

Policy: MP020

Section: Medical Benefit Policy

Subject: Solid Organ Transplant Services

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	x	ACA	x
CHIP	x		

I. Policy: Solid Organ Transplant Services

II. Purpose/Objective:

To provide a policy of coverage regarding Solid Organ Transplant Services

III. Responsibility:

- A. Medical Directors
- **B.** Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that Geisinger Health Plan (GHP) determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
 - Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
 - Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION: Approved solid organ transplantation is covered when medically indicated. Transplant evaluation, transplant services and post-transplant care are coordinated through the current contracted transplant management vendor.

INDICATIONS: REQUIRES PRIOR MEDICAL DIRECTOR AUTHORIZATION (except corneal transplant)

Treatment guidelines for transplant and related follow-up are continuously changing due to rapid advances and research. Approved transplant services are covered according to the individual contract language. Except for corneal transplants, Geisinger Health Plan (GHP) requires prior authorization for services related to transplants and follow-up treatment. The following transplants are considered for coverage when appropriate criteria, as determined by GHP medical director and the current contracted transplant management vendor are met.

- Heart
- Heart & Lung
- Lung & Lobar Lung
- Liver
- Renal
- Renal & Pancreas/ Solitary Pancreas (after a successful Kidney)
- Small Bowel
- Small Bowel/Liver and Multi-visceral

Additional consultation and/or evaluation may be required in the following situations. Documentation of those consultations and reports of additional testing must be submitted to GHP for review.

- Documented evidence of recent graft loss
- Documented evidence of malignancy (treated) within the last 5 years
- Active psychiatric and behavioral disorder
- HIV infection without AIDS and with sustained CD4 counts greater than 200/mm³
- Chronic peptic ulcer disease, GI bleeding, diverticulitis.
- Active illicit drug or alcohol use

GHP covers the following services to the extent of any limitation as may be listed in the benefit document, applicable rider or applicable medical benefit policy when a covered organ or tissue transplant is performed:

• Compatibility testing of prospective organ/tissue donors who are members of the family of a patient selected for an organ transplant; and

- Live organ/tissue donor fees; and
- Cadaveric organ/tissue procurement preservation, storage and transportation fees as billed by the Organ Procurement Organization (OPO); and
- Charges for activating the donor search process for donors in the registry, HLA-DR sample procurement and typing, donor physical examinations and laboratory tests as well as bone marrow/stem cell procurement.

For Medicare Business Segment

GHP covers all medically necessary and non-investigational/experimental organ and tissue transplants, as covered by Medicare. When Medically Necessary, the following transplants are covered: Kidney (cadaver and living donor), kidney/pancreas, cornea, heart, heart/lung, single lung, double lung, liver (cadaver and living donor), liver/pancreas, small bowel, pancreas/small bowel, bone marrow, stem cell, pancreas, liver/small bowel transplants, and multivisceral transplants.

For Medicaid Business Segment:

GHP covers all medically necessary and non-investigational/experimental organ and tissue transplants, as approved by the PA Dept. of Human Services.

EXCLUSIONS:

GHP does **NOT** provide coverage for procedures and services provided as being related to an investigational technology, including, but not limited to, services and procedures that would otherwise be covered, and hospital admissions solely for the purpose of providing an investigational technology, or research protocol. Routine care provided during an approved clinical trial is covered. Please see MP312 Routine Care in Clinical trials. These services and procedures are considered experimental, investigational or unproven because of insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these treatments on health outcomes when compared to established treatments or technologies.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Colucci WS. Indications and contraindications for cardiac transplantation. UpToDate 2008. http://www.uptodate.com.

Steinman TI, Becker BN, Frost AE, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplantation.* 2001; 71(9):1189-1204.

Center for Medicare and Medicaid Services, National Coverage Determination number 260.9, Heart transplantation, Available at http://www.cms.hhs.gov/mcd/results.asp?show=all&t=200762614430 Accessed on 08/24/21

Devlin J, O'Grady J. Indications for referral and assessment in adult liver transplantation: a clinical guideline. *Gut.* December 1999; 45(suppl VI):1-22.3.

Center for Medicare and Medicaid Services, National Coverage Determination number 260.1, Adult Liver Transplantation, revision effective 6-19-06, Available at: <u>http://www.cms.hhs.gov/mcd/search.asp</u> Accessed on 08/23/21

Arcasoy SM, Kotloff RM. Medical process: lung transplantation. The New England Journal of Medicine. 1999; 340(14):1081-1091.

American Thoracic Society. International guidelines for the selection of lung transplant candidates. American Journal of Respiratory and Critical Care Medicine. July, 1998; 158(1):335-339.

Becker BN, Odorico JS, Becker YT, et al. Simultaneous pancreas-kidney and pancreas transplantation. Journal of the American Society of Nephrology. 2001;12(11):2517-27.

Centers for Medicare and Medicaid Services, National Coverage Decision number 260.3, revised May, 2006. Available At: <u>http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=260.3&ncd_version=3&basket=ncd%3A260%2E3%3A3%3APancreas</u>+Transplants Accessed on 09/24/08.

Centers for Medicare and Medicaid Services, National Coverage Decision number 260.5 Intestinal and Muti-Visceral Transplantation, revised May, 2006, Available at; <u>www.cms.hhs.</u> Accessed on 08/24/21

Wijtvliet VPWN, Plaeke P, Abrams S, et al. Donor-derived cell-free DNA as a biomarker for rejection after kidney transplantation: A systematic review and meta-analysis. Transpl Int. 2020;33(12):1626-1642

Center for Medicare and Medicaid Services, National Coverage Determination number 260.3 Pancreas Transplants Accessed 08/24/21

Kataria A, Kumar D, Gupta G. Donor-derived cell-free DNA in solid organ transplant diagnostics: Indications, limitations, and future directions. Transplantation. 2021 Jan 27.

Cambridge WA, Fairfield C, Powell JJ, et al. Meta-analysis and meta-regression of survival after liver transplantation for unresectable perihilar cholangiocarcinoma. Ann Surg. 2021 Feb 1;273(2):240-250

Alexopoulos SP, Wu WK, Ziogas IA, et al. Adult combined heart-liver transplantation: The United States experience. Transpl Int. 2022 Jan 4;35:10036

Cotter TG, Wang J, Peeraphatdit T, et al. Simultaneous heart-liver transplantation for congenital heart disease in the United States: Rapidly increasing with acceptable outcomes. Hepatology. 2021 Apr;73(4):1464-1477.

Leard LE, Holm AM, Valapour M, et al. Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation. J HeartLung Transplant. 2021 Nov;40(11):1349-1379

Tracy KM, Matsuoka LK, Alexopoulos SP. Update on combined heart and liver transplantation: evolving patient selection, improving outcomes, and outstanding questions. Curr Opin Organ Transplant. 2023 Apr 1;28(2):104-109.

Writing Committee; Kittleson MM, Ruberg FL, Ambardekar AV, et al. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023 Mar 21;81(11):1076-1126. Epub 2023 Jan 23. Erratum in: J Am Coll Cardiol. 2023 Mar 21;81(11):1135

This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/03

Revised: 8/04; 8/06; 8/07(wording); 10/08 (addition of documentation requirements); 10/15 revised title; 10/16, 9/19 (revise criteria); 9/24 (verbiage revision)

Reviewed: 8/05; 10/09; 10/10, 10/11, 10/12, 10/13, 10/14, 9/17, 9/18, 9/20, 9/21, 9/22, 9/23

CMS UM Oversight Committee Approval: 12/23; 11/8/24

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endors ement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.