

MSK Levels of Evidence



Level 1

FDA-recognized biomarker predictive of response to an FDA-approved drug in this indication

Level 2A

Standard of care biomarker predictive of response to an FDA-approved drug in this indication*

Standard Therapeutic Implications

*Includes biomarkers that are recommended as standard of care by the NCCN or other expert panels but not necessarily FDA-recognized for a particular indication

Level 2B

Standard of care biomarker predictive of response to an **FDA-approved** drug **in another indication** but not standard of care for this indication

Level 3A

Compelling clinical evidence supports the biomarker as being predictive of response to a drug **in this indication** but neither biomarker and drug are standard of care

Investigational
Therapeutic
Implications
possibly directed to
clinical trials

Level 3B

Compelling clinical evidence supports the biomarker as being predictive of response to a drug **in another indication** but neither biomarker and drug are standard of care

Level 4

Compelling biological evidence supports the biomarker as being predictive of response to a drug but neither biomarker and drug are standard of care

Hypothetical Therapeutic Implications

Based on preliminary, non-clinical data

Level R1

Standard of care biomarker predictive of resistance to an FDA-approved drug in this indication

Standard Therapeutic Implications