



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Extracorporeal Shock Wave Lithotripsy (ESWL) for Pancreatic Stones

Policy #: 224

Latest Review Date: July 2024

Category: GI/GU

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **extracorporeal shock wave lithotripsy (ESWL)** as a **covered benefit** for individuals with **symptomatic intraductal pancreatic stones** who have **failed initial endoscopic treatment** and who are not otherwise candidates for surgery.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contracts and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 extraction 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).

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.

KEY POINTS:

The most recent update with literature review covers the period through July 11, 2024.

Summary of Evidence

The majority of patients with pancreatic stones are successfully treated with endoscopic techniques. However, the endoscopic removal of pancreatic duct stones can be difficult and is possible only in a subset of patients. Those with multiple stones, stones in the body and tail of the pancreatic duct, impacted stones, or stones behind a pancreatic duct stricture generally are not manageable by endoscopic techniques. The removal of large stones often will require lithotripsy with extracorporeal or intraductal instruments.

The literature regarding 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.

Most series reported success rates in carefully selected patients in whom endoscopic stone extraction seems feasible. A number of uncontrolled case series reported overall success at complete stone clearance in an average of 60% of patients. Clinical improvement was seen in about 75%. The rate of symptom improvement is thus greater than the rate of complete stone clearance. Follow-up has been relatively short, between 6 and 44 months. In one recent study, 20% of patients referred for endoscopic therapy of chronic pancreatitis had ductal anatomy that allowed stone extraction. Of these, half had complete clearance of ductal stones, although 95% of treated patients had complete or partial pain relief. After a mean follow-up of 2 years, less than half of the initial responders continued to have pain relief. Stones may recur after successful extraction in up to 25% of patients. Complications of stone removal occur, on average, in less than 20% of patients.

Schneider et al reported on a group of 50 who underwent a total of 119 lithotripsy sessions. 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 et al conducted a retrospective review of 125 patients with pancreatic stones treated with endoscopy followed by ESWL. 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.

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 et al 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.

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 et al in a German institution, 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 et al 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.

KEY WORDS:

Extracorporeal shock wave lithotripsy, ESWL, lithotripsy, pancreatic stones

APPROVED BY GOVERNING BODIES:

FDA approved.

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT code:

48999	Unlisted procedure, pancreas
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REFERENCES:

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3. Duan WX, Wei WZ, Yang X, et al. [Effect of pancreatic extracorporeal shock wave lithotripsy on chronic pancreatitis stones]. *Zhonghua Wai Ke Za Zhi*. 2023 Jul 1;61(7):590-595.
4. Endo S, Kawaguchi S, Satoh T, et al. Extracorporeal shock wave lithotripsy and endoscopic pancreatic stenting without pancreatic sphincterotomy for the treatment of pancreatolithiasis: a case series. *Clin J Gastroenterol*. 2023 Aug;16(4):615-622.
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Scand J Gastroenterol. 2018 Oct-Nov;53(10-11):1399-1403. doi: 10.1080/00365521.2018.1508611. Epub 2018 Oct 24.

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10. Ohara H, Hoshino M, Hayakawa T, et al. Single application extracorporeal shock wave lithotripsy is the first choice for patients with pancreatic duct stones. *Am J Gastroenterol* 1996; 91:1388.
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12. Schneider HT, May A, Benninger J, et al. Piezoelectric shock wave lithotripsy of pancreatic duct stones. *Am J Gastroenterol* 1994; 89:2042.

POLICY HISTORY:

Adopted for Blue Advantage, April 2005

Available for comment May 12-June 27, 2005

Medical Policy Group, April 2007

Medical Policy Group, April 2009

Medical Policy Group, August 2019

Medical Policy Group, August 2021

Medical Policy Group, July 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, July 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.

Medical Policy Group, July 2024: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

UM Committee, July 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.