SYMPTOMS ASSESSMENT (SA)

| DATA SECTION | COMPLETION INSTRUCTIONS |
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| GENERAL INFORMATION | The Symptoms Assessment is designed to measure the symptoms and overall health as perceived by the patient. |
| | This form should be completed by the patient at the baseline visit, Treatment days 7, 14, and 28, Treatment weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48, and Follow-up visits 4, 12, 24, and 48, or at the time of premature discontinuation during the treatment or follow-up period. |
| | If the patient is not able to complete the form without help, the coordinator may ask the patient about each symptom and have the patient indicate the number that best reflects how he/she is feeling. |
| | After completing the survey: |
| | Record whether the survey was completed by the patient alone or by the patient with assistance. |
| | Review the form for any missing items. If there are any incomplete items ask the patient to provide a response. |
| | Make sure that each item has a single response marked. |
| | If the patient does not understand the question, a coordinator may read the question to him. Do not rephrase the question. If the patient does not answer the question, indicate whether the response is unknown or the patient refused to answer the question. |
| | Record the patient's ID number in the top right hand corner of the page. |
| | Indicate the time point that corresponds to the visit. |
| | <u>Premature discontinuation</u>: (1) Treatment is discontinued prior to 48 weeks other than for those determined to be non-responders at Treatment week 24. All forms required at Treatment week 48 must be completed at the time that study medication is discontinued. (2) Follow-up is discontinued during the first 24 weeks. All forms required at follow-up week 24 must be completed at the time of the discontinued follow-up. |
| | SPECIFIC INSTRUCTIONS: |
| | Today's date: Record the date (month/day/year) on which the patient filled out the questionnaire. |
| | Question 2: Mark the line with an " " that best describes how the patient feels overall. |
| | Question 3: Mark the line with an " " that best reflects how the symptom has made the patient feel during the <i>past week</i> . |