TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: **Porfimer sodium**

INDICATION: Cholangiocarcinoma of the biliary tract, unresectable, after double stenting

COMPENDIA TRANSPARENCY REQUIREMENTS	
1	Provide criteria used to evaluate/prioritize the request (therapy)
2	Disclose evidentiary materials reviewed or considered
3	Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest
4	Provide meeting minutes and records of votes for disposition of the request (therapy)

EVALUATION/PRIORITIZATION CRITERIA: **A, C, S**
*to meet requirement 1

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant **advance** over current therapies
C	**Cancer** or cancer-related condition
E	Quantity and robustness of **evidence** for use support consideration
L	**Limited** alternative therapies exist for condition of interest
P	**Pediatric** condition
R	**Rare** disease
S	**Serious**, life-threatening condition

Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]

TRUVEN HEALTH ANALYTICS

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Ortner,M.E.J., et al: Successful Photodynamic Therapy for Nonresectable Cholangiocarcinoma: A Randomized Prospective Study. Gastroenterology Nov 2003; Vol 125, Issue 5; pp. 1355-1363	Key bias criteria evaluated were (1) random sequence generation of randomization, (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, and no additional biases were identified.	S
Gao,F., et al: Systematic review: Photodynamic therapy for unresectable cholangiocarcinoma. Journal of Hepato-Biliary-Pancreatic Sciences 2010; Vol 17, Issue 2; pp. 125-131.		3
Cheon,Y.K., et al: Longterm outcome of photodynamic therapy compared with biliary stenting alone in patients with advanced hilar cholangiocarcinoma. HPB Mar 2012; Vol 14, Issue 3; pp. 185-193.		3
Knuppel,M., et al: Combination of conservative and interventional therapy strategies for intra- and extrahepatic cholangiocellular carcinoma: A retrospective survival analysis. Gastroenterology Research and Practice 2012		3

Witzigmann,H., et al: Surgical and palliative management and outcome in 184 patients with hilar cholangiocarcinoma: palliative photodynamic therapy plus stenting is comparable to r1/r2 resection. Ann Surg Aug 2006; Vol 244, Issue 2; pp. 230-239.		3
Kahaleh,M., et al: Unresectable Cholangiocarcinoma: Comparison of Survival in Biliary Stenting Alone Versus Stenting With Photodynamic Therapy. Clinical Gastroenterology and Hepatology 2008; Vol 6, Issue 3; pp. 290-297		3
Quyn,A.J., et al: Photodynamic therapy is associated with an improvement in survival in patients with irresectable hilar cholangiocarcinoma. HPB 2009; Vol 11, Issue 7; pp. 570-577.		3
Pereira,S.P., et al: Safety and long term efficacy of porfimer sodium photodynamic therapy in locally advanced biliary tract carcinoma. Photodiagnosis and Photodynamic Therapy 2012; Vol 9, Issue 4; pp. 287-292		3
Itoi,T., et al: Salvage therapy in patients with unresectable hilar cholangiocarcinoma. Digestive Endoscopy Jul 2006; Vol 18, Issue 3; pp. 232-238.		3

Dumoulin,F.L., et al: Phase II study of photodynamic therapy and metal stent as palliative treatment for nonresectable hilar cholangiocarcinoma. Gastrointestinal Endoscopy Jun 2003; Vol 57, Issue 7; pp. 860-867.		3
Berr,F., et al: Photodynamic therapy for advanced bile duct cancer: evidence for improved palliation and extended survival. Hepatology Feb 2000; Vol 31, Issue 2; pp. 291-298		3
Fuks,D., et al: Biliary drainage, photodynamic therapy and chemotherapy for unresectable cholangiocarcinoma with jaundice. Journal of Gastroenterology and Hepatology 2009; Vol 24, Issue 11; pp. 1745-1752.		3
Harewood,G.C., et al: Pilot study to assess patient outcomes following endoscopic application of photodynamic therapy for advanced cholangiocarcinoma. Journal of Gastroenterology and Hepatology 2005; Vol 20, Issue 3; pp. 415-420.		3
Shim,C.S.: Photodynamic therapy for hilar cholangiocarcinoma. Photodiagnosis and Photodynamic Therapy 2011; Vol 8, Issue 2; pp. 218-219		4

Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	Thomas McNeil Beck, MD	None
Felicia Gelsey, MS	None	Jeffrey A. Bubis, DO	Other payments: Dendreon
		James E. Liebmann, MD	None
		Keith A. Thompson, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, DO	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	PDT has been always posed as an interesting approach in a variety of cancer issues. This approach seems intriguing. Would like more data, however, to improve the “strength of recommendation.”	N/A
Thomas McNeil Beck, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	A large benefit in a small number of cases - a rare disease entity. Confirmatory studies could be done. I am uncertain of the availability of this technology.	N/A
Jeffrey A. Bubis, DO	Effective	Class IIa - Recommended, In Most Cases	In a randomized trial, overall survival was improved.	N/A

James E. Liebmann, MD	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	Unresectable cholangiocarcinoma is a miserable disease which responds poorly to treatment and is uniformly fatal. The Ortner, et al study is intriguing. There is a biologic and anatomic rationale for photodynamic therapy in this cancer and the 5-fold increase in median survival in the PDT-treated group is remarkable (though the 98 day median OS in the control group seems short). A recent review (Lee TY, Clin Endosc, 46(1):38-44, 1/2013) noted one other, even smaller, randomized trial of PDT that resulted in improved survival in patients with cholangiocarcinoma. What is lacking, of course, is a trial of PDT vs standard chemotherapy (cisplatin/gemcitabine) or hepatic artery infusion/embolization. Intra-biliary PDT should only be performed in a center with experience with the procedure.	N/A
Keith A. Thompson, MD	Effective	Class IIa - Recommended, In Most Cases	None	N/A