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

OMB Control Number: 0910-0847
Expiration Date: 12/31/2022

National Survey of Physician Experiences with Lenalidomide, Pomalidomide, or Thalidomide

Thank you for agreeing to participate in this survey relating to your experiences prescribing lenalidomide, pomalidomide, or thalidomide. This research is being conducted by investigators at Brigham and Women's Hospital / Harvard Medical School on behalf of the US Food and Drug Administration (FDA). If you have NOT prescribed lenalidomide, pomalidomide, or thalidomide 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!

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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.

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Section A: Prescribing and Certification Requirements

We will start the survey by getting a better understanding of your experience with lenalidomide, pomalidomide, or thalidomide.

A1. Approximately when was the last time you prescribed lenalidomide, pomalidomide, or thalidomide?

☐☐ month ☐☐☐☐ year

A2. Approximately how many of your patients have you prescribed lenalidomide, pomalidomide, or thalidomide to over the last 3 years?

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

A3. Approximately how many <u>women of reproductive potential</u> have you prescribed lenalidomide, pomalidomide, or thalidomide to over the last 3 years?

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

As you may know, lenalidomide, pomalidomide, and thalidomide are subject to special FDA safety programs. Before prescribing lenalidomide, pomalidomide, or thalidomide, 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 <u>first</u> complete the certification process for lenalidomide, pomalidomide, or thalidomide?

☐☐ years ago

A5. How well do you recall the certification process that allowed you to begin to prescribe lenalidomide, pomalidomide, or thalidomide?

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

A6. Did the <u>certification process</u> for lenalidomide, pomalidomide, or thalidomide provide information on the following risks?

	Yes	No	I don't remember
a. Birth defects (women of reproductive potential)	☐1	☐2	☐3
b. hematological toxicity	☐1	☐2	☐3
c. Liver damage	☐1	☐2	☐3
d. Respiratory infections	☐1	☐2	☐3
e. Venous thromboembolism	☐1	☐2	☐3
f. Vision impairment	☐1	☐2	☐3

A7. When you start a patient on lenalidomide, pomalidomide, or thalidomide, 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)	☐1	☐2	☐3	☐4	☐5	☐6
a. Hematological toxicity	☐1	☐2	☐3	☐4	☐5	☐6
c. Liver damage	☐1	☐2	☐3	☐4	☐5	☐6
d. Respiratory infections	☐1	☐2	☐3	☐4	☐5	☐6
e. Venous thromboembolism	☐1	☐2	☐3	☐4	☐5	☐6

f. Vision impairment	☐1	☐2	☐3	☐4	☐5	☐6

A8. Using a scale from 1 (most) to 4 (least), please rank the following risks to patients receiving lenalidomide, pomalidomide, or thalidomide in order of their magnitude of concern <u>to you</u>.

1 Birth defects (women of reproductive potential ☐
2 hematological toxicity ☐
3 Liver damage ☐
4 Venous thromboembolism ☐

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 lenalidomide, pomalidomide, or thalidomide.

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 lenalidomide, pomalidomide, or thalidomide 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 lenalidomide, pomalidomide, or thalidomide has a certification process, while other drugs I prescribe for my patients with pulmonary arterial hypertension do not have a certification process.	☐1	☐2	☐3	☐4	☐5
b. The certification process provided me with useful information about lenalidomide, pomalidomide, or thalidomide.	☐1	☐2	☐3	☐4	☐5
c. The certification process for lenalidomide, pomalidomide, or thalidomide took too long to complete.	☐1	☐2	☐3	☐4	☐5
d. The educational materials provided as part of the certification process should include information about any clinically important risk of lenalidomide, pomalidomide, or thalidomide.	☐1	☐2	☐3	☐4	☐5
e. The educational materials provided as part of the certification process should include information about how well lenalidomide, pomalidomide, or thalidomide is expected to work.	☐1	☐2	☐3	☐4	☐5
f. The certification process effectively explained the testing required of patients receiving lenalidomide, pomalidomide, or thalidomide.	☐1	☐2	☐3	☐4	☐5
g. Prescribers should be required to pass a quiz covering drug risks and testing requirements to complete the lenalidomide, pomalidomide, or thalidomide certification process.	☐1	☐2	☐3	☐4	☐5
h. Physicians should be required to repeat the certification process each year while they are active prescribers of lenalidomide, pomalidomide, or thalidomide.	☐1	☐2	☐3	☐4	☐5

i. Physicians should be compensated for having to complete the certification process for lenalidomide, pomalidomide, or thalidomide.	☐1	☐2	☐3	☐4	☐5

Section B: Patient Initiation and Monitoring

As you may know, prior to and while taking lenalidomide, pomalidomide, or thalidomide, patients are also required to follow certain "safe use requirements".

B1. To receive an initial prescription for lenalidomide, pomalidomide, or thalidomide, patients must do the following:

	Yes	No	Not sure
a. Get a liver function test	☐1	☐2	☐3
b. Get a pregnancy test (women of reproductive potential)	☐1	☐2	☐3
c. Get a urinalysis	☐1	☐2	☐3
d. Use two forms of contraception (women of reproductive age)	☐1	☐2	☐3

B2. When you prescribe lenalidomide, pomalidomide, or thalidomide, 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 lenalidomide, pomalidomide, or thalidomide?

☐1 Yes
☐2 No → **GO TO B6.**

B5. What materials do you or your team provide describing the risks or harms of lenalidomide, pomalidomide, or thalidomide? 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 lenalidomide, pomalidomide, or thalidomide, 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 lenalidomide, pomalidomide, or thalidomide.	☐1	☐2	☐3	☐4	☐5
b. The paperwork involved with the safe use requirements facilitates discussion about lenalidomide, pomalidomide, or thalidomide between patients and me or my team.	☐1	☐2	☐3	☐4	☐5
c. The safe use requirements are burdensome for most patients.	☐1	☐2	☐3	☐4	☐5
d. The safe use requirements have often caused a delay in my patients receiving their medication.	☐1	☐2	☐3	☐4	☐5
e. Insurance issues have often caused a delay in my patients receiving their medication.	☐1	☐2	☐3	☐4	☐5
f. Insurance issues are more burdensome than safe use requirements for most patients.	☐1	☐2	☐3	☐4	☐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 lenalidomide, pomalidomide, or thalidomide.

	Very easy	Somewhat easy	Neither easy nor hard	Somewhat hard	Very hard
a. The physician certification process	☐1	☐2	☐3	☐4	☐5
b. The patient enrollment process	☐1	☐2	☐3	☐4	☐5
c. Testing patients	☐1	☐2	☐3	☐4	☐5
d. Reporting testing findings	☐1	☐2	☐3	☐4	☐5

C2. How willing would you be to prescribe lenalidomide, pomalidomide, or thalidomide if it was not subject to…?

	Very willing	Somewhat willing	Neither willing nor unwilling	Somewhat unwilling	Very unwilling
a. Physician certification requirements	☐1	☐2	☐3	☐4	☐5
b. Patient safe use requirements	☐1	☐2	☐3	☐4	☐5

C3. How often are patients needing lenalidomide, pomalidomide, or thalidomide 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 lenalidomide, pomalidomide, or thalidomide outweigh the negatives.	☐1	☐2	☐3	☐4	☐5
b. Patient safe use requirements for lenalidomide, pomalidomide, or thalidomide outweigh the negatives.	☐1	☐2	☐3	☐4	☐5

C5. What feedback would you give FDA or the manufacturer on the physician certification process for lenalidomide, pomalidomide, or thalidomide? *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 FDA or the manufacturer on the patient safe use requirements for lenalidomide, pomalidomide, or thalidomide? *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 lenalidomide, pomalidomide, or thalidomide 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 lenalidomide, pomalidomide, or thalidomide during vs. before the pandemic.

	Much easier	Somewhat easier	Neither easier nor harder	Somewhat harder	Much harder
a. The patient enrollment process	☐1	☐2	☐3	☐4	☐5
b. Testing patients	☐1	☐2	☐3	☐4	☐5
c. Reporting testing findings	☐1	☐2	☐3	☐4	☐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 lenalidomide, pomalidomide, or thalidomide 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 lenalidomide, pomalidomide, or thalidomide 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.*

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

☐25 Pulmonology
☐26 Radiology
☐27 Rheumatology
☐28 Sleep medicine
☐29 Surgery
☐30 Urology
☐31 Other (Please specify: _____)

E6. In what ZIP code is your practice located?

☐☐☐☐☐

E7. In what clinical settings do you prescribe lenalidomide, pomalidomide, or thalidomide? *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 Celgene, the brand-name manufacturer of lenalidomide, pomalidomide, and thalidomide, 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