MEDICAL DEVICE ADOPTION IN MANAGED CARE SETTINGS

RAND Health

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Description of Interviews with Managed Care Organizations

The interview will take between 30 and 45 minutes.

The goal is to learn about your managed care organization’s experience with coverage, payment, and medical necessity decisions involving new medical devices or significant changes in the use of a particular technology. While the project focus is on decisions by managed care organizations (MCOs) such as yours, we are also interested in decisions by other organizations—for example, manufacturers, medical groups, hospitals, HCFA, and employers—that affect the use of devices in treating your enrollees.

Using specific devices with which you are particularly familiar as an organizing tool, we will ask you a series of questions about your coverage decision making processes (including the coverage, payment, and medical necessity decisions) as a way of understanding how new technologies come to your attention, how you make coverage decisions, who is involved, what information you rely on, what criteria or considerations are involved, and how these decisions are implemented.

RAND will strictly protect the confidentiality of any sensitive or proprietary information supplied by the people we interview. Such in-
information will be shared only with RAND staff involved in the project and will not be shared with anyone outside of RAND.

ISSUES WE WOULD LIKE TO COVER

Coverage Decision Making

1. What are the events that trigger an explicit coverage decision by your MCO (e.g., patient demands, physician demands, surveillance of the literature, claims, litigation, marketing by manufacturers)?

2. Does your MCO consider coverage for devices during clinical trials and, if so, under what conditions (e.g., pre-FDA clearance, as part of a formal IDE trial, at a designated center of excellence)?

3. What process or processes are used for evaluating a new device or related procedure for coverage? How is this process staffed?

4. What sources of information (e.g., peer-reviewed journals, government agency reports, opinions of national or local experts, practice guidelines, etc.) are used in the decision making process? What sources of information are considered the most important?

5. To what extent are manufacturers involved in the coverage decision making process? What information, processes or activities on the part of device manufacturers, if any, are helpful to MCOs as they consider coverage? What weight do you place on information provided by the manufacturer or research sponsored by manufacturers (vis-à-vis weight given to peer-reviewed articles, opinions of medical groups, opinions of your own medical staff, etc.)?

6. Are there other organizations whose decisions or input often affect whether you cover a device (e.g., hospitals in your plan, capitlated medical groups in the plan, utilization review contractors, carve out companies, employers/purchasers)?

7. How are those coverage decisions transmitted, to whom, under what circumstances, and how or when are they revisited? What factors would cause your MCO to reconsider a coverage decision?
**Setting the Payment Level**

8. Once a general decision is made to cover a new technology, how is the specific payment level for the new technology determined?

**Medical Necessity Decisionmaking**

9. Once a general decision is made to cover a new technology, how is medical necessity typically determined in individual cases? Under what circumstances can determinations be especially difficult?

**Lessons Learned**

Based on all of your experience:

1. What are the main difficulties for MCOs in making appropriate, timely coverage decisions about new medical devices?

2. What are the most revealing examples of successes and failures in the health care industry as it relates to device adoption in the managed care settings? What can MCOs learn from these experiences? What can manufacturers learn?

3. In your experience, what are the keys to cooperative and productive interactions between device manufacturers and MCOs? More generally, what might manufacturers do to assist MCOs as they make coverage decisions and medical necessity decisions?