# Provider Led Entity

# Appropriate Use Criteria: Strength of Recommendations

*August 8, 2017*

*The CDI Quality Institute follows the recommendation framework defined by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group to evaluate the strength of recommendations concerning diagnostic testing. Considerations used to determine a recommendation are listed below. These considerations will vary depending on the purpose of testing: triaging, diagnosis or screening.*

**A)** **<u>Strong recommendation for testing/Green</u>** - A strong recommendation for testing is one for which the committee is confident that the desirable effects of testing outweigh its undesirable effects.

- High or moderate quality of evidence that the diagnostic test performance is increased and/or risks of testing are decreased;
- Benefits outweigh the risks with one or more of the following -
  - Significant improvements in diagnostic performance, outcome or patient management complementing or offsetting changes in the safety profile and/or patient tolerance,
  - Improved safety / tolerance profile with comparable estimates of accuracy;
  - Confident that testing has a positive impact on patient outcomes and/or patient management;
- Confident that the guideline can be implemented in targeted patient populations and practice settings;
- Confident that the estimates of test performance and patient safety can be reproduced in the targeted patient populations or practice settings;
- Confident that patient values, preferences or variability support recommendations for patient testing;
- One or more high quality organizational guidelines (subspecialty society, AHRQ Comparative Effectiveness, FDA Best Practice, NCD/LCD, PLE and/or USPSTF) state that imaging is recommended.

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**B)** **<u>Conditional recommendation for imaging/Yellow</u>** - A conditional recommendation for imaging is one for which the desirable effects of testing probably outweigh its undesirable effects although some uncertainty exists. A conditional recommendation implies that not all individuals may be served by the recommended imaging modality and that individual patient's circumstances, preferences and values should be considered on a case by case basis.*

- Low quality of evidence that the diagnostic test performance is increased and/or risks of testing are decreased;
- Benefits probably outweigh the risks with one or more of the following
  - Probable improvements in diagnostic performance, outcome or patient management complementing or offsetting changes in the safety profile and/or patient tolerance,
  - Probable improvements in the safety / tolerance profile with comparable estimates of test performance,
  - Testing probably has a positive impact on patient outcome and/or patient management;
- Guideline can probably be implemented in targeted patient populations and practice settings;
- Estimates of test performance and patient safety can probably be reproduced in the targeted patient populations or practice settings;
- Patient values and preferences probably support recommendations for testing;
- One or more high quality organizational guidelines (subspecialty society, AHRQ Comparative Effectiveness, FDA Best Practice, NCD/LCD, PLE or USPSTF) state that the use of imaging is reasonable;

*This may include considerations of secondary indications for imaging such as:

- Contraindication to the primary exam modality,
- Specific clinical circumstances that require use of a secondary modality (e.g. CT to assess spine/bone fusion),
- Primary testing with inconclusive results,
- Primary testing with results that are incongruent with the patient's clinical diagnosis,
- Complementary testing needed for characterization (e.g. CT for bone tumor or to characterize an abnormality on bone scan), or
- Complementary testing needed for surgical planning.

**C)** **<u>Conditional recommendation against imaging/Orange</u>** - A conditional recommendation against imaging is one for which the undesirable effects of imaging probably outweigh its desirable effects although some uncertainty exists.

- Low quality of evidence that the diagnostic test performance is inferior to other testing strategies and/or the risks of testing are increased;
- Risks probably outweigh the benefits with one or more of the following -
  - Consequences of false positives and false negatives probably outweigh any improvements in diagnostic test performance,
  - Safety / tolerance profile probably worse without a significant or meaningful improvement in diagnostic performance, patient management change or patient outcomes,
  - Testing probably has a negative impact on patient outcomes and/or patient management;
- Recommendation for imaging probably cannot be implemented in the targeted patient populations and/or practice settings;
- Estimates of test performance and patient safety probably cannot be reproduced in the targeted patient population and/or practice setting; and/or
- Patient values and preferences probably do not support recommendations for testing.

**D)** **<u>Recommendation against imaging/Red</u>** - A recommendation against imaging is one for which the undesirable effects of imaging outweigh any desirable effects.

- High or moderate quality of evidence that diagnostic test performance is decreased and/or there are significant risks with testing;
- Risks outweigh the benefits with one or more of the following -
  - Consequences of false positives and false negatives outweigh any improvements in accuracy,
  - Worse safety / tolerance profile without a significant or meaningful improvement in diagnostic performance, patient management or patient outcomes,
  - Confident that testing would have a negative impact on patient outcomes and or patient management;
- Proposed testing strategy is impractical or not feasible in targeted patient population and/or practice settings;
- Estimates of test performance and improved patient safety cannot be reproduced in the targeted patient populations or practice settings;
- Patient values, preferences or variability do not support recommendations for testing;
- One or more organizations (subspecialty society, AHRQ Comparative Effectiveness, FDA Best Practice, NCD/LCD, PLE and/or USPSTF) which recommend against the use of imaging.

**I) No recommendation**

- Insufficient evidence – Confidence in the estimates or accuracy and/or risk are so low that any recommendation would be speculative;
- Irrespective of the level of evidence, the trade-offs are so closely balanced, and/or the values and preferences are not know or too variable to make a recommendation.
- Testing or not testing would result in very different outcomes and the patient's reactions to the outcome of testing are likely to be so different that it makes little sense to think about typical values and preferences; and/or
- USPSTF Grade I.

**General considerations for diagnostic testing recommendations**

Notes concerning the use of imaging for diagnosis:

- Used instead of an existing diagnostic test;
- Primary criterion is increased accuracy resulting in significant improvements in the management, care or outcomes of patients. (For example, increased detection of disease for which effective treatment exists for that condition, or improved detection eliminates the need for additional testing);
- May recommend replacement of a more invasive or expensive test to avoid complications and morbidity associated with testing. (This needs to be considered in light of the incidence of complications associated with the more invasive testing. More invasive testing may have more morbidity, however the incidence of these complications may be rare.);
- May recommend a more invasive or expensive test if improvements in accuracy or patient outcome outweigh the risks, costs and inconvenience of that test;
- May downgrade a recommendation for testing if there is significant concern or uncertainty about the impact of false negative tests on patient population outcomes;
- May downgrade a recommendation for testing if there is significant concern or uncertainty about the impact of additional testing on patient populations with false positive findings;
- May recommend new imaging exams with smaller improvements in accuracy if they result in low additional costs, minimal inconvenience and no significant safety concerns; and
- May recommend imaging exams with high sensitivity in patients at risk for high morbid conditions.

Notes concerning the use of diagnostic imaging for triage:

- Used before the existing test or existing diagnostic pathway;
- Exams with high sensitivity and high negative predictive value (NPV) may be used to screening for high risk disease;
- May be less accurate however have other advantages such as low cost or simplicity;
- May reduce the use of existing more invasive, cumbersome or expensive tests; and
- Designs may be limited with verification of the diagnosis only in patients who test negative on the triage exam but positive on the existing test.

Notes concerning the use of diagnostic imaging as an add-on test:

- Positioned after the existing imaging pathway;
- Exams with high specificity and positive predictive value (PPV) may be used to increase the accuracy of a diagnosis for conditions in which confirmation of the diagnosis or treatment of disease is associated with high cost and/or morbidity;
- May be limited to subgroups of patients;
- May be used to limit the number of false positives with the existing pathway (Study designs may be limited and may focus on the verification of a diagnosis in patients who test positive on the existing test, but negative on the add-on test.); and/or
- May be used to increase the sensitivity of the existing pathway. (Studies may verify the diagnosis in patients who test negative with the existing test but test positive with the add-on test.)

**Sources**

Andrew JC, Schünemann H, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation – determinates of a recommendation's direction and strength. J Clin Epidemiol 2013;66:726-735.

Schünemann H, Oxman AD, Brozek J, et al. GRADE: grading quality of evidence and strength of recommendations for diagnostic tests and strategies. BMJ 2008;336:1106-1110.

Schunemann H, Brozek J, Guyatt G, Oxman A. GRADE Handbook. Available at http://gdt.guidelinedevelopment.org/app/handbook/handbook.html#h.f7lc8w9c3nh8