



A Taxonomy of PBRsAs

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Distinguishing Among PBRsAs

- What is the source of the decision uncertainty that affects the final positive and a negative decision?
 - Uncertainty in internal validity (efficacy; small sample size; inappropriate comparators)
 - Uncertainty in external validity (real-world performance; compliance; link from surrogate to long-term outcomes;
 - Heterogeneity—differential response/benefits among patients
 - Diffusion uncertainty—(beyond initial indication) changing or appropriate population subgroups and usage over time?

patients eligible for reimbursement indication



