Transjugular Intrahepatic Portosystemic Shunt (TIPS)

Archived Medical Policy

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Policy # 00124
Original Effective Date: 08/26/2002
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), except when changed by contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Policy / Guidelines
Based on review of available data, the Company may consider transjugular intrahepatic portosystemic shunt (TIPS) to be eligible for coverage.

Coverage may be provided when:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Patient Selection Criteria
TIPS may be considered eligible for coverage in the following circumstances:

- Treatment of acute variceal bleeding that cannot be successfully controlled with medical treatment or sclerotherapy; or
- Treatment of recurrent variceal bleeding in patients who are resistant to, or intolerant of, conventional medical management, sclerotherapy, or pharmacologic therapy; or
- Treatment of refractory ascites; or
- As initial therapy of variceal hemorrhage; or
- As a prophylactic therapy in patients considered at high risk for initial variceal bleeding.

Background/Overview
Transjugular intrahepatic portosystemic shunt, or TIPS, is used to create a low-resistance channel between the hepatic vein and the intrahepatic portion of the portal vein by deployment of an expandable metal stent. TIPS functions like a side-to-side surgical portacaval shunt, but its placement does not require anesthesia and major surgery.

The TIPS procedure has been investigated as a treatment of many of the complications of portal hypertension; i.e., acute and chronic variceal varices and refractory ascites. TIPS has also been used prophylactically in liver transplant candidates who are awaiting a donor organ and who are considered at high risk of variceal bleeding.

Rationale/Source
The TIPS procedure was initially investigated and has been widely used as a treatment of both acute and recurrent varices. Treatment alternatives include various types of transesophageal endoscopic therapy, such as sclerotherapy or ligation. Several randomized trials comparing TIPS with sclerotherapy or ligation...
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as a treatment of variceal rebleeding have been published. As an example, in 1997, Rossle and colleagues published a study of 126 patients with a history of variceal bleeding to receive either a TIPS procedure of endoscopic treatment consisting of sclerotherapy or banding/ligation. During a mean 14-month follow-up period, the 1-year rebleeding rate was 15% in the patients undergoing TIPS compared to 41% in the endoscopically treated group. The transjugular-intrahepatic-portosystemic shunt is a new interventional treatment for portal hypertension. The aim of their study was to compare the transjugular shunt with endoscopic treatment for the prophylaxis of recurrent variceal bleeding. Although there was no difference in survival between the 2 groups, the incidence of hepatic encephalopathy was higher in the shunt group (36% vs. 18%, p = 0.011). These results are similar to the randomized study of Sauer and colleagues and Cabrera and colleagues who also reported that, compared to transendoscopic treatment, TIPS was associated with a decreased rebleeding rate but higher incidence of hepatic encephalopathy. While the randomized trial of Pomier-Layrargues and colleagues reported a similar incidence of hepatic encephalopathy in both the sclerotherapy and TIPS group, it should be noted that unlike other studies, hepatic encephalopathy was reported in a very high percentage of the sclerotherapy group. Overall, these results suggest that the TIPS procedure should be limited to those patients with variceal bleeding who fail initial transesophageal endoscopic therapy.

More recently, the technique has been investigated as a treatment of refractory ascites associated with portal hypertension, and a prophylactic technique in liver transplant candidates with esophageal varices considered at high risk of esophageal bleeding. Alternative treatments for ascites include periodic paracentesis or peritoneovenous shunting. In 2000, Rossle and colleagues published a trial of 60 patients with refractory or recurrent ascites who were randomly assigned to either large volume paracentesis or a TIPS procedure. (6) A complete response was defined as the elimination of ascites and a partial response as the presence of ascites not requiring paracentesis. The primary outcome was survival without liver transplantation. The mean follow-up was 44 to 45 months. Among patients in the TIPS group, 15 of the 29 died and 1 underwent liver transplantation. In the paracentesis group, 23 of the 31 patients died, and 2 required liver transplantation. While this difference was not statistically significant on univariate analysis, the difference was statistically significant in a multivariate analysis that adjusted for differences in clinical variable between the 2 groups. These results contrast with an earlier, smaller randomized trial of 25 patients, in which those assigned to the paracentesis group had improved survival. However, the small size of the trial and the fact that the shunt procedure failed in 25% of the patients limit interpretation. While clearly patients with refractory ascites represent a patient population with a grim overall prognosis, the TIPS procedure may be considered as a treatment alternative to repeated paracenteses.

A review of the peer-reviewed literature on MEDLINE from the period of 2001 through February 2003 found articles on 4 randomized controlled trials that support the current policy positions. For treatment of variceal bleeding, the recent Sauer trial found endoscopic ligation plus propranolol was preferred for initial treatment for prevention of recurrent variceal bleeding and recommended reserving TIPS for recurrent bleeding after failure of adequate endoscopic and pharmacologic treatment. The Escorsell trial compared TIPS for
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prevention of variceal rebleeding to drug therapy alone using propranolol plus isosorbide-5-mononitrate and also recommended TIPS should not be used as first-line therapy but only after failure of medical and endoscopic treatments. In a comparison of TIPS versus endoscopic variceal band ligation, Gulberg and colleagues found similar mortality rates in both groups and concluded TIPS was not superior to variceal band ligation. For treatment of refractory ascites in 70 cirrhosis patients comparing TIPS versus paracentesis plus albumin, Gines and colleagues found TIPS reduced the rate of ascites recurrence and hepatorenal syndrome. However, in the TIPS group, patient survival rates did not improve and the frequency of severe encephalopathy increased when compared to the paracentesis group. Each of these study conclusions are consistent with the above statements that TIPS should be limited to patients who fail first-line treatments for variceal rebleeding and refractory ascites; therefore, the policy statement is unchanged.

References

Policy History
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08/31/2004 Medical Director review
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*Investigational* - A medical treatment or procedure, a drug, device, or biological product, is investigational if the efficacy has not been clearly tested or which has not been incorporated into standard medical practice. Any determination that a medical treatment or procedure, a drug, device, or biological product, is investigational will be made by Us in our sole discretion. Such determinations may be made based on the determination that the medical treatment or procedure, drug, device, or biological product:
A. Cannot be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and which has not been approved for marketing at the time the drug or device is sought to be furnished; or
B. Needs further studies or clinical trials to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s);
2. Published reports and articles in authoritative medical and scientific literature;
3. Reference to federal regulations; or
4. Consultation with provider organizations or committees.
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