Description of Interviews with Device Manufacturers

The interviews will take about one hour.

We seek to learn about manufacturer experience with medical necessity, coverage and reimbursement decisions affecting commercialization of medical devices. While the project focus is on decisions by managed care organizations (MCOs), we are also interested in decisions by other organizations—for example, medical groups, hospitals, the Health Care Financing Administration, and state Medicaid programs—that affect use of devices in treating enrollees of MCOs.

We have requested an interview with your company with a particular device in mind. We will also ask you to identify another device that you manufacture or are developing, if any, for which MCO decisions are particularly important for commercialization.

RAND will strictly protect the confidentiality of any sensitive or confidential information supplied by interview subjects. Such 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 DISCUSS

Background information

- Regarding the company and parent, if any: number of employees, annual sales of devices in the US, R&D or manufacturing activities in California, device R&D costs as a fraction of all costs

Experience with each specific device (up to two)

- Brief description of the device (e.g., uses, approximate price, availability of other technologies for the same diagnostic or therapeutic purposes)

- What clinical evidence has been developed related to effectiveness and safety? For example: numbers, methods, and sizes of clinical trials; whether results have been published in peer-reviewed journals; whether trials conducted were more extensive than would have been required for FDA approval

- What additional evidence has been developed related to cost-effectiveness of the device?

- How important are MCO decisions to the commercialization of the device?

- How MCOs have made medical necessity, coverage and payment decisions for the device (e.g., how the device has come to the attention of MCOs, key MCO decision makers, information used, information requested of you by MCOs, timeliness of decisions)

- Role of clinical and cost-effectiveness evidence in MCO decision making regarding this device. In your opinion, have these studies been carefully considered by MCOs? Have they been accepted as persuasive? Have MCOs requested additional information from you? From others?

- How MCO decisions have affected sales of the device to date

- Roles and processes of other types of organizations whose decisions are important in determining sales of the device (e.g., medical groups, hospitals)
• General description of marketing effort for device. For example: Do you advertise in medical or other professional journals? Do you promote the device directly to MCOs? If so, what are the roles of the individuals to whom you market? Nature and form of information provided? Do you promote the device directly to individuals in other types of organizations? If so, to individuals in what roles? Nature and form of information provided? Do you promote the device directly to patients? If so, how?

• What additional clinical trials or other studies of the device are in process or planned?

• Have you considered undertaking further clinical trials or other studies of the device? What were the key considerations in deciding whether to proceed?

Lessons learned

Based on all of your experience:

• Under what circumstances are MCO decisions critical for successful commercialization? What are the keys to successful commercialization under these circumstances?

• What factors other than MCO decisions are often critical for successful commercialization? What are the major impediments to success?

• What are the major pros and cons of developing clinical and cost-effectiveness evidence that is not required by the FDA?