ICCTG C PROTOCOL #1 G	Deferral Criteria (Administrative)	Patient ID:     Patient Initials:     Clinical Center:     Contact Week: _0     Date:/ /
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(Patient Interview Complted at the Baseline 1 and 2 visits.)

1.	Have you initiated any new medications for interstitial cystitis		
	during the past 4 weeks?	$\square_1$ Yes	$\square_0$ No
	If <b>YES</b> , indicate below:		

If **YES**, defer until the patient has been on the medication AT THE SAME DOSE for at least 4 weeks.

Name of Medication	Date of first dose	Dose	Date of last change in dose	Dose
	/ // month day year		/ / month day year	
	/ / / month day year		/ / / month day year	
	/ / / month day year		/ / / month day year	
	/ / / month day year		/ / / month day year	

2.	During the past 6 weeks, have you undergone urethral dilation,		
	cystometrogram, urodynamics, bladder cystoscopy/hydrodistention	1	
	under general or regional anesthesia, or bladder biopsy under		
	general or regional anesthesia?	□ <sub>1</sub> Yes	□ <sub>0</sub> No
	If <b>YES</b> , indicate below:		

If YES, defer until at least 6 weeks from the date of the procedure.

Procedure	Date
	/ / / month day year
	/ / / month day year
	/ / / month day year

		Deferral Criteria (Administrative)	Patient ID: Contact Week: <u>0</u>	
3.	,	ne culture and/or clinical evidence ction (UTI) during the past 6 wee		□ <sub>0</sub> No
	If <b>YES</b> , repeat the urine cult Date of negative culture:	ure and defer at least 6 weeks aft / /	ter the date of the ne	egative culture.
4.	Have you seen blood in you the past 12 weeks? If <b>YES</b> , indicate below:	r urine (gross hematuria) during	□ <sub>1</sub> Yes	□ <sub>0</sub> No
	If <b>YES</b> , defer until the patien Date of last episode:	t has been without the condition $f_{\rm m}$	for at least 12 weeks	5.
5.	Do you have now or have yo during the past 12 weeks? If <b>YES</b> , indicate below:	ou had active genital herpes	□ <sub>1</sub> Yes	□ <sub>0</sub> No
	If <b>YES</b> , defer until the patien Date episode resolved:	t has been without the condition $\frac{1}{2}$	for at least 12 weeks	3.
6.	Have you received treatmen within the past 4 weeks? If <b>YES</b> , indicate below:	t with Elmiron® or hydroxyzine	□ <sub>1</sub> Yes	□ <sub>0</sub> No

If **YES**, defer until at least 4 weeks have passed since the date of last dose.

Drug Name	Date of last dose
	/ / month day year
	/ / / month day year
	/ / / month day year
	/ / / month day year
	/ / / month day year

	Bolonal Ontonia	Patient ID: Contact Week: <u>0</u>	
7.	Have you received intravesical BCG during the past 24 weeks? If <b>YES</b> , Indicate below:	P □ <sub>1</sub> Yes	□ <sub>0</sub> No
	If <b>YES</b> , defer until at least 24 weeks have passed since the last Date of last dose: / /	t dose of BCG.	
8.	Have you had any intravesical treatment <b>other than</b> BCG during the past 12 weeks? If <b>YES</b> , Indicate below:	□ <sub>1</sub> Yes	□ <sub>0</sub> No

If YES, defer until at least 12 weeks have passed since the date of last dose.

Drug Name	Date of last dose
	/ / / month day year
	/ / month day year
	/ / month day year
	/ / / month day year

9.	Have you had any of the following surgeries during the past		
	24 weeks: urinary incontinence, cystocele (bladder hernia repair),		
	or rectocele (rectal hernia repair)?	□ <sub>1</sub> Yes	□ <sub>0</sub> No
	If <b>YES,</b> Indicate below:		

If YES, defer until at least 24 weeks have passed since the date of surgery:

Surgery	Date of surgery
	/ / / month day year

Patient ID: \_\_\_\_ \_\_\_ \_\_\_ Contact Week: \_0\_

## FEMALES ONLY:

10.	Have you had any of the following surgeries during the past			
	24 weeks: transvaginal, prolapse, or any form of hysterectomy?	$\square_1$ Yes	□ <sub>0</sub> No	
	If <b>YES</b> , Indicate below:			

If **YES**, defer until at least 24 weeks have passed since the date of surgery.

Surgery	Date of Surgery	
	/ / / month day year	
	/ / / month day year	
	/ / / month day year	
	/ / / month day year	

11.	Have you had a vaginal delivery or a cesarean section within the past 24 weeks? If <b>YES</b> , Indicate below:	□ <sub>1</sub> Yes	□ <sub>0</sub> No
	If <b>YES</b> , defer until at least 24 weeks have passed since this date. Date: / /		
MAL	ES ONLY:		
12.	Have you ever had the following surgical procedures:		

TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilation of the prostate, open prostatectomy, or any other prostate surgery or treatment such as cryotherapy or thermal therapy?  $\Box_1$  Yes  $\Box_0$  No *If* **YES**, *Indicate below:* 

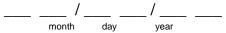
If YES, defer until at least 26 weeks have passed since this date.
Date: / /

Patient ID: \_\_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ Contact Week: \_0\_

If there is at least one YES response, the patient will be deferred.

Please indicate the approximate date the patient will be eligible.

(If more than one deferral criterion, use the date for the longest deferral period.)



*If all responses are "NO", continue with the screening process.*