**Government Business Division**
**Policies and Procedures**

| **Section (Primary Department)**<br>**Health Care Management - Transplant Services** | | **SUBJECT (Document Title)**<br>**Transplant Approval Policy - Solid Organ/BMT/Stem Cell** | |
|---|---|---|---|
| **Effective Date**<br>12/13/1999 | **Date of Last Review**<br>07/05/2019 | **Date of Last Revision**<br>04/29/2020 | **Dept. Approval Date**<br>04/29/2020 |
| **Department Approval/Signature :** | | | |

**Policy applies to health plans operating in the following State(s). Applicable products noted below.**

| **Products** | | | | |
|---|---|---|---|---|
| ☒ **Medicaid** | ☐ Arkansas | ☐ Indiana | ☐ Nevada | ☐ Tennessee |
| ☒ **Medicare/SNP** | ☐ California | ☐ Iowa | ☐ New Jersey | ☐ Texas |
| ☒ **MMP/Duals** | ☐ Colorado | ☒ Kentucky | ☐ New York – Empire | ☐ Virginia |
| | ☐ District of Columbia | ☐ Louisiana | ☐ New York (WNY) | ☐ Washington |
| | ☐ Florida | ☐ Maryland | ☐ North Carolina | ☐ Wisconsin |
| | ☐ Georgia | ☐ Minnesota | ☐ South Carolina | ☐ West Virginia |

## POLICY:

The purpose of this policy is to provide a consistent process for the approval of members in need of transplant services.

## DEFINITIONS:

**CMS -** Centers for Medicare and Medicaid Services

**Medicare Advantage members -** Members who have elected to enroll in a Medicare managed care program.

**Transplant -** The transfer of an organ or tissue from one part or individual to another.

## PROCEDURE:

The Health Care Management department (HCM) assists members requiring transplant services through the coordination of medical services and adjunctive needs in order to obtain the most appropriate and medically necessary services available under the scope of the benefit package.

a) A request for transplant services is received from a provider.
b) The request is transferred to the corporate Transplant Services team.
c) The member's eligibility and transplant-specific benefits are verified. The requestor is notified both verbally and in writing if the request is not a covered benefit. (Reference the Health Care Management Denial - Core Process Procedure for denial and reconsideration processes).
d) All organ transplant procedures must be performed at a Medicare-approved transplant program.
e) The request is reviewed utilizing nationally recognized clinical criteria (i.e., GBD Medical Policies and UM Guidelines, McKesson, MCG™) and state Medicaid guidelines, as applicable, to determine if it meets medical necessity criteria for transplant. For Medicare

Advantage, CMS coverage guidelines are utilized. If no CMS guideline is available, then GBD Medical Policies and UM Guidelines are used. For MMP, CMS coverage guidelines are utilized. If no CMS guideline is available, then State Medicaid guidelines are used (if available). If State Medicaid guidelines are not available, then GBD Medical Policies and UM Guidelines are used.

f) If medical necessity is not met, the health plan or regional Medical Director (or designee) reviews the request, then prepares a letter of notification to the requesting provider and member informing them that the condition for the requested transplant did not meet medical necessity criteria and initiates the denial process. **Reference the Health Care Management Denial - Core Process Procedure for denial and reconsideration processes.**
g) If medical necessity criteria are met, the pre-transplant evaluation is authorized.
h) The Claims Department, reinsurance carrier and appropriate transplant network are notified of the case, as needed, by the Transplant Services team.
i) Health plan or regional Provider Relations is contacted if the transplanting facility and/or physicians are out-of-network and single case rates are needed.
j) Upon receipt of the clinical results of the transplant evaluation, Transplant Services reviews the record for completeness. The transplant facility is notified of the need for any applicable additional records. Documentation of social history must be included. For members with a recent history of substance abuse (drug or alcohol), the following documentation must be received:
    i) Evidence of completion of drug or alcohol rehabilitation program;
    ii) Length of time member has been substance-free; and,
    iii) At least one negative random drug screen if the member has a previous history of IV drug abuse.
k) The submitted clinical information is reviewed utilizing nationally recognized clinical criteria (i.e. GBD Medical Policies and UM Guidelines, McKesson, MCG™) and state Medicaid guidelines, as applicable, to determine if it meets medical necessity criteria for transplant approval. For Medicare Advantage, CMS coverage guidelines are utilized. If no CMS guideline is available, then GBD Medical Policies and UM Guidelines are used. For MMP, CMS coverage guidelines are utilized. If no CMS guideline is available, then State Medicaid guidelines are used (if available). If State Medicaid guidelines are not available, then GBD Medical Policies and UM Guidelines are used.
l) If medical necessity is not met, the Medical Director (or designee) reviews the request, then prepares a letter of notification to the requesting provider and member informing them that the requested transplant did not meet medical necessity criteria and initiates the denial process. **Reference the Health Care Management Denial - Core Process Procedure for denial and reconsideration processes.**
m) If the member and/or provider appeal, the health plan or regional office adheres to the approved appeal process which may include the use of external consultants to assist in making medical necessity determinations.

n) Transplant Services notifies the facility of approval via verbal and/or written communication, followed by written notification to the member (or family, if appropriate).
o) Transplant Services coordinates care with the health plan or regional office throughout the transplantation process, including notification of approval to the Utilization Management and Case Management teams. A monthly transplant list is sent to the health plan and/or regional office leadership via e-mail.
p) Transplant Services utilizes a variety of system applications for member tracking, program monitoring and reporting capabilities.

**REFERENCES:**

Centers for Medicare and Medicaid Services at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?show=all&t=2009721162447
GBD Medical Policies and UM Guidelines at https://pulse.antheminc.com/webcenter/portal/medpolicy/pages_medicalpolicies?contentID=PULSE_038438
MCG™ (Milliman Care Guidelines) at http://careweb.careguidelines.com/ed14/index.html
McKesson CareEnhance Review Manager at http://www.mckesson.com

**Related Policies or Procedures:**
California Medicaid Transplant Policy - CA_CAXX_100 Major Organ Transplants - Identification and Referral for Medi-Cal Recipients
Clinical Criteria for Utilization Management Decisions - Core Process
Health Care Management Denial - Core Process
Health Care Management Denial - Core Process – KY
Health Care Management Denial – LA
Out of Network Authorization Process
Pre-Certification of Requested Services - Core Process
Pre-Certification of Requested Services – LA
Priority Complex Case (PCC) Policy and Process
Transplant Guidelines within Case Management

**RESPONSIBLE DEPARTMENTS:**

**Primary Department**:
Health Care Management (HCM) - Transplant Services

**Exceptions:**

Cornea transplants; tissue transplants - the process is managed by the health plan or regional office.

**Appendix:**

**Kentucky**

Per Appendix H of the Medicaid Managed Care Contract, Organ Transplant Services not Considered Investigational by FDA are a covered benefit. Transplants are subject to the requirements of Kentucky Administrative Regulations (907 KAR 1:350). The health plan utilization management process follows Kentucky Revised Statute 304.17A and Kentucky Medicaid Managed Care Contract sections 21.1, 21.2, 21.3; and does not allow reconsiderations.

Kentucky Administrative Regulations at:
**https://apps.legislature.ky.gov/law/kar/TITLE907.HTM**

**REVISION HISTORY:**

| Review Date | Changes |
|---|---|
| 04/29/2020 | • Off-Cycle review to revise KY exception language |
| 01/21/2020 | • Off cycle review<br>• Revised for LA Emergency Contract<br>• Updates to LA Appendix<br>• Updates to LA Related Policies & Procedures |
| 07/05/2019 | • Annual Review<br>• Added AR as an applicable market<br>• Added MN as an applicable market<br>• Updated Links to Resources<br>• Revised format to include an Appendix for each Health Plan<br>• Health Plan details moved from Exceptions section to the new Appendix section |
| 09/04/2018 | • Off-cycle modification to reflect modifications required for AHCA Contract No. FP068 signed 08/01/2018 that becomes effective 12/1/2018<br>• Adopted for all Florida Simply Healthcare Medicaid Plans |
| 08/10/2018 | • Off-cycle edits to add MN as an applicable market and modify KY exception language |
| 05/24/2018 | • Annual review<br>• Updated links to resources<br>• Revised Exception language for KY, NV, SC & VA |
| 07/27/2017 | • Off-cycle edits to revise k & l of procedure section<br>• Added related P&P |

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|---|---|
| 03/23/2017 | • Annual review<br>• Added Western NY as an applicable market<br>• Updated to include MMP<br>• Revision to 1e and 1k of Procedure section<br>• Added language to include regional offices along with health plans throughout the document<br>• Added a related policy/procedure<br>• Deleted Medicare notification from Exceptions section |
| 03/17/2016 | • Annual review<br>• Added IA as an applicable market. Removed WV as an applicable market.<br>• Revision to 1c of Procedure section<br>• Revisions to FL exception language; added exception language for IA & TX |
| 03/11/2015 | • Updated to change name from WellPoint to Anthem. Expanded the Exceptions section to include health plans with specific requirements. |
| 04/25/2013 | • Updated to reflect the current clinical criteria (i.e., added WellPoint Medical Policies and Clinical UM Guidelines and deleted Aetna CPB). |