

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. STUDY ID #: A2. VISIT # BASELINETBAS

A3. DATE INTERVIEW COMPLETED: ___ / ___ / ___ MONTH DAY YEAR A4. INTERVIEWER INITIALS: _____

A5. CONSENT OBTAINED? YES 1 NO 2 A6. WHICH FORM VERSION WAS USED? ENGLISH 1 SPANISH 2

A7. ARE THESE REPEAT MEASURES DUE TO PREVIOUSLY EXPIRED MEASURES? YES 1 NO 2

SECTION B: ELIGIBILITY AND RELATED HEALTH CONDITIONS

This section includes questions about your general health, and conditions you may have had earlier in your life, or conditions that you have now.

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DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY OF THE FOLLOWING CONDITIONS?		YES	NO	a. SOURCE CODE
B1.	Do you consistently use a wheel chair to get around?	1	2	
B2.	Have you ever had cancer of the lower urinary tract (includes bladder cancer)?	1	2	
B3.	Have you ever had pelvic radiation therapy for any reason?	1	2	
B4.	Are you currently receiving chemotherapy?	1	2	
B5.	Do you currently use a catheter to empty your bladder?	1	2	
B6.	Have you ever had urethral diverticulum (pocket or outpouching in the urethra)?	1	2	
B7.	Have you ever had augmentation cystoplasty (surgical expansion of the bladder) or an artificial urethral sphincter?	1	2	
B8.	Do you have implanted nerve stimulators for urinary symptoms?	1	2	
B9.	Do you have Parkinson's disease?	1	2	
B10.	Do you have multiple sclerosis?	1	2	
B11.	Do you have spina bifida?	1	2	
B12.	Have you ever had a spinal cord injury or trauma?	1	2	
B13.	Are you under current evaluation or treatment for chronic pelvic pain (painful bladder syndrome)?	1	2	

B14. ANY "YES" CODES TO ITEMS B1 – B13? YES 1 → **INELIGIBLE; SKIP TO SECTION D**
NO 2

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DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY OF THE FOLLOWING CONDITIONS?		YES	NO	<i>a.</i> SOURCE CODE
B15.	Have you had more than 3 episodes of a urinary tract infection, treated with antibiotics, in the past 12 months?	1	2	

B16. WHAT IS THE PATIENT’S MENOPAUSE / HORMONE REPLACEMENT STATUS? ASK,

Do you currently consider yourself to be pre-menopausal, post-menopausal or somewhere in between (peri-menopausal)? (**PROBE:** Menopausal is defined as not having had a menstrual period for the past 12 months.)

- PRE-MENOPAUSAL 1 → **SKIP TO SECTION C**
- POST-MENOPAUSAL 2
- SOMEWHERE IN-BETWEEN..... 3
- NOT SURE..... 4

B17. DOES THE PATIENT CURRENTLY USE ANY OF THE FOLLOWING? ASK,

Do you currently use....

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		YES	NO	<i>i.</i> SOURCE CODE
a.	...an oral estrogen, either pills or caplets?	1	2	
b.	...an estrogen patch?	1	2	
c.	...natural estrogen, non-prescription ?	1	2	
d.	...a vaginal estrogen cream?	1	2	
e.	...an intravaginal estrogen, either tablet or ring?	1	2	
f.	...estrogen injections?	1	2	

SECTION C: MEDICAL, SURGICAL OR BEHAVIORAL TREATMENT FOR INCONTINENCE

C1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY LAPAROSCOPIC, ENDOSCOPIC, OPEN OR OTHER **PELVIC SURGERY IN THE LAST 3 MONTHS?** ASK,

Have you had any **pelvic** surgery in the past 3 months?

YES 1

NO..... 2 → **SKIP TO C3**

C2. RECORD NAMES, CODES AND DATES OF ANY PELVIC SURGERIES IN THE PAST 3 MONTHS. SAY,
Tell me a little bit more about pelvic surgeries you've had in the last 3 months.

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	a.	b.	c.	d.	e.
	NAME OF PELVIC SURGERY	SURGICAL CODE	SPECIFY, IF SURG CODE = 07	DATE OF SURGERY	SOURCE CODE
1.				___ / ___ / _____	
2.				___ / ___ / _____	
3.				___ / ___ / _____	
4.				___ / ___ / _____	

C3. CLASSIFY THE PATIENT'S PELVIC SURGERY STATUS

NO RECENT DISQUALIFYING PELVIC SURGERY 1

RECENT DISQUALIFYING PELVIC SURGERY < 3 MONTHS AGO 2 → **INELIGIBLE *; SKIP TO SECTION D**

***THE PATIENT MAY BE ELIGIBLE AT A LATER DATE.**

C4. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY SURGERY SPECIFICALLY FOR THE TREATMENT OF URINARY INCONTINENCE? ASK,

Have you ever had any surgery specifically for the treatment of urinary incontinence?

YES 1

NO..... 2 ➔ **SKIP TO C6**

C5. RECORD NAMES, CODES AND DATES OF ANY SURGERY SPECIFICALLY FOR THE TREATMENT OF URINARY INCONTINENCE. SAY,

Tell me a little bit more about that...(surgeries you've ever had specifically for the treatment of urinary incontinence.)

PROBE: IF PATIENT HISTORY OF SLING, DETERMINE IF SYNTHETIC

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	a.	b.	c.	d.
	TYPE OF SURGERY	SURGICAL CODE	DATE OF SURGERY	SOURCE CODE
1.			_ _ / _ _ / _ _ _ _ _	
2.			_ _ / _ _ / _ _ _ _ _	
3.			_ _ / _ _ / _ _ _ _ _	
4.			_ _ / _ _ / _ _ _ _ _	
5.			_ _ / _ _ / _ _ _ _ _	
6.			_ _ / _ _ / _ _ _ _ _	
7.			_ _ / _ _ / _ _ _ _ _	

C6. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF A HISTORY OF SURGICAL PLACEMENT OF A SYNTHETIC SLING FOR TREATMENT OF SUI?

YES 1 ➔ **INELIGIBLE; SKIP TO SECTION D**

NO..... 2

C7. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF **ANY OTHER PELVIC SURGERIES**? ASK,
Have you ever had any **other** pelvic surgery, including a Cesarean delivery?

YES 1

NO 2 → **SKIP TO C9**

C8. RECORD NAMES, CODES AND DATES OF **ANY OTHER PELVIC SURGERIES**. SAY,
Tell me a little bit more about any other pelvic surgeries you've ever had.

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	a.	b.	c.	d.	e.
	TYPE OF PELVIC SURGERY	SURGICAL CODE	SPECIFY, IF SURG CODE = 07	DATE OF SURGERY	SOURCE CODE
1.				_ _ / _ _ / _ _ _ _	
2.				_ _ / _ _ / _ _ _ _	
3.				_ _ / _ _ / _ _ _ _	
4.				_ _ / _ _ / _ _ _ _	
5.				_ _ / _ _ / _ _ _ _	

C9. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NON-SURGICAL** TREATMENT FOR URINARY INCONTINENCE? ASK,

Have you ever received any **non-surgical** treatment for your urinary incontinence?

YES 1

NO 2 → **SKIP TO SECTION D**

C10. RECORD THE NAMES, CODES AND DATES OF ALL NON-SURGICAL TREATMENTS FOR UI. SAY,

Tell me a little bit more about that / those... (non-surgical treatments for urinary incontinence)

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	a.	b.	c.	d.
	TYPE OF TREATMENT	TREATMENT CODE	DATES OF TREATMENT	SOURCE CODE
1.			FROM: ___ / ___ / ___ TO: ___ / ___ / ___	
2.			FROM: ___ / ___ / ___ TO: ___ / ___ / ___	
3.			FROM: ___ / ___ / ___ TO: ___ / ___ / ___	
4.			FROM: ___ / ___ / ___ TO: ___ / ___ / ___	
5.			FROM: ___ / ___ / ___ TO: ___ / ___ / ___	

SECTION D: ELIGIBILITY SUMMARY

D1. DOES THE PATIENT MEET ALL ELIGIBILITY CRITERIA AS REQUIRED IN THIS FORM?

(REVIEW CODES TO ITEMS B14, C3 AND C6)

YES 1 → **CONTINUE SCREENING**

NO 2 → **INELIGIBLE; END SCREENING**

Attachment

PELVIC SURGERY CODES	
01	Abdominoplasty
02	Anterior repair
03	Cesarean delivery
04	Femoral hernia repair
05	Hysterectomy
06	Inguinal hernia repair
07	Laparoscopy
08	Posterior repair
09	Removal of an ectopic pregnancy
10	Removal of an ovarian cyst
11	Removal of both ovaries
12	Removal of one ovary
13	Supracervical hysterectomy
14	Tubal ligation
15	D and C (dilatation and curettage)
16	Colpopexy (abdominal)
17	Colpopexy (vaginal)
18	UNKNOWN TYPE
19	OTHER

PELVIC SURGERY FOR UI CODES	
20	Anterior repair, Kelly plication, suburethral plication
21	Collagen injection
22	Durasphere injection
23	Laparoscopic Burch colposuspension
24	Marshall-Marchetti-Krantz (MMK) bladder suspension
25	Needle suspensions: Raz, Pereyra, Gittes
26	Open Burch colposuspension
27	Sling procedure (autologous or cadaveric)
28	Sling procedures (synthetic material)
38	UNKNOWN TYPE
39	OTHER

TREATMENT CODES	
40	Medicine (drug treatment)
41	Bladder training (including behavior changes involving the timing of urination or changes in fluid intake)
42	Pelvic muscle exercises (Kegel exercises)
43	Electrical stimulation
44	Electromagnetic therapy
45	Biofeedback
46	Acupuncture or other alternative medicine techniques
58	UNKNOWN TYPE
59	OTHER