Asthma Clinical Research Network
NIH/NHLBI

BAGS

# SIGNIFICANT ASTHMA EXACERBATION

SAE

Patient ID: 1 __ __ __ __
Patient Initials: __ __ __
Visit Number: __ __
Current Date: __ __ / __ __ / __ __
month day year
Interviewer ID: __ __ __ __

*(Clinic Coordinator completed)*

***This form is to be filled out each time a patient experiences an asthma exacerbation according to the definition below.***

**01** 1. Did the patient experience an increase in cough, chest tightness, or wheezing? ❑1 Yes ❑0 No

2. Did the patient experience any of the following conditions?

**02A** 2a. An increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours? ❑1 Yes ❑0 No

**02B** 2b. An increase in rescue inhaler use ≥ 16 total puffs per 24 hours for a period of 48 hours? ❑1 Yes ❑0 No

**02C** 2c. A fall in PEFR to 65% of reference? ❑1 Yes ❑0 No

***If you did not answer YES to Question #1 AND at least one item in Question #2, the patient did not experience a significant asthma exacerbation as defined in the Manual of Operations. DO NOT COMPLETE THIS FORM.***

***If the patient has experienced a significant asthma exacerbation but has not yet completed the RUN-IN period, STOP. The patient is ineligible for the study. Please complete the Termination of Study Participation form (TERM).***

**03** 3. Was the significant asthma exacerbation related to the routine pulmonary function testing? *(Check one box only)*

❑1 Definitely related
❑2 Probably related
❑3 Relationship undetermined
❑4 Probably not related
❑5 Definitely not related

**04** 4. Was the significant asthma exacerbation related to the Beta-Agonist Reversibility testing? *(Check one box only)*

❑1 Definitely related
❑2 Probably related
❑3 Relationship undetermined
❑4 Probably not related
❑5 Definitely not related

| Code | Question | Response |
|---|---|---|
| 05 | 5. Was the significant asthma exacerbation related to the Methacholine Challenge testing? *(Check one box only)* | ❑1 Definitely related<br>❑2 Probably related<br>❑3 Relationship undetermined<br>❑4 Probably not related<br>❑5 Definitely not related |
| 06 | 6. Was the asthma exacerbation resolved by increasing PRN use of the rescue inhaler? | ❑1 Yes ❑0 No |
| 07 | 7. Did the patient seek care for the asthma exacerbation? If ***No***, skip to Question #9. | ❑1 Yes ❑0 No |
| | 8. What type of care was sought? | |
| 08A | 8a. Study Investigator? | ❑1 Yes ❑0 No |
| 08A1 | If ***Yes***, indicate type of contact. | ❑1 Scheduled clinic visit<br>❑2 Unscheduled clinic visit<br>❑3 Phone contact |
| 08B | 8b. Primary Care or Other Physician?<br>Name of physician: ______________________ | ❑1 Yes ❑0 No |
| 08B1 | If ***Yes***, indicate type of contact. | ❑1 Scheduled clinic visit<br>❑2 Unscheduled clinic visit<br>❑3 Phone contact |
| 08C | 8c. Emergency Room visit?<br>Name of hospital: ______________________ | ❑1 Yes ❑0 No |

| | | | |
|---|---|---|---|
| **09** | 9. | Was the patient hospitalized?<br>Name of hospital: ________________ | ☐$_1$ Yes ☐$_0$ No |
| **09A** | | If ***Yes***, was intubation and ventilation assistance required? | ☐$_1$ Yes ☐$_0$ No |
| **10** | 10. | Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids?<br>If ***Yes***, | ☐$_1$ Yes ☐$_0$ No |
| **10A** | | 10a. Start date of glucocorticoid: | ___ ___ / ___ ___ / ___ ___<br>*month* *day* *year* |
| **10B** | | 10b. Stop date of glucocorticoid: *(actual or proposed)* | ___ ___ / ___ ___ / ___ ___<br>*month* *day* *year* |
| **11** | 11. | Was the asthma exacerbation treated as outlined in the Manual of Operations?<br>If ***No***, describe ________________<br>________________<br>________________ | ☐$_1$ Yes ☐$_0$ No |
| **12** | 12. | Was the patient deemed a treatment failure due to a previous asthma exacerbation? | ☐$_1$ Yes ☐$_0$ No |
| **13** | 13. | Is the patient a treatment failure? ***If any of the shaded boxes in Questions #9 - #12 are checked, the patient is a treatment failure.***<br>☞ If Yes, the patient should continue to participate in the study if possible. | ☐$_1$ Yes ☐$_0$ No |

If the patient will not continue participating in the study, please complete the Termination of Study Participation form (TERM).