
Medical Policy



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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: TRANSPLANT-LUNG/DOUBLE LUNG AND LIVER (COMBINED)

Description/Background

Combined transplantation of the lungs and liver is recommended for patients who would not be expected to survive sequential transplantation of the organs. This option should be considered for patients with end-stage lung and liver disease with acceptable long-term prognosis who have failed standard medical and surgical therapy. In the combined double-lung and liver transplant, both the recipient's lungs and diseased liver are removed and replaced by the donor's lungs and liver. All thoracic and abdominal organs are obtained from a single donor by means of standard harvest techniques. Patients awaiting combined double lung and liver transplant are enrolled through the United Network for Organ Sharing Organ Procurement and Transplantation Network database.

Regulatory Status

N/A

Medical Policy Statement

Combined lung and double lung and liver transplants have been established. It may be considered a useful therapeutic procedure in carefully selected patients when criteria are met.

Inclusionary and Exclusionary Guidelines

Note: Final patient eligibility for combined lung/liver transplant is subject to the judgment and discretion of the requesting transplant center. Please refer to the Liver Transplant policy for full inclusionary criteria for liver transplant patients, and Lung/Double Lung Transplant policy for full inclusionary criteria for lung transplant patients.

Inclusions:

Combined lung, double lung and liver transplantation may be indicated in individuals who qualify for lung, double lung or liver transplantation and have advanced irreversible lung or liver disease.

Indications for combined lung-double lung and liver transplant include but are not limited to progressive chronic lung/liver disease unresponsive to other medical and surgical therapy. In general, patients are selected for combined lung-liver transplant if one or more of the following apply:

- A lung transplant is typically required for irreversible, chronic lung diseases for which there is no further medical or surgical therapy available and survival is limited.
- Bilateral lung transplantation is typically required when chronic lung infection disease is present, i.e., associated with cystic fibrosis and bronchiectasis. Some but not all cases of pulmonary hypertension will require bilateral lung transplantation.
- A liver transplant is typically required for irreversibly damaged livers for which there is no further medical or surgical therapy available, prognosis is poor and end stage liver disease (e.g., alcoholic liver disease, viral hepatitis, autoimmune hepatitis, protoporphyria, biliary cirrhosis, vascular disease, trauma or toxic reactions, etc.)
- End stage lung disease and end stage liver disease not amenable to any other form of therapy

The consideration for risk-reducing procedure (e.g., CABG) performed at the same time as the organ transplant is a consideration based on the medical consultation review.

Exclusions:

- Lung, double lung and liver combined transplants are considered investigational in all other situations.

Potential Contraindications for Transplant/Retransplant:

Note: Final patient eligibility for transplant is subject to the judgment and discretion of the requesting transplant center.

Potential contraindications represent situations where proceeding with transplant is not advisable in the context of limited organ availability. Contraindications may evolve over time as transplant experience grows in the medical community. Clinical documentation supplied to the health plan should demonstrate that attending staff at the transplant center have considered *all* contraindications as part of their overall evaluation of potential organ transplant recipients and have decided to proceed.

- Known current malignancy, including metastatic cancer;
- Recent malignancy with high risk of recurrence;
- History of cancer with moderate risk of recurrence;
- Untreated systemic infection making immunosuppression unsafe, including chronic infection;
- Other irreversible end-stage disease not attributed to liver or lung disease;
- Systemic disease that could be exacerbated by immunosuppression;
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Liver Specific Guidelines for Alcohol Related Hepatitis

- Patients with ongoing alcohol and/or drug abuse. (Evidence for abstinence may vary among liver transplant programs, but generally, a minimum of 3 months is required or enrollment in a sanctioned program)
- Patients who are being considered for approval for a liver transplant who have liver disease related to alcohol use disorder must be evaluated for ongoing alcohol use.
- To determine candidacy for liver transplant in the setting of alcohol related hepatitis, guidelines such as the Dallas consensus criteria and the SALT criteria must be met. (see appendix for additional information).

All transplants must be prior authorized through the Human Organ Transplant Program.

*Please note there are individual transplant policies for each of these organs (Lung Transplant, Liver Transplant) which contain more detailed information.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

47133	47135	47136	47140	47141	47142
47143	47144	47145	47146	47147	32850
32853	32854	32855	32856		

Other codes (investigational, not medically necessary, etc.):

N/A

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition.

Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

Due to the nature of the disease condition, there are no randomized controlled trials comparing double lung and liver transplant with alternatives. Systematic reviews are based on case series and registry data. The extant randomized controlled trials compare surgical technique, infection prophylaxis, and immunosuppressive therapy and are not germane to this evidence review.

Between 1990 and 1995, Couetil et al (1995), studied combined heart-lung or lung-liver transplantation among 25 patients accepted for the combined transplant program.¹ Among the 25 patients, nine died awaiting transplantation and 10 underwent one of the following procedures: heart-lung-liver transplantation (n=5), en bloc double lung-liver transplantation (n=1), sequential double lung-liver transplantation (n=3), and bilateral lobar lung transplantation from a split left lung and reduced liver transplantation (n=1). There were 5 male and 5 female patients. The ages of the recipients ranged from 10 to 24 years. Mean forced expiratory volume in 1 second was 29% and mean forced vital capacity was 35% of predicted values. All patients were infected with resistant *Pseudomonas*, three with *Pseudomonas cepacea*, and two patients had *Aspergillus* species in addition. All patients had severe cirrhosis with portal hypertension. Four patients had a history of esophageal variceal bleeding and two had had previous portosystemic shunts. The operation was performed as a two-stage procedure, the intrathoracic operation being completed before the abdominal stage was begun. Cardiopulmonary bypass was used in all patients because of poor clinical condition. Immunosuppression consisted of azathioprine, cyclosporine, and prednisone, as for isolated lung transplantation. There were two perioperative deaths, one caused by primary liver failure and the second by early lung dysfunction. For the first 3 months after transplantation pulmonary infection was the most common cause of morbidity. Other complications included tracheal stenosis (n = 1), bronchial stenosis (n = 1), biliary stricture (n = 2), and severe ascites (n = 3). All were successfully treated. Obliterative bronchiolitis developed in three patients. This was stabilized with FK 506 in two patients; the other patient underwent retransplantation at 38 months but eventually died of bleeding. Actuarial survival was 70% at 1 year and remained unchanged at 3 years. Significant functional improvement was observed in all survivors. The authors concluded that for patients who have chronic respiratory failure with advanced cirrhosis, lung transplantation combined with liver transplantation can be performed with a satisfactory outcome.

Yi et al (2014) reviewed a large single-center combined lung and liver transplantation (CLLT).² Eight consecutive CLLT performed during 2009-2012 were retrospectively reviewed. One patient received a third simultaneous heart transplant. Mean age was 42.5 ± 11.5 years. Pulmonary indications included cystic fibrosis (CF) (n = 3), idiopathic pulmonary fibrosis (n = 2), α 1-antitrypsin deficiency (AATD) (n = 1) and pulmonary hypertension (n = 2). Liver indications were CF (n = 3), hepatitis C (n = 2), AATD (n = 1), cryptogenic (n = 1), and cardiac/congestive (n = 1). Urgency was reflected by median lung allocation score (LAS) of 41 (36.0-89.0) and median predicted FEV1 of 25.7%. Median donor age was 25 (20-58) years with median cold ischemia times of 147 minutes and 6.1 hours for lung and liver, respectively. Overall patient survival at 30 days, 90 days and 1 year was 87.5%, 75.0% and 71.4%, respectively. One patient had evidence of acute lung rejection, and no patients had liver allograft rejection. Early postoperative mortalities (90 days) were caused by sepsis in 2

recipients who exhibited the highest LAS of 69.9 and 89.0. The remaining recipients had a median LAS of 39.5 and 100% survival at 1-year. Median length of stay was 25 days (7-181). Complications requiring operative intervention included bile duct ischemia (n = 1) and bile leak (n = 1), ischemia of the bronchial anastomosis (n = 1), and necrotizing pancreatitis with duodenal perforation (n = 1). This series reflects a large single-center CLLT experience. Sepsis is the most common cause of death. The procedure should be considered for candidates with LAS < 50.

According to Salman et al (2018), combined lung and liver transplantation is an established therapy for patients with cystic fibrosis.³ The initial sequence has primarily been lung first. The sequence changed to liver first in 2006. The author presents outcomes of this procedure. The records of combined lung and liver transplant patients treated at one institution between April 1999 and November 2016 were reviewed retrospectively. A total of 27 patients received a combined lung-liver transplant at this facility. Seventeen patients underwent lung-liver transplant beginning with the lung transplantation. In this group, 5 patients had cystic fibrosis (lung first). The other 10 patients received the liver transplant first (liver first). All patients in this group had cystic fibrosis as underlying disease. The lung-first group showed a trend towards longer stays in the intensive care unit (ICU) and in the hospital [median 17 days in the ICU, interquartile range (IQR) 3-47 and 55 in-hospital days, IQR 29-108] than the liver-first group (median 6 days in the ICU, IQR 4-19 and 33 in hospital days, IQR 26-63). The 90-day, 1- and 5-year survival rates were 80%, 60% and 20% in the lung-first group vs. 90%, 79% and 79% in the liver-first group. The author concluded that the liver-first sequence results in favorable outcomes in the cohort of combined lung-liver transplants.

Freischlag et al (2018) reviewed institutional medical records and United Network for Organ Sharing database for patients at an institution that underwent lung-liver transplants (LLT) from 2000 to 2016.⁴ Twelve LLTs were performed from 2000 to 2016 including 9 male and 3 female recipients with a median age of 28.36 years. Indications for lung transplantation were cystic fibrosis, idiopathic pulmonary fibrosis, and pulmonary fibrosis secondary to hepatopulmonary syndrome. Indications for liver transplantation were cystic fibrosis, alcoholic cirrhosis, idiopathic cirrhosis, and alpha-1 antitrypsin deficiency. Median forced expiratory volume in 1 second at transplant was 27.8% ($\pm 20.38\%$), and mean Model for End-Stage Liver Disease was 10.5 (± 4.68). Median hospital stay was 44.5 days. Seventy-five percent of recipients had 1+ new infection during their transplant hospitalization. Patients experienced 0.68 incidences of acute rejection per year with a 41.7% (95% confidence interval, 21.3%-81.4%) probability of freedom from rejection in the first-year. Patient survival was 100% at 30 days, 91.6% at 1 year, and 71.3% at 3 years. At the time of analysis, 7 of 12 patients were alive, of whom 3 survived over 8 years post-LLT. Causes of death were primary liver graft failure, bronchiolitis obliterans syndrome, and solid tumor malignancies. The results indicate that LLT is associated with comparable survival to other LLT series and provides a granular assessment of infectious and rejection rates in this rare population.

Summary of Evidence

Current medical literature has proven the effectiveness and safety of combined double lung and liver transplants in carefully selected patients with end-stage lung and liver disease. The first simultaneous lung and liver transplant was performed in 1994. Since then as of December 2016, eighty-four (84) lung/double lung-liver transplants have occurred based on data from UNOS. These surgeries have been performed on small yet select patient profile. The goal of combined transplants is to give the patient the best chance at survival. When neither organ

transplant can be performed as an isolated procedure, due to severe deterioration and high potential for post-operative death, due to liver failure or pulmonary failure, a simultaneous approach is favored. Also, the patient selected rarely has a medical alternative such as a sequential organ transplant. If not done together, the end stage disease of each organ, separately in effect, dooms the patient, decreasing the likelihood of survival to an untenable level. The three year survival rate for the lung-liver simultaneous transplant is 75% which is higher than the lung transplant three-year survival and equal to the success rate of a single liver transplant. Other studies show that combined lung and liver transplantation have a morbidity and mortality equal to that of separate replacements. Also, there is evidence in the literature of better immunological outcome with less acute rejection when both organs are from the same donor.

Government Regulations

National:

Lung transplantation is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria- approximately 57 programs in the U.S. The Centers for Medicare and Medicaid Services have stated that under certain limited cases, exceptions to the facility-related criteria may be warranted if there is justification and the facility ensures safety and efficacy objectives.^{5,6}

Decision Memo for Liver Transplantation for Malignancies (CAG-00091R)

Effective June 21, 2012, Medicare Administrative Contractors (MAC) acting within their respective jurisdictions may determine coverage of adults liver transplantation for the following malignancies:

- Extrahepatic unresectable cholangiocarcinoma (CCA)
- Liver metastases due to a neuroendocrine tumor (NET) and
- Hemangioendothelioma (HAE)

In 2001, CMS released a National Coverage Determination (NCD) on Liver Transplantation for Malignancies which provides that liver transplantation is reasonable and necessary for HCC. Specifically, the NCD provides Medicare coverage for adult liver transplantation for HCC when the following conditions are met:

- The patient is not a candidate for subtotal liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement;
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and
- The transplant is furnished in a facility which is approved by CMS as meeting institutional coverage criteria for liver transplants (See 65 FR 15006).

In 2002, CMS released a decision memorandum and NCD on Liver Transplantation for Malignancies other than Hepatocellular Carcinoma, in which CMS delineated the reasons for continuing Medicare non-coverage of liver transplantation for malignancies other than HCC. Specifically, our determination was based on the review of non-HCC malignancies and treatment options available at that time, and a technology assessment for non-HCC malignancies. CMS determined that the evidence was not adequate to conclude that liver transplantation in patients with non-HCC malignancies was clinically effective. Therefore,

CMS determined that the item or service was experimental and CMS continued its national non-coverage of liver transplantation for malignancies other than HCC.

Adult Liver Transplant:

Medicare covers adult liver transplantation for end-stage liver disease and hepatocellular carcinoma when performed in a facility which is approved by the Centers for Medicare and Medicaid Services (CMS) as meeting institutional coverage criteria for liver transplants. Adult liver transplantation is excluded for other malignancies. The following conditions must be met for coverage of hepatocellular carcinoma:

- The patient is not a candidate for subtotal liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement; and
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone.

Pediatric Liver Transplant:

Liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Liver transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application which CMS approves documenting that:

- The hospital's pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in the "Federal Register" notice of April 12, 1991;
- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and
- The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric liver transplant patients.

Local:

No local coverage decision for this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Transplant-Heart
- Transplant-Heart and Lung (Combined)
- Transplant-Liver
- Transplant-Lung and Lobar Lung
- Transplant-Lung-Double Lung and Liver (Combined)
- Transplant-Pancreas

- Transplant-Small Bowel and Liver/Multivisceral
 - Transplant-Small Bowel (Isolated)
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References

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2. Yi SG, Burroughs SG, Loebe M, et al. Combined lung and liver transplantation: analysis of a single-center experience. Liver Transpl. Jan 2014;20(1):46-53.
3. Salman J, Grannas G, Lus F, et al. The liver-first approach for combined lung and liver transplantation. Eur J Cardiothorac Surg. 2018;54(6):1122-1127.
4. Freischlag KW, Messina J, Ezekian B, et al. Single-center long-term analysis of combined liver-lung transplant outcomes. Transplantation Direct.2018;4: e349.
5. Medicare approved lung transplant centers. Updated 9/10/2018. Available online at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Transplant.html> Last accessed September 2024.
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7. Barshes, NR,et al. Transplantation. 2005 Nov 15;80(9):1161-7
8. Moreno CP, et al. Transplant Proc. 2008 Nov;4(9): 3126-7
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10. MCMC External Three Panel Review, Double Lung-Liver Transplant, Aug 2012.
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12. Asrani SK, Trotter J, Lake J, et al. Meeting report: the DALLAS consensus conference on liver transplantation for alcohol related hepatitis. Liver Transpl. Jan 2020; 26(1):127-140
13. Lee BP, Vittinghoff E, Hsu C, et al. Predicting low-risk for sustained alcohol use after early liver transplant for acute alcoholic hepatitis: the SALT score. Hepatology. Apr 2019; 69(4):1477-1487
14. Blue Cross Blue Shield Association, "Lung and Lobar Lung Transplant," Medical Policy Reference Manual, Policy # 7.03.7. Issue 8:2017. Original policy date 7/31/96. Last review date September 2023.
15. Blue Cross Blue Shield Association. Liver Transplant and Combined Liver/Kidney Transplant. Medical Policy Reference Manual. Policy # 7.03.06. Issue 9:2017. Original policy date 12/1/95. Last review date September 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2024, the date the research was completed.

APPENDIX:

DALLAS Consensus Statement on Liver Transplantation for Alcohol Related Hepatitis¹²

SUMMARY OF RECOMMENDATIONS

General recommendations: Alcohol related hepatitis

1. There should be efforts to standardize nomenclature and definition of alcohol related hepatitis (AH) with an emphasis on use of less stigmatizing terminology.
2. Patients with severe AH may be assessed for corticosteroid therapy.
3. Select patients with severe AH that are unresponsive or ineligible for medical management may be considered for liver transplantation.
4. Predicting response to therapy or pre-LT mortality is best achieved by assessing response over time (change in Model for end stage liver disease (MELD) score, Lille score or a combination of MELD score plus Lille). Mortality is lower for those that have a Lille score <0.45, respond to therapy, have a declining bilirubin, or are abstinent and these patients may not require LT.
5. An inflexible period of abstinence prior to transplantation is not desirable. Acceptance for LT listing should be based upon the severity of liver dysfunction and a comprehensive psychosocial evaluation.

Recommendations for LT for alcohol related hepatitis

A. The goals of LT for AH include:

1. Avoiding LT in patients who will recover without it
2. Avoiding futility and achieving short- and long-term survival comparable to other indications for LT
3. Avoiding creation of further disparity in LT either by indication (versus other indications), geography, sex, race, insurance status or other sociodemographic factors.
4. Identification of LT candidates likely to have long-term abstinence
5. Incorporation treatment of alcohol use disorder (AUD) into pre and post-LT care
6. Consensus of paramedical and medical staff

B. Criteria related to AH

1. First presentation with decompensated alcohol-related liver disease
2. Absence of severe uncontrolled medical or psychiatric comorbidities.
3. Non-response to or ineligible for medical therapy.

C. Criteria related to AUD

1. Establish acceptable risk of relapse by assessment with a multidisciplinary psychosocial team including a social worker and an addiction medicine specialist/mental health professional with addiction and transplantation expertise.
2. Assessment of coherent patient by addiction specialist (i.e., not intubated or floridly encephalopathic).

<ol style="list-style-type: none"> 3. Lack of repeated unsuccessful attempts at addiction rehabilitation. 4. Lack of current other substance use/dependency. 5. Acceptance of ALD diagnosis with insight. 6. Commitment of patient to lifelong sobriety and support of sober caregivers to assist patient with abstinence goals. 7. Presence of close, supportive family members or caregivers
D. Post LT requirements <ol style="list-style-type: none"> 1. Pre-LT confirmation of plan for AUD treatment after LT 2. Robust post-transplant monitoring for alcohol slips or relapse during post-LT clinic appointments to include direct interviewing of patient and caregivers about alcohol use. 3. Routine monitoring of alcohol use (e.g., with Phosphatidylethanol (PEth), Urinary ethyl glucuronide) for at least 2 years, with frequency and duration individualized beyond this time period.
E. Center requirements <ol style="list-style-type: none"> 1. Transparency in the candidate selection process and structured collection of objective data to assess outcomes 2. Ongoing support of abstinence that is integrated into post LT care such as concurrent follow-up by addiction specialist/mental health professional with addiction and transplantation expertise. 3. Oversight of program adherence to harmonize listing practices and outcomes.
<small>LT: liver transplant; AH: alcohol related hepatitis; AUD: alcohol use disorder; Peth: phosphatidylethanol; ETG: urinary ethyl glucuronide</small>

The SALT Score¹³

SALT Score to Predict Sustained Alcohol Use Post-LT

Variable	Points
>10 Drinks/day at Presentation	+4
≥2 Prior Failed Rehabilitation Attempts	+4
Any History of Prior Alcohol-Related Legal Issues	+2
History of Non-THC Illicit Substance abuse	+1

The SALT Score was generated from a full LASSO logistic point-score model to predict sustained alcohol use post-LT. The score assigns points to variables which were associated with sustained alcohol use post-LT, and ranges 0–11. Using a cutoff of 5, the SALT score had a c-statistic estimate of 0.76 to predict sustained alcohol use post-LT.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/20	11/26/19		Joint policy established
1/1/21	10/20/20		Routine policy maintenance, no change in policy status.
1/1/22	10/19/21		Routine policy maintenance, no change in policy status.
1/1/23	10/18/22		Routine policy maintenance, added "<10 score may be considered when appropriate", no change in policy status.
1/1/24	10/26/23		Added statement to inclusion section. Title change to start with "Transplant." Appendix added to policy on DALLAS consensus statement and on SALT score, routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
1/1/25	10/15/24		Changes made to inclusion/exclusion section. No change in status. Vendor managed: N/A (ds)

Next Review Date: 4th Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRANSPLANT-LUNG/DOUBLE LUNG AND LIVER (COMBINED)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Coverage per policy criteria
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.