ClinicalPath

Philosophy and Guidance for ClinicalPath Committees

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Last Updated: April 2020

Our Philosophy on Standardization

We believe that standardization to best evidence-supported care leads to the best overall outcomes for patients. This is not "cookbook" medicine – instead, it ensures that physicians should consistently apply the best evidence-based thinking for that specific patient's unique presentation. This approach ensures personalized care and reduces unwarranted or unexplainable variation.

With standardization comes many other benefits as well–from predictability of symptoms and cost of care and lower inventory levels, to more efficient and safer drug admixture and administration and better patient teaching for symptom management.

Finally, measurement of outcomes is more feasible with consistency of care.

On Pathway Rate Goal:

When the literature demonstrates that a given regimen is superior to others; or is equally effective and less toxic; or is equal in effectiveness and toxicity but less costly, the ClinicalPath Committees select and standardize to that regimen with an expectation that it will be the best fit for 70-80% of patients.

We acknowledge that not all patients, even with a similar presentation, will fit the ClinicalPath Pathway. Instead of expecting 100% adherence to the pathway, we've built a process for providers to go "off pathway" and share those learnings at the ClinicalPath Committee meetings.

A high-level goal for On Pathway Rate is 80%, with the understanding that this goal may vary by disease, organization and physician based on strength of data, availability of options and patient mix.

ClinicalPath Committee Guidance

Levels of Evidence

The ClinicalPath Committees have the latitude to compare treatments never studied head-to-head and to give preference to lower levels of evidence (phase II vs. phase III study) when the outcomes are more compelling. The only requirement is that studies considered must be either published in a peer-reviewed journal or in abstract form at a meeting of oncology peers.

Specificity for Doses, Schedule and Cycles

The ClinicalPath Committees delineate the actual doses, schedule and number of cycles (or "until progression") for each treatment plan based on the original clinical trial unless current standard of care is a lower dosing scheme. It is understood that actual doses, schedules and number of cycles may vary slightly starting with cycle 1 of non-curative treatment plans. Additionally, it is understood that dose reductions or delays in cycle 2+ are always appropriate based on patient presentation.

When Cost Can Be Incorporated?

With no current clear societal decision on the value of a quality adjusted life year, cost should only be considered when the ClinicalPath Committees assess that efficacy and toxicities between two or more treatments are comparable. The Committees have the freedom to decide whether an improved response rate is clinically meaningful and can always create an "Other Patient Scenario" for financial concerns that provides a lower cost but still effective therapy.

When Head-to-Head Data are Missing

Even when the data are unclear (lacking head-to-head comparisons) and the recommendations are based on expert opinion, we believe standardization to the best thinking of committees of practicing oncologists delivers better outcomes than chaos and unexplained variability.

Prioritizing a Primary Recommendation

The ClinicalPath Committees review the published data for a specific state and stage of disease and assess whether any treatment has been demonstrated to have superior efficacy (clinically relevant) or, if not, lower toxicities or, if not, lower cost to the payer/patient. If the cost to the payer/patient is comparable, then the Committee is asked to still select one treatment as the primary recommendation in order to drive to lower cost care. However, if other drugs have a comparable cost (ASP), those can also be added as an "Other Patient Scenario" for "Formulary Dictates Alternative" (see below).

Accounting for Frequently Occurring "Other Patient Scenarios"

If, after selecting a primary recommendation, the ClinicalPath Committees believe that frequently occurring other patient scenarios exist, those scenarios can be delineated as additional patient presentations with a different primary treatment (still following the efficacy, toxicity, cost hierarchy). Examples of these Other Patient Scenarios include:

- Poor performance status
- Contraindication to the primary treatment recommendation
- Patient convenience/preferences (shorter infusion time, oral drug, fewer visits)
- Formulary dictates alternative drug
- Primary treatment received in a prior line –OR–patient has not yet received a critical therapy in a prior line

These "Other Patient Scenarios" are counted in all reporting metrics as On Pathway but are not meant to be an exhaustive list. It is the expectation that the overall pathway rate should still be in the 70-90% range including the Other Patient Scenarios.

Finally, if "Other Patient Scenarios" have been created in the past but are no longer needed in order to achieve an overall On Pathway Rate of 70-80%, the Committee should vote to remove them.