Policy for Lithotripsy to treat Renal Calculi (Kidney Stones).
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Renal Calculi (Kidney Stones)

Epidemiological data suggests that the prevalence of renal calculi (kidney stones) is increasing. The number of hospital episodes increased by 70% over a 15-year period between 2000 and 2015, from 51,035 episodes to 86,742 episodes (HES). The lifetime prevalence of renal (kidney) stone disease is 13%. Consequently, the direct costs of treatment are increasing as well as the indirect socioeconomic burdens on reduced quality of life, sickness leave and medical follow-up (NICE, 2015).

Treatment for Renal Calculi (Kidney Stones)

Extracorporeal Shockwave Lithotripsy is a non-invasive outpatient treatment that focuses ultrasound shock waves on renal stones to fragment them and facilitate spontaneous passage. (NICE, 2015). The complete treatment takes about 45 to 60 minutes (National Kidney Foundation, 2015)

Lithotripsy can have some side effects and most patients have some blood in the urine for a few days. The shattered stone fragments may also cause discomfort as they pass through the urinary tract. Sometimes, the stone is not completely shattered, and additional treatments may be needed (National Kidney Foundation, 2015).

Evidence review of treatment options.

There is good evidence that small stones <5mm in diameter usually pass spontaneously, and require little medical intervention other than simple analgesia. Larger stones, 5-10mm, become increasingly difficult to pass, and are less likely to be expelled without active stone removal. In these cases, however, where there is no clinical risk or indication for stone removal such as obstruction, infection, severe pain etc., and patients are asymptomatic, there remains debate on whether active stone management is necessary, as many stones that do not pass will not necessarily result in any long term symptoms and may remain stable.

Therefore, the European Association of Urology suggests a range of indications for which active stone removal in patients with kidney stones could be considered, and suggests that in the absence of these indications there is no strong evidence to confirm that lithotripsy is preferable to observation. Even though lithotripsy confers a greater chance of stone clearance for stones approaching 10mm compared to observation, complications of the technique may not justify an approach in asymptotic and uncomplicated patients with small stones.
Eligibility Criteria:

NICE are due to publish guidance on the use of lithotripsy for patients with renal calculi in 2019, therefore whilst awaiting this guideline, the CCG will commission the use of lithotripsy for renal calculi in the following circumstances:

- The renal calculus (kidney stone) must be 5mm or larger
- The patient is symptomatic (obstruction, infection, severe pain)

AND

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance:

