Directness
- Precision of the estimated effect
- 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 quality of evidence, McKesson adopted the following categories:

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
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<tbody>
<tr>
<td>High</td>
<td>Additional research is considered very unlikely to change our confidence in the estimate of effect</td>
</tr>
<tr>
<td>Medium</td>
<td>Further research is likely to have an important impact on the estimate of effect</td>
</tr>
<tr>
<td>Low</td>
<td>Further research is very likely to change the estimate of effect</td>
</tr>
<tr>
<td>Very Low</td>
<td>Our estimate of effect is very uncertain</td>
</tr>
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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. Initial drafts of the InterQual content are created by McKesson’s clinical staff based on the exhaustive review and critical
appraisal of external guidelines, medical and behavioral literature, and extensive internal peer review. The drafts reflect the analysis and synthesis of all information collected.

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)
- Quality 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 usual practice are also taken into consideration. For recommendations on tests, imaging, or other diagnostic interventions, clinical utility (i.e., whether the test result will impact patient management and improve outcomes) and diagnostic accuracy are also taken into consideration.

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. 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 clinicians and 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.

Detailed notes and literature references provide the clinical basis for decisions. Areas of conflicting studies are noted. A stance is taken and documented with a rationale. Standards of care are noted for key areas by documenting in a note, “McKesson consultants agree…”. This signifies content that is consensus-based as to the current standard of care, which is used for areas not conducive to randomized controlled trials.

Step 4: External Peer Review

Once a criteria subset is created or updated, it is sent for peer review by a group of independent experts drawn from McKesson’s external clinical review panel. This multidisciplinary panel is comprised of over 850 board-certified, practicing clinicians, all of whom have been screened for any conflict of interest. Clinicians are widely dispersed geographically and practice in numerous 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 practice-changing new literature about to be published; and second, to validate criteria which rely upon the standard of care, especially in areas not conducive to randomized controlled trials. The number of expert clinicians assembled is in direct correlation to the strength of the evidence for the topic. For cases that do not lend themselves to clinical trials, 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 with additional external reviewers to ensure accuracy.

Step 5: Quality Assurance and Release

Quality is instilled throughout the development process to ensure effectiveness and the correct interpretation and application of the evidence. Prior to release, medical coders work with the team to assure 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 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 assure clinical accuracy of the content. Extensive clinical revisions accompany each release outlining the changes made and their rationale. Releases occur annually in the spring for all criteria products and as often as quarterly to reflect key changes in the literature for any product affected.

Summary

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