

Physician Experience Interview Guide: Alvimopan

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Good **[morning/afternoon/evening]**. May I speak with **[Dr. X]**?

Hi, my name is **[Y]**, and I am calling as part of a study on physician experiences prescribing alvimopan, in which you agreed to take part. This research is being conducted by contractors at Brigham and Women's Hospital / Harvard Medical School on behalf of the U.S. Food and Drug Administration (FDA).

Your participation in this interview is voluntary, and you may withdraw at any time. Your responses will be aggregated with other responses and analyzed in a de-identified manner. The entire interview will last approximately one hour. If you complete the full interview, we will send you a \$100 Amazon gift card as a token of appreciation for your participation or donate the money to a charity of your choice. Is this still a good time for us to talk? **(IF NO: ARRANGE A TIME TO CALL BACK.)**

Section A: Prescribing and Training History **(expect to spend about 10 minutes on this section)**

1. Approximately when was the last time you prescribed alvimopan?
2. Approximately how many—number and percentage—of your patients undergoing short bowel resection surgery have you prescribed alvimopan to over the last 3 years?
3. Before you started prescribing alvimopan, did you receive any training on its risks, benefits, and safe prescribing practices? If so, can you describe the training process?
 - o **IF YES:** Probe on length of training, content, organizers, strengths, and weaknesses

o **IF NO:**

- What resources, if any, did you use to get information on alvimopan?
- Do you think a training session would have been useful? Why?

Section B: Patient Counseling

(Expect to spend about 35 minutes on this section.)

Now we'll turn to your experiences prescribing alvimopan. As you may know, the FDA requires a special safety program for the drug called a Risk Evaluation and Mitigation Strategy or REMS. The purpose of the REMS program is to ensure alvimopan is used in a way that its benefits outweigh its risks.

4. To your knowledge, why does alvimopan have a REMS program?

(Describe risks and benefits here if needed)

5. To your knowledge, what is the primary safe use requirement under the REMS program?

(If uncertain: Note that no more than 15 doses of the drug can be provided to a patient due to increased risk of myocardial infarction with long-term use.)

6. How concerned are you about the risk of MI with long-term use of alvimopan? Why?

7. Do you usually have conversations with your patients before you start them on alvimopan?

- o If no, why? SKIP TO Q9.
- o If yes, PROCEED TO Q8.

8. Can you describe the conversations you have with patients before you start them on alvimopan?

- o What risks of alvimopan are you most concerned about and why?
- o What risks do you usually discuss with them?
- o How do your patients react to these risks?
- o Do you routinely inquire about immediate past use of narcotics?

9. Have you had patients seek another treatment option after hearing about alvimopan risks? If so, how frequently does this happen? Why?

- o Are there feasible alternatives to alvimopan? If so, what are they?

10. Do your patients receive from you or your team any other materials describing the risks of taking alvimopan? If YES, what materials?
- o For example, published articles or stories, links to manufacturer or non-manufacturer websites, or pamphlets or brochures produced by the manufacturer, you, or your institution.

Section C: Impact of Alvimopan REMS Program
(expect to spend about 10 minutes on this section)

11. Are you aware of processes in place at your hospital to ensure that the safe-use requirements around alvimopan are met? If so, can you describe them?
- o To the best of your knowledge, who is involved in those processes?
12. Does ensuring safe prescribing and use of alvimopan change your normal workflow around patient care (as compared to other drugs)? If so, how?
13. Has the prescribing limit on alvimopan had an impact on patient care? If so, how often does this occur, and what do you do?
- o Probe: if more than 15 doses are needed, discharge takes place within 7 days, etc.
14. Would you be more likely to prescribe alvimopan if it were not subject to the safe use requirement? Why?
- o Are there other factors that affect your decision to prescribe alvimopan? If so, what are they? (Probe: efficacy, availability of viable alternatives, tolerability, etc.)
15. Do you have any additional recommendations for improving safe prescribing and use of alvimopan overall?

Section D: Wrap-Up
(expect to spend about 3-5 minutes on this section)

16. Is there anything I haven't asked about that you would like to discuss?

To wrap up, I have a few demographic questions.

17. What gender do you identify as?
- o *Male*
 - o *Female*

o Prefer not to answer

18. Which of the following best describes your race?

- o American Indian or Alaska Native*
- o Asian*
- o Black or African-American*
- o Native Hawaiian or Other Pacific Islander*
- o White*
- o Prefer not to answer*

19. Are you of Hispanic, Latino, or Spanish origin?

- o Yes*
- o No*

20. What year did you graduate from medical school?

21. What best describes your specialty?

Not to be offered as possible answers

- | | |
|----------------------------------|--------------------------------------|
| <i>o Allergy/Immunology</i> | <i>o Orthopedics</i> |
| <i>o Anesthesiology</i> | <i>o Otolaryngology</i> |
| <i>o Cardiology</i> | <i>o Pathology</i> |
| <i>o Dermatology</i> | <i>o Pediatrics</i> |
| <i>o Endocrinology</i> | <i>o Physical Medicine and Rehab</i> |
| <i>o Emergency Medicine</i> | <i>o Plastic Surgery</i> |
| <i>o Family/General Practice</i> | <i>o Preventive Medicine</i> |
| <i>o Geriatrics</i> | <i>o Psychology</i> |
| <i>o Internal Medicine</i> | <i>o Pulmonology</i> |
| <i>o Medical Genetics</i> | <i>o Radiology</i> |
| <i>o Neurological Surgery</i> | <i>o Rheumatology</i> |
| <i>o Nephrology</i> | <i>o Sleep medicine</i> |
| <i>o Neurology</i> | <i>o Surgery</i> |
| <i>o Obstetrics/Gynecology</i> | <i>o Urology</i> |
| <i>o Oncology</i> | <i>o Other (Please specify)</i> |
| <i>o Ophthalmology</i> | |

22. In what ZIP code is your practice located?

23. In what clinical settings do you prescribe alvimopan? You may select more than one.

- Outpatient clinic (solo practice)
- Outpatient clinic (group practice)
- Community hospital (non-military/VA)
- Academic hospital (non-military/VA)
- Military or VA hospital
- Other (Please specify)

24. What percentage of your professional time is spent in direct patient care?

25. Have you received any of the following from a manufacturer of alvimopan over the past three years?

- Speaker fees
- Payment for membership on an advisory board
- Research grants
- Other benefits (Please specify)

That is all the questions I have for you. Is there anything I haven't asked about that you would like to discuss? How should we provide the token of appreciation? [If they would like it sent to them, ask for email address]. We will send it within the week.

If additional questions arise, please contact the study principal investigator, Dr. Ameet Sarpatwari at 617-525-8890.

Thank you for your time and your insights. I appreciate your speaking with me.