

Patient number

Date of visit
month day year

NIH - BPH CLINICAL TRIAL: PILOT STUDY

INTERIM VISIT CHECKLIST

This form should be completed at any visits that are not scheduled follow-up visits.

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. Visit Information

1. Date of visit (IVSTDT)

month day year

2. Week of visit (IVIWK)

C. Reason for Interim Visit (Check all that apply)

Complete Parts II and III of this form for ALL reasons listed below.

- 1. AUA symptom score 4 point event (IRAUA4) Complete AUA Symptom Score Event Form (E01)
- 2. AUA symptom score 8 point event (IRAUA8) Complete AUA Symptom Score Event Form (E01)
- 3. Creatinine rise event (IRCR) Complete Creatinine Rise Event Form (E02)
- 4. Acute urinary retention event (IRUR)
- 5. Recurrent urinary tract infection event (IRUTI) Complete Urinary Event Form (E03)
- 6. Incontinence event (IRINC)
- 7. Adverse event (IRAE) Complete Adverse Event Form (E04)
- 8. Blood pressure management (IRBPM)
- 9. Dispense more medication (IRMED) Complete Parts II and III of this form ONLY
- 10. Intercurrent illness event (IRII) Complete Part IV of this form

Patient number

Date of visit / /
month day year

Part II / BLOOD PRESSURE MANAGEMENT

D. Blood Pressure

1. Supine Blood Pressure (After lying 5 minutes)

a. Heart Rate **(IBPLHR)** bpm

b. Blood Pressure **(IBPLS)/(IBPLD)** / mmHg

2. Standing Blood Pressure (Immediately)

a. Heart Rate 1 **(IBPSHR1)** bpm

b. Blood Pressure Reading 1 **(IBPSS1)/(IBPSD1)** / mmHg

Wait 2 minutes

c. Heart Rate 2 **(IBPSHR2)** bpm

d. Blood Pressure Reading 2 **(IBPSS2)/(IBPSD2)** / mmHg

E. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? **(IORTHYP)** YES NO

Orthostatic hypotension is defined as a decrease of 20mmHg or more in supine to standing systolic blood pressure or a decrease of 10mmHg or more in supine to standing diastolic blood pressure or the development of significant postural hypotension.

Part III / DISPENSING OF MEDICATION

F. Number of days since last visit **(IDDAYS)**

G. Doxazosin Compliance

1. Is the patient taking coded medication? **(IDDCODE)** YES NO

If YES, CONTINUE. If NO, SKIP to Section H.

Patient number

Date of visit
month day year

2. Dose of doxazosin (IDDDOSE) 1 mg 2 mg 4 mg 8 mg
1 2 3 4
3. Number of doxazosin tablets dispensed at the last visit (ICDDISL)
4. Number of doxazosin tablets returned today (IDDRET)
5. Compliance (IDDCOMP)
$$\frac{\text{tabs dispensed (\#3)} - \text{tabs returned (\#4)}}{\text{days since last visit (question F)}} \times 100$$
 %

NOTE: Counsel patient if less than 80% compliant with doxazosin.

6. Number of doxazosin tablets dispensed today (IDDDIST)

DOXAZOSIN LABELS

Remove labels from coded medication before dispensing.

Affix labels here.

H. Finasteride Compliance

1. Is the patient taking the coded medication? (IDFCODE) YES NO
1 2

If YES, CONTINUE.

Patient number

Date of visit
month day year

2. Number of finasteride tablets dispensed at the last visit (IDFDISL)

3. Number of finasteride tablets returned today (IDFRET)

4. Compliance (IDFCOMP)
$$\frac{\text{tabs dispensed (\#2) - tabs returned (\#3)}}{\text{days since last visit (question F)}} \times 100$$
 %

NOTE: Counsel patient if less than 80% compliant with finasteride.

5. Number of finasteride tablets dispensed today (IDFDIST)

FINASTERIDE LABEL

Remove label from coded medication before dispensing.
Affix label here.

Part IV / INTERCURRENT ILLNESS EVENT

I. Intercurrent Illness Information

1. Specify intercurrent illness:

2. Is this a serious event? (IIISE)

YES NO
1 2

3. Specify action taken:

Patient number

Date of visit
month day year

4. Intercurrent illness event declared? **(IIIDEC)** YES NO
1 2

Consultation with the Clinical Review Committee is required to declare an intercurrent illness stop point (i.e. discontinuation of coded medications).

If YES:

a. Date of confirmation by Clinical Review Committee **(IIICONF)**
month day year

Initials of person completing form **(FORMIN)**
first last

Date form completed **(FORMDT)**
month day year

Signature