

ICCTG PROTOCOL #1

Deferral Criteria (Administrative)

Patient ID: _____
 Patient Initials: _____
 Clinical Center: _____
 Contact Week: 0
 Date: ____ / ____ / ____
 month day year
 RC ID: _____

(Patient Interview Completed at the Baseline 1 and 2 visits.)

1. Have you initiated any new medications for interstitial cystitis during the past 4 weeks?

☐₁ Yes

☐₀ No

If **YES**, 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 under general or regional anesthesia, or bladder biopsy under general or regional anesthesia?

☐₁ Yes

☐₀ No

If **YES**, 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

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3. Have you had a positive urine culture and/or clinical evidence of bacterial urinary tract infection (UTI) during the past 6 weeks? ☐₁ Yes ☐₀ No

If **YES**, indicate below:

If **YES**, repeat the urine culture and defer at least 6 weeks after the date of the negative culture.

Date of negative culture: ____ / ____ / ____

4. Have you seen blood in your urine (gross hematuria) during the past 12 weeks? ☐₁ Yes ☐₀ No

If **YES**, indicate below:

If **YES**, defer until the patient has been without the condition for at least 12 weeks.

Date of last episode: ____ / ____ / ____

5. Do you have now or have you had active genital herpes during the past 12 weeks? ☐₁ Yes ☐₀ No

If **YES**, indicate below:

If **YES**, defer until the patient has been without the condition for at least 12 weeks.

Date episode resolved: ____ / ____ / ____

6. Have you received treatment with Elmiron® or hydroxyzine within the past 4 weeks? ☐₁ Yes ☐₀ No

If **YES**, indicate below:

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

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7. Have you received intravesical BCG during the past 24 weeks? ☐₁ Yes ☐₀ No

If **YES**, Indicate below:

*If **YES**, defer until at least 24 weeks have passed since the last dose of BCG.*

Date of last dose: ____ / ____ / ____

8. Have you had any intravesical treatment **other than** BCG during the past 12 weeks? ☐₁ Yes ☐₀ No

If **YES**, Indicate below:

*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)? ☐₁ Yes ☐₀ No

If **YES**, 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

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FEMALES ONLY:

10. Have you had any of the following surgeries during the past 24 weeks: transvaginal, prolapse, or any form of hysterectomy? ☐₁ Yes ☐₀ No

If YES, 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? ☐₁ Yes ☐₀ No

If YES, Indicate below:

If YES, defer until at least 24 weeks have passed since this date.

Date: ____ / ____ / ____

MALES 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? ☐₁ Yes ☐₀ No

If YES, Indicate below:

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

Date: ____ / ____ / ____

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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.)

____ / ____ / ____
month day year

If all responses are “NO”, continue with the screening process.