

Patient number

Date form completed
month day year

NIH - BPH CLINICAL TRIAL: PILOT STUDY
CLINICAL REVIEW COMMITTEE REPORT

This form is completed by the Clinical Review Committee as documentation of the classification for a patient that had a pre-defined clinical event, discontinued one or both coded medications or discontinued follow-up visits. The Committee's classification is based on a review of the patient's complete data record in the master database at the Biostatistical Coordinating Center (BCC). The original of this form is kept at the BCC. A copy is sent to the corresponding clinical center to be filed in the patient's binder.

A. Patient Identification

1. Clinic number (CLINIC)
2. Patient Identification number (PATID)
clinic patient
3. Patient's initials (INITS)
first last
4. Patient's date of birth (DOB)
month day year
5. CRC form number (CRCNO)

B. CRC Classification

Specify the classification for this patient: (WCLASS)
(check one)

- 1 Death (Complete Section C)
- 2 AUA symptom score event (Complete Section D)
- 3 Creatinine rise event (Complete Section E)
- 4 Urinary event (Complete Section F)
- 5 Treatment non-compliance (Complete Section G)
- 6 Inactive follow-up (Complete Section H)
- 7 Crossover to known therapy (Complete Section I)

Patient number

Date form completed
month day year

C. Death Specification

Date of death (WDDATE)
month day year

2. Probable cause of death (WDCAUS)

D. AUA Symptom Score Specification

Specify the type of AUA Symptom Score event: (WSSTYP) 4 point event
(check one) 8 point event

2. AUA Symptom Score

a. Baseline (WSSBAS)

b. Initial Event (WSSIEV)

c. Confirming Event (WSSCEV)

3. Date of initial event (WSSEVDT)
month day year

IF THIS IS AN 8 POINT EVENT, CONTINUE

4. Was the patient taking coded medication(s)? (WSSCODE) YES NO

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 5

Coded medication(s) discontinued: Doxazosin (WSSMDD)
 Finasteride (WSSMDF)

b. Date coded medication(s) discontinued (WSSMDDT)
month day year

5. Is the patient continuing follow-up visits? (WSSCFUV) YES NO

IF NO

Date of last visit (WSSLVST)
month day year

Patient number

Date form completed
month day year

E. Creatinine Rise Specification

Creatinine results

- a. Baseline (WCRBAS) . mg/dl
- b. Initial Event (WCRIEV) . mg/dl
- c. Confirming Event (WCRCEV) . mg/dl

2. Date of initial event (WCREVDT)
month day year

3. Was the patient taking coded medication(s)? (WCRCODE) YES NO
 1 2

IF YES, THEN CONTINUE IF NO, SKIP TO Question 4

- a. Coded medication(s) discontinued: 1 Doxazosin (WCRMDD)
 1 Finasteride (WCRMDF)

b. Date coded medication(s) discontinued (WCRMDDT)
month day year

4. Is the patient continuing follow-up visits? (WCRCFUV) YES NO
 1 2

IF NO:

a. Date of last visit (WCRLVST)
month day year

F. Urinary Event Specification

- 1 Specify the type of urinary event: (WUETYP) 1 Acute urinary retention event (check one)
 2 Recurrent urinary tract infection
 3 Incontinence event

2. Date of event (WUEEVDT)
month day year

Patient number Date form completed
month day year

3. Was the patient taking coded medication(s)? (WUECODE) YES NO
 1 2

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 4.

a. Coded medication(s) discontinued 1 Doxazosin (WUEMDD)
 1 Finasteride (WUEMDF)

b. Date coded medication(s) discontinued (WUEMDDT)
month day year

4. Is the patient continuing follow-up visits? (WUECFUV) YES NO
 1 2

IF NO:

a. Date of last visit (WUELVST)
month day year

G. Treatment Non-compliance Specification

Specify the primary reason for discontinuing coded medications (WTNRSN)

2 Coded medication(s) discontinued 1 Doxazosin (WTNMDD)
 1 Finasteride (WTNMDF)

3 Date coded medications discontinued (WTNMDDT)
month day year

H. Inactive Follow-up Specification

1 Specify the primary reason for discontinuing follow-up visits (WIFRSN)

2 Date of last visit (WIFMDDT)
month day year

Patient number

Date form completed
month day year

Crossover to Known Therapy Specification

Specify the primary reason for crossover to known therapy (WCTRSN)
(check one)

¹ Medical therapy

² Invasive therapy

If medical therapy, CONTINUE. If invasive therapy, SKIP to Question 3

2. Specify the medical therapy
(check all that apply)

¹ Alpha-1 blocker (WCTMA1)

¹ 5-alpha inhibitor (WCTM5A)

¹ Other medication (WCTMO)
specify: _____ (WCTMOX)

SKIP to Question 4

3. Specify the invasive therapy (WCTIT)
(check one)

¹ TURP

² TUIP

³ Radical prostatectomy

⁴ Open prostatectomy

4. Was the patient taking coded medication(s)? (WCTCODE)

YES NO
 ¹ ²

IF YES, THEN CONTINUE IF NO, SKIP TO Question 5

a. Coded medication(s) discontinued

¹ Doxazosin (WCTMDD)

¹ Finasteride (WCTMDF)

b. Date coded medication(s) discontinued (WCTMDDT)

month day year

Patient number

Date form completed
month day year

5. Is the patient continuing follow-up visits? (WCTCFUV) YES NO
 1 2

IF NO:

a. Date of last visit (WCTLVST)
month day year

J Conclusion of Report

1 Additional comments:

Initials of person completing form
(FORMIN) first last

Date form completed
(FORMDT) month day year

Signature _____