



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.

- B3. Did the patient receive any other newly initiated treatment 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 if 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.

Example 1: Ms. X



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



## 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

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

YES ..... 1

NO ..... 2 → SKIP TO B3

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: \_\_\_\_\_

**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: \_\_\_\_\_

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

BE-DRI

Example 2: Ms. Y



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.

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

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

YES ..... 1

NO ..... 2 → SKIP TO B3



Example 2: Ms. Y

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

Detrol ..... 1↓ 2

a. Date of request to resume drug treatment: 09 / 01 / 2004  
Month Day Yearb. Reason cited by patient for resuming drug treatment: Started to  
Leak again

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: \_\_\_\_\_

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    14 Months ..... VS09  
                   6 Months ..... VS07    20 Months ..... VS10  
                   8 Months ..... VS08    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 ..... 1NO ..... 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**B2. Did the patient receive newly initiated **drug treatment** for urge UI since her last visit?YES ..... 1NO ..... 2 → **SKIP TO B3**

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: \_\_\_\_\_

Other Anticholinergic ..... 1↓ 2

a. Specify:

Cytospaz

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

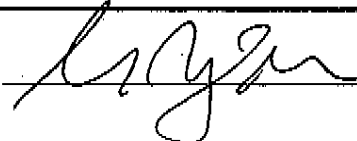
NO ..... 2 → SKIP TO SECTION C

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:

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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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:

01/31/2005  
MONTH DAY YEAR

A4. Initials of Person Completing this Form:

C J L

## 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

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

YES ..... 1

NO ..... 2 → SKIP TO B3

## 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: \_\_\_\_\_

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: \_\_\_\_\_

Month

Day

Year

Example 2: Ms. Y

TREATMENT CODES	
01	Behavioral treatment
02	Neuromodulation
03	Botox injections
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