BE-DRI

Question by Question Specifications Guide
Form 261: UI Treatment Status
Version 09/01/04 (A)

I. Purpose
The UI Treatment Status Form is designed to capture data regarding any treatment for urge urinary incontinence post-intervention.

II. Administration
This form is to be completed by a certified BE-DRI Interviewer/Data Collector at Visits 6-11.

III. Section by Section Review

Section A: General Study Information

A1. **Study ID Number:** Affix the patient ID label in the space provided in the A1 field and in the upper right hand corner of each subsequent page of the Data Form. Do not handwrite ID numbers as transcription errors are common and handwritten numbers are often illegible.

A2. **Visit Number:** Circle the appropriate visit, from choices VS06-VS11.

A3. **Date Form Completed**: Enter the date on which the form is completed. All dates must be in the format of mm/dd/yyyy.

A4. **Study Staff Initials:** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If there is no middle initial, strike a dash in the second space. If the last name is hyphenated or if there are 2 last names, enter the initials of the first last name in the third space.

Section B: Treatment for Urge Incontinence Post-Intervention

B1. **Did the patient receive any newly initiated treatment for urge UI since her last visit?** Code “1” (YES) or “2” (NO) as appropriate. The key to this question is whether or not treatments are “newly initiated.” Anything documented on a previous F261 would not be considered “newly initiated.” Proceed to B1a if code = 1. Skip to Section C if code = 2.

B1a. **Was UTI ruled out or diagnosed and treated by the MD Investigator or another practitioner prior to initiation of the new treatment for urge UI?** Code “1,” “2,” or “3” as appropriate. If code=3, F290 (Protocol Deviation) must be completed to explain.

B2. **Did the patient receive newly initiated drug treatment for urge UI since her last visit?** Code “1” (YES) or “2” (NO) as appropriate. Again, the critical part of this question is whether or not the drug treatment is “newly initiated.” Proceed to B2a if code = 1. Skip to B3 if code = 2.

B2a. **Circle yes or no for all drug treatments newly initiated for urge UI:** Code “1” (YES) or “2” (NO) as appropriate for both **Detrol** and **Other Anticholinergic**. If code = 1, answer subquestions a-b and/or a-c respectively. Exact dates and reasons for resuming drug therapy are critical information in regards to the BE-DRI study outcomes.

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B3. **Did the patient receive <u>any other newly initiated treatment</u> for urge UI since her last visit?** Code "1" (YES) or "2" (NO) as appropriate. Again, the key to answering this question is whether or not the treatment is "newly initiated." Anything documented on a previous F261 would not be considered "newly initiated." Proceed to B3a if code = 1. Skip to Section C if code = 2.

If code = 1, complete the chart below by documenting the following:
Column i: Newly initiated treatment;
Column ii: Corresponding code (Treatment Codes are included as an attachment to F261);
Column iii: Specification **<u>if</u>** code = 06 (Other Intravesical Therapy) or 99 (Other);
Column iv: Date of treatment (using mm/dd/yyyy format);
Column v: Reason for request.

SEE ATTACHED EXAMPLE CASES FROM EVALUATION STAFF TRAINING FOR MORE INFORMATION ON HOW TO USE FORM 261

Section C: Principle Investigator's Signature

C1. **Principal Investigator's Signature:** PI must sign and date this form for it to be considered complete.

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Part II: Evaluation Training
F261

Ms. X

Randomization Date: 06/01/2004
VS05 Date: 08/01/2004

No UTI reported since VS05

No treatment for urge incontinence reported since VS05

F261: UI Treatment Status, version 09/01/04 (A)

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit #

4 Months .... (VS06)	14 Months VS09
6 Months VS07	20 Months VS10
8 Months VS08	26 Months VS11

A3. Date Form Completed: 09 / 30 / 2004 (MONTH DAY YEAR)

A4. Initials of Person Completing this Form: CJL

SECTION B: TREATMENT FOR URGE INCONTINENCE POST-INTERVENTION

B1. Did the patient receive any newly initiated treatment for **urge UI** since her last visit?

YES 1

NO .... (2) ➔ **SKIP TO SECTION C**

B1a. Was UTI ruled out or diagnosed and treated by the MD Investigator or another practitioner prior to initiation of the new treatment for urge UI?

YES, UTI RULED OUT.. 1

YES, UTI DIAGNOSED, TREATED AND RESOLVED 2

NO .... 3 ➔ **COMPLETE F290: PROTOCOL DEVIATION**

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B2. Did the patient receive newly initiated **drug treatment** for urge UI since her last visit?

YES 1

NO .... 2 ➔ **SKIP TO B3**

Affix ID Label Here

B2a. Circle yes or no for all drug treatments newly initiated for **urge UI**:

	YES	NO
Detrol	1↓	2

a. Date of request to resume drug treatment: __ __ / __ __ / __ __ __ __ (Month / Day / Year)

b. Reason cited by patient for resuming drug treatment: ____________________

	YES	NO
Other Anticholinergic	1↓	2

a. Specify: ____________________

b. Date of request to resume drug treatment: __ __ / __ __ / __ __ __ __ (Month / Day / Year)

c. Reason cited by patient for resuming drug treatment: ____________________

B3. Did the patient receive **any other** newly initiated treatment for urge UI since her last visit?

YES 1

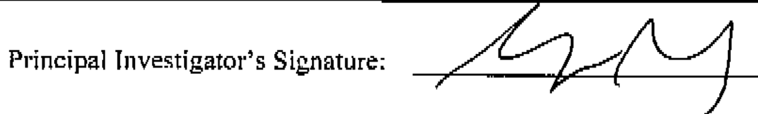
NO .... 2 → **SKIP TO SECTION C**

B3a. Record all treatments for urge UI newly initiated since the last visit, including the date of treatment and the patient's reason for requesting the treatment. Treatments include: behavioral treatment, neuromodulation, botox injections, myomectomy, electrical stimulation, other intravesical therapy or any other treatment for urge UI. (See Treatment Codes attached).

	i. TREATMENT	ii. CODE	iii. IF CODE 06 OR 99, SPECIFY :	iv. DATE OF TREATMENT	v. REASON FOR REQUEST
a.				__ __ / __ __ / __ __ __ __	
b.				__ __ / __ __ / __ __ __ __	
c.				__ __ / __ __ / __ __ __ __	

SECTION C: PRINCIPAL INVESTIGATOR'S SIGNATURE

Principal Investigator's Signature:



Date: 09 / 30 / 2004 (Month / Day / Year)

Example 1: Ms. X

TREATMENT CODES	
01	Behavioral treatment
02	Neuromodulation
03	Botox injections
04	Myomectomy
05	Electrical stimulation
06	Other Intravesical Therapy
99	Other

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Part II: Evaluation Training
F261

Ms. Y

Randomization Date: 06/01/2004
VS05 Date: 08/01/2004

Had UTI on 08/15/2004, treated with Macrobid x 7 days.

VS06: Began Detrol: 09/01/2004
Received Neuromodulation: 08/05/2004

VS07: UTI ruled out.
Continued Detrol
Began Cytospaz; 10/24/2004
Received Botox Injections: 10/15/2004

VS08: Continued Detrol and Cytospaz.
No new treatment reported since last visit.

Example 2: Ms. Y

F261: UI Treatment Status, version 09/01/04 (A)

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit #
4 Months .... (VS06) circled
6 Months VS07
8 Months VS08
14 Months VS09
20 Months VS10
26 Months VS11

A3. Date Form Completed: 09 / 30 / 2004
MONTH DAY YEAR

A4. Initials of Person Completing this Form: CJL

SECTION B: TREATMENT FOR URGE INCONTINENCE POST-INTERVENTION

B1. Did the patient receive any newly initiated treatment for **urge UI** since her last visit?

YES .... (1) circled

NO .... 2 → **SKIP TO SECTION C**

B1a. Was UTI ruled out or diagnosed and treated by the MD Investigator or another practitioner prior to initiation of the new treatment for urge UI?

YES, UTI RULED OUT 1

YES, UTI DIAGNOSED, TREATED AND RESOLVED .... (2) circled

NO .... 3 → **COMPLETE F290: PROTOCOL DEVIATION**

B2. Did the patient receive newly initiated **drug treatment** for urge UI since her last visit?

YES .... (1) circled

NO .... 2 → **SKIP TO B3**

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Affix ID Label Here

Example 2: Ms. Y

B2a. Circle yes or no for all drug treatments newly initiated for **urge UI**:

	YES	NO
Detrol	(1↓)	2

a. Date of request to resume drug treatment: 09/01/2004 (Month/Day/Year)

b. Reason cited by patient for resuming drug treatment: Started to Leak again

	YES	NO
Other Anticholinergic	1↓	(2)

a. Specify: ______

b. Date of request to resume drug treatment: __/__/____ (Month/Day/Year)

c. Reason cited by patient for resuming drug treatment: ______

B3. Did the patient receive **any other** newly initiated treatment for urge UI since her last visit?

YES .... (1)

NO .... 2 ➔ **SKIP TO SECTION C**

B3a. Record all treatments for urge UI newly initiated since the last visit, including the date of treatment and the patient's reason for requesting the treatment. Treatments include: behavioral treatment, neuromodulation, botox injections, myomectomy, electrical stimulation, other intravesical therapy or any other treatment for urge UI. (See Treatment Codes attached).

	i. TREATMENT	ii. CODE	iii. IF CODE 06 OR 99, SPECIFY :	iv. DATE OF TREATMENT	v. REASON FOR REQUEST
a.	Neuro-modulation	02		08/05/2004	Leaking.
b.				__/__/____	
c.				__/__/____	

SECTION C: PRINCIPAL INVESTIGATOR'S SIGNATURE

Principal Investigator's Signature: [signature] Date: 09/30/2004 (Month/Day/Year)

Example 2: Ms. Y

TREATMENT CODES	
01	Behavioral treatment
02	Neuromodulation
03	Botox injections
04	Myomectomy
05	Electrical stimulation
06	Other Intravesical Therapy
99	Other

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F261: UI Treatment Status, version 09/01/04 (A)

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit #
4 Months VS06
6 Months .... (VS07) [circled]
8 Months VS08
14 Months VS09
20 Months VS10
26 Months VS11

A3. Date Form Completed: 11 / 30 / 2004 (MONTH / DAY / YEAR)

A4. Initials of Person Completing this Form: CJL

SECTION B: TREATMENT FOR URGE INCONTINENCE POST-INTERVENTION

B1. Did the patient receive any newly initiated treatment for **urge UI** since her last visit?

YES .... (1) [circled]

NO .... 2 → **SKIP TO SECTION C**

B1a. Was UTI ruled out or diagnosed and treated by the MD Investigator or another practitioner prior to initiation of the new treatment for urge UI?

YES, UTI RULED OUT.. (1) [circled]

YES, UTI DIAGNOSED, TREATED AND RESOLVED 2

NO.. 3 → **COMPLETE F290: PROTOCOL DEVIATION**

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B2. Did the patient receive newly initiated **drug treatment** for urge UI since her last visit?

YES .... (1) [circled]

NO .... 2 → **SKIP TO B3**

Affix ID Label Here

Example 2: Ms. Y

B2a. Circle yes or no for all drug treatments newly initiated for **urge UI**:

	YES	NO
Detrol	1↓	(2)

a. Date of request to resume drug treatment: __ __/__ __/__ __ __ __ (Month / Day / Year)

b. Reason cited by patient for resuming drug treatment: ____________________

	YES	NO
Other Anticholinergic	(1↓)	2

a. Specify: Cytospaz

b. Date of request to resume drug treatment: 10/24/2004 (Month / Day / Year)

c. Reason cited by patient for resuming drug treatment: going on vacation - wanted as precaution

B3. Did the patient receive **any other** newly initiated treatment for urge UI since her last visit?

YES .... (1)

NO .... 2 → **SKIP TO SECTION C**

B3a. Record all treatments for urge UI newly initiated since the last visit, including the date of treatment and the patient's reason for requesting the treatment. Treatments include: behavioral treatment, neuromodulation, botox injections, myomectomy, electrical stimulation, other intravesical therapy or any other treatment for urge UI. (See Treatment Codes attached).

	i. TREATMENT	ii. CODE	iii. IF CODE 06 OR 99, SPECIFY :	iv. DATE OF TREATMENT	v. REASON FOR REQUEST
a.	Botox Injections	03		10/15/2004	Leaking
b.				__/__/____	
c.				__/__/____	

SECTION C: PRINCIPAL INVESTIGATOR'S SIGNATURE

Principal Investigator's Signature: [signature] Date: 11/30/2004 (Month / Day / Year)

Example 2: Ms. Y

TREATMENT CODES	
01	Behavioral treatment
02	Neuromodulation
03	Botox injections
04	Myomectomy
05	Electrical stimulation
06	Other Intravesical Therapy
99	Other

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Example 2: Ms. Y

F261: UI Treatment Status, version 09/01/04 (A)

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit #
- 4 Months VS06
- 6 Months VS07
- 8 Months .... (VS08)
- 14 Months VS09
- 20 Months VS10
- 26 Months VS11

A3. Date Form Completed: 01 / 31 / 2005 (MONTH DAY YEAR)

A4. Initials of Person Completing this Form: CJL

SECTION B: TREATMENT FOR URGE INCONTINENCE POST-INTERVENTION

B1. Did the patient receive any newly initiated treatment for **urge UI** since her last visit?

YES 1

NO .... (2) → **SKIP TO SECTION C**

B1a. Was UTI ruled out or diagnosed and treated by the MD Investigator or another practitioner prior to initiation of the new treatment for urge UI?

YES, UTI RULED OUT 1

YES, UTI DIAGNOSED, TREATED AND RESOLVED 2

NO .... 3 → **COMPLETE F290: PROTOCOL DEVIATION**

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B2. Did the patient receive newly initiated **drug treatment** for urge UI since her last visit?

YES 1

NO .... 2 → **SKIP TO B3**

Affix ID Label Here

Example 2: Ms. Y

B2a. Circle yes or no for all drug treatments newly initiated for **urge UI**:

	YES	NO
Detrol	1↓	2

a. Date of request to resume drug treatment: __ __ / __ __ / __ __ __ __ (Month Day Year)

b. Reason cited by patient for resuming drug treatment: ____________________

	YES	NO
Other Anticholinergic	1↓	2

a. Specify:

b. Date of request to resume drug treatment: __ __ / __ __ / __ __ __ __ (Month Day Year)

c. Reason cited by patient for resuming drug treatment: ____________________

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B3. Did the patient receive **any other** newly initiated treatment for urge UI since her last visit?

YES.................... 1

NO...................... 2 ➔ **SKIP TO SECTION C**

B3a. Record all treatments for urge UI newly initiated since the last visit, including the date of treatment and the patient's reason for requesting the treatment. Treatments include: behavioral treatment, neuromodulation, botox injections, myomectomy, electrical stimulation, other intravesical therapy or any other treatment for urge UI. (See Treatment Codes attached).

	i. TREATMENT	ii. CODE	iii. IF CODE 06 OR 99, SPECIFY :	iv. DATE OF TREATMENT	v. REASON FOR REQUEST
a.				__ __ / __ __ / __ __ __ __	
b.				__ __ / __ __ / __ __ __ __	
c.				__ __ / __ __ / __ __ __ __	

SECTION C: PRINCIPAL INVESTIGATOR'S SIGNATURE

Principal Investigator's Signature: Date: 01 / 31 / 2005 (Month Day Year)

Example 2: Ms. Y

TREATMENT CODES	
01	Behavioral treatment
02	Neuromodulation
03	Botox injections
04	Myomectomy
05	Electrical stimulation
06	Other Intravesical Therapy
99	Other

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