Extracorporeal Shock Wave Lithotripsy for Pancreatic Stones

Medical Policy

Section Surgery

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Description

Chronic pancreatitis is a painful inflammatory disease leading to destruction of the pancreatic parenchyma, potentially leading to pancreatic insufficiency. Persistent and unbearable pain is frequently present, which may in part be related to increased pancreatic pressure due to obstructing stones or strictures of the pancreatic duct. Endoscopic decompression of the pancreatic duct is frequently attempted, including sphincterotomy, to enhance drainage of stones and facilitate the endoscopic extraction of stone material using a basket, similar to techniques used for extracting biliary tract stones. If the pancreatic duct stone is too large to deliver intact through the sphincter orifice, the stone may be crushed mechanically in situ (referred to as mechanical lithotripsy).

Extracorporeal shock wave lithotripsy (ESWL) has been investigated as an alternative to open surgical treatment in the subset of patients who have not responded to endoscopic approaches and would otherwise be considered candidates for a surgical approach. Multiple sessions may be required to adequately fragment the stones. In most instances ESWL is followed by an additional endoscopic procedure to remove stone fragments.

Policy

Extracorporeal shock wave lithotripsy (ESWL) may be considered medically necessary as a treatment of patients with symptomatic intraductal pancreatic stones who have failed initial endoscopic treatment and who are otherwise candidates for surgery.

Policy Guidelines

ESWL may be preceded by endoscopic pancreatic sphincterotomy and followed by further endoscopic procedures to extract stone fragments.
The number of ESWL procedures is based on presence of stone fragments in association with continuing symptoms. Many patients will require more than 1 ESWL treatment.

CPT code 43265 describes 'endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic retrograde destruction, lithotripsy of calculus/calculi, any method.' However, this CPT code primarily refers to the use of mechanical lithotripsy done at the time of ERCP. Thus this CPT code would not apply to ESWL, which is performed extracorporeally, and not endoscopically. There is no specific CPT code for ESWL of pancreatic stones.

Rationale

The majority of patients with pancreatic stones are successfully treated with endoscopic techniques; the literature regarding extracorporeal shock wave lithotripsy (ESWL) for pancreatic stones consists primarily of single institution case series of patients who have previously failed endoscopic therapy and who would otherwise be considered candidates for a surgical approach. Therefore, the patients serve as their own control. While technical outcomes focus on clearance of stones, relevant clinical outcomes focus on pain relief and avoidance of surgery.

Schneider and colleagues reported on a group of 50 who underwent a total of 119 lithotripsy sessions. (1) Stone fragmentation was successful in 86% of patients; 38% of patients achieved spontaneous stone discharge after ESWL; while 22% required a further endoscopic procedure. In 40% of patients, residual fragments remained. A total of 82% of patients became pain free; which did not differ among those who were rendered stone free compared to those with residual stones. At a mean follow-up of 20 months in 39 patients, 90% reported either pain relief or pain-free status. A total of 12% of patients were referred for surgery during the follow-up procedure, generally for reasons unrelated to pancreatic stones; i.e., duct stricture, pancreas abscess, or pseudocyst, etc. Farnbacher and colleagues conducted a retrospective review of 125 patients with pancreatic stones treated with endoscopy followed by ESWL. (2) Of the 101 of 125 patients presenting with acute pain immediately before treatment, 93% became completely pain free after completion of the therapy. A total of 52% experienced relapses during the mean follow-up period of 29 months. Other case series have also reported 80%–90% immediate improvement in pain. (3-6)

The majority of case series focuses on patients who have failed prior endoscopic therapy. In addition, endoscopic sphincterotomy is typically performed prior to ESWL to facilitate drainage of the fragmented stones. Ohara and colleagues reported on a unique protocol in which ESWL was the initial treatment of choice for pancreatic lithiasis without prior endoscopic procedure. In a case series of 32 patients, complete clearance of the stones was obtained in 75% without the necessity of endoscopic extraction of fragments. (7)

Results from the cited case series suggest that ESWL has a role in the management of pancreatic lithiasis as a conservative alternative to surgical decompression when endoscopic methods fail. However, the literature does not provide adequate data to establish firm patient selection criteria, in terms of stone number, size, and location, or the ESWL treatment parameters. For example, some studies report treatment using no anesthesia, mild sedation, or general anesthesia, related in part to the energy level of the shock waves. In the protocol used by Brand and colleagues in a German institution, (6) patients were hospitalized for treatment and received ESWL once or twice a day at low energy levels. Patients received a median of 13
treatment sessions, with a range of 2 to 72 sessions. In contrast, in the study of Kozarek and colleagues from the United States, patients received general or epidural anesthesia and received a single treatment session, with repeat treatment at a later time, if the initial treatment was unsuccessful. In this case series, 40 patients underwent a total of 46 procedures. (4)

2005 Update

A review of the literature from 2003 through June 2005 did not identify additional literature that would prompt reconsideration of the policy statement. The policy statement remains unchanged. No further review is scheduled.

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