

Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Physician Surveys on Experiences with REMS Programs

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National Survey of Physician Experiences with Ambrisentan

Thank you for agreeing to participate in this survey relating to your experiences prescribing ambrisentan. This research is being conducted by investigators at Brigham and Women's Hospital / Harvard Medical School and is sponsored by the US Food and Drug Administration (FDA). If you have NOT prescribed ambrisentan in the last year, **please email Sandra Applebaum, MS (sandra.applebaum@luminasllc.com) at Luminas, the survey administrator, and DO NOT proceed further.**

Your participation in the survey 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 survey methods have been approved by the Institutional Review Board at Brigham and Women's Hospital and the FDA Research Involving Human Subjects Committee.

The survey should take approximately 20 minutes to complete. In addition to the \$20 enclosed in this packet, following completion, you will be asked for your email address and emailed a \$80 Amazon gift card as a token of appreciation. This survey is not connected in any way with a pharmaceutical manufacturer.

We appreciate your contribution to this important topic. Thank you in advance for your participation!

Instructions for Completing the Survey

- As a reminder, you can take the survey online if you prefer at the following link: [\[link\]](#).
- Using a blue or black pen, place an "X" in the box next to the appropriate response as shown: .
- If asked to provide a written response to a question, please PRINT legibly in the space provided.
- If completing the paper questionnaire, please return it in the enclosed postage-paid envelope.

Section A: Prescribing and Certification Requirements

We will start the survey by getting a better understanding of your experience with ambrisentan.

A1. Approximately when was the last time you prescribed ambrisentan?

month year

A2. Approximately how many of your patients have you prescribed ambrisentan to over the last 3 years?

₁ 1-10 patients
₂ 11-20 patients
₃ 21 or more patients

A3. Approximately how many women of reproductive potential have you prescribed ambrisentan to over the last 3 years?

₁ 1-5 patients
₂ 6-10 patients
₃ 11 or more patients

As you may know, ambrisentan is subject to a special FDA safety program. Before prescribing ambrisentan, physicians must go through a certification process administered by the manufacturer. The certification process typically involves such activities as reviewing certain materials, training, and filling out forms.

A4. Approximately how many years ago did you first complete the certification process for ambrisentan?

years ago

A5. How well do you recall the certification process that allowed you to begin to prescribe ambrisentan?

₁ Very well
₂ Moderately well
₃ Slightly well
₄ Not well at all

A6. Did the certification process for ambrisentan provide information on the following risks?

| | Yes | No | I don't remember |
|--|---------------------------------------|---------------------------------------|---------------------------------------|
| a. Birth defects (women of reproductive potential) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| b. Decreased hemoglobin count | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| c. Decreased sperm count (men) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| d. Pulmonary edema | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| e. Respiratory infections | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| f. Stroke | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |

A7. When you start a patient on ambrisentan, how often do you discuss the following risks?

| | Never (0% of the time) | Rarely (1%-5% of the time) | Sometimes (6%-25% of the time) | Often (26%-50% of the time) | Most of the time (51%-75% of the time) | Always/almost always (76% of the time or more) |
|--|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---|---|
| a. Birth defects (women of reproductive potential) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ | <input type="checkbox"/> ₆ |
| b. Decreased hemoglobin count | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ | <input type="checkbox"/> ₆ |
| c. Decreased sperm count (men) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ | <input type="checkbox"/> ₆ |
| d. Pulmonary edema | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ | <input type="checkbox"/> ₆ |
| e. Respiratory infections | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ | <input type="checkbox"/> ₆ |
| f. Stroke | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ | <input type="checkbox"/> ₆ |

A8. Using a scale from 1 (most) to 4 (least), please rank the following risks to patients receiving ambrisentan in order of their magnitude of concern to you.

- 1 Birth defects (women of reproductive potential)
- 2 Decreased sperm count (men)
- 3 Decreased hemoglobin count
- 4 Pulmonary edema

A9. Using a scale from 1 (most) to 5 (least), please rank the usefulness of the following sources of information in contributing to your understanding of the risks of ambrisentan.

- 1 Clinical decision support tools (e.g., UpToDate, MicroMedex, ePocrates)
- 2 Manufacturer sales representatives' presentations or materials
- 3 Professional colleagues
- 4 Studies and other articles published in medical journals
- 5 The drug's FDA-approved labeling

**A10. At first, how frequently must the testing required for ambrisentan be performed?
If fewer than 10 weeks, please enter as 2 digits, e.g., 04.**

Every weeks

A11. Please indicate to what extent you agree or disagree with the following statements.

| | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|--|--|--|--|--|
| a. It is reasonable that ambrisentan has a certification process, while other drugs I prescribe for my patients with pulmonary arterial hypertension do not have a certification process. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| b. The certification process provided me with useful information about ambrisentan. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| c. The certification process for ambrisentan took too long to complete. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| d. The educational materials provided as part of the certification process should include information about any clinically important risk of ambrisentan. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| e. The educational materials provided as part of the certification process should include information about how well ambrisentan is expected to work. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| f. The certification process effectively explained the testing required of patients receiving ambrisentan. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| g. Prescribers should be required to pass a quiz covering drug risks and testing requirements to complete the ambrisentan certification process. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| h. Physicians should be required to repeat the certification process each year while they are active prescribers of ambrisentan. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |
| i. Physicians should be compensated for having to complete the certification process for ambrisentan. | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> |

Section B: Patient Initiation and Monitoring

As you may know, prior to and while taking ambrisentan, patients are also required to follow certain “safe use requirements”.

B1. To receive an initial prescription for ambrisentan, patients must do the following:

| | Yes | No | Not sure |
|---|---------------------------------------|---------------------------------------|---------------------------------------|
| a. Get a liver function test | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| b. Get a pregnancy test (women of reproductive potential) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| c. Get a urinalysis | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |
| d. Use at least one form of contraception (women of reproductive potential) | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ |

B2. When you prescribe ambrisentan, how long, on average, do you or someone on your team spend explaining to patients the safe use requirements related to the drug?

- ₁ We do not discuss safe use requirements with my patients.
- ₂ 5 minutes or less
- ₃ 6-10 minutes
- ₄ 11-15 minutes
- ₅ More than 15 minutes

B3. Who on your clinical team is primarily responsible for helping patients complete administrative paperwork or enrollment forms involved with the safe use requirements?

- ₁ I am
- ₂ A nurse practitioner or registered nurse
- ₃ A physician assistant
- ₄ Other (Please specify: _____)
- ₅ No one

B4. Do your patients receive from you or your team any other materials describing the risks of taking ambrisentan?

- ₁ Yes
- ₂ No → **GO TO B6.**

B5. What materials do you or your team provide describing the risks or harms of ambrisentan? Please check all that apply.

- ₁ Published articles or stories
- ₂ Links to manufacturer website
- ₃ Links to any non-manufacturer websites
- ₄ Pamphlets or brochures produced by the manufacturer
- ₅ Pamphlets or brochures produced by you or your institution
- ₆ Other materials (Please specify: _____)

B6. After learning about the safe use requirements for ambrisentan, how often do your patients seek another treatment option instead?

- ₁ Never (0% of the time)
- ₂ Rarely (1%-5% of the time)
- ₃ Sometimes (6%-25% of the time)
- ₄ Often (26%-50% of the time)
- ₅ Most of the time (51%-75% of the time)

6 Always/almost always (76% of the time or more)

B7. In your estimation, how frequently do your patients follow the testing schedule that is part of the safe use requirements?

- 1 Never (0% of the time)
- 2 Rarely (1%-5% of the time)
- 3 Sometimes (6%-25% of the time)
- 4 Often (26%-50% of the time)
- 5 Most of the time (51%-75% of the time)
- 6 Always/almost always (76% of the time or more)

B8. Please indicate to what extent you agree or disagree with the following statements.

| | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| a. The testing requirement is clinically necessary for safe use of ambrisentan. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| b. The paperwork involved with the safe use requirements facilitates discussion about ambrisentan between patients and me or my team. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| c. The safe use requirements are burdensome for most patients. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| d. The safe use requirements have often caused a delay in my patients receiving their medication. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| e. Insurance issues have often caused a delay in my patients receiving their medication. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| f. Insurance issues are more burdensome than safe use requirements for most patients. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

Section C: Overall Experiences and Perceptions and Reforms

C1. Please rate how easy or hard it is to complete the following tasks related to prescribing ambrisentan.

| | Very easy | Somewhat easy | Neither easy nor hard | Somewhat hard | Very hard |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| a. The physician certification process | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| b. The patient enrollment process | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| c. Testing patients | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| d. Reporting testing findings | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

C2. How willing would you be to prescribe ambrisentan if it was not subject to...?

| | Very willing | Somewhat willing | Neither willing nor unwilling | Somewhat unwilling | Very unwilling |
|---|----------------------------|----------------------------|-------------------------------|----------------------------|----------------------------|
| a. Physician certification requirements | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| b. Patient safe use requirements | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

C3. How often are patients needing ambrisentan referred to you by other physicians in your specialty because they are not certified to prescribe it?

- ₁ A lot
- ₂ Sometimes
- ₃ Never

Please indicate to what extent you agree or disagree with the following statements:

C4. Overall, the positives of the ...

| | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| a. Prescriber certification process for ambrisentan outweigh the negatives. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| b. Patient safe use requirements for ambrisentan outweigh the negatives. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

C5. What feedback would you give the FDA or the manufacturer on the physician certification process for ambrisentan? Please print clearly in the box below. If you need more space, continue on the back cover. Be sure to include the question number.

C6. What feedback would you give the FDA or the manufacturer on the patient safe use requirements for ambrisentan? Please print clearly in the box below. If you need more space, continue on the back cover. Be sure to include the question number.

Section D: Pandemic Impact

D1. Did you prescribe ambrisentan prior to the start of the COVID-19 pandemic in March 2020?

- ₁ Yes
- ₂ No

D2. IF YOU ANSWERD NO TO D1, SKIP TO D3. IF YOU ANSWERED YES TO D1, please rate how much easier or harder it was to complete the following tasks related to prescribing ambrisentan during vs. before the pandemic.

| | Much easier | Somewhat easier | Neither easier nor harder | Somewhat harder | Much harder |
|-----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| a. The patient enrollment process | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| b. Testing patients | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |
| c. Reporting testing findings | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ | <input type="checkbox"/> ₃ | <input type="checkbox"/> ₄ | <input type="checkbox"/> ₅ |

D3. Were you aware of the pandemic policy related to required testing under special FDA drug safety programs?

- ₁ Yes
- ₂ No

In March 2020, the FDA announced it would permit drug manufacturers and health care providers to make accommodations for laboratory tests required under the drug safety programs during the COVID-19 pandemic, such as allowing patients to take home pregnancy tests instead of using a blood test.

D4. Did the manufacturers of ambrisentan change the drug's pregnancy testing requirements in response to the pandemic?

- ₁ Yes
- ₂ No
- ₃ I don't know

D5. Did you change pregnancy testing requirements for your patients taking ambrisentan in response to the pandemic (independent of the drug manufacturers)?

- ₁ Yes (If yes, describe briefly: _____)
- ₂ No

Section E: Demographics

E1. What gender do you identify as...? Mark only one.

- ₁ Male
- ₂ Female
- ₃ Prefer not to answer

E2. Which of the following best describes your race? Mark one or more.

- ₁ American Indian or Alaska Native
- ₂ Asian
- ₃ Black or African-American
- ₄ Native Hawaiian or Other Pacific Islander
- ₅ White
- ₆ Prefer not to answer

E3. Are you of Hispanic, Latino, or Spanish origin?

- ₁ Yes
- ₂ No

E4. What year did you graduate from medical school?

E5. Which of the following best describes your specialty? You may select up to 2.

- | | |
|---|--|
| <input type="checkbox"/> ₁ Allergy/Immunology | <input type="checkbox"/> ₁₃ Neurology |
| <input type="checkbox"/> ₂ Anesthesiology | <input type="checkbox"/> ₁₄ Obstetrics/Gynecology |
| <input type="checkbox"/> ₃ Cardiology | <input type="checkbox"/> ₁₅ Oncology |
| <input type="checkbox"/> ₄ Dermatology | <input type="checkbox"/> ₁₆ Ophthalmology |
| <input type="checkbox"/> ₅ Endocrinology | <input type="checkbox"/> ₁₇ Orthopedics |
| <input type="checkbox"/> ₆ Emergency Medicine | <input type="checkbox"/> ₁₈ Otolaryngology |
| <input type="checkbox"/> ₇ Family/General Practice | <input type="checkbox"/> ₁₉ Pathology |
| <input type="checkbox"/> ₈ Geriatrics | <input type="checkbox"/> ₂₀ Pediatrics |
| <input type="checkbox"/> ₉ Internal Medicine | <input type="checkbox"/> ₂₁ Physical Medicine and Rehab |
| <input type="checkbox"/> ₁₀ Medical Genetics | <input type="checkbox"/> ₂₂ Plastic Surgery |
| <input type="checkbox"/> ₁₁ Neurological Surgery | <input type="checkbox"/> ₂₃ Preventive Medicine |
| <input type="checkbox"/> ₁₂ Nephrology | <input type="checkbox"/> ₂₄ Psychology |

- ₂₅ Pulmonology
- ₂₆ Radiology
- ₂₇ Rheumatology
- ₂₈ Sleep medicine

- ₂₉ Surgery
- ₃₀ Urology
- ₃₁ _____
specify: _____)

Other (Please

E6. In what ZIP code is your practice located?

E7. In what clinical settings do you prescribe ambrisentan? You may select more than one.

- ₁ Outpatient clinic (solo practice)
- ₂ Outpatient clinic (group practice)
- ₃ Community hospital (non-military/VA)
- ₄ Academic hospital (non-military/VA)
- ₅ Military or VA hospital
- ₆ Other (Please specify: _____)

E8. What percentage of your professional time is spent in direct patient care?

percent

E9. Have you received any of the following from Gilead, the brand-name manufacturer of ambrisentan, over the past three years? Please select all that apply.

- ₁ Speaker fees
- ₂ Payment for membership on an advisory board
- ₃ Research grants
- ₄ Other benefits (Please specify: _____)

E10. Please provide your email address to receive your gift card: _____

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY. PLEASE RETURN YOUR COMPLETED QUESTIONNAIRE IN THE ENCLOSED ENVELOPE OR MAIL IT TO:

*Adapt, Inc.
Physician Survey
5610 Rowland Road
Suite 160
Minnetonka, MN 55343*