TimeLine for BCG/ Interferon Biadder Instillations

6 Week Break	Month 12 Cystoscopy	3 Month Break	Month 3 Cystoscopy	Week 1 BCG/ Interferon treatment
Month 18 Cystoscopy	3 Month Break	Month 9 Cystoscopy	6 Week Break	Week 2 BCG/ Interferon treatment
3 Month Break	Month 15 Cystoscopy	6 Week Break	Month 4-5 BCG/ Interferon treatment	Week 3 BCG/ Interferon treatment
Month 21 Cystoscopy	6 Week Break	Month 10-11 BCG/ Interferon treatment	Month 4-5 BCG/ Interferon treatment	Week 4 BCG/ Interferon treatment
3 Month Break	Month 16-17 BCG/ Interferon treatment	Month 10-11 BCG/Interferon treatment	Month 4-5 BCG/ Interferon treatment	Week 5 BCG/ Interferon treatment
Month 24 Cystoscopy	Month 16-17 BCG/ Interferon treatment	Month 10-11 BCG/ Interferon treatment	6 week Break	Week 6 BCG/ Interferon treatment
DONE	Month 5-17 BCG/ Injerferon treatment	6 Week Break	Month 6 Cystoscopy	6 Week Break

Time line for BCG/Interferon Bladder Instillation

6 weekly induction treatments of:

1 vial BCG/50 million units of interferon each instillation

6 week break - then

Cystoscopy under anesthesia with random bladder biopsies, bilateral upper tract retrograde pyelogram and washings- if clear

6 week break - then

3 weekly maintenance treatments

Week one 1/3rd vial BCG/50 million units of interferon Week two – 1/10th vial BCG/50 million units of interferon Week three – 1/10th vial BCG/50 million units of interferon

6 week break - then

Cystoscopy - if clear

3 month break - then

Cystoscopy - if clear

6 week break - then

3 weekly maintenance treatments

Week one 1/3rd vial BCG/50 million units of interferon Week two – 1/10th vial BCG/50 million units of interferon Week three – 1/10th vial BCG/50 million units of interferon

6 week break - then

Cystoscopy - if clear

3 month break -then

Cystoscopy - if clear

6 week break - then

3 weekly maintenance treatments

Week one 1/3rd vial BCG/50 million units of interferon Week two – 1/10th vial BCG/50 million units of interferon Week three – 1/10th vial BCG/50 million units of interferon

6 week break -then

Cystoscopy - if clear

3 month break - then

Cystoscopy - if clear

3 month break - then

Cystoscopy - if clear

DONE!

University of Iowa Department of Urology BCG Instillation Treatments.

Before your appointment:

• If you are taking a diuretic (water pill), do not take your pill that morning unless medically necessary.

• Do not drink caffeinated beverages (coffee, tea, soda) for 6-8 hours before your

BCG treatment and for 2 hours afterwards

• If you see blood in your urine the morning of your appointment or the day before, call and the treatment should be rescheduled.

After your appointment

- Try to hold the BCG for a full 2 hours after instillation, but do not force holding if you feel a strong urge to urinate.
- Normal fluid intake is recommended after the instillation, but remember to avoid caffeinated beverages for the first 2 hours.

• You may leave the clinic immediately after instillation

Common side effects

• Dysuria, urinary urgency, frequency, fevers or chills & flu like symptoms. These are normal AS LONG as they don't last longer than 48 hours

Call us if the following occurs:

- Fever > 38 degrees Celsius
- Bloody urine interfering with urination or lasting >48 hours
- Inability to urinate
- Pain or swelling
- Nausea or Vomiting

You DO NOT need to lay down and move side to side, daily activities will give enough movement to treat entire bladder

Contact Information:

Monday-Thursday 7:00 am- 5:30 pm Erica Brown, ARNP 319-467-5072 or you may contact the Urology Clinic Monday-Friday 8:00-5:00 pm at 319-356-2421.

Night's, weekends & holidays, call the operator at 319-356-1616 and ask for the Urology Resident on call.

Recommendations for Treatment of BCG Toxicity

Sign/Symptoin	Intensity & Description	Therapeutic Response
Cystitis: dysuria, urgency, frequency	0 - None 1 - mild, transient <48 hrs 2 - moderate, < 3 days 3 - mod-severe, > 3 days 4 - severe, persistent >10 days	0,1 - no treatment 2 - antispasmodics 3 - delay &/or reduce dose 4 - cancel further Rx this cycle; add antibiotics +/- steroid taper if persistent
Hematuria (gross)	0 - none 1 - mild, transient <48 hrs 2 - moderate, < 3 days 3 - mod-severe, > 3 days 4 - severe w/ clots or obstruction or >10 days	0,1 - no treatment 2 - push fluids 3 - delay &/or reduce dose 4 - cancel further Rx this cycle
Fever & Chills	0 - None 1 - mild < 100.5, < 48 hrs 2 - moderate < 101.5, < 48hr 3 - mod-severe <102.5, < 48hr 4 - severe >102.5 or > 48 hrs or rigors	0,1 - no treatment or Tylenol 2 - preRx w/ NSAIDs 3 - delay &/or reduce dose; consider fluoroquinolone 4 - cancel all further Rx this cycle, start INH/rifampin
Flu-like Sxs: myalgia, malaise, arthalgias, headache	0 - None 1 - mild 2 - moderate 3 - mod-severe 4 - severe	0,1 - no treatment 2 - NSAIDs 3 - delay &/or reduce dose 4 - cancel further Rx this cycle
Other Adverse Events WHO Criteria	0 - none 1 - mild 2 - moderate 3 - severe 4 - life threatening	0,1 - no treatment 2 - delay &/or reduce dose until condition clears 3 - cancel further Rx this cycle 4 - cancel all future Rx

Antibiotic Guidelines

- Routine use of prophylactic antibiotics is discouraged in the absence of documented bacterial cystitis excepting when the patient has a prosthetic device such as heart value or orthopedic hardware. When antibiotics are indicated, a non-quinolone antibiotic is recommended, preferably a penicillin, cephalosporin, sulfa, or nitrofurantoin.
- Fluoroquinolone antibiotics are cidal to BCG and may be useful for treating early grade 3 toxicity. A minimum of 7 days is probably necessary.
- INH (300 mg/day) plus rifampin (600 mg/day) should be considered for refractory grade 3 or suspected grade 4 toxicity. Vitamin B-6 (50 mg/day) should accompany prolonged treatment. Grade 4 toxicity may require a 3rd drug such as ethambutol (1200 mg/day). BCG is uniformly resistant to cycloserine and this agent should NOT be used. Early systemic steroids (e.g. prednisone 40 mg/day) may be life-saving in cases of frank BCG sepsis. Antibiotics must accompany steroid use.

Recommendations for Intravesical Instillation: Drug Administration

- Recommended catheter for most men is a 16 Fr latex or silicone coude' foley.
- A 10cc "Urojet" with 2% lidocaine jelly is recommended for men to minimize trauma. Balloon inflation is not generally required.
- Recommended catheter for most women is a 14 Fr straight "robnell-type" with water soluble Sugilube or KY jelly.
- Make an extra effort to completely drain the bladder through the catheter before BCG/IFNα instillation. Apply gentle crede' pressure to facilitate complete emptying.
- In men be sure to pull through the jelly plug by inserting the "urojet" to the catheter and drawing back. This will help to get the residual urine to drain through the catheter.
- Instill the BCG/IFNα within 2 hours of mixing-preferably sooner.
- BCG/IFN α and anything that comes in contact with BCG must be disposed of in a biohazard waste container.

Information/Recommendations

- Bacillus Calmette-Guerin has been in use since the 1980's & is the most proven & effective form of immunotherapy at this point in time. Immunotherapy has a mechanism of action different from that of chemotherapy. It uses materials made by your own body or made in the laboratory to boost, direct and restore your body's natural defenses against disease.
- BCG which is an inactivated form of the bacterium mycobacterium tuberculosis, is given both intravesically mixed in a saline solution and instilled directly into the bladder via a catheter.
- BCG has resulted in complete tumor regression in ½ of more of treated patients with papillary tumors and in more than 70% of those with CIS. Controlled studies have demonstrated a significant reduction in tumor recurrence- that persist for 5 years or more.
- You may neutralize the live bacteria, by pouring 2 cups of household bleach into the water and letting it stand for 15-20 minutes.
- Avoid direct skin contact during and after urinating. Cleanse the genital area & hands thoroughly.
- Sex: Men having this treatment can pass on BCG during sex. To protect your partner from coming in contact with the BCG, you should not have sex for 48 hours after each treatment. Use a condom if you have sex during the other times & for 6 weeks after the treatment has ended.
- Oncovite Antioxidant Multivitamins, this has been shown to help decrease the long-term recurrence rate of bladder cancer by 40% when receiving BCG treatments. Take two tablets twice daily.

Oncovite can be ordered by your pharmacist through the manufacturer, Mission Pharmacal (1-800-531-3333). You can buy Oncovite online at http://www.drugstore.com for \$19.99/100 capsule bottle.