



Coverage Considerations

**Incorporating Integrated Diagnostics into Precision
Oncology Care**

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Four critical elements necessary to establish coverage and reimbursement



Benefits

Is the health care technology in a covered category of benefits?



Coding

Is there a specific CPT code that can be used to bill for the service?



Clinical Coverage

Has a favorable coverage determination been obtained usually in the form of a medical policy or coverage determination?

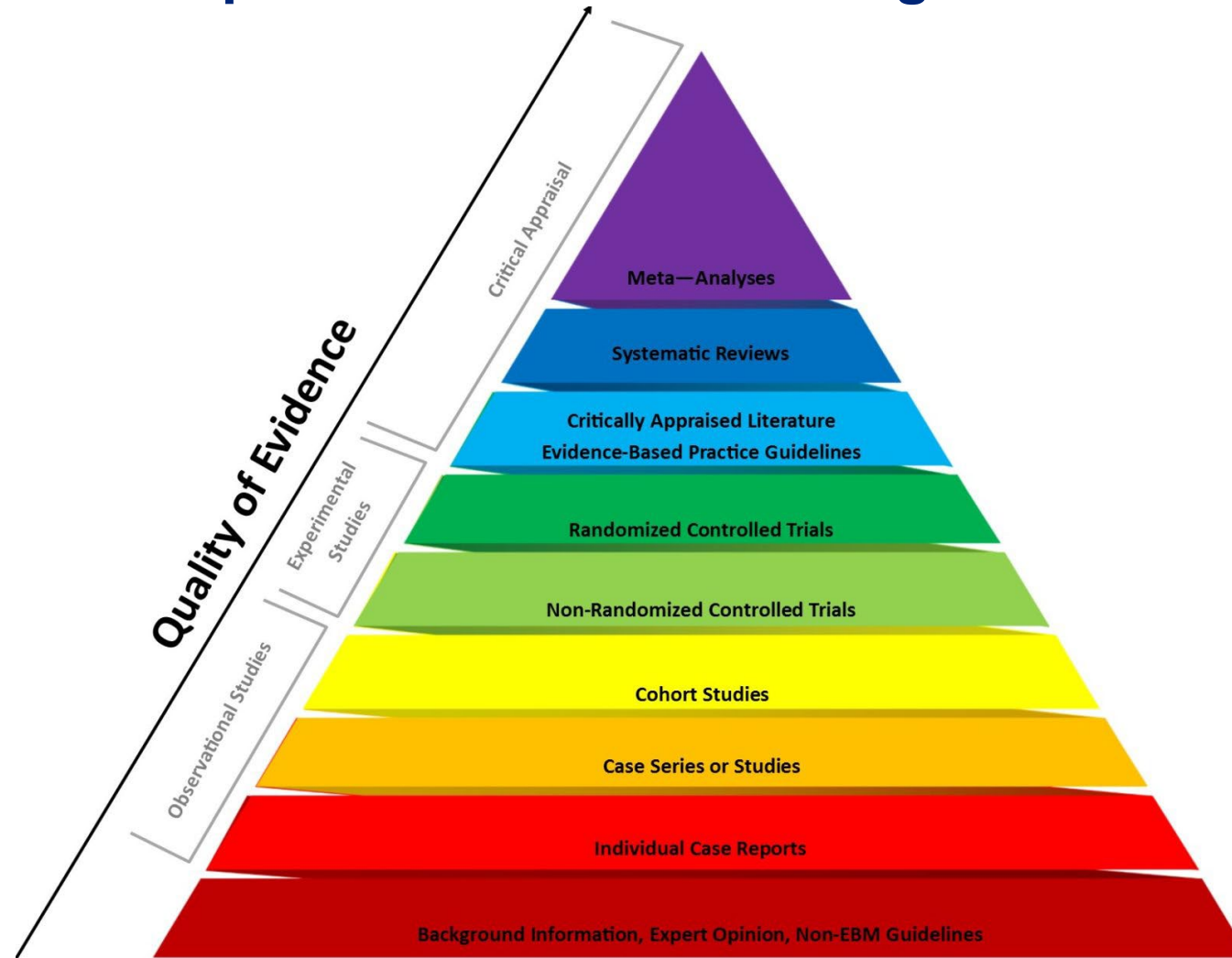


Reimbursement

Appropriate levels of therapy?



High level of evidence required for clinical coverage



<https://libguides.cmich.edu/cmed/ebm> based on the EBM Page Generator (2006) from Dartmouth College and Yale University and the Coursera MOOC “Understanding Clinical Research: Behind the Statistics” (2016).

Clinical utility critical in making clinical coverage determinations

To have clinical utility, a genetic test must lead to an **action** that has been shown to improve patient outcomes



Targeting therapy

- Patients with mutation are **treated with a specific therapy** will improve their survival or quality of life compared with other available treatments

Diagnostic testing

- Lead to a **change in clinical management** that **improves the health outcome** of the individual or their family members, or by providing closure by ending a diagnostic odyssey.

Predictive testing

- Lead to a **change in clinical management** that **improves the health outcome** of the individual or their family members, or by providing closure by ending a diagnostic odyssey.

Necessary but *not* sufficient

- **Analytic validity** - accuracy of the laboratory process used to perform the test
- **Clinical validity** - ability of the test to correctly identify the health condition or disorder.

Moving from clinical coverage to value

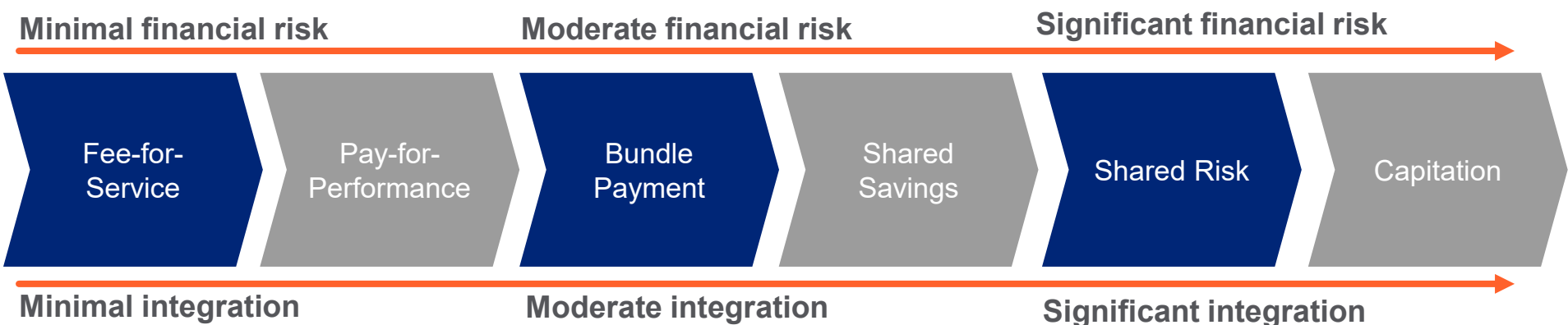
$$\text{Value} = \frac{\text{Outcomes}}{\text{Cost}}$$

What is Value Based Care?

- A model that pays providers based on **indicators of value**, such as outcomes, efficiency, and quality.
- Evolves provider reimbursement from **fee-for-service** to **fee-for-value**, including provider risk.
- A commitment to **clinical transformation** and an **investment** in tools, data and analytics, collaboration.
- The models often **complement** existing payer-provider agreements, rather than replace them.

Value Based Care risk continuum

- The transition takes time, is challenging and is best approached in an incremental manner.



In Summary

- In fee-for-service model, establishing the four critical elements necessary coverage and reimbursement will be necessary for payment for integrated diagnostics in oncology
 - Benefits category (if not adequately addressed by current categories)
 - Clinical coverage
 - CPT code(s)
 - Reimbursement
- If integrated diagnostics deliver greater value in cancer care, then adoption may be accelerated through Value Based Care models