

## **Patient Instructions for BCG Immunotherapy**

**BCG** stands for Bacillus Calmette-Guerin, a living but weakened tuberculosis vaccine developed by Drs. Calmette and Guerin in France in 1921. It has been and continues to be used as a vaccine to protect against TB and has been given to over one billion infants. Based on studies directed by Dr. Lamm, BCG was first approved by the FDA in 1990 to treat bladder cancer. It is currently the most effective treatment for CIS (carcinoma in situ) and high grade, non muscle invasive cancer.

**Risks** of BCG therapy are significant, but the benefits of treatment far outweigh the risks for most patients. Like aspirin and almost every medicine, BCG treatment can be fatal. (Many more people have died from aspirin than BCG.) The living bacteria can cause serious infection and allergic reactions if it is taken up in the blood stream. Serious reactions can include infection of the liver, lungs, kidneys, testes, bone and blood vessels. BCG is sensitive to antibiotics, but only certain antibiotics such as Cipro, Levaquin, Ofloxacin, isoniazid, rifampin and ethambutol. The most serious BCG reaction is sepsis- blood stream infection associated with hypotension (low blood pressure or shock). When this occurs steroid treatment is also required.

**What to expect with BCG:** You should not expect to have any serious reaction- these are quite rare and can be avoided by reducing the dose of BCG. With the first and second of the 6 initial weekly BCG instillations most people have no symptoms other than the irritation associated with passing the catheter. Beginning with the second or third instillation you may have some mild burning and increased frequency of urination, and occasionally some bleeding occurs. These symptoms often increase with later treatments, but if they are bothersome the dose of BCG can be reduced. Burning and frequency generally last for 1 to 3 days and may be associated with malaise or mild “flu-like” symptoms typical of many vaccinations. Sometimes nausea may occur, along with low grade fever or a mild chilling sensation. Dr. Lamm will give you a prescription for two antibiotics to take should shaking chills, temperature above 101, or severe, prolonged burning and frequency occur. These antibiotics (usually Cipro or Ofloxacin twice daily and isoniazid once daily) are specific for BCG. Please call before taking the antibiotics, but if you cannot connect, go ahead and take as directed.

**The BCG Schedule** generally used is my 3 week maintenance program that was found in the Southwest Oncology Group study to markedly reduce not only tumor recurrence but also disease progression when compared to 6 week induction BCG alone. I have modified the regimen as follows: Full strength BCG is used for the initial 6 instillations, often with the addition of skin vaccination as used in my original studies. The dose is reduced if needed to avoid side effects. Maintenance BCG (once a week for 3 weeks) is begun at 3 months using 1/3 dose BCG, unless no side effects were noted during induction. 3 week maintenance is repeated at 6, 12, 18 and 24 months, and then at years 3, 4, 5 and 6 followed by every other year for years 8, 10 and 12. The extended maintenance beyond 3 years is used only for patients who are at increased risk for progression due to high grade tumor, CIS, or lamina propria invasion.

**Call for** high fever, shaking chills, flank pain, or other serious side effects. Rarely a reaction to BCG may occur many months after BCG has been given. Night sweats, weight loss, or chronic illness can occur.

**Questions?** Most questions have already been asked and answered on my website: **BCGOncology.com**. Just click “Ask Dr. Lamm” if you have a new one!

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