

Health Evidence Review Commission

Coverage Guidance Policy on

Consideration of Evidence Discovered After Formal Public Comment Period

For coverage guidances, HERC generally only includes studies during its initial Coverage Guidance development (before the relevant subcommittee reviews the first draft) or when these studies are submitted during the formal written comment period. These studies are reviewed based on how well they address the pre-specified scope of the Coverage Guidance and their methodological quality.

In exceptional circumstances, however, the HERC recognizes the need to review studies submitted by stakeholders or discovered by staff outside the formal comment process. To minimize biases which may be introduced by consideration of evidence at other times in the process, HERC has approved this policy, outlining the circumstances which may justify consideration of new evidence when it is discovered outside the formal routine guidance process and public comment period.

Decisions about whether to delay the process for a new study will be made by staff, based on where a coverage guidance is in the development process and the importance of the evidence in question.

The new study or studies need to be likely to alter a recommendation in a way that would significantly impact health outcomes or cost for the population in question. Such studies are also typically:

- Randomized controlled trials or systematic reviews of randomized trials demonstrating comparative effectiveness or harm, or large registry or population-based studies demonstrating harm, AND are of
- Moderate or high quality according to HERC criteria

If staff learns of a study after the formal comment period ends, staff will make a determination of the importance of the study in question based on the criteria above. Staff would delay the process as needed in order to incorporate the study and update the existing literature search to assure that there are not any additional studies which may be appropriate to include. For studies that do not meet these criteria, they could be resubmitted at the next scheduled two-year topic rescan. New coverage guidance topics can also be nominated for consideration annually.

In the case of new evidence (that meets the criteria above) being identified after a Coverage Guidance has already been approved by the originating subcommittee, it would be referred back to that subcommittee before coming to HERC and VbBS. Less significant changes may be incorporated by the Commission during the final approval process.