Public Statement:

Extracorporeal shock wave lithotripsy (ESWL) for gallstones is a non-invasive procedure for disintegrating gallstones. High-intensity shock waves (500–1500 shocks over 30–120 minutes) are focused sonographically on the gallstones. This procedure is covered for patients with symptomatic single gallstones 20mm or less in diameter who are not surgical candidates.

Medical Policy Statement:

Extracorporeal shock wave lithotripsy (ESWL) for gallstones, in conjunction with ursodiol therapy, is considered medically necessary and is covered for patients:

1. With symptomatic non-calcified single gallstones measuring 20 mm or less AND
2. Who are either not considered candidates for either open or laparoscopic cholecystectomy due to comorbidities, OR
3. Who actively refuse a surgical option.

Background:

Enthusiasm for ESWL treatment of gallstones was initially prompted by successful ESWL treatment of kidney stones. Fragmented renal stones could be flushed out relatively easily through the urinary flow. However, in the dependent gallbladder, the fragmented gallstones were often retained and could lead to recurrent biliary colic. In
the early 1990s interest in ESWL of gallstones waned as laparoscopic cholecystectomy emerged as the treatment of choice for symptomatic cholelithiasis. Research on ESWL treatment of gallstones refocused on its use as an adjunct to ursodiol treatment. In this setting, ESWL was used as a treatment to increase the effectiveness of ursodiol therapy by fragmenting the stones thus increasing their surface area. In fact the clinical studies presented to the FDA as part of the approval process focused on the ability of ESWL to enhance the effectiveness of ursodiol alone. The labeled indication for ESWL for gallstones suggests that the drug be given 2 weeks prior to ESWL and then continued up to 20 months after ESWL or until a stone-free state is achieved.

The FDA approval was based on several different studies performed in the 1980s. The data from these studies were reanalyzed to permit a comparison between the outcomes of ursodiol treatment alone and ursodiol treatment combined with ESWL treatment. This complex statistical analysis is difficult to follow in the available FDA advisory committee minutes. However, the data suggest that the clearance rate of gallstones was 60% better in those receiving the combined therapy compared to those receiving ursodiol alone. The best results were seen in those with a single non-calcified gallstone measuring less than 20 mm in diameter. However, it is clear that cholecystectomy still represents the treatment of choice, due to the prompt resolution of symptoms in appropriately selected patients and the absence of stone recurrence, which may recur at a rate of 10% per year in the absence of cholecystectomy. Approximately 500,000 patients per year undergo cholecystectomy. Of these, perhaps 150,000 would be considered candidates on the basis of stone number and size alone. Only a small percentage of these patients would not be considered surgical candidates.

A 10-year prospective study on 192 patients who were followed following complete eradication of stone (n = 159) or stones (n = 33) identified 108 patients without recurrence (median of 6.7 years). By actuarial analysis, the cumulative recurrence rates for these 192 stone-free patients were 27% at 3 years, 41% at 5 years, and 54% at 10 years. The authors concluded, "The long-term results are unsatisfactory and ESWL of gallbladder stones should be offered only in special cases.

ESWL for pancreatic stones was reported in a retrospective study from Japan: 117 patients were treated. 70 patients were followed up after 3 years (evaluated retrospectively) Immediate pain relief was achieved in 97% and complete removal of stones achieved in 56%. In follow-up, 49 of the 70 continued to be asymptomatic.

A case report from Japan described a 16 y.o. patient who had undergone excision of a choledochal cyst at age 3, but developed symptomatic stones at the proximal end of the hepatico-jejunostomy anastomosis was treated with ESWL (6 sessions) with complete elimination of the stones. Based on this one case the authors concluded that ESWL "could be a treatment of choice for bile duct stone formation after choledochal cyst excision."

A Cochrane Review of Effectiveness done by the Swedish Council on Technology Assessment in Health Care concluded, "Treatment of the gallbladder with lithotripsy
must be tested further in Randomized Controlled Trial study before introducing the method in clinical practice."

References:


**Application to Products**

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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