



Australian Government

Department of Health

MSAC Application 1673

Single operator, single use, peroral cholangiopancreatography (POCPS) for the diagnosis of indeterminate biliary strictures and removal of difficult biliary stones

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name: Boston Scientific

ABN: 45071 676 063

Business trading name: Boston Scientific Pty Ltd

Primary contact name: REDACTED

Primary contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

2. (a) Are you a lobbyist acting on behalf of an Applicant?

Yes

No

(b) If yes, are you listed on the Register of Lobbyists?

N/A

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Single operator, single use, peroral cholangiopancreatography (POCPS)

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Diagnostic application:

Biliary strictures present a significant diagnostic challenge, especially when no aetiology can be ascertained after laboratory evaluation, abdominal imaging, endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) (1). The implications of missing a malignancy in patients with biliary strictures are grave, due to the aggressive nature of cancer found in the bile ducts (2). Consequently, surgical resection is common for indeterminate biliary strictures with suspected malignancy, even though 15–24% of these patients will have benign aetiology (3). An accurate way to determinate malignancy pre-operatively is therefore highly desirable to avoid unnecessary surgery.

Therapeutic application:

Biliary stones are routinely removed at the time of ERCP, however, approximately 10- 15% of these stones cannot be removed by conventional extraction techniques (4). These difficult stones present significant clinical challenges including prolonged procedure times, multiple ERCP sessions, and invasive surgical intervention (5).

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Single operator, single use peroral cholangiopancreatography (POCPS) enables high resolution imaging and therapy during an ERCP procedure. The POCPS system consists of a catheter which is passed through the standard working channel of the ERCP duodenoscope, directly into the pancreatic and biliary ducts (6). This system produces high-definition, direct endoscopic visualisation of the pancreatobiliary system. This is a significant advantage over conventional ERCP fluoroscopic images which, according to Australian clinicians, are limited by their poor sensitivity resulting in up to 10% of strictures remaining indeterminate.

The POCPS catheter is compatible with a full suite of diagnostic and therapeutic accessories, enabling a single physician to visualise and treat a range of pancreatobiliary diseases (7).

Based on the inputs from Australian clinical experts and the availability of evidence, this application will be focusing on two key indications for POCPS:

- Diagnostic application: diagnosis of indeterminate biliary strictures.
Patients with biliary strictures which have failed standard diagnostic approaches may face multiple repeated procedures, delays in diagnosis and the possibility of unnecessary surgical resection of benign strictures (8). POCPS enables faster, more accurate diagnosis of these strictures through direct visualisation of the bile ducts and tissue sampling, when combined with biopsy forceps (9).
- Therapeutic application: removal of difficult biliary stones.
Patients with stones which cannot be removed by conventional extraction techniques often require multiple repeated procedures and/or invasive surgical interventions. When combined with a lithotripsy device, POCPS offers a highly effective approach to clearing difficult biliary stones through electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL) fragmentation under direct visualisation (5).

6. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

N/A

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

N/A

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. A new item for a specific single consultation item
iv. A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
 No

(g) If yes, please advise:

N/A

7. What is the type of service:

- Therapeutic medical service
 Investigative medical service
 Single consultation medical service
 Global consultation medical service
 Allied health service
 Co-dependent technology
 Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

- i. To be used as a screening tool in asymptomatic populations
ii. Assists in establishing a diagnosis in symptomatic patients
iii. Provides information about prognosis
iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
 Prosthesis or device
 No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

N/A

(b) If yes, please list the relevant PBS item code(s):

N/A

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

N/A

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Trade name: N/A

Generic name: N/A

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

Yes

No

(b) If yes, please provide the following information (where relevant):

N/A

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

Yes

No

An application will be made to list single operator, single use, peroral cholangiopancreatography (POCPS) on Part C of the Prostheses List.

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian marketplace which this application is relevant to?

Yes

No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

N/A

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables: guide wires, biliary stents, duodenoscope, cannulation catheters, sphincterotome

Multi-use consumables: N/A

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

- 13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:**

Type of therapeutic good: POCPS and accessory devices (see Appendix I)

Manufacturer's name: Multiple (see Appendix I)

Sponsor's name: Multiple (see Appendix I)

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**

Class III

AIMD

N/A

- 14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?**

Yes (If yes, please provide supporting documentation as an attachment to this application form)

No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?**

Yes (if yes, please provide details below)

No

ARTG listing, registration or inclusion number: Multiple (see Appendix I)

TGA approved indication(s), if applicable: Multiple (see Appendix I)

TGA approved purpose(s), if applicable: Multiple (see Appendix I)

- 15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?**

Yes (please provide details below)

No

Date of submission to TGA: N/A

Estimated date by which TGA approval can be expected: N/A

TGA Application ID: N/A

TGA approved indication(s), if applicable: N/A

TGA approved purpose(s), if applicable: N/A

- 16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

Yes (please provide details below)

No

Estimated date of submission to TGA: N/A

Proposed indication(s), if applicable: N/A

Proposed purpose(s), if applicable: N/A

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

Diagnostic application: indeterminate biliary strictures					
	Type of study design	Title of journal article or research project	Short description of research (max 50 words)	Website link to journal article or research	Date of publication
1.	Systematic review and meta-analysis	Single-operator cholangioscopy and targeted biopsies in the diagnosis of indeterminate biliary strictures: a systematic review	Study on the pooled diagnostic accuracy of POCPS-guided biopsy for the diagnosis of indeterminate biliary strictures (10 studies, n = 456)	Single-operator cholangioscopy and targeted biopsies in the diagnosis of indeterminate biliary strictures: a systematic review - PubMed (nih.gov)	2015
2.	Systematic review and meta-analysis	Efficacy and Safety of Digital Single-Operator Cholangioscopy in the Diagnosis of Indeterminate Biliary Strictures by Targeted Biopsies: A Systematic Review and Meta-Analysis	Study on the pooled diagnostic accuracy and safety of POCPS-guided biopsy for the diagnosis of indeterminate biliary strictures (11 studies, n = 356)	Efficacy and Safety of Digital Single-Operator Cholangioscopy in the Diagnosis of Indeterminate Biliary Strictures by Targeted Biopsies: A Systematic Review and Meta-Analysis - PubMed (nih.gov)	2020
3.	Systematic review and meta-analysis	Is single-operator peroral cholangioscopy a useful tool for the diagnosis of indeterminate biliary lesion? A systematic review and meta-analysis	Study comparing the pooled diagnostic accuracy of POCPS-guided biopsy compared to POCPS visual impression for the diagnosis of indeterminate biliary strictures (8 studies, n = 672)	Is single-operator peroral cholangioscopy a useful tool for the diagnosis of indeterminate biliary lesion? A systematic review and meta-analysis - Gastrointestinal Endoscopy (giejournal.org)	2015
4.	Prospective, multicentre, RCT	Digital single-operator peroral cholangioscopy-guided biopsy sampling versus ERCP-guided brushing for indeterminate biliary strictures: a prospective, randomized, multicenter trial (with video)	Study comparing the diagnostic accuracy and safety of POCPS-guided biopsy and ERCP-guided brushing for the diagnosis of indeterminate biliary strictures (n = 60)	Digital single-operator peroral cholangioscopy-guided biopsy sampling versus ERCP-guided brushing for indeterminate biliary strictures: a prospective, randomized, multicenter trial (with video) - PubMed (nih.gov)	2020

Diagnostic application: indeterminate biliary strictures					
	Type of study design	Title of journal article or research project	Short description of research (max 50 words)	Website link to journal article or research	Date of publication
5.	Prospective, single centre, comparative, cohort study	Diagnostic accuracy of conventional and cholangioscopy-guided sampling of indeterminate biliary lesions at the time of ERCP: a prospective, long-term follow-up study	Study comparing the diagnostic accuracy of POCPS-guided biopsy and ERCP-guided brushing for the diagnosis of indeterminate biliary strictures (n = 26)	Diagnostic accuracy of conventional and cholangioscopy-guided sampling of indeterminate biliary lesions at the time of ERCP: a prospective, long-term follow-up study - ScienceDirect	2012
6.	Prospective, multicentre, cohort study	Using single-operator cholangioscopy for endoscopic evaluation of indeterminate biliary strictures: results from a large multinational registry	Multicentre, Asia-Pacific study on the diagnostic accuracy, procedural success, safety, and impact on management of POCPS-guided biopsy and POCPS visual impression for the diagnosis of indeterminate biliary strictures (n = 289)	Using single-operator cholangioscopy for endoscopic evaluation of indeterminate biliary strictures: results from a large multinational registry - PubMed (nih.gov)	2020

Therapeutic application: Difficult biliary stones					
	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
7.	Systematic review and meta-analysis	Single-operator peroral cholangioscope in treating difficult biliary stones: A systematic review and meta-analysis	Study on the pooled safety and procedural success of POCPS-guided EHL/LL for the treatment of difficult biliary stones (24 studies, n = 2786)	Single-operator peroral cholangioscope in treating difficult biliary stones: A systematic review and meta-analysis - PubMed (nih.gov)	2018

Therapeutic application: Difficult biliary stones					
	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
8.	Systematic review and meta-analysis	Efficacy and safety of peroral cholangioscopy with intraductal lithotripsy for difficult biliary stones: a systematic review and meta-analysis	Study comparing the pooled safety and procedural success of POCPs-guided EHL and POCPs-guided LL for the treatment of difficult biliary stones (35 studies, n = 1762)	Efficacy and safety of peroral cholangioscopy with intraductal lithotripsy for difficult biliary stones: a systematic review and meta-analysis - PubMed (nih.gov)	2021
9.	Prospective, multicentre, RCT	Randomized trial of cholangioscopy-guided laser lithotripsy versus conventional therapy for large bile duct stones (with videos)	Study comparing safety and procedural success of POCPs-guided LL and conventional ERCP extraction techniques (mechanical lithotripsy or large balloon dilation) for large biliary stones (n = 60)	Randomized trial of cholangioscopy-guided laser lithotripsy versus conventional therapy for large bile duct stones (with videos) - PubMed (nih.gov)	2018
10.	Prospective, single-centre, RCT	Digital cholangioscopy-guided laser versus mechanical lithotripsy for large bile duct stone removal after failed papillary large balloon dilation: a randomized study	Study comparing the safety and procedural success of POCPs-guided LL and ERCP (radiologically guided) mechanical lithotripsy of difficult CBD stones (n = 32)	Digital cholangioscopy-guided laser versus mechanical lithotripsy for large bile duct stone removal after failed papillary large-balloon dilation: a randomized study - PubMed (nih.gov)	2019
11.	Prospective, multi-centre, cohort study	Cholangioscopy-guided lithotripsy for difficult bile duct stone clearance in a single session of ERCP: results from a large multinational registry demonstrate high success rates	International multicentre study on procedural success, safety and impact on management of POCPs-guided EHL/LL for the treatment of difficult biliary stones (n = 156)	Cholangioscopy-guided lithotripsy for difficult bile duct stone clearance in a single session of ERCP: results from a large multinational registry demonstrate high success rates - PubMed (nih.gov)	2019

Therapeutic application: Difficult biliary stones					
	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
12.	Retrospective, single-centre, cohort study	Peroral Cholangioscopy-guided Electrohydraulic Lithotripsy with a SpyGlass DS Versus a Conventional Digital Cholangioscope for Difficult Bile Duct Stones	Study on the safety and procedural success of POCPS-guided LL for the treatment of difficult biliary stones (n = 32)	Peroral Cholangioscopy-guided Electrohydraulic Lithotripsy with a SpyGlass DS Versus a Conventional Digital Cholangioscope for Difficult Bile Duct Stones (nih.gov)	2020
13.	Retrospective, single-centre, cohort study	Safety and efficacy of SpyGlass cholangiopancreatography in routine clinical practice in a regional Singapore hospital	Study on safety and procedural success of POCPS-guided LL for the treatment of difficult biliary stones (n = 28)	Safety and efficacy of SpyGlass cholangiopancreatography in routine clinical practice in a regional Singapore hospital - PubMed (nih.gov)	2019
14.	Retrospective, single-centre, cohort study	Liver Resection for Intrahepatic Stones	Study on safety and procedural success of liver resection for intrahepatic stones (n = 174)	Liver Resection for Intrahepatic Stones Gastrointestinal Surgery JAMA Surgery JAMA Network	2005
15.	Retrospective, single-centre, cohort study	The Surgical Management of Concomitant Gallbladder and Common Bile Duct Stones	Study on safety and procedural success of surgical management of gallbladder/ biliary stones (n = 174)	The Surgical Management of Concomitant Gallbladder and Common Bile Duct Stones (hindawi.com)	2015
16.	Retrospective, single-centre, cohort study	Surgical (Open and laparoscopic) management of large difficult CBD stones after different sessions of endoscopic failure: A retrospective cohort study	Study on safety and procedural success of open and laparoscopic surgical management of difficult biliary stones (n = 85)	https://pubmed.ncbi.nlm.nih.gov/31198552/	2019
17.	Non-systematic review	Role of Open Choledochotomy in the Treatment of Choledocholithiasis	Non-systematic review of endoscopic sphincterotomy and open choledochotomy for the treatment of biliary stones	Role of open choledochotomy in the treatment of choledocholithiasis - ScienceDirect	1993

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

Diagnostic application: indeterminate biliary strictures					
	Study design	Title of research	Short description of research	Website link to research	Date
1.	Retrospective, comparative, cohort study	Prospective Evaluation of Biliary Tissue Sampling With ERCP	Study on the safety, test accuracy and procedural success of multiple biliary sampling techniques including POCPS-guided biopsy and ERCP-guided brush cytology in patients with indeterminate strictures (n = 500)	Prospective Evaluation of Biliary Tissue Sampling With ERCP - Full Text View - ClinicalTrials.gov	May 2026
2.	Prospective, single-centre, RCT	Diagnostic Accuracy of ERCP-guided Versus Cholangioscopy-guided Tissue Acquisition in Patients With Indeterminate Biliary Strictures Suspected to be Intrinsic - a Randomized Controlled Study	Study comparing the safety, test accuracy and procedural success of POCPS-guided biopsy and ERCP-guided brush cytology in patients with indeterminate strictures (n = 60)	Diagnostic Accuracy of ERCP-guided Versus Cholangioscopy-guided Tissue Acquisition in Patients With Indeterminate Biliary Strictures Suspected to be Intrinsic . - Full Text View - ClinicalTrials.gov	Unknown
3.	Prospective, single-centre, RCT	Optimizing the Role of ERCP in Evaluating Indeterminate Bile Duct Strictures	Study comparing the safety, test accuracy and procedural success of POCPS-guided biopsy, fluorescence in situ hybridization and ERCP-guided brush cytology compared with ERCP-guided brush cytology alone in patients with indeterminate strictures (n = 48)	Endoscopic Retrograde Cholangiopancreatography (ERCP) Based Sampling of Indeterminate Bile Duct Strictures - Full Text View - ClinicalTrials.gov	Unknown
Therapeutic application: difficult biliary stones					
4.	Prospective, single-centre, RCT	Spyglass DS Peroral Cholangioscope Guided LL or EHL Versus BML for Endoscopic Removal of Complicated Bile Duct Stones	Study comparing the safety and procedural success of POCPS-guided EHL/LL and ERCP (radiologically guided) mechanical lithotripsy for the treatment of difficult biliary stones (n = 86)	Spyglass DS Peroral Cholangioscope Guided LL or EHL Versus BML for Endoscopic Removal of Complicated Bile Duct Stones - Full Text View - ClinicalTrials.gov	December 2023

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

Gastroenterological Society of Australia (GESA)

- 20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

Gastroenterological Society of Australia (GESA)

- 21. List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

Letter of support from consumer organisations will be send directly to MSAC

- 22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

None

- 23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert 1: **REDACTED**

Email address: REDACTED

Justification of expertise: REDACTED

Name of expert 2: **REDACTED**

Email address: REDACTED

Justification of expertise: REDACTED

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

Diagnostic application: Indeterminate biliary strictures

A biliary stricture is an abnormal narrowing of the bile duct, obstructing the passageway that carries bile from the liver to the bowel (10). Various disorders can result in the narrowing of the biliary ducts.

The most common benign conditions include:

- Iatrogenic (injury from surgical procedures)
- Primary sclerosing cholangitis (chronic inflammatory disease of the bile ducts)
- Chronic pancreatitis (inflammation of the pancreas)

The most common malignant conditions include:

- Cholangiocarcinoma (bile duct cancer), which has an incidence of 4.6 per 100,000 in Australia (11)

ERCP is the most widely used diagnostic procedure for determining the malignancy of strictures. ERCP is done under X-ray guidance using a duodenoscope (an endoscope designed for the examination of the duodenum), which is inserted perorally. Contrast medium is then injected through the endoscope, creating two dimensional images to localise and characterise the extent of bile duct pathology. Diagnostic options during an ERCP procedure include blind intraductal biopsies and cytology brushings (12). Although still widely used, these sampling techniques are limited by poor sensitivity and often yields inadequate specimens. As a result, up to 10% of biliary strictures remain indeterminate after ERCP with tissue sampling.

Cholangiocarcinoma is a rare but highly aggressive cancer. Whilst the 5-year survival rate has close to doubled over the past 2 decades, those diagnosed in Australia each year still have one of the lowest five-year survival rates of all cancers at less than 20% (13). Indeterminate biliary strictures pose a complex challenge to patients and physicians and should be considered malignant unless proven otherwise (30). Consequently, surgical resection is the preferred option in patients who have indeterminate biliary strictures with suspected malignancy due to the risk of failing to spot malignancy, even though 15–24% of these patients will ultimately have a benign aetiology (3).

Current international clinical guidelines recommend POCPs as a tool for pre-operatively determining malignancy in patients with indeterminate biliary strictures to reduce the significant morbidity and cost associated with unnecessary surgical interventions (14).

Therapeutic application: Difficult biliary stones

Gallstones are one of the most common diseases worldwide, with an estimated prevalence of 25–30% in Australians over the age of 50 years. In 10–18% of these patients, a gallstone will migrate from the gallbladder to the biliary ducts. Less frequently, stones will originate in the biliary ducts themselves (15).

Factors that lead to stone formation include excessive bile cholesterol, low bile salt levels, decreased gallbladder motility, and the phosphatidylcholine molecule, which prevents the crystallisation of cholesterol. Stones formed mainly from cholesterol are termed cholesterol stones, and those mainly from bilirubin are termed pigment stones (16).

The main risk factors for cholesterol stone formation include female sex, pregnancy, high dose oestrogen treatment, increasing age, ethnicity (higher prevalence in Native American Indians and lower prevalence in black Americans, Africans, and people from China, Japan, India, and Thailand), genetic traits, obesity,

high serum triglyceride levels, low levels of high density cholesterol, rapid weight loss, high calorific diet, refined carbohydrate diet, lack of physical activity, cirrhosis and Crohn's disease. Haemolysis and chronic bacterial or parasitic infections are considered the main risk factors for pigment stones (16).

Nearly 55% of patients with biliary stones are symptomatic, commonly presenting with pain, jaundice, cholangitis, and/or acute biliary pancreatitis (16). Asymptomatic stones found incidentally in the biliary ducts may also require treatment, due to the high risk of complications (17).

ERCP with endoscopic sphincterotomy and stone extraction is the approach commonly used to clear stones from the biliary ducts. Although conventional techniques for stone removal are highly effective, they may fail or be infeasible in 10-15% of patients (2). Biliary stones may be difficult to remove if they are impacted, lodged behind strictures, large in size (> 15 mm in diameter) or located in regions of the biliary tree which are difficult to target endoscopically (18).

Currently, patients with difficult stones in the pancreato-biliary system including hepatic ducts undergo multiple ERCP procedures, exposing the patient to a substantial risk of complications, thereby increasing morbidity and mortality. Consequently, if ERCP fails, a proportion of patients are referred for surgery, either choledochotomy (extra-hepatic stones) or liver resection (intra-hepatic stones), even in the presence of substantial comorbidity and prolonged hospitalisation (19).

Current international clinical guidelines strongly recommends that POCPs-guided EHL or LL be considered when other endoscopic treatment options fail to achieve duct clearance (20).

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Diagnostic application: Indeterminate biliary strictures

A biliary stricture is typically noted on the CT/MRI of patients with cholestatic clinical patterns which includes abdominal pain, nausea, fatigue, pruritus, dark urine, light stool, jaundice and abnormal liver tests (elevated alkaline phosphatase and bilirubin levels). Occasionally strictures are identified incidentally via diagnostic imaging in non-jaundiced patients with or without liver chemistry abnormalities. When abdominal imaging cannot identify a stricture in patients with cholestatic clinical patterns, or the aetiology of an identified stricture is uncertain, patients will be referred to undertake an ERCP and/or EUS procedure. If the conventional diagnostic ERCP and/or EUS results are inconclusive, these patients will be eligible for POCPs.

Therefore, the proposed population for diagnostic POCPs, patients with indeterminate biliary strictures, will be eligible for the proposed medical service following inconclusive results from conventional diagnostic ERCP and/or EUS procedures. These patients will typically be referred for a follow up ERCP with POCPs at an endoscopic unit with the equipment and staff training to perform POCPs (22).

Therapeutic application: Difficult biliary stones

A biliary stone is typically noted on a trans-abdominal ultrasound (TUS) of patients with cholestatic clinical patterns which includes abdominal pain, nausea, fatigue, pruritus, dark urine, light stool, jaundice and abnormal liver tests (elevated alkaline phosphatase and bilirubin levels). When abdominal imaging cannot identify a stone in patients with cholestatic clinical patterns, ERCP is often used to both diagnose and treat biliary stones. If biliary stone removal fails or is infeasible via conventional ERCP extraction techniques, patients will be eligible for POCPs.

Therefore, the proposed population for therapeutic POCPs, patients with difficult biliary stone, will be eligible for the proposed medical service following failed or infeasible removal of stones via conventional ERCP extraction techniques. As with indeterminate biliary strictures, POCPs for patients with difficult biliary stones will typically be performed during a follow up ERCP at a referral centre. However, in some cases POCPs may be performed during the index ERCP procedure following failed or infeasible standard ERCP extraction techniques in endoscopic units which have both the equipment and specialist POCPs training.

Contraindications associated with the use of this medical service for both diagnostic and therapeutic indications include:

- Patients for whom ERCP is medically contraindicated
- Contraindications specific to endoscopic pancreato-biliary duct exploration and cannulation.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

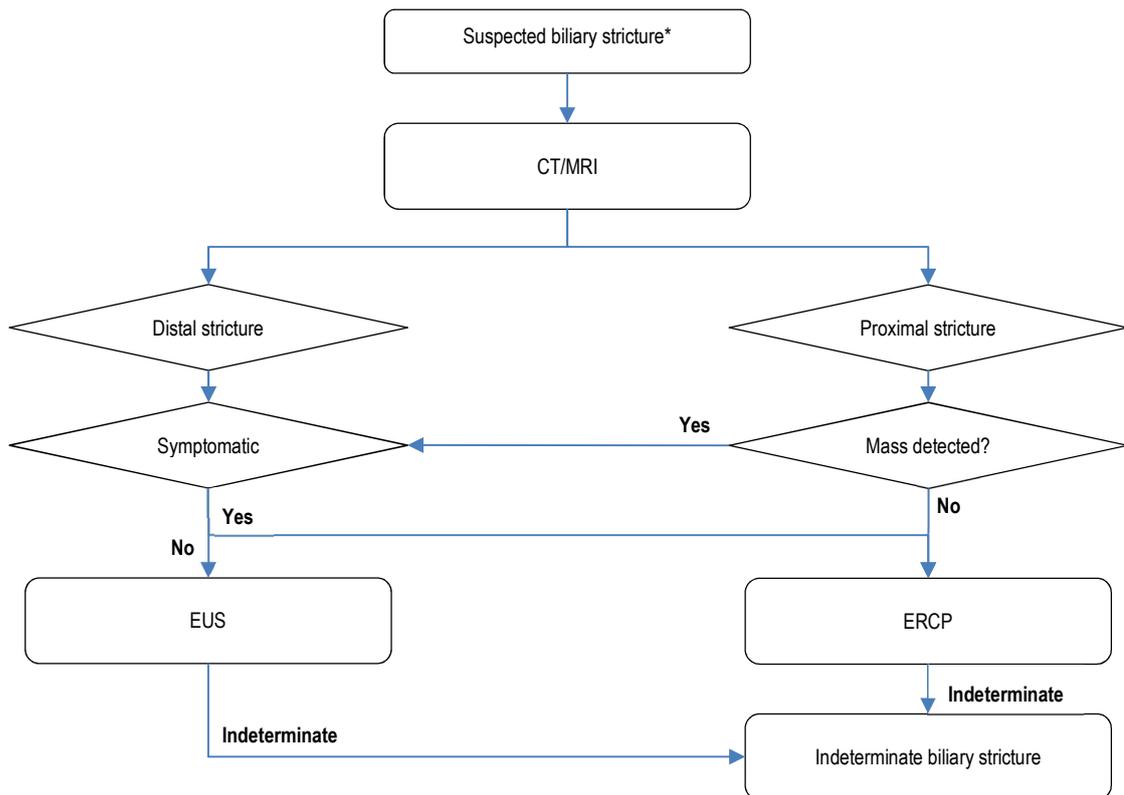
Current international clinical guidelines make consistent recommendations for POCPS-guided diagnosis of indeterminate biliary strictures and treatment of difficult biliary stones, based on comprehensive reviews of the extensive published data for POCPS in these indications.

Face-to-face clinician interviews were conducted to provide the greatest insight into the current Australian clinical management pathway before a patient would be considered eligible for POCPS. The clinical algorithms for each of the proposed populations represents the current practice of medical centres in Australia who have access to POCPS without reimbursement.

Diagnostic application: Indeterminate biliary strictures

Patients with a suspected biliary stricture typically present with cholestatic clinical patterns, investigated through CT/MRI. EUS is performed if the patient is asymptomatic and the CT/MRI detects a mass or distal stricture. ERCP is performed when no mass is detected or if the patient is symptomatic. POCPS, used during an ERCP procedure, is indicated for patients with indeterminate results from conventional diagnostic ERCP and/or EUS procedures (Figure 1).

Figure 1 Clinical management pathway before patients are eligible for diagnostic POCPS



Abbreviations: CT = Computerized Tomography, ERCP = Endoscopic Retrograde Cholangiopancreatography, EUS = Endoscopic Ultrasound MRI = Magnetic Resonance Imaging, POCPS = Peroral Cholangiopancreatotomy

* Patients with suspected biliary stricture typically present with cholestatic clinical patterns including abdominal pain, nausea, fatigue, pruritus, dark urine, light stool, jaundice and/or abnormal liver tests (elevated alkaline phosphatase and bilirubin levels).

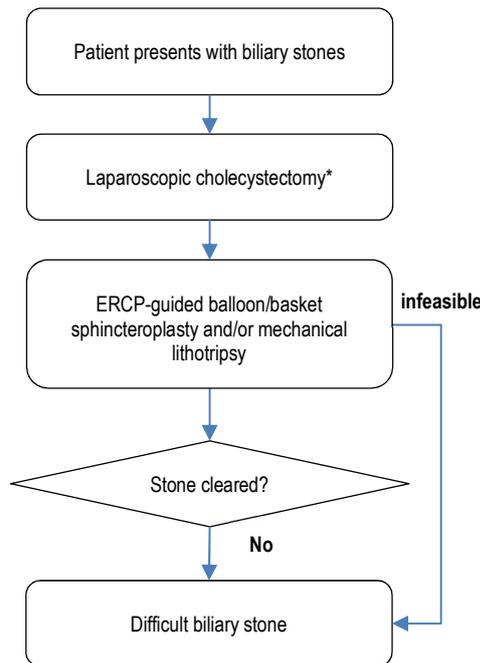
Therapeutic application: Difficult biliary stones

Patients with a suspected gallstone and/or biliary stone typically present with cholestatic clinical patterns, investigated through a trans-abdominal ultrasound (TUS). When abdominal imaging cannot identify a stone in patients with cholestatic clinical patterns, ERCP is used to both diagnose and treat biliary stones.

Patients with biliary stones typically undergo laparoscopic cholecystectomy (removal of the gallbladder) before or after clearing the biliary ducts.

The majority of biliary stones can be cleared by ERCP with sphincterotomy and stone extraction (ERCP guided balloon/basket sphincteroplasty and/or mechanical lithotripsy). Patients who have failed or have stones which are infeasible to remove via conventional ERCP extraction techniques, are eligible for PCOCS guided EHL or LL.

Figure 2 Clinical management pathway before patients are eligible for therapeutic POCPS



Abbreviations: EHL = Electrohydraulic Lithotripsy, ERCP = Endoscopic Retrograde Cholangiopancreatography, LL = Laser Lithotripsy, POCPS = Peroral Cholangiopancreatography,

* Laparoscopic cholecystectomy may be done, prior-to or following an ERCP procedure.

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

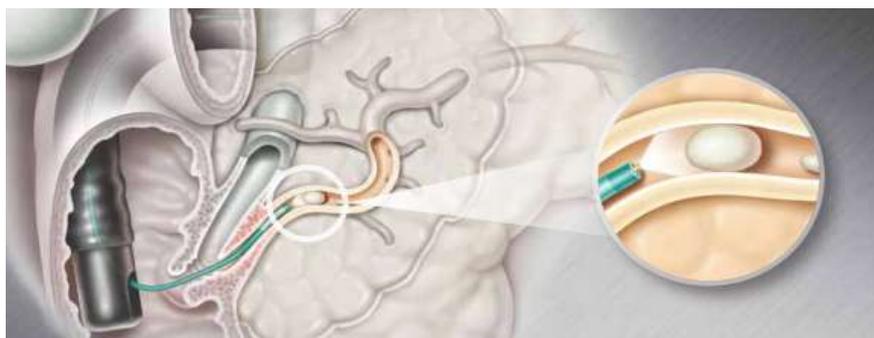
Key components

A single-operator, single use peroral cholangiopancreatography system allows clinicians to visually examine the biliary ducts and take biopsy samples (Figure 3) and treat difficult biliary stones by either EHL or LL (Figure 4). The system produces high-definition digital images, a significant advantage over conventional ERCP fluoroscopic images which are low definition, indirect and colourless.

Figure 3 POCPS diagnostic application



Figure 4 POCPS therapeutic application



The components are listed below:

- A flexible catheter with single-operator controls which can be inserted into the working channel of the duodenoscope. The distal end of the catheter has a video image sensor with illumination and egress points for the working channel and two irrigation channels.
 - Irrigation channel: for injecting irrigation fluid to clear the field of view
 - Working channel: for aspiration and applying accessories, including biopsies forceps and EHL /LL fibres
- POCPS is compatible with a range of diagnostic and therapeutic accessories delivered through the working channel
 - **Diagnostic application:** The biopsy forceps (single use) allow biopsy specimens to be taken under direct visualisation (Figure 3)
 - **Therapeutic application:** Lithotripsy devices including EHL and LL allows a shock wave to be delivered directly to the stone, generated by a high voltage spark or a laser beam respectively (Figure 4). These procedures cannot be performed in an ERCP without POCPS as clinicians need to clearly see the biliary ducts when using these lithotripsy techniques to avoid damage to the surrounding tissues (21).

Clinical steps

POCPS is always used in conjunction with an ERCP procedure. The system can be set up and attached to the working channel of a standard ERCP duodenoscope in under 5 minutes. POCPS is designed to be performed by a single endoscopist who can operate deflection wheels which control both the duodenoscope and POCPS system (21).

This system has overcome many of the limitations of earlier direct cholangiopancreatography devices which require two endoscopists, are fragile and have poor visualization capabilities (22).

The current clinical steps for both diagnostic and therapeutic applications of POCPS are as follows:

1. The procedure starts as a regular ERCP, with the introduction of a duodenoscope through the mouth into the duodenum
2. Often sphincterotomy is performed for better access to the biliary tree
3. A guidewire is inserted under fluoroscopy and in symptomatic patients a stent may be placed in the blocked duct to allow normal drainage, which can be performed prior to or following POCPS.
4. POCPS catheter is passed over the guidewire into the biliary ducts
5. Guidewire is removed
6. Diagnostic and therapeutic accessories are delivered through the working channel.
 - **Diagnostic application:** biopsy forceps are passed through the working channel to facilitate site-specific specimen acquisition under direct visualization throughout the pancreatico-biliary system (Figure 3)
 - **Therapeutic application:** For the treatment of difficult biliary stones, either EHL or LL fibres are passed through the working channel, under direct visualization for focused treatment (Figure 4).

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

This submission does not pertain to a specific trademarked device.

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

The proposed diagnostic and therapeutic applications of POCPS are both readily used in Australia by gastroenterologists in large tertiary clinical practices. However, as these procedures are not currently reimbursed by the MBS, there is inequity in access depending on where a patient is treated.

Diagnostic application: Indeterminate biliary strictures

Conventional diagnostic ERCP and EUS are well established in Australian practice for the first-line approach to diagnose a biliary stricture and are currently billed under item 30484 and 30690/30692, respectively. The rationale for use of POCPS during an ERCP procedure following indeterminate results from standard diagnostic approaches, is to provide an accurate way to determine malignancy to avoid further repeated procedures, delays in diagnosis and unnecessary surgery.

Therapeutic application: Difficult biliary stones

As with biliary strictures, conventional therapeutic ERCP is well established for the first-line approach to remove biliary stones and is billed under the same item code as diagnostic ERCP procedures (30484). The rationale for the use of EHL/LL-guided POCPS during an ERCP procedure following failure of standard ERCP extraction techniques, is to avoid further repeated procedures and surgery in these patients. EHL/LL are well established techniques used in Australian clinical practice and are currently reimbursed for urological stones under item 36656/36809.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

N/A

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

POCPS will be used during an ERCP procedure, with the proposed service being billed instead of the current ERCP item code (30484). As with ERCP, the proposed service often will take place in combination with sphincterotomy (30485).

32. If applicable, advise which health professionals will primarily deliver the proposed service:

POCPS is intended for use in endoscopic units which have both the equipment and expert staff to carry out ERCP. The intended user is a clinician trained in ERCP endoscopy, most commonly a gastroenterologist.

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

N/A

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

POCPS is limited to use in centres with endoscopic units which have both the equipment and expert staff with experience in ERCP endoscopy with specialist POCPS training.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

Sponsors offers training and ongoing in-case support at no extra cost, as part of the POCPS purchase.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

POCPS may be useful in both elective and emergency ERCP procedures. It is provided at a public or private hospital as an inpatient procedure as the procedure requires sedation or general anaesthesia and antibiotic prophylaxis, typically requiring an overnight stay.

37. Is the proposed medical service intended to be entirely rendered in Australia?

- Yes
- No

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

In the absence of POCPS, patients with indeterminate biliary strictures will undertake on average up to two additional ERCP (radiologically guided) procedures with brush cytology and/or blind intraductal biopsy. For each repeated ERCP procedure, endoscopic sphincterotomy will also be performed (item 30485).

In the absence of POCPS, patients with difficult biliary stones will attempt on average up to two additional ERCP (radiologically guided) mechanical lithotripsy procedures, if feasible. Some clinicians indicated that up to 8 repeated procedures may be performed in patients with difficult biliary stones. For each repeated ERCP procedure, endoscopic sphincterotomy will also be performed (item 30485). For the portion of patients for whom ERCP (radiologically guided) mechanical lithotripsy is unfeasible, choledochotomy (extra-hepatic stones) or liver resection (intra-hepatic stones) is performed (Table 1). The estimated percentage of patients treated by each comparator is to be advised by clinicians and will be presented in the final submission.

39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

- Yes (please list all relevant MBS item numbers below)
 No

Table 1 Comparators for the proposed diagnostic and therapeutic application of POCPS

Population	Comparator	MBS item number	MBS Item descriptor	Fee
Indeterminate biliary strictures	ERCP (radiologically guided) with brush cytology and/or blind intraductal biopsy.	30484	Endoscopic retrograde cholangiopancreatography	\$376.30
		30485	Endoscopic sphincterotomy*	\$580.90
Difficult biliary stones	ERCP (radiologically guided) mechanical lithotripsy	30484	Endoscopic retrograde Cholangiopancreatography**	\$376.30
		30485	Endoscopic sphincterotomy*	\$580.90
	Choledochotomy	30454	Choledochotomy without cholecystectomy***	\$1359.40
		30457	Choledochotomy, intrahepatic, involving removal of intrahepatic bile duct calculi	\$1,422.55
	Liver resection	30414	Liver, subsegmental resection of, (local excision), other than for trauma	\$711.35
		30415	Liver, segmental resection of, other than for trauma	\$1,422.55

* Endoscopic sphincterotomy is billed concurrently with an ERCP procedure

** MSAC has not yet assessed cost-effectiveness of mechanical lithotripsy for removal of biliary stones, however it is routinely used in Australian clinical practice. Therapeutic ERCP procedures typically bill item 30484 and the remaining cost is absorbed by the hospital budget.

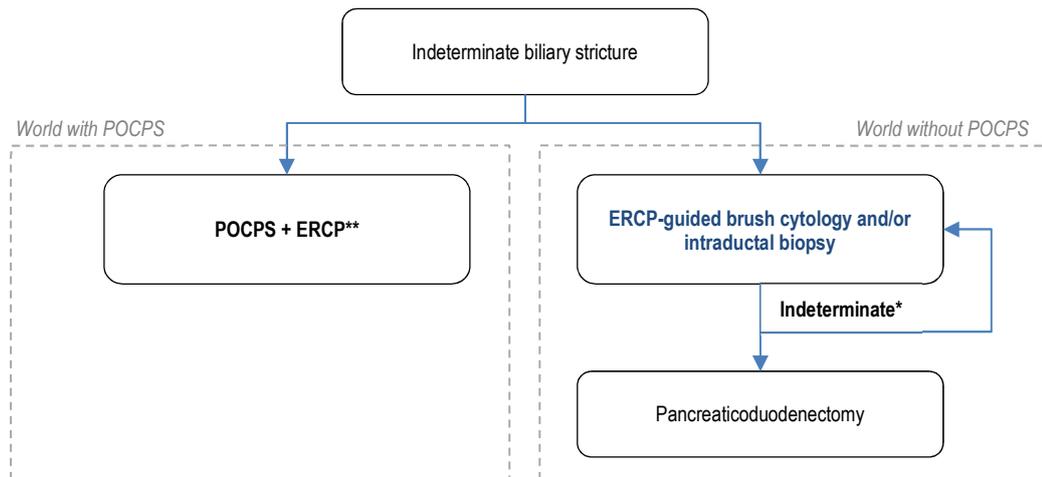
*** From 1 July 2021, Medicare Benefits Schedule (MBS) items for general surgery services are changing to reflect contemporary practice. The price and descriptor for item 30454 reflects these upcoming changes.

40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):

Diagnostic application: Indeterminate biliary strictures

A biliary stricture with inconclusive results from diagnostic EUS and/or ERCP will typically undergo multiple repeat ERCP procedures. Depending on the likelihood of malignancy, patients with indeterminate results from standard ERCP diagnostic approaches may repeat the ERCP procedure on average up to 2 times before surgically resecting the stricture (pancreaticoduodenectomy) (Figure 5).

Figure 5 Clinical management algorithm for the diagnosis of indeterminate biliary strictures



Abbreviations: ERCP = Endoscopic Retrograde Cholangiopancreatography

Blue = Comparator to POCPS

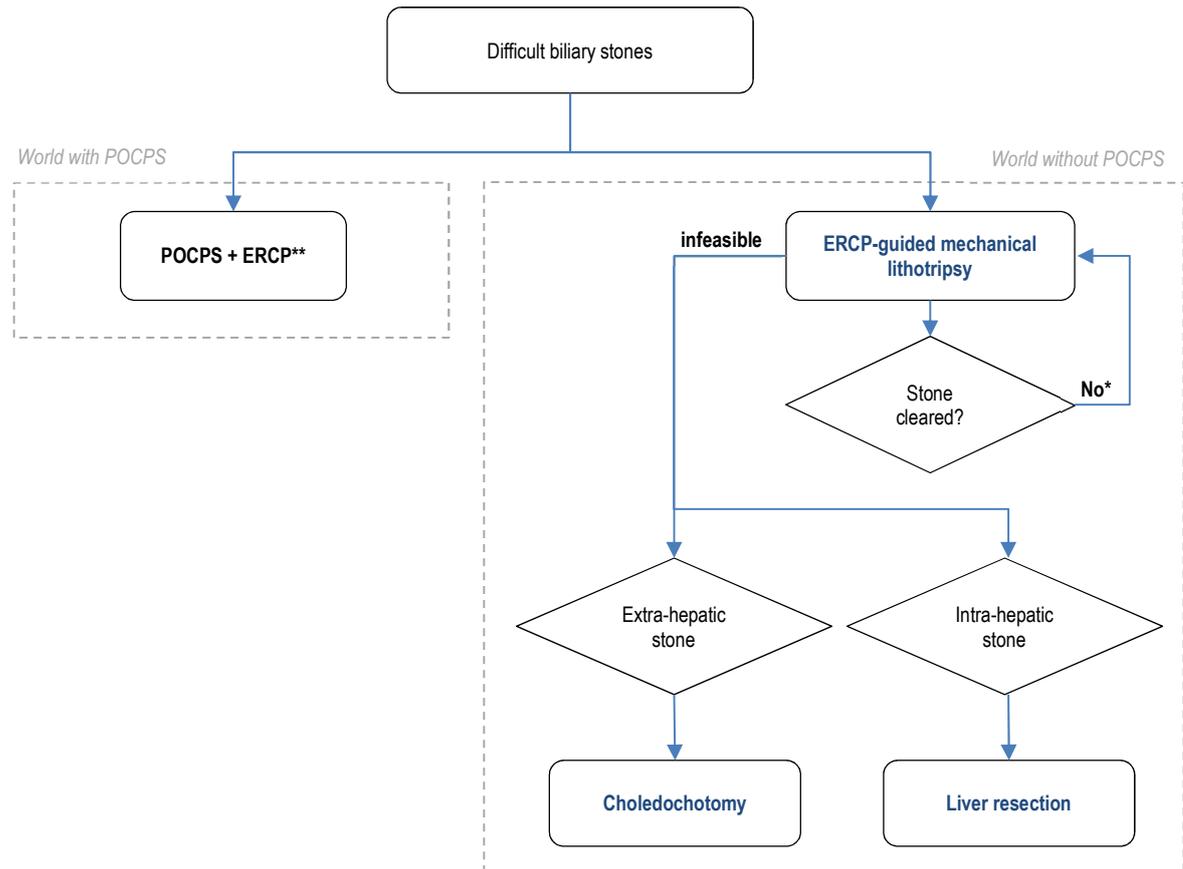
* Depending on the likelihood of malignancy, patients with indeterminate results from standard ERCP diagnostic approaches may repeat the ERCP procedure up to 2 times before surgical resection. Based on feedback from key opinion leaders, for some patients an ERCP procedure will be repeated up to 8 times.

** Procedures are unlikely to be repeated for each patient due to the high sensitivity of diagnostic POCPS vs ERCP-guided brush cytology and/or intraductal biopsy (95.5% vs 66.7%, $P < 0.02$) (23).

Therapeutic application: difficult biliary stones

A biliary stone which failed removal via conventional ERCP extraction techniques (ERCP-guided balloon/basket sphincteroplasty and mechanical lithotripsy) will typically undergo multiple repeated ERCP-guided extraction attempts before this method is deemed infeasible and surgical removal is considered. For the proportion of patients for whom ERCP-guided balloon/basket sphincteroplasty and/or mechanical lithotripsy is infeasible, surgical resection will be considered (choledochotomy for extra-hepatic stones and liver resection for intra-hepatic stones).

Figure 6 Clinical management algorithm for the removal of difficult biliary stones



Abbreviations: EHL = Electrohydraulic Lithotripsy, ERCP = Endoscopic Retrograde Cholangiopancreatography, LL = Laser Lithotripsy, POCPS = Peroral Cholangiopancreatography

Blue = Comparator to POCPS

* Depending on the surgical candidacy of the patient and the severity of the biliary obstruction, ERCP-guided extraction techniques are on average repeated up to 2 times for patients with difficult biliary stones before this method is deemed infeasible and surgical removal is considered. Based on feedback from key opinion leaders, for some patients an ERCP procedure will be repeated up to 8 times.

** Procedures are unlikely to be repeated for each patient due to the high rate of stone clearance for therapeutic POCPS vs ERCP-guided mechanical lithotripsy (100% vs 63%, P < 0.01) (24).

(a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

- In addition to (i.e. it is an add-on service)
- Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

Conventional diagnostic ERCP and/or EUS will remain as the first-line diagnostic approach for determining the malignancy of strictures. For patients who fail to achieve a diagnosis via these modalities, POCPS-

guided visualisation and/or targeted biopsy performed during an ERCP procedure will replace brush cytology and/or blind intraductal biopsy performed during an ERCP for patients.

POCPS guided EHL/LL performed during an ERCP procedure will fully replace mechanical lithotripsy performed during an ERCP procedure for patients with difficult biliary stones (failed or infeasible removal of stone via conventional ERCP extraction techniques).

POCPS guided EHL/LL performed during an ERCP procedure will partially replace choledochotomy and liver resection for the removal of difficult biliary stones. A proportion of patients who are medically contraindicated for ERCP procedures will receive surgical intervention as a first line procedure for difficult biliary stones.

41. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

The consequence of introducing POCPS for patients with indeterminate biliary strictures is expected to be a reduction in the number of repeated ERCPs and surgical resections. This is based on the feedback of multiple key opinion leaders along with an array of evidence demonstrating the superiority in achieving a diagnosis with POCPS when compared to ERCP-guided brush cytology. This is supported by multicentre, prospective studies which have cited a change in management in up to 86% of patients with indeterminate biliary strictures, with up to 25% of clinicians changing their decision to perform surgery (25, 26).

Similarly to indeterminate strictures, the consequence of introducing POCPS for patients with difficult biliary stones is expected to be a reduction in the number of repeated ERCP procedures and surgical resections. This is based on the feedback of multiple key opinion leaders, an array of evidence demonstrating the superior procedural success of POCPS when compared to ERCP-guided mechanical lithotripsy and linked evidence demonstrating the avoidance of surgery for these patients (27).

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

42. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

Diagnostic application: indeterminate biliary strictures

Based on the evidence available for the proposed medical service, POCPS has demonstrated superior procedural success (adequate tissue sampling and successful visualisation) and test accuracy without compromising safety (adverse events) when compared to ERCP-guided brush cytology and/or blind intraductal biopsy (Table 2).

A preliminary assessment of linked health outcomes has shown superiority when compared to ERCP-guided brush cytology and/or blind intraductal biopsy. POCPS has demonstrated significant change in management (change in diagnosis, utilisation, avoidance of surgery, overall impact on management) linked to superior health outcomes resulting from the treatment selected as a consequence.

Therapeutic application: difficult biliary stones

POCPS has demonstrated superior procedural success (stone clearance) without compromising safety when compared to ERCP (radiologically guided) with mechanical lithotripsy. A preliminary assessment has identified superior health outcomes linked to procedural success has demonstrated superiority when compared to the health outcomes of ERCP (radiologically guided) with brush cytology and/or blind intraductal biopsy (Table 2).

Table 2 Clinical claims for POCPS

Population	Comparator	Outcome	Clinical claim
Indeterminate biliary strictures	ERCP (radiologically guided) with brush cytology and/or blind intraductal biopsy.	Procedural success	Superior
		Test accuracy	Superior
		Safety	Non-inferior
		Linked health outcomes	Superior
Difficult biliary stones	ERCP (radiologically guided) mechanical lithotripsy	Procedural success	Superior
		Safety	Non-inferior
		Linked health outcomes	Superior
	Choledochotomy	Procedural success	Non-inferior
		Safety	Superior
		Linked health outcomes	Superior
	Liver resection	Procedural success	Non-inferior
		Safety	Superior
		Linked health outcomes	Superior

43. Please advise if the overall clinical claim is for:

- Superiority
 Non-inferiority

44. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Diagnostic application: indeterminate biliary strictures

Safety Outcomes:

Adverse events, serious adverse events, procedure related adverse events

Clinical Effectiveness Outcomes:

Procedural success: Adequate tissue sampling, successful visualisation

Test accuracy: Sensitivity, specificity, overall accuracy, negative predicted value, positive predicted value

Change in management: Change in diagnosis, utilisation, avoidance of surgery, overall impact on management

Therapeutic application: difficult biliary stones

Safety Outcomes:

Adverse events, serious adverse events, procedure related adverse events

Clinical Effectiveness Outcomes:

Procedural success: complete stone clearance, single session stone clearance, number of sessions needed for stone clearance.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

45. Estimate the prevalence and/or incidence of the proposed population:

The number of patients eligible for POCPS for diagnosis of indeterminate biliary strictures was estimated based on the number of requested ERCP MBS items in 2019 (7,847), proportion of ERCPs used for the diagnosis of indeterminate strictures (19.70%) and proportion of patients who fail an ERCP procedure (10%)(28). The number of patients eligible for POCPS for the diagnosis of indeterminate biliary strictures was estimated to be 155 in 2019.

The estimated number of patients eligible for POCPS for removal of difficult biliary stone was estimated based on the number of ERCP procedures in 2019 (7,847), proportion of ERCPs used for removal of biliary stones (45.5%) and proportion of patients who fail an ERCP procedure (10%)(28). The number of patients eligible for POCPS for the removal of difficult biliary stones was estimated to be 357 in 2019.

46. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

N/A.

POCPS is not intended to be used as an ongoing medical service.

47. How many years would the proposed medical service(s) be required for the patient?

N/A.

POCPS is not intended to be used as an ongoing medical service.

48. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

As POCPS is an acute procedure, utilisation is expected to closely reflect the number of eligible patients. Procedures are unlikely to be repeated for each patient due to the high sensitivity of diagnostic POCPS (95.5%) and high rate of stone clearance (100%) for therapeutic POCPS (23, 24).

49. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

POCPS is expected to grow at the same rate as the population. Assuming a population growth rate of 1.4%, the preliminary estimate for the number of POCPS procedures for the diagnosis of indeterminate biliary strictures over the next three years are REDACTED.

The estimated number of POCPS procedures for removal of difficult biliary stones are REDACTED.

These are both conservative estimates, with the assumption that after listing POCPS will be used in all follow up ERCP procedures. A more detailed utilisation analysis will be presented in the Assessment Report.

PART 8 – COST INFORMATION

50. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

Based on the reimbursement schedules in comparable healthcare systems, the cost of providing POCPS guided visualisation and/or tissues sampling, is estimated to cost 0.63% more than ERCP alone (\$612.90) (5). For each POCPS procedure, sphincterotomy (item 30485) is also billed, totalling the reimbursement costs to \$1,194 per procedure for the diagnosis of indeterminate biliary strictures.

Based on the reimbursement schedules in comparable healthcare systems, POCPS guided-EHL/LL is likely to cost 1.28% more than ERCP alone, accounting for the cost of lithotripsy and the additional time to extract stones (\$857.964) (5). Sphincterotomy (item 30485) is also billed for therapeutic applications of POCPS, totalling the reimbursement costs to \$1,439 per procedure for the removal of difficult biliary stones.

51. Specify how long the proposed medical service typically takes to perform:

The estimated total procedure time for POCPS -guided visualisation/biopsy of indeterminate biliary strictures, inclusive of ERCP, is 30-115 minutes (29).

The estimated total procedure time for POCPS -guided removal of difficult biliary stones, inclusive of ERCP, is 40-235 minutes (29).

52. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 5 – Diagnostic imaging services
<p>MBS XXXXX</p> <p>Single operator, single use peroral cholangiopancreatography (POCPS) with/without biopsy, for the diagnosis of indeterminate biliary strictures, defined as strictures with indeterminate results from conventional diagnostic ERCP and/or EUS procedures, during an endoscopic retrograde cholangiopancreatography (ERCP) procedure, not being a service to which item 30484 is applied.</p> <p>(Anaes.)</p> <p>Fee: \$612.90 Benefit: 75% = \$459.68</p>

Category 3 – Therapeutic Procedures
<p>MBS XXXXX</p> <p>Single operator, single use peroral cholangiopancreatography (POCPS) guided electrohydraulic/laser lithotripsy for removal of difficult bile stones, defined as stones with failed or infeasible removal via conventional ERCP extraction techniques, during an endoscopic retrograde cholangiopancreatography (ERCP) procedure, not being a service to which item 30484 is applied.</p> <p>(Anaes.)</p> <p>Fee: \$857.96 Benefit: 75% = \$643.47</p>

Appendix I

Table 3: TGA registered POCPS devices and accessories used for the diagnosis of indeterminate strictures and removal of difficult bile stones

Population	ARTG number	Approval date	Manufacturer	Product name	Intended purpose
Both	236205 ^b	14/04/2015	Boston Scientific Corporation	Flexible video choledochoscope	The Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts
Both	335180 ^a	25/04/2020	Boston Scientific Corporation	Light source/processing unit, endoscope	A dedicated line powered device, functioning as both a light source and a processing unit intended to be used together with endoscopes, primarily video endoscopes. Specifically, the device is intended to provide illumination and receive, process, and output images
Indeterminate biliary strictures	137089 ^b	2/04/2007	Boston Scientific Corporation	Endoscopic forceps, biopsy, flexible	Single use biopsy forceps intended to collect tissue endoscopically for histologic examination.
Difficult biliary stones	290522 ^b	21/06/2017	Northgate Technologies Inc (Nortech)	Lithotripter, internal, electrohydraulic	The probe is intended to be used with an Electrohydraulic Lithotripter for the intracorporeal fragmentation of urinary/renal and biliary stones (calculi).
	290314 ^c	16/06/2017	Northgate Technologies Inc (Nortech)	Lithotripter, internal, electrohydraulic	Indicated to be used with an Electrohydraulic Lithotripsy (EHL) Probe for the intracorporeal fragmentation of urinary/renal and biliary stones (calculi).
	320152 ^b	15/07/2019	Boston Scientific Corporation	Urogenital surgical laser system beam guide, single-use	Intended to be connected to a surgical laser system to direct and deliver laser energy for surgical incision/excision, vaporization, ablation, hemostasis, and coagulation of soft tissue. Surgical procedures can include treatment for Benign Prostatic Hyperplasia (BPH) and other soft tissue applications including bladder tumors and urethral strictures
	287772 ^c	11/04/2017	Boston Scientific Corporation	Surgical Ho:YAG laser system	A mains electricity (AC-powered) device assembly in which input energy is used to excite a doped glass/crystal medium to emit a high I-power laser beam intended for general surgery and multiple specialised surgical applications (non-dedicated). It vaporise or ablates soft tissue with moderate haemostasis, little charring, and thin zone of necrosis. It includes a light source, delivery or positioning device(s), controls and foot-switch and emits a midinfrared wavelength. It does not include frequency doubling technology.

a Medical device class I

b Medical device class IIa

c Medical device class IIb

Source: <https://www.ebs.tga.gov.au/>, accessed February 2021

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