

Patient number

Date of visit
month day year

NIH - BPH TRIAL

AUA SYMPTOM SCORE EVENT REPORT

This form should be completed if the patient experiences a 4 point rise in AUA symptom score.

Part I / IDENTIFICATION

A. Patient Identification

1. Patient number (PATID)

clinic patient

2. Patient's initials (INITS)

first last

3. Patient's date of birth (DOB)

month day year

B. Initial Visit Information

1. Date of initial clinical event visit (AVSTDT)

month day year

2. Week of initial clinical event visit (AIVWK)

3. Type of visit (AIVTYP)

¹ Follow-up Visit
 ² Interim Visit

Part II / AUA SYMPTOM SCORE 4 POINT EVENT

A. Initial 4 Point Event Visit

1. AUA symptom score (AI4SS)

2. Is the value in A.1 greater than or equal to 4 points more than the baseline symptom score (see patient label)? (AI4GRT)

YES NO
 ¹ ²

If YES, CONTINUE.

If the patient was taking sinus medication, a new diuretic or has an infection, the clinic director should take corrective measures before continuing. After corrective measures have been taken, and not less than 2 weeks or greater than 4 weeks from the initial AUA symptom score 4 point event visit, the patient should be scheduled for a confirming visit.

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3. Are corrective measures necessary? (AI4CM)

YES NO
1 2

If YES:

a. What is the reason for corrective measures? (Check only one) (AI4CMR)

- 1 Sinus medication
2 New diuretic
3 Infection
4 Other (Specify below) (AI4CMRX)
- _____

If there is no need for corrective measures, schedule the patient for a confirming visit in not less than 2 weeks or greater than 4 weeks from the initial AUA symptom score 4 point event visit. The Interim Visit Checklist should also be completed during this confirming visit.

B. Confirming 4 Point Event Visit

1. Date of visit (AC4DT)

month day year

2. Week of visit (AC4WK)

3. AUA symptom score (AC4SS)

4. Is the value in B.3 greater than or equal to 4 points more than the baseline symptom score (see label)? (AC4GRT)

YES NO
1 2

If the symptom score in question B.3 is greater than or equal to 4 points more than the baseline AUA symptom score, this documents an AUA symptom score 4 point event. If the patient is on coded medication, coded medication should be discontinued at the discretion of the Principle Investigator.

5. AUA symptom score 4 point event declared? (AC4DEC)

1 2

6. Is the patient on coded medications? (AC4MED)

1 2

If YES, CONTINUE.

7. Will the coded medications be discontinued? (AC4MDIS)

1 2

If YES, CONTINUE.

8. Date coded medication discontinued (AC4DISC)

month day year

Initials of person completing form (FORMIN)

first last

Form entered in computer?

Signature of P.I. _____

Date _____