

## **Lithotripsy**

### **Introduction**

Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure with which this section will concern itself.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force.

A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

### **Lithotripter Utilization**

Lithotripter utilization can be reasonably estimated by the incidence of urinary stone disease. Urinary stone disease, or urolithiasis, is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease is approximately 16 per 10,000 population<sup>1</sup>. Not all cases of urinary stone disease would be appropriately treated by lithotripsy. It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The annual treatment capacity of a lithotripter has been estimated to be 1,000 to 1,500 cases.

The number of lithotripsy procedures reported in North Carolina for the period of 2010-2011 was 10,456 procedures. There were 14 lithotripsy units operated by eight providers. Procedures were provided by a fixed unit at one facility, and by 13 mobile units operated by seven providers. There was one need determination for a lithotripter in Mecklenburg County in the North Carolina 2007 State Medical Facilities Plan and the certificate of need was awarded to The Stone Institute. Given the 14 lithotripsy units, the average number of procedures per lithotripter for the 2010-2011 fiscal year is 747.

### **Access**

Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

### **Lithotripsy Need Determination Methodology**

North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the estimate of urinary stone disease cases and is based on the assumption that 90 percent could be treated by ESWL.

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<sup>1</sup> Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis". In Clinical Manual of Urology, by Philip M. Hanno, Alan J. Wein, S. Bruce Malkowicz. McGraw-Hill Professional Publisher.

The standard methodology used for determining need for lithotripters is calculated as follows:

- Step 1: Divide the July 1, 2013 estimated population of the state, available from the North Carolina Office of State Budget and Management, by 10,000 and multiply the result by 16, which is the incidence of urinary stone disease per 10,000 population.
- Step 2: Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.
- Step 3: Divide the result of Step 2 by 1,000, which is the low range of the annual treatment capacity of a lithotripter, and round to the nearest whole number.
- Step 4: Sum the number of existing lithotripters in the state, lithotripters not yet operational but for which a certificate of need has been awarded, and lithotripter need determinations from previous years for which a certificate of need has yet to be awarded.
- Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state.

### **Lithotripsy Need Determination**

With an annual treatment capacity of a lithotripter being estimated at from 1,000 to 1,500 cases, the maximum number of lithotripters needed in the state would be 14, based on 14,451 estimated cases and 1,000 procedures per lithotripter. There are 14 lithotripters in the state, and the methodology indicates a maximum need of 14 lithotripters in the state. As a result, it is determined that there is no need for additional lithotripters anywhere in the state.

### **Lithotripsy Services in North Carolina**

The eight providers that offer lithotripsy services in North Carolina are listed on the following pages.