

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: ____ / ____ / ____
MONTH DAY YEAR

A4. Initials of Person Completing this Form: ____

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 Yearb. Reason cited by patient for resuming drug treatment: _____
_____**Other Anticholinergic**

1↓

2

a. Specify: _____
_____b. Date of request to resume drug treatment: ____/____/____
Month Day Yearc. 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 SIGNATUREPrincipal Investigator's Signature: _____ Date: ____/____/____
Month Day Year

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

BE-DRI