



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Transjugular Intrahepatic Portosystemic Shunts (TIPS)

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Coverage Policy

CIGNA covers the insertion of a transjugular intrahepatic portosystemic shunt (TIPS) as medically necessary for esophageal, gastric or ectopic variceal bleeding or ascites when there is failure, contraindication or intolerance of conventional medical management, including sclerotherapy and pharmacologic therapy.

CIGNA does not cover the insertion of a transjugular intrahepatic portosystemic shunt (TIPS) for any other indication including prophylactic care or initial treatment of esophageal, gastric or ectopic varices because it is considered not medically necessary.

General Background

The liver performs numerous functions that are critical for life including the storage of vitamins, conversion of nutrients into clotting factors and bile, and detoxification of blood. When the liver fails, these processes are impeded, resulting in multi-system effects. Some of the more serious complications that can occur as a result of liver disease are the development of portal hypertension, varices (i.e., esophageal, gastric or ectopic), jaundice, cholestasis, liver enlargement, ascites (i.e. an accumulation of fluid in the abdominal cavity), hepatic encephalopathy, and renal failure (LaBerge, 2006; Singhal, 2006). The transjugular intrahepatic portosystemic

shunt (TIPS) has been proposed as an option for the treatment of varices or ascites when other established treatments (i.e., pharmacotherapy, banding, sclerosing, ligation or paracentesis) have either failed or are contraindicated, or the patient is intolerant to those treatments.

Varices

Varices are dilated veins caused by elevated pressure in the portal venous system. The most common locations for varices are within the walls of the esophagus, stomach/duodenum, or rectum. The initial treatment of esophageal varices includes those aimed at reducing their risk of bleeding. This may include the use of nonselective beta-blockers (e.g., propranolol, timolol, or nadolol) and nitrates. When bleeding does occur, endoscopic therapeutic measures may include the use of variceal ligation, banding or sclerosing. Varices that are refractory to these therapeutic measures may require the additional support of a balloon tamponade (i.e., as a bridge to additional endoscopic therapy [ET]), the surgical formation of a distal splenorenal shunt or a liver transplant (LaBerge, 2006).

The presence of gastric varices may be found during a screening endoscopy if caused by portal hypertension. They may also be suspected when physical examination reveals signs of portal hypertension or chronic liver disease, including ascites, splenomegaly, or dilated abdominal veins. The initial treatment of gastric variceal hemorrhage includes endoscopic injection or obliteration. A therapeutic paracentesis may be performed to relieve pressure on the lungs, liver and pancreas caused by the build-up of ascitic fluid. When bleeding cannot be controlled by these measures, a balloon occluded retrograde transvenous obliteration (i.e., BORTO) may be performed; gastric variceal ligation or an intra-gastric balloon tamponade may be placed as a bridge to further therapy. Liver transplantation may also be suggested (Ginès, 2007; LaBerge, 2006; Prakash, 2003).

Ectopic varices are large portosystemic venous collaterals that appear anywhere in the abdomen except within the cardioesophageal region. These varices are commonly found during endoscopic examination in patients with portal hypertension. Although ectopic varices can occur at several sites, bleeding varices are most commonly found in the duodenum and at sites of previous bowel surgery, including stomas. Management of bleeding from these varices depends on the cause of portal hypertension. Pharmacologic therapy may be initiated to reduce splanchnic blood flow and variceal pressure from esophagogastric varices. Once the source of the bleeding is identified, therapy is focused on sclerosing or embolizing the vessels that surround and feed the varix. Banding may not be beneficial on these vessels unless the entire vessel can be isolated. If bleeding continues in spite of embolization of the ectopic varices, the patient may need to undergo surgical excision/ligation of the varix or the creation of a portosystemic shunt (Wolf, 2007; LaBerge, 2006).

Transjugular Intrahepatic Portosystemic Shunt (TIPS)

The TIPS procedure has been developed in an attempt to improve patient morbidity and mortality outcomes. This nonsurgical procedure can be performed under local anesthesia, which decreases the additional risks of general anesthesia (Prakash, 2003). A TIPS forms a fistula between the hepatic vein and portal vein that bypasses the liver and is created under fluoroscopic and ultrasonographic guidance. The technique for constructing a TIPS involves passing a catheter through the jugular vein to the level of the hepatic vein. An expandable stent is inserted to maintain the shunt between the portal and hepatic veins. The goal of this shunt creation is to decrease portal pressure gradients to less than the 12 mm Hg necessary for the formation of esophageal varices (LaBerge, 2006; Singhal, 2006).

A TIPS may be recommended if variceal bleeding recurs after two or more endoscopic attempts at preventing rebleeding. The procedure has also been associated with favorable effects in renal function, including an increase in sodium excretion and reduction in the activity of antinatriuretic systems, which result in the elimination of ascites in some patients and the decrease of diuretic requirements in others. The technical success rate in constructing a TIPS is more than 90%, with almost universal control of active bleeding. When necessary, the shunt can be revised with low morbidity rates. The frequency of patients requiring TIPS revision within the first year after placement is as high as 67% but drops to below 40% in subsequent years. Other limitations to TIPS include the development of transient deterioration of liver function in 20–30% of patients, and up to 25% of these patients may also develop new or worsened encephalopathy. Contraindications to the TIPS procedure include portal vein thrombosis, inferior vena cava obstruction, and polycystic liver disease; worsening liver failure with encephalopathy, coagulopathy, hepatoma, and sepsis (Singhal, 2006; Prakash, 2003).

U.S. Food and Drug Administration (FDA)

There are several commercially available shunts and specifically designed systems that may be used to perform a TIPS procedure. These sets are approved by the FDA's Center for Devices and Radiological Health (CDRH). The Wallstent® TIPS (manufactured by Boston Scientific Corp., Plymouth, MN.) was the first transjugular intrahepatic portosystemic shunt to receive approval by the CDRH in January 1998. Other systems include the Colapinto® transjugular and biopsy set, the Haskal® TIPS set, the Rosch-Uchida® transjugular liver access set (manufactured by Cook, Inc., Bloomington, IN); and the Angiodynamics® TIPS set (manufactured by Angiodynamics, Queensbury, NY) (this list may not be all-inclusive).

Literature Review

The safety and efficacy of TIPS for variceal bleeding and ascites has been investigated in randomized controlled trials (RCTs). Study populations have ranged from 85–140 with follow-up ranging from 16–60 months. TIPS has been compared to peritoneovenous (PV) shunts, distal spleno-renal shunt (DSRS), endoscopic variceal ligation (EVL), and medical therapy. Studies have demonstrated either no significant differences between treatments in the resolution of ascites, rebleeding rates, and length of survival or greater improvement with the placement of a TIPS (Narahara, et al., 2010; Henderson, et al., 2006; Rosemurgy, et al., 2004; Sanyal, et al. 2003; Sauer, et al., 2002). Several meta-analyses of RCTs have also evaluated and supported the effectiveness of TIPS (Salerno, et al., 2007; Khan, et al., 2006; Saab, et al., 2006; D'Amico, et al., 2005). Hepatic encephalopathy has been observed more often in TIPS patients compared to those who receive comparable interventions.

Professional Societies/Organizations

Clinical guidelines from the European Association for the Study of the Liver (EASL) state that repeated large-volume paracentesis plus albumin is the first line of treatment for refractory ascites. TIPS should be considered in patients with very frequent requirement of large-volume paracentesis, or in those in whom paracentesis is ineffective (e.g., due to the presence of loculated ascites). In selected patients the procedure may be helpful for recurrent symptomatic hepatic hydrothorax. TIPS cannot be recommended in patients with severe liver failure, concomitant active infection, progressive renal failure, or severe cardiopulmonary diseases (EASL, 2010).

The American Association for the Study of Liver Diseases (AASLD) published updated guidelines in 2009 on the role of TIPS in the management of portal hypertension. The AASLD guidance on the use of TIPS for varices includes the following:

- The use of TIPS to prevent bleeding from varices that have never bled is contraindicated because of increased risk of morbidity and mortality.
- TIPS is effective in controlling acute bleeding from varices that is refractory to medical therapy and is preferred to surgery in this situation.
- TIPS should not be used for the prevention of rebleeding in patients who have bled only once from esophageal varices, and its use should be limited to those who fail pharmacological and endoscopic therapy.
- A TIPS is effective in the prevention of rebleeding from gastric and ectopic varices (including intestinal, stomal, and anorectal varices) and is the preferred approach for the prevention of rebleeding in this group of patients.
- In patients with good liver function, either a TIPS or a surgical shunt are appropriate choices for the prevention of rebleeding in patients who have failed medical therapy.
- In patients with poor liver function, TIPS is preferred to surgical therapy for the prevention of rebleeding in patients who have failed medical therapy.

The AASLD guidelines for the use of TIPS as treatment of ascites associated with cirrhosis, refractory hepatic hydrothorax, and hepatorenal syndrome (HRS) are:

- Although TIPS will decrease the need for repeated large-volume paracentesis in patients with refractory ascites associated with cirrhosis, it should be used only in those patients who are intolerant of repeated large-volume paracentesis.
- A TIPS is effective in the control of hepatic hydrothorax, but it should be used only in patients whose effusion cannot be controlled by diuretics and sodium restriction.
- A TIPS is not recommended for the treatment of HRS, especially type 1 HRS, pending the publication of controlled trials.

Their guidance for TIPS usage for Budd-Chiari Syndrome (BCS), veno-occlusive disease or sinusoidal obstruction syndrome and hepatopulmonary syndrome include:

- The decision to create a TIPS in a patient with BCS should be based on the severity of disease, and only patients with moderate disease appear to be reasonable candidates for a TIPS.
- Patients with BCS and mild disease can be managed medically, whereas those with more severe disease or acute hepatic failure are best managed by liver transplantation.
- The use of TIPS to treat sinusoidal obstruction syndrome cannot be recommended.
- The use of TIPS to treat hepatopulmonary syndrome is recommended (Boyer and Haskal, 2010).

A practice guideline issued by the World Gastroenterology Organization (WGO) in 2008 states that a TIPS is a good alternative for the management of esophageal varices and variceal hemorrhage when endoscopic treatment and pharmacotherapy fail. TIPS should also be considered in uncontrollable fundic variceal bleeding or recurrence despite combined pharmacological and endoscopic therapy. The WGO guideline notes that portosystemic shunts are associated with lower rates of variceal rebleeding in comparison to sclerotherapy/banding, but they increase the incidence of hepatic encephalopathy (WGO, 2008).

The American Association for the Study of Liver Diseases (AASLD) guidelines on the prevention and management of gastroesophageal varices and variceal hemorrhage in cirrhosis state that shunt therapy (i.e., surgery or TIPS) should not be used in the primary prevention of variceal hemorrhage because clinical trials have shown that shunting blood away from the liver is accompanied by more frequent encephalopathy and higher mortality. TIPS should be considered in patients who are Child A or B who experience recurrent variceal hemorrhage despite combination pharmacological and endoscopic therapy (AASLD, 2007).

Summary

Numerous studies have been published in the evidence-based peer-reviewed literature supporting the use of transjugular intrahepatic portosystemic shunts (TIPS) in the treatment of varices that are refractory to medical and pharmacological management. Patients who undergo a TIPS procedure may require additional surveillance in order to ensure that the shunt placement and patency remain open for therapeutic effects. This procedure is also described within numerous textbooks as part of the armamentarium of treatment modalities for ascites, portal hypertension and varices that are refractory to medical management.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (TIPS) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (TIPS) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recanalization/dilatation, stent placement and all associated imaging guidance and documentation)

ICD-9-CM Diagnosis Codes	Description
456.0	Esophageal varices with bleeding
456.20	Esophageal varices in diseases classified elsewhere; with bleeding
456.8	Varices of other sites

789.51 – 789.59	Ascites
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Not Medically Necessary/Not Covered when used to report the insertion of a transjugular intrahepatic portosystemic shunt (TIPS) for any other indication including prophylactic care or initial treatment of esophageal, gastric or ectopic varices:

ICD-9-CM Diagnosis Codes	Description
V07.8	Need for other specified prophylactic or treatment measure
V07.9	Unspecified prophylactic or treatment measure All other codes

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	7/15/2008	0461	Transjugular Intrahepatic Portosystemic Shunts (TIPS)

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